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MICROSATELLITE INSTABILITY

DECLARATION OF DR. RICHARD GOLDBERG

I currently hold the opinions expressed in this declaration. However, my analysis may continue, and I may acquire additional information and/or attain supplemental insights that may result in added observations.

I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: 1/22/2025

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Richard Goldberg
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I. QUALIFICATIONS

1. My name is Richard Goldberg. I am a medical oncologist. A copy of my CV is attached as Appendix A.

2. I received my A.B. *cum laude* from Harvard University in 1975 and my M.D. from the State University of New York Upstate Medical University in 1979. I trained as a Resident in Internal Medicine at Emory University Hospitals between 1979 and 1982 and then completed a fellowship in Medical Oncology at the Vincent T. Lombardi Cancer Research Center at Georgetown University between 1982 and 1984. I am board certified in Internal Medicine and Medical Oncology.

3. I have cared for cancer patients for nearly forty years focusing on patients with gastrointestinal and, particularly, colorectal cancers. Over those years, I have either treated directly or supervised the treatment of thousands of patients, including many patients who were treated with pembrolizumab. After completing my fellowship, I initially worked at the Geisinger Medical Center and Clinic in Danville, Pennsylvania for approximately ten years. While at Geisinger, I was an active practitioner caring for cancer patients, supervised residents, coordinated the research collaboration with the Mayo Clinic, and served as the Assistant and then Associate Director of the Department of Medicine.

4. Based upon my research and clinical work, I was then recruited to the Mayo Clinic in Rochester, Minnesota, where I worked for almost another decade. While there, I served as Co-Chair of the Mayo Cancer Center Gastrointestinal Cancer Research Program, coordinating the Center's gastrointestinal clinical and research programs. During my time at the Mayo Clinic, I also ran the Gastrointestinal Cancer Committee of the North Central Cancer Treatment Group (NCCTG), an international research consortium funded by the National Cancer Institute (NCI). That group and others with which I have subsequently been affiliated (see below) develop, run, and analyze multi-institutional and often international trials to advance cancer treatment and our understanding of cancer biology. While at Mayo Clinic, while working with an international multidisciplinary research group sponsored by the NCI called the Familial Colorectal Cancer Registry, I developed an interest and expertise in cancer susceptibility syndromes such as Lynch Syndrome. Patients with Lynch Syndrome have an inherited defect in enzymes that repair errors in DNA occurring during cell replication that leads to a condition termed microsatellite instability (MSI). This finding proved to be highly relevant to the development of pembrolizumab. In addition to setting the research agenda in GI cancers for the Cancer Center and the NCCTG, I was active in teaching and mentoring residents and fellows, many of

whom have gone on to take leadership roles at Mayo Clinic and at other cancer centers in the United States and Canada.

5. In 2003, I joined the University of North Carolina at Chapel Hill, where I served as the Richard M. Goldberg Professor of Gastrointestinal Oncology¹, Associate Director for Clinical Research of the NCI-funded Lineberger Comprehensive Cancer Center, Chief in the Division of Hematology/Oncology, and was the first Physician-in-Chief of the North Carolina Cancer Hospital that we opened during that time. During my eight years at UNC, I became the Chairman of the Cancer and Leukemia Group B (CALGB) Gastrointestinal Cancer Committee, another NCI funded cooperative oncology research group which subsequently merged with NCCTG to form the Alliance for Clinical Trials in Oncology (the Alliance). It is important to note that UNC Health Care System includes the UNC School of Medicine and that UNC Medical Center, the flagship academic medical center of UNC Health Care System, is a teaching hospital.

6. In 2011, I joined The Ohio State University Wexner Medical Center in Columbus, Ohio where I served as the first Physician-in-Chief of The James Cancer Hospital and Solove Research Institute, Associate Director of the OSU James Comprehensive Cancer Center and, for a time, as Acting Chief of the

¹ The funds for this professorship were donated by Sanofi in honor of my research contributions that led to the FDA approval of oxaliplatin in the US.

Division of Medical Oncology. During my tenure we opened the new James Cancer Hospital, and my role there was to be the lead physician for the third largest cancer hospital in US. I also held an endowed professorship that helped to support my research. In addition, I saw patients, taught medical students, residents, and fellows and conducted research.

7. In 2017, I joined West Virginia University as the endowed DeLynn Professor of Oncology and the Director of the West Virginia University Cancer Institute and the Mary Babb Randolph Cancer Center. My responsibilities at West Virginia University included managing the clinical cancer program to which we recruited nearly 40 new physicians during my tenure and that role also involved coordinating the efforts of more than 400 employees. I led the basic, clinical, and population sciences research efforts and was responsible for teaching medical and graduate students, residents, and fellows. The Cancer Institute sponsors a Cancer Cell Biology Graduate Program leading to a PhD for which I held responsibility. I retired from medical practice and my role as the Institute director at the end of 2019 to become an emeritus faculty member. I continue to mentor oncology and other faculty members in career development and the conduct of clinical research. I also have founded Oncology Developments LLC in order to provide consulting services for pharmaceutical companies developing new drugs for the treatment of GI cancers, for technology companies developing biomarkers, and to be an expert

witness in patent law disputes for companies or universities in need of such services.

8. As the names suggest all my workplaces were “teaching hospitals,” including Geisinger Medical Center, Mayo Clinic and Hospitals, UNC Medical Center, Ohio State’s James Cancer Hospital, and West Virginia University Hospital. These are institutions that engage in medical education and training, and all have their own or have an affiliation with a medical school. Such institutions are critical to our healthcare system. We rely on teaching hospitals to provide the necessary hands-on learning opportunities for medical students and residents and to provide the most sophisticated and intensive care possible while pioneering new treatments. My time at all five of these institutions thus was spent, in part, helping to train a new generation of physicians and other healthcare professionals. My teaching responsibilities included lecturing medical students, supervising residents and fellows (including in connection with their treatment of cancer patients), and mentoring young faculty members. These efforts were supported through NCI funded training grants that I submitted and was awarded on a competitive basis including a K12, T32, and R25 award. These awards help trainees initiate research careers by supporting both their first research efforts and their continuing education.

9. Over the years, I also have served on the program and organizing committees for large international symposia, coordinated Continuing Medical Education (CME) events, presented the results of research studies, and lectured on topics related to GI cancers in venues all over the world including North America, Europe, Asia, Australia, South America, and Africa. Some examples of this include the American Society of Oncology (ASCO) annual meeting as well as ASCO's sponsored Annual GI Cancer Symposium. I have served repeatedly on the program committees for these meetings including chairing the committee for the GI Symposium. At the 10th anniversary of that meeting, I was invited to give the plenary lecture entitled Ten Years of Progress in Colorectal Cancer, an honor recognizing my contributions to the field. For nearly a decade, I ran the national Perspectives in Colorectal Cancer Symposium in addition to many other smaller congresses. I have been an invited visiting professor, lecturing and mentoring trainees, at multiple universities including Stanford, Yale, Duke, Oxford, Vanderbilt, University of Chicago, and elsewhere. I also have visited a number of nonacademic centers to lecture to general medical audiences as well as giving endowed lectureships to the public. It has been a great learning experience as well as opportunity to teach these diverse audiences.

10. Over the nearly four decades of my career, I both participated in the development of numerous antineoplastic agents and witnessed the dramatic

evolution of medical practice, the incredible progress in oncology, and in the treatment of gastrointestinal cancers. When I began my career, there was one drug approved for the treatment of colorectal cancer: 5-fluorouracil. Today, there are more than a dozen. I dedicated much of my career to helping design, conduct, run, and report clinical trials testing new drugs and drug combinations. Some of that work led directly to new drug approvals (irinotecan, oxaliplatin, somatostatin, pembrolizumab etc.) and also supported new indications for approved drugs. Much of this effort focused on research to understand inherited cancer susceptibility syndromes, develop novel treatments, and to unravel the biologic heterogeneity of cancer with all of these efforts dedicated to improving the treatment of patients suffering from gastrointestinal cancers, particularly those with colorectal cancer.

11. I participated in the initial three arm trial funded by Johns Hopkins University and Swim Across America that treated 2 cohorts of patients with advanced, refractory colorectal cancer. Cohort A enrolled patients with tumors that manifested microsatellite instability (i.e. MSI-H) and Cohort B enrolled patients with tumors that were found to be microsatellite stable (i.e. MSS). Cohort C enrolled patients found to have tumors that manifested microsatellite instability (MSI-H) and had originated from organs other than the colon or rectum. This study was reported by Le et al. and I am a coauthor on that paper. The results of

this trial led to the FDA approval of pembrolizumab for the treatment of tumors that manifested microsatellite instability regardless of their organ of origin. This was the first tumor agnostic (regardless of the site of origin of the primary cancer) indication ever approved by the FDA. This trial is listed on ClinicalTrials.gov and is identified there by its designated number, NCT01876511.²

12. I have held committee leadership roles with two NCI supported cooperative oncology groups—the North Central Cancer Treatment Group (NCCTG) and the CALGB (later the Alliance)—and was the first chair of the NCI’s Colorectal Cancer Task Force. The Task Force brought together the leading researchers in gastroenterology, surgery, radiation, and medical oncology from the United States and Canada to develop the research agenda for the NCI supported National Clinical Trials Network. I also represented the Task Force on the Gastrointestinal Cancer Steering Committee that coordinated all of the NCI’s clinical trial portfolio in GI cancer. As Chair of the Gastrointestinal Cancer Committee of the NCCTG, I was responsible for developing the research agenda for collaborating physicians around the United States and Canada who combined efforts to advance the treatment for our patients. My current role in the Alliance is

² NCT01876511, “Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors (Cohorts A, B and C),” ClinicalTrials.gov (June 10, 2013), available at <https://clinicaltrials.gov/study/NCT01876511?tab=history&a=1>, (EX1005).

the Associate Group Chair for Cancer Center Collaborations and I serve on the leadership team and the board of the Alliance and the Alliance Foundation.

13. In my positions with both the NCCTG and the Alliance, I also have worked with a number of additional national clinical trial cooperative groups like the Eastern Cooperative Oncology Group (ECOG, now known as ECOG-ACRIN), The National Surgical Breast and Bowel Group (NSABP), which is now known as NRG, and the Cancer and Leukemia Group B (CALGB) to organize and run trials of various oncology therapies. Cooperative groups are critical to oncology drug development in the United States.

14. In each of the cancer centers that I have worked in we also develop clinical trials with pharmaceutical companies. These studies are often Phase I (designed to assess safety while also evaluating efficacy as a secondary endpoint) or early Phase II studies (designed to assess activity and safety in a more homogenous group of patients such as patients with advanced colorectal cancer). The clinical development of a new cancer therapy is an expensive, meticulous, and difficult process. Large cooperative groups often aid those efforts by running large clinical trials. Not only do these organizations have the resources and relationships necessary to help write, garner approval for, run and analyze large trials, but they generally are comprised of many true experts in the field with decades of experience. Sometimes cooperative groups and individual cancer centers or small

consortia of cancer centers will partner with pharmaceutical companies. In most cases the company will provide funding for as well as their drug to conduct such studies. In the study in question, NCT01876511, Merck provided the pembrolizumab used in the study but did not fund the trial which was underwritten by Johns Hopkins University and a charitable group that raises money to fund cancer research, Swim Across America. In general, the pharmaceutical company may work with the cooperative group or cancer center to share its own experience with the drug and its toxicities and collaborate on study design with the cooperative group, the cancer center, the NCI, and the Food and Drug Administration (FDA). In some but not all cases, the ultimate design and protocol are left to the expert oncologists and scientists at the cooperative group or cancer center who are ultimately overseen by the NCI and FDA. In this case, Merck initially only approved the protocol which was written by Johns Hopkins University researchers and provided pembrolizumab for the trial.

15. I also have served and continue to serve on several editorial boards of peer-reviewed journals, and (as detailed in my CV) have more than 700 publications in the field. Many of these papers have been published in high impact journals such as the New England Journal of Medicine, Science, the Lancet, the Journal of the American Medical Association (JAMA), the Journal of Clinical Oncology, the Annals of Oncology and others. I serve as a Section Editor for GI

Cancers that involves approving and updating multiple chapters across the spectrum for UpToDate and I was recently promoted to Executive Editor for their oncology program. UpToDate is an online comprehensive medical textbook that is frequently used as a reference by MDs at all levels to provide the latest in evidence-based medicine. My CV provides a more exhaustive recounting of my professional experience in the clinical research of gastrointestinal cancers and my contributions to the medical literature in this field.

16. As I noted above, I have cared directly for or supervised the care of many patients receiving pembrolizumab during the conduct of this trial and since its FDA approval to treat MSI-H colorectal cancer and MSI-H tumors originating outside the colon or rectum in the US. Over that period, I also have attended and spoken at dozens of professional conferences, lectures, and meetings at which pembrolizumab, its use, and/or the management of its toxicities were discussed.

17. This is the third patent case for which I have provided expert opinion testimony. Prior to Johns Hopkins University's retention of me as an expert in this case, I have testified by declaration in a patent law dispute on behalf of Genentech in a suit that they initiated against Amgen regarding patent infringement related to the sale of the biosimilar to bevacizumab known as Mvasi. That lawsuit was settled prior to initiation of a trial. I testified in federal court in Delaware on behalf of Taiho in its successful defense of its patents regarding Lonsurf, a drug used to

treat patients with treatment refractory colorectal cancer and gastric cancer. I have also served as an expert witness in several malpractice trials (none of which occurred within the last four years). I am being compensated at a rate of \$900 per hour (\$450 per hour for travel). My compensation does not depend in any way on the outcome of this case.

II. LEGAL FRAMEWORK ON WHICH MY OPINIONS ARE BASED

18. I understand that in a proceeding before the U.S. Patent Trial and Appeal Board (PTAB), patent challengers (i.e. petitioners) must prove by a preponderance of the evidence that each Asserted Claim of the Asserted Patents is invalid.

19. I understand that a claim may be found invalid as obvious “if the differences between the subject matter sought to be patented and the prior art are such that the claimed subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”

20. I understand that an obviousness inquiry requires consideration of the following factors: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) the objective indicia of nonobviousness.

21. I understand that alleged prior art references are to be looked at from the viewpoint of a person of ordinary skill in the art. I also understand that a party challenging the validity of a patent claim composed of several limitations does not meet its burden by merely demonstrating that each of the claim's limitations was independently known in the prior art. Identifying a reason why those elements would be combined can be important because inventions in many instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

22. I further understand that to prove obviousness there must be a reasonable expectation of success in making the claimed invention in light of what was known in the prior art.

23. I understand that objective indicia evidence may be the "most probative evidence of nonobviousness," and that a fact finder must consider such evidence before making an obvious determination. A non-exhaustive list of such objective indicia includes: (1) the commercial success of the patented invention; (2) a long-felt but unresolved need that was satisfied by the claimed invention; (3) the failure of others to develop or practice the claimed invention; (4) skepticism of the claimed invention by those in the relevant field; (5) unexpected or surprising results from the claimed invention; (6) copying of the claimed invention by others; (7) acceptance of the claimed invention, as shown, for example, by praise from

others in the industry, adoption of the claimed invention, or licensing of the claimed invention; and (8) teaching away from the claimed invention.

24. I understand that for objective indicia to be probative of non-obviousness, the patentee must show a “nexus,” or factual connection, between the objective indicia and the claimed invention. For example, there must be a nexus between the claimed invention and its commercial success, i.e., the commercial success must be due to the inventive aspects of the claimed invention. I understand the nexus requirement is satisfied if, for example, the patentee shows that the thing that has commercial success is the invention disclosed and claimed in the patent.

25. I understand that obviousness is analyzed from the perspective of one skilled in the art at the time the invention was made. In other words, the use of hindsight is not permitted.

26. I have been advised by counsel for Johns Hopkins University to base my opinions on the viewpoint of a person of ordinary skill in the art in as of July 2015, and have done so in my analysis below. I understand that Johns Hopkins University contends that a person of ordinary skill in the art on or about the claimed priority date of the '187 Patent would have had a M.D. or graduate-level degree (or equivalent work experience) in the fields of immunology, genetics, or a related field and at least five years of experience (i) conducting immunology research relating to oncology, (ii) conducting genetics research relating to

oncology, or (iii) developing and conducting clinical trials on novel cancer therapies in those fields. I understand that less work experience may be compensated by a higher level of education and vice versa. Under this definition, I qualified as a person of ordinary skill well before July 2015.

III. KEYTRUDA AND ITS MSI-H RELATED FDA-APPROVED INDICATIONS SATISFIED A LONG-FELT, UNMET NEED FOR EFFECTIVE TREATMENTS FOR MSI-H CANCER

27. In my opinion, Keytruda (pembrolizumab) and its microsatellite instability-high (MSI-H) related FDA-approved indications,³ which embody the inventions claimed in the '187 Patent, fulfilled a long-felt, but previously unmet need for an effective treatment for MSI-H cancer, with the most pressing need being treatments for metastatic cancer.

A. Background of MSI-H Cancers

1. History of MSI-H Cancers

28. The notion that certain families exhibit a propensity to develop colorectal and endometrial cancers, and that these cancers often manifested at much younger ages than usual, was first advanced in the 1960s by Dr. Henry Lynch, a clinical oncologist with genetics training, practicing at Creighton University in Omaha. Dr. Lynch treated many cancer patients who came from large families common in rural Nebraska's farm communities. Some of these

³ An "indication" is an FDA approved use of a drug for a specific disease or condition and is described on the drug label.

families had multiple afflicted members who died of early onset colon cancer or endometrial cancer. The families that had these clusters of young onset CRC and endometrial cancers were designated as having what came to be known as “Lynch Syndrome” based on their clinical histories. He, therefore, hypothesized that these cancers could be the result of an inherited cancer susceptibility syndrome. Dr. Lynch was not a laboratory scientist, so his findings were descriptive. He did not discover the molecular biology that was causative himself. Initially his observations were met with tremendous skepticism by a medical community that favored environmental exposures rather than genetics as the causative force behind the development of cancer.⁴

29. Later, laboratory investigators including Albert de la Chapelle, who I worked with at Ohio State, Bert Vogelstein at Johns Hopkins, and investigators from Sweden elucidated the biologic abnormality of the mismatch repair defect that is the causative genetic abnormality that results in Lynch syndrome and is observed in some microsatellite high colorectal cancers.⁵ Other patients with colorectal cancer did not have an inherited genetic susceptibility; they acquired

⁴ Boland, “Henry T. Lynch, MD (January 4, 1928 – June 2, 2019),” *Gastroenterology* (Oct. 2019).

⁵ Aaltonen et al., “Replication errors in benign and malignant tumors from hereditary nonpolyposis colorectal cancer patients,” *Cancer Res.*, 54:1645–1648 (1994), (EX2277); Aarnio et al., “Cancer risk in mutation carriers of DNA-mismatch repair genes,” *Int. J. Cancer* 81:214–218 (1999), (EX2278).

their mismatch repair defect for unknown reasons, likely the result of some interplay between hereditary factors and as yet unidentified mutagen exposure.

30. Despite the awareness of MSI-H cancers for more than 25 years, no treatments tailored for MSI-H cancer were available prior to FDA’s 2017 approval of pembrolizumab for treating MSI-H cancers. Moreover, prior to JHU’s clinical study, no studies indicated that treatment of MSI-H cancers with PD-1 inhibitors would be successful or that MSI-H would be a useful biomarker for identifying patients who would respond to treatment with pembrolizumab or any other drug regardless of cancer type.

2. The Epidemiology of Colorectal Cancer and Inherited Cancer Susceptibility

31. CRC is a representative specific example used here to illustrate the long felt need for an effective treatment for MSI-H cancers arising from any organ in the human body. CRC is the third most common cancer and the second most lethal cancer in the US and worldwide⁶. While its incidence increases with advancing age, the incidence in older patients is falling as screening tests that detect, and permit excision of, premalignant polyps are more widely implemented⁷.

⁶ Bray et al., “Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries,” *CA Cancer J Clin.* (Apr. 4, 2024), (EX2091).

⁷ Zeineddine et al., “Survival improvement for patients with metastatic colorectal cancer over twenty years,” *NPJ Precis Oncol.* (Feb. 13, 2023), (EX2092).

Simultaneously, the CRC incidence rate is rising in younger patients below the age of 50, a phenomenon that remains largely unexplained⁸. A subset of younger patients inherited their cancer susceptibility, and they have a condition such as Lynch Syndrome or another hereditary syndrome that predisposes them to develop CRC at an early age⁹. As discussed above, Lynch syndrome is a familial condition in which errors that occur as DNA is replicated during cell division cannot be repaired as they are in normal individuals. Patients with Lynch Syndrome often develop cancer early in life and are predisposed to develop cancers in multiple organs, but the most common site of disease is CRC. It is estimated that about 3-5% of CRC patients have Lynch Syndrome Cancers, and individuals with Lynch Syndrome tend to develop cancers that are less responsive to standard chemotherapy agents.¹⁰ Regardless of the reason for developing cancer, younger individuals with CRC are characterized as having early onset colorectal cancer.

⁸ Patel et al., “The rising tide of early-onset colorectal cancer: a comprehensive review of epidemiology, clinical features, biology, risk factors, prevention, and early detection,” *Lancet Gastroenterol Hepatol* (Jan. 25, 2022), (EX2093); Sinicrope, “Increasing Incidence of Early-Onset Colorectal Cancer,” *N Engl J Med* (April 21, 2022), (EX2094).

⁹ Sinicrope, “Lynch Syndrome-Associated Colorectal Cancer,” *N Engl J Med*. (Aug. 23; 2018), (EX2095).

¹⁰ Sargent et al., “Defective mismatch repair as a predictive marker for lack of efficacy of fluorouracil-based adjuvant therapy in colon cancer,” *J Clin Oncol*. (Jul. 10, 2010), (EX2096).

32. Most patients with advanced CRC regardless of their age at diagnosis did in 2010-15, and still do in 2024, succumb to their disease within several years of diagnosis. Prior to the discovery that PD-1 inhibitors can be extremely effective in some, but not all, patients in the Lynch subgroup by the JHU research team and their collaborators, Lynch Syndrome patients and patients with an acquired mismatch repair defect with CRC had few effective options to stem the progression of their disease. Even with these discoveries there remains unmet needs for people with CRC, particularly among those with mCRC.

a. Clinical Trial Endpoints

33. Clinical trials endpoints defined by the National Cancer Institute (NCI) in the US include response rate (RR, the number of patients manifesting tumor shrinkage divided by the number of patients given a particular treatment in a study), progression free survival (PFS, the time interval between starting a treatment and the detection of worsening disease), and overall survival (OS, the time from treatment initiation to death). PFS and OS are generally expressed as the median time it takes for the entire pool of patients enrolled in a trial who are treated with a specific intervention to reach these endpoints. The rate of 5-year OS is also an important benchmark as recurrence of CRC is unusual after that long a time interval.

3. Cancer Staging and Survival Rates

34. CRC, along with other types of cancers, is divided into Stages I-IV using a classification system which is updated regularly through consensus by expert panels convened by the American Joint Commission on Cancer (AJCC).¹¹ With recent advances in surgery, drug treatments, and radiation the cure rates for localized CRC have been increasing over time. Currently, in 2024, the cure rates for Stage I disease (limited to the inner lining of the colon or rectum) are ~95%, Stage II disease (limited to the two outer layers of the colon or rectum) ~85%, and Stage III disease (limited to the colon or rectum and nearby regional lymph nodes) ~72%. These statistics have not improved significantly in the last decade.

35. Stage IV CRC denotes CRC that has spread beyond the colon or rectum and regional lymph nodes to involve organs outside of the confines of the colon adjacent to the site of origin of the primary tumor or to distant organs. A classification as Stage IV CRC indicates that a patient has metastatic disease (mCRC). Almost 25% of CRC cases are diagnosed at a metastatic stage, and 50%

¹¹ I am the current chair of the AJCC staging panel for appendix, colorectal, and anal cancers and have worked with the AJCC for nearly twenty years. Our expert panel is currently evaluating the current staging system described below. See Keung et al., “The eighth edition American Joint Committee on Cancer (AJCC) melanoma staging system: implications for melanoma treatment and care,” *Expert Rev Anticancer Ther.* (Aug. 18, 2018), (EX2097).

of patients will develop metastasis over time.¹² A subset of patients with Stage IV disease (10-20%) will have limited spread of their cancer that is amenable to resection, ablation, drug treatment, and/or radiation. Patients in this subgroup of Stage IV have traditionally had the greatest potential to become long term survivors among people with mCRC, although the subset of people with MSI-H CRC tumors now have the greatest potential for long term survival due to the JHU team's discovery¹³. Long term survival in patients with stage IV CRC has been and remains rare, however, particularly in patients who are not candidates for resection or ablation of their limited metastatic sites (see below). At least that was the case prior to the discovery that pembrolizumab was highly effective and often curative for treatment of mCRC in patients with tumors that are MSI-H.

36. Survival rates in Stage IV cancers of other types are similarly low, with the exception of testicular cancer.

¹² Ogunwobi et al., "Biomarkers in colorectal cancer: current research and future prospects," *Int. J. Mol. Sci.* 21, 1–20 (July 2020), (EX2098).

¹³ Kong et al., "Prolonged surveillance of colorectal cancer patients after curative surgeries beyond five years of follow-up," *Ann Transl Med* (Oct. 8, 2019), (EX2099).

Cancer Type	New Cases ¹⁴	Estimated Deaths ¹⁵	Stage IV 5-year Survival % ¹⁶
Oral Cavity & Pharynx	45,780	8,650 (18.9%)	33.5 & 39%
Esophageal	16,980	15,590 (91.8%)	4.8%
Gastric	24,590	10,720 (43.6%)	5.2%
Small Bowel	9,410	1,260 (13.4%)	5% ¹⁷
Cholangiocarcinoma	10,910	3,700 (33.9%)	3% ¹⁸
Liver/Intrahepatic Bile Duct	35,660	24,550 (66.8%)	2.4%
Pancreatic/Ampullary	48,960	40,560 (82.3%)	2.7%
Breast	224,190	40,730 (18.2%)	27%
Ovarian	21,290	14,180 (66.6%)	29%
Endometrial	54,870	10,170 (18.5%)	9%
Cervical	12,900	4,100 (31.8%)	17.2%
Prostate	220,800	27,540 (12.5%)	30%
Bladder	74,000	16,000 (21.6%)	4.8%
Testicular	8,430	380 (4.5%)	73.7%

¹⁴ Siegel et al., “Cancer statistics, 2015,” CA Cancer J Clin. (Jan. 5, 2015), (EX2251).

¹⁵ *Id.*

¹⁶ Noone et al. (eds), “SEER Cancer Statistics Review (CSR), 1975-2015,” National Cancer Institute. Bethesda, MD, based on November 2017 SEER data submission, posted to the SEER web site, April 2018, available at https://seer.cancer.gov/csr/1975_2015/, (EX2252).

¹⁷ Small bowel cancer is not included in the National Cancer Institute SEER Cancer Statistics Review, but one estimate is 5% in 2024. *See* “Survival statistics for small intestine cancer,” Canadian Cancer Society, available at <https://cancer.ca/en/cancer-information/cancer-types/small-intestine/prognosis-and-survival/survival-statistics>, (EX2253); *see also* Chen et al., “Small bowel adenocarcinoma,” Clin. Colon Rectal Surg. (2018), (EX2279).

¹⁸ Cholangiocarcinoma is not included in the National Cancer Institute SEER Cancer Statistics Review, but the ACS estimate is 3% in 2024. *See* “Survival Rates for Bile Duct Cancer,” American Cancer Society, available at <https://www.cancer.org/cancer/types/bile-duct-cancer/detection-diagnosis-staging/survival-by-stage.html>, (EX2254).

B. Therapies Available for Cancer Patients in 2010-2015

1. Chemotherapy and targeted therapy in CRC

37. Again, CRC is an instructive example used here to illustrate the types of therapies available for cancer patients in 2010-2015. Before the priority date of the '187 Patent, which I have been informed by counsel was July 10, 2015, clinical oncologists had two options for the management of mCRC, relying on two classes of drugs: cytotoxic chemotherapy agents and targeted therapies. Notably, both MSI-H and MSS (microsatellite stable patients) metastatic cancer patients were treated the same way when using these drugs. As previously noted, there was no treatment specifically tailored for MSI-H CRC.

38. Cytotoxic drugs interfere with cell division and their effects often do not discriminate between dividing cancer cells and dividing host cells. These drugs typically cause side effects because of their interference with the division of rapidly dividing cells in organs such as the bone marrow and gastrointestinal tract. Cytotoxic drugs available for the treatment of mCRC in the relevant time interval included 5-FU, capecitabine, irinotecan, and oxaliplatin. The common side effects associated with these cytotoxic drugs included nausea, vomiting, diarrhea, decreased appetite, immune suppression, anemia, susceptibility to infection, numbness and tingling in fingers and toes, fatigue, allergic drug reactions, and other toxicities.

39. Targeted therapies are designed to engage with a specific cellular process most often by binding to a protein expressed on the surface of tumor cells. Targeted therapies available for treatment of mCRC at that time included bevacizumab, ziv-aflibercept, cetuximab, and panitumumab. Drawbacks of these drugs included increased chances of bleeding or developing blood clots, rash, nausea, vomiting, fatigue, allergic drug reactions, and others.

40. The first active chemotherapy agent used to treat CRC, 5-Fluorouracil (5-FU), was developed in the early 1970s. In the era when 5-FU was the only available active drug for treatment of patients with mCRC, the median survival was ~12 months¹⁹. Only ~ 1% of patients treated on clinical trials in this era were alive 5 years after diagnosis, *i.e.* 5-year OS of 1%.²⁰. A drug that is in the same family of agents as 5-FU that can be administered orally, called capecitabine, was FDA approved in 1998 and is used interchangeably with 5-FU. The addition of a second novel drug that was FDA approved in 1996, irinotecan, is frequently administered in combination with 5-FU, a regimen referred to as IFL. These two

¹⁹ “Modulation of fluorouracil by leucovorin in patients with advanced colorectal cancer: evidence in terms of response rate,” Advanced Colorectal Cancer Meta-Analysis Project (June 10, 1992), (EX2100).

²⁰ Dy et al., “Long-term survivors of metastatic colorectal cancer treated with systemic chemotherapy alone: a North Central Cancer Treatment Group review of 3811 patients,” N0144, Clin. Colorectal Cancer (Apr. 8, 2009), (EX2101).

agents combined led to an improved median OS of 14.8 months and a 5-year OS to ~3.8%.²¹

41. In 2004 data from clinical trials testing two important new regimens that led to incremental benefits were published. First, the addition of the anti-VEGF (vascular endothelial growth factor) targeted monoclonal antibody bevacizumab to a regimen of irinotecan and 5-FU (i.e. IFL) ushered in the era of targeted therapies using monoclonal antibodies in the treatment of CRC. Bevacizumab targets the development of blood vessels (angiogenesis) that must provide a blood supply to tumors to enable their growth and spread. It was a novel targeted agent at the time it was introduced in that it does not target cancer cells but rather the ingrowth of blood vessels into tumors. Treatment with the IFL plus bevacizumab regimen led to a median OS of 20.3 months (5-year OS not reported).²²

42. The second advance arose from the development and testing of Oxaliplatin, a platinum-based chemotherapy agent, that must be combined with 5-FU (FOLFOX) or capecitabine (CapeOX) to be effective. Data from the NCI

²¹ Saltz et. al., “Irinotecan plus fluorouracil and leucovorin for metastatic colorectal cancer,” Irinotecan Study Group, N. Engl. J. Med. (Sept. 28, 2000), (EX2102); Sanoff et al., “Five-year data and prognostic factor analysis of oxaliplatin and irinotecan combinations for advanced colorectal cancer: N9741,” J. Clin. Oncol. (Dec. 10, 2008), (EX2103).

²² Hurwitz et al., “Bevacizumab plus irinotecan, fluorouracil, and leucovorin for metastatic colorectal cancer,” N. Engl. J. Med. (June 3, 2004), (EX2104).

funded trial N9741 (for which I was the lead author and principal investigator) indicated that patients with mCRC treated with the oxaliplatin-based FOLFOX regimen had a median OS of 20.2 months. A subsequent analysis indicated that FOLFOX treated patients had a 5-year OS of 9.8%.²³ Also, in 2004 a monoclonal antibody targeting a cell surface protein called the EGFR (epidermal growth factor receptor), cetuximab, was approved for treatment of refractory mCRC²⁴. That approval was followed in 2006 with approval of a second agent with a similar mechanism of action and efficacy results, panitumumab.²⁵

43. Thus, in 2012 the approved drugs for treatment of mCRC included the chemotherapy agents 5-FU and capecitabine, irinotecan, and oxaliplatin, and the

²³ Saltz et. al., “Irinotecan plus fluorouracil and leucovorin for metastatic colorectal cancer,” Irinotecan Study Group, N. Engl. J. Med. (Sept. 28, 2000), (EX2102).

²⁴ Saltz et al., “Phase II trial of cetuximab in patients with refractory colorectal cancer that expresses the epidermal growth factor receptor,” J. Clin. Oncol. (Apr. 1, 2004), (EX2105); Van Cutsem et al., “Cetuximab and chemotherapy as initial treatment for metastatic colorectal cancer,” N. Engl. J. Med. (Apr. 2, 2009), (EX2106).

²⁵ Van Cutsem et al., “Open-label phase III trial of panitumumab plus best supportive care compared with best supportive care alone in patients with chemotherapy-refractory metastatic colorectal cancer,” J. Clin. Oncol. (May 1, 2007), (EX2107).

targeted therapy agents bevacizumab, cetuximab, panitumumab, ziv-aflibercept,²⁶ and regorafenib.²⁷

44. In 2017, the results of the CALGB 80405 trial that finished accruing patients in 2012 and compared initial chemotherapy paired with either cetuximab or bevacizumab in mCRC patients were published. The median OS for the cetuximab plus chemotherapy regimens was 30 months and for the chemotherapy plus bevacizumab regimens was 29 months.²⁸ This represented a small but important advance over the previously available treatments, but most patients with mCRC still did then and still do succumb to their disease. Based upon my work with the patient advocacy group Fight Colorectal Cancer, I understand that for patients and their family members these advances were viewed as important but insufficient to meet their needs. They are eager for medical research to find a cure in addition to finding life extending strategies that are non-curative.

²⁶ Ziv-aflibercept has a similar mechanism of action as does bevacizumab and was never widely used in the US so I do not discuss it further in this report. *See* Tabernero et al., “Aflibercept versus placebo in combination with fluorouracil, leucovorin and irinotecan in the treatment of previously treated metastatic colorectal cancer: prespecified subgroup analyses from the VELOUR trial,” *Eur. J. Cancer* (Jan. 2014) (EX2108).

²⁷ Benson et al., “Colon cancer, version 3.2014.,” *J. Natl. Compr. Canc. Netw.* (July 12, 2014), (EX1009).

²⁸ Venook et al., “Effect of First-Line Chemotherapy Combined With Cetuximab or Bevacizumab on Overall Survival in Patients With KRAS Wild-Type Advanced or Metastatic Colorectal Cancer: A Randomized Clinical Trial,” *JAMA* (June 20, 2017), (EX2109).

45. Today, in 2024 optimal patient management in patients treated on clinical trials can lead to median OS as high as 35 months, but according to statistics published by the American Cancer Society the 5-year OS now still only approaches 13%. (<https://www.cancer.org/cancer/types/colon-rectal-cancer/detection-diagnosis-staging/survival-rates.html>, accessed 9/24). In contrast, the 5-year OS for mCRC patients in the JHU study treated with pembrolizumab is 57.5%, representing a nearly five-fold boost in that metric.²⁹

2. Constructing chemotherapy +/- targeted therapy regimens

46. Once multiple drugs become available for the treatment of a solid tumor such as CRC, the concept of lines of therapy became relevant (i.e. first-line therapy, second-line therapy, etc.). Patients receive first-line therapy until their tumors become refractory to that treatment or the toxicity becomes prohibitive. They then progress to subsequent treatment lines. In CRC, as in the treatment algorithms for most cancers, the usual initial treatment approach is to add several chemotherapy drugs together as the use of multiple agents simultaneously, a strategy that often improves outcomes over single agent treatment.³⁰ For example, 5-FU (or its oral equivalent capecitabine) is often paired with oxaliplatin (called

²⁹ Conversation with Dr. Dung Le.

³⁰ McRee et al., “Optimal management of metastatic colorectal cancer: current status,” *Drugs* (May 7, 2011), (EX2110); Lucas et al., “A decade of advances in cytotoxic chemotherapy for metastatic colorectal cancer,” *Clin Colorectal Cancer* (Dec. 10, 2011), (EX2111).

FOLFOX or CapeOX) or irinotecan (called IFL or FOLFIRI). Sometimes FOLFOX and FOLFIRI are combined into a three-drug regimen known as FOLFOXIRI.

47. It is common to add targeted therapies to these chemotherapy backbones. Examples are FOLFOX or FOLFIRI + bevacizumab or FOLFOX or FOLFIRI + cetuximab. In the US, it is most common to use FOLFOX or CapeOx + bevacizumab or cetuximab as first-line therapy. First-line therapy refers to the first regimen employed to treat a patient with metastatic cancer. Typically, second-line therapy would consist of an irinotecan-based regimen if an oxaliplatin-based regimen is used in the first-line or visa versa. The first-line of treatment is generally the most effective as tumors develop resistance to chemotherapy treatments as they are exposed to them. The response rate (RR) (ranging from 55-65%) and progression-free survival (PFS) (ranging from 10-12 months) for first-line therapy is higher than for second-line therapy. Response rates in second-line therapy range from 10-15% with median associated PFS of ~6-8 months and median overall survival (OS) of 10-14 months.³¹

³¹ Modest et al., “Treatment sequencing in metastatic colorectal cancer,” *Eur. J. Cancer* (March 2019), (EX2112).

3. Third and Later Line Therapy

48. Outcomes for patients with mCRC have also been only modestly improved by the testing and FDA approval of several agents specifically for treatment of patients whose disease has become refractory to the first- and second-line regimens as described above. For example, regorafenib, a multitargeted tyrosine kinase inhibitor, was approved in 2012 and the oral agent trifluridine combined with tipiracil was approved in 2015 for treatment of refractory mCRC.³² As is typical for agents deployed in the treatment of CRC patients with heavily pretreated cancers, the response rates associated with these two drugs were very low (<3%). In these studies, the patients received the experimental agent as third-line treatment after patients' disease had progressed on two prior drug regimens. Effective treatment options were so limited in this setting that the control arms for both studies involved no anticancer therapy and consisted of best supportive care. Patients assigned to the best supportive care arms of these trials received no anti-cancer therapy but were treated as needed according to their symptoms with pain medicines, appetite stimulants, bowel regimens, and received help in meeting their daily needs for physical and emotional assistance. A synonym for supportive care

³² Grothey et al., "Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomised, placebo-controlled, phase 3 trial," *Lancet*. (Jan. 26, 2013), (EX2113); Mayer et al., "Randomized trial of TAS-102 for refractory metastatic colorectal cancer," *N. Engl. J. Med.* (May 14, 2015), (EX2114).

is “comfort care”, care whose main goal is to help patients with limited life expectancies to live as well as possible given their terminal illnesses.

49. Until regorafenib and trifuridine/tipiracil were approved there was no effective mCRC third-line therapy. The median OS with best supportive care in both studies was ~ 4.5 months. With regorafenib treatment the response rate was 2.4% and the median OS was 6.4 months and with trifluridine/tipiracil the response rate was 1.6 % and the median OS was 7.1 months.³³ While both agents were quickly adopted into practice, the benefits from treatment with either option were limited and patients, patient advocacy groups, and practitioners all were and still are clamoring for more and better treatment options. There was then and remains now an unmet medical need to improve outcomes for patients with mCRC who are not MSI-H/dMMR and therefore are not eligible for treatment with PD-1 inhibitors.

C. Available Therapies in Other Cancer Types 2010-2015

50. The evolution of treatment of other solid tumors originating elsewhere in the body generally follow the principles described above for CRC. (Solid tumors originate in body organs, as distinct from tumors that originate in the bone marrow

³³ Grothey et al., “Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomised, placebo-controlled, phase 3 trial,” *Lancet*. (Jan. 26, 2013), (EX2113); Mayer et al., “Randomized trial of TAS-102 for refractory metastatic colorectal cancer,” *N. Engl. J. Med.* (May 14, 2015), (EX2114).

and are characterized mainly by the presence of malignant cells in the bloodstream. Those cancers are often classified as liquid tumors). Initially cytotoxic chemotherapy agents were developed as single agents in the setting of treatment refractory advanced disease. Once a drug was shown to have efficacy it was most often combined with other cytotoxic agents on the principle that multiple drugs would be more effective (albeit also more toxic) than single agent treatments. Once specific drivers of the development and progression of specific cancers were discovered, drugs were designed and tested to target those drivers. These agents are often antibodies like pembrolizumab that either switch off or switch on relevant biologic processes. Often these targeted therapies are combined with cytotoxic agents. In testicular cancer, for example, combination chemotherapy proved to be highly effective, leading to 5-year survival rates exceeding 70% (see table above) even in the setting of advanced disease. In most other cancers 5-year overall survival rates remained less than 10% for patients with advanced disease despite the administration of combinations of cytotoxic and targeted agents (see table above). In contrast, the 5-year OS for non-CRC patients in the JHU study treated with pembrolizumab according to the method described in the '187 Patent is 50.3%, again representing a nearly five-fold boost in that metric.³⁴

³⁴ Conversation with Dr. Dung Le.

D. No Effective Immuno-Oncology (IO) Treatments for Cancer Generally Prior to JHU's Clinical Trial

51. At the same time as cancer patients were facing these limited treatment options, immuno-oncology was beginning to offer a new hope for patients in which it would be effective. The term immuno-oncology treatment refers to manipulating the host's immune system to recognize and destroy tumors. The agents that modulate the immune system are often referred to as IO drugs.³⁵

52. Before the priority date of the '187 Patent, Immuno-Oncology (IO) agents were in development by laboratory- and clinic-based research teams working in both academia and industry. Clinical trial findings from that era led to approvals of a new class of IO drugs that allowed oncologists to finally harness the immune system for cancer treatment after decades of study during which there had not been success in that arena. These new drugs work differently than the previously developed chemo- and targeted therapies in that they recruit the patient's own immune system to kill cancer cells. Their discovery and clinical development ushered in a new era in immune system-based cancer treatment. These new agents have been a boon for some patients, often resulting in prolonged complete remissions or cures.

³⁵ Topalian et al., "Immune checkpoint blockade: a common denominator approach to cancer therapy," *Cancer Cell* (Apr. 13, 2015), (EX1013).

53. These discoveries changed and continue to change the paradigm for treatment of people with solid tumors originating from a multitude of different organs. However, they have only been helpful for a subset of patients. Some tumors prove to be exceptionally sensitive to IO drugs, while others originating in the same organ in different patients remain totally refractory to them.

54. Multiple strategies to uncloak tumor cells so that the immune system could be employed to recognize and destroy tumors cells were tested with minimal success until the discovery of PD-1, PD-L1, and CTLA-4 inhibitory antibodies. Nivolumab and pembrolizumab are monoclonal antibodies that target PD-1, a protein present on the surface of tumor cells and of cells that are members of the immune system that reside adjacent to tumor cells. The binding of these antibodies inactivates the cloaking system that allows cancer cells to evade the immune system. Prior to JHU's clinical trial that demonstrated that PD-1 inhibitors were effective in treating MSI-H/dMMR solid tumors, PD-1 inhibitors had shown promise in melanoma and non-small cell lung cancer but had failed to be effective in treating other cancers, including CRC.

55. BMS scientists developed the first clinically effective PD-1 inhibitor, nivolumab. An initial study on the use of nivolumab, which was led by Hopkin's scientist Suzanne Topalian, enrolled 296 patients who had a variety of tumor types,

all with disease refractory, or resistant, to standard therapies.³⁶ Although this trial was mainly conducted to assess safety and tolerability, the outcomes of the treatment on the tumors harbored by these heavily pretreated patients were also assessed. The response rate (RR) in treated patients who had melanoma was 28% and in those with non-small cell lung cancer the RR was 18%. Lesser efficacy was seen in patients with other tumor types. These results were startling as most often few, if any, responses are seen in this type of a heavily pretreated patient population with tumor types that by their nature have limited sensitivity to standard chemotherapy regimens even in first-line therapy.

56. Based on these promising early indications of activity in these two tumor types and the BMS experience with nivolumab, Merck conducted its own studies using pembrolizumab in melanoma and non-small cell lung cancer. The Merck studies in patients with melanoma and non-small cell lung cancer showed similar activity as that observed with nivolumab in these diseases.³⁷

³⁶ Topalian et al., “Safety, activity, and immune correlates of anti-PD-1 antibody in cancer,” N. Engl. J. Med. (June 28, 2012), (EX1013).

³⁷ Robert et al., “Pembrolizumab versus Ipilimumab in Advanced Melanoma,” N. Engl. J. Med. (June 25, 2015), (EX2116); Reck et al., “Pembrolizumab versus Chemotherapy for PD-L1-Positive Non-Small-Cell Lung Cancer,” N. Engl. J. Med. (Nov. 10, 2016), (EX2117).

1. CRC patients in the Topalian Phase I trial

57. As a part of the Phase I study of nivolumab, the Topalian research team treated 14 patients with colorectal cancer (CRC) none of whom had a response to the drug.³⁸ During the later stages of the study an additional 19 CRC patients were treated. One of the 33 CRC patients responded to therapy.³⁹ Treatment of other types of cancer beyond melanoma and non-small cell lung cancer in the Topalian trials similarly failed. A response in 1/33 patients would generally be regarded as too low to justify conducting a Phase II trial to investigate the efficacy in CRC or any tumor type. Also making CRC a less interesting target for ongoing study of a PD-1 inhibitor is the fact that CRC is not associated with known mutagen exposure and therefore those tumors would not likely have the high mutational burden and high level of mutation associated neoantigens thought to possibly explain why PD-1 inhibitors worked in melanoma and non-small cell lung cancers.⁴⁰

³⁸ Brahmer et al., “Phase I Study of Single-Agent Anti–Programmed Death-1 (MDX-1106) in Refractory Solid Tumors: Safety, Clinical Activity, Pharmacodynamics, and Immunologic Correlates,” J. Clinical Oncology (July 1, 2010), (EX2024).

³⁹ Topalian et al., “Safety, activity, and immune correlates of anti-PD-1 antibody in cancer,” N. Engl. J. Med. (June 28, 2012), (EX1013).

⁴⁰ Topalian et al., “Safety, activity, and immune correlates of anti-PD-1 antibody in cancer,” N. Engl. J. Med. (June 28, 2012), (EX1013).

58. CRCs look very similar under the microscope; most are moderately differentiated adenocarcinomas (adenocarcinomas arise from organs with glands- in CRC these glands produce mucous that aids the passage of stool). Around this time, the heterogeneity of tumors was increasingly being recognized despite their homogenous appearance and the potential therapeutic implications of those differences was being explored. This exploration coincided with the improved understanding of the biologic processes that drive tumor development and tumor progression that the Vogelstein lab has focused on for decades.

2. Generating a hypothesis to explain why one CRC patient responded to nivolumab

59. Rather than simply dismissing PD-1 inhibitors' potential in CRC, Dr. Topalian and her team sought to determine if the one CRC patient who had a sustained response to treatment had any distinguishing characteristics. She and her team consulted with Bert Vogelstein and members of his scientific team. The Vogelstein lab has concentrated on elucidating genetic alterations that occur as a part of colorectal cancer carcinogenesis. Luis Diaz, a member of the Vogelstein team, proposed that the responding CRC patient might have a defect in the repair mechanism that corrects errors that occur in DNA replication as an explanation for the sensitivity of that patient's tumor to nivolumab.⁴¹ This defect is known as

⁴¹ David Shaywitz, "The Startling History Behind Merck's New Cancer Blockbuster," FORBES (July 26, 2017), (EX2051).

microsatellite instability and such patients are classified as having MSI-High or MSI-H tumors. The team went back to that patient's pathologic specimen and learned that the tumor in the responding patient was, indeed, MSI-H.

3. Thinking outside the box

60. The finding that PD-1 inhibitors had the potential to be an active agent for a subset of patients with colorectal cancer (CRC) was unexpected. Even more unexpected was the finding that PD-1 inhibitors had the potential to be an active agent for all solid MSI-H tumors, let alone the sixteen specific cancers ultimately claimed in the '187 Patent. This discovery required teams of scientists at Johns Hopkins University working in different laboratories and clinics who were studying the genetics, immunology, and the treatment of colorectal cancers to go up a flight of stairs to caucus. Together they generated the hypothesis that PD-1 inhibitors would be effective treatment in the subset of CRCs and other cancers that have an inherited or acquired defect in the repair of mistakes that occur during the replication of DNA during cell division. This mismatch repair defect is inherited in patients with Lynch Syndrome but can also be acquired in patients through a process known as epigenetic silencing.⁴² The JHU teams posited that this defect in DNA mismatch repair that generates abnormal sections of DNA

⁴² Boland et al., "Microsatellite instability in colorectal cancer," *Gastroenterology* (May 2010), (EX2045).

called microsatellites would result in an accumulation of mutations in DNA that would translate to the presence of mutated proteins on the surfaces of tumor cells that the patient's own immune system could target, like the BMS and Merck teams had observed in melanoma and small-cell lung cancer patients. Estimates are that MSI-H CRC accounts for 10-15% of people with mCRC.

4. Finding support for a trial in MSI-H cancer patients

61. I understand from conversations with the JHU scientists that when they tried to interest the research teams at both BMS and Merck in funding a trial to test their hypothesis, neither company's teams were interested. Despite this disappointing news, the Hopkins team was determined to initiate a clinical trial in CRC patients and patients with other cancer types to test their hunch. They devised a study with two cohorts of CRC patients: Cohort A: patients with MSI-H tumors and Cohort B: those with MSS (microsatellite stable patients). They included a third cohort, (Cohort C) made up of patients with tumors originating from organs other than the colon or rectum that were MSI-H. Because they were unable to obtain pharmaceutical company funding, they funded it with JHU resources and obtained additional support through a grant from the charitable organization Swim Across America.⁴³ Merck's support of the study was limited to providing the pembrolizumab. While the Merck team approved the study protocol,

⁴³ "Issue 38," The Cancer Letter, Vol. 43, No. 38 (Oct. 13, 2017), (EX2121, 4).

the study was designed, funded, and executed by JHU researchers. To speed accrual in a group of patients with a relatively rare subtype of cancer, MSI-H tumors, they also recruited teams at collaborating institutions (including my own) who helped accrue and treat patients enrolled on the study. Without the dogged persistence of Dr. Vogelstein and his colleagues, this study would not have been done. The JHU team also patented their approach with multiple filings including the filing of the '187 Patent, which claimed a method of treating endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer, cholangiocarcinoma, pancreatic cancer, prostate cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer, testicular cancer and oral cancer (hereafter the "Claimed MSI-H Cancers").

5. The Results of the Hopkins Study

62. The seminal JHU sponsored study was designed in 2012 and began enrolling patients in September 2013.⁴⁴ The preliminary results were startling and unexpected leading to the publication of an interim report by Le et al published in the New England Journal of Medicine (NEJM) in on May 30, 2015.⁴⁵ To put this in context, it is unusual for the NEJM to publish Phase II studies and studies that are still in progress (and this was especially true in that era), indicating that the

⁴⁴ Conversation with Dr. Dung Le.

⁴⁵ Le, et al., "PD-1 Blockade in Tumors with Mismatch-Repair Deficiency," N. Engl. J. Med. (June 25, 2015), (EX1031).

expert peer reviewers for the NEJM found the results to be both unexpected and important. Because of studies like this one that show unexpected results and established a new precedent, it is now more common for NEJM to accept papers detailing interim results of early phase trials. In many ways, this study was the breakthrough study that broke the mold. Now the editors at NEJM more commonly publish studies with highly unexpected findings even before those trials have mature results. Such studies are of high interest to their readership and often are practice changing. They also have a favorable effect on the journal's impact factor (a metric used to measure the scientific importance of a journal by calculating the average number of times articles published in the journal are cited in a given year).

63. An update with longer patient follow-up was published in Science in July 2017.⁴⁶ These are highly selective journals with high impact factors (NEJM: 158, ranked 3rd of 168 medical journals, Science 44.7) indicating the peer reviewers' estimate of the importance of these findings. In Cohort A, the patients with MSI-H mCRC, the response rate was 40% and the PFS at 20 weeks was 78%. The median OS had not been reached at the time of reporting and, notably, 21% of patients in cohort A had a complete response to their treatment. Complete

⁴⁶ Le et al., "Mismatch repair deficiency predicts response of solid tumors to PD-1 blockade," Science (July 28, 2017), (EX2118).

responses are seldom seen in patients with mCRC even in first-line therapy. The response in Cohort C was similar, with a complete response rate of 14% and a partial response rate of 57%, and PFS at 20 weeks of 67%. As with Cohort A, the median OS had not been reached at the time of reporting.

64. Pembrolizumab was initially tested in the setting of treatment refractory disease and so the efficacy and tolerability data that came from the trials that led to the approval of regorafenib and trifluridine/tipiracil are appropriate comparators. Contrast these outcomes to the previously noted results of the third-line studies that led to the FDA approvals for regorafenib (RR = 2.4%, median PFS = 1.9 months, median OS = 6.4 months) and trifluoridine/tipiracil (RR = 1.6 months, median PFS = 2.0 months, median OS = 7.1 months). In contrast, in the patients with CRC that was not MSI-H (the MSS cohort) the RR = 0, PFS = 2.2 months and OS = 5.0 months. These results were like those seen in the control arms of the regorafenib and trifluoridine/tipiracil studies where patients received best supportive care without active drug therapy.

65. The importance of the results of the JHU study is also reflected in the FDA granting priority review status to expedite the examination of the data regarding treatment with pembrolizumab for MSI-H. As listed on the FDA website “a Priority Review designation will direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant

improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.” The FDA conditions for priority review include evidence of increased effectiveness in treatment, prevention, or diagnosis of condition; or that provide evidence of an improvement in safety and effectiveness.⁴⁷ FDA priority reviews must be completed by the agency within 6 rather than the standard 10 months of the filing of a completed application.

66. The importance of the results of the JHU study is also reflected in the FDA granting Breakthrough Therapy Designation for the treatment of patients with MSI-H metastatic colorectal cancer.⁴⁸ The Breakthrough Therapy Designation is “intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.”⁴⁹ Merck explained that “the Breakthrough Therapy Designation in advanced colorectal cancer is based on data from a Phase 2

⁴⁷“Review Designation Policy: Priority (P) and Standard (S),” Center for Drug Evaluation and Research: Manual of Policies and Procedures, Office of New Drugs, available at <https://www.fda.gov/media/72723/download>, (EX2280).

⁴⁸ “Merck Receives Breakthrough Therapy Designation from U.S. Food and Drug Administration for KEYTRUDA® (pembrolizumab) in Advanced Colorectal Cancer,” Merck, News Release, (Nov. 2, 2015), (EX2062).

⁴⁹ *Id.*

study evaluating the activity of KEYTRUDA in cancers with microsatellite instability, a well-established feature seen in cells with certain types of DNA repair defects. Findings from the study, led by researchers from Johns Hopkins Kimmel Cancer Center, were presented at the 2015 American Society of Clinical Oncology (ASCO) annual meeting and were published simultaneously in the *New England Journal of Medicine*.”⁵⁰

67. In my experience, attaining Breakthrough Therapy Designation is rare and is reserved for only the most promising therapies. I have authored and participated in hundreds of clinical trials in my career, and the JHU MSI-H clinical trial is the only one that achieved Breakthrough Therapy Designation.

68. It should be noted that these studies were all approved by institutional review boards at the institutions where patients were enrolled. Institutional review boards are specifically tasked with determining if the proposed clinical trial is ethical in its treatment of patients. JHU’s study could not have moved forward without independent approval by each participating institution’s IRB. Had the results of the trial been obvious before it was conducted, *i.e.* that it was obvious that the MSS cohort would not respond, it would have been unethical to construct such a protocol, let alone enroll patients to cohort B, and the IRBs would not have

⁵⁰ *Id.*

approved the trial.⁵¹ While those patients did not have MSI-H tumors and the results of the study showed that group did not respond to pembrolizumab, those results were not predictable or known prior to conducting the trial.

69. The activity of pembrolizumab had not been evaluated prior to this trial in a cohort of patients with mCRC to determine if such patients could benefit from treatment. While pembrolizumab is a PD-1 inhibitor like nivolumab, which had been tested in a group of patients with tumors assumed to be MSS,⁵² it is a different drug. Therefore, it was important to independently test pembrolizumab's potential for benefit in mCRC patients with MSS tumors. Since MSS tumors make up the vast majority of mCRCs, assessing pembrolizumab's activity in this setting was a vital step in assessing the drug's potential.

70. Indeed, it would have been unethical to treat a cancer patient with a therapy *expected* not to work on the patient's cancer. Patients with progressive cancer would risk losing precious time that could be spent receiving an alternative treatment that had some hope of working. During the time spent receiving the ineffective therapy, the patient's cancer may also progress to the point where they

⁵¹ Ethical Guidelines, "Ethics in Clinical Research," NIH Clinical Center, available at <https://www.cc.nih.gov/recruit/ethics>, (EX2119); "The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research," Department of Health, Education, and Welfare (April 18, 1979), (EX2120).

⁵² I understand that the other 32 CRC patients who did not respond to treatment with nivolumab were of unknown MSI status and therefore assumed to be MSS.

may not qualify to receive a different therapy. As a result, doctors would not have prescribed a therapy known not to work, and patients would not have wanted to take it.

E. The Impact of Pembrolizumab for Treating MSI-H Tumors.

1. Individual Patients

71. The patients treated on the JHU study by Le et al were remarkably impacted by their treatment. As an investigator on this study, I treated several patients with MSI-H CRC. Two of my patients, both of whom had MSI-H mCRC, are alive, disease free, and have been off all treatment for more than 10 years. One, Beth Carner, was a 26-year-old young woman who had very advanced disease when I met her. When she first saw me, she had tumors in her neck, breasts, and abdomen and really had only two choices: the trial or signing up for hospice. She was in a wheelchair that day because of spread of the tumor to her femur that had recently been surgically repaired. Her Mayo Clinic based oncology team had been given her a life expectancy projection of 2 months the week before we met. Beth's response to treatment with Keytruda was so dramatic that I described it as "The Lazarus effect", referring the parable in the New Testament where Lazarus rises from the dead.⁵³ Within about a year of starting treatment, she showed no evidence of cancer, and she appears to be cured now a decade after

⁵³ "Issue 38," The Cancer Letter, Vol. 43, No. 38 (Oct. 13, 2017), (EX2121).

stopping treatment. Her story was told as a part of an article in The Cancer Letter (June 10, 2022),⁵⁴ and she was interviewed in a podcast as a part of the Cancer Letter's Cancer History Project.⁵⁵ Her response to this treatment made history.

72. A similar story appeared in the Washington Post on May 28, 2017 relating the story of Stephanie Joho, a CRC patient who received her treatment under the clinical trial at Johns Hopkins University.⁵⁶ When Ms. Joho began treatment with Keytruda in August 2014, her cancer was “raging out of control” and she was “in agony from a malignant mass in her midsection.”⁵⁷ With no other options, she enrolled in the JHU clinical trial for pembrolizumab, and “within just days the excruciating back pain had eased.”⁵⁸ Over months of treatment, Ms. Joho's tumor shrank and ultimately disappeared. She stopped treatment with pembrolizumab in August 2016, “free from all signs of disease.”⁵⁹

⁵⁴ “Issue 23,” The Cancer Letter, Vol. 48, No. 23 (June 10, 2022), (EX2122).

⁵⁵ “How Beth Carner went from six weeks left to live with stage 4 colon cancer to complete remission,” Cancer History Project (June 10, 2022), available at <https://cancerhistoryproject.com/article/how-beth-carner-went-from-six-weeks-left-to-live-with-stage-4-colon-cancer-to-complete-remission/>, (EX2123).

⁵⁶ Laurie McGinley, “‘This is not the end’: Using immunotherapy and a genetic glitch to give cancer patients hope,” Washington Post (May 28, 2017), available at https://www.washingtonpost.com/national/health-science/this-is-not-the-end-experimental-therapy-that-targets-genes-gives-cancer-patients-hope/2017/05/28/cdce31de-365c-11e7-b373-418f6849a004_story.html, (EX2006).

⁵⁷ *Id.*, 1-2.

⁵⁸ *Id.*, 2.

⁵⁹ *Id.*

73. The extraordinary results of treatment of MSI-H non-CRC patients with pembrolizumab was also highlighted in the press. The New York Times described how “[t]he 86 cancer patients were a disparate group, with tumors of the pancreas, prostate, uterus or bone.”⁶⁰ It reported how “[o]ne woman had a cancer so rare there were no tested treatments.”⁶¹ Specifically, Adrienne Skinner, “had an extraordinarily rare and deadly cancer, ampullary cancer, that arises at the end of the bile duct,” with a “dire prognosis.”⁶² After being scheduled for a radical and potentially dangerous surgery to remove part of her pancreas, small intestine, and gall bladder, her tumor was discovered to be MSI-H, and she was treated in JHU’s clinical study instead of surgery. Three months after her first dose of pembrolizumab, Adrienne’s tumor was reported to be gone.⁶³ Her treatment was so successful Adrienne’s doctor told her, “[i]f someone hadn’t told me you have ampullary cancer, I would not have known.”⁶⁴

74. Circumstances like this when patients with very advanced disease can have their future so dramatically altered from incurable to cured are almost

⁶⁰ “Cancer Drug Proves to Be Effective Against Multiple Tumors,” The New York Times (June 8, 2017), available at <https://www.nytimes.com/2017/06/08/health/cancer-drug-keytruda-tumors.html>, (EX2005, 1).

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*, 4.

⁶⁴ *Id.*

unheard of, and this is the only such treatment I have encountered in my 35 years of practicing oncology. They, their families, and we as their caregivers sometimes get to participate in miracles, and that is what this discovery felt like at the time. Without JHU's invention, MSI-H CRC patients would have faced a limited set of treatment options that would have quickly run out. JHU's invention met this long-felt need for treating and in many cases curing MSI-H CRC cancers that would have previously been a death sentence for those patients.

2. Impact on Clinical Practice

a. MSI Testing Before and After 2017

75. Prior to the 2017 MSI-H approval for Keytruda, testing for MSI was rarely ordered by clinical oncologists. The most common reason for MSI testing at that time was to determine if a patient has the inherited defect in DNA mismatch repair that was diagnostic for Lynch Syndrome. This condition leads to multiple errors in the DNA of newly formed cells after cells divide and predisposes patients to develop both multiple cancers and earlier onset of disease than typically observed in individuals without this condition. MSI testing in these patients was done for the purpose of recommending early deployment of more intensive than standard cancer surveillance protocols to screen individuals and their family members who were diagnosed with Lynch Syndrome. In patients whose tumors exhibited MSI-H status, but the DNA repair defect was not present in their normal

(germline) tissues no special screening strategies were recommended beyond screening for subsequent new cancers. Most often this testing was ordered by a medical geneticist and not a medical oncologist.

76. The 2014 National Comprehensive Cancer Network (NCCN) CRC Guidelines recommended MSI-H screening under two circumstances: (1) screening for Lynch Syndrome and (2) Stage II colon cancers.⁶⁵ MSI testing was recommended for Stage II patients because patients with MSI-H tumors have a better prognosis than patients with MSS tumors and oncologists typically would omit postoperative chemotherapy in that limited circumstance. No mention is made regarding any relevance of MSI testing in determining treatment in Stage I, III, or IV colon cancer as the treatment recommendations were not influenced by knowing the status of the tumor's mismatch repair proficiency at that time.⁶⁶

77. The only other NCCN guideline before 2017 that mentions the use of MSI testing is in the guideline for patients with endometrial cancer.⁶⁷ The recommendations focus on making a diagnosis of Lynch Syndrome and were, again, targeted at identifying individuals and families with an inherited cancer

⁶⁵ Benson et al., "Colon cancer, version 3.2014.," J. Natl. Compr. Canc. Netw. (July 12, 2014), (EX1009); "Colon Cancer Version 3.2014, NCCN Clinical Practice Guidelines in Oncology," J Natl Compr Canc Netw. (Jan. 27, 2014), (EX1020, 48).

⁶⁶ *Id.*

⁶⁷ "Uterine Neoplasms Version 1.2014, NCCN Clinical Practice Guidelines in Oncology," J Natl Compr Canc Netw. (Nov. 27, 2013), (EX1089).

susceptibility syndrome. Endometrial and colorectal cancers are the most commonly occurring cancers in individuals with Lynch Syndrome.

78. There was no discussion of performing MSI testing in patients with endometrial or any other solid tumor for the purposes of influencing treatment decisions (as opposed to identifying familial risk) in NCCN guidelines prior to 2017.

79. After 2017, when the FDA indication for pembrolizumab treatment of MSI high tumors was approved, the standard of care changed dramatically. Prior to that time MSI was not a biomarker that was known to be of any use for determining treatment choices in patients with advanced cancers. Very few oncologists would have ever ordered the test. While many clinical oncologists were aware that patients with Lynch Syndrome had a defect in DNA mismatch repair, they associated MSI testing with young onset colorectal and endometrial cancer and patients with a family history of colorectal and/or endometrial cancer. The test was not used for screening purposes outside of the research setting except in the potential management of Stage II colon cancer as noted above. Based on the data reported in the Le et al paper published in NEJM there was a flurry of interest in applying these dramatic findings in their practices. Oncologists had to learn how and when to test for a tumor's MSI status and hospital and third-party laboratories had to develop testing procedures with rapid turnaround times to meet

the needs of their clinical colleagues who were in the trenches making treatment decisions.

80. After the 2017 approval, NCCN guidelines added the recommendation to test patients for MSI-H for the purpose of prescribing pembrolizumab (Keytruda) for multiple cancers including gastric, pancreatic, cholangiocarcinoma, hepatocellular, small intestine, ampullary, anal, prostate, bladder, endometrial, ovarian, cervical, neuroendocrine, thyroid, and breast cancers, among others.⁶⁸

81. As a gastrointestinal oncologist, the finding of the relevance of MSI status as a useful biomarker to indicate potential sensitivity to pembrolizumab and PD-1 inhibitors was a dramatic change. This was especially true considering the incredible responses that I had observed in the colorectal cancer patients that I had personally managed on the JHU study. The prospect of complete and potentially long-term responses led our team and others to order MSI testing on every gastrointestinal cancer patient with advanced (Stage IV) disease at the appropriate time when they met the FDA approved indication for PD-1 inhibitor use in the

⁶⁸ See EX2255-2269 (NCCN Guidelines on gastric cancer, pancreatic adenocarcinoma, hepatocellular carcinoma, biliary tract cancers, small bowel adenocarcinoma, ampullary adenocarcinoma, prostate cancer, bladder cancer, uterine neoplasms, ovarian cancer, cervical cancer, neuroendocrine and adrenal tumors thyroid carcinoma, and breast cancer); *see also* EX2270-2272 (NCCN Guidelines on esophageal and esophagogastric junction cancers, testicular cancer, and head and neck cancers).

course of their disease. Gastrointestinal oncologists such as myself manage 11 different types of cancers that arise in the gastrointestinal tract, including the claimed small bowel cancer, gastric cancer, ampullary cancer, cholangiocarcinoma, pancreatic cancer, esophageal cancer, and liver cancer. After the 2017 approval, teams all over the US began testing for MSI on a routine basis for those cancers.

IV. NEXUS

82. As a practicing oncologist until I stopped seeing patients in 2017, I prescribed Keytruda (pembrolizumab) to my MSI-H patients. When I did so, I followed the instructions in the Keytruda label, and I know that other physicians who administer Keytruda do, too. The Keytruda label includes indications, or diseases, for which FDA has approved the use of the drug.⁶⁹ These indications on the label dictate the uses for which doctors may prescribe Keytruda and the uses for which Merck may market the drug. These indications are also used by insurance companies to determine whether a treatment qualifies for insurance coverage.

83. Prior to approving Keytruda for use in treating MSI-H cancer, FDA first approved Keytruda for treatment of patients with:

⁶⁹ See, e.g., Merck & Co., Inc., “KEYTRUDA® (pembrolizumab),” Full Prescribing Information (May 23, 2017), (EX2124).

- “unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor” in September 2014.⁷⁰
- “metastatic NSCLC [Non-Small Cell Lung Cancer] whose tumors express PD-L1 as determined by an FDA-approved test and who have disease progression on or after platinum-containing chemotherapy” in October 2015,⁷¹
- “recurrent or metastatic HNSCC [Head and Neck Squamous Cell Carcinoma] with disease progression on or after platinum-containing chemotherapy” in August 2016.⁷²
- “adult and pediatric patients with refractory cHL [Classical Hodgkin Lymphoma], or who have relapsed after 3 or more prior lines of therapy” in March 2017.⁷³
- “locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy” in May 2017.⁷⁴

84. In May 2017, FDA granted accelerated approval “for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient: solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or colorectal cancer that has progressed following treatment

⁷⁰ Merck & Co., Inc., “KEYTRUDA® (pembrolizumab),” Full Prescribing Information (Sept. 4, 2014), (EX1055).

⁷¹ Merck & Co., Inc., “KEYTRUDA® (pembrolizumab),” Full Prescribing Information (Oct. 2015), (EX2125).

⁷² Merck & Co., Inc., “KEYTRUDA® (pembrolizumab),” Full Prescribing Information (Aug. 2016), (EX2126).

⁷³ Merck & Co., Inc., “KEYTRUDA® (pembrolizumab),” Full Prescribing Information (Mar. 2017), (EX2127).

⁷⁴ Merck & Co., Inc., “KEYTRUDA® (pembrolizumab),” Full Prescribing Information (May 18, 2017), (EX2128).

with a fluoropyrimidine, oxaliplatin, and irinotecan.”⁷⁵ The label noted that “indication is approved under accelerated approval based on tumor response rate and durability of response.”⁷⁶ The label also cites five clinical trials in which the efficacy of Keytruda was evaluated in MSI-H patients, including KEYNOTE 016, which is JHU’s original clinical trial (NCT01876511).⁷⁷

85. Prior to granting the MSI-H indication for Keytruda, the FDA had not granted a drug approval to treat patients with any type of cancer who manifested a particular biomarker, in this case for cancers that were MSI-H and refractory to standard therapies. A new term was coined for this novel approval; the indication was characterized as being “tumor agnostic.” The concept of a tumor agnostic approval for any drug was unexpected and groundbreaking.

86. Subsequently, the FDA approved a second indication based on MSI-H status on March 21, 2022, for “for the treatment of adult patients with advanced endometrial carcinoma that is MSI-H or dMMR...who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.”⁷⁸ This approval allowed doctors to prescribe Keytruda to

⁷⁵ Merck & Co., Inc., “KEYTRUDA® (pembrolizumab),” Full Prescribing Information (May 23, 2017), (EX2124).

⁷⁶ *Id.*

⁷⁷ *Id.*, 41-42.

⁷⁸ Merck & Co., Inc., “KEYTRUDA® (pembrolizumab),” Full Prescribing Information (May 2022), (EX2300); *see also* EX2305.

patients with advanced endometrial carcinoma who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

87. Prior to the May 2017 approval of the MSI-H indication, Keytruda was not approved for any indication that allowed for the treatment of fifteen of the sixteen Claimed MSI-H Cancer patients.⁷⁹ Practically, this meant that doctors would generally not prescribe Keytruda to patients with one of the Claimed MSI-H Cancers outside of the context of a clinical trial.⁸⁰ Without approved indications for the Claimed MSI-H Cancers, Merck was not able to market Keytruda for use by doctors to treat the majority of these cancers.

88. As a well-known clinician and researcher, I had the opportunity to see patients from across North America who sought my care as their primary oncologist or as a consulting oncologist who would work with their home team on their care strategies. At Ohio State University we rapidly adopted universal MSI testing for our patients and used PD-1 inhibitors when appropriate. For patients

⁷⁹ As I note above, Keytruda was approved to treat recurrent or metastatic Head and Neck Squamous Cell Carcinoma (HNSCC), a subtype of oral cancer. HNSCC patients were generally not tested for MSI status.

⁸⁰ If Merck had a compassionate care program for Keytruda, doctors could prescribe the medication off-label, but Merck would not be able to charge and therefore those uses would not contribute to Keytruda sales. Off-label prescriptions outside of a compassionate care program are rare as it is unlikely that the patient's insurance would cover this expensive drug in that circumstance making administration prohibitively expensive for most patients.

coming for consultations, we would do the MSI testing and guide their local oncologists on the use of pembrolizumab in the patients with MSI-H tumors in accord with Merck's product labeling. I also lectured at meetings and courses worldwide about these new findings and the use of these agents to educate practicing oncologists about these findings.⁸¹ For the first time we could offer the prospect of long-term survival to patients with advanced, treatment refractory mCRC and other metastatic MSI-H solid tumors. Thus, the approval of Keytruda to treat MSI-H cancers completely changed the standard of care for those patients.

89. An oncologist reviewing the Keytruda label would understand that a patient with a Claimed MSI-H Cancer treated under either of these indications would be treated in response to determining that that patient's tumor is either MSI-H or dMMR by testing the patient's tumor.

90. Claim 1 of the '187 Patent claims:

A method for treating a patient having a solid tumor selected from the group consisting of: endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer, cholangiocarcinoma, pancreatic cancer, prostate cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer, testicular cancer and oral cancer, the method comprising:

in response to determining that the solid tumor is microsatellite instability high or DNA mismatch repair deficient, treating a patient having a solid tumor selected from the group consisting of: endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer, cholangiocarcinoma, pancreatic cancer, prostate cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer,

⁸¹ I note that these lectures were not funded by Merck.

testicular cancer and oral cancer with a therapeutically effective amount of pembrolizumab

based on a determination that the solid tumor has progressed following at least one prior cancer treatment,

and further based on previous testing of a biological sample obtained from the patient that the patient's solid tumor exhibits at least one marker for high microsatellite instability or DNA mismatch repair deficiency.

91. I understand that the other claims of the '187 Patent also include the requirement that the patient's cancer is MSI-H or dMMR, the patient's tumor has progressed following a prior treatment, and treating the MSI-H patient with a therapeutically effective amount of pembrolizumab (Keytruda).

92. Each step of the method of treatment described in the '187 Patent is described in the MSI-H related Indications 1.8 on the Keytruda label (in the June 2020 version of the Keytruda label). Treatment with Keytruda according to Indication 1.15 (Endometrial Carcinoma) added to the March 2022 label also practices the claimed method. The Indications and Usage section describes the use of Keytruda as a second-line treatment for MSI-H/dMMR cancer. The Dosage and Administration section instructs physicians to select MSI-H patients for treatment with Keytruda based on the patient testing positive for MSI-H/dMMR. The Recommended Dosage section identifies the appropriate dosage of Keytruda to administer once the patient's cancer has been identified as MSI-H/dMMR. The Clinical Trials section includes clinical trial results showing that the recommended dosages of Keytruda® are therapeutically effective among cancer patients with

MSI-H or dMMR solid tumors relevant to Indications 1.8 and 1.15. As an example, the disclosure of each step of Claim 1 of the '187 Patent in the Keytruda label is shown in the chart below.

1[pre]. A method for treating a patient having a solid tumor selected from the group consisting of endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer, cholangiocarcinoma, pancreatic cancer, prostate cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer, testicular cancer and oral cancer, the method comprising:

The Keytruda® label instructs physicians to select patients for treatment with Keytruda according to Indication 1.8 and Indication 1.15, added in March 2022:

1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer

KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

- solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or
- colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

This indication is approved under accelerated approval based on tumor response rate and durability of response [see *Clinical Studies* (14.8)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Limitations of Use: The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established.

EX2129, 5.

1.15 Endometrial Carcinoma

KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is not MSI-H or dMMR, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see *Dosage and Administration* (2.1)].

EX2300, 6.

The Claimed MSI-H Cancers are each solid tumors that a physician would treat under Indications 1.8 and 1.15.

1[a]. in response to determining that the solid tumor is microsatellite instability high or DNA mismatch repair deficient, treating a patient having a solid tumor selected from the group consisting of: endometrial cancer, small bowel cancer, gastric cancer, ampullary cancer, cholangiocarcinoma, pancreatic cancer, prostate cancer, breast cancer, esophageal cancer, liver cancer, ovarian cancer, uterine cancer, cervical cancer, bladder cancer, testicular cancer and oral cancer with a therapeutically effective amount of pembrolizumab

The Recommended Dosage section of the Keytruda® label provides the recommended dosages of Keytruda®, administered in response to determining that the solid tumor is MSI-H/dMMR, as well as the duration/timing of treatment based on the indication, wherein the indication is directed to cancers confirmed to be MSI-H/dMMR, including the Claimed MSI-H Cancers:

2.2 Recommended Dosage

Table 1: Recommended Dosage

Indication	Recommended Dosage of KEYTRUDA	Duration/Timing of Treatment
Monotherapy		
Adult patients with NSCLC, SCLC, HNSCC, cHL, PMBCL, locally advanced or metastatic Urothelial Carcinoma, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, Gastric Cancer, Esophageal Cancer, Cervical Cancer, HCC, MCC, TMB-H Cancer, or cSCC	200 mg every 3 weeks* or 400 mg every 6 weeks*	Until disease progression, unacceptable toxicity, or up to 24 months

* 30-minute intravenous infusion

EX2129, 7-8; *see also* EX2300, 8.

The Keytruda® label includes clinical trial results showing that the recommended dosages of Keytruda® are therapeutically effective among cancer patients with MSI-H/dMMR solid tumors, including Claimed MSI-H Cancers, relevant to Indications 1.8 and 1.15:

14.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer

The efficacy of KEYTRUDA was investigated in patients with MSI-H or mismatch repair deficient (dMMR), solid tumors enrolled in one of five uncontrolled, open-label, multi-cohort, multi-center, single-arm trials. Patients with active autoimmune disease or a medical condition that required immunosuppression were ineligible across the five trials. Patients received either KEYTRUDA 200 mg every 3 weeks or KEYTRUDA 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. A maximum of 24 months of treatment with KEYTRUDA was administered. For the purpose of assessment of anti-tumor activity across these 5 trials, the major efficacy outcome measures were ORR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ, and DoR.

Table 51: Response by Tumor Type

	N	Objective Response Rate n (%)	95% CI	Duration of Response range (months)
CRC	90	32 (36%)	(26%, 46%)	(1.6+, 22.7+)
Non-CRC	59	27 (46%)	(33%, 59%)	(1.9+, 22.1+)
Endometrial cancer	14	5 (36%)	(13%, 65%)	(4.2+, 17.3+)
Biliary cancer	11	3 (27%)	(6%, 61%)	(11.6+, 19.6+)
Gastric or GE junction cancer	9	5 (56%)	(21%, 86%)	(5.8+, 22.1+)
Pancreatic cancer	6	5 (83%)	(36%, 100%)	(2.6+, 9.2+)
Small intestinal cancer	8	3 (38%)	(9%, 76%)	(1.9+, 9.1+)
Breast cancer	2	PR, PR		(7.6, 15.9)
Prostate cancer	2	PR, SD		9.8+
Bladder cancer	1	NE		
Esophageal cancer	1	PR		18.2+
Sarcoma	1	PD		
Thyroid cancer	1	NE		
Retroperitoneal adenocarcinoma	1	PR		7.5+
Small cell lung cancer	1	CR		8.9+
Renal cell cancer	1	PD		

CR = complete response

PR = partial response

SD = stable disease

PD = progressive disease

NE = not evaluable

EX2129, 73-75.

As a Single Agent for the Treatment of Advanced MSI-H or dMMR Endometrial Carcinoma

The efficacy of KEYTRUDA was investigated in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. The trial enrolled 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma in Cohorts D and K who received at least one dose of KEYTRUDA. MSI or MMR tumor status was determined using polymerase chain reaction (PCR) or immunohistochemistry (IHC), respectively. Patients with autoimmune disease or a medical condition that required immunosuppression were ineligible. Patients received KEYTRUDA 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression. Patients treated with KEYTRUDA without disease progression could be treated for up to 24 months. Assessment of tumor status was performed every 9 weeks for the first 12 months, and every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ.

Table 80: Efficacy Results in Patients with Advanced MSI-H or dMMR Endometrial Carcinoma in KEYNOTE-158

Endpoint	KEYTRUDA n=90*
Objective Response Rate	
ORR (95% CI)	46% (35, 56)
Complete response rate	12%
Partial response rate	33%
Duration of Response	n=41
Median in months (range)	NR (2.9, 55.7+)
% with duration ≥12 months	68%
% with duration ≥24 months	44%

* Median follow-up time of 16.0 months (range 0.5 to 62.1 months)

+ Denotes ongoing response

NR = not reached

EX2300, 114-115.

1[b]. based on a determination that the solid tumor has progressed following at least one prior cancer treatment,

The Keytruda® label instructs physicians to select patients having a solid tumor that has progressed following prior treatment for treatment with Keytruda according to Indication 1.8 and Indication 1.15, added in March 2022:

1.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer

KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

- solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or
- colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

This indication is approved under accelerated approval based on tumor response rate and durability of response [see *Clinical Studies (14.8)*]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Limitations of Use: The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established.

EX2129, 5.

1.15 Endometrial Carcinoma

KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of patients with advanced endometrial carcinoma that is not MSI-H or dMMR, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation [see *Dosage and Administration (2.1)*].

EX2300, 6.

1[c]. and further based on previous testing that the patient's solid tumor exhibits at least one marker for high microsatellite instability or DNA mismatch repair deficiency.

The Dosage and Administration section (Section 2) of the Keytruda Label instructs physicians to select patients having a cancer that is either MSI-H or dMMR for treatment with Keytruda according to Indications 1.8 and 1.15. That section further refers physicians to Clinical Studies section 14.8 that instructs physicians to test or have tested the patient tumor's MSI-H/dMMR status.

2 DOSAGE AND ADMINISTRATION

2.1 Patient Selection for NSCLC, HNSCC, Urothelial Carcinoma, Gastric Cancer, Esophageal Cancer, Cervical Cancer, MSI-H or dMMR Cancer, MSI-H or dMMR CRC, or TMB-H Cancer

Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in:

- stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation [see Clinical Studies (14.2)].
- metastatic NSCLC [see Clinical Studies (14.2)].
- first-line treatment of metastatic or unresectable, recurrent HNSCC [see Clinical Studies (14.4)].
- metastatic urothelial carcinoma [see Clinical Studies (14.7)].
- metastatic gastric cancer [see Clinical Studies (14.10)]. If PD-L1 expression is not detected in an archival gastric cancer specimen, evaluate the feasibility of obtaining a tumor biopsy for PD-L1 testing.
- metastatic esophageal cancer [see Clinical Studies (14.11)].
- recurrent or metastatic cervical cancer [see Clinical Studies (14.12)].

For the MSI-H/dMMR indications, select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens [see Clinical Studies (14.8, 14.9)].

EX2129, 7; *see also* EX2300, 7 (referring to sections 14.7 and 14.8).

Further, the Dosage and Administration section refers physicians to Clinical Studies section 14.8 that instructs physicians to test or have tested the patient tumor's MSI-H/dMMR status:

14.8 Microsatellite Instability-High or Mismatch Repair Deficient Cancer

The efficacy of KEYTRUDA was investigated in patients with MSI-H or mismatch repair deficient (dMMR), solid tumors enrolled in one of five uncontrolled, open-label, multi-cohort, multi-center, single-arm trials. Patients with active autoimmune disease or a medical condition that required immunosuppression were ineligible across the five trials. Patients received either KEYTRUDA 200 mg every 3 weeks or KEYTRUDA 10 mg/kg every 2 weeks. Treatment continued until unacceptable toxicity or disease progression that was either symptomatic, rapidly progressive, required urgent intervention, or occurred with a decline in performance status. A maximum of 24 months of treatment with KEYTRUDA was administered. For the purpose of assessment of anti-tumor activity across these 5 trials, the major efficacy outcome measures were ORR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ, and DoR.

The identification of MSI-H or dMMR tumor status for the majority of patients (135/149) was prospectively determined using local laboratory-developed, polymerase chain reaction (PCR) tests for MSI-H status or immunohistochemistry (IHC) tests for dMMR. Fourteen of the 149 patients were retrospectively identified as MSI-H by testing tumor samples from a total of 415 patients using a central laboratory developed PCR test. Forty-seven patients had dMMR cancer identified by IHC, 60 had MSI-H identified by PCR, and 42 were identified using both tests.

EX2129, 73-74; *see also* EX2300, 89-90 (section 14.7).

The Clinical Studies section 14.15 also instructs physicians to test or have tested the patient tumor's MSI-H/dMMR status in endometrial cancer:

As a Single Agent for the Treatment of Advanced MSI-H or dMMR Endometrial Carcinoma

The efficacy of KEYTRUDA was investigated in KEYNOTE-158 (NCT02628067), a multicenter, non-randomized, open-label, multi-cohort trial. The trial enrolled 90 patients with unresectable or metastatic MSI-H or dMMR endometrial carcinoma in Cohorts D and K who received at least one dose of KEYTRUDA. MSI or MMR tumor status was determined using polymerase chain reaction (PCR) or immunohistochemistry (IHC), respectively. Patients with autoimmune disease or a medical condition that required immunosuppression were ineligible. Patients received KEYTRUDA 200 mg intravenously every 3 weeks until unacceptable toxicity or documented disease progression. Patients treated with KEYTRUDA without disease progression could be treated for up to 24 months. Assessment of tumor status was performed every 9 weeks for the first 12 months, and every 12 weeks thereafter. The major efficacy outcome measures were ORR and DoR as assessed by BICR according to RECIST v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ.

EX2300, 114.

93. In my opinion, an oncologist prescribing Keytruda to a cancer patient under the MSI-H-related indications described above would necessarily practice the method of treatment claimed in at least Claim 1 of the '187 Patent. As a result, there is a nexus between the claims of the '187 Patent and the methods of treating the Claimed MSI-H Cancers according to the Keytruda label.

APPENDIX A

RICHARD M. GOLDBERG, MD
CURRICULUM VITAE

Updated: 7/12/2024

PERSONAL INFORMATION



Richard M. Goldberg, M.D.
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Morgantown, WV 26508
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EDUCATION

Fellowship:	July 1982 to June 1984 Vincent T. Lombardi Cancer Research Center Georgetown University Washington, DC Medical Oncology
Intern/Resident:	July 1979 to June 1982 Emory University Hospitals Atlanta, GA Intern, Junior, and Senior Assistant Resident in Internal Medicine
M.D.:	September 1975 to May 1979 State University of New York Upstate Medical University Syracuse, NY
A.B. cum laude:	September 1971 to May 1975 Harvard University Cambridge, MA

CERTIFICATIONS

- Diplomate, American Board of Internal Medicine - 1982
- Diplomate, ABIM Subspecialty; Medical Oncology - 1986
- Medical Licensure: Current: West Virginia (2017-) 27476 (inactive)
Past: Ohio (2011-17)
North Carolina (2004-2011)
Minnesota (1994-2004)
Pennsylvania (1984-1994)
Virginia (1982-1985)
Georgia (1980-1982)

PROFESSIONAL EXPERIENCE - EMPLOYMENT HISTORY

8/1/2024-present	Editor-in Chief for Oncology, UpToDate
10/8/2021-present	Adjunct Professor, West Virginia University School of Medicine
5/1/2020-present	Professor Emeritus, West Virginia University School of Medicine
7/1/2023-present.	Member, Friends Board of Directors, West Virginia Public Broadcasting
8/1/2023-present	Member, Board of Directors, Exesalibero Pharmaceuticals LLC
1/1/2020-present	Member, Board of Directors, and Director of Clinical Science, Fightcolorectalcancer.org
1/1/2020-present	CEO Oncology Developments LLC, Consultant for academic medical centers, the pharmaceutical industry and expert witness services
8/2011-present	Associate Group Chair Alliance for Clinical Trials in Oncology
1/1/2020-present	Director Emeritus of the West Virginia University Cancer Institute and the Mary Babb Randolph Cancer Center
1/31/17-12/31/2019	Director of the West Virginia University Cancer Institute and the Mary Babb Randolph Cancer Institute Professor of Medicine Laurence S. & Jean J. DeLynn Chair of Oncology
10/2011-12/31/2016	Professor of Medicine, The Ohio State University Wexner Medical Center - Columbus, OH - Physician-in-Chief, The James Cancer Hospital and Solove Research Institute at The Ohio State University - Columbus, OH - Associate Director of Outreach for the James Cancer Center and Solove Research Institute at The Ohio State University - The Klotz Family Chair in Cancer Research
4/2015-4/2016	Acting Chief, Division of Medical Oncology, The Ohio State University Wexner Medical Center Columbus, OH
8/2003-10/2011	Professor and Chief, Division of Hematology/Oncology - The Richard M. Goldberg Distinguished Professor of Gastrointestinal Cancer Research University of North Carolina at Chapel Hill - Chapel Hill, NC - Physician-in-Chief, The NC Cancer Hospital at University of North Carolina at Chapel Hill - Chapel Hill, NC - Associate Director of Clinical Research for the UNC Lineberger Comprehensive Cancer Center University of North Carolina at Chapel Hill - Chapel Hill, NC
2010-2015	Chair and Chief Executive Officer, ARCAD US Foundation (Aide et Recherche en Cancerologie Digestive)
2010-2017	Co-Chair, Society of Translational Oncology

3/2010-8/2011	Associate Group Chair for Intergroup Affairs of the Cancer and Leukemia Group B (CALGB)
6/2006-2/2010	Chair, Gastrointestinal Cancer Committee (CALGB)
6/1998-5/2003	Consultant in Medical Oncology Mayo Clinic-Rochester, MN
1995-2003	Co-Chair, Mayo Cancer Center Gastrointestinal Cancer Research Program
11/1994-8/2003	Chair, Gastrointestinal Cancer Committee (NCCTG)
11/1994-6/1998	Senior Associate Consultant in Medical Oncology Mayo Clinic - Rochester, MN
8/1984-10/1994	Associate in Medical Oncology Geisinger Medical Center and Clinic - Danville, PA
1992-1994	Vice Chairman, Departments of Medicine, Geisinger Medical Center and Clinic - Danville, PA
1990-1992	Assistant Chairman, Departments of Medicine, Geisinger Medical Center and Clinic - Danville, PA
1983-1984	Home Care Physician Hospice of Northern Virginia - Arlington, VA

EXPERT WITNESS EXPERIENCE

2019-2021	Genentech assertion of patent rights for bevacizumab with makers of biosimilars Resolution: settled out of court in favor of Genentech
2020-2023	Taiho assertion of patent rights for Lonsurf challenged by 4 generic drug makers Resolution: Federal Judge in the Delaware found for Taiho in all four disputed matters

HONORS AND AWARDS

2021.	Honorary member, Azerbaijan Society of Oncologists
2020	Ruesch Center for the Cure of Gastrointestinal Cancers 2020 Luminary Award in GI Cancers
2020	Shafer Memorial Lecture, Georgetown University, Washington DC
2019	Garlove Annual Memorial Lectureship, Lexington, KY
2016	OSU Award for Outstanding Patient Satisfaction
2016, 20-24	ASCO Advocacy Champion
2015	One of five nominees; Giants in Oncology Award for Gastrointestinal Cancer
2013	Bob Pinedo Cancer Care Prize Lectureship: Ten Years of Progress in the Management of Colorectal Cancer at the GI Cancer Symposium Elected to be a Fellow of the American Society of Clinical Oncology
2012	Charles G. Moertel Lectureship, The Alliance for Clinical Trials in Oncology
2011	ASCO Statesman Award Third Susan Treadwell Fellow, Providence Hospital - Anchorage, Alaska
2006-2007	President, International Society of Gastrointestinal Oncology
2007	Volkman Memorial Lectureship, Eastern Carolina University - Greenville, NC
2006	Susan B. Lester Lectureship in Cancer at the University of Kentucky - Lexington, KY

2005	Frisbee Memorial Lectureship, Yale University - New Haven, CT
2003	Mayo Clinic Individual Achievement Award
	Recipient "Cancer Fighting Hero" award from Minnesota State Division of the American Cancer Society
	Identified as one of 318 Leading Cancer Specialists by Good Housekeeping
2001-2020	Listing in The Best Doctors in America
2004-2020	Listing in Best Oncologists
2001-2020	Listing in Castle Connolly Best Doctor
	Listing in Who's Who in Engineering and Science
	Listing in Who's Who in the World
	Listing in 2000 Notable American Men
	Listing in Who's Who
1986 & 1987	Commendations for Teaching Excellence
1989	Fellow, American College of Physicians
1978	Alpha Omega Alpha Membership

BOOKS AND CHAPTERS

1. Smith F and **Goldberg R**. Colorectal and Pancreatic Cancer. In: Pinedo H, ed. *Cancer Chemotherapy Update 1984*. Amsterdam: Excerpta Medica; 1984.
2. **Goldberg R** and Woolley P. Nonsurgical Treatment of Gastric Cancer. In: Moossa AR ed. *Comprehensive Textbook of Clinical Oncology*. Baltimore: Williams and Wilkins; 1986:1042-1052.
3. **Goldberg RM** and Erlichman C. New Agents in the Treatment of Colon Cancer. In: Bleiberg H, Rougier P, Wilke, H-J, ed. *Management of Colorectal Cancer*. London: Martin Dunitz Ltd; 1998:331-344.
4. Loprinzi CL, **Goldberg RM**, Peethambaram P. Cancer Anorexia/Cachexia. In: Berger A, Levy M, Portenoy R, Weissman D, ed. *Principals and Practice of Supportive Oncology*. Philadelphia: Lippincott-Raven Publishers; 1998:133-140.
5. **Goldberg RM** and Loprinzi CL. Cancer Anorexia/Cachexia. In: von Gunten CF, ed. *Palliative Care and Rehabilitation of Cancer Patients*. Boston: Kluwer Academic Publishers; 1999:31-42.
6. McMurrick PJ, Nelson H, **Goldberg RM**, Haddock M. Therapy of Tumors of the Anal Canal. In: Torosian MH, ed. *Integrated Cancer Management-Surgery, Medical Oncology and Radiation Therapy*. New York: Marcel Dekker, Inc.; 1999:195-220.
7. **Goldberg RM**. Gastrointestinal Tract Cancers. In: Casciato DA; Lowitz BB, ed. *Manual of Clinical Oncology, 4th edition*. Baltimore, MD: Williams and Wilkins, Inc.; 2000:172-217.
8. Gunderson LL, Haddock MG, **Goldberg RM**, Burch PA, Trastek V, Donohue J, Nelson H. Alimentary Cancer Chapter. In: *Clinical Oncology, eighth edition*. Philadelphia, PA: W.B. Saunders; 2001:685-764.
9. **Goldberg RM** and Erlichman C. New Chemotherapy Approaches in Colorectal Cancer. In: Bleiberg H, Kemeny N, Rougier P, Wilke, H-J, ed. *Colorectal Cancer: A Clinical Guide to Therapy*. London: Martin Dunitz Ltd; 2002:629-638.
10. **Goldberg RM** and Sargent D. The Mayo Clinic/ NCCTG Regimen in the Treatment of Colon Cancer. In: Bleiberg H, Kemeny N, Rougier P, Wilke H-J, ed. *Colorectal Cancer: A Clinical Guide to Therapy*. London: Martin Dunitz Ltd; 2002:431-440.

11. Jacobson S*, Alberts S, **Goldberg RM**. Oxaliplatin in the Treatment of Colorectal Cancer. In Saltz L, ed. *Colorectal Cancer: Multimodality Management*. Totowa, NJ: Humana Press; 2002:525-567.
12. **Goldberg RM**, Martenson JA, Alberts SM. Chemotherapy and Radiation Therapy of Pancreatic Cancer. In: Rustgi AK, Crawford J, ed. *Gastrointestinal Cancers*. Edinburgh: WB Saunders Co.; 2003:449-462.
13. Sargent D, **Goldberg R**, Limburg P. Gastrointestinal Cancers. In: Machin D, Day S, Green S, ed. *Textbook of Clinical Trials*. John Wiley & Sons Ltd; 2003:117-139.
14. Erlichman C, **Goldberg RM**, Sargent DJ. The Mayo/NCCTG Experience with 5-FU and Leucovorin in Patients with Advanced Colorectal Cancer and in the Adjuvant Setting. In: *Fluoropyrimidines in Cancer Therapy, Cancer Drug Discovery and Development Series*. Totowa, NJ: Humana Press; 2003:191-199.
15. Alberts SR and **Goldberg RM**. Gastrointestinal Tract Cancers. In: Williams, DA, ed. *Manual of Clinical Oncology, 5th edition*. Baltimore, MD: Williams and Wilkins Inc.; 2004:185-232.
16. Gill S* and **Goldberg RM**. Colorectal Cancer. In: Bayless TM and Diehl AM, ed. *Adjuvant and Advanced Disease Chemotherapy in Advanced Therapy in Gastroenterology and Liver Disease, 5th edition*. Hamilton, Ontario: BC Decker Inc.; 2004:563-569.
17. Ilson DH, Gill S, **Goldberg RM**. Cancers of the Gastrointestinal Tract. In: Govindan R, ed. *DeVita, Hellman, and Rosenberg's Cancer Principles and Practice of Oncology Review, 1st edition*. Philadelphia, PA: Lippincott, Williams, and Wilkins; 2005:174-212.
18. Kelly H* and **Goldberg RM**. Chapter 15: Clinical Trials and Emerging Therapies. In: Levin B, Ades T, Brooks D, Crane CH, Hoff PM, Limburg PJ, Rothenberger DA, ed. *Complete Guide to Colorectal Cancer, 1st edition*. Atlanta, GA: American Cancer Society; 2006:209-220.
19. Spunt SL, Furman WL, La Quaglia M, Bondy M, **Goldberg RM**. Colon and Rectal Cancer. In: Bleyer A, O'Leary M, Burr R, Ries LAG, ed. *Cancer Epidemiology in Older Adolescents and Young Adults 15 to 29 years of Age, Including SEER Incidence and Survival: 1975-2000*. Bethesda, MD: National Cancer Institute (NIH Pub No. 06-5767); 2006:123-134.
20. O'Neil BH, Kelly H, Morse MA, **Goldberg RM**. Adjuvant Chemotherapy for Colorectal Cancer. In: Saltz L, ed. *Colorectal Cancer: Evidence-based Chemotherapy Strategies*. (Current Clinical Oncology series edited by Markman M). Totowa, NJ: Humana Press; 2006:133-157.
21. Sargent D, **Goldberg R**, Limburg P. Gastrointestinal Cancers. In: Machin D, Green S, ed. *Textbook of Clinical Trials*. Chichester, England: John Wiley & Sons; 2006:81-104.
22. Alberts SR and **Goldberg RM**. Gastrointestinal Tract Cancers. In: Casciato DA, Territo MC, ed. *Manual of Clinical Oncology, 6th edition*. Philadelphia, PA: Williams and Wilkins, Inc; 2009:188-207.
23. Raftery L, Bernard S, **Goldberg RM**. Management of the Gastrointestinal Side Effects of Therapy in Older Adults with Cancer. In: Hurria A, Cohen H, ed. *Practical Geriatric Oncology, 1st edition*. New York: Cambridge University Press; 2010:400-418.
24. Gupta Mohile S, Kaur HP, **Goldberg RM**. Management of Colon and Rectal Cancer in Older Adults. In: Hurria A, Cohen H, ed. *Practical Geriatric Oncology, 1st edition*. New York: Cambridge University Press; 2010:148-170.
25. Jessup JM, **Goldberg RM**, Asare, EA, et al. Colon and Rectum. In: Amin MB, Edge S, Greene F, Byrd DR, Brookland RK, et al. ed. *AJCC Cancer Staging Manual 8th edition*. Springer International; 2017: 251-274.

26. Welton ML, Steele SR, Goodman KA, **Goldberg, RM**, et al. Anus. In: Amin MB, Edge S, Greene F, Byrd DR, Brookland RK, et al. ed. *AJCC Cancer Staging Manual 8th edition*. Springer International; 2017: 275-284.

PEER-REVIEWED ARTICLES

1. Stefanik D, **Goldberg R**, Byrne P, Smith F, Ueno W, Smith L, Bachenheimer L, Beiser C, Dritschilo A. *Local-Regional Failure in Patients Treated with Adjuvant Chemotherapy for Breast Cancer*. J Clin Oncol. 3: 660-665, 1985. PMID: 3998783.
2. **Goldberg RM**, Ayoob M, Silgals R, Ahlgren JD, Neefe JR. *Phase II Trial of Lymphoblastoid Interferon in Metastatic Malignant Melanoma*. Cancer Treat Rep. 69: 813-816, 1985. PMID: 4016791.
3. **Goldberg R**, Smith F, Ueno W, Ahlgren JD, Schein PS. *5-fluorouracil, Adriamycin, and Mitomycin in the Treatment of Adenocarcinoma of Unknown Primary*. J Clin Oncol. 4: 395-399, 1986. PMID: 3754004.
4. Korec S, Schein P, Smith F, Neefe J, Woolley P, **Goldberg R**, Phillips T. *Treatment of Cancer-Associated Hemolytic Uremic Syndrome with Staphylococcal Protein A Immunoperfusion*. J Clin Oncol. 4: 210-215, 1986. PMID: 3944604.
5. **Goldberg R**: *Cured in my lifetime?* Geisinger Quarterly. 4: 28, 1987.
6. Letendre L, Niedringhaus R, Therneau T, Gastineau D, **Goldberg R**, Gerstner JB, Mailliard JA, Gundlach WJ, Kardinal CG, Pierre RV. *Treatment of Acute Nonlymphocytic Leukemia in the Elderly with Intermediate High-Dose Cytosine Arabinoside*. Med Pediatr Oncol. 17: 79-82, 1989. PMID: 2704340.
7. Windschitl HE, O'Connell MJ, Wieand HJ, Krook JE, Rubin J, Moertel CG, Kugler JW, Pfeifle DM, **Goldberg RM**, Laurie JA. *A Clinical Trial of Biochemical Modulation of 5-Fluorouracil with N-Phosphonoacetyl-L-Aspartate and Thymidine in Advanced Gastric and Anaplastic Colorectal Cancer*. Cancer. 66: 853-856, 1990. PMID: 2201430.
8. **Goldberg RM**, Jett JR, Therneau T, Johnson PS, Tschetter LK, Krook JE, Veeder MH, Owen D, Etzell PS, Andres DF. *Bolus versus Infusion Regimens of Etoposide and Cisplatin in Treatment of Non-Small Cell Lung Cancer: A Study of the North Central Cancer Treatment Group*. J Natl Cancer Inst. 82: 1899-1903, 1990. PMID: 2174464.
9. Loprinzi CL, Ellison NM, **Goldberg RM**, Michalak JC, Burch PA. *Alleviation of Cancer Anorexia and Cachexia; Studies of the Mayo Clinic and the North Central Cancer Treatment Group*. Semin Oncol. 17 (6 Suppl 9): 8-12, 1990. PMID: 2259930.
10. Mahood DJ, Dose AM, Loprinzi CL, Veeder MH, Athmann LM, Therneau TM, Sorenson JM, Gainey DK, Mailliard JA, Gusa NL, Finck GK, Johnson C, **Goldberg RM**. *Inhibition of Fluorouracil-Induced Stomatitis by Oral Cryotherapy*. J Clin Oncol. 9: 449-452, 1991. PMID: 1999715. (Reprinted in *Classic Papers and Current Comments: Highlights of Supportive Care Research* 4:337-340, 1999.
11. Long HJ 3rd, Wieand HS, Foley JF, Niedringhaus RD, Laurie JA, Morton RF, **Goldberg RM**, Mailliard JA, Malkasian GD, Edmondson JH. *Phase II Evaluation of Menogaril in Patients with Advanced Cervical Carcinoma. A Collaborative Trial of the North Central Cancer Treatment Group and Mayo Clinic*. Invest New Drugs. 9: 349-351, 1991. PMID: 1839536.
12. **Goldberg, RM**. *Perspectives from Populations Applied to the Perspective of the Patient*. Geisinger Bulletin. 41:4-8, 1991.

13. Ahlgren JD, Trocki O, Gullo JJ, **Goldberg RM**, Muir WA, Sisk R, Schacter L. *Protracted Infusion of 5-FU with Weekly Low-Dose Cisplatin as Second-Line Therapy in Patients with Metastatic Colorectal Cancer Who Have Failed 5-FU Monotherapy.* Cancer Invest. 9: 27-33, 1991. PMID: 2012994.
14. Loprinzi CL, **Goldberg RM**, Burnham NL. *Cancer-Associated Anorexia and Cachexia. Implications for Drug Therapy.* Drugs. 43: 499-506, 1992. PMID: 1377116.
15. Loprinzi CL, Michalak JC, Schaid DJ, Maillaird JA, Athmann LM, **Goldberg RM**, Tschetter LK, Hatfield AK, Morton RF. *Phase III Evaluation of Four Doses of Megestrol Acetate as Therapy for Patients with Cancer Anorexia and/or Cachexia.* J Clin Oncol. 12: 762-767, 1993. PMID: 8478668.
16. **Goldberg RM**, Loprinzi CL, O'Fallon JR, Veeder MH, Miser AW, Maillaird JA, Michalak JC, Dose AM, Rowland KM Jr, Burnham NL. *Transdermal Clonidine for Ameliorating Tamoxifen-Induced Hot Flashes.* J Clin Oncol. 12: 155-158, 1994. (Reprinted in Classic Papers and Current Comments: Highlights of Supportive Care Research 4:350-353, 1999. PMID: 8270972.
17. Loprinzi CL, **Goldberg RM**, O'Fallon JR, Quella SK, Miser AW, Mynderse LA, Brown LD, Tschetter LK, Wilwerding MB, Dose AM, Oesterling JE. *Transdermal Clonidine for Ameliorating Post-Orchiectomy Hot Flashes.* J Urol. 151: 634-636, 1994. PMID: 8308973.
18. Ingle JN, Foley JF, Maillaird JA, Krook JE, Hartmann LC, Jung SH, Veeder MH, Gesme DH Jr, Hatfield AK, **Goldberg RM**. *Randomized Trial of Cyclophosphamide, Methotrexate, and 5-Fluorouracil with or without Estrogenic Recruitment in Women with Metastatic Breast Cancer.* Cancer. 73:2337-2343, 1994. PMID: 8168039.
19. Loprinzi CL, Kuross SA, O'Fallon JR, Gesme DH Jr, Gerstner JB, Rospond RM, Cobau CD, **Goldberg RM**. *Randomized Placebo-Controlled Evaluation of Hydrazine Sulfate in Patients with Advanced Colorectal Cancer.* J Clin Oncol. 12: 1121-1125, 1994. PMID: 8201373. (Reprinted in Classic Papers and Current Comments: Highlights of Clinical Gastrointestinal Cancer Research, 1998 and in Classic Papers and Current Comments: Highlights of Supportive Care Research 4: 372-376, 1999.)
20. Loprinzi CL, **Goldberg RM**, Su JQ, Maillaird JA, Kuross SA, Maksymuk AW, Kugler JW, Jett JR, Ghosh C, Pfeifle DM, Wender DB, Burch PA. *Placebo-Controlled Trial of Hydrazine Sulfate in Patients with Newly Diagnosed Non-Small-Cell Lung Cancer.* J Clin Oncol. 12 1126-1129, 1994. PMID: 8201374. (Reprinted in Classic Papers and Current Comments 2:253-257, 1997.)
21. Long HJ, Nelimark RA, SU JQ, Garneau SC, Levitt R, **Goldberg RM**, Poon MA, Kugler JW. *Phase II Evaluation of 5-Fluorouracil and Low-Dose Leucovorin in Cisplatin-Refractory Advanced Ovarian Carcinoma.* Gynecol Oncol. 54: 180-183, 1994. PMID: 8063243.
22. Erickson LD, Hartmann LC, Su JQ, Nielson SNJ, Pfeifle DM, **Goldberg RM**, Levitt R, Stanhope CR. *Cyclophosphamide, Cisplatin, and Leuprolide Acetate in Patients with Debulked Stage III or IV Ovarian Carcinoma.* Gynecol Oncol. 54 196-200, 1994. PMID: 8063245.
23. **Goldberg RM**, Krook J, Maksymuk AW, Marschke RF Jr. *Treatment of Non-Small Cell Lung Cancer with Short Term Infusion of Cisplatin and Etoposide: A Review of the Literature.* J Infus Chemo. 4:151-154, 1994.
24. Jett JR, Su JQ, Krook JE, **Goldberg RM**, Kugler JW. *Measurable or Assessable Disease in Lung Cancer Trials: Does It Matter?* J Clin Oncol. 12: 2677-2681, 1994. PMID: 7989943.
25. Levitt R, Buckner JC, Cascino TL, Burch PA, Morton RF, Westberg MW, **Goldberg RM**, Gallagher JG, O'Fallon JR, Scheithauer BW. *A Phase II Study of Amonafide in Patients with Recurrent Glioma.* J NeuroOncol; 23: 87-93, 1995. PMID: 7623074.

26. **Goldberg RM**, Moertel CG, Wieand HS, Krook JE, Schutt AJ, Veeder MH, Mailliard JA, Dalton RJ: *A Phase III Evaluation of a Somatostatin Analogue (Octreotide) in the Treatment of Patients with Asymptomatic Advanced Colon Carcinoma. North Central Cancer Treatment Group And The Mayo Clinic.* Cancer. 15 :961-966, 1995. PMID: 8625221.
27. **Goldberg RM**, Loprinzi CL, Malliard JA, O'Fallon JR, Krook JE, Ghosh C, Hestorff RD, Chong SF, Reuter NF, Shanahan TG. *Pentoxifylline for Treatment of Cancer Anorexia and Cachexia? A Randomized, Double-Blind, Placebo-Controlled Trial.* J Clin Oncol. 13: 2856-2859, 1995. PMID: 7595749.
28. Schleusner JT, Tazelaar HD, Jung SH, Cha SS, Cera PJ, Myers JL, Creagan ET, **Goldberg RM**, Marschke RF Jr. *Neuroendocrine Differentiation Is an Independent Prognostic Factor in Chemotherapy-Treated Non-Small Cell Lung Carcinoma.* Cancer. 77: 1284-1291, 1996. PMID: 8608504.
29. **Goldberg RM**, Dispensieri A. *Practical Management of Malignant Ascites.* PrimePractice 2. 1996; Issue 3. (CD-ROM).
30. Cascino TL, Veeder MH, Buckner JC, O'Fallon JR, Wiesenfeld M, Levitt R, **Goldberg RM**, Kuross SA, Morton RF, Scheithauer BW. *A Phase II Study of 5-Fluorouracil and Leucovorin in Recurrent Primary Brain Tumors.* J Neurooncol. 30: 243-246, 1996. PMID: 8943099.
31. Pitot, HC, Wender DB, O'Connell MJ, Schroeder G, **Goldberg RM**, Rubin J, Mailliard JA, Knost JA, Ghosh C, Kirschling RJ, Levitt R, Windschitl HE. *A Phase II Trial of Irinotecan In Patients with Metastatic Colorectal Carcinoma.* J Clin Oncol. 15: 2910-2919, 1997. PMID: 9256135.
32. **Goldberg RM**, Hatfield AK, Kahn M, Knost JA, O'Connell MJ, Krook JE, Mailliard JA, Wiesenfeld M, Schaefer PL, Maksymiuk AW, Moertel CG. *Prospectively Randomized North Central Cancer Treatment Group Trial of Intensive-Course Fluorouracil Combined with the I-Isomer of Intravenous Leucovorin, Oral Leucovorin, or Intravenous Leucovorin for the Treatment of Advanced Colorectal Cancer.* J Clin Oncol. 15: 3320-3329, 1997. PMID: 9363861.
33. **Goldberg RM**, Reid JM, Ames MM, Sloan JA, Rubin J, Erlichman C, Kuffel MJ, Fitch TR. *Phase I and Pharmacologic Trial of Fazarabine (Ara-AC) with Granulocyte Colony-Stimulating Factor.* Clin Cancer Res. 3: 2363-2370, 1997. PMID: 9815635.
34. **Lloyd RV**, Schroeder G, Jin L, **Goldberg RM**. *Prevalence and Prognostic Significance of Neuroendocrine Differentiation in Colorectal Carcinomas.* Endocr Pathol. 9: 35-42, 1998. PMID: 12114660.
35. **Goldberg RM**, Fleming TR, Tangen CM, Moertel CG, Macdonald JS, Haller DG, Laurie JA. *Surgery for Recurrent Colon Cancer: Strategies for Identifying Resectable Recurrence and Success Rates after Resection.* Ann Intern Med. 129: 27-35, 1998. PMID: 9652996.
36. **Goldberg RM**, Erlichman C. *Irinotecan Plus 5-FU and Leucovorin In Advanced Colorectal Cancer: North American Trials.* Oncology (Williston Park). 12 (8 Suppl 6): 59-63, 1998. PMID: 9726093.
37. Alberts SR, Erlichman C, Reid JM, Sloan JA, Ames MM, Richardson RL, **Goldberg RM**. *Phase I Study of the Duocarmycin Semisynthetic Derivative KW-2189 Given Daily for Five Days Every Six Weeks.* Clin Cancer Res. 4:2111-2117, 1998. PMID: 9748127.
38. **Goldberg RM**. *Is Repeated Treatment with a 5-Fluorouracil-Based Regimen Useful in Colorectal Cancer?* Semin Oncol. 25 (5 Suppl 11): 21-8, 1998. PMID: 9786313.
39. Pitot HC, McElroy EA Jr, Reid JM, Windebank AJ, Sloan JA, Erlichman C, Bagniewski PG, Walker DL, Rubin J, **Goldberg RM**, Adjei AA, Ames MM. *Phase I Trial of Dolostatin-10 (NSC*

- 376128) in *Patients with Advanced Solid Tumors*. Clin Cancer Res. 5: 525-531, 1999. PMID: 10100703.
40. Alberts S, Goldberg RM. *Review of "Therapy for Early-Stage Colorectal Cancer"* by M Peeters and DG Haller. Oncology (Williston Park). 13: 315-317, 1999. PMID: 10204153.
 41. Halling KC, French AJ, McDonnell SK, Burgart LJ, Schaid DJ, Peterson BJ, Moon-Tasson L, Sargent DJ, O'Connell MJ, Witzig TE, Farr GH, Jr, **Goldberg RM**, Thibodeau SN. *Microsatellite Instability and 8p Allelic Imbalance in Stage B2 and C Colorectal Cancer*. J Natl Cancer Inst 91: 1295-1303, 1999. (Accompanied by an editorial). PMID: 10433618.
 42. **Goldberg RM**. *Liver Limited Colorectal Cancer Metastases: Specific Strategies for a Special Patient Subset*. Amer Soc Clin Oncol, 1999 Fall Educational Book 70-75, 1999.
 43. Erlichman C, Goldberg RM, Pitot HC, O'Connell MJ. *Optimum Doses of Irinotecan*. Lancet. 353: 1275-6, 1999. PMID: 10217115.
 44. **Goldberg RM**, Loprinzi CL. *Cancer Anorexia/Cachexia*. Cancer Treat Res. 100: 31-41, 1999. PMID: 10645495.
 45. Adjei AA, Kastrissious H, **Goldberg RM**, Sloan JA, Alberts SR, Pitot H, Reid J, Klein CE, Hanson L, Atherton Skaff P, Rubin J, Erlichman C. *Phase I and Pharmacokinetic Study of Irinotecan and Docetaxel in Patients with Advanced Solid Tumors: Preliminary Evidence of Clinical Activity*. J Clin Oncol. 18: 1116-1123, 2000. PMID: 10694565.
 46. Adjei AA, Erlichman C, Sloan JA, Pitot HC, **Goldberg RM**, Peethambaram P, Atherton Skaff P, Hanson LJ, Jett J, Reid JM. *Phase I and Pharmacologic Study of Sequences of Gemcitabine and the Multitargeted Antifolate Agent in Patients with Advanced Solid Tumors*. J Clin Oncol. 18:1748-1757, 2000 . PMID: 10764436.
 47. Sargent D, **Goldberg RM** , Mahoney M, Hillman D, McKeough T, Hamilton S, Darcy J, Anderson V, Krook J, O'Connell M. *Rapid Reporting and Review of an Increased Incidence of a Known Adverse Event*. J Natl Cancer Inst. 92: 1011-1013, 2000. PMID: 1086131
 48. Pitot HC, **Goldberg RM**, Reid JM, Sloan JA, Skaff P, Erlichman C, Rubin J, Burch PA, Adjei AA, Alberts SA, Schaaf LJ, Elfring G, Miller LL. *Phase I Dose Finding and Pharmacokinetic Trial of Irinotecan Hydrochloride (CPT-11) Using a Once-Every-Three-Week Dosing Schedule for Patients with Advanced Solid Tumor Malignancy*. Clin Cancer Res. 6: 2236-2244, 2000. PMID: 10873073.
 49. **Goldberg RM**. *Gastroesophageal cancers: forward motion?* Amer Soc Clin Oncol, 2000 Educational Book 36:504-510, 2000.
 50. **Goldberg RM**. *Is There A Standard Therapy For Advanced Esophageal Cancer?* Proceedings of the ASCO Clinical Practice Forum, 2000; 79-82, 2000.
 51. **Goldberg RM**. *Adjuvant Therapy after Resection of Liver Limited Colorectal Cancer Metastases*. Proceedings of the ASCO Clinical Practice Forum 2000; 73-77, 2000.
 52. Burch PA, Ghosh C, Schroeder G, Allmer C, Woodhouse CL, **Goldberg RM**, Addo F, Bernath A, Tschetter LK, Windschitl HE, Cobau CD. *Phase II Evaluation of Continuous-Infusion 5-Fluorouracil, Leucovorin, Mitomycin-C and Oral Dipyridamole in Advanced Measurable Pancreatic Cancer: A North Central Cancer Treatment Group Trial*. Am J Clin Oncol. 23: 534-537, 2000. PMID: 11039519.
 53. Pitot HC, Knost JA, Mahoney MR, Kugler J, Krook JE, Hatfield AK, **Goldberg RM**. *A North Central Cancer Treatment Group Phase II Trial of 9-Aminocamptothecin in Previously Untreated*

Patients with Measurable Metastatic Colorectal Carcinoma. Cancer. 89: 1699-1705, 2000. PMID: 11042563.

54. Kumar SK, **Goldberg RM**. *Adjuvant Chemotherapy for COLON CANCER.* Curr Oncol Rep. 3: 94-101, 2001. PMID: 11177740.
55. Pitot HC, **Goldberg RM**. *Future Directions in Adjuvant Therapy for Stage III Colon Carcinoma.* Oncology (Williston Park). 15 (3 Suppl 5): 31-36, 2001. PMID: 11301838.
56. Erlichman C, Adjei A, Alberts S, Sloan J, Atherton P, **Goldberg R**, Pitot H, Rubin J, Klee G, Humphrey R. *Phase I Study of the Matrix Metalloproteinase Inhibitor, BAY 12-9566*.* Ann Oncol. 12: 389-395, 2001. PMID: 11332153.
57. Sargent DJ, **Goldberg RM**. *A Flexible Design for Multiple Armed Screening Trials.* Stat Med. 20: 1051-1060, 2001. PMID: 11276035.
58. Sargent DJ, Chan V, **Goldberg RM**. *A Three-Outcome Design for Phase II Clinical Trials.* Control Clin Trials. 22: 117-125, 2001. PMID: 11306150.
59. Alberts SR, Erlichman C, Sloan J, Okuno SA, Burch PA, Rubin J, Pitot HC, Atherton PJ, **Goldberg RM**, Kaufmann SH. *Phase I Trial of Gemcitabine and CPT-11 Given Weekly for Four Weeks every Six Weeks.* Ann Oncol. 12: 627-31, 2001. PMID: 11432620.
60. Galanis E, **Goldberg R**, Reid J, Atherton P, Sloan J, Pitot H, Rubin J, Adjei AA, Burch P, Safgren SL, Witzig TE, Ames MM, Erlichman C. *Phase I Trial of Sequential Administration of Raltitrexed (Tomudex) and 5-Iodo-2'-Deoxyuridine (IdUrd).* Ann Oncol. 12: 701-707, 2001. PMID: 11432631.
61. Macdonald JS, **Goldberg RM**, Saltz LB, Haller DG, Simon R. *Critical Analysis of Recent Phase III Studies for the Treatment of Colorectal Cancer: Implications for Future Clinical Trial Design.* Oncology Spectrums. 2: 255-269, 2001.
62. Sargent DJ, **Goldberg RM**, Jacobson SD, Macdonald JS, Labianca R, Haller DG, Shepherd LE, Seitz J-F, Francini G. *A Pooled Analysis of Adjuvant Chemotherapy for Resected Colon Cancer in Elderly Patients.* N Engl J Med. 345: 1091-97, 2001. PMID: 11596588.
63. Lindor NM, Burgart LJ, Leontovich O, **Goldberg RM**, Cunningham JM, Sargent DJ, Walsh-Vockley C, Petersen GM, Walsh MD, Leggett BA, Young JP, Barker M, Jass JR, Hopper J, Gallinger S, Bapat B, Redston M, Thibodeau SN. *Immunohistochemistry Versus Microsatellite Instability Testing in Phenotyping Colorectal Tumors.* J Clin Oncol. 20: 1043-1048, 2002. PMID: 11844828.
64. Pitot HC, Reid JM, Sloan JA, Ames MM, Adjei AA, Rubin J, Bagniewski PG, Atherton P, Rayson D, **Goldberg RM**, Erlichman C. *A Phase I Study of Bizelesin (NSC 615291) in Patients with Advanced Solid Tumors.* Clin Cancer Res. 8: 712-717, 2002. PMID: 11895900.
65. Sloan JA, **Goldberg RM**, Sargent DJ, Vargas-Chanes D, Nair S, Cha SS, Novotny PJ, Poon MA, O'Connell MJ, Loprinzi CL. *Women Experience Greater Toxicity with Fluorouracil-Based Chemotherapy for Colorectal Cancer.* J Clin Oncol. 20: 1491-1498, 2002. PMID: 11896096.
66. Adjei AA, Reid JM, Diasio RB, Sloan JA, Smith DA, Rubin J, Pitot HC, Alberts SR, **Goldberg RM**, Hanson LJ, Atherton P, Ames MM, Erlichman C. *Comparative Pharmacokinetic Study of Continuous Venous Infusion Fluororacil and Oral Fluororacil with Eniluracil in Patients with Advanced Solid Tumors.* J Clin Oncol. 20: 1683-1691, 2002. PMID: 11896120.
67. Allegra CJ, Parr AL, Wold LE, Mahoney MR, Sargent DJ, Johnson P, Klein P, Behan K, O'Connell MJ, Levitt R, Kugler J, Tria Tirona M, **Goldberg RM**. *An Investigation of the*

Prognostic and Predictive Value of Thymidylate Synthase, P53, and Ki-67 in Patients with Locally Advanced Colon Cancer. J Clin Oncol. 20: 1735-1743, 2002. PMID: 11919229.

68. Alberts SA, Townley PM, **Goldberg RM**, Cha SS, Sargent DJ, Dakhil SR, Krook JE, Buckner JC, Fitch TR, Wiesenfeld M, Mailliard JA. *Gemcitabine and oxaliplatin for patients with advanced or metastatic pancreatic cancer: A North Central Cancer Treatment Group (NCCTG) phase I study.* Ann Oncol. 2002 Apr;13(4): 553-557. PMID: 12056705.
69. **Goldberg RM**. N9741: A Phase III Study Comparing Irinotecan to Oxaliplatin-Containing Regimens in Advanced Colorectal Cancer. Clin Colorectal Cancer. 2:81, 2002. PMID: 12453321.
70. Adjei AA, Reid JM, Erlichman C, Pitot HC, **Goldberg RM**, Alberts SR, Hanson L, Ruben S, Boerner S, Atherton P, Ames MM, Kaufmann SH. *A Phase I and Pharmacologic Study of Pyrazoloacridine (NSC 366140) and Carboplatin in Patients with Locally Advanced or Metastatic Cancer.* Invest New Drugs. 20: 297-304, 2002. PMID: 12201492.
71. Gunderson LL, Sargent DJ, Tepper J, O'Connell MJ, Allmer C, Smalley SR, Martenson JA, Haller DG, Mayer R, Rich TA, Ajani J, Macdonald J, **Goldberg RM**. *Impact of TN Stage in Survival and Disease Relapse in Adjuvant Rectal Cancer Pooled Analysis.* Int J Radiat Oncol Biol Phy. 54: 386-392, 2002. PMID: 12243812.
72. **Goldberg RM**, Kaufmann SH, Atherton P, Sloan JA, Adjei AA, Pitot HC, Alberts AR, Rubin J, Miller LL, Erlichman C. *A Phase I Study of Sequential Irinotecan and 5-Fluorouracil/Leucovorin.* Ann Oncol. 13: 1674-1680, 2002. PMID: 12377659.
73. Hobday TJ, **Goldberg RM**. *Perspectives on the Role of Sequential or Combination Chemotherapy for First-Line and Salvage Therapy in Advanced Colorectal Cancer.* Clin Colorectal Cancer. 2: 161-169, 2002. PMID: 12482332.
74. Hobday TJ, Kugler JW, Mahoney MR, Sargent DJ, Sloan JA, Fitch TR, Krook JE, O'Connell MJ, Mailliard JA, Tirona MT, Tschetter LK, Cobau CD, **Goldberg RM**. *Efficacy and Quality-Of-Life Data Are Related in a Phase II Trial of Oral Chemotherapy in Previously Untreated Patients with Metastatic Colorectal Carcinoma.* J Clin Oncol. 20: 4574-80, 2002. PMID: 12454115.
75. **Goldberg RM**, Sargent DJ, Morton RF, Mahoney MR, Krook JE, O'Connell MJ. *Early Detection of Toxicity and Adjustment of Ongoing Clinical Trials: The History and Performance of the North Central Cancer Treatment Group's Real-Time Toxicity Monitoring Program.* J Clin Oncol. 20: 4591-6, 2002. PMID: 12454117.
76. Alberts SR, Fishkin PA, Burgart LJ, Cera PJ, Mahoney MR, Morton RF, Johnson PA, Nair S, **Goldberg RM**. *CPT-11 for Bile Duct and Gallbladder Carcinoma: A Phase II North Central Cancer Treatment Group (NCCTG) Study.* Int J Gastrointest Cancer. 32: 107-114, 2002. PMID: 12794246.
77. Jatoi A, Tria Tirona M, Cha SS, Alberts SR, Rowland KM, Morton RF, Nair S, Kardinal CG, Stella PJ, Mailliard JA, Sargent DJ, **Goldberg RM**. *A Phase II Trial of Docetaxel and CPT-11 in Patients with Metastatic Adenocarcinoma of the Esophagus, Gastroesophageal Junction, and Gastric Cardia.* Int J Gastrointest Cancer. 32: 115-124, 2002. PMID: 12794247.
78. Adjei AA, Dy GK, Erlichman C, Reid JM, Sloan JA, Pitot HC, Alberts SR, **Goldberg RM**, Hanson LJ, Atherton PJ, Watanabe T, Geary RS, Holmlund J, Dorr FA. *A Phase I Trial of ISIS 2503, An Antisense Inhibitor of H-Ras in Combination with Gemcitabine in Patients with Advanced Cancer.* Clin Cancer Res. 9: 115-123, 2003. PMID: 12538459.
79. **Goldberg RM**. *Evolving Therapy and Management of Metastatic Colon Cancer.* Clin Adv Hematol Oncol. 1: 159-60, 2003. PMID: 16224396.

80. Kakar S, Burgart LJ, Thibodeau SN, Rabe KG, Petersen GM, **Goldberg RM**, Lindor NM. *Frequency of Loss of Hmlh1 Expression in Colorectal Carcinoma Increases with Advancing Age.* Cancer. 97: 1421-1427, 2003. PMID: 12627505.
81. Alberts SR, Townley PM, **Goldberg RM**, Cha SS, Sargent DJ, Moore Jr DF, Krook JE, Pitot HC, Fitch TR, Wiesenfeld M, Mailliard JA. *Gemcitabine and Oxaliplatin for Metastatic Pancreatic Adenocarcinomas: A North Central Cancer Treatment Group (NCCTG) Phase II Study.* Ann Oncol. 14: 580-585, 2003. PMID: 12649105.
82. Martenson JA, Vigliotti APG, Pitot HC, Geeraerts LH, Sargent DJ, Haddock MG, Ghosh C, Keppen MD, Fitch TR, **Goldberg RM**. *A Phase I Study of Radiation Therapy and Twice Weekly Gemcitabine and Cisplatin In Patients with Locally Advanced Pancreatic Cancer.* Int J Radiat Oncol Biol Phys, 55: 1305-1310, 2003. PMID: 12654442.
83. Gill S, **Goldberg RM**. *New Developments in Therapy for Colorectal Cancer.* Curr Oncol Rep. 5: 183-191, 2003. PMID: 12667415.
84. Gunderson LL, Haddock MG, Braich T, Lanza L, Wong WW, **Goldberg R**. *Trastek v. Chemoradiation For Esophageal Cancer.* 2003 Educational Book, Annu Meet Amer Soc Clin Oncol, 441-449, 2003.
85. Benson AB 3rd, **Goldberg RM**. *Optimal Use of the Combination of Irinotecan and 5-Fluorouracil.* Semin Oncol. 30 (3 Suppl 6); 68-77, 2003. PMID: 12802797.
86. Adjei AA, Croghan GA, Erlichman C, Marks RS, Reid JM, Sloan JA, Pitot HC, Alberts SR, **Goldberg RM**, Hanson LJ, Bruzek LM, Atherton P, Thibault A, Palmer PA, Kaufmann SH. *A Phase I Trial of the Farnesyl Protein Transferase Inhibitor R115777 in Combination with Gemcitabine and Cisplatin in Patients with Advanced Cancer.* Clin Can Res. 9: 2520-2526, 2003. PMID: 12855626.
87. Ribic CM, Sargent DJ, Moore MJ, Thibodeau SN, French AJ, **Goldberg RM**, Hamilton SR, Laurent-Puig P, Gryfe RN, Shepherd LE, Tu D, Redston M, Gallinger S. *Tumor Microsatellite-Instability Status as a Predictor of Benefit from 5-Fluorouracil-Based Adjuvant Chemotherapy for Colon Cancer.* N Engl J Med. 349: 247-257, 2003. PMID: 12867608.
88. Gill S, Thomas RR, **Goldberg RM**. *New Targeted Therapies in Gastrointestinal Cancers.* Curr Treat Options Oncol. 4: 393-403, 2003. PMID: 12941199.
89. Goetz M*, Erlichman C, Windebank AJ, Reid JM, Sloan JA, Atherton P, Adjei AA, Rubin J, Pitot H, Galanis E, Ames MM, **Goldberg RM**. *Phase I and Pharmacokinetic Study of Two Different Schedules of Oxaliplatin, Irinotecan, Fluorouracil, and Leucovorin in Patients with Solid Tumors.* J Clin Oncol. 21: 3761-3769, 2003. PMID: 12963697.
90. Gill S, Thomas RR, **Goldberg RM**. *Colorectal Cancer Chemotherapy (Review Article).* Ailment Pharmacol Ther. 18: 683-92, 2003. PMID: 14510741.
91. Atalay G, Cardoso F, Paesmans M, **Goldberg RM**, Bleiberg H. *Second Line Treatment in Advanced Colon Cancer: Are Multiple Phase II Trials Informative Enough to Guide Clinical Practice?* Anticancer Drugs. 14: 703-713, 2003. PMID: 14551503.
92. O'Neil BH, **Goldberg RM**. *Novel Chemotherapeutic and Targeted Agents in Metastatic Colorectal Cancer: The Time Has Arrived.* Expert Opin Investig Drugs. 12: 1939-49, 2003. PMID: 14640938.
93. **Goldberg RM**, Sargent DJ, Morton RF, Fuchs CS, Ramanathan RK, Williamson SK, Findlay BP, Pitot HC, Alberts SA. *A Randomized Controlled Trial of Fluorouracil plus Leucovorin,*

Irinotecan, and Oxaliplatin Combinations in Patients with Previously Untreated Metastatic Colorectal Cancer. J Clin Oncol. 22: 23-30, 2004. PMID: 14665611.

94. Gill S, **Goldberg RM**. *First-Line Treatment Strategies to Improve Survival in Patients with Advanced Colorectal Cancer. Drugs. 64: 27-44, 2004 PMID: 14723557.*
95. Egan JA, Bandarenko N, Hay SN, Paradowski L, **Goldberg R**, Nিকেলেইট V, Brecher ME. *Differentiating Thrombotic Microangiopathies Induced by Severe Hypertension from Anemia and Thrombocytopenia Seen in Thrombotic Thrombocytopenia Purpura. J Clin Apher. 24: 125-9, 2004. PMID: 15493050.*
96. Grothey A, **Goldberg RM**, Schmoll HJ. *Survival of Patients with Advanced Colorectal Cancer Improves with the Availability of Fluorouracil-Leucovorin, Irinotecan, and Oxaliplatin in the Course of Treatment. J Clin Oncol. 22: 1209-1214, 2004. PMID: 15051767.*
97. Gunderson LL, Sargent DJ, Tepper J, Wolmark N, O'Connell MJ, Begovic M, Allmer C, Colangelo C, Smalley SR, Haller DG, Martenson JA, Mayer RJ, Rich TA, Ajani JA, Macdonald JS, Willett CG, **Goldberg RM**. *Impact of T and N stage and Treatment on Survival and Relapse an Adjuvant Rectal Cancer - A Pooled Analysis. J Clin Oncol. 22: 1785-1796, 2004. PMID: 15067027. Accompanied by an editorial.*
98. Gill S*, Loprinzi CL, Sargent DJ, Thome SD, Alberts SR, Haller DG, Benedetti J, Francini G, Shepherd LE, Seitz JF, Labianca R, Chen W, Cha SS, Heldebrant MP, **Goldberg RM**. *Pooled Analysis of Fluorouracil- Based Adjuvant Therapy for Stage II and III Colon Cancer: Who Benefits and by How Much? J Clin Oncol. 22: 1797-1806, 2004. PMID: 15067028. Accompanied by an editorial.*
99. Garritty MM, Burgart LJ, Murphy LM, Furth AF, Mahoney MR, Hill E, Riehle DL, Wiesenfeld M, Windschitl HE, Krook JE, Tria Tirona M, Michalak JC, Sargeant DJ, **Goldberg RM**, O'Connell MJ, Meyers CH, Witzig TE. *Prognostic Value of Proliferation, Apoptosis, Defective DNA Mismatch Repair, and P53 Overexpression in Patients with Resected Dukes' B2 or C Colon Cancer: A North Central Cancer Treatment Group Study. J Clin Oncol. 22: 1572-1582, 2004. PMID: 15117979.*
100. Penland SK, **Goldberg RM**. *Current Strategies in Previously Untreated Advanced Colorectal Cancer. Oncology (Williston Park). 18: 715-722, 2004. PMID: 15214592.*
101. Lindor NM, Sloan J, **Goldberg R**, Bowen D, Nigon S, Roche A, Petersen G, Thibodeau SN, Burgart L, Leontovich O, Morlan BW. *Colorectal Tumor Microsatellite Instability Test Results: Perspectives from Patients. Hered Cancer Clin Pract. 2: 69-75, 2004. PMID: 20233473.*
102. **Goldberg RM**. *Current Approaches to First-Line Treatment of Advanced Colorectal Cancer. Clin Colorectal Cancer. 4 Suppl 1: S9-15, 2004. PMID: 15212700.*
103. Martenson Jr JA, Willett CG, Sargent DJ, Mailliard JA, Donohue JH, Gunderson LL, Thomas JR CR, Fisher B, Benson III AB, Myerson R, **Goldberg RM**. *Phase III Study of Adjuvant Chemotherapy and Radiation Therapy Compared with Chemotherapy Alone in the Surgical Adjuvant Treatment of Colon Cancer: Results of Intergroup Protocol 0130. J Clin Oncol. 22: 3277-3283, 2004. PMID: 15249584. Accompanied by an editorial.*
104. **Goldberg RM**, Gill S. *Recent Phase III Trials of Fluorouracil, Irinotecan, and Oxaliplatin as Chemotherapy for Metastatic Colorectal Cancer. Cancer Chemother Pharmacol. 54 Suppl 1: S57-64, 2004. PMID: 15309516.*
105. Grothey A, **Goldberg RM**. *A Review of Oxaliplatin and Its Clinical Use in Colorectal Cancer. Expert Opin Pharmacother. 5: 2159-2170, 2004. PMID: 15461551.*

106. Penland SK, **Goldberg RM**. *Combining Anti-VEGF Approaches with Oxaliplatin in Advanced Colorectal Cancer*. Clin Colorectal Cancer. 4 Suppl 2: S74-80, 2004. PMID: 15479483.
107. Delaunoy T*, **Goldberg RM**, Sargent DJ, Morton RF, Fuchs CS, Findlay BP, Thomas SP, Salim M, Stella PJ, Mailliard JA. *Mortality Associated With Daily Bolus 5-Fluorouracil/Leucovorin Administered in Combination with Either Irinotecan or Oxaliplatin. Results from Intergroup Trial N9741*. Cancer. 101: 2170-2176, 2004. PMID: 15470715.
108. **Goldberg RM**, Venook AP, Schilsky RL. *Cetuximab in the Treatment of Colorectal Cancer*. Clin Adv Hematol Oncol. 2: 1-10; quiz 11-12, 2004. PMID: 16170891.
109. D'Andre SD, Sargent DJ, Cha SS, Buroker TR, Kugler JW, **Goldberg RM**, O'Connell MJ, Poon MA. *5-Fluorouracil-Based Chemotherapy for Advanced Colorectal Cancer in Elderly Patients: A North Central Cancer Treatment Group Study*. Clin Colorectal Cancer. 4: 325-331, 2005. PMID: 15663836.
110. O'Neil BH, **Goldberg RM**. *Chemotherapy for Advanced Colorectal Cancer: Let's Not Forget How We Got Here (Until We Really Can)*. Semin Oncol. 32: 35-42, 2005. PMID: 15726504.
111. Delaunoy T, Alberts SR, Sargent DJ, Green E, **Goldberg RM**, Krook J, Fuchs C, Ramanathan RK, Williamson SK, Morton RF, Findlay BP. *Chemotherapy Permits Resection of Metastatic Colorectal Cancer: Experience from Intergroup N9741*. Ann Oncol. 16: 425-429, 2005. [Epub ahead of print]. PMID: 15677624.
112. Poplin EA, Benedetti JK, Estes NC, Haller DG, Mayer RJ, **Goldberg RM**, Weiss GR, Rivkin SE, Macdonald JS. *Phase III Southwest Oncology Group 9415/Intergroup 0153 Randomized Trial of Fluorouracil, Leucovorin, and Levamisole Versus Fluorouracil Continuous Infusion and Levamisole for Adjuvant Treatment of Stage III and High-Risk Stage II Colon Cancer*. J Clin Oncol. 23: 1819-1825, 2005. PMID: 15774775.
113. Lindor NM, Rabe K, Petersen G, Haile R, Casey G, Gallinger S, Bapat B, Aaronson M, Hopper J, Jass J, LeMarchand L, Grove J, Terdimann J, Conrad P, Potter J, Newcomb P, Moslein G, Siegmund K, Ziogas A, Anton-Culver H, **Goldberg R**, Thibodeau SN, Boardman L, Seminara D. *Lower Cancer Incidence in Amsterdam-I Criteria Families without Mismatch Repair Deficiency: Familial Colorectal Cancer Type X*. JAMA. 293: 1979-1985, 2005. PMID: 15855431. Accompanied by an editorial.
114. Gill S, **Goldberg RM**. *Duration of Adjuvant Therapy for Colorectal Cancer: Are We Overtreating Our Patients?* Nat Clin Pract Oncol. 2: 276-7, 2005. PMID: 16264965.
115. Dy GK*, Suri A, Reid JM, Sloan JA, Pitot HC, Alberts SR, **Goldberg RM**, Atherton PJ, Hanson LJ, Burch PA, Rubin J, Erlichman C, Adjei AA. *A Phase IB Study of the Pharmacokinetics of Gemcitabine and Pemetrexed, When Administered in Rapid Sequence to Patients with Advanced Solid Tumors*. Cancer Chemother Pharmacol. 55: 522-530, 2005. [Epub ahead of print]. PMID: 15754203.
116. Meyerhardt JA, Sloan JA, Sargent DJ, **Goldberg RM**, Pollak M, Morton RF, Ramanathan RK, Williamson SK, Findlay BP, Fuchs CS. *Associations between Plasma Insulin-Like Growth Factor Proteins and C-Peptide and Quality of Life in Patients with Metastatic Colorectal Cancer*. Cancer Epidemiol Biomarkers Prev. 14: 1402-1410, 2005. PMID: 15941948.
117. Kelly H, **Goldberg RM**. *Systemic Therapy for Metastatic Colorectal Cancer; Current Options, Current Evidence*. J Clin Oncol. 23: 4553-4560, 2005. PMID: 16002847.
118. Gill S, Lindor NM, Burgart LJ, Smalley R, Leontovich O, French A, **Goldberg RM**, Sargent DJ, Jass JR, Hopper JL, Jenkins MA, Young J, Barker MA, Walsh MD, Ruszkiewicz AR, Thibodeau

SN. *Isolated Loss of PMS2 Expression in Colorectal Cancers: Frequency, Patient Age, and Familial Aggregation.* Clin Cancer Res. 11: 6466-6671, 2005. PMID: 16166421.

119. Hillner BE, Schrag D, Sargent DJ, Fuchs CS, **Goldberg RM.** *Cost-Effectiveness Projections of Oxaliplatin and Infusional Fluorouracil Versus Irinotecan and Bolus Fluorouracil in First-Line Therapy for Metastatic Colorectal Carcinoma.* Cancer. 104: 1871-1884, 2005. PMID: 16177989.
120. Venook AP, Blanke CD, Niedzwiecki D, Lenz HJ, Taylor JR, Hollis DR, Sutherland S, **Goldberg RM.** *Cancer and Leukemia Group B/Southwest Oncology Group Trial 80405: A Phase III Trial of Chemotherapy and Biologics for Patients with Untreated Advanced Colorectal Adenocarcinoma.* Clin Colorectal Cancer. 5: 292-294, 2005. PMID: 16356309.
121. Ackland SP, Jones M, Tu D, Simes J, Yuen J, Sargeant AM, Dhillon H, **Goldberg R,** Abdi E, Shepherd L, Moore M. *A Meta-Analysis of Two Randomised Trials of Early Chemotherapy in Asymptomatic Metastatic Colorectal Cancer.* Br J Cancer. 93: 1236-1243, 2005. PMID: 16265352.
122. Alberts SR, Horvath WL, Sternfeld WC, **Goldberg RM,** Mahoney MR, Dakhil SR, Levitt R, Rowland K, Nair S, Sargent DJ, Donohue JH. *Oxaliplatin, Fluorouracil, and Leucovorin for Patients with Unresectable Liver-Only Metastases from Colorectal Cancer: A North Central Cancer Treatment Group Phase II study.* J Clin Oncol. 23: 9243-9249, 2005. [Epub ahead of print]. PMID: 16230673.
123. Sargent DJ, Wieand S, Haller DG, Garay R, Benedetti J, Labianca R, Seitz JF, O'Callaghan CJ, Francini G, Grothey A, O'Connell M, Catalano P, Blanke CD, Kerr D, Green E, Wolmark N, Andre T, **Goldberg RM,** de Gramont A. *Disease-Free Survival versus Overall Survival as a Primary End Point for Adjuvant Colon Cancer Studies: Individual Patient Data from 20,898 Patients on 18 Randomized Trials.* J Clin Oncol. 23: 8664-8670, 2005. [Epub ahead of print]. PMID: 16260700.
124. **Goldberg RM.** *Advances in the Treatment of Metastatic Colorectal Cancer.* Oncologist. 10 Suppl 3: 40-8, 2005.
125. **Goldberg RM,** Hurwitz HI, **Fuchs CS.** *Angiogenesis Inhibition in the Treatment of Colorectal Cancer Part 3 of A 3-Part Series: Targeting VEGF--Current and Future Research Directions.* Clin Adv Hematol Oncol. 3: 1-10; quiz 11, 2005. PMID: 16555433.
126. Mahoney MR, Sargent DJ, O'Connell MJ, **Goldberg RM,** Schaefer PL, Buckner JC. *Dealing with a Deluge of Data: An Assessment of Adverse Event Data on North Central Cancer Treatment Group Trials.* J Clin Oncol. 23: 9275-9281, 2005. PMID: 16361625. (Erratum in *J Clin Oncol.* 23: 24:1015.)
127. Delaunoy T, Limburg PJ, **Goldberg RM,** Lymp JF, Loftus EV, Jr. *Colorectal Cancer Prognosis among Patients with Inflammatory Bowel Disease.* Clin Gastroenterol Hepatol. 4: 335-342, 2006. PMID: 16527697.
128. Beaven AW, **Goldberg RM.** *Adjuvant Therapy for Colorectal Cancer: Yesterday, Today, and Tomorrow.* Oncology (Williston Park). 20: 461-469, 2006. PMID: 16739745.
129. Sinicrope FA, Rego RL, Halling KC, Foster NR, Sargent DJ, LaPlant B, French A, Allegra CJ, Laurie JA, **Goldberg RM,** Witizig TE, Thibodeau SN. *Thymidylate Synthase Expression in Colon Carcinomas with Microsatellite Instability.* Clin Canc Res. 12: 2738-2744, 2006. PMID: 16675565.
130. Ryan DP, Niedzwiecki DN, Hollis D, Mediema BE, Wadler S, Tepper JE, **Goldberg RM,** Mayer RJ. *Phase I/II Study of Preoperative Oxaliplatin, Fluorouracil, and External-Beam Radiation*

Therapy in Patients with Locally Advanced Rectal Cancer: Cancer and Leukemia Group B 89901. J Clin Oncol. 24: 2557-2562, 2006. [Epub ahead of print]. PMID: 16636336.

131. **Goldberg RM**, Niedzwiecki D, Bertagnolli M, Blackstock AW, Tepper JE, Mayer RJ. *Cancer and Leukemia Group B Gastrointestinal Cancer Committee.* Clin Cancer Res. 12(11 Pt 2): 3589s-3595s, 2006. PMID: 16740790.
132. **Goldberg RM**, Philip PA, Grothey A, Ryan DP. *Colorectal Cancer; Assessing Clinical Strategies for Management in the Adjuvant Setting.* Medical Crossfire. 7: 1-15, 2006.
133. Schaaf LJ, Hammond LA, Tipping SJ, **Goldberg RM**, Goel R, Kuhn JG, Miller LL, Compton LD, Cisar LA, Elfring GL, Gruia G, McGovren JP, Pirodda N, Yin D, Sharma A, Duncan BA, and Rothenberg ML. *Phase 1 and Pharmacokinetic Study of Intravenous Irinotecan in Refractory Solid Tumor Patients with Hepatic Dysfunction.* Clin Cancer Res. 15: 12 3782-3791, 2006. PMID: 16778106.
134. Van Cutsem E, Dicato M, Arber N, Benson A, Cunningham D, **Diaz-Rubio E**, Glimelius B, **Goldberg R**, Haller D, Haustermans K, Koo-Kang Y, Labianca R, Lang I, Minsky B, Nordlinger B, Roth A, Rougier P, Schmoll H-J, Sobrero A, Tabernero J, Szawlowski A, van de Velde C. *The Neo-Adjuvant, Surgical and Adjuvant Treatment of Gastric Adenocarcinoma. Current Expert Opinion Derived from the Seventh World Congress on Gastrointestinal Cancer, Barcelona, 2005.* Ann Oncol. 17 Suppl 6: vi13-8, 2005. PMID: 16809641.
135. **Goldberg RM**, Sargent DJ, Morton RF, Fuchs CS, Ramanathan RK, Williamson SK, Findlay BP, Pitot HC, Alberts SA. *Randomized Controlled Trial of Reduced-Dose Bolus Fluorouracil Plus Leucovorin and Irinotecan or Infused Fluorouracil Plus Leucovorin and Oxaliplatin in Patients with Previously Untreated Metastatic Colorectal Cancer: A North American Intergroup Trial.* J Clin Oncol. 24: 3347-3353, 2006. PMID: 16849748.
136. **Goldberg RM**, Hurwitz HI, Fuchs CS. *The Role of Targeted Therapy in the Treatment of Colorectal Cancer.* Clin Adv Hematol Oncol. 4(8 Suppl 17): 1-10; quiz 11-2., 2006. PMID: 17139241.
137. **Goldberg RM**, Tabah-Fisch I, Bleiberg H, de Gramont A, Tournigand C, Andre T, Rothenberg ML, Green E, Sargent DJ. *Pooled Analysis of Safety and Efficacy of Oxaliplatin Plus Fluorouracil/Leucovorin Administered Bimonthly in Elderly Patients with Colorectal Cancer.* J Clin Oncol. 24: 4085-4091, 2006. PMID: 16943526.
138. Sinicrope FA, Rego RL, Halling KC, Foster N, Sargent DJ, La Plant B, French AJ, Garrity M, Burgart LJ, Laurie JA, **Goldberg RM**, Thibodeau SN, Witzig TE. *Prognostic Impact of Microsatellite Instability and DNA Ploidy in Human Colon Carcinoma Patients.* Gastroenterology. 131 729-737, 2006. PMID: 16952542.
139. Patel DD, **Goldberg RM**. *Cetuximab-Associated Infusion Reactions: Pathology and Management.* Oncology (Williston Park). 20: 1373-1382, 2006. PMID: 17112000.
140. **Goldberg RM**. *Therapy for Metastatic Colorectal Cancer.* The Oncologist. 11: 981-987, 2006. PMID: 17030638.
141. O'Neil BH, Bůžková P, Farrah H, Kashatus D, Sanoff H, **Goldberg RM**, Baldwin AS, Funkhouser WK. *Expression of Nuclear Factor-Kappa B Family Proteins in Hepatocellular Carcinomas.* Oncology. 12: 97-104, 2007. [Epub ahead of print]. PMID: 18025803.
142. **Goldberg RM**. *Which Strategies Will Lead to Progress in the Management of Colorectal Cancer?* Gastrointest Cancer Res. 1(4 Suppl 2): S33-6, 2007. PMID: 19360145.

143. Skelton MR, **Goldberg RM**, O'Neil BH. *A Case of Oxaliplatin-Related Posterior Reversible Encephalopathy Syndrome*. Clin Colorectal Cancer. 6: 386-388, 2007. PMID: 17311705.
144. Gill S, Blackstock AW, **Goldberg RM**. *Colorectal Cancer*. Mayo Clin Proc. 82: 114-129, 2007. PMID: 17285793.
145. **Goldberg RM**, Rothenberg ML, Van Cutsem E, Benson AB III, Blanke CD, Diasio RB, Grothey A, Lenz H-J, Meropol NJ, Ramanathan RK, Becerra CHR, Wickham R, Armtroug D, Viele C. *The Continuum of Care: A Paradigm for the Management of Metastatic Colorectal Cancer*. The Oncologist. 12: 38-50, 2007. PMID: 17227899.
146. Goel A, Nagasaka T, Arnold CN, Inoue T, Hamilton C, Niedzwiecki D, Compton C, Mayer RJ, **Goldberg R**, Bertagnolli MM and Boland CR. *The CpG Island Methylator Phenotype and Chromosomal Instability Are Inversely Correlated in Sporadic Colorectal Cancer*. Gastroenterology. 132: 127-138, 2007. [Epub ahead of print]. PMID: 17087942.
147. Sinicrope FA, Rego RL, Garrity-Park MM, Foster NR, Sargent DJ, **Goldberg RM**, Wiesenfeld M, Witzig TE, Thibodeau SN, Burgart LJ. *Alterations in Cell Proliferation and Apoptosis in Colon Cancers with Microsatellite Instability*. Int J Cancer. 120: 1232-1238, 2007. PMID: 17187355.
148. Venook AP, Blanke CD, Niedzwiecki D, Lenz HJ, Taylor JR, Hollis DR, Sutherland S, **Goldberg RM**. *Revisiting the Cancer and Leukemia Group B/Southwest Oncology Group 80405 Trial: A Phase III Trial of Chemotherapy and Biologic Agents for Patients with Untreated Advanced Colorectal Adenocarcinoma*. Clin Colorectal Cancer. 6: 536-538, 2007. PMID: 17553204.
149. O'Neil B, **Goldberg RM**. *On the State of the Art of Adjuvant Chemotherapy for Colon Cancer*. Gastrointest Cancer Res. 1: 115-7, 2007. PMID: 19262717
150. Sanoff HK, Bleiberg H, **Goldberg RM**. *Managing Older Patients with Colorectal Cancer*. J Clin Oncol. 25: 1891-1897, 2007. PMID: 17488988.
151. Alberts SR, Kim GP, Mahoney MR, Gornet MK, Rubin J, Ames M, Goetz MP, Weinshilboum RM, Nicol SJ, **Goldberg RM**. *Pemetrexed and Oxaliplatin for Metastatic Colorectal Cancer: Results of a Phase I Mayo Cancer Center Research Consortium Trial, MC0248*. Clin Colorectal Cancer. 6: 572-577, 2007. PMID: 17681103.
152. Marshall JL, Haller DG, de Gramont A, Hochster HS, Lenz HJ, Ajani JA, **Goldberg RM**. *Adjuvant Therapy for Stage II and III Colon Cancer: Consensus Report of the International Society of Gastrointestinal Oncology*. Gastrointest Cancer Res. 1: 146-154, 2007. PMID: 19262703.
153. Bendell J, **Goldberg RM**. *Targeted Agents in the Treatment of Pancreatic Cancer: History and Lessons Learned*. Curr Opin Oncol. 19: 390-395, 2007. PMID: 17545806.
154. O'Neil BH, **Goldberg RM**. *Should Gemcitabine Be Used as Adjuvant Chemotherapy in Patients with Resectable Pancreatic Cancer?* Nature Clin Prac Gastroenterol Hepatol. 4: 362-363, 2007. [Epub ahead of print]. PMID: 17471277.
155. Ashley AA*, Sargent DJ, Grothey A, Campbell ME, Morton RF, Fuchs CS, Ramanathan RK, Williamson SK, Findlay BP, Alberts SR, Pitot HC, **Goldberg RM**. *Updated Efficacy and Toxicity Analysis of Irinotecan and Oxaliplatin (IROX) from Intergroup Trial N9741 in First-Line Treatment of Metastatic Colorectal Cancer*. Cancer. 110: 670-677, 2007. PMID: 17559146.
156. Saltz LB, Niedzwiecki D, Hollis D, **Goldberg R**, Hantel A, Thomas JP, Fields A, Carver G, Mayer RJ. *Irinotecan Fluorouracil Plus Leucovorin Is Not Superior to Fluorouracil Plus Leucovorin Alone as Adjuvant Treatment for Stage III Colon Cancer: Results of CALGB 89803*. J Clin Oncol. 25: 3456-3461, 2007. PMID: 17687149.

157. Dy GK, Krook JE, Green EM, Sargent DJ, Morton RF, Fuchs CS, Ramanathan RK, Williamson SK, Findlay BP, Pockaj BA, Sticca RP, Alberts SR, Pitot IV HC, **Goldberg RM**. *Impact of Complete Response to Chemotherapy on Overall Survival In Advanced Colorectal Cancer: Results from Intergroup N9741*. J Clin Oncol. 25: 3469-3474, 2007. PMID: 17687151.
158. Allegra C, Blanke B, Buyse M, **Goldberg R**, Grothey A, Meropol NJ, Saltz L, Venook A, Yothers G, Sargent D. *End points in Advanced Colon Cancer Clinical Trials: A Review and Proposal*. J Clin Oncol. 25: 3572-3575, 2007. PMID: 17704403.
159. O'Neil BH, Allen R, Spigel D, Stinchcombe T, Moore D, Berlin J, **Goldberg RM**. *High Incidence of Cetuximab-Related Infusion Reactions in Tennessee and North Carolina and the Association with Atopic History*. J Clin Oncol. 25: 3644-36458, 2007. PMID: 17704414.
160. Hoskins JM, **Goldberg RM**, Qu P, Ibrahim JB, and McLeod HL. *UGT1A1*28 Genotype and Irinotecan-Induced Neutropenia: Dose Matters*. J Nat Cancer Inst. 99: 1290-1295, 2007. [Epub ahead of print]. PMID: 17728214.
161. Stinchcombe TE, Socinski MA, Walko CM, O'Neil BH, Collichio FA, Ivanova A, Mu H, Hawkins MJ, **Goldberg RM**, Lindley C, Dees, CE. *Phase I and Pharmacokinetic Trial of Carboplatin and Albumin-Bound Paclitaxel, ABI-007 (Abraxane) on Three Treatment Schedules in Patients with Solid Tumors*. Cancer Chemother Pharmacol. 60:759-766, 2007; [Epub ahead of print]. PMID: 17285317.
162. Sargent DJ, Patiyl S, Yothers G, Haller DJ, Gray R, Benedetti J, Buyse M, Labianca R, Seitz JF, O'Callaghan CJ, Francini G, Grothey A, O'Connell M, Catalano PJ, Kerr D, Green E, Wieand HS, **Goldberg RM**, de Gramont A. *End points for Colon Cancer Adjuvant Trials: Observations and Recommendations Based on Individual Patient Data from 20,898 Patients Enrolled onto 18 Randomized Trials from the ACCENT Group*. J Clin Oncol. 25: 4569-4574, 2007. [Epub ahead of print]. PMID: 17876008.
163. Sanoff HK, **Goldberg RM**, Pignone MP. *A Systematic Review of the Use of Quality of Life Measures in Colorectal Cancer Research with Attention to Outcomes in Elderly Patients*. Clin Colorectal Cancer. 6: 700-709, 2007. PMID: 18039423.
164. **Goldberg RM**, Marshall JL, Kachnic LA, Venook AP. *Section I: Essentials of Ensuring Excellence in Cancer Care*. Gastrointest Cancer Res. 1(6 Suppl): S1-3, 2007. PMID: 19330057.
165. **Goldberg RM**, Marshall JL, Ajani JA, Philip PA, O'Reilly EM, Venook AP. *Section IV: Significance of Recent Study Results and Future Research Directions in Gastrointestinal Oncology*. Gastrointest Cancer Res. 1(6 Suppl): S13-6, 2007. PMID: 19330058.
166. Posner MC, Niedzwiecki DN, Venook AP, Hollis DR, Schilsky RL, **Goldberg RM**. *A Phase II Prospective Multi-Institutional Trial of Adjuvant Active Specific Immunotherapy Following Curative Resection of Colorectal Cancer Hepatic Metastases: Cancer and Leukemia Group B Study 89903*. Ann Surg Oncol. 15: 158-164, 2008. PMID: 18008108.
167. Sanoff HK, **Goldberg RM**. *Colorectal Cancer Treatment in Older Patients*. Gastrointest Cancer Res. 1: 248-253, 2007. PMID: 19262903.
168. Yen-Rovollo JL, **Goldberg RM**, McLeod HL. *Can inhibiting dihydropyrimidine dehydrogenase limit hand-foot syndrome caused by fluoropyrimidines?* Clin Cancer Res. 14: 8-13, 2008. PMID: 18172246.
169. Grothey A, Hedrick EE, Mass RD, Sarkar S, Suzuki S, Ramanathan RK, Hurwitz HI, **Goldberg RM**, Sargent DJ. *Response-Independent Survival Benefit in Metastatic Colorectal Cancer: A Comparative Analysis of N9741 and AVF2107*. J Clin Oncol. 26: 183-189, 2008. PMID: 18182660.

170. Shah U, **Goldberg RM**. *Dealing with Discordance: Managing A Case Where the Patient Looks Better and the CT Scan Looks Worse*. Gastrointest Cancer Res. 2: 45-46, 2008. PMID: 19259322.
171. Tepper J, Krasna MJ, Niedzwiecki D, Hollis D, Reed CE, **Goldberg R**, Kiel K, Willett C, Sugarbaker D, Mayer R. *Phase III Trial of Trimodality Therapy with Cisplatin, Fluorouracil, Radiotherapy, and Surgery Compared with Surgery Alone for Esophageal Cancer: CALGB 9781*. J Clin Oncol. 26: 1086-92, 2008. PMID: 18309943.
172. Köhne C-H, Folprecht G, **Goldberg RM**, Rougier P. *Chemotherapy in Elderly Patients with Colorectal Cancer*. The Oncologist. 13: 390-402, 2008. PMID: 18448553.
173. **Goldberg RM**, Carrato A. *Accomplishments in 2007 in the Treatment of Advanced Colorectal Cancer*. Gastrointest Cancer Res. 2008 May; 2(3 Suppl):S19-24. PMID: 19352463.
174. **Goldberg RM**. *As Federal Funding for Cancer Is Cut, Researchers Struggle*. Gastrointest Cancer Res. 2: 165, 2008. PMID: 19259296.
175. Stinchcombe TE, Socinski MA, Lee CB, Hayes DN, Moore DT, **Goldberg RM**, Dees EC. *Phase I Trial of Nanoparticle Albumin-Bound Paclitaxel in Combination with Gemcitabine in Patients with Thoracic Malignancies*. J Thor Oncol. 3: 521-526, 2008. PMID: 18449006.
176. O'Connell MJ, Campbell ME, **Goldberg RM**, Grothey A, Seitz J-F, Benedetti J, André T, Haller DG, and Sargent DJ, (for the ACCENT Collaborative Group). *Survival Following Recurrence in Stage II and III Colon Cancer: Findings from the ACCENT Data Set*. J Clin Oncol. 26: 2336-2341, 2008. PMID: 18467725.
177. French AJ, Sargent DJ, Burgart LJ, Foster NR, Kabat BF, **Goldberg R**, Shepherd L, Windschitl HE, Thibodeau SN. *Prognostic Significance of Defective Mismatch Repair and BRAF-V600E in Patients with Colon Cancer*. Clin Cancer Res. 14: 3408-3415, 2008. PMID: 18519771.
178. Chan JA, Meyerhardt JA, Niedzwiecki D, Hollis D, Saltz LB, Mayer RJ, Thomas J, Schaefer P, Whittom R, Hantel A, **Goldberg RM**, Warren RS, Bertagnolli M, Fuchs CS. *Association of Family History with Cancer Recurrence and Survival among Patients with Stage III Colon Cancer*. JAMA. 299: 2515-2523, 2008. PMID: 18523220.
179. Van Cutsem E, Dico M, Haustermans K, Arber N, Bosset J-F, Cunningham D, de Gramont A, Diaz-Rubio E, Ducreux M, **Goldberg R**, Glynn-Jones R, Haller D, Kang Y-K, Kerr D, Labianca R, Minsky B, Moore M, Nordlinger B, Rougier P, Scheithauer W, Schmoll H-J, Sobrero A, Tabernero J, Tempero M, Van de Velde C, Zalcberg J. *The Diagnosis and Management of Rectal Cancer: Expert Discussion and Recommendations Derived from the 9th World Congress on Gastrointestinal Cancer, Barcelona, 2007*. Ann Oncol. 19 Suppl 6:vi1-8, 2008. PMID: 18539618.
180. Meropol NJ, Niedzwiecki D, Shank B, Colacchio TA, Ellerton J, Valone F, Budinger S, Day JM, Hopkins J, Tepper J, **Goldberg RM**, Mayer RJ. *Induction therapy for Poor-Prognosis Anal Canal Carcinoma: A Phase II Study of the Cancer and Leukemia Group B (CALGB 9281)*. J Clin Oncol. 26: 3229-3234, 2008. PMID: 18490648.
181. Caudle AS, Kim HJ, Tepper JE, O'Neil BH, Lange LA, **Goldberg RM**, Bernard SA, Calvo BF, Meyers MO. *Diabetes Mellitus Affects Response to Neoadjuvant Chemoradiotherapy in the Management of Rectal Cancer*. Ann Surg Oncol. 15: 1931-1936, 2008. PMID: 18418656.
182. Shah U, **Goldberg RM**. *Sequential Versus Combination Therapy in the Treatment of Patients with Advanced Colorectal Cancer*. Clin Colorectal Cancer. 7: 315-320, 2008. PMID: 18794063.
183. O'Neil BH, **Goldberg RM**. *Innovations in Chemotherapy for Metastatic Colorectal Cancer: An Update of Recent Clinical Trials*. Oncologist. 13: 1074-1083, 2008. PMID: 18922828.

184. Davies JM, **Goldberg RM**. *First-Line Therapeutic Strategies in Metastatic Colorectal Cancer*. Oncology (Williston Park). 22: 1470-1479, 2008. PMID: 19133603.
185. Sanoff HK, Sargent DJ, Campbell ME, Morton RF, Fuchs CS, Ramanathan RK, Williamson SK, Findlay BP, Pitot HC, **Goldberg RM**. *N9741: Five-Year Data and Prognostic Factor Analysis of Oxaliplatin and Irinotecan Combinations for Advanced Colorectal Cancer: N9741*. J Clin Oncol. 26: 5721-5727, 2008. PMID: 19001325.
186. Raftery L, Sanoff H, **Goldberg RM**. *Colon Cancer in Older Adults*. Semin Oncol. 35: 561-568, 2008. PMID: 19027460.
187. Fuchs CS, **Goldberg RM**, Sargent DJ, Meyerhardt JA, Wolpin BM, Green EM, Pitot HC, Pollack M. *Plasma Insulin-Like Growth Factors, Insulin-Like Binding Protein-3, and Outcome in Metastatic Colorectal Cancer: Results from Intergroup Trial N9741*. Clin Canc Res. 14: 8263-8269, 2008. PMID: 19073970.
188. O'Neil BH, **Goldberg RM**. *What is the standard chemotherapy for colorectal cancer patients with resectable liver metastases?* Nat Clin Pract Oncol. 2009 Jan;6(1):14-16. PMID: 19002130.
189. McWhinney S, **Goldberg RM**, McLeod HL. *Platinum Neurotoxicity Pharmacogenetics*. Mol Cancer Ther. 8: 10-16, 2009. PMID: 19139108.
190. Sargent D, Sobrero A, Grothey A, O'Connell M, Buyse M, Andre T, Zhang Y, Green E, Labianca R, O'Callaghan C, Seitz J-F, Francini G, Haller D, Yothers G, **Goldberg R**, de Gramont A. (for the Adjuvant Colon Cancer Endpoints (ACCENT) Group). *Evidence for Cure by Adjuvant Therapy in Colon Cancer: Observations Based on Individual Patient Data from 20,898 Patients on 18 Randomized Trials*. J Clin Oncol. 27: 872-877, 2009. PMID: 19124803.
191. Cmelak AJ, Lordick F, Borner M, **Goldberg RM**, Saif MW. *Management of Infusion Reactions in Clinical Trials and Beyond: The US and EU Perspectives*. Oncology (Williston Park). 23 (Suppl 1): 18-25, 2009. PMID: 19385163.
192. Shah U, O'Neil B, Allen J, **Goldberg RM**, Bernard S, Moore D, Venook AP, Morse MM. *A Phase II Study of Long-Acting Octreotide in Patients with Advanced Hepatocellular Carcinoma and CLIP Score of 3 or Higher*. Gastrointest Cancer Res. 3: 45-8, 2009. PMID: 19461906.
193. Bertagnolli MM, Warren RS, Niedzwiecki D, Mueller E, Compton CC, Redston M, Hall M, Hahn HP, Jewell SD, Mayer RJ, **Goldberg RM**, Saltz LB, Loda M. *p27^{Kip1} in Stage III Colon Cancer: Implications for Outcome Following Adjuvant Chemotherapy in Cancer and Leukemia Group B protocol 89803*. Clin Cancer Res. 15: 2116-2122, 2009. PMID: 19276255.
194. Sargent DJ, Köhne CH, Sanoff HK, Bot BM, Seymour MT, de Gramont A, Porschen R, Saltz L, Rougier P, Tournigand C, Douillard JY, Grothey A, **Goldberg RM**. *Pooled and Safety and Efficacy Analysis Examining the Effect of Performance Status on Outcomes in Nine First-Line Treatment Trials Using Individual Data from Patients with Metastatic Colorectal Cancer*. J Clin Oncol. 27: 1948-1955, 2009. PMID: 19255311.
195. Bertagnolli MM, Niedzwiecki D, Compton CC, Hahn HP, Hall M, Damas B, Jewell SD, Mayer RJ, **Goldberg RM**, Saltz LB, Warren RS, Redston M. *Microsatellite Instability Predicts Improved Response to Adjuvant Therapy with Irinotecan, Fluorouracil and Leukovorin in Stage III Colon Cancer: Cancer and Leukemia Group B Protocol 89803*. J Clin Oncol. 27: 1814-1821, 2009. PMID: 19273709.
196. Dy GK, Hobday TJ, Nelson D, Windschitl HE, O'Connell MJ, Alberts SJ, **Goldberg RM**, Nikcevich DA, Sargent DJ. *Long-term Survivors of Metastatic Colorectal Cancer Treated with Systemic Chemotherapy Alone: A North Central Cancer Treatment Group Review of 3811 Patients, N0144*. Clin Colorectal Cancer. 8: 88-93, 2009. PMID: 19739269.

197. Wong Y-N, Meropol NJ, Speier W, Sargent D, **Goldberg RM**, Beck JR. *Cost Implications of New Treatments for Advanced Colorectal Cancer*. Cancer. 115: 2081-2091, 2009. PMID: 19309745.
198. Kim GP, Sargent DJ, Mahoney MR, Rowland JR KM, Philip PA, Mitchell E, Matthews AP, Fitch TR, **Goldberg RM**, Alberts SR, Pitot HC. *Phase III Non-Inferiority Trial Comparing Irinotecan with Oxaliplatin, Fluorouracil, and Leucovorin in Patients with Advanced Colorectal Carcinoma Previously Treated with Fluorouracil: N9841*. J Clin Oncol. 27: 2848-54, 2009. PMID: 19380443.
199. Allegra CJ, Yothers G, O'Connell MJ, Sharif S, Colangelo LH, Lopa SH, Pertelli NJ, **Goldberg RM**, Atkins JN, Seay TE, Fehrenbacher L, Moulton B, Chu L, Pajon ER, Wolmark N. *Initial Safety Report of NSABP C-08: A Randomized Phase III Study of Modified FOLFOX6 with or without Bevacizumab for the Adjuvant Treatment of Patients with Stage II or II Colon Cancer*. J Clin Oncol. 27: 3385-90, 2009. PMID: 19414665.
200. Hillman S, An M, O'Connell M, **Goldberg R**, Schaefer P, Buckner J, and Sargent D. *Evaluation of the optimal number of lesions needed for tumor evaluation using the response evaluation criteria in solid tumors: a North Central Cancer Treatment Group Investigation*. J Clin Oncol. 27: 3205-3210, 2009. PMID: 19414682.
201. Gill S, **Goldberg RM**. *Cetuximab, Chemotherapy and KRAS Status in mCRC*. Nat Rev Clin Oncol. 6: 379-80, 2009. PMID: 19561631.
202. **Goldberg RM**, Meropol NJ, Tabernero J. *Accomplishments in 2008 in the Treatment of Advanced Metastatic Colorectal Cancer*. Gastrointest Cancer Res. 3(Supplement 2): S23-7, 2009. PMID: 20011561.
203. Sanoff H, Sargent DJ, Green EM, McLeod HM, **Goldberg RM**. *Racial differences in Advanced Colorectal Cancer Outcomes and Pharmacogenetics: A Subgroup Analysis of a Large Randomized Clinical Trial*. J Clin Oncol. 27: 4109-4115, 2009. PMID: 19636001.
204. **Goldberg RM**, Sargent DJ, Morton RF, Green E, Sanoff HK, McLeod H, Buckner J. *NCCTG Study N9741: Leveraging Learning from an NCI Cooperative Group Phase III Trial*. Oncologist. 14: 970-978, 2009. PMID: 19828593.
205. Kulke MH, Tempero MA, Niedzwiecki D, Hollis DR, Kindler HL, Cusnir M, Enzinger PC, Gorsch SM, **Goldberg RM**, Mayer RJ. *Randomized Phase II Study of Gemcitabine Administered at a Fixed Dose Rate or in Combination with Cisplatin, Docetaxel, or Irinotecan in Patients with Metastatic Pancreatic Cancer: CALGB 89904*. J Clin Oncol. 27: 5506-5512, 2009. [Epub ahead of print]. PMID: 19858396.
206. Ogino S, Meyerhardt JA, Irahara N, Niedzwiecki D, Hollis D, Saltz LB, Mayer RJ, Schaefer P, Whittom R, Hantel A, Benson III A, **Goldberg RM**, Bertagnolli MM, Fuchs CS. *KRAS Mutation in Stage III Colon Cancer and Clinical Outcome Following Intergroup Trial CALGB 89803*. Clin Cancer Res. 15: 7322-7329, 2009. PMID: 19934290.
207. de Gramont A, Hubbard J, Shi Q, O'Connell MJ, Buyse M Benedetti J, Bot B, O'Callaghan C, Yothers G, **Goldberg RM**, Blanke CD, Benson A, Deng Q, Alberts SR, Andre T, Wolmark N, Grothey A, Sargent D. *Association between Disease-Free Survival and Overall Survival when Survival Is Prolonged after Recurrence in Patients Receiving Cytotoxic Adjuvant Therapy for Colon Cancer: Simulations Based on the 20,800 Patient ACCENT Data Set*. J Clin Oncol. 28: 460-465, 2010. [Epub ahead of print]. PMID: 20008641.
208. Rakhra-Burris TK, Auman JT, Deverka P, Dressler LG, Evans JP, **Goldberg RM**, Havener TM, Hoskins JM, Jonas DE, Long KM, Motsinger-Reif AA, Irvin WJ, Richards KL, Roederer MW, Valgus JM, Riper M, Vernon JA, Zamboni WC, Wagner MJ, Walko CM, E Weck K, Wiltshire T, McLeod HL. *Institutional Profile: UNC Institute for Pharmacogenomics and Individualized*

Therapy: Interdisciplinary Research for Individual Care. Pharmacogenomics. 11: 13-21, 2010. PMID: 20017668.

209. McCabe MS, Wood WA, and **Goldberg RM**. *When the Family Requests Withholding the Diagnosis: Who Owns the Truth?* J Oncol Pract. 6: 94-96, 2010 . PMID: 20592784.
210. Tang H, Foster NR, Grothey A, Ansell SM, **Goldberg RM**, Sargent DJ. *Comparison of Error Rates in Single-Arm versus Randomized Phase II Cancer Clinical Trials.* J Clin Oncol. 28: 1936-1941, 2010. [Epub ahead of print]. PMID: 20212253.
211. Ramanathan RK, Rothenberg ML, de Gramont A, Tournigand C, **Goldberg RM**, Gupta S, André T. *Incidence and Evolution of Oxaliplatin-Induced Peripheral Sensory Neuropathy in Diabetic Patients with Colorectal Cancer: A Pooled Analysis of Three Phase III Studies.* Ann Oncol. 21: 754-758, 2010. PMID: 19887466.
212. Sanoff HK, **Goldberg RM**, Pignone MP. *Assessing the Quality of Initial Consultations Regarding Adjuvant Colon Cancer Therapy.* Clin Colorectal Cancer. 9: 113-118, 2010. PMID: 20378506.
213. O'Neil BH, Raftery L, Calvo BF, Chakravathi B, Ivanova A, Meyers MO, Kim HJ, Yeh JJ, Chan E, Wise PE, Caskey LS, Bernard SA, Sanoff HK, **Goldberg RM**, Tepper JE. *A Phase I Study of Bortezomib in Combination with Standard 5-Fluorouracil and External-Beam Radiation Therapy for the Treatment of Locally Advanced or Metastatic Rectal Cancer.* Clin Colorectal Can. 9: 119-125, 2010. PMID: 20378507.
214. Novotny PJ, Smith D, Guse L, Rummans TA, Hartmann L, Alberts S, **Goldberg R**, Gregory D, Johnson M, Sloan JA. *A Pilot Study Assessing Social Support among Cancer Patients Enrolled on Clinical Trials: A Comparison of Younger versus Older Adults.* Cancer Manag Res. 2: 133-142, 2010. PMID: 21188104.
215. Raftery L, **Goldberg RM**. *Optimal Delivery of Cytotoxic Chemotherapy for Colon Cancer.* Cancer J. 16: 214-219, 2010. PMID: 20526099.
216. McLeod HL, Sargent DJ, Marsh S, Green EM, King CR, Fuchs CS, Ramanathan RK, Williamson SK, Findlay B, Thibodeau S, Grothey A, Morton RF, and **Goldberg RM**. *Pharmacogenetic Predictors of Adverse Events and Response to Chemotherapy in Metastatic Colorectal Cancer: Results from North American Gastrointestinal Intergroup Trial N9741.* J Clin Oncol. 28: 3227-3233, 2010. [Epub ahead of print]. PMID: 20530282.
217. Kindler HL, Niedzwiecki D, Hollis D, Sutherland S, Schrag D, Hurwitz H, Innocenti F, Mulcahy MF, O'Reilly E, Wozniak TF, Picus J, Bhargava P, Mayer RJ, Schilsky RL, **Goldberg RM**. *Gemcitabine plus Bevacizumab Compared with Gemcitabine plus Placebo in Patients with Advanced Pancreatic Cancer: Phase III Trial of the Cancer and Leukemia Group B (CALGB 80303).* J Clin Oncol. 28: 3617-3622, 2010. [Epub ahead of print]. PMID: 20606091.
218. **Goldberg RM**, Sargent DJ, McLeod H. *Leveraging Learning from a Phase III Colorectal Cancer Clinical Trial: Outcomes, Methodology, Meta-Analysis and Pharmacogenetics.* Trans Am Clin Climatol Assoc. 121: 21-32, 2010. PMID: 20697547.
219. Ng K, Meyerhardt JA, Chan JA, Niedzwiecki D, Hollis DR, Saltz LB, Mayer RJ, Benson AB 3rd, Schaefer PL, Whittom R, Hantel A, **Goldberg RM**, Fuchs CS. *Multivitamin use is not associated with cancer recurrence or survival in patients with stage III colon cancer: findings from CALGB 89803.* J Clin Oncol. 28: 4354-4363, 2010. [Epub ahead of print]. PMID: 20805450.
220. O'Reilly EM, Niedzwiecki D, Hall M, Hollis D, Bekaii-Saab T, Pluard T, Douglas K, Abou-Alfa GK, Kindler HL, Schilsky RL, **Goldberg RM**; Cancer and Leukemia Group B. *A Cancer and Leukemia Group B Phase II Study of Sunitinib Malate in Patients with Previously Treated*

- Metastatic Pancreatic Adenocarcinoma (CALGB 80603)*. *Oncologist*. 15: 1310-1319, 2010. [Epub ahead of print]. PMID: 21148613.
221. Davies JM, **Goldberg RM**. *Optimum Chemotherapy Regimens for Neoadjuvant Therapy of Hepatic Colorectal Metastases*. *J Surg Oncol*. 102: 946-954, 2010. PMID: 21165997.
 222. **Goldberg RM**, Ryan DP. *Scan? Cure? Sure!* *Oncologist*. 16: 254-256, 2011. PMID 21349952.
 223. Allegra CJ, Yothers G, O'Connell MJ, Sharif S, Petrelli NJ, Colangelo LH, Atkins JN, Seay TE, Fehrenbacher L, **Goldberg RM**, O'Reilly S, Chu L, Azar CA, Lopa S, Wolmark N. *Phase III Trial Assessing Bevacizumab in Stages II and III Carcinoma of the Colon: Results of NSABP Protocol C-08*. *J Clin Oncol*. 29: 11-16, 2011. [Epub ahead of print]. PMID 20940184.
 224. McRee AJ, Cowherd S, Wang AZ, **Goldberg RM**. *Chemoradiation Therapy in the Management of Gastrointestinal Malignancies*. *Future Oncol*. 7: 409-426, 2011. PMID: 21417904.
 225. Ng K, Sargent DJ, **Goldberg RM**, Meyerhardt JA, Green EM, Pitot HC, Hollis BW, Pollak MN, Fuchs CS. *Vitamin D Status in Patients with Stage IV Colorectal Cancer: Findings from Intergroup Trial N9741*. *J Clin Oncol*. 29: 1599-1606, 2011. [Epub ahead of print]. PMID 21422438.
 226. McRee AJ, **Goldberg RM**. *Optimal Management of Metastatic Colorectal Cancer: Current Status*. *Drugs*. 71: 869-884, 2011. PMID: 21568364.
 227. Sargent D, Shi Q, Yothers G, Van Cutsem E, Cassidy J, Saltz L, Wolmark N, Bot B, Grothey A, Buyse M, de Gramont A; Adjuvant Colon Cancer End-points (ACCENT) Group. *Two or Three Year Disease-Free Survival (DFS) as a Primary End-Point in Stage III Adjuvant Colon Cancer Trials with Fluoropyrimidines with or without Oxaliplatin or Irinotecan: Data from 12,676 Patients from MOSAIC, X-ACT, PETACC-3, C-06, C-07 and C89803*. *Eur J Cancer*. 47: 990-6, 2011. [Epub ahead of print]. PMID: 21257306.
 228. Huen JM, Grothey A, Branda ME, **Goldberg RM**, Sargent DJ. *Tumor Status at 12 Weeks Predicts Survival in Advanced Colorectal Cancer: Findings from NCCTG N9741*. *Oncologist*. 16: 859-867, 2011. [Epub ahead of print]. PMID: 21632455.
 229. Sanoff HK, Bernard S, **Goldberg RM**, Morse MA, Garcia R, Woods L, Moore DT, O'Neil BH. *Phase II Study of Capecitabine, Oxaliplatin, and Cetuximab for Advanced Hepatocellular Carcinoma*. *Gastrointest Cancer Res*. 4: 78-83, 2011. PMID: 22043322.
 230. Jessup JM, Gunderson LL, Greene FL, Washington MK, Compton CC, Sobin LH, Minsky B, **Goldberg RM**, Hamilton SR. *2010 Staging System for Colon and Rectal Carcinoma*. *Ann Surg Oncol*. 18: 1513-1517, 2011.
 231. Mamon HJ, Niedzwiecki D, Hall MJ, Tan BR, Mayer RJ, Tepper JE, **Goldberg RM**, Blackstock AW, Fuchs CS; Cancer and Leukemia Group B. *A Phase 2 Trial of Gemcitabine, 5-Fluorouracil, and Radiation Therapy in Locally Advanced Nonmetastatic Pancreatic Adenocarcinoma*. *Cancer*. 117: 2620-2628, 2011. [Epub ahead of print]. PMID: 21656739.
 232. O'Neil BH, Funkhouser WK, Calvo BF, Meyers MO, Kim HJ, **Goldberg RM**, Bernard SA, Caskey L, Deal AM, Wright F, Baldwin AS, Tepper JE. *Nuclear Factor κ -Light Chain-Enhancer of Activated B Cells Is Activated by Radiotherapy and Is Prognostic for Overall Survival in Patients with Rectal Cancer Treated with Preoperative Fluorouracil-Based Chemoradiotherapy*. *Int J Radiat Oncol Biol Phys*. 80: 705-711, 2011. PMID: 20630669.
 233. Blanke CD, Bot BM, Thomas DM, Bleyer A, Kohne CH, Seymour MT, de Gramont A, **Goldberg RM**, Sargent DJ. *Impact of Young Age on Treatment Efficacy and Safety in Advanced Colorectal*

Cancer: A Pooled Analysis of Patients from Nine First-Line Phase III Chemotherapy Trials. J Clin Oncol. 29: 2781-2786, 2011. [Epub ahead of print]. PMID: 21646604.

234. Blanke CD, **Goldberg RM**, Grothey A, Mooney M, Roach N, Saltz LB, Welch JJ, Wood WA, Meropol NJ; NCI GI Steering Committee Colon Cancer Task Force. *KRAS and Colorectal Cancer: Ethical and Pragmatic Issues in Effecting Real-Time Change in Oncology Clinical Trials and Practice.* Oncologist. 16: 1061-1068, 2011. [Epub ahead of print]. PMID:21737577.
235. Niedzwiecki D, Bertagnolli MM, Warren RS, Compton CC, Kemeny NE, Benson AB 3rd, Eckhardt SG, Alberts S, Porjosh GN, Kerr DJ, Fields A, Rougier P, Pipas JM, Schwartz JH, Atkins J, O'Rourke M, Perry MC, **Goldberg RM**, Mayer RJ, Colacchio TA. *Documenting the Natural History of Patients with Resected Stage II Adenocarcinoma of the Colon after Random Assignment to Adjuvant Treatment with Edrecolomab or Observation: Results from CALGB 9581.* J Clin Oncol. 29: 3146-3152, 2011. [Epub ahead of print]. PMID: 21747085.
236. Bertagnolli MM, Redston M, Compton CC, Niedzwiecki D, Mayer RJ, **Goldberg RM**, Colacchio TA, Saltz LB, Warren RS. *Microsatellite Instability and Loss of Heterozygosity at Chromosomal Location 18q: Prospective Evaluation of Biomarkers for Stages II and III Colon Cancer--A Study of CALGB 9581 and 89803.* J Clin Oncol. 29: 3153-3162, 2011. [Epub ahead of print]. PMID: 21747089.
237. Davies JM, **Goldberg RM**. *Treatment of Metastatic Colorectal Cancer.* Semin Oncol. 38: 552-60, 2011. PMID: 21810514.
238. Lucas A, O'Neil BH, **Goldberg RM**. *A Decade of Advances in Cytotoxic Chemotherapy for Metastatic Colorectal Cancer.* Clin Colorectal Cancer. 10: 238-244, 2011. [Epub ahead of print]. PMID: 21820973.
239. Ng K, Ogino S, Meyerhardt JA, Chan JA, Chan AT, Niedzwiecki D, Hollis D, Saltz LB, Mayer RJ, Benson AB 3rd, Schaefer PL, Whittom R, Hantel A, **Goldberg RM**, Bertagnolli MM, Venook AP, Fuchs CS. *Relationship between Statin Use and Colon Cancer Recurrence and Survival: Results from CALGB 89803.* J Natl Cancer Inst. 103: 1540-1551, 2011. [Epub ahead of print]. PMID: 21849660.
240. An MW, Mandrekar SJ, Branda ME, Hillman SL, Adjei AA, Pitot HC, **Goldberg RM**, Sargent DJ. *Comparison of Continuous versus Categorical Tumor Measurement-Based Metrics to Predict Overall Survival in Cancer Treatment Trials.* Clin Cancer Res. 17: 6592-6599, 2011. [Epub ahead of print]. PMID: 21880789.
241. Yothers G, Sargent DJ, Wolmark N, **Goldberg RM**, O'Connell MJ, Benedetti JK, Saltz LB, Dignam JJ, Blackstock AW; ACCENT Collaborative Group. *Outcomes among Black Patients with Stage II and III Colon Cancer Receiving Chemotherapy: An Analysis of ACCENT Adjuvant Trials.* J Natl Cancer Inst. 103: 1498-1506, 2011. [Epub ahead of print]. PMID: 21997132.
242. Chibaudel B, Bonnetain F, Shi Q, Buyse M, Tournigand C, Sargent DJ, Allegra CJ, **Goldberg RM**, de Gramont A. *Alternative End Points to Evaluate a Therapeutic Strategy in Advanced Colorectal Cancer: Evaluation of Progression-Free Survival, Duration of Disease Control, and Time to Failure of Strategy--An Aide et Recherche en Cancerologie Digestive Group Study.* J Clin Oncol. 29: 4199-4204, 2011. [Epub ahead of print]. PMID: 21969501.
243. Buyse M, Sargent DJ, **Goldberg RM**, de Gramont A; ARCAD Clinical Trials Program. *The ARCAD Advanced Colorectal Cancer Database: Open for Business.* Ann Oncol. 23: 281-2, 2012. [Epub ahead of print]. PMID: 22104572
244. Roberts AS, Campa MJ, Gottlin EB, Jiang C, Owzar K, Kindler HL, Venook AP, **Goldberg RM**, O'Reilly EM, Patz EF Jr. *Identification of Potential Prognostic Biomarkers in Patients with*

Untreated, Advanced Pancreatic Cancer from a Phase 3 Trial (Cancer and Leukemia Group B 80303). Cancer. 118: 571-578, 2012. [Epub ahead of print]. PMID: 21713765.

245. Innocenti F, Owzar K, Cox NJ, Evans P, Kubo M, Zembutsu H, Jiang C, Hollis D, Mushiroda T, Li L, Friedman P, Wang L, Glubb DM, Hurwitz HI, Giacomini KM, McLeod HL, **Goldberg RM**, Schlisky R, Kindler HL, Nakamura Y, Ratain MJ. *A Genome-Wide Association Study of Overall Survival in Pancreatic Cancer Patients Treated with Gemcitabine in CALGB 80303.* Clin Cancer Res. 18: 577-84, 2012. [Epub ahead of print]. PMID: 22142827.
246. Franko J, Shi Q, Goldman CD, Pockaj BA, Nelson GD, **Goldberg RM**, Pitot HC, Grothey A, Alberts SR, Sargent DJ. *Treatment of Colorectal Peritoneal Carcinomatosis With Systemic Chemotherapy: A Pooled Analysis of North Central Cancer Treatment Group Phase III Trials N9741 and N9841.* J Clin Oncol. 30: 263-267, 2012. [Epub ahead of print]. PMID: 22162570.
247. Ogino S, Shima K, Meyerhardt J, McCleary N, Ng K, Hollis D, Saltz LB, Mayer RJ, Schaefer P, Whittom R, Hantel A, Benson AB, Spiegelman D, **Goldberg RM**, Bertagnolli MM, Fuchs CS. *Predictive and Prognostic Roles of BRAF Mutation in Stage III Colon Cancer: Results from Intergroup Trial CALGB 89803.* Clin Cancer Res. 18: 890-900, 2012. [Epub ahead of print]. PMID: 22147942.
248. Alberts SR, Sargent DJ, Nair S, Mahoney MR, Mooney M, Thibodeau SN, Smyrk TC, Sinicrope FA, Chan E, Gill S, Kahlenberg MS, Shields AF, Quesenberry JT, Webb TA, Farr GH Jr, Pockaj BA, Grothey A, **Goldberg RM**. *Effect of Oxaliplatin, Fluorouracil and Leucovorin with or without Cetuximab on Survival among Patients with Resected Stage III Colon Cancer: A Randomized Trial.* JAMA. 307: 1383-1393, 2012. PMID: 22474202.
249. Sugihara K, Ohtsu A, Shimada Y, Mizunuma N, Lee PH, de Gramont A, **Goldberg RM**, Rothenberg ML, André T, Brienza S, Gomi K. *Safety Analysis Of FOLFOX4 Treatment in Colorectal Cancer Patients: A Comparison between Two Asian Studies and Four Western Studies.* Clin Colorectal Cancer. 11: 127-137, 2012. [Epub ahead of print]. PMID: 22099928.
250. Vijayaraghavan A, Efrusy MB, Göke B, Kirchner T, Santas CC, **Goldberg RM**. *Cost-Effectiveness of KRAS Testing in Metastatic Colorectal Cancer Patients in the United States and Germany.* Int J Cancer. 131: 438-445, 2012. [Epub ahead of print]. PMID: 21898389.
251. Sanoff HK, Carpenter WR, Stürmer T, **Goldberg RM**, Martin CF, Fine JP, McCleary NJ, Meyerhardt JA, Niland J, Kahn KL, Schymura MJ, Schrag D. *Effect of adjuvant chemotherapy on survival of patients with Stage III Colon Cancer Diagnosed after Age 75 years.* J Clin Oncol. 30: 2624-2634, 2012. [Epub ahead of print]. PMID: 22665536.
252. Carpenter WR, Meyer AM, Wu Y, Qaqish B, Sanoff HK, **Goldberg RM**, Weiner BJ. *Translating Research into Practice: The Role of Provider-Based Research Networks in the Diffusion of an Evidence-Based Colon Cancer Treatment Innovation.* Med Care. 50: 737-748, 2012. PMID: 22437624.
253. Sanoff HK, Carpenter WR, Freburger J, Li L, Chen K, Zullig LL, **Goldberg RM**, Schymura MJ, Schrag D. *Comparison of Adverse Events during 5-Fluorouracil versus 5-Fluorouracil/Oxaliplatin Adjuvant Chemotherapy for Stage III Colon Cancer: A Population-Based Analysis.* Cancer. 118: 4309-4320, 2012. [Epub ahead of print]. PMID: 22294436.
254. Sargent DJ, Buyse M, Matheson A, **Goldberg RM**, de Gramont A; ARCAD Clinical Trials Program. *The ARCAD Clinical Trials Program: An Update and Invitation.* Oncologist. 17: 188-191, 2012. [Epub ahead of print]. PMID: 22302228.
255. Wu, C, **Goldberg RM**. *New Drugs in the Frontier of Treatment of Metastatic Colorectal Cancer.* Curr Colorectal Cancer Rep. 8: 161-69, 2012.

256. Grothey A, Cutsem EV, Sobrero A, Siena S, Falcone A, Ychou M, Humblet Y, Bouché O, Mineur L, Barone C, Adenis A, Tabernero J, Yoshino T, Lenz HJ, **Goldberg RM**, Sargent DJ, Cihon F, Cupit L, Wagner A, Laurent D; CORRECT Study Group. *Regorafenib Monotherapy for Previously Treated Metastatic Colorectal Cancer (CORRECT): An International, Multicentre, Randomised, Placebo-Controlled, Phase 3 Trial*. Lancet. 381: 303-312, 2013. [Epub ahead of print]. PMID: 23177514.
257. Wu C, **Goldberg RM**. *Colorectal Cancer in 2012: Revisiting Landmark Trials and Identifying New Therapies*. Nat Rev Clin Oncol.10: 71-2, 2013 [Epub ahead of print]. PMID: 23296108.
258. Sinicrope FA, Foster NR, Yothers G, Benson A, Seitz JF, Labianca R, **Goldberg RM**, de Gramont A, O'Connell MJ, Sargent DJ; Adjuvant Colon Cancer Endpoints (ACCENT) Group. *Body Mass Index at Diagnosis and Survival Among Colon Cancer Patients Enrolled in Clinical Trials of Adjuvant Chemotherapy*. Cancer. 119: 1528-1536, 2013. [Epub ahead of print]. PMID: 23310947.
259. Van Loon K, Wigler D, Niedzwiecki D, Venook AP, Fuchs C, Blanke C, Saltz L, **Goldberg RM**, Meyerhardt JA. *Comparison of Dietary and Lifestyle Habits among Stage III and Metastatic Colorectal Cancer Patients: Findings from CALGB 89803 and CALGB 80405*. Clin Colorectal Cancer. 12: 95-102, 2013. PMID: 23317558.
260. Rafferty L, Tepper JE, **Goldberg RM**, Blackstock AW, Aklilu M, Bernard SA, Ivanova A, Davies JM, O'Neil BH. *A Two-Cohort Phase 1 Study of Weekly Oxaliplatin and Gemcitabine, Then Oxaliplatin, Gemcitabine, and Erlotinib during Radiotherapy for Unresectable Pancreatic Carcinoma*. Am J Clin Oncol. 36: 250-253, 2013. PMID: 22547007.
261. Sugihara K, Ohtsu A, Shimada Y, Mizunuma N, Gomi K, Lee PH, de Gramont A, Rothenberg ML, André T, Brienza S, **Goldberg RM**. *Analysis of Neurosensory Adverse Events Induced by FOLFOX4 Treatment in Colorectal Cancer Patients: A Comparison Between Two Asian Studies and Four Western Studies*. Cancer Med. 1: 198-206, 2012. PMID: 23342269.
262. Haraldsdottir S, **Goldberg RM**. *Recent advances in treatment of metastatic colorectal cancer*. Clinical Investigation. 11: 1109-1122, 2012.
263. **Goldberg RM**, Haraldsdottir S. *Decade of discoveries leads to decreased diagnosis, mortality rates*. 2013 Gastrointestinal Cancers Symposium Daily News. Jan 25, 2013, Issue 2 p1 & 4.
264. Venook AP, Niedzwiecki D, Lopatin M, Ye X, Lee M, Friedman PN, Frankel W, Clark-Langone K, Millward C, Shak S, **Goldberg RM**, Mahmoud NN, Warren RS, Schilsky RL, Bertagnolli MM. *Biologic Determinants of Tumor Recurrence in Stage II Colon Cancer: Validation Study of the 12-Gene Recurrence Score in Cancer and Leukemia Group B (CALGB) 9581*. J Clin Oncol. 31: 1775-1781, 2013. [Epub ahead of print]. PMID: 23530100.
265. Bekaii-Saab T, **Goldberg, RM**. *FOLFIRINOX in Locally Advanced Pancreas Adenocarcinoma: Back to the Future?* Oncologist. 18: 487-489, 2013. PMID: 23704222.
266. Haraldsdottir S, Wu C, Bloomston M, **Goldberg RM**. *What Is the Optimal Neo-Adjuvant Treatment for Liver Metastasis?* Ther Adv Med Oncol. 5: 221-234, 2013. PMID: 23858331.
267. Wu C, **Goldberg RM**. *Managing Choices for Older Patients with Colon Cancer*. Am Soc Clin Oncol Educ Book. 2013: 190-193. PMID: 23714498.
268. Sanoff HK, **Goldberg RM**. *How We Treat Metastatic Colon Cancer in Older Adults*. J Geriatr Oncol. 4: 295-301, 2013. PMID: 24472471.
269. Warren RS, Altrea CE, Niedzwiecki D, Weinberg VK, Donner DB, Mayer RJ, **Goldberg RM**, Compton CC, Zuraek MB, Ye C, Saltz LB, Bertagnolli MM. *Association of TP53 Mutational*

Status and Gender with Survival after Adjuvant Treatment for Stage III Colon Cancer: Results of CALGB 89803. Clin Cancer Res. 19: 5777-5787, 2013. [Epub ahead of print]. PMID: 23983256.

270. Sinicrope FA, Mahoney MR, Smyrk TC, Thibodeau SN, Warren RS, Bertagnolli MM, Nelson GD, **Goldberg RM**, Sargent DJ, Alberts FR. *Prognostic Impact of Deficient DNA Mismatch Repair in Patients with Stage III Colon Cancer from a Randomized Trial of FOLFOX-Based Adjuvant Chemotherapy. J Clin Oncol.* 31: 3664-3672, 2013. [Epub ahead of print]. PMID: 24019539.
271. Nixon AB, Pang H, Starr MD, Friedman PN, Bertagnolli MM, Kindler HL, **Goldberg RM**, Venook AP, Hurwitz HI; for the Alliance for Clinical Trials In Oncology. *Prognostic and Predictive Blood-Based Biomarkers in Patients with Advanced Pancreatic Cancer: Results from CALGB80303 (Alliance). Clin Cancer Res.* 19: 6957-6966, 2013. [Epub ahead of print]. PMID: 24097873.
272. Garrett CR, Bekaii-Saab TS, Ryan T, Fisher GA, Clive S, Kavan P, Shacham-Shmueli E, Buchbinder A, **Goldberg RM**. *Randomized Phase 2 Study of Pegylated SN-38 (EZN-2208) or Irinotecan Plus Cetuximab in Patients with Advanced Colorectal Cancer. Cancer.* 119: 4223-4230, 2013. [Epub ahead of print]. PMID: 24105075.
273. Goetz MP, McKean HA, Reid JM, Mandrekar SJ, Tan AD, Kuffel MA, Safgren SL, McGovern RM, **Goldberg RM**, Grothey AA, McWilliams R, Erlichman C, Ames MM. *UGT1A1 Genotype-Guided Phase I Study of Irinotecan, Oxaliplatin, and Capecitabine. Invest New Drugs.* 31: 1559-1567, 2013. [Epub ahead of print]. PMID: 24114122.
274. Ogino S, Liao X, Imamura Y, Yamauchi M, McCleary NJ, Ng K, Niedzwiecki D, Saltz LB, Mayer RJ, Whittom R, Hantel A, Benson AB 3rd, Mowat RB, Spiegelman D, **Goldberg RM**, Bertagnolli MM, Meyerhardt JA, Fuchs CS; Alliance for Clinical Trials in Oncology. *Predictive and Prognostic Analysis of PIK3CA Mutation in Stage III Colon Cancer Intergroup Trial. J Natl Cancer Inst.* 105: 1789-1798, 2013. PMID: 24231454.
275. Sanoff HK, Renfro LA, Poonnen P, Ambadwar P, Sargent DJ, **Goldberg RM**, McLeod H. *Germline Variation in Colorectal Risk Loci Does Not Influence Treatment Effect or Survival in Metastatic Colorectal Cancer. PLoS One.* 2014 Apr 11;9(4):e94727. PMID: 24727911.
276. Gonsalves WI, Mahoney MR, Sargent DJ, Nelson GD, Alberts SR, Sinicrope FA, **Goldberg RM**, Limburg PJ, Thibodeau SN, Grothey A, Hubbard JM, Chan E, Nair S, Berenberg JL, McWilliams RR, Alliance for Clinical Trials in Oncology. *Patient and Tumor Characteristics and BRAF and KRAS Mutations in Colon Cancer, NCCTG/Alliance N0147. J Natl Cancer Inst.* 106: 1093, 2014. PMID: 24925349.
277. Yoon HH, Tougeron D, Shi Q, Alberts SR, Mahoney MR, Nelson GD, Nair SG, Thibodeau SN, **Goldberg RM**, Sargent DJ, Sinicrope FA. *KRAS Codon 12 and 13 Mutations in Relation to Disease-Free Survival in BRAF-Wild Type Stage III Colon Cancers from an Adjuvant Chemotherapy Trial (N0147 Alliance). Clin Cancer Res.* 20: 3033-43, 2014. [Epub ahead of print]. PMID: 24687927.
278. Huang J, Nair SG, Mahoney MR, Nelson GD, Shields AF, Chan E, **Goldberg RM**, Gill S, Kahlenberg MS, Quesenberry JT, Thibodeau SN, Smyrk TC, Grothey A, Sinicrope FA, Webb TA, Farr GH Jr, Pockaj BA, Berenberg JL, Mooney M, Sargent DJ, Alberts SR; Alliance for Clinical Trials in Oncology. *Comparison of FOLFIRI with or without Cetuximab in Patients with Resected Stage III Colon Cancer; NCCTG (Alliance) Intergroup Trial N0147. Clin Colorectal Cancer.* 13: 100-9, 2014. [Epub ahead of print]. PMID: 24512953.

279. Haraldsdottir S, Hampel H, Wei L, Wu C, Frankel W, Bekaii-Saab T, de la Chapelle A, **Goldberg RM**. *Prostate Cancer Incidence in Males with Lynch Syndrome*. Genet Med. 16: 553-7, 2014. [Epub ahead of print]. PMID: 24434690.
280. McRee AJ, Davies JM, Sanoff HG, **Goldberg RM**, Bernard S, Claire Dees E, Keller K, Ivanova A, O'Neil BH. *A Phase I Trial of Everolimus in Combination With 5-FU/LV, MFOLFOX6 And MFOLFOX6 Plus Panitumumab in Patients with Refractory Solid Tumors*. Cancer Chemother Pharmacol. 74:117-23, 2014. [Epub ahead of print]. PMID: 24819684.
281. Shiovitz S, Bertagnolli MM, Renfro LA, NamE, Foster NR, Dzieciatkowski S, Luo Y, Lao VV, Monnat RF Jr, Emond MJ, Maizels N, Niedzwiecki D, **Goldberg RM**, Saltz LB, Venook A, Warren RS, Grady WM, Alliance for Clinical Trials in Oncology. *CpG Island Methylator Phenotype is Associated with Response to Adjuvant Irinotecan-Based Therapy for Stage 3 Colon Cancer*. Gastroenterology. 147: 637-45, 2014. [Epub ahead of print]. PMID: 24859205.
282. O'Neil BH, Cainap C, Van Cutsem, Gorbunova V, Karapetis CS, Berlin J, **Goldberg RM**, Qin Q, Qian J, Ricker JL, Fischer J, McKee MD, Carlson DM, Kim TW. *Randomized Phase II Open-Label Study of mFOLFOX6 in Combination with Linifanib or Bevacizumab for Metastatic Colorectal Cancer*. Clin Colorectal Cancer. 13: 156-163, 2014. [Epub ahead of print]. PMID: 25066269.
283. Lieu CH, Renfro LA, de Gramont A, Meyers JP, Maughan TS, Seymour MT, Saltz L, **Goldberg RM**, Sargent DJ, Eckhardt SG, Eng C. *Association of Age with Survival in Patients with Metastatic Colorectal Cancer: Analysis from the ARCAD Clinical Trials Program*. J Clin Oncol. 32: 2975-84, 2014. [Epub ahead of print]. PMID: 25002720.
284. Pavelitz T, Renfro L, Foster NR, Caracol A, Welsch P, Lao VV, Grady WB, Niedzwiecki D, Saltz LB, Bertagnolli MM, **Goldberg RM**, Rabinovitch PS, Emond M, Monnat RF Jr, Maizels N. *MRE11-Deficiency Associated with Improved Long-Term Disease Free Survival and Overall Survival in a Subset of Stage III Colon Cancer Patients in Randomized CALGB 89803 Trial*. PLoS One. 2014 Oct 13; 9(10): e108483. PMID: 25310185.
285. Ciombor KK, **Goldberg RM**. *Current Evidence and Controversies in the Incorporation of Biologics for Metastatic Colorectal Cancer*. Hepatic Oncol. 1, 331-345, 2014. PMID: 30190967.
286. Lee AM, Shi Q, Pavey E, Alberts SR, Sargent DJ, Sinicrope FA, Berenberg JL, **Goldberg RM**, Diasio RB. *DPYD Variants as Predictors of 5-Fluorouracil Toxicity in Adjuvant Colon Cancer Treatment (NCCTB N0147)*. J Natl Cancer Inst. 106: 298, 2014. PMID: 25381393.
287. Nichols SD, Albert S, Shirley L, Schmidt C, Abdel-Misih S, El-Dika S, Groce JR, Wu C, **Goldberg RM**, Bekaii-Saab T, Bloomston M. *Outcomes in Patients with Obstructive Jaundice from Metastatic Colorectal Cancer and Implications for Management*. J Gastrointest Surg. 18: 2186-91, 2014. PMID: 25300799.
288. Ciombor KK, Haraldsdottir S, **Goldberg RM**. *How Can Next-Generation Sequencing (Genomics) Help Us in Treating Colorectal Cancer?* Curr Colorectal Cancer Rep. 10:372-379, 2014. PMID: 25395895.
289. Shi Q, de Gramont A, Grothey A, Zalcborg J, Chibaudel B, Schmoll HJ, Seymour MT, Adams R, Saltz L, **Goldberg RM**, Punt CJ, Douillard JY, Hoff PM, Hecht JR, Hurwitz H, Díaz-Rubio E, Porschen R, Tebbutt NC, Fuchs C, Souglakos J, Falcone A, Tournigand C, Kabbinar FF, Heinemann V, Van Cutsem E, Bokemeyer C, Buyse M, Sargent DJ. *Individual Patient Data Analysis of Progression-Free Survival versus Overall Survival as a First-Line End Point for Metastatic Colorectal Cancer in Modern Randomized Trials: Findings from the Analysis and Research in Cancers of the Digestive System Database*. J Clin Oncol. 33:22-8, 2015. [Epub ahead of print]. PMID: 25385741.

290. Sharma MR, Gray E, **Goldberg RM**, Sargent DJ, Karrison TG. *Resampling the N9741 Trial to Compare Tumor Dynamic Versus Conventional End Points In Randomized Phase II Trials*. J Clin Oncol. 33: 36-41, 2015. [Epub ahead of print]. PMID: 25349295.
291. Mikhail S, Ciombor K, Noonan A, Wu C, **Goldberg R**, Zhao W, Wei L, Mathey K, Yereb M, Timmers C, Bekaii-Saab T. *Upfront Molecular Testing in Patients with Advanced Gastro-esophageal Cancer: Is It Time Yet?* Oncotarget. 6:22206-13, 2015. PMID: 26082439
292. Lamont EB, Schilsky RL, He Y, Muss H, Cohen HJ, Hurria A, Meilleur A, Kindler HL, Venook A, Lilenbaum R, Niell H, **Goldberg RM**, Joffe S; Alliance for Clinical Trials in Oncology. *Generalizability of Trial Results to Elderly Medicare Patients with Advanced Solid Tumors (Alliance 70802)*. J Natl Cancer Inst. 107(1):336, 2015. PMID: 25432408.
293. Nordlinger B, Poston GJ, **Goldberg RM**. *Should the results of the new EPOC trial change practice in the management of patients with resectable metastatic colorectal cancer confined to the liver?* J Clin Oncol. 2015 Jan 20;33(3):241-3. doi: 10.1200/JCO.2014.58.3989. Epub 2014 Nov 17. PMID: 25403221.
294. Ng K, Meyerhardt JA, Chan AT, Sato K, Chan JA, Niedzwiecki D, Saltz LB, Mayer RJ, Benson AB 3rd, Schaefer PL, Whittom R, Hantel A, **Goldberg RM**, Venook AP, Ogino S, Giovannucci EL, Fuchs CS. *Aspirin And Cox-2 Inhibitor Use In Patients with Stage III Colon Cancer*. J Natl Cancer Inst. 107:345, 2015. PMID: 25432409.
295. Sinicrope FA, Shi Q, Smyrk TC, Thibodeau SN, Dienstmann R, Guinney J, Bot BM, Tejpar S, Delorenzi M, **Goldberg RM**, Mahoney M, Sargent DJ, Alberts SR. *Molecular markers identify subtypes of stage III colon cancer associated with patient outcomes*. Gastroenterology. 148: 88-99, 2015. [Epub ahead of print]. PMID: 25305506.
296. **Goldberg RM**. *Genomic Profiling in Gastrointestinal Cancer: Are We Ready To Use These Data to Make Treatment Decisions?* Oncologist. 2015 Dec;20(12):1448-56. doi: 10.1634/theoncologist.2015-0263. Epub 2015 Oct 28. PMID: 26512044; PMCID: PMC4679091.
297. Ciombor KK, Wu C, **Goldberg RM**. *Recent Therapeutic Advances in the Treatment of Colorectal Cancer*. Annu Rev Med. 66: 83-95, 2015. [Epub ahead of print]. PMID: 25341011.
298. Blazer M, Wu C, **Goldberg RM**, Phillips G, Schmidt C, Muscarella P, Wuthrick E, Williams TM, Reardon J, Ellison EC, Bloomston M, Bekaii-Saab T. *Neoadjuvant Modified (m) FOLFIRINOX for Locally Advanced Unresectable (LAPC) and Borderline Resectable (BRPC) Adenocarcinoma of the Pancreas*. Ann Surg Oncol. 22:1153-9, 2015. [Epub ahead of print]. PMID: 25358667.
299. Le DT, Uram JN, Wang H, Bartlett BR, Kemberling H, Eyring AD, Skora AD, Lubner BS, Azad NS, Laheru D, Biedrzycki B, Donehower RC, Zaheer A, Fisher GA, Crocenzi TS, Lee JJ, Duffy SM, **Goldberg RM**, de la Chapelle A, Koshiji M, Bhaijee F, Huebner T, Hruban RH, Wood LD, Cuka N, Pardoll DM, Papadopoulos N, Kinzler KW, Zhou S, Cornish TC, Taube JM, Anders RA, Eshleman JR, Vogelstein B, Diaz LA Jr. *PD-1 Blockade in Tumors with Mismatch-Repair Deficiency*. N Engl J Med. 372: 2509-20, 2015. [Epub ahead of print]. PMID: 26028255.
300. Yoon HH, Shi Q, Alberts SR, **Goldberg RM**, Thibodeau SN, Sargent DJ, Sinicrope FA, Alliance for Clinical Trials in Oncology. *Racial Differences in BRAF/KRAS Mutation Rates and Survival in Stage III Colon Cancer Patients*. J Natl Cancer Inst. 2015, Jul 9; 107(10). pii: djv186. PMID: 26160882.
301. Tabernero J, Lenz HJ, Siena S, Sobrero A, Falcone A, Ychou M, Humblet Y, Bouché O, Mineur L, Barone C, Adenis A, Yoshino T, **Goldberg RM**, Sargent DJ, Wagner A, Laurent D, Teufel M, Jeffers M, Grothey A, Van Cutsem E. *Analysis of Circulating DNA And Protein Biomarkers To Predict the Clinical Activity of Regorafenib and Assess Prognosis in Patients with Metastatic*

- Colorectal Cancer: A Retrospective, Exploratory Analysis of the CORRECT Trial*. Lancet Oncol. 16: 937-48, 2015. [Epub ahead of print]. PMID: 26184520.
302. Sinicrope FA, Mahoney MR, Yoon HH, Smyrk TC, Thibodeau SN, **Goldberg RM**, Nelson GD, Sargent DJ, Alberts SR. *Analysis of Molecular Markers By Anatomic Tumor Site in Stage III Colon Carcinomas from Adjuvant Chemotherapy Trial NCCTG N0147 (Alliance)*. Clin Cancer Res. 21: 5294-304, 2015. [Epub ahead of print]. PMID: 26187617.
 303. Ciombor KK, Goldberg RM. *Update on Anti-Angiogenesis Therapy In Colorectal Cancer*. Curr Colorectal Cancer Rep. 11: 378-387, 2015. PMID: 27551256.
 304. Renfro LA, Loupakakis F, Adams RA, Seymour MT, Schmoll HJ, Douillard JY, Hurwitz H, Fuchs CS, Diaz-Rubio E, Porschen R, Tournigand C, Chibaudel B, Falcone A, Tebbutt NC, Punt CJ, Hecht JR, Bokemeyer C, Van Cutsem E, **Goldberg RM**, Saltz LB, de Gramont A, Sargent DJ, Lenz HJ. *Body Mass Index Is Prognostic in Metastatic Colorectal Cancer: Pooled Analysis of Patients from First-Line Clinical Trials in the ARCAD Database*. J Clin Oncol. 34:144-50, 2016. [Epub ahead of print]. PMID: 26503203.
 305. Ahn DH, **Goldberg RM**. *Colorectal Clinical Trials: What Is On the Horizon?* Future Oncol. 12: 525-31, 2016. [Epub ahead of print]. PMID: 26777152.
 306. Lee AM, Shi Q, Alberts SR, Sargent DJ, Sinicrope FA, Berenberg JL, Grothey A, Polite B, Chan E, Gill S, Kahlenberg MS, Nair SG, Shields AF, **Goldberg RM**, Diasio RB. *Association Between DPYD c.1129-5923 C>G/hapB3 and Severe Toxicity to 5-Fluorouracil-Based Chemotherapy In Stage III Colon Cancer Patients: NCCTG N0147 (Alliance)*. Pharmacogenet Genomics. 26: 133-37, 2016. [Epub ahead of print]. PMID: 26658227.
 307. Enzinger PC, Burtness BA, Niedzwiecki D, Ye X, Douglas K, Ilson DH, Villalflor VM, Cohen SJ, Mayer RJ, Venook A, Benson AB 3rd, **Goldberg RM**. *CALGB 80403 (Alliance)/E1206: A randomized Phase II Study of Three Chemotherapy Regimens Plus Cetuximab in Metastatic Esophageal and Gastroesophageal Junction Cancers*. J Clin Oncol. 34:2736-42, 2016. [Epub ahead of print]. PMID:27382098.
 308. Phipps AI, Shi Q, Limburg PJ, Nelson GD, Sargent DJ, Sinicrope FA, Chan E, Gill S, **Goldberg RM**, Kahlenberg M, Nair S, Shields AF, Newcomb PA, Alberts FR, Alliance for Clinical Trials in Oncology. *Alcohol Consumption and Colon Cancer Prognosis Among Participants in North Central Cancer Treatment Group Phase III Trial N0147*. Int J Cancer. 139: 986-95 2016. [Epub ahead of print]. PMID: 27060850.
 309. Ciombor KK, **Goldberg RM**. *Update on Anti-Angiogenesis Therapy in Colorectal Cancer*. Curr Colorectal Cancer Rep. 2015 Dec;11(6):378-387. doi: 10.1007/s11888-015-0292-3. PMID: 27551256; PMCID: PMC4991548.
 310. Haraldsdottir S, Hampel H, Wu C, Weng DY, Shields PG, Frankel WL, Pan X, de la Chapelle A, **Goldberg RM**, Bekaii-Saab T. *Patients with Colorectal Cancer Associated with Lynch Syndrome and MLH1 Promoter Hypermethylation Have Similar Prognoses*. Genet Med. 18: 863-8, 2016. [Epub ahead of print]. PMID: 26866578.
 311. Niedzwiecki D, Frankel WL, Venook AP, Ye X, Friedman PN, **Goldberg RM**, Mayer RJ, Colacchio TA, Mulligan JM, Davison TS, O'Brien E, Kerr P, Johnston PG, Kennedy RD, Harkin DP, Schilsky RL, Bertagnolli MM, Warren RS, Innocenti F. *Association Between Results of a Gene Expression Signature Assay and Recurrence-Free Interval in Patients with Stage II Colon Cancer in Cancer and Leukemia Group B 9581 (Alliance)*. J Clin Oncol. 34: 3047-53, 2016. [Epub ahead of print]. PMID: 27432924.

312. Zhu J, Deane NG, Lewis KB, Padmanabhan C, Washington MK, Ciombor KK, Timmers C, **Goldberg RM**, Beauchamp RD, Chen X. *Evaluation of Frozen Tissue-Derived Prognostic Gene Expression Signatures in FFPE Colorectal Cancer Samples.* Sci Rep. 2016 Sep 14;6:33273. PMID: 27623752.
313. Ciombor KK, **Goldberg RM**. *Highlights in Gastrointestinal (Colorectal) Cancer Treatment: The Primary Tumor Sidedness Debate and Advances In Immunotherapy.* JAMA Oncol. 2: 1537-1538, 2016. PMID: 27684887.
314. **Goldberg RM**. *In Memoriam: A tribute to Daniel J. Sargent, Ph.D.* Oncologist 2016 Dec; 21: 1509-1521, 2016. [Epub ahead of print]. PMID: 27956661.
315. Singh PP, Shi Q, Foster NR, Grothey A, Nair SG, Chan E, Shields AF, **Goldberg RM**, Gill S, Kahlenberg MS, Sinicrope FA, Sargent DJ, Alberts SR. *Relationship between Metformin use and Recurrence and survival in patients with resected stage III colon cancer receiving adjuvant chemotherapy: results from North Central Cancer Treatment Group N0147 (Alliance).* Oncologist. 21: 1509-1521, 2016. [Epub ahead of print]. PMID: 27881709.
316. Taieb J, Le Malicot K, Shi Q, Penault Lorca F, Bouché O, Tabernero J, Mini E, **Goldberg RM**, Folprecht G, Luc Van Laethem J, Sargent DJ, Alberts SR, Francois Emile J, Laurent Puig P, Sinicrope FA. *Prognostic value of BRAF and KRAS mutations in MSI and MSS stage III colon cancer.* J Natl Cancer Inst. 109: 472-480, 2016. [Epub ahead of print]. PMID: 28040692.
317. Jansson-Knodell CL, Foster NR, Sargent DJ, Limburg PJ, Thibodeau SN, Smyrk TC, Sinicrope FA, Jahagirdar B, **Goldberg RM**, Alberts SR. *Family history of colorectal cancer and its impact on survival in patients with resected stage III colon cancer: results from NCCTG Trial N0147 (Alliance).* J Gastrointest Oncol. 2017 Feb;8(1):1-11. PMID:28280603.
318. Niedzwiecki D, Hasson RM, Lenz HJ, Ye C, Redston M, Ogino S, Fuchs CS, Compton CC, Mayer RJ, **Goldberg RM**, Colacchio TA, Saltz LB, Warren RS, Bertagnolli MM. *A Study Of Thymidylate Synthase Expression as a Biomarker for Resectable Colon Cancer: Alliance (Cancer and Leukemia Group B) 9581 and 89803.* Oncologist. 2017;22: 107-114, 2017. [Epub ahead of print]. PMID: 27821793.
319. Sinicrope FA, Shi Q, Allegra CJ, Smyrk TC, Thibodeau SN, **Goldberg RM**, Meyers JP, Pogue-Geile KL, Yothers G, Sargent DJ, Alberts SR. *Association Of DNA Mismatch Repair And Mutations in BRAF And KRAS With Survival After Recurrence in Stage III Colon Cancers : A Secondary Analysis of 2 Randomized Clinical Trials.* JAMA Oncol. 3: 472-480, 2017. PMID: 28006055.
320. Ciombor KK, **Goldberg RM**. *Primary tumor sidedness as prognostic and predictive biomarker in metastatic colorectal cancer: further validation of a potentially practice-changing variable.* JAMA Oncol. 3: 165-166, 2017. PMID: 27722749.
321. Pearlman R, Frankel WL, Swanson B, Zhao W, Yilmaz A, Miller K, Bacher J, Bigley C, Nelsen L, Goodfellow PJ, **Goldberg RM**, Paskett E, Shields PG, Freudenheim JL, Stanich PP, Lattimer I, Arnold M, Liyanarachchi S, Kalady M, Heald B, Greenwood C, Paquette I, Prues M, Draper DJ, Lindeman C, Kuebler JP, Reynolds K, Brell JM, Shaper AA, Mahesh S, Buie N, Weeman K, Shine K, Haut M, Edwards J, Bastola S, Wickham K, Khanduja KS, Zacks R, Pritchard CC, Shirts BH, Jacobson A, Allen B, de la Chapelle A, Hampel H; Ohio Colorectal Cancer Prevention Initiative Study Group. *Prevalence and spectrum of germline cancer susceptibility gene mutations among patients with early-onset colorectal cancer.* JAMA Oncol. 3:464-471, 2017. PMID: 27978560.
322. Renfro LA, **Goldberg RM**, Grothey A, Sobrero A, Adams R, Seymour MT, Heinemann V, Schmoll HJ, Douillard JY, Hurwitz H, Fuchs CS, Diaz-Rubio E, Porschen R, Tournigand C,

- Chibaudel B, Hoff PM, Kabbinavar FF, Falcone A, Tebbutt NC, Punt CJA, Hecht JR, Souglakos J, Bokemeyer C, Van Cutsem E, Saltz L, de Gramont A, Sargent DJ; ARCAD Clinical Trials Program. *Clinical Calculator for Early Mortality in Metastatic Colorectal Cancer: An Analysis Of Patients From 28 Clinical Trials In the Aide et Recherche en Cancérologie Digestive Database*. J Clin Oncol. 35: 1929-37, 2017. [Epub ahead of print]. PMID: 28414610.
323. Venook AP, Niedzwiecki D, Lenz HJ, Fruth B, Meyerhardt JA, Schrag D, Greene C, O'Neil BH, Atkins JN, Berry S, O'Reilly EM, **Goldberg RM**, Hochster HS, Schilsky RL, Bertagnolli MM, El Khoueiry AB, Watson P, Benson AB 3rd, Mulkerin DL, Mayer RJ, Blancke C. *Effect of first-line chemotherapy combined with cetuximab or bevacizumab on overall survival in patients with KRAS wild-type advanced or metastatic colorectal cancer: a randomized clinical trial*. JAMA. 317: 2392-2401, 2017. PMID 28632865.
324. Ahn DH, Wu C, Wei L, Williams TM, Wuthrick E, Abdel-Misih S, Harzman A, Husain S, Schmidt C, **Goldberg RM**, Bekaii-Saab T. *The Efficacy of Adjuvant Chemotherapy in Patients with Stage II/III Resected Rectal Cancer Treated with Neoadjuvant Chemoradiation Therapy*. Am J Clin Oncol. 40: 531-34, 2017 [Epub ahead of print]. PMID: 25723741.
325. Haraldsdottir S, Rafnar T, Frankel WL, Einarsdottir S, Sigurdsson A, Hampel H, Snaebjornsson P, Masson G, Weng D, Arngrimsson R, Kehr B, Yilmaz A, Haraldsson S, Sulem P, Stefansson T, Shields PG, Sigurdsson F, Bekaii-Saab T, Moller PH, Steinarsdottir M, Alexiusdottir K, Hitchins M, Pritchard CC, de la Chapelle A, Jonasson JG, **Goldberg RM**, Stefansson K. *Comprehensive Population-wide analysis of Lynch Syndrome in Iceland reveals founder mutations in MSH6 and PMS2*. Nat Commun. 8:14755, 2017. PMID: 28466842.
326. **Goldberg RM**, Weil L, Fernandez S. *The evolution of clinical trials in oncology: defining who benefits from new drugs using innovative study designs*. Oncologist. 22: 1015-19, 2017. [Epub ahead of print]. PMID: 28620092.
327. Le DT, Durham JN, Smith KN, Wang H, Bartlett BR, Aulakh LK, Lu S, Kemberling H, Wilt C, Luber BS, Wong F, Azad NS, Rucki AA, Laheru D, Donehower R, Zaheer A, Fisher GA, Crocenzi TS, Lee JJ, Greten TF, Duffy AG, Ciombor KK, Eyring AD, Lam BH, Joe A, Kang SP, Holdhoff M, Danilova L, Cope L, Meyer C, Zhou S, **Goldberg RM**, Armstrong DK, Bever KM, Fader AN, Taube J, Housseau F, Spetzler D, Xiao N, Pardoll DM, Papadopoulos N, Kinzler KW, Eshleman JR, Vogelstein B, Anders RA, Diaz LA Jr. *Mismatch-repair deficiency predicts response of solid tumors to PD-1 blockade*. Science 357: 409-413, 2017. [Epub ahead of print]. PMID: 28596308.
328. Wing MR, Reeser JW, Smith AM, Reeder M, Martin D, Jewell BM, Datta J, Miya J, Monk JP, Mortazavi A, Otterson GA, **Goldberg RM**, VanDeusen JB, Cole S, Dittmar K, Jaiswal S, Kinzie M, Waikhom S, Freud AG, Zhou XP, Chen W, Bhatt D, Roychowdhury S. *Analytic validation and real-time clinical application of an amplicon-based targeted gene panel for advanced cancer*. Oncotarget 8: 75822-75833, 2017. [Epub ahead of print]. PMID:29100271.
329. Zaanan A, Shi Q, Taieb J, Alberts SR, Meyers JP, Smyrk TC, Julie C, Zawadi A, Tabernero J, Mini E, **Goldberg RM**, Folprecht G, Van Laethem JL, Le Malicot K, Sargent DJ, Laurent-Puig P, Sinicrope FA. *Role of Deficient DNA Mismatch Repair Status in Patients With Stage III Colon Cancer Treated With FOLFOX Adjuvant Chemotherapy: A Pooled Analysis From 2 Randomized Clinical Trials*. JAMA Oncol. 4: 379-83, 2018 [Epub ahead of print]. PMID:28983557.
330. Le DT, Hubbard-Lucey VM, Morse MA, Heery CR, Dwyer A, Marsilje TH, Brodsky AN, Chan E, Deming DA, Diaz LA Jr, Fridman WH, **Goldberg RM**, Hamilton SR, Housseau F, Jaffee EM, Kang SP, Krishnamurthi SS, Lieu CH, Messersmith W, Sears CL, Segal NH, Yang A, Moss RA, Cha E, O'Donnell-Tormey J, Roach N, Davis AQ, McAbee K, Worrall S, Benson AB. *A Blueprint*

to Advance Colorectal Cancer Immunotherapies. Cancer Immunol Res. 5: 942-949; 2017. [Epub ahead of print]. PMID: 29038296.

331. Fuchs CS, Niedzwiecki D, Mamon HJ, Tepper JE, Ye X, Swanson RS, Enzinger PC, Haller DG, Dragovich T, Alberts SR, Bjarnason GA, Willett CG, Gunderson LL, **Goldberg RM**, Venook AP, Ilson D, O'Reilly E, Ciombor K, Berg DJ, Meyerhardt J, Mayer RJ. *Adjuvant Chemoradiotherapy With Epirubicin, Cisplatin, and Fluorouracil Compared With Adjuvant Chemoradiotherapy With Fluorouracil and Leucovorin After Curative Resection of Gastric Cancer: Results From CALGB 80101 (Alliance)*. J Clin Oncol. 35:3671-3677; 2017. [Epub ahead of print]. PMID:28976791.
332. Dotan E, Cohen SJ, Starodub AN, Lieu CH, Messersmith WA, Simpson PS, Guarino MJ, Marshall JL, **Goldberg RM**, Hecht JR, Wegener WA, Sharkey RM, Govindan SV, Goldenberg DM, Berlin JD. *Phase I/II Trial of Labetuzumab Govitecan (Anti-CEACAM5/SN-38 Antibody-Drug Conjugate) in Patients With Refractory or Relapsing Metastatic Colorectal Cancer*. 35:3338-3346; 2017. Epub 2017 Aug 17. PMID: 28817371.
333. Sjoquist KM, Renfro LA, Simes RJ, Tebbutt NC, Clarke S, Seymour MT, Adams R, Maughan TS, Saltz L, **Goldberg RM**, Schmoll HJ, Van Cutsem E, Douillard JY, Hoff PM, Hecht JR, Tournigand C, Punt CJA, Koopman M, Hurwitz H, Heinemann V, Falcone A, Porschen R, Fuchs C, Diaz-Rubio E, Aranda E, Bokemeyer C, Souglakos I, Kabbinavar FF, Chibaudel B, Meyers JP, Sargent DJ, de Gramont A, Zalcberg JR; Fondation Aide et Recherche en Cancerologie Digestive Group. *Personalizing Survival Predictions in Advanced Colorectal Cancer: The ARCAD Nomogram Project*. J Natl Cancer Inst. 110: 638-648, 2018, [Epub ahead of print]. PMID: 29267900.
334. Ciombor KK, **Goldberg R**; *Hypermutated Tumors and Immune Checkpoint Inhibition*. Drugs; 78:155-162, 2018. [Epub ahead of print] PMID: 29350327.
335. Salem ME, Puccini A, Grothey A, Raghavan D, **Goldberg RM**, Xiu J, Korn WM, Weiberg BA, Hwang JJ, Shields AF, Marshall JL, Phillip PA, Lenz HJ. *Landscape of Tumor Mutation Load, Mismatch Repair Deficiency, and PD-L1 Expression in a Large Patient Cohort of Gastrointestinal Cancers*. Mol Cancer Res 16: 805-812, 2018. [Epub ahead of print]. PMID: 29523759.
336. Phipps AI, Shi Q, Zemla TJ, Dotan E, Gill S, **Goldberg RM**, Hardikar S, Jahagirdar B, Limburg PJ, Newcomb PA, Shields A, Sinicrope FA, Sargent DJ, Alberts SR. *Physical Activity and Outcomes in Patients with Stage III Colon Cancer: A Correlative Analysis of Phase III Trial NCCTG N0147 (Alliance)*. Cancer Epidemiol Biomarkers Prev. 27: 696-703, 2018. [Epub ahead of print]. PMID: 29563133.
337. Hampel H, Pearlman R, Beightol M, Zhao W, Jones D, Frankel WL, Goodfellow PJ, Yilmaz A, Miller K, Bacher J, Jacobson A, Paskett E, Shields PG, **Goldberg RM**, de la Chapelle A, Shirts BH, Pritchard CC; Ohio Colorectal Cancer Prevention Initiative Study Group. *Assessment of Tumor Sequencing as a Replacement for Lynch Syndrome Screening and Current Molecular Tests for Patients With Colorectal Cancer*. JAMA Oncol. 4: 806-813, 2018. PMID: 29596542.
338. Das S, Ciombor KK, Haraldsdottir S, **Goldberg RM**. *Promising New Agents for Colorectal Cancer*. Curr Treat Options Oncol. 2018 May 11;19(6):29. doi: 10.1007/s11864-018-0543-z. Review. PMID: 29752549.
339. **Goldberg RM**, Montagut C, Wainberg ZA, Ronga P, Audhuy F, Taieb J, Stintzing S, Siena S, Santini D. *Optimising the use of cetuximab in the continuum of care for patients with metastatic colorectal cancer*. ESMO Open. 2018 May 5:e000353. doi: 10.1136/esmoopen-2018-000353. eCollection 2018. Review. PMID: 29765773.
340. Salem ME, Puccini A, Xiu J, Raghavan D, Lenz HJ, Korn WM, Shields AF, Philip PA, Marshall JL, **Goldberg RM**. *Comparative Molecular Analyses of Esophageal Squamous Cell Carcinoma,*

Esophageal Adenocarcinoma, and Gastric Adenocarcinoma. Oncologist. 23: 1319-1327, 2018. [Epub ahead of print] PMID:29866946.

341. Sanoff HK, **Goldberg RM**, Ivanova A, O'Reilly S, Kasbari SS, Kim RD, McDermott R, Moore DT, Zamboni W, Grogan W, Cohn AL, Bekaii-Saab TS, Leonard G, Ryan T, Olowokure OO, Fernando NH, McCaffrey J, El-Rayes BF, Horgan AM, Sherrill GB, Yacoub GH, O'Neil BH. *Multicenter, randomized, double-blind phase 2 trial of FOLFIRI with regorafenib or placebo as second-line therapy for metastatic colorectal cancer.* Cancer. 124: 3118-3126, 2018. doi: 10.1002/cncr.31552. [Epub ahead of print]. PMID: 29905927.
342. Puccini A, Lenz HJ, Marshall JL, Arguello D, Raghavan D, Korn WM, Weinberg BA, Poorman K, Heeke AL, Philip PA, Shields AF, **Goldberg RM**, Salem ME. *Impact of Patient Age on Molecular Alterations of Left-Sided Colorectal Tumors.* Oncologist. 24: 319-326, 2019. [Epub ahead of print] PMID: 30018131.
343. Innocenti F, Ou FS, Qu X, Zemla TJ, Niedzviecki D, Tam R, Mahajan S, **Goldberg RM**, Bertagnolli MM, Blanke CD, Sanoff H, Atkins J, Polite B, Venook AP, Lenz HJ, Kabbarah O. *Mutational Analysis of Patients with Colorectal Cancer in CALGB/SWOG 80405 Identifies New Roles of Microsatellite Instability and Tumor Mutational Burden for Patient Outcome.* J Clin Oncol. 37: 1217-1227, 2019. [Epub ahead of print]. PMID: 30865548.
344. Tokunaga R, Xiu J, Johnston C, **Goldberg RM**, Philip PA, Seeber A, Naseem M, Lo JH, Arai H, Battaglin F, Puccini A, Berger MD, Soni S, Zhang W, Hwang JJ, Shields AF, Marshall JL, Baba H, Kom WM, Lenz HJ. *Molecular Profiling of Appendiceal Adenocarcinoma and Comparisons with Right-sided and Left-sided Colorectal Cancer.* Clin Cancer Res. 25: 3096-3103, 2019. [Epub ahead of print]. PMID 30692096.
345. Lenz HJ, Ou FS, Venook AP, Hochster HS, Niedzwiecki D, **Goldberg RM**, Mayer RJ, Bertagnolli MM, Blanke CD, Zemla T, Qu X, Wirapati P, Tejpar S, Innocenti F, Kabbarah O. *Impact of Consensus Molecular Subtype on Survival in Patients With Metastatic Colorectal Cancer: Results From CALGB/SWOG 80405 (Alliance).* J Clin Oncol. 237: 1876-85, 2019. [Epub ahead of print]. PMID: 31042420.
346. Yuan C, Renfro L, Ambadwar PB, Ou FS, McLeod HR, Innocenti F, Meyerhardt JA, Wolpin BM, **Goldberg RM**, Grothey A, Fuchs CS, Ng K. *Influence of genetic variation in the vitamin D pathway on plasma 25-hydroxyvitamin D3 levels and survival among patients with metastatic colorectal cancer.* Cancer Causes Control. 30: 757-65, 2019. [Epub ahead of print]. PMID: 31104167.
347. El-Deiry WS, **Goldberg RM**, Lenz HS, Shields AF, Gibney GT, Tan AR, Brown J, Eisenberg B, Heath EL, Phuphanich S, Kim E, Brenner AJ, Marshall JL. *The current state of molecular testing in the treatment of patients with solid tumors.* Ca Cancer J Clin. 69: 305-43, 2019. [Epub ahead of print]. PMID: 31104167.
348. Alliance Cancer in the Older Adult Committee, Adjei A, Buckner JC, Cathcart-Rake E, Chen H, Cohen HJ, Dao D, De Luca JE, Feliciano J, Freedman RA, **Goldberg RM**, Hopkins J, Hubbard J, Jatoi A, Karuturi M, Kemeny M, Kimmick GG, Klepin HD, Krok-Schoen JL, Lafky JM, Le-Rademacher JG, Li D, Lichtman SM, Maggiore R, Mandelblatt J, Morrison VA, Muss HB, Ojelabi MO, Sedrak MS, Subbiah N, Sun V, Tuttle S, VanderWalde N, Wildes T, Wong ML, Woyach J. *Arti Hurria, M.D.: A tribute to her shining legacy in the Alliance for Clinical Trials in Oncology.* J Geriatr Oncol. 2019 Jun 11. pii: S1879-4068(19)30158-4. doi: 10.1016/j.jgo.2019.05.011. [Epub ahead of print]. PMID:31201095
349. Guercio BJ, Zhang S, Ou FS, Venook AP, Niedzwiecki D, Lenz HJ, Innocenti F, O'Neil BH, Shaw JE, Polite BN, Hochster HS, Atkins JN, **Goldberg RM**, Sato K, Ng K, Van Blarigan E,

Mayer RJ, Blanke CD, O'Reilly EM, Fuchs CS, Meyerhardt JA. *Associations of Physical Activity with Survival and Progression in Metastatic Colorectal Cancer: Results From Cancer and Leukemia Group B (Alliance)/SWOG 80405*. J Clin Oncol. 37: 2620-31, 2019. [Epub ahead of print] PMID:31408415.

350. Abou-Alfa GK, Shi Q, Knox JJ, Kaubisch A, Niedzwiecki D, Posey J, Tan BR Jr, Kavan P, Goel R, Lammers PE, Bekaii-Saab TS, Tam VC, Rajdev L, Kelley RK, El Dika I, Zemla T, Potaracke RI, Balletti J, El-Khoueiry AB, Harding JH, Suga JM, Schwartz LH, **Goldberg RM**, Bertagnolli MM, Meyerhardt J, O'Reilly EM, Venook AP. *Assessment of Treatment With Sorafenib Plus Doxorubicin vs Sorafenib Alone in Patients With Advanced Hepatocellular Carcinoma: Phase 3 CALGB 80802 Randomized Clinical Trial*. JAMA Oncol. 2019 Sep 5. doi: 10.1001/jamaoncol.2019.2792. [Epub ahead of print] PMID: 31486832
351. Burzykowski T, Coart E, Saad ED, Shi Q, Sommeijer DW, Bokemeyer C, Díaz-Rubio E, Douillard JY, Falcone A, Fuchs CS, **Goldberg RM**, Hecht JR, Hoff PM, Hurwitz H, Kabbinavar FF, Koopman M, Maughan TS, Punt CJA, Saltz L, Schmoll HJ, Seymour MT, Tebbutt NC, Tournigand C, Van Cutsem E, de Gramont A, Zalcberg JR, Buyse M; Aide et Recherche en Cancerologie Digestive Group. *Evaluation of Continuous Tumor-Size-Based End Points as Surrogates for Overall Survival in Randomized Clinical Trials in Metastatic Colorectal Cancer*. JAMA Netw Open. 2019 Sep 4;2(9): e1911750. doi: 10.1001/jamanetworkopen.2019.11750. PMID:31539075
352. Yuan C, Sato K, Hollis BW, Zhang S, Niedzwiecki D, Ou FS, Chang IW, O'Neil BH, Innocenti F, Lenz HJ, Blanke CD, **Goldberg RM**, Venook AP, Mayer RJ, Fuchs CS, Meyerhardt JA, Ng K. Clin Cancer Res. *Plasma 25-Hydroxyvitamin D Levels and Survival in Patients with Advanced or Metastatic Colorectal Cancer: Findings from CALGB/SWOG 80405 (Alliance)*. Clin Cancer Res. 25:7497-7505, 2019. [Epub ahead of print] PMID:31548349
353. Penney KL, Banbury BL, Bien S, Harrison TA, Hua X, Phipps AI, Sun W, Song M, Joshi AD, Alberts SR, Allegra CJ, Atkins J, Colangelo LH, George TJ, **Goldberg RM**, Lucas PC, Nair SG, Shi Q, Sinicrope FA, Wolmark N, Yothers G, Peters U, Newcomb PA, Chan AT. *Genetic Variant Associated with Survival of Patients with Stage II-III Colon Cancer*. Clin Gastroenterol Hepatol. 2019 Dec 4. pii: S1542-3565(19)31386-2. doi: 10.1016/j.cgh.2019.11.046. [Epub ahead of print]. PMID:31811950
354. Salem ME, Battaglin F, **Goldberg RM**, Puccini A, Shields AF, Arguello D, Korn WM, Marshall JL, Grothey A, Lenz HJ. *Molecular Analyses of Left- and Right-Sided Tumors in Adolescents and Young Adults with Colorectal Cancer*. Oncologist. 2019 Dec 17. pii: the oncologist.2019-0552. doi: 10.1634/theoncologist.2019-0552. [Epub ahead of print], PMID:31848314
355. Salem ME, Yin J, **Goldberg RM**, Pederson LD, Wolmark N, Alberts SR, Taieb J, Marshall JL, Lonardi S, Yoshino T, Kerr RS, Yothers G, Grothey A, Andre T, De Gramont A, Shi Q. *Evaluation of the change of outcomes over a 10-year period in patients with stage III colon cancer: pooled analysis of 6501 patients treated with fluorouracil, leucovorin, and oxaliplatin in the ACCENT database*. Ann Oncol. 31:480-486, 2020. Epub 2020 Jan 16. PMID: 32085892
356. Cohen R, Vernerey D, Bellera C, Meurisse A, Henriques J, Paoletti X, Rousseau B, Alberts S, Aparicio T, Boukovinas I, Gill S, **Goldberg RM**, Grothey A, Hamaguchi T, Iveson T, Kerr R, Labianca R, Lonardi S, Meyerhardt J, Paul J, Punt CJA, Saltz L, Saunders MP, Schmoll HJ, Shah M, Sobrero A, Souglakos I, Taieb J, Takashima A, Wagner AD, Ychou M, Bonnetain F, Gourgou S, Yoshino T, Yothers G, de Gramont A, Shi Q, André T; ACCENT Group. *Guidelines for time-to-event end-point definitions in adjuvant randomised trials for patients with localised colon cancer: Results of the DATECAN initiative*. Eur J Cancer. 2020 Mar 12;130:63-71. doi: 10.1016/j.ejca.2020.02.009. [Epub ahead of print]. PMID: 32172199

357. Brown JC, Zhang S, Ou FS, Venook AP, Niedzwiecki D, Lenz HJ, Innocenti F, O'Neil BH, Shaw JE, Polite BN, Denlinger CS, Atkins JN, **Goldberg RM**, Ng K, Mayer RJ, Blanke CD, O'Reilly EM, Fuchs CS, Meyerhardt JA. *Diabetes and clinical outcome in patients with metastatic colorectal cancer: CALGB 80405 (Alliance)*. JNCI Cancer Spectr. 2019 Oct 17;4(1):pkz078. doi: 10.1093/jncics/pkz078. eCollection 2020 Feb. PMID: 32259016
358. Zimmer K, Puccini A, Xiu J, Baca Y, Spizzo G, Lenz HJ, Battaglin F, **Goldberg RM**, Grothey A, Shields AF, Salem ME, Marshall JL, Korn WM, Wolf D, Kocher F, Seeber A. *WRN-Mutated Colorectal Cancer Is Characterized by a Distinct Genetic Phenotype*. Cancers (Basel). 2020;12(5):E1319. Published 2020 May 22. doi:10.3390/cancers12051319
359. Sinicrope FA, Shi Q, Hermitte F, Zemla TJ, Mlecnik B, Benson AB, Gill S, **Goldberg RM**, Kahlenberg MS, Nair SG, Shields AF, Smyrk TC, Galon J, Alberts SR. *Contribution of Immunoscore and Molecular Features to Survival Prediction in Stage III Colon Cancer*. JNCI Cancer Spectr. 2020;4(3): pkaa023. Published 2020 Apr 5. doi:10.1093/jncics/pkaa023
360. Spizzo G, Puccini A, Xiu J, **Goldberg RM**, Grothey A, Shields AF, Arora SP, Khushmann M, Salem ME, Battaglin F, Baca Y, El-Deiry WS, Philip PA, Nasseem M, Hall M, Marshall JL, Kocher F, Amann A, Wolf D, Korn WM, Lenz H, Seeber A. *WRN-Mutated Colorectal Cancer Is Characterized by a Distinct Genetic Phenotype*. ESMO Open. 2020 Jun;5(3):e000682. doi: 10.1136/esmoopen-2020-000682. PMID: 32576609.
361. Zimmer K, Puccini A, Xiu J, Baca Y, Spizzo G, Lenz HJ, Battaglin F, **Goldberg RM**, Grothey A, Shields AF, Salem ME, Marshall JL, Korn WM, Wolf D, Kocher F, Seeber A. *WRN-Mutated Colorectal Cancer Is Characterized by a Distinct Genetic Phenotype*. Cancers (Basel). 2020 May 22;12(5):1319. doi: 10.3390/cancers12051319. PMID: 32455893.
362. Washington MK, **Goldberg RM**, Chang GJ, Limburg P, Lam AK, Salto-Tellez M, Arends MJ, Nagtegaal ID, Klimstra DS, Rugge M, Schirmacher P, Lazar AJ, Odze RD, Carneiro F, Fukayama M, Cree IA; *WHO Classification of Tumours Editorial Board. Diagnosis of Digestive System Tumours*. Int J Cancer. 2020 Jul 16. doi: 10.1002/ijc.33210. Online ahead of print. PMID: 32674220.
363. Liu Y, Lyu J, Bell Burdett K, Sibley AB, Hatch AJ, Starr MD, Brady JC, Hammond K, Marmorino F, Rossini D, **Goldberg RM**, Falcone A, Cremolini C, Owzar K, Ivanova A, Moore DT, Lee MS, Sanoff HK, Innocenti F, Nixon AB. *Prognostic and Predictive Biomarkers in Metastatic Colorectal Cancer Patients Receiving Regorafenib* [published online ahead of print, 2020 Aug 3]. Mol Cancer Ther. 19:2146-2154, 2020. PMID: 32747417
364. Puccini A, Poorman K, Salem ME, Soldato D, Seeber A, **Goldberg RM**, An Shields AF, Xiu J, Battaglin F, Berger MD, Tokunaga R, Naseem, Barzi A, Iqbal, Zhang W, Soni S, Hwang JJ, Philip PA, Sciallero S, Korn WM, Marshall JL, Lenz H-J. *Comprehensive genomic profiling of gastroenteropancreatic neuroendocrine neoplasms (GEP-NENs)* [published online ahead of print, 2020 Sep 3]. Clin Cancer Res. 2020;clincanres.1804.2020. doi:10.1158/1078-0432.CCR-20-1804. PMID: 32883742
365. Wagner AD, Grothey A, Andre T, Dixon JG, Wolmark N, Haller DG, Allegra CJ, de Gramont A, VanCutsem E, Alberts SR, George TJ, O'Connell MJ, Twelves C, Taieb J, Saltz LB, Blanke CD, Francini E, Kerr R, Yothers G, Seitz JF, Marsoni S, **Goldberg RM**, Shi Q. *Sex and adverse events of adjuvant chemotherapy in colon cancer: an analysis of 34,640 patients in the ACCENT database*. J Natl Cancer Inst. 2020 Aug 24:djaa124. doi: 10.1093/jnci/djaa124. Online ahead of print. PMID: 32835356
366. Mackintosh C, Yuan C, Ou FS, Zhang S, Niedzwiecki D, Chang IW, O'Neil BH, Mullen BC, Lenz HJ, Blanke CD, Venook AP, Mayer RJ, Fuchs CS, Innocenti F, Nixon AB, **Goldberg RM**,

- O'Reilly EM, Meyerhardt JA, Ng K. Association of coffee intake with survival in patients with advanced or metastatic colorectal cancer. *JAMA Oncol.* 2020 Sep 17. doi: 10.1001/jamaoncol.2020.3938. Online ahead of print. PMID: 32940631
367. Zaanen A, Shi Q, Taieb J, Alberts SR, Meyers JP, Smyrk TC, Julie C, Zawadi A, Tabernero J, Mini E, **Goldberg RM**, Folprecht G, Van Laethem JL, Le Malicot K, Sargent DJ, Laurent-Puig P, Sinicrope FA. *Clinical outcomes in patients with colon cancer with microsatellite instability of sporadic or familial origin treated with adjuvant FOLFOX with or without cetuximab: a pooled analysis of the PETACC8 and N0147 trials.* *JCO Precis Oncol.* 2020 Feb 26;4:PO.19.00237. doi: 10.1200/PO.19.00237. eCollection 2020. PMID: 32923882
 368. Lopes GS, Tournigand C, Olswold CL, Cohen R, Kempf E, Saltz L, **Goldberg RM**, Hurwitz H, Fuchs C, de Gramont A, Shi Q. *Adverse event load, onset, and maximum grade: A novel method of reporting adverse events in cancer clinical trials.* *Clin Trials.* 2020 Oct 1;1740774520959313. doi: 10.1177/1740774520959313. Online ahead of print. PMID: 32998522 [Molecular characterization of appendiceal goblet cell carcinoid.](#)
 369. Arai H, Baca Y, Battaglin F, Kawanishi N, Wang J, Soni S, Zhang W, Millstein J, Johnston C, **Goldberg RM**, Philip PA, Seeber A, Xiu J, Hwang JJ, Shields AF, Marshall JL, Korn WM, Lenz HJ. *Molecular characterization of goblet cell appendiceal carcinoids.* *Mol Cancer Ther.* 2020 Oct 9;molcanther.0318.2020. doi: 10.1158/1535-7163.MCT-20-0318. Online ahead of print. PMID: 33037134
 370. Seeber A, Zimmer K, Kocher F, Puccini A, Xiu J, Nabhan C, Elliott A, **Goldberg RM**, Grothey A, Shields AF, Battaglin F, El-Deiry WS, Philip PA, Marshall JL, Hall M, Korn WM, Lenz HJ, Wolf D, Feistritz C, Spizzo G. *Molecular characteristics of BRCA1/2 and PALB2 mutations in pancreatic ductal adenocarcinoma.* *ESMO Open.* 2020 Nov;5(6):e000942. doi: 10.1136/esmoopen-2020-000942. PMID: 33229504.
 371. Labadie JD, Hua X, Harrison TA, Banbury BL, Huyghe JR, Sun W, Shi Q, Yothers G, Alberts SR, Sinicrope FA, **Goldberg RM**, George TJ, Penney KL, Phipps AI, Cohen SA, Peters U, Chan AT, Newcomb PA. *Genetic predictors of severe skin toxicity in stage III colon cancer patients treated with cetuximab: NCCTG N0147 (Alliance).* *Cancer Epidemiol Biomarkers Prev.* 2020 Nov 17;cebp.1274.2020. doi: 10.1158/1055-9965.EPI-20-1274. Online ahead of print. PMID: 33203692
 372. Van Blarigan EL, Zhang S, Ou FS, Venlo A, Ng K, Atreya C, Van Loon K, Niedzwiecki D, Giovannucci E, Wolfe EG, Lenz HJ, Innocenti F, O'Neil BH, Shaw JE, Polite BN, Hochster HS, Atkins JN, **Goldberg RM**, Mayer RJ, Blanke CD, O'Reilly EM, Fuchs CS, Meyerhardt JA. *Association of Diet Quality With Survival Among People With Metastatic Colorectal Cancer in the Cancer and Leukemia B and Southwest Oncology Group 80405 Trial.* *JAMA Netw Open.* 2020 Oct 1;3(10):e2023500. doi: 10.1001/jamanetworkopen.2020.23500. PMID: 33125497
 373. Guercio BJ, Zhang S, Venook AP, Ou FS, Niedzwiecki D, Lenz HJ, Innocenti F, Mullen BC, O'Neil BH, Shaw JE, Polite BN, Hochster HS, Atkins JN, **Goldberg RM**, Brown JC, O'Reilly EM, Mayer RJ, Blanke CD, Fuchs CS, Meyerhardt JA. *Body Mass Index and Weight Loss in Metastatic Colorectal Cancer in CALGB (Alliance)/SWOG 80405.* *JNCI Cancer Spectr.* 2020 Mar 31;4(3):pkaa024. doi: 10.1093/jncics/pkaa024. eCollection 2020 Jun. PMID: 33134818
 374. Tokunaga R, Xiu J, **Goldberg RM**, Philip PA, Seeber A, Battaglin F, Arai H, Lo JH, Naseem M, Puccini A, Berger MD, Soni S, Zhang W, Chen S, Hwang JJ, Shields AF, Marshall JL, Baba H, Korn WM, Lenz HJ. *The impact of ARID1A mutation on molecular characteristics in colorectal cancer.* *Eur J Cancer.* 2020 Nov;140:119-129. doi: 10.1016/j.ejca.2020.09.006. Epub 2020 Oct 17. PMID: 33080474.

375. Seeber A, Zimmer K, Kocher F, Puccini A, Xiu J, Nabhan C, Elliott A, **Goldberg RM**, Grothey A, Shields AF, Battaglin F, El-Deiry WS, Philip PA, Marshall JL, Hall M, Korn WM, Lenz HJ, Wolf D, Feistritz C, Spizzo G. *Molecular characteristics of BRCA1/2 and PALB2 mutations in pancreatic ductal adenocarcinoma*. ESMO Open. 2020 Nov;5(6):e000942. doi: 10.1136/esmoopen-2020-000942.PMID: 33229504
376. Labadie JD, Hua X, Harrison TA, Banbury BL, Huyghe JR, Sun W, Shi Q, Yothers G, Alberts SR, Sinicrope FA, **Goldberg RM**, George TJ, Penney KL, Phipps AI, Cohen SA, Peters U, Chan AT, Newcomb PA. *Genetic Predictors of Severe Skin Toxicity in Patients with Stage III Colon Cancer Treated with Cetuximab: NCCTG N0147 (Alliance)*. Cancer Epidemiol Biomarkers Prev. 2021 Feb;30(2):404-411. doi: 10.1158/1055-9965.EPI-20-1274. Epub 2020 Nov 17. PMID: 33203692; PMCID: PMC7909617.
377. Cohen R, Taieb J, Fiskum J, Yothers G, **Goldberg R**, Yoshino T, Alberts S, Allegra C, de Gramont A, Seitz JF, O'Connell M, Haller D, Wolmark N, Erlichman C, Zaniboni A, Lonardi S, Kerr R, Grothey A, Sinicrope FA, André T, Shi Q. *Microsatellite instability in patients with Stage III colon cancer receiving fluoropyrimidine with or without oxaliplatin: an ACCENT pooled analysis of 12 adjuvant trials*. J Clin Oncol. 2021 Feb 20;39(6):642-651. doi: 10.1200/JCO.20.01600. Epub 2020 Dec 23.PMID: 33356421.
378. Sinicrope FA, Chakrabarti S, Laurent-Puig P, Huebner L, Smyrk TC, Tabernero J, Mini E, **Goldberg RM**, Zaanen A, Folprecht G, Van Laethem JL, Le Malicot K, Shi Q, Alberts SR, Taieb J. *Prognostic variables in low and high-risk stage III colon cancers treated in two adjuvant chemotherapy trials*. Eur J Cancer. 2020 Dec 17;144:101-112. doi: 10.1016/j.ejca.2020.11.016. Online ahead of print. PMID: 33341444
379. Guercio BJ, Zhang S, Ou FS, Venook AP, Niedzwiecki D, Lenz HJ, Innocenti F, Pollak MN, Nixon AB, Mullen BC, O'Neil BH, Shaw JE, Polite BN, Benson AB 3rd, Atkins JN, **Goldberg RM**, Brown JC, O'Reilly EM, Mayer RJ, Blanke CD, Fuchs CS, Meyerhardt JA. *IGF-Binding Proteins, Adiponectin, and Survival in Metastatic Colorectal Cancer: Results from CALGB (Alliance)/SWOG 80405 JNCI Cancer Spectr*. 2020 Aug 27;5(1):pkaa074. doi:10.1093/jncics/pkaa074. eCollection 2021 Feb. PMID: 33426464.
380. Holcombe RF, Verschraegen CF, Chapman AE, Gaffney D, **Goldberg RM**, Mesa RA, Milhem M, Mims M, Mitchell EP, Mulkerin D, Vijayakumar S. *Status of the Clinician Investigator in America: An Essential Healthcare Provider Driving Advances in Cancer Care*. J Natl Compr Canc Netw. 2021 Feb 2;19(2):122-125. doi: 10.6004/jnccn.2020.7685. Print 2021 Feb.PMID: 33545684
381. Arai H, Elliott A, Xiu J, Wang J, Battaglin F, Kawanishi N, Soni S, Zhang W, Millstein J, Sohal D, **Goldberg RM**, Hall MJ, Scott AJ, Khushman M, Hwang JJ, Lou E, Weinberg BA, Marshall JL, Lockhart AC, Stafford P, Zhang J, Moretto R, Cremolini C, Korn WM, Lenz HJ. *The landscape of alterations in DNA damage response pathways in colorectal cancer*. Clin Cancer Res. 2021 Mar 25;3635.2020. doi: 10.1158/1078-0432.CCR-20-3635. Online ahead of print.PMID: 33766816
382. Meyerhardt JA, Shi Q, Fuchs CS, Meyer J, Niedzwiecki D, Zemla T, Kumthekar P, Guthrie KA, Couture F, Kuebler P, Bendell JC, Kumar P, Lewis D, Tan B, Bertagnolli M, Grothey A, Hochster HS, **Goldberg RM**, Venook A, Blanke C, O'Reilly EM, Shields AF. *Effect of Celecoxib vs Placebo Added to Standard Adjuvant Therapy on Disease-Free Survival Among Patients With Stage III Colon Cancer: The CALGB/SWOG 80702 (Alliance) Randomized Clinical Trial*. JAMA. 2021 Apr 6;325(13):1277-1286. doi: 10.1001/jama.2021.2454.PMID: 33821899
383. Lopes GS, Tournigand C, Olswold CL, Cohen R, Kempf E, Saltz L, **Goldberg RM**, Hurwitz H, Fuchs C, de Gramont A, Shi Q. *Adverse event load, onset, and maximum grade: A novel method*

of reporting adverse events in cancer clinical trials. Clin Trials. 2021 Feb;18(1):51-60. doi: 10.1177/1740774520959313. Epub 2020 Oct 1. PMID: 32998522.

384. Pearlman R, Frankel WL, Swanson BJ, Jones D, MD, Zhao W, Yilmaz A, Miller K, Bacher J, Bigley C, Nelsen L, Goodfellow, **Goldberg RM**, Paskett E, Shields PG, Freudenheim JL, Stanich PP, Lattimer I, Arnold M, Prior TW, PhD2,11; Haut M, Kalady MF, Heald B, Paquette I, Draper DJ, Brell JM, Mahesh S, Kisa Weeman K, Bastola S, Zangmeister J, Gowda A, Kencana F, Malcolm A, Liu Y, Cole S, Bane C, Li C, Rehms E, Pritchard CC, Brian H. Shirts BH, Angela Jacobson A, Cummings SA, de la Chapelle A, and Hampel H, on behalf of the Ohio Colorectal Cancer Prevention Initiative Study Group. *Prospective Statewide Study of Universal Screening for Hereditary Colorectal Cancer: The Ohio Colorectal Cancer Prevention Initiative*. JCO Precis Oncol 5:779-791, 2021.
385. Hua X, Dai JY, Lindström S, Harrison TA, Lin Y, Alberts SR, Alwers E, Berndt SI, Brenner H, Buchanan DD, Campbell PT, Casey G, Chang-Claude J, Gallinger S, Giles GG, **Goldberg RM**, Gunter MJ, Hoffmeister M, Jenkins MA, Joshi AD, Ma W, Milne RL, Murphy N, Pai RK, Sakoda LC, Schoen RE, Shi Q, Slattery ML, Song M, White E, Le Marchand L, Chan AT, Peters U, Newcomb PA. *Genetically Predicted Circulating C-Reactive Protein Concentration and Colorectal Cancer Survival: A Mendelian Randomization Consortium Study*. Cancer Epidemiol Biomarkers Prev. 2021 May 10;cebp.1848.2021. doi: 10.1158/1055-9965.EPI-20-1848. Epub ahead of print. PMID: 33972368.
386. Wang J, Xiu J, Baca Y, Battaglin F, Arai H, Kawanishi N, Soni S, Zhang W, Millstein J, Salhia B, **Goldberg RM**, Philip PA, Seeber A, Hwang JJ, Shields AF, Marshall JL, Astsaturov I, Craig Lockhart A, Gatalica Z, Michael Korn W, Lenz HJ. *Large-scale analysis of KMT2 mutations defines a distinctive molecular subset with treatment implication in gastric cancer*. Oncogene. 2021 Jun 23. doi: 10.1038/s41388-021-01840-3. Epub ahead of print. PMID: 34163031.
387. Jin Z, Dixon JG, Fiskum JM, Parekh HD, Sinicrope FA, Yothers G, Allegra CJ, Wolmark N, Haller D, Schmoll HJ, de Gramont A, Kerr R, Taieb J, Van Cutsem E, Tveit E, O'Connell M, Saltz LB, Sadahiro S, Blanke CD, Tomita N, Seitz JF, Erlichman C, Yoshino T, Yamanaka T, Marsoni S, Andre T, Mahipal A, **Goldberg RM**, George TJ, Shi Q. *Clinicopathological and Molecular Characteristics of Early-Onset Stage III Colon Adenocarcinoma: An Analysis of the ACCENT Database*. J Natl Cancer Inst. 021 Aug 18;113(12):1693-704. doi: 10.1093/jnci/djab123. Epub ahead of print. 2021 Aug 18. PMID: 34405233.
388. Sinicrope FA, Shi Q, Smyrk TC, **Goldberg RM**, Cohen SJ, Gill S, Kahlenberg MS, Nair S, Shield AF, Jahagirdar BN, Jacobson SB, Foster NR, Pollak MN, Alberts SR. *Association of Adiponectin and Vitamin D With Tumor Infiltrating Lymphocytes and Survival in Stage III Colon Cancer*. JNCI Cancer Spectr. 2021 Jul 23;5(5):pkab070. doi: 10.1093/jncics/pkab070. PMID: 34485815; PMCID: PMC84101
389. Puccini A, Seeber A, Xiu J, **Goldberg RM**, Soldato D, Grothey A, Shields AF, Salem ME, Battaglin F, Berger MD, El-Deiry WS, Tokunaga R, Naseem M, Zhang W, Arora SP, Khushman MM, Hall MJ, Philip PA, Marshall JL, Korn WM, Lenz HJ. *Molecular differences between lymph nodes and distant metastases compared with primaries in colorectal cancer patients*. NPJ Precis Oncol. 2021 Oct 27;5(1):95. doi: 10.1038/s41698-021-00230-y. PMID: 34707195
390. Arai H, Elliott A, Millstein J, Xiu J, Ou FS, Innocenti F, Wang J, Battaglin F, Jayachandran P, Kawanishi N, Soni S, Zhang W, Sohal D, **Goldberg RM**, Hall MJ, Scott AJ, Khushman M, Hwang JJ, Lou E, Weinberg BA, Lockhart AC, Shields AF, Abraham JP, Magee D, Stafford P, Zhang J, Venook AP, Korn WM, Lenz HJ. *Molecular characteristics and clinical outcomes of patients with Neurofibromin 1-altered metastatic colorectal cancer*. Oncogene. 41(2):260-267;2022 Epub ahead of print. Nov 2, 2021. doi: 10.1038/s41388-021-02074-z. PMID: 34728807.

391. Cerniglia M, Xiu J, Grothey A, Pishvaian MJ, Baca Y, Hwang JJ, Marshall JL, VanderWalde AM, Shields AF, Lenz HJ, Korn WM, Salem M, Philip PA, **Goldberg RM**, Zeng J, Kim SS. Association of Homologous Recombination-DNA Damage Response Gene Mutations with Immune Biomarkers in Gastroesophageal Cancers. *Mol Cancer Ther*. 21(1):227-236:2022. molcanther.0879.2020. doi: 10.1158/1535-7163.MCT-20-0879. Epub ahead of print. Nov 1: 2021PMID: 34725190.
392. **Goldberg RM**, Adams R, Buyse M, Eng C, Grothey A, André T, Sobrero AF, Lichtman SM, Benson AB, Punt CJA, Maughan T, Burzykowski T, Sommeijer D, Saad ED, Shi Q, Coart E, Chibaudel B, Koopman M, Schmoll HJ, Yoshino T, Taieb J, Tebbutt NC, Zalcberg J, Tabernero J, Van Cutsem E, Matheson A, de Gramont A. *Clinical Trial Endpoints in Metastatic Cancer: Using Individual Participant Data to Inform Future Trials Methodology*. *J Natl Cancer Inst*. 2021 Dec 4:djab218. doi: 10.1093/jnci/djab218. Epub ahead of print. PMID: 34865086.
393. Yin J, Dawood S, Cohen R, Meyers J, Zalcberg J, Yoshino T, Seymour M, Maughan T, Saltz L, Van Cutsem E, Venook A, Schmoll HJ, **Goldberg R**, Hoff P, Hecht JR, Hurwitz H, Punt C, Diaz Rubio E, Koopman M, Cremolini C, Heinemann V, Tournigard C, Bokemeyer C, Fuchs C, Tebbutt N, Souglakos J, Douillard JY, Kabbinarav F, Chibaudel B, de Gramont A, Shi Q, Grothey A, Adams R. *Impact of geography on prognostic outcomes of 21,509 patients with metastatic colorectal cancer enrolled in clinical trials: an ARCAD database analysis*. *Ther Adv Med Oncol*. 2021; 13:17588359211020547 Epub 2021 June 30 PMID: 34262614 PMCID: 8252342 DOI: 10.1177/17588359211020547
394. McCleary NJ, Zhang S, Ma C, Ou FS, Bainter TM, Venook AP, Niedzwiecki D, Lenz HJ, Innocenti F, O'Neil BH, Polite BN, Hochster HS, Atkins JN, **Goldberg RM**, Ng K, Mayer RJ, Blanke CD, O'Reilly EM, Fuchs CS, Meyerhardt JA. *Age and comorbidity association with survival outcomes in metastatic colorectal cancer: CALGB 80405 analysis*. *J Geriatr Oncol*. 2022 Jan 29:S1879-4068(22)00007-8. doi: 10.1016/j.jgo.2022.01.006. Epub ahead of print. PMID: 35105521.
395. Christou N, Bergen ES, Canton C, Le Malicot K, Di Bartolomeo M, Galli F, Galli F, Labianca R, Shi Q, Alberts SR, **Goldberg RM**, Lepage C, Sinicrope FA, Taieb J. *Impact of diabetes and metformin use on recurrence and outcome in stage II-III colon cancer patients-A pooled analysis of three adjuvant trials*. *Eur J Cancer*. 2022 Mar 10;166:100-111. doi: 10.1016/j.ejca.2022.02.005. Epub ahead of print. PMID: 35279470.
396. Seeber A, Battaglin F, Zimmer K, Kocher F, Baca Y, Xiu J, Spizzo G, Novotny-Diermayr V, Rieder D, Puccini A, Swensen J, Ellis M, **Goldberg RM**, Grothey A, Shields AF, Marshall JL, Weinberg BA, Sackstein PE, Lim KH, Tan GS, Nabhan C, Korn WM, Amann A, Trajanoski Z, Berger MD, Lou E, Wolf D, Lenz HJ. *Comprehensive Analysis of R-Spondin Fusions and RNF43 Mutations Implicate Novel Therapeutic Options in Colorectal Cancer*. *Clin Cancer Res*. 2022 May 2;28(9):1863-1870. doi: 10.1158/1078-0432.CCR-21-3018. PMID: 35254413; PMCID: PMC9064897.
397. McCleary NJ, Harmsen WS, Haakenstad E, Cleary JM, Meyerhardt JA, Zalcberg J, Adams R, Grothey A, Sobrero AF, Van Cutsem E, **Goldberg RM**, Peeters M, Tabernero J, Seymour M, Saltz LB, Giantonio BJ, Arnold D, Rothenberg ML, Koopman M, Schmoll HJ, Pitot HC, Hoff PM, Tebbutt N, Masi G, Souglakos J, Bokemeyer C, Heinemann V, Yoshino T, Chibaudel B, deGramont A, Shi Q, Lichtman SM. *Metastatic Colorectal Cancer Outcomes by Age Among ARCAD First- and Second-Line Clinical Trials*. *JNCI Cancer Spectr*. 2022 Mar 2;6(2):pkac014. doi: 10.1093/jncics/pkac014. PMID: 35603849; PMCID: PMC8935011.
398. Puccini A, Poorman K, Catalano F, Seeber A, **Goldberg RM**, Salem ME, Shields AF, Berger MD, Battaglin F, Tokunaga R, Naseem M, Zhang W, Philip PA, Marshall JL, Korn WM, Lenz HJ.

Molecular profiling of signet-ring-cell carcinoma (SRCC) from the stomach and colon reveals potential new therapeutic targets. Oncogene. 2022 Jun;41(26):3455-3460. doi: 10.1038/s41388-022-02350-6. Epub 2022 May 26. PMID: 35618879; PMCID: PMC9457205.

399. Sinicrope FA, Shi Q, Catteau A, Poage GM, Zemla TJ, Mlecnik B, Benson AB, Gill S, **Goldberg RM**, Kahlenberg MS, Nair SG, Shields AF, Smyrk TC, Galon J, Alberts SR. *Immunoscore Is Prognostic in Low-Risk and High-Risk Stage III Colon Carcinomas Treated with Adjuvant Infusional Fluorouracil, Leucovorin, and Oxaliplatin in a Phase III Trial.* JCO Precis Oncol. 2022 Aug;6:e2200010. doi: 10.1200/PO.22.00010. PMID: 35952316; PMCID: PMC9384943.
400. Park HA, Edelmann D, Canzian F, Harrison TA, Hua X, Shi Q, Silverman A, Schneider M, **Goldberg RM**, Alberts SR, Hoffmeister M, Brenner H, Chan AT, Peters U, Newcomb PA, Chang-Claude J. *Predictive polygenic score for outcome after first-line oxaliplatin-based chemotherapy in colorectal cancer patients using supervised principal component analysis.* Cancer Epidemiol Biomarkers Prev. 2022 Aug 19:EPI-22-0320. doi: 10.1158/1055-9965.EPI-22-0320. Epub ahead of print. PMID: 35984985.
401. Franko J, Yin J, Adams RA, Zalcborg J, Fiskum J, Van Cutsem E, **Goldberg RM**, Hurwitz H, Bokemeyer C, Kabbinavar F, Curtis A, Meyers J, Chibaudel B, Yoshino T, de Gramont A, Shi Q; ARCAD collaborators. *Trajectories of body weight change and survival among patients with mCRC treated with systemic therapy: Pooled analysis from the ARCAD database.* Eur J Cancer. 2022 Oct;174:142-152. doi: 10.1016/j.ejca.2022.07.021. Epub 2022 Aug 19. PMID: 35994794.
402. Kocher F, Puccini A, Untergasser G, Martowicz A, Zimmer K, Pircher A, Baca Y, Xiu J, Haybaeck J, Tymoszek P, **Goldberg RM**, Petrillo A, Shields AF, Salem ME, Marshall JL, Hall M, Korn WM, Nabhan C, Battaglin F, Lenz HJ, Lou E, Choo SP, Toh CK, Gasteiger S, Pichler R, Wolf D, Seeber A. *Multi-omic characterization of pancreatic ductal adenocarcinoma relates CXCR4 mRNA expression levels to potential clinical targets.* Clin Cancer Res. 2022 Sep 16:CCR-22-0275. doi: 10.1158/1078-0432.CCR-22-0275. Epub ahead of print. PMID: 36112544.
403. Malla M, Fuqua J, Mukherjee S, **Goldberg RM**. *Optimal First-Line Therapy for Metastatic Adenocarcinoma of the Esophagus.* Curr Treat Options Oncol. 2022 Oct 22:1–13. doi: 10.1007/s11864-022-01029-0. Epub ahead of print. PMID: 36272049; PMCID: PMC9589739.
404. Gallois C, Shi Q, Meyers JP, Iveson T, Alberts SR, de Gramont A, Sobrero AF, Haller DG, Oki E, Shields AF, **Goldberg RM**, Kerr R, Lonardi S, Yothers G, Kelly C, Boukovinas I, Labianca R, Sinicrope FA, Souglakos I, Yoshino T, Meyerhardt JA, André T, Papamichael D, Taieb J. *Prognostic Impact of Early Treatment and Oxaliplatin Discontinuation in Patients With Stage III Colon Cancer: An ACCENT/IDEA Pooled Analysis of 11 Adjuvant Trials.* J Clin Oncol. 2022 Oct 28;JCO2102726. doi: 10.1200/JCO.21.02726. Epub ahead of print. PMID: 36306483.
405. Lee S, Ma C, Shi Q, Kumar P, Couture F, Kuebler P, Krishnamurthi S, Lewis D, Tan B, **Goldberg RM**, Venook A, Blanke C, O'Reilly EM, Shields AF, Meyerhardt JA. *Potential Mediators of Oxaliplatin-Induced Peripheral Neuropathy from Adjuvant Therapy in Stage III Colon Cancer: Findings From CALGB (Alliance)/SWOG 80702.* J Clin Oncol. 2022 Nov 11;JCO2201637. doi: 10.1200/JCO.22.01637. Epub ahead of print. PMID: 36367997.
406. Argilés G, Mulet N, Valladares-Ayerbes M, Viéitez JM, Grávalos C, García-Alfonso P, Santos C, Tobeña M, García-Paredes B, Benavides M, Cano MT, Loupakis F, Rodríguez-Garrote M, Rivera F, **Goldberg RM**, Cremolini C, Bennouna J, Ciardiello F, Tabernero JM, Aranda E; Spanish Cooperative Group for the Treatment of Digestive Tumors (TTD) and UNICANCER GI; The, REARRANGE investigators; Principal investigator, Argilés G, Tabernero J; Steering Committee; Investigators. *A randomised phase 2 study comparing different dose approaches of induction treatment of regorafenib in previously treated metastatic colorectal cancer patients*

(REARRANGE trial). Eur J Cancer. 2022 Oct 14;177:154-163. doi: 10.1016/j.ejca.2022.09.037. Epub ahead of print. PMID: 36335783.

407. Malla M, Fekrmandi F, Malik N, Hatoum H, George S, **Goldberg RM**, Mukherjee S. *The evolving role of radiation in pancreatic cancer*. Front Oncol. 2023 Jan 11;12:1060885. doi: 10.3389/fonc.2022.1060885. PMID: 36713520; PMCID: PMC9875560.
408. Janczewski LM, Faski J, Nelson H, Gollub MJ, Eng C, Brierley JD, Palefsky JM, **Goldberg RM**, Washington MK, Asare EA, Goodman KA; American Joint Committee on Cancer Expert Panel on Cancers of the Lower Gastrointestinal, Anus Disease Site. *Survival outcomes used to generate version 9 American Joint Committee on Cancer staging system for anal cancer*. CA Cancer J Clin. 2023 Apr 28. doi: 10.3322/caac.21780. Epub ahead of print. PMID: 37114458.
409. Wang QL, Ma C, Yuan C, Shi Q, Wolpin BM, Zhang Y, Fuchs CS, Meyer J, Zemla T, Cheng E, Kumthekar P, Guthrie KA, Couture F, Kuebler P, Kumar P, Tan B, Krishnamurthi S, **Goldberg RM**, Venook A, Blanke C, Shields AF, O'Reilly EM, Meyerhardt JA, Ng K. *Plasma 25-hydroxyvitamin D levels and survival in stage III colon cancer: Findings from CALGB/SWOG 80702 (Alliance)*. Clin Cancer Res. 2023 May 11: CCR-23-0447. doi: 10.1158/1078-0432.CCR-23-0447. Epub ahead of print. PMID: 37166477.
410. McGarrah P, Hubbard J, Novotny PJ, Branda ME, Sargent DS, Morton RF, Fuchs CS, Benson AB, Williamson SK, Findlay BP, Alberts SR, **Goldberg RM**, Sloan JA. *Baseline Quality of Life is a Strong and Independent Prognostic Factor for Overall Survival in Metastatic Colorectal Cancer*. Cancer Control. 2023 Jan-Dec;30:10732748231185047. doi: 10.1177/10732748231185047. PMID: 37339926; PMCID: PMC10286175.
411. Park HA, Edelmann D, Canzian F, Seibold P, Harrison TA, Hua X, Shi Q, Silverman A, Benner A, Macaudo A, Schneider M, **Goldberg RM**, Alberts SR, Hoffmeister M, Brenner H, Chan AT, Peters U, Newcomb PA, Chang-Claude J. *Genome-wide study of genetic polymorphisms predictive for outcome from first-line oxaliplatin-based chemotherapy in colorectal cancer patients*. Int J Cancer. 2023 Aug 4. doi: 10.1002/ijc.34663. Epub ahead of print. PMID: 37539667.
412. Janczewski LM, Browner AE, Cotler JH, Nelson H, Kakar S, Carr NJ, Hanna NN, Holowatyj AN, **Goldberg RM**, Washington MK, Asare EA, Overman MJ; American Joint Committee on Cancer Expert Panel on Cancers for the Lower Gastrointestinal Appendix Disease Site. *Survival outcomes used to validate version 9 of the American Joint Committee on Cancer staging system for appendiceal cancer*. CA Cancer J Clin. 2023 Jun 26. doi: 10.3322/caac.21806. Epub ahead of print. PMID: 37358310.
413. Van Blarigan EL, Ma C, Ou FS, Bainter TM, Venook AP, Ng K, Niedzwiecki D, Giovannucci E, Lenz HJ, Polite BN, Hochster HS, **Goldberg RM**, Mayer RJ, Blanke CD, O'Reilly EM, Ciombor KK, Meyerhardt JA. *Dietary fat in relation to all-cause mortality and cancer progression and death among people with metastatic colorectal cancer: Data from CALGB 80405 (Alliance)/SWOG 80405*. Int J Cancer. 2023 Jan 15;152(2):123-136. doi: 10.1002/ijc.34230. Epub 2022 Aug 20. PMID: 35904874; PMCID: PMC9691576.
414. Brown JC, Ma C, Shi Q, Zemla T, Couture F, Kuebler P, Kumar P, Tan B, Krishnamurthi S, Chang V, **Goldberg RM**, Venook AP, Blanke CD, O'Reilly EM, Shields AF, Meyerhardt JA. *Physical activity in recurrent colon cancer: Cancer and Leukemia Group B/SWOG 80702 (Alliance)*. Cancer. 2023 Aug 31. doi: 10.1002/cncr.35007. Epub ahead of print. PMID: 37651160.
415. Ou FS, Ahn DH, Dixon JG, Grothey A, Lou Y, Kasi PM, Hubbard JM, Van Cutsem E, Saltz LB, Schmoll HJ, **Goldberg RM**, Venook AP, Hoff P, Douillard JY, Hecht JR, Hurwitz H, Punt CJA, Koopman M, Bokemeyer C, Fuchs CS, Diaz-Rubio E, Tebbutt NC, Cremolini C, Kabbinarar FF, Bekaii-Saab T, Chibaudel B, Yoshino T, Zalcborg J, Adams RA, de Gramont A, Shi Q.

Evaluation of Intratumoral Response Heterogeneity in Metastatic Colorectal Cancer and Its Impact on Patient Overall Survival: Findings from 10,551 Patients in the ARCAD Database. Cancers (Basel). 2023 Aug 15;15(16):4117. doi: 10.3390/cancers15164117. PMID: 37627145; PMCID: PMC10452983.

416. Brown JC, Ma C, Shi Q, Zemla T, Couture F, Kuebler P, Kumar P, Tan B, Krishnamurthi S, Chang V, **Goldberg RM**, Venook AP, Blanke CD, O'Reilly EM, Shields AF, Meyerhardt JA. *Physical activity in recurrent colon cancer: Cancer and Leukemia Group B/SWOG 80702 (Alliance).* Cancer. 2023 Dec 1;129(23):3724-3734. doi: 10.1002/cncr.35007. Epub 2023 Aug 31. PMID: 37651160.
417. Taieb J, Sinicrope FA, Pederson L, Lonardi S, Alberts SR, George TJ, Yothers G, Van Cutsem E, Saltz L, Ogino S, Kerr R, Yoshino T, **Goldberg RM**, André T, Laurent-Puig P, Shi Q. *Different prognostic values of KRAS exon 2 submutations and BRAF V600E mutation in microsatellite stable (MSS) and unstable (MSI) stage III colon cancer: an ACCENT/IDEA pooled analysis of seven trials.* Ann Oncol. 2023 Nov;34(11):1025-1034. doi: 10.1016/j.annonc.2023.08.006. Epub 2023 Aug 23. PMID: 37619846.
418. Gallois C, Shi Q, Meyers JP, Iveson T, Alberts SR, de Gramont A, Sobrero AF, Haller DG, Oki E, Shields AF, **Goldberg RM**, Kerr R, Lonardi S, Yothers G, Kelly C, Boukovinas I, Labianca R, Sinicrope FA, Souglakos I, Yoshino T, Meyerhardt JA, André T, Papamichael D, Taieb J. *Prognostic Impact of Early Treatment and Oxaliplatin Discontinuation in Patients With Stage III Colon Cancer: An ACCENT/IDEA Pooled Analysis of 11 Adjuvant Trials.* J Clin Oncol. 2023 Feb 1;41(4):803-815. doi: 10.1200/JCO.21.02726. Epub 2022 Oct 28. PMID: 36306483.
419. Janczewski LM, Browner A, Cotler J, Nelson H, Ballman KV, LeBlanc M, Gollub MJ, Eng C, Brierley JD, Palefsky JM, **Goldberg RM**, Goodman KA, Washington MK, Asare EA, Palis B. *Data-driven optimization of version 9 American Joint Committee on Cancer staging system for anal cancer.* Cancer. 2023 Dec 22. doi: 10.1002/cncr.35155. Epub ahead of print. PMID: 38140735.
420. Battaglin F, Baca Y, Millstein J, Yang Y, Xiu J, Arai H, Wang J, Ou FS, Innocenti F, Mumenthaler SM, Jayachandran P, Kawanishi N, Lenz A, Soni S, Algaze S, Zhang W, Khoukaz T, Roussos Torres E, Seeber A, Abraham JP, Lou E, Philip PA, Weinberg BA, Shields AF, **Goldberg RM**, Marshall JL, Venook AP, Korn WM, Lenz HJ. *CCR5 and CCL5 gene expression in colorectal cancer: comprehensive profiling and clinical value.* J Immunother Cancer. 2024 Jan 11;12(1):e007939. doi: 10.1136/jitc-2023-007939. PMID: 38212126.
421. Malla M, Kumar Deshmukh S, Wu S, Samec T, Olevian D, Naili R, Bassel ER, Xiu J, Farrell A, Lenz HJ, Lou E, Goel S, Spetzler D, **Goldberg RM**, Hazlehurst L. *Mesothelin expression correlates with elevated inhibitory immune activity in patients with colorectal cancer.* Res Sq [Preprint]. 2023 Dec 28;rs.3.rs-3787873. doi: 10.21203/rs.3.rs-3787873/v1. PMID: 38234761; PMCID: PMC10793489.
422. Arai H, Yang Y, Baca Y, Millstein J, Denda T, Ou FS, Innocenti F, Takeda H, Kubota Y, Doi A, Horie Y, Umemoto K, Izawa N, Wang J, Battaglin F, Jayachandran P, Algaze S, Soni S, Zhang W, **Goldberg RM**, Hall MJ, Scott AJ, Hwang JJ, Lou E, Weinberg BA, Marshall J, Goel S, Xiu J, Michael Korn W, Venook AP, Sunakawa Y, Lenz HJ. *Predictive value of CDC37 gene expression for targeted therapy in metastatic colorectal cancer.* Eur J Cancer. 2024 Feb 10; 201:113914. doi: 10.1016/j.ejca.2024.113914. Epub ahead of print. PMID: 38359495.
423. Battaglin F, Ou FS, Qu X, Hochster HS, Niedzwiecki D, **Goldberg RM**, Mayer RJ, Ashouri K, Zemla TJ, Blanke CD, Venook AP, Kabbarah O, Lenz HJ, Innocenti F. *HER2 Gene Expression Levels Are Predictive and Prognostic in Patients With Metastatic Colorectal Cancer Enrolled in*

CALGB/SWOG 80405. J Clin Oncol. 2024 Mar 8;JCO2301507. doi: 10.1200/JCO.23.01507. Epub ahead of print. PMID: 38457761.

424. Gallois C, Shi Q, Pederson LD, André T, Iveson TJ, Sobrero AF, Alberts S, de Gramont A, Meyerhardt JA, George T, Schmoll HE, Souglakos I, Harkin A, Labianca R, Sinicrope FA, Oki E, Shields AF, Boukovinas I, Kerr R, Lonardi S, Yothers G, Yoshino T, **Goldberg RM**, Taieb J, Papamichael D. *Oxaliplatin-Based Adjuvant Chemotherapy in Older Patients With Stage III Colon Cancer: An ACCENT/IDEA Pooled Analysis of 12 Trials*. J Clin Oncol. 2024 Mar 28;JCO2301326. doi: 10.1200/JCO.23.01326. Epub ahead of print. PMID: 38547438.
425. Taieb J, Basile D, Seligmann J, Argiles G, André T, Gallois C, **Goldberg RM**, Yothers G, Sobrero A, Meyerhardt JA, Souglakos J, Labianca R, Iveson T, Church DN, Arnold D, Tie J, Gill S, Laurent-Puig P, Yoshino T, Lonardi S, Shi Q. *Standardizing data collection in adjuvant colon cancer trials: A consensus project from the IDEA and ACCENT international consortia and national experts*. Eur J Cancer. 2024 Jul;206:114118. doi: 10.1016/j.ejca.2024.114118. Epub 2024 May 15. PMID: 38810317.
426. Cohen R, Raeisi M, Chibaudel B, Shi Q, Yoshino T, Zalcborg JR, Adams R, Cremolini C, Van Cutsem E, Heinemann V, Tabernero J, Punt CJA, Arnold D, Hurwitz HI, Douillard JY, Venook AP, Saltz LB, Maughan TS, Kabbinarav F, Bokemeyer C, Grothey A, Mayer RJ, Kaplan R, Tebbutt NC, Randolph Hecht J, Giantonio BJ, Díaz-Rubio E, Sobrero AF, Peeters M, Koopman M, **Goldberg RM**, Andre T, de Gramont A. *Prognostic value of liver metastases in colorectal cancer treated by systemic therapy: An ARCAD pooled analysis*. Eur J Cancer. 2024 Jun 10;207:114160. doi: 10.1016/j.ejca.2024.114160. Epub ahead of print. PMID: 38896997.
427. Malla M, Deshmukh SK, Wu S, Samec T, Olevian DC, El Naili R, El-Rayes B, Xiu J, Farrell A, Lenz HJ, Lou E, Goel S, Spetzler D, **Goldberg RM**, Hazlehurst L. *Mesothelin expression correlates with elevated inhibitory immune activity in patients with colorectal cancer*. Cancer Gene Ther. 2024 Aug 22. doi: 10.1038/s41417-024-00816-1. Epub ahead of print. PMID: 39174744.

EDITORIALS

1. **Goldberg RM**. *ODAC Clears a Path for Dostarlimab, A Drug that may “Beat the Reaper” in Locally Advanced Rectal Cancer*. The Cancer Letter, 49;6, 13-17, 2023.
2. Johnson W, Ripley-Burgess D, Hampel H, May F, Davis A, Goldberg RM. *All Colorectal Cancer Patients Require Germline Testing at Diagnosis and Somatic Testing at Advanced Disease Diagnosis*. The Cancer Letter, 48;28, 4-10, 2022.
3. Limburg PJ, Kisiel JB, **Goldberg RM**. *In Memoriam, David A. Ahlquist, M.D.* Gastroenterology. 2021 Jun 1;S0016-5085(21)03078-X. doi: 10.1053/j.gastro.2021.06.001. Epub ahead of print. PMID: 34087184.
4. **Goldberg RM**. *In Memoriam: A Tribute to Daniel J. Sargent, Ph.D.* Oncologist. 21:1540-1541, 2016. PMID: 27956661.
5. Nordlinger B, Poston GJ, **Goldberg RM**. *Should the Results of the New EPOC Trial Change Practice in the Management of Patients with Resectable Metastatic Colorectal Cancer Confined to the Liver?* J Clin Oncol. 33: 241-3, 2015. [Epub ahead of print]. PMID: 25403221.
6. **Goldberg RM**. *Genomic Profiling In Gastrointestinal Cancer: Are We Ready to Use These Data to Make Treatment Decisions?* Oncologist. 20: 1448-56, 2015. [Epub ahead of print]. PMID: 26512044.

7. Bekaii-Saab T, **Goldberg RM**. *FOLFIRINOX in locally advanced pancreas adenocarcinoma: back to the future?* Oncologist. 18:487-9, 2013. PMID: 23704222.
8. **Goldberg RM**. *Even slam-dunk applications can benefit from public scrutiny and discussion at ODAC*. The Cancer Letter. 28.32:3;1-5. August 10, 2012.
9. **Goldberg RM**. *Strategic options on behalf of patients with metastatic colorectal cancer: mass tumor murder versus serial tumor killing*. Onkologie. 33:291-292, 2010. PMID: 20523091.
10. **Goldberg RM**, Bertagnolli MM. *VICTOR spoiled?* J Clin Oncol. 28:4546-8, 2010. [Epub ahead of print]. PMID 2083795.
11. **Goldberg RM**. *Managing liver-dominant metastatic colorectal cancer*. Gastrointestinal Cancers Symposium Daily News, 1/23/2010. Page 4.
12. Cmclak AJ, **Goldberg RM**. *Infusion reactions associated with monoclonal antibodies in patients with solid tumors. Introduction*. Oncology (Williston Park). 23(2 Suppl 1):5-6, 2009. PMID:19385160.
13. Wood WA, McCabe MS, **Goldberg RM**. *Commentary: disclosure in oncology - to whom does the truth belong?* Oncologist, 2009 Jan;14(1):77-82. PMID: 19147691.
14. **Goldberg RM**, O'Neil BH. *Colorectal cancer: irinotecan therapy-following a trail of breadcrumbs?* Nat Rev Gastroenterol Hepatol. 2009 Sep;6(9):507-9.
15. **Goldberg RM**. *As federal funding is cut researchers struggle*. Gastrointest Cancer Res. 2:165, 2009. PMID: 19713983.
16. Cunningham D, **Goldberg RM**, Kahnec LA. *Therapeutic approaches to metastatic colorectal cancer*. Section editor. 3:109-136, 2007.
17. Kelly Sanoff H, **Goldberg RM**. *Searching for standards of care in gastroesophageal cancers: The Hwang article reviewed*. Oncology (Huntington) 21: 591-592, 2007.
18. O'Neil B, **Goldberg RM**. *On the state of the art of adjuvant chemotherapy for colon cancer*. Gastrointest Cancer Res. 1:115-7, 2007. PMID:19262717.
19. Kelly H*, **Goldberg RM**. *The Fakih/Padmanabhan article reviewed*. Oncology (Huntington) 20: 596- 601, 2006.
20. Love N and **Goldberg RM** eds, *Management of cancer of the colon and rectum in the adjuvant and metastatic settings*. Patterns of Care in Medical Oncology 3:1-48, 2006.
21. **Goldberg RM**. *Intensive surveillance after Stage II or III colorectal cancer: is it worth it?* J Clin Oncol. 2005 Dec 19; [Epub ahead of print], 24:330-331, 2006. PMID: 16365175.
22. Cunningham D, **Goldberg RM**. *Therapeutic approaches to metastatic colorectal cancers* (section Editor). Current Colorectal Cancer Reports. 9/2005.
23. **Goldberg RM**, *Lessons learned from the edrecolomab story: How a checkered past became a checkered flag for monoclonal antibodies in colorectal cancer therapy*. Onkologie 28: 311-2, 2005, Epub ahead of print, 5/2005. PMID: 15933417.
24. **Goldberg RM**. *Cetuximab*. Nat Rev Drug Discov. Suppl:S10-1, 2005. PMID: 15962524.
25. Tepper J, **Goldberg RM**, *An embarrassment of riches: Neo-adjuvant therapy of rectal cancer*. J Clin Oncol, 23: 1339-1341, 2005, Epub ahead of print, 1/2005. PMID: 15684316.
26. **Goldberg RM**. *Perspectives on oxaliplatin in the treatment of patients with gastrointestinal cancers* (guest editor) Sem Oncol, 30(4) Suppl 15: 1-5, 2003.
27. Jatoi A, Loprinzi C, Sloan J, **Goldberg RM**. *Is ATP, like STP®, a performance enhancing additive for the tanks of cancer patients?* Invited editorial J Natl Cancer Inst 92: 290-291, 2000. PMID: 10675386.
28. Pitot HC, **Goldberg RM**. *Invited commentary on Danjanov N, and Meropol NJ. Oral therapy for colorectal cancer: How can we choose?* Oncology 14:813-814, 2000.
29. **Goldberg RM**, Witzig T. *Invited editorial review of "Influence of erythropoietin on transfusion requirements in patients*

30. receiving preoperative chemo-radiotherapy for rectal cancer” by E Levine, C Laborde, E Hambrick, et al. Dis Colon
31. Rectum 42:1069-1071,1999.
32. **Goldberg RM**, *Breast cancer* (editorial), *Geisinger Bulletin* 41:2, 1991.

LETTERS TO THE EDITOR

1. Innocenti F, Ou FS, Qu X, Zemla T, Niedzwiecki D, Tam R, Mahajan S, **Goldberg RM**, Bertagnolli MM, Blanke CD, Sanoff H, Atkins J, Polite B, Venook AP, Lenz HJ, Kabbarah O. Reply to S. Sorscher. *J Clin Oncol*. 2019 Sep 1;37(25):2291-2293. doi: 10.1200/JCO.19.01366. Epub 2019 Jul 3. PMID: 31268798.
2. **Goldberg RM**, Wei L, Fernandez S, In Reply. Oncologist 2018 Jan; 23(1): 136 PMID: 29133518.
3. Niedzwiecki D, Frankel WL, Venook AP, Ye X, Friedman PN, **Goldberg RM**, Mayer RJ, Colacchio TA, Mulligan JM, Davison TS, O'Brien E, Kerr P, Johnston PG, Kennedy RD, Harkin DP, Schilsky RL, Bertagnolli MM, Warren RS, Innocenti F. Reply to L. Casadaban et al. J Clin Oncol. 2017 Apr 20;35(12):1373-1374. Epub 2017 Jan 23. PMID:28113023
4. Nordlinger BM, Poston GJ, **Goldberg RM**. Reply to J.N. Primrose et al and C.-H. Köhne. J Clin Oncol. 2015 Jun 1. pii: JCO.2014.60.4751.[Epub ahead of print]. PMID: 26033799.
5. Buyse M, Sargent DJ, **Goldberg RM**, de Gramont A; on behalf of the ARCAD Clinical Trials Program. *The ARCAD advanced colorectal cancer database--open for business*. Ann Oncol, 2012 Jan;23(1):281-282. Epub 2011 Nov 21. PMID:22104572. O'Neill BH, Goldberg RM. In Reply. *Oncologist*, 14:194-96, 2009.
6. Sanoff HK, Bleiberg H, **Goldberg RM**. Reply to JCO/2007/131243. Age-group specific gap between treatment cost of and mortality due to breast and colorectal cancer Imre Boncz et al. J Clin Oncol, 25(28) 4502-4503.
7. Niedzwiecki D, Frankel WL, Venook AP, Ye X, Friedman PN, **Goldberg RM**, Mayer RJ, Colacchio TA, Mulligan JM, Davison TS, O'Brien E, Kerr P, Johnston PG, Kennedy RD, Harkin DP, Schilsky RL, Bertagnolli MM, Warren RS, Innocenti F. Reply to L. Casadaban et al. J Clin Oncol. 2017 Apr 20;35(12):1373-1374. doi: 10.1200/JCO.2016.71.2646. Epub 2017 Jan 23. No abstract available. PMID:28113023
8. Hobday T, Sloan J, **Goldberg RM**, In reply. J Clin Oncol, 21: 3179, 2003.
9. Sargent DJ, **Goldberg RM**, Jacobson SD. Chemotherapy in the elderly - Reply. N Engl J Med, 346(8):623, 2002.
10. **Goldberg RM**, O'Connell MJ, Sargent DJ. Letter to the Editor, The Cancer Letter, 28:5-6, 2002.
11. Erlichman C, **Goldberg R**, O'Connell MJ. Irinotecan plus fluorouracil and leucovorin for metastatic colorectal cancer. N Engl J Med, 344: 305, 2001.
12. Erlichman C, **Goldberg RM**, Pitot HC, O'Connell MJ. Optimum doses of irinotecan. Lancet, 353: 1275-1276, 1999.
13. **Goldberg RM**, Fleming TR, Tangen CM. Surgery for recurrent colon cancer. Ann Int Med, 130: 239-240, 1999.
14. O'Connell MJ, Kahn MJ, Shepherd LE, Erlichman C, **Goldberg RM**. Optimal duration of fluorouracil plus levamisole colon cancer surgical adjuvant therapy. J Clin Oncol, 14: 2887, 1996. PMID: 8874353.

15. **Goldberg RM**, Wieand HS, Krook JE, Schutt AJ, Veeder MH, Mailliard JA, Dalton RJ. A Phase III evaluation of a somatostatin analogue (Octreotide) in the treatment of patients with asymptomatic advanced colon carcinoma. *Cancer*, 77:1956-1957, 1996.
16. Niedzwiecki D, Frankel WL, Venook AP, Ye X, Friedman PN, **Goldberg RM**, Mayer RJ, Colacchio TA, Mulligan JM, Davison TS, O'Brien E, Kerr P, Johnston PG, Kennedy RD, Harkin DP, Schilsky RL, Bertagnolli MM, Warren RS, Innocenti F. *Reply to L Casadaban et al.* *J Clin Oncol*. 35:1373-1374, 2017. PMID: 28113023.
17. Nordlinger BM, Poston GJ, **Goldberg RM**. *Reply to J.N. Primrose and C-H Kohne.* *J Clin Oncol*. 33:2408-9, 2015. PMID: 26033799.
18. **Goldberg RM**, Wei L, Fernandez S. In Reply. *Oncologist*, 23: 136, 2018. PMID: 29133518.
19. Innocenti F, Ou FS, Qu X, Niedzwiecki D, Tam R, Mahajan S, **Goldberg RM**, Bertagnolli MM, Blanke CD, Sanoff H, Adkins J, Polite B, Venook AP, Kabbarah O. *Reply to S. Sorscher.* *J Clin Oncol*, 2019 Jul 3: JCO1901366. Epub ahead of print. PMID: 31268798.

PUBLISHED ABSTRACTS

Add to Collection

1. Lenz H-J, Nicolaides T, Elliott A, **Goldberg RM**, Marshall J, Lou E, Shields AF, Sohal D, Weinberg BA, Spetzler D, Abraham J, Xiu J, Korn WM. *Analysis of HLA gene expression in patients with D-MMR/MSI-H Colorectal cancer resistant to immune checkpoint inhibitors.* *J Clin Oncol* 41, 2023 (suppl 4; abstr 202).
2. Arai H, Gandhi N, Battaglin F, Algaze S, Jayachandran P, Soni S, Wu Z, Lo JH, Sohal DPS, **Goldberg RM**, Hall MJ, Scott AJ, Hwang JJ, Lou E, Weinberg BA, Marshall J, Goel S, Korn WM, Lenz H-J. *The role of expression of CD47 in colorectal cancer (CRC).* *J Clin Oncol* 41, 2023 (suppl 4; abstr 240).
3. Battaglin F, Baca Y, Walker P, Xiu J, Soni S, Jayachandran P, Algaze S, Mittal P, Zhang W, Wong A, Goldberg RM, Weinberg BA, Lou E, Shields FA, Marshall JL, Goel S, Nasertorabi F, Korn WM, Lenz H-J. *Molecular correlates of DSCR1 expression in colorectal cancer (CRC).* *J Clin Oncol* 41, 2023 (suppl 4; abstr)
4. Battaglin F, Krause H, Elliot A, Abraham J, Soni S, Algaze S, Jayachandran P, Arai H, Zhang W, Lo JH, Mittal P, Weinberg BA, Lou E, Shields AF, **Goldberg RM**, Goel S, Marshall J, Liang G, Korn WM, Lenz H-J. *SETD2 gene expression and the molecular landscape of colorectal cancer (CRC).* *J Clin Oncol* 41, 2023 (suppl 4; abstr 184).
5. Malla M, Deshmukh SK, Wu S, Xiu J, ck Farrell AP, Lenz H-J, Lou E, Goel S, Spetzler D, Parikh AR, Hazlehurst L, **Goldberg RM**. *Comprehensive characterization of mesothelin expression in colorectal cancer.* *J Clin Oncol* 41, 2023 (suppl 4; abstr 245)
6. Zhang W, Millstein J, Yang Y, Ou F-S, Innocenti F, Arai H, Soni S, Mumenthaler SM, Algaze S, Jayachandran P, Bertagnolli MM, Deming DJ, Niedzwiecki D, **Goldberg RM**, Mayer RJ, Blanke CD, Venook AP, Kabbarah O, Battaglin F, Lenz H-J. *Predictive value of MAOB gene expression for targeted therapy in patients (pts) with metastatic colorectal*

cancer (mCRC) enrolled in CALGB (Alliance)/SWOG 80405. J Clin Oncol 40, 2022 (suppl 16; abstr 3580). (Poster)

7. Kohn CG, Ou F-S, Ma C, Larson NB, Zemla TJ, Yuan C, Niedzwiecki D, Hollis BW, Nixon AB, Lenz H-J, Blanke CD, **Goldberg RM**, Mayer RJ, Venook AP, O'Reilly EM, Meyerhardt JA, Ng K. *Gene expression of vitamin D (VitD) pathway markers and survival in patients (Pts) with metastatic colorectal cancer (mCRC): CALGB/SWOG 80405 (Alliance)* J Clin Oncol 40, 2022 (suppl 16; abstr 3553). (Poster)
8. Lo JH, Battaglin F, Baca Y, Xiu J, Brodskiy P, Algaze S, Jayachandran P, Arai H, Zhang W, Weinberg BA, Shroff RT, Sohal DPS, Lou E, Shields AF, **Goldberg RM**, Marshall J, Korn WM, Soni S, Lenz H-J. *DEFB1 gene expression and the molecular landscape of colorectal cancer (CRC)*. J Clin Oncol 40, 2022 (suppl 16; abstr 3523). (Poster)
9. Cohen R, Raeisi M, Yothers G, Schmoll H-J, Haller DG, Bachet J-B, Chibaudel B, Wolmark N, Yoshino T, **Goldberg RM**, Kerr R, Lonardi S, George TJ, Shmueli ES, Sharara L, Andre T, Shi Q, De Gramont A. *Using T stage to predict outcomes of adjuvant oxaliplatin (OX)-based chemotherapy (CT) in stage III colon cancer (CC): An ACCENT pooled analysis*. J Clin Oncol 40, 2022 (suppl 16; abstr 3606). (Poster)
10. Battaglin F, Xiu J, Brodskiy P, Algaze S, Jayachandran P, Arai H, Soni S, Zhang W, Weinberg BA, Lou E, Shields AF, **Goldberg RM**, Marshall J, Korn WM, Lenz H-J. *Comprehensive characterization of PTPRT expression in colorectal cancer (CRC)*. J Clin Oncol 40, 2022 (suppl 16; abstr 3538). (Poster)
11. Algaze S, Baca Y, Brodskiy P, Xiu J, Battaglin F, Yang Y, Millstein J, Jayachandran P, Arai H, Soni S, Zhang W, Goldberg RM, Weinberg BA, Lou E, Shields AF, Marshall J, Korn WM, Lenz H-J. *Characterization of TIM3 and its ligands in colorectal cancer*. J Clin Oncol 40, 2022 (suppl 16; abstr 3547). (Poster)
12. Lenz A, Zeng J, Xiu J, \Algaze S, Jayachandran P, Soni S, Lo JH, Arai H, Zhang W, Brodskiy P, Hosein PJ, Weinberg BA, Lou E, Shields AF, Goldberg RM, Marshall J, Korn WM, Lenz H-J, Battaglin F, Roussos Torres ET. *Claudin 18 (CLDN18) gene expression and related molecular profile in gastric cancer (GC)*. J Clin Oncol 40, 2022 (suppl 16; abstr 4048). (Poster)
13. Lo JH, Battaglin F, Baca Y, Xiu J, Brodskiy P, Algaze S, Jayachandran P, Arai H, Zhang W, Weinberg BA, Shroff RT, Sohal DPS, Lou E, Shields AF, **Goldberg RM**, Marshall J, Korn WM, Soni S, Lenz H-J. *DEFB1 gene expression and the molecular landscape of colorectal cancer (CRC)*. J Clin Oncol 40, 2022 (suppl 16; abstr 3523). (Poster)
14. Battaglin F, Elliott A, Zhang J, Stafford P, Helmstetter A, Oberley MJ, Arai H, Jayachandran P, Kawanishi N, Soni S, Lo JH, Zhang W, Weinberg BA, Lou E, Shields AF, Spetzler D, **Goldberg RM**, Marshall J, Korn WM, Lenz H-J; *Identification and characterization of recurrent neoantigens in upper gastrointestinal (GI) cancers*. J Clin Oncol 40, 2022 (suppl 15; abstr 246). Podium presentation.

15. Battaglin F, Xiu J, Zeng J, Baca Y, Jayachandran P, Kawanishi N, Arai H, **Goldberg RM**, Lockhart AC, Hwang J, Seeber A, Zhang W, Mumenthaler SM, Shields AF, Marshall JL, Neman J, Korn WM, Lenz H-J; *Comprehensive characterization of neurotransmitters and neuronal signaling (NT) pathway alterations in colorectal cancer (CRC)*". J Clin Oncol 40, 2022 (suppl 15; abstr 3527). Poster.
16. Jayachandran P, Yin J, Xiu J, Brodskiy P, Arai H, Abraham J, Battaglin F, Shivani Soni S, Hall MJ, Khushman, MM, Sohal D, Weinberg BA, **Goldberg RM**, Lou E, Zhang W, Millstein J, Korn WM, Lenz H-J; *LRP1B and GRM3 expression in colorectal cancer*. J Clin Oncol 40, 2022 (suppl 15; abstr 177). Poster.
17. Franko J, Yin J, Adams R, Zalcborg JR, Fiskum J, VanCutsem E, Goldberg RM, Hurwitz HI, Bokemeyer C, Kabbinavar FF, Curtis A, Chibaudel B, Yoshino T, A De Gramont A, Shi Q; *Trajectories of body weight change and survival among mCRC patients treated with systemic therapy: Pooled analysis from the ARCAD database*. J Clin Oncol 40, 2022 (suppl 15; abstr 80). Poster.
18. Seeber A, Kocher F, Pircher A, Puccini A, Baca Y, Xiu J, Zimmer K, Haybaeck J, Spizzo G, **Goldberg RM**, AGrothey A, Shields AF, Salem ME, Marshall J, Hall MJ, Korn WM, Nabhan C, Battaglin F, Lenz H-J, Wolf DG; *High CXCR4 expression in pancreatic ductal adenocarcinoma as characterized by an inflammatory tumor phenotype with potential implications for an immunotherapeutic approach*. J Clin Oncol 39, 2021 (suppl 15; abstr 4021). Poster discussion.
19. Jayachandran P, Baca Y, Xiu J, Zhang J, Battaglin F, Arai H, **Goldberg RM**, Weinberg BA, Lou E, Hall MJ, Khushman MM, Sohal D, Soni S, Wang J, Zhang W, Millstein J, Korn WM, Lenz H-J; *Globo H expression in metastatic colorectal cancer (CRC)*. J Clin Oncol 39, 2021 (suppl 15; abstr 3527). Poster
20. Battaglin F, Xiu J, Jia Zeng J, Baca Y, Jayachandran P, Kawanishi N, Arai H, Deshpande K, Goldberg RM, Lockhart AC, Hwang JJ, Seeber A, Zhang W, Mumenthaler SM, Shields AF, Marshall J, Korn WM, Neman J, Lenz H-J; *Comprehensive characterization of neurotransmitters and neuronal signaling (NT) pathway alterations in colorectal cancer (CRC)*. J Clin Oncol 39, 2021 (suppl 15; abstr 3537). Poster
21. Lou E, Baca Y, Joanne Xiu J, Nelson A, Subramanian S, Salem ME, Beg MS , Fontana E, Diab M, Philip PA, **Goldberg RM**, Pandey R, Arkenau T, Sun W, Lenz H-J, Anthony Frank Shields, Wafik S. El-Deiry, Wolfgang Michael Korn; *Increased neutrophil infiltration and lower prevalence of tumor mutation burden and microsatellite instability are hallmarks of RAS mutant colorectal cancers*. J Clin Oncol 39, 2021 (suppl 15; abstr 3563). Poster.
22. DiNardo K, Ma C, Ou F-S, Yuan C, Guercio BJ, Oyarvide VM, Van Blarigan E, Niedzwiecki D, Chang I-W, Hei Lenz H-J, Blanke CD, Venook AP, Mayer RJ, Fuchs CS, Innocenti F, Nixon AB, **Goldberg RM**, O'Reilly EM, Meyerhardt JA, Ng K; *Influence of dietary insulin scores on survival in patients with metastatic colorectal cancer (mCRC): Findings from CALGB (Alliance) 80405*. J Clin Oncol 39, 2021 (suppl 15; abstr 3568). Poster.
23. Van Blarigan E, Ma C, Ou F-S, Venook AP, Ng K, Niedzwiecki D, Giovannucci EL, Lenz H-J, Innocenti F, Shaw JE, Polite BN, Hochster HS, **Goldberg RM**, RobMayer RJ, O'Reilly EM, Fuchs CS, Meyerhardt JA; *Dietary fat in relation to overall and progression-free survival among*

patients (pts) with advanced or metastatic colorectal cancer (CRC): Data from CALGB 80405 (Alliance). J Clin Oncol 39, 2021 (suppl 15; abstr 3588). Poster.

24. Sinicrope FA, Shi Q, Smyrk TC, **Goldberg RM**, StevCohen SJ, Gill S, Kahlenberg MS, Nair S, Shields AF, BalJahagirdar BN, Jacobson SB, Foster NR, Pollak MN, Alberts SR; Association of plasma adiponectin with tumor infiltrating lymphocytes and survival in patients with stage III colon cancer (NCCTG N0147; Alliance). J Clin Oncol 39, 2021 (suppl 15; abstr 3591). Poster.
25. Jin Z, Dixon JG, Parekh H, Sinicrope, FA Yothers G, Haller DG, Schmoll H, De Gramont A, l Kerr R, Taieb J, Van Cutsem E, Twelves C, Saltz LB, Tomita N, Yoshino T, Andre T, Mahipal A, **Goldberg RM**, George TJ, Shi Q; *Clinicopathological and molecular characteristics of early-onset stage III colon adenocarcinoma: An analysis of 25 studies with 35,713 patients in the Adjuvant Colon Cancer End Points (ACCENT) database.* J Clin Oncol 39, 2021 (suppl 15; abstr 3597). Poster.
26. Seeber A, Kocher F, Pircher A, Puccini A, Baca Y, Xiu J, Zimmer K, Haybaeck J, Spizzo G, **Goldberg RM**, Grothey A, Shields AF, Salem ME, Marshall J, Hall MJ, Korn WM, Nabhan C, Battaglin F, Lenz H-J, Domi Wolf DGF; *High CXCR4 expression in pancreatic ductal adenocarcinoma as characterized by an inflammatory tumor phenotype with potential implications for an immunotherapeutic approach.* J Clin Oncol 39, 2021 (suppl 15; abstr 4021).
27. Sinicrope FA, Shi Q, Smyrk TC, Goldberg RM, Cohen SJ, Gill S, Kahlenberg MS, Nair N, Shields AF, Jahagirdar BN, Jacobson SB, Foster NR, Pollak MN. Alberts SA; *Association of plasma adiponectin with tumor infiltrating lymphocytes and survival in patients with stage III colon cancer (NCCTG N0147; Alliance).* J Clin Oncol 39, 2021 (suppl 15; abstr 3591). Poster
28. Meyerhardt JA, Shi Q, Fuchs CS, Niedzwiecki D, Zemla TJ , Kumthekar P, Guthrie KA, Couture F, Kuebler JP, Bendell JC, Kumar P, Lewis DA, Tan BR, Bertagnolli MM, Grothey A, Hochster HS, **Goldberg RM**, Venook AP, Blanke CD, Shields AF; *Celecoxib in addition to standard adjuvant therapy with 5-fluorouracil, leucovorin, oxaliplatin (FOLFOX) in stage III colon cancer: Results from CALGB/SWOG 80702.* J Clin Oncol 38, 2020 (suppl; abstr 4003). Oral presentation.
29. Stein MK, A Elliott A, Hwang JJ, Lou E, Khushman MM, Scott AJ, Marshall J, Sohal D, Weinberg BA, **Goldberg RM**, Salem ME, Korn WM, Grothey A; *The landscape of MAP3K1/MAP2K4 alterations in gastrointestinal (GI) malignancies.* J Clin Oncol 38: 2020 (suppl; abstr 4113). Poster presentation.
30. Battaglin F, Ou F-S, Qu X, Bertagnolli MM, Hochster HS, Niedzwiecki D, **Goldberg RM**, Mayer RJ, Zemla TJ, Blanke CD, Venook AP, Kabbarah O, Lenz H-J, Innocenti I; *Predictive and prognostic value of HER2 gene expression and HER2 amplification in patients with metastatic colorectal cancer (mCRC) enrolled in CALGB/SWOG 80405 (Alliance).* J Clin Oncol 38: 2020 (suppl; abstr 4086)
31. Arai H, Elliott A, Wang J, Battaglin F, Soni S, Zhang W, Sohal D, Goldberg RM, Hall MJ, Scott AJ, Khushman M, Hwang JJ, Lou E, Weinberg BA, Marshall J, Lockhart AC, Phillip Stafford P, Jian Zhang J, W. Michael Korn WM, Heinz-Josef Lenz H-J; *The landscape of DNA damage response (DDR) pathway in colorectal cancer (CRC).* J Clin Oncol 38: 2020 (suppl; abstr 4064)
32. Arai H, Elliott A, Xiu, S, Wang J, Battaglin F, Soni S, Zhang W, Sohal D, **Goldberg RM**, Hall MJ, Scott AJ, Khushman M, JiHwang JJ, Lou E, Weinberg BA, Marshall J, Lockhart AC,

- Anthony Frank Shields FA, W. Michael Korn WM, Heinz-Josef Lenz H-J. *Somatic alterations of NF1 in colorectal cancer*. J Clin Oncol 38: 2020 (suppl; abstr 4066)
33. Battaglin F, Xiu J, Baca Y, **Goldberg RM**, Grothey A, Shields AF, Seeber A, Salem ME, Puccini A, Tokunaga R, Naseem M, Arai H, Wang J, Berger MD, Zhang W, Philip PA, J L Marshall, Korn WM, Lenz HJ. *Comprehensive molecular characterization of brain metastases (BM) from colorectal cancer (CRC)* Annals of Oncology, Volume 30, Issue Supplement_5, October 2019.
 34. Battaglin F, Xiu J, Baca Y, Shields AF, **Goldberg RM**, Seeber A, Habib D, Soni A, Puccini A, Tokunaga R, Arai H, Wang J, Berger MD, Astsaturov IA, Lockhart AC, Zhang W, Marshall J, Korn WM, Lenz H-J, El-Khoueiry AB. *Comprehensive molecular profiling of IDH1/2 mutant biliary cancers (BC)*. J Clin Oncol 38, 2020 (suppl 4; abstr 479). Poster presentation.
 35. Malla M, Rozich N, Hassan A, Hayat M, Chen S, Nusrat S, **Goldberg RM**, Morris KT. *Correlation of mesothelin (MSLN) expression with future peritoneal metastases (PM) in colorectal cancer (CRC)*. J Clin Oncol 38, 2020 (suppl 4; abstr 176). Poster presentation.
 36. Tournigand C, Lopes G, Olswold CL, Adams R, Zalcborg JR, Van Cutsem E, Saltz LB, **Goldberg RM**, Hurwitz H, Bokemeyer C, Fuchs CS, Chibaudel B, Grothey A, De Gramont A, Shi Q. *How to improve toxicity evaluation in clinical trials? Testing new metrics from irinotecan or oxaliplatin-based treatments in metastatic colorectal cancer (mCRC): A pooled analysis from 2,349 patients in ARCAD database*. J Clin Oncol 38, 2020 (suppl 4; abstr 89). Poster presentation.
 37. Arai H, Baca Y, Johnston C, Goldberg RM, Philip PA, Seeber A, Battaglin F, J Xiu J, Wang J, Soni S, Zhang W, Hwang JJ, Shields AF, Marshall J, Korn WM, Lenz H-J. *Molecular characterization of appendiceal goblet cell carcinoid*. J Clin Oncol 38, 2020 (suppl 4; abstr 231). Poster presentation.
 38. Salem ME, Xiu J, Puccini A, A Grothey, **Goldberg RM**, Hwang JJ, Gatalica Z, Feldman R, Saul M, Korn WM, Hall MJ, El-Deiry W, Shields AF, Marshall JL, Lenz H-J, VanderWalde AM. *Comparative molecular analyses between microsatellite stable BRAFV600E mutant colorectal cancers and BRAFV600E mutant melanomas*. Annals of Oncology, Volume 30, Issue Supplement 5, October 2019.
 39. Seeber S, Kocher F, Xiu J, Spizzo G, Puccini A, Swensen J, Ellis M, **Goldberg RM**, Grothey A, Shields AF, Salem ME, Battaglin F, El-Deiry WS, Tokunaga R, Naseem M, Philip PA, Marshall J, Korn WM, Lenz H-J, Gatalica Z. *Molecular landscape of colorectal cancers harboring R-spondin fusions*. J Clin Oncol 37, 2019 (suppl; abstr 3588). Poster
 40. Battaglin F, Xiu J, Baca Y, **Goldberg RM**, Grothey A, Shields AF, Seeber A, Salem ME, Puccini A, Tokunaga R, Naseem M, Arai H, Wang J, Berger MD, Zhang W, Philip PA, John L. Marshall JL, Korn WM, Lenz H-J. *Comprehensive molecular characterization of brain metastases (BM) from colorectal cancer (CRC)*. ESMO Congress 2019, Poster Discussion 2 – Translational research - 30.09.2019, Tarragona Auditorium (Hall 7).
 41. Sinicrope FA, Huebner LJ, Laurent-Puig P, Smyrk TC, Tabernero J, Mini E, **Goldberg RM**, Folprecht G, Zaanan A, Le Malicot K, Shi Q, Alberts SR, Taieb J; *Relative contribution of clinical and molecular features to outcome within low and high risk T and N groups in stage III colon cancer (CC)*. J Clin Oncol 37, 2019 (suppl; abstr 3520). Poster discussion.
 42. Spizzo G, Puccini A, Xiu J, **Goldberg RM**, Grothey A, Shields AF, Patel Arora S, Khushman MM, Salem ME, Battaglin F, El-Deiry WS, Tokunaga R, Philip PA, Hall MJ, Marshall J, Kocher F, Korn WM, Lenz H-J, Seeber A. *Frequency of BRCA mutation in biliary tract cancer and its correlation with tumor mutational burden (TMB) and microsatellite instability (MSI)*. J Clin Oncol 37, 2019 (suppl; abstr 4085). Poster.

43. Seeber A, Puccini A, Xiu J, **Goldberg RM**, Grothey A, Shields AF, Salem ME, Battaglin F, El-Deiry WS, Tokunaga R, Philip PA, Marshall J, Kocher F, Hall MJ, Korn WM, Lenz H-J, Spizzo G; *Association of BRCA-mutant pancreatic cancer with high tumor mutational burden (TMB) and higher PD-L1 expression*. J Clin Oncol 37, 2019 (suppl; abstr 4133). Poster.
44. Tokunaga R, Xiu J, **Goldberg RM**, Philip PA, Seeber A, Battaglin F, Arai H, Lo JH, Puccini A, Naseem M, Berger MD, Soni S, Zhang W, Sting Chen W, Hwang JJ, Shields AF, Marshall J, Baba H, W. WM, Lenz H-J. *Gene mutations of SWI/SNF complex and molecular profile in colorectal cancer*. J Clin Oncol 37, 2019 (suppl; abstr 3600). Poster
45. Zaanan A, Shi Q, Taieb J, Alberts SR, Meyers JP, Smyrk TC, Julié C, Zawadi A, Tabernero J, Mini E, **Goldberg RM**, Folprecht G, J-L VAN Laethem, Le Malicot K, Sargent DJ, Laurent-Puig P, Sinicrope FA. *Is the predictive and prognostic impact of sporadic and familial microsatellite instable stage III colon cancer different? A pooled analysis of the PETACC8 and NCCTG N0147 (Alliance) trials*. J Clin Oncol 37, 2019 (suppl; abstr 3583). Poster
46. Stein MK, Xiu J, Martin MG, I Grothey A, Prouet P, Owsley J, Williard FW Glazer ES, Vandiver Dickson P, Shibata D, Yakoub D, **Goldberg RM**, Korn WM, Shields AF, Hwang JJ, Lenz H-J, Deneve JL. *Molecular comparison between peritoneal metastases (PM) and primary gastric (GC) and gastroesophageal junction (GEJ) cancer*. J Clin Oncol 37, 2019 (suppl; abstr 4053). Poster
47. Guercio BJ, Venook AP, Zhang S, Ou F-S, Niedzwiecki D, Lenz H-J, Innocenti F, Pollak MN, Nixon AB, Mahoney MR, O'Neil B, Shaw JE, Polite BN, C. Denlinger CS, Atkins JN, **Goldberg RM**, Mayer RJ, Blanke CD, Fuchs CS, Meyerhardt JA. *Associations of insulin-like growth factor binding proteins and adiponectin with disease progression and mortality in metastatic colorectal cancer: Results from CALGB/SWOG 80405 (Alliance)*. J Clin Oncol 37, 2019 (suppl; abstr 3035). Poster
48. Jeter JM, Hampel H, Stanich P, Pearlman R, Hinton A, Hays JL, **Goldberg RM**. *A phase II study of PD-1 inhibition for the prevention of colon adenomas in patients with Lynch syndrome and a history of partial colectomy*. J Clin Oncol 37, 2019 (suppl; abstr TPS1587). Poster
49. Puccini A, Xiu J, **Goldberg RM**, Grothey A, Shields AF, Salem ME, Seeber A, Battaglin F, Berger MD, El-Deiry WS, Tokunaga R, Naseem M, Zhang W, Patel Arora SK, Khushman MM, Hall MJ, Philip PA, Marshall J, Korn WM, Lenz H-J. *Molecular differences between lymph nodes (LNs) and distant metastases (mets) in colorectal cancer (CRC)*. J Clin Oncol 37, 2019 (suppl; abstr 3130). Poster.
50. Shi Q, de Gramont A, Dixon JG, Yin J, Van Cutsem E, Taieb J, Alberts SR, Wolmark N, Schmoll H-J, Saltz LB, **Goldberg RM**, Kerr R, Lonardi S, Yoshino T, Yothers G, Grothey A, Andre T, Salem ME, Adjuvant Colon Cancer ENd PoinTs (ACCENT) Group. *Re-evaluating disease-free survival (DFS) as an endpoint versus overall survival (OS) in adjuvant colon cancer (CC) trials with chemotherapy +/- biologics: An updated surrogacy analysis based on 18,886 patients (pts) from the Accent database*. J Clin Oncol 37, 2019 (suppl; abstr 3502). Oral presentation.
51. Puccini A, Poorman K, Salem ME, **Goldberg RM**, Shields AF, Berger MD, Battaglin F, Tokunaga R, Saul M, Naseem M, Zhang W, Soni S, Korn WM, Philip PA, Marshall JL, Lenz H-J. *Comprehensive molecular profiling of signet-ring-cell carcinoma (SRCC) from the stomach and colon*. J Clin Oncol 37, 2019 (suppl 4: abstr 60). Poster
52. Hall MJ, J. Bodor JN, Xiu J, Feldman R, Handorf EA, Grothey A, **Goldberg RM**, Worriolow WM, Hwang J, Kim E, Lenz H-J, Raghavan D, Shields A, Korn WM, Marshall JL, Salem ME. *Gene-specific features (MLH1, MSH2, MSH6, PMS2) of mismatch repair (MMR) protein expression and somatic mutations, microsatellite instability (MSI), and tumor mutational burden*

- (TMB) in MSI-H and MMR-mutated tumor genomic profiles. J Clin Oncol 37, 2019 (suppl 4: abstr 505). Poster
53. Naseem M, Xiu J, Salem M, **Goldberg RM**, Vanderwalde A, Grothey A, Philip PA, Seeber A, Puccini A, Tokunaga R, Battaglin F, Berger MD, Barzi A, Hanna D, Zhang W, Hwang JJ, Shields AF, Marshall JL, Korn WM, Lenz H-J. *Characteristics of Colorectal Cancer (CRC) Patients with BRCA1 and BRCA2 Mutations*. J Clin Oncol 37, 2019 (suppl 4: abstr 606). Poster
 54. Cerniglia M, Xiu J, Grothey A, Pishvaian MJ, Hwang JJ, Marshall J, Vanderwalde AM, Shields AF, Lenz H-J, Salem ME, Philip PA, **Goldberg RM**, Korn WM, Kim SS. *Association of DNA damage response and repair genes (DDR) mutations and microsatellite instability (MSI), PD-L1 expression, tumor mutational burden (TMB) in gastroesophageal cancers*. J Clin Oncol 37, 2019 (suppl 4: abstr 63). Poster
 55. Guercio BJ, Sui Zhang S, Venook AP, Ou F-S, Niedzwiecki D, Lenz H-J, Innocenti F, Mahoney M⁴, O'Neil BH, Shaw JE, Polite BN, Hochster HS, Atkins JN, **Goldberg RM**, Mayer RJ, Blanke CD, Fuchs CS, Meyerhardt JA. *Body mass index, weight loss, and progression and mortality in metastatic colorectal cancer (Alliance)*. Proc Am Assoc Can Res.2019. Poster
 56. Puccini A, Poorman K, Salem ME, **Goldberg RM**, Shields AF, Xiu J, Korn WM, Seeber A, Berger MD, Tokunaga R, Naseem M, Battaglin F, Barzi A, Iqbal S, Zhang W, Soni S, Hwang JJ, Philip PA, Marshall J, Lenz H-J; *Comprehensive genomic profiling of 724 gastroenteropancreatic neuroendocrine tumors (GEP-NETs)*. J Clin Oncol 36, 2018, (suppl:abstr 4098). Poster
 57. Salem ME, Grothey A, Kim ES, Xiu J, **Goldberg RM**, Korn WM, Shields AF, Seeber A, Hwang JJ, Philip PA, Lenz H-J, Raghavan D, Marshall J; *Impact of MLH1, PMS2, MSH2, and MSH6 alterations on tumor mutation burden (TMB) and PD-L1 expression in 1,057 microsatellite instability-high (MSI-H) tumors*. J Clin Oncol 36, 2018, (suppl:abstr 3572). Poster
 58. Battaglin F, Xiu J, Winerip M, **Goldberg RM**, Philip PA, Seeber A, Puccini A, Tokunaga R, Naseem M, Soni S, McSkane M, Berger MD, Barzi A, Zhang W, Hwang JJ, Shields AF, Marshall J, Korn WM, Lenz H-J; *Circadian clock gene PER1 mutations in colorectal cancer (CRC)*. J Clin Oncol 36, 2018, (suppl:abstr 12106). Poster
 59. Jagosky J, **Goldberg RM**, Raghavan D, Puccini A, Shields AF, Arguello D, Korn WM, Andreas Seeber A, Hwang JJ, Philip PA, Marshall J, Kim ES, Lenz H-J, Salem ME; *Molecular analyses of left- and right-sided tumors in adolescents and young adults (AYA) with colorectal cancer (CRC)*. J Clin Oncol 36, 2018, (suppl:abstr 3577). Poster
 60. Cheung WY, Andre T, Grothey A, Kerr R, Dixon J, Haller DG, De Gramont A, Alberts SR, Twelves C, O'Connell MJ, Saltz LB, Lonardi S, Yoshino T, Yothers G, **Goldberg RM**, Shi Q; *Association of adverse events (AEs) with outcomes in early stage colon cancer (CC): An analysis of 10,695 CC patients from the ACCENT database*. J Clin Oncol 36, 2018, (suppl:abstr 3601). Poster
 61. Wagner AD, Grothey A, Andre T, Dixon J, Wolmark N, Haller DG, Allegra CJ, VanCutsem E, George Jr.TJ, De Gramont A, Alberts SR, Twelves C, O'Connell MJ, Saltz LB, Blanke CD, Francini G, Kerr R, **Goldberg RM**, Yothers G, Shi Q; *Association of sex and adverse events (AEs) of adjuvant chemotherapy (ACT) in early stage colon cancer (CC): A pooled analysis of 28,636 patients (pts) in the ACCENT database*. J Clin Oncol 36, 2018, (suppl:abstr 3603). Poster
 62. Penney K, Banbury BL, Shi Q, Allegra CJ, Alberts SR, Peters U, Yothers G, Sinicrope FA, Sun W, Wolmark N, Nair SG, Harrison T, **Goldberg RM**, Lucas P, George T, Colangelo LH, Atkins J, Newcomb PA, Chan AT; *Genome-wide association with survival in stage II-III colon cancer clinical trials (NCCTG N0147, Alliance for Clinical Trials in Oncology; NSABP C-08, NRG Oncology)*. J Clin Oncol 36, 2018, (suppl:abstr 3582). Poster

63. Sehdev A, Niedzwiecki D, Venook A, Lenz HJ, Innocenti F, Mahoney M, Shaw JE, Polite BN, Hochster H, Atkins JN, **Goldberg RM**, Mayer RJ, Schilsky R, Bertagnolli M, Blanke CD, O'Neil BH. *Association of RAS mutations with race in metastatic colorectal cancer: CALGB/SWOG 80405 (Alliance)*. 2018 Gastrointestinal Cancers Symposium. Abstract Number 638. Poster
64. Ou FS, Lou Y, Van Cutsem E, Saltz L, Schmoll HJ, **Goldberg RM**, Hoff P, Douillard JY, Hecht R, Hurwitz H, Punt C, Bokemeyer C, Fuchs C, Diaz-Rubio E, Tebbut N, Falcone A, Kabbinar FF, De Gramont A, Grothey A, Shi Q. *Evaluation of lesion-based response at 12 weeks (LBR12) of treatment (Rx) in metastatic colorectal cancer (mCRC): Findings from 9,092 patients (pts) in the ARCAD database*. 2018 Gastrointestinal Cancers Symposium. Abstract Number 612. Poster
65. Ferraro D, Zalcborg JR, Shi Q, Meyers JP, Seymour MT, Saltz L, Maughan T, **Goldberg RM**, Van Cutsem E, Heinemann V, Hurwitz H, Falcone A, Diaz-Rubio E, Chibaudel B, Fuchs C, Porschen R, Bokemeyer C, De Gramont A, Price T, Adams R. *Associations of incidence of common adverse events (AEs) and survival outcomes in metastatic colorectal cancer (mCRC) patients (pts) treated with first line chemotherapy: Findings from 9,812 pts in the ARCAD database*. 2018 Gastrointestinal Cancers Symposium. Abstract Number 617. Poster
66. Sinicrope F, Shi Q, Hermitte F, Heying E, Benson AB, Gill S, **Goldberg RM**, Kahlenberg M, Nair S, Shields AF, Sargent D, Galon J, Alberts SR. *Immunoscore to provide prognostic information in low-(T1-3N1) and high-risk (T4 or N2) subsets of stage III colon carcinoma patients treated with adjuvant FOLFOX in a phase III trial (NCCTG N0147; Alliance)*. 2018 Gastrointestinal Cancers Symposium. Abstract Number 614. Poster
67. Salem M, Yin J, **Goldberg RM**, Pederson L, Wolmark N, Alberts S, Taieb J, Marshall J, Lonardi S, Yoshino T, Kerr R, Yothers G, Grothey A, Andre T, De Gramont A, Shi Q. *Evaluation of outcomes over time (1998-2009) of patients (pt) with stage III colon cancer receiving adjuvant FOLFOX: Analysis of 7,230 patients from MOSAIC, C07, C08, N0147, AVANT, and PETACC8 trials in the ACCENT database*. 2018 Gastrointestinal Cancers Symposium. Abstract Number 724. Poster
68. Salem M, Yin J, **Goldberg RM**, Pederson L, Wolmark N, Alberts S, Taieb J, Marshall J, Lonardi S, Yoshino T, Kerr R, Yothers G, Grothey A, Andre T, De Gramont A, Shi Q. *Outcomes over time (1998-2009) of stage II colon cancer patients (pts) receiving adjuvant FOLFOX: Pooled analysis of 1,122 pts in the ACCENT database*. 2018 Gastrointestinal Cancers Symposium. Abstract Number 728. Poster
69. Salem ME, Xiu J, Puccini A, Philip PA, **Goldberg RM**, Hwang JJ, Kc B, Korn W, Shields A, Lenz HJ, Marshall J. *Molecular characterization of intestinal (IS) and diffuse subtypes (DS) of gastric adenocarcinomas*. 2018 Gastrointestinal Cancers Symposium. Abstract Number 60. J Clin Oncol 37, 2019 (suppl 4: abstr 63). Poster
70. Koenig KL, Wu CS, Chen W, Frankel WL, Jones D, Zhao W, Mikhail S, Roychowdhury S, Hays JL, Noonan AM, **Goldberg RM**, Bekaii-Saab TS, Ciombor KK. *Genomic profiling of young adults with colorectal cancer: A single-institution experience*. 2017 ASCO Annual Meeting Abstracts. Abstract Number e15168.
71. Ou FS, Hubbard JM, Kasi PM, Dixon J, Van Cutsem E, Saltz L, Schmoll HJ, Punt CJ, **Goldberg RM**, Hoff P, Douillard JY, Hecht JR, Hurwitz H, Bokemeyer C, Fuchs C, Diaz-Rubio E, Sargent DJ, De Gramont A, Shi Q, Grothey A, ARCAD. *Heterogeneity in early lesion changes on treatment as a marker of poor prognosis in patients (pts) with metastatic colorectal cancer (mCRC) treated with first line systemic chemotherapy ± biologic: Findings from 9,092 pts in the ARCAD database*. 2017 ASCO Annual Meeting Abstracts. Abstract Number 3535. Poster

72. Newcomb PA, Sun W, Hua X, Banbury BL, Phipps AI, Kocarnik J, Harrison TA, Shi Q, Sinicrope FA, Thibodeau SN, Chan E, Gill S, **Goldberg RM**, Kahlenberg MS, Nair S, Shields AF, Jahagirdar BN, Peters U, Alberts SR, Chan AT. *Genetic correlates of therapeutic toxicities of stage III colon carcinoma patients treated with adjuvant FOLFOX+/-cetuximab (NCCTG N0147, Alliance)*. 2017 ASCO Annual Meeting Abstracts. Abstract Number 3604. Poster
73. Sinicrope FA, Shi Q, Smyrk TC, **Goldberg RM**, Heying EN, Cohen SJ, Gill S, Kahlenberg MS, Nair S, Shields AF, Sargent DJ, Jahagirdar BN, Pollak MN, Alberts SR. *Analysis of serum vitamin D levels and prognosis in stage III colon carcinoma patients treated with adjuvant FOLFOX+/-cetuximab chemotherapy: NCCTG N0147 (Alliance)*. 2017 ASCO Annual Meeting Abstracts. Abstract Number 3516.
74. Venook AP, Ou FS, Lenz HJ, Kabbarah O, Qu X, Niedzwiecki D, Zemla T, **Goldberg RM**, Hochster HS, O'Neil BH, Sanoff HK, Mayer RJ, Bertagnolli MM, Blanke CD, Innocenti F. *Primary (1°) tumor location as an independent prognostic marker from molecular features for overall survival (OS) in patients (pts) with metastatic colorectal cancer (mCRC): Analysis of CALGB / SWOG 80405 (Alliance)*. 2017 ASCO Annual Meeting Abstracts. Abstract Number 3503.
75. Innocenti F, Ou FS, Zemla T, Niedzwiecki D, Qu X, Tam R, Mahajan S, **Goldberg RM**, Mayer RJ, Bertagnolli MM, Sanoff HK, Hochster HS, Blanke CD, Venook AP, Lenz HJ, Kabbarah O. *Somatic DNA mutations, MSI status, mutational load (ML): Association with overall survival (OS) in patients (pts) with metastatic colorectal cancer (mCRC) of CALGB/SWOG 80405 (Alliance)*. 2017 ASCO Annual Meeting Abstracts. Abstract Number 3504.
76. Sinicrope FA, Shi Q, Hermitte F, Heying EN, Benson AB, Gill S, **Goldberg RM**, Kahlenberg MS, Nair S, Shields AF, Sargent DJ, Galon J, Alberts SR. *Association of immune markers and Immunoscore with survival of stage III colon carcinoma (CC) patients (pts) treated with adjuvant FOLFOX: NCCTG N0147 (Alliance)*. 2017 ASCO Annual Meeting Abstracts. Abstract Number 3579.
77. Lenz HJ, Ou FS, Venook AP, Hochster HS, Niedzwiecki D, **Goldberg RM**, Mayer RJ, Bertagnolli MM, Blanke CD, Zemla T, Qu X, Innocenti F, Kabbarah O. *Impact of consensus molecular subtyping (CMS) on overall survival (OS) and progression free survival (PFS) in patients (pts) with metastatic colorectal cancer (mCRC): Analysis of CALGB/SWOG 80405 (Alliance)*. 2017 ASCO Annual Meeting Abstracts. Abstract Number 3511.
78. Zalcberg JR, Shi Q, Angela Ferraro D, Meyers JP, Saltz L, **Goldberg RM**, Van Cutsem E, Hurwitz H, Fuchs C, Bokemeyer C, Sargent DJ, De Gramont A, Price TJ, Adams R. *Impact of overall severity of adverse events (AEs) on long-term outcomes in metastatic colorectal cancer (mCRC) patients (pts) treated with first line systemic chemotherapy: Findings from 3,971 pts in the ARCAD database*. 2017 ASCO Annual Meeting Abstracts. Abstract Number 3582.
79. Abou-Alfa GK, Niedzwieski D, Knox JJ, Kaubisch A, Posey J, Tan BR, Kavan P, Goel R, Murray JJ, Bekaii-Sabb TS, Tam VC, *Rajdev* L, Kelley RK, Siegel A, Balletti J, Harding JJ, Schwartz LH, **Goldberg RM**, Bertagnolli MM, Venook AP. *Phase III randomized study of sorafenib plus doxorubicin versus sorafenib in patients with advanced hepatocellular carcinoma (HCC): CALGB 80802 (Alliance)*. 2016 Gastrointestinal Cancers Symposium. Oral General Session 6: Hepatocellular Carcinoma Tumor Board (ARS). Abstract Number 192.
80. Le DT, Uram JN, Wang H, Kemberling H, Eyring A, Bartlett B, **Goldberg RM**, Crocenzi TS, Fisher GA, Lee JJ, Greten TF, Laheru D, Azad NS, Donehower RC, Lubner B, Koshiji M, Eshleman JR, Anders RA, Vogelstein B, Diaz LA. *PD-1 blockade in mismatch repair deficient non-colorectal gastrointestinal cancers*. 2016 Gastrointestinal Cancers Symposium. Oral Abstract Session: Cancers of the Pancreas, Small Bowel, and Hepatobiliary Tract. Abstract Number 195.

81. Ahn DH, Ahn C, Jain A, Mikhail S, Wu C S-Y, **Goldberg RM**, Ciombor KK, Noonan AM, Sadavartia P, Shroff RT, Javle MM, Chen JL, Bekaii-Saab TS. *Next Generation Sequencing (NGS) to reveal mutations in IDH1 and its effect on patient (pt) outcomes in advanced biliary tract cancer (aBTC) who received gemcitabine and cisplatin (GC)*. 2016 Gastrointestinal Cancers Symposium. Poster Session B: Cancers of the Pancreas, Small Bowel, and Hepatobiliary Tract. Abstract Number 287.
82. Bupathi M, Ahn DH, Ciombor KK, Wu, C S-Y, Mikhail S, **Goldberg RM**, Noonan AM, Stephens J, Reardon J, Hays JL, Bekaii-Saab TS. *Irinotecan and infusional 5-fluorouracil (mFOLFIRI) in patients with refractory advanced pancreas cancer (APC): A single institution experience*. 2016 Gastrointestinal Cancers Symposium. Poster Session B: Cancers of the Pancreas, Small Bowel, and Hepatobiliary Tract. Abstract Number 215.
83. Koenig KL, Burkart J, Mikhail S, Wu C S-Y, Noonan AM, **Goldberg RM**, Bekaii-Saab TS, Ciombor KK. *Therapeutic impact and timing of gastrointestinal malignancy genomic profiling: A single-institution experience*. 2016 Gastrointestinal Cancers Symposium. Poster Session C Board #E11.
84. O'Neil B, O'Reilly S, Kasbar S, Kim R, McDermott R, Moore D, Grogan W, Cohn A, Bekaii-Saab T, Ivanova A, Olowokure O, Fernando N, McCaffrey J, El-Rayes B, Horgan A, Ryan T, Sherrill G, Yacoub G, **Goldberg RM**, Sanoff H. *A multicenter, randomized, double-blinded phase II trial of FOLFIRI + regorafenib or placebo for patients with metastatic colorectal cancer who failed one prior line of oxaliplatin-containing therapy*. Ann Oncol, 27: Suppl 6, 464PD, 2016.
85. Grothey A, Falcone A, Humblet Y, Bouche O, Minner L, Adenis A, Tabernero J, Yoshino T, Lenz H-J, **Goldberg RM**, Huang L, Wagner A, Van Cutsem E. *Characteristics of patients (pts) with metastatic colorectal cancer (mCRC) treated with regorafenib (REG) who had progression-free survival (PFS) > 4 months (m): Subgroup analysis of the phase 3 CORRECT trial*. Ann Oncol 27:Suppl 6, 516P, 2016.
86. Sinicrope FA, Smyrk TC, Foster NR, Meyers JP, Thibodeau SN, **Goldberg RM**, Shi Q, Sargent DJ, Alberts SR. *Association of tumor infiltrating lymphocytes (TILs) with molecular subtype and prognosis in stage III colon cancers (CC) from a FOLFOX-based adjuvant chemotherapy trial*. J Clin Oncol 34, 2016 (suppl; abstr 3518)
87. Sinicrope FA, Shi Q, Allegra CJ, Smyrk TC, Thibodeau SN, **Goldberg RM**, Meyers JP, Yothers G, Sargent DJ, Alberts SR. *Molecular markers and survival after recurrence in stage III colon cancers from NCCTG N0147 and NSABP C-08 adjuvant chemotherapy trials*. J Clin Oncol 34, 2016 (suppl; abstr 3600).
88. Wu C S-Y, Shi Q, Tomsic J, Meyers JP, Frankel WL, Timmers CD, Saltz L, Alberts SR, Niedzwiecki D, Sargent DJ, Hampel H, De La Chapelle A, **Goldberg RM**. *Deletions in HSP110 T17 and patient prognosis in stage III microsatellite instable (MSI) colon cancers: Findings from CALGB 89803 and NCCTG N0147*. J Clin Oncol 34, 2016 (suppl; abstr e15148).
89. Le DT, Uram JN, Wang H, Bartlett B, Kemberling H, Eyring A, Azad NS, Laheru D, Donehower RC, Crocenzi TS, **Goldberg RM**, Fisher GA, Lee JJ, Greten TF, Koshiji M, Kang S-M P, Anders RA, Eshleman JR, Vogelstein B, Diaz LA. *Programmed death-1 blockade in mismatch repair deficient colorectal cancer*. J Clin Oncol 34, 2016 (suppl; abstr 103)
90. Abou-Alfa GK, Niedzwieski D, Knox JJ, Kaubisch A, Posey J, Benjamin R, Tan BR, Petr Kavan P, Rakesh Goel R, Lammers PE, Bekaii-Saab TS, Tam VC, Rajdev L, Kelley RK, Siegel AB, Balletti J, Harding JJ, Schwartz LH, **Goldberg RM**, Bertagnolli MM, Venook AP. *Phase III randomized study of sorafenib plus doxorubicin versus sorafenib in patients with advanced*

hepatocellular carcinoma (HCC): CALGB 80802 (Alliance). *J Clin Oncol* 34, 2016 (suppl; abstr 4003).

91. Venook AP, Niedzwiecki D, Innocenti F, Fruth B, Greene C, O'Neil BH, Shaw JE, Atkins JN, Horvath LE, Polite BN, Meyerhardt JA, O'Reilly EM, Goldberg RM, Hochster HS, Blanke CD, Schilsky RL, Mayer RJ, Bertagnolli MM, Lenz H-J. *Impact of primary (1°) tumor location on overall survival (OS) and progression-free survival (PFS) in patients (pts) with metastatic colorectal cancer (mCRC): Analysis of CALGB/SWOG 80405 (Alliance).* *J Clin Oncol* 34, 2016 (suppl; abstr 3504).
92. Le DT, Uram JN, Wang H, Kemberling H, Eyring A, Bartlett B, **Goldberg R**, Crocenzi TS, Fisher GA, Lee JJ, Greten TF, Laheru D, Azad NS, Donehower RC, Lubner B, Koshiji M, Eshleman JR, Anders RA, Vogelstein B, Diaz LA; *PD-1 blockade in mismatch repair deficient non-colorectal gastrointestinal cancers.* *J Clin Oncol* 34, 2016 (suppl 4S; abstr 195)s
93. Krishna K, Blazer MA, Wei L, Ahn DH, Sing-Ying Wu C, Ciombor KK, Mikhail S, Noonan AM, **Goldberg RM**, Bekaii-Saab TS. *Modified gemcitabine and nab-paclitaxel in patients with metastatic pancreatic cancer (MPC): A single-institution experience.* *J Clin Oncol* 33, 2015 (suppl 3; abstr 366).
94. Lee AM, Shi Q, Alberts SR, Sargent DJ, Sinicrope FA, Berenberg JL, **Goldberg RM**, Diasio RB. HapB3 and the deep intronic variant c.1129-5923 C>G of the dihydropyrimidine dehydrogenase gene (DPYD) to predict toxicity in stage III colon cancer (CC) patients (pts) (NCCTG Alliance N0147). *J Clin Oncol* 33, 2015 (suppl 3; abstr 508).
95. Coart E, Saad ED, Shi Q, Willemien Sommeijer D, Zalberg JR, Maughan T, **Goldberg RM**, Schmoll H-J, Punt CJA, Van Cutsem E, Douillard J-Y, Hoff PM, Tebbutt NC, Fuchs CS, Falcone A, Tournigand C, de Gramont A, Sargent DJ, Burzykowski T, Buyse ME, ARCAD Group. *Trial-level association between response-based endpoints (RBEs) and progression-free (PFS)/overall survival (OS) in first-line therapy for metastatic colorectal cancer (mCRC) in the ARCAD database.* *J Clin Oncol* 33, 2015 (suppl 3; abstr 666).
96. Grothey A, Falcone A, Humblet Y, Bouche O, Laurent Mineur, Adenis A, Tabernero J, Yoshino T, Lenz H-J, **Goldberg RM**, Xu L, Wagner A, Eric Van Cutsem E. *Subgroup analysis of patients with metastatic colorectal cancer (mCRC) treated with regorafenib (REG) in the CORRECT trial who had progression-free survival (PFS) longer than 4 months.* *J Clin Oncol* 33, 2015 (suppl 3; abstr 710).
97. Sinicrope Fa, Shi Q, Thibodeau SN, **Goldberg RM**, Sargent DJ, Alberts SR. *Molecular subtyping of colon cancers and distinct prognostic groups (NCCTG N0147) (Alliance).* *J Clin Oncol* 32:5s, 2014 (suppl; abstr 3512). Poster discussion N0147.
98. Yoon HH, Shi Q, Alberts SR, **Goldberg RM**, Thibodeau SN, Sargent DJ, Sinicrope FA. *Racial differences in KRAS/BRAF mutation rates and survival in colon cancer (NCCTG N0147 [Alliance]).* *J Clin Oncol* 32:5s, 2014 (suppl; abstr 3536). Poster N0147.
99. Sinicrope FA, Yoon HH, Mahoney MR, Nelson GD, Thibodeau SN, **Goldberg RM**, Sargent DJ, Alberts SR. Overall survival result and outcomes by KRAS, BRAF, and DNA mismatch repair in relation to primary tumor site in colon cancers from a randomized trial of adjuvant chemotherapy: NCCTG (Alliance) N0147. *J Clin Oncol* 32:5s, 2014 (suppl; abstr 3525). Poster discussion N0147.
100. Venook A, Niedzwiecki D, Lenz H, Mahoney M, Innocenti F, O'Neil B, Hochster H, Goldberg R, Schilsky R, Mayer R, Polite B, Atkins J, Shaw JE, Bertagnolli M, Blanke C. LBA10 CALGB/SWOG 80405: Analysis Of Patients Undergoing Surgery As Part Of Treatment Strategy *Annals of Oncology*, Volume 25, Issue suppl 4, September 2014.

101. Venook AP, Niedzwiecki D, Lenz H-J, Innocenti F, Mahoney MR, O'Neil BH, Shaw JE, Polite BN, Hochster HS, Atkins JN, **Goldberg RM**, Mayer RJ, Schilsky RL, Bertagnolli MM, Blanke CD, CALGB/SWOG 80405. *Phase III trial of irinotecan/5-FU/leucovorin (FOLFIRI) or oxaliplatin/5-FU/leucovorin (mFOLFOX6) with bevacizumab (BV) or cetuximab (CET) for patients (pts) with KRAS wild-type (wt) untreated metastatic adenocarcinoma of the colon or rectum (mCRC)*. J Clin Oncol 32:5s 2014 (suppl; abstr LBA3) 80405 Plenary presentation.
102. Renfro LA, Loupakakis F, Adams RA, Seymour MT, Schmoll H-J, Douillard J-Y, Hurwitz H, FRuchs CS, Diaz-Rubio E, Porschen R, Tournigand C, Falcone A, Tebbutt NC, Hecht JR, Punt CJA, **Goldberg RM**, Saltz L, de Gramont A, Sargent DJ, Lenz H-J. *Body mass index (BMI) as prognostic in metastatic colorectal cancer (mCRC): A pooled analysis of 21 first-line trials in the ARCAD database*. J Clin Oncol 32:5s, 2014 (suppl; abstr 3537) Poster, N9741.
103. Sommeijer DJ, Shi Q, Saad ED, Coart E, Buyse ME, Burzykowski T, Meyers JP, Maughan T, Adams RA, Seymour MT, Saltz L, **Goldberg RM**, Douillard J-Y, Schmoll H-J, Punt CJA, Tournigand C, Chibaudel B, de Gramont A, Sargent DJ, Zalcborg JR, for the ARCAD group. *Early predictors of prolonged overall survival (OS) in patients (pts) on first-line chemotherapy (CT) for metastatic colorectal cancer (mCRC): An ARCAD study with individual patient data (IPD) on 10,962 pts*. J Clin Oncol 32:5s, 2014 (suppl; abstr 3538). Poster discussion N9741.
104. Haraldsdottir S, Hampel H, Frankel W, Wu C, Pan X, Bekaii-Saab T, **Goldberg RM**. *Effect of genetic counseling on detection of Lynch syndrome (LS) in colorectal cancer (CRC) patients (pts)*. Presented at 2014 Gastrointestinal Cancers Symposium, San Francisco, CA, January, 2014. Published in J Clin Oncol 32, 2014 (suppl 3; abstr 419).
105. Haraldsdottir S, Wu C, Hampel H, Frankel W, Pan X, Bekaii-Saab T, **Goldberg RM**. *Universal screening for Lynch syndrome (LS) in colorectal cancer (CRC) and survival*. Presented at 2014 Gastrointestinal Cancers Symposium, San Francisco, CA, January, 2014. Published in J Clin Oncol 32, 2014 (suppl 3; abstr 415).
106. Niedzwiecki D, Frankel W, Venook AP, Ye X, Friedman PN, **Goldberg RM**, Mayer RJ, Colacchio TA, Kennedy RD, Davison T, O'Brien EJ, Mulligan J, Johnston PG, Harkin DP, Schilsky RL, Bertagnolli MM, Innocenti F. *Association between ColDx assay result and recurrence-free interval in stage II colon cancer patients on CALGB (Alliance) 9581*. Presented at 2014 Gastrointestinal Cancers Symposium, San Francisco, CA, January, 2014. Published in J Clin Oncol 32, 2014 (suppl 3; abstr 455).
107. Blazer MA, Wu C, **Goldberg RM**, Phillips GS, Schmidt CR, Muscarella P, El-Dika SS, Walker JP, Krishna SG, Groce JR, Wuthrick EJ, Williams TM, Efries D, Smith YT, Mathey K, Wagner M, Reardon J, Ellison EC, Bloomston M, Bekaii-Saab TS. *Tolerability and efficacy of modified FOLFIRINOX (mFOLFIRINOX) in patients with borderline-resectable pancreatic cancer (BRPC) and locally advanced unresectable pancreatic cancer (LAURPC)*. Presented at 2014 Gastrointestinal Cancers Symposium, San Francisco, CA, January, 2014. Published in J Clin Oncol 32, 2014 (suppl 3; abstr 275).
108. **Goldberg RM**. Clinical conundrum: to treat or not to treat a patient with stage II pMMR or dMMR colon cancer? - Observation. Presented at 2014 Gastrointestinal Cancers Symposium, San Francisco, CA, January, 2014.
109. **Goldberg RM**. *Jumpstarting your career: how to give a talk and write a paper*. Presented at 2014 Gastrointestinal Cancers Symposium, San Francisco, CA, January, 2014.
110. **Goldberg RM**. *Clinical trials outcomes in patients from different populations*. In: Program and Proceedings of the Sixth AACR Conference on The Science of Cancer Health

Disparities in Racial/Ethnic Minorities and the Medically Underserved, Pg 80-81. 2013 December 6-9; Atlanta, GA. Plenary Session 2.

111. **Goldberg, RM.** *Clinical trials outcomes in patients from different populations.* In: Program and Proceedings of the Sixth AACR Conference on The Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved, Pg 80-81. 2013 December 6-9; Atlanta, GA. Plenary Session 2.
112. Vogel A, van Cutsem E, Sobrero A, Siena S, Falcone A, Ychou M, Humblet Y, Buchet O, Mineur L, Barone C, Adenis A, Tabernero J, Yoshino T, Lenz HJ, **Goldberg RM**, Cihon F, Wagner A, Grothey A. *Regorafenib in progressive metastatic colorectal cancer (mCRC): Analysis of age subgroups in the phase III CORRECT trial.* Onkologie 36: Oct 2013 (suppl 7, pages 69-70).
113. Karthaus M, Lenz HF, van Cutsem E, Sobrero A, Siena S, Falcone A, Ychou M, Humblet Y, Bouche O, Mineur L, Barone C, Adenis A, Tabernero J, Yoshino T, **Goldberg RM**, Cihon F, Wagner A, Grothey A. *Analysis of plasma protein biomarkers from the CORRECT phase III study of regorafenib for metastatic colorectal cancer.* Onkologie 36: Oct 2013 (suppl 7, page 70).
114. Hofheinz R, Grothey A, Sobrero AF, Siena S, Falcone A, Ychou M, Humblet Y, Bouche O, Mineur L, Barone C, Adenis A, Tabernero J, Yoshino T, Lenz HJ, **Goldberg RM**, Wagner A, Cihon F, van Cutsem E. *Time course of regorafenib-associated adverse events in the phase III CORRECT study.* Onkologie 36: Oct 2013 (suppl 7, pages 117-118).
115. Karthaus M, Jeffers M, van Cutsem E, Sobrero AF, Siena S, Falcone A, Ychou M, Humblet Y, Bouche O, Mineur L, Barone C, Adenis A, Tabernero J, Yoshino T, Lenz HJ, **Goldberg RM**, Wagner A, Grothey A. *Mutational analysis of biomarker samples from the CORRECT study: correlating mutation status with clinical response to regorafenib.* Onkologie 36: Oct 2013 (suppl 7, page 117).
116. Lieu C, Renfro L, De Gramont A, Maughan TS, Seymour MT, Saltz L, **Goldberg RM**, Sargent D, Eckhardt SG, Eng C. *The impact of young age on survival in patients with metastatic colorectal cancer: Analysis from the ARCAD Clinical Trials Program.* European Journal of Cancer 49: Sep 2013 (suppl 2, page S483, abstr 2158).
117. Haraldsdottir S, Wu CS-Y, Pan XJ, Hampel H, **Goldberg RM**, Bekaii-Saab TS. *Differences in outcome between colorectal cancer (CRC) patients (pts) with Lynch syndrome (LS) versus MLH1 hypermethylation (MLH1 HM).* In: Proceedings of the 2013 ASCO Annual Meeting. 49th Annual Meeting. 2013 May 31-June 4; Chicago, IL. J Clin Oncol 31, 2013 (suppl; abstr 1556). General Poster Session.
118. Patel JN, Deal AM, O'Neil BH, Ibrahim J, Sherrill GB, Davies JM, Bernard SA, **Goldberg RM**, Olajide OA, Atluri P, Inzerillo JJ, McLeod HL, Walko CM. *Application of pharmacokinetic (PK)-guided 5-fluorouracil (FU) in clinical practice.* In: Proceedings of the 2013 ASCO Annual Meeting. 49th Annual Meeting. 2013 May 31-June 4; Chicago, IL. J Clin Oncol 31, 2013 (suppl; abstr 2595). General Poster Session.
119. Lee A, Shi Q, Pavey ES, Sargent DJ, Alberts SR, Sinicrope FA, Berenberg J, **Goldberg RM**, Diasio RB. *Validation of DPYD variants DPYD*2A, I560S, and D949V as predictors of 5-fluorouracil (5-FU)-related toxicity in stage III colon cancer (CC) patients from adjuvant trial NCCTG N0147.* In: Proceedings of the 2013 ASCO Annual Meeting. 49th Annual Meeting. 2013 May 31-June 4; Chicago, IL. J Clin Oncol 31, 2013 (suppl; abstr 3510). Poster Discussion Session.
120. Lenz H-J, Van Cutsem E, Sobrero AF, Siena S, Falcone A, Ychou M, Humblet Y, Bouche O, Mineur L, Barone C, Adenis A, Tabernero J, Yoshino T, **Goldberg RM**, Sargent DJ, Cihon F, Wagner A, Laurent D, Jeffers M, Grothey A. *Analysis of plasma protein biomarkers from the*

CORRECT phase III study of regorafenib for metastatic colorectal cancer. In: Proceedings of the 2013 ASCO Annual Meeting. 49th Annual Meeting. 2013 May 31-June 4; Chicago, IL. J Clin Oncol 31, 2013 (suppl; abstr 3514). Poster Discussion Session.

121. Sommeijer DW, Shi Q, Meyers JP, Sjoquist KM, Hoff PM, Seymour MT, Cassidy J, **Goldberg RM**, Douillard J-Y, Hecht JR, Hurwitz H, Tournigand C, Tebbutt NC, Aranda E, Souglakos J, Kabbinavar FF, Chibaudel B, De Gramont A, Sargent DJ, Zalcberg JR, for the ARCAD Group. *Prognostic value of early objective tumor response (EOTR) to first-line systemic therapy in metastatic colorectal cancer (mCRC): Individual patient data (IPD) meta-analysis of randomized trials from the ARCAD database.* In: Proceedings of the 2013 ASCO Annual Meeting. 49th Annual Meeting. 2013 May 31-June 4; Chicago, IL. J Clin Oncol 31, 2013 (suppl; abstr 3520). Poster Discussion Session.
122. Sinicrope FA, Mahoney MR, Smyrk TC, Thibodeau SN, **Goldberg RM**, Nelson GD, Sargent DF, Alberts SR. Prognostic impact of KRAS and BRAF^{V600E} mutations stratified by tumor site in resected stage III colon cancer patients treated with adjuvant mFOLFOX6 with or without cetuximab: NCCTG N0147 (Alliance). In: Proceedings of the 2013 ASCO Annual Meeting. 49th Annual Meeting. 2013 May 31-June 4; Chicago, IL. J Clin Oncol 31, 2013 (suppl; abstr 3523). Poster Discussion Session.
123. Shi Q, De Gramont A, Buyse ME, Grothey A, Schmoll H-J, Seymour MT, Adams RA, Saltz L, **Goldberg RM**, Punt CJA, Douillard J-Y, Hecht JR, Hurwitz H, Diaz-Rubio E, Porschen R, Tebbutt NC, Fuchs CS, Souglakos J, Falcone A, Sargent DJ, for the ARCAD Group. *Individual patient data (IPD) analysis of progression-free survival (PFS) versus overall survival (OS) as an endpoint for metastatic colorectal cancer (mCRC) in modern trials: Findings from the 16,700 patients (pts) ARCAD database.* In: Proceedings of the 2013 ASCO Annual Meeting. 49th Annual Meeting. 2013 May 31-June 4; Chicago, IL. J Clin Oncol 31, 2013 (suppl; abstr 3533). Poster Discussion Session.
124. Van Cutsem E, Sobrero A, Siena S, Falcone A, Ychou M, Humblet Y, Bouche O, Mineur L, Barone C, Adenis A, Argilés G, Yoshino T, Lenz H-J, **Goldberg RM**, Sargent DJ, Cihon F, Wagner A, Laurent D, Cupti L, Grothey A. *Regorafenib (REG) in progressive metastatic colorectal cancer (mCRC): Analysis of age subgroups in the phase III CORRECT trial.* In: Proceedings of the 2013 ASCO Annual Meeting. 49th Annual Meeting. 2013 May 31-June 4; Chicago, IL. J Clin Oncol 31, 2013 (suppl; abstr 3636). General Poster Session.
125. Grothey A, Sobrero AF, Siena S, Falcone A, Ychou M, Humblet Y, Bouche O, Mineur L, Barone C, Adenis A, Argiles G, Yoshino T, Lenz H-J, **Goldberg RM**, Sargent DJ, Cihon F, Wagner A, Cupit L, Laurent D, Van Cutsem E. *Time profile of adverse events (AEs) from regorafenib (REG) treatment for metastatic colorectal cancer (mCRC) in the phase III CORRECT study.* In: Proceedings of the 2013 ASCO Annual Meeting. 49th Annual Meeting. 2013 May 31-June 4; Chicago, IL. J Clin Oncol 31, 2013 (suppl; abstr 3637). General Poster Session.
126. Wu CS-Y, Wei L, Glass K, Wilson J, Abdel-Misih S, Williams TM, Martin LK, Haraldsdottir S, Harzman A, Husain S, Schmidt CR, Arnold M, **Goldberg RM**, Bekaii-Saab TB. *Effect of postoperative chemotherapy (CT) on survival in patients (pts) with resected rectal cancer who received neoadjuvant therapy.* In: Proceedings of the 2013 ASCO Annual Meeting. 49th Annual Meeting. 2013 May 31-June 4; Chicago, IL. J Clin Oncol 31, 2013 (suppl; abstr e14535). (This abstract not presented at 2013 ASCO Annual Meeting but has been published in conjunction with the meeting.)
127. Haraldsdottir S, Hampel H, Wei L, Wu C S-Y, Bekaii-Saab TS, De La Chapelle A, **Goldberg RM**. *Prostate cancer incidence in males with Lynch syndrome.* In: Proceedings of the

- 2013 Gastrointestinal Cancers Symposium. 2013 January 24-26; San Francisco, CA. *J Clin Oncol* 30: 2012 (suppl 34; abstr 366). General Poster Session.
128. Jeffers M, Van Cutsem E, Sobrero AF, Siena S, Falcone A, Ychou M, Humblet Y, Bouche O, Mineur L, Barone C, Adenis A, Tabernero J, Yoshino T, Lenz H-J, **Goldberg RM**, Sargent DJ, Cihon F, Wagner A, Laurent D, Grothey A. *Mutational analysis of biomarker samples from the CORRECT study: Correlating mutation status with clinical response to regorafenib*. In: Proceedings of the 2013 Gastrointestinal Cancers Symposium. 2013 January 24-26; San Francisco, CA. *J Clin Oncol* 30: 2012 (suppl 34; abstr 381). General Poster Session.
 129. Grothey A, Van Cutsem E, Sobrero AF, Siena S, Falcone A, Ychou M, Humblet Y, Bouche O, Mineur L, Barone C, Adenis A, Tabernero J, Yoshino T, Lenz H-J, **Goldberg RM**, Sargent DJ, Cihon F, Wagner A, Laurent D, Cupit L. *Time course of regorafenib-associated adverse events in the phase III CORRECT study*. In: Proceedings of the 2013 Gastrointestinal Cancers Symposium. 2013 January 24-26; San Francisco, CA. *J Clin Oncol* 30: 2012 (suppl 34; abstr 467). General Poster Session.
 130. Wu CS-Y, Wei L, Glass K, Wilson J, Abdel-Misih S, Martin LK, Haraldsdottir S, Harzman A, Husain S, Schmidt CR, Arnold M, **Goldberg RM**, Bekaii-Saab TS. *Survival differences in patients (pts) with resected rectal cancer who received neoadjuvant therapy with or without postoperative chemotherapy (CT)*. In: Proceedings of the 2013 Gastrointestinal Cancers Symposium. 2013 January 24-26; San Francisco, CA. *J Clin Oncol* 30: 2012 (suppl 34; abstr 518). General Poster Session.
 131. **Goldberg RM**, Garrett CR, Berkowitz NC, Bekaii-Saab TS, Ryan, T, Fisher GA, Clive S, Kavan P, Shmueli E, Buchbinder A. *Phase II study of EZN-2208 (PEG-SN38) with or without cetuximab in patients with metastatic colorectal cancer (CRC)*. *J Clin Oncol* 30. 2012. (suppl 4; abstr 448). Poster Presentation.
 132. Atreya CE, Warren RS, Niedzwiecki D, Mayer RJ, **Goldberg RM**, Compton CC, Zuraek M, Bergsland EK, Ye, C, Weinberg VK, Bertagnolli MM. *A novel interaction of genotype, gender, and adjuvant treatment in survival after resection of stage III colon cancer: Results of CALGB 89803*. *J Clin Oncol* 30. 2012. (suppl 4; abstr 452). Poster Presentation.
 133. Van Cutsem E, Sobrero AF, Siena S, Falcone A, Ychou M, Humblet Y, Bouche O, Mineur L, Barone C, Adenis A, Tabernero J, Yoshino T, Lenz H, **Goldberg RM**, Sargent DJ, Cihon F, Wagner A, Laurent D, Grothey A. *Phase III CORRECT trial of regorafenib in metastatic colorectal cancer (mCRC)*. *J Clin Oncol* 30. 2012 (suppl; abstr 3502). Poster Presentation.
 134. Sinicrope FA, Mahoney M, Smyrk TC, Thibodeau SN, **Goldberg RM**, Nelson GD, Sargent DJ, Alberts SR. *Prognostic impact of BRAF and KRAS mutations and their relationship to DNA mismatch repair (MMR) status in 2,686 stage III colon cancer patients (pts) treated in a phase III study of adjuvant FOLFOX with or without cetuximab: NCCTG N0147*. *J Clin Oncol* 30. 2012 (suppl; abstr 3514). Poster Presentation.
 135. Warren RS, Chloé EA, Niedzwiecki D, Mayer RJ, **Goldberg RM**, Compton CC, Weinberg VK, Bertagnolli MM. *A novel interaction of genotype, gender, and adjuvant treatment in survival after resection of stage III colon cancer: Results of CALGB 89803*. *J Clin Oncol* 30. 2012 (suppl; abstr 3517). Poster Presentation.
 136. O'Neil BH, Cainap C, Van Cutsem E, Gorbunova VA, Karapetis CS, Berlin J, **Goldberg RM**, Qin Q, Qian J, Ricker JL, McKee MD, Carlson DM, Kim TW. *Randomized phase II open-label study of Mfolfox6 in combination with linifanib or bevacizumab for metastatic colorectal cancer*. *J Clin Oncol* 30. 2012. (suppl; abstr 3532). Poster Presentation.

137. Sloan JA, Qian S, Lee A, Diasio RB, Pavey ES, Sargent DJ, **Goldberg RM**, Sinicrope FA, Mahoney MR, Alberts SR. Relationship between genetic markers and quality of life (QOL) in stage III colon cancer (CC) patients (pts) prior to adjuvant treatment (N0147). J Clin Oncol 30. 2012. (suppl; abstr 3617). Poster Presentation.
138. Grothey A, Heun JM, Branda M, **Goldberg RM**, Sargent DJ. *New lesions versus growth of existing disease: Does it impact prognosis?* J Clin Oncol 29:15s, 2011 (suppl; abstr 2579). Poster presentation.
139. Venook AP, Niedzwiecki D, Lopatin M, Lee M, Friedman PN, Frankel W, Clark-Langone K, Yoshizawa C, Millward C, Shak S, **Goldberg RM**, Mahmoud NN, Schilsky RL, Bertagnoli MM. *Validation of a 12-gene colon cancer recurrence score (RS) in patients (pts) with stage II colon cancer (CC) from CALGB 9581.* J Clin Oncol 29:15s, 2011 (suppl; abstr 3518). Poster Discussion.
140. Huang J, Sargent DJ, Mahoney MR, Shields AF, Chan E, **Goldberg RM**, Gill S, Kahlenberg MS, Quesenberry JT, Smyrk TC, Grothey A, Sinicrope F, Nair SG, Alberts SR. *Pilot experience with adjuvant FOLFIRI with or without cetuximab in patients with resected stage III colon cancer: NCCTG Intergroup N0147.* J Clin Oncol 29:15s, 2011 (suppl; abstr 3522). Poster Discussion.
141. Mahoney MR, Sloan JA, Hubbard JM, Liu H, Shields AF, Chan E, **Goldberg RM**, Gill S, Kahlenberg MS, Nair SG, Sargent DJ, Alberts SR. *Quality of life (QOL) for patients treated with FOLFOX with or without cetuximab (Cmab) following complete resection of colorectal cancer (CRC): Results from North Central Cancer Treatment Group (NCCTG) phase III trial N0147.* J Clin Oncol 29:15s, 2011 (suppl; abstr 3541). Poster.
142. Franko J, Shi Q, Goldman CD, Pockaj BA, Nelson GD, **Goldberg RM**, Pitot HC, Grothey A, Alberts SR, Sargent DJ. Treatment of colorectal peritoneal carcinomatosis with systemic chemotherapy: A pooled analysis of NCCTG's phase III trials N9741 and N9841. J Clin Oncol 29:15s, 2011 (suppl; abstr 3571). Poster.
143. Alberts SR, Thibodeau SN, Sargent DJ, Mahoney MR, Sinicrope F, Shields AF, Chan E, **Goldberg RM**, Gill S, Kahlenberg MS, Quesenberry JT, Smyrk TC, Grothey A, Nair SG. *Influence of KRAS and BRAF mutational status and rash on disease-free survival (DFS) in patients with resected stage III colon cancer receiving cetuximab (Cmab): Results from NCCTG N0147.* J Clin Oncol 29:15s, 2011 (suppl; abstr 3607). Poster.
144. Sugihara K, Ohtsu A, Shimada Y, Mizunuma N, Lee P, de Gramont A, **Goldberg RM**, Rothenberg ML, Andre T, Brienza S. Allergic reactions (ARs) induced by FOLFOX4 treatment in colorectal cancer: A comparative analysis between Asian and Western patients (pts). J Clin Oncol 29:15s, 2011 (suppl; abstr 3623). Poster presentation.
145. Fuchs CS, Tepper JE, Niedzwiecki D, Hollis D, Mamon HJ, Swanson R, Haller DG, Dragovich T, Alberts SR, Bjarnason GA, Willett CG, Enzinger PC, **Goldberg RM**, Venook AP, Mayer RJ. *Postoperative adjuvant chemoradiation for gastric or gastroesophageal junction (GEJ) adenocarcinoma using epirubicin, cisplatin, and infusional (CI) 5-FU (ECF) before and after CI 5-FU and radiotherapy (CRT) compared with bolus 5-FU/LV before and after CRT: Intergroup trial CALGB 80101.* J Clin Oncol 29:15s, 2011 (suppl; abstr 4003). Podium Presentation.
146. Sloan JA, Mahoney MR, Sargent DJ, Hubbard JM, Liu H, Basch EM, Shields AF, Chan E, **Goldberg RM**, Gill S, Kahlenberg MS, Alberts SR. *Was it worth it (WIWI)? Patient satisfaction with clinical trial participation: Results from North Central Cancer Treatment Group (NCCTG) phase III trial N0147.* J Clin Oncol 29:15s, 2011 (suppl; abstr 6122). Poster Presentation.

147. Nixon AB, Pang H, Starr M, Hollis D, Friedman PN, Bertagnolli MM, Kindler HL, **Goldberg RM**, Venook AP, Hurwitz H. *Prognostic and predictive blood-based biomarkers in patients with advanced pancreatic cancer: Results from CALGB 80303*. J Clin Oncol 29:15s, 2011 (suppl; abstr 10508). Podium Presentation.
148. Van Loon K, Wigler D, Niedzwiecki D, Hollis D, Venook AP, Blanke CD, Saltz L, **Goldberg RM**, Fuchs CS, Meyerhardt JA. *A comparison of dietary and lifestyle habits among stage III and metastatic colorectal cancer patients*. J Clin Oncol 29:15s, 2011 (suppl; abstr e14026).
149. Sinicrope F, Foster NR, Yothers GA, Benson AB, Haller DG, Seitz J, Labianca R, Benedetti J, **Goldberg RM**, de Gramont A, Sargent DJ. *Body mass index (BMI) as a prognostic and predictive factor in stage II/III colon cancer: An analysis of the ACCENT database*. J Clin Oncol 29:15s, 2011 (suppl; abstr e21126).
150. O'Reilly EM; Niedzwiecki D, Hall M, Hollis D, Bekaii-Saab T, Pluart T, Douglas K, Abou-Alfa GK, Kindler HL, Schilsky RL, **Goldberg RM**; Cancer and Leukemia Group B. *A Cancer and Leukemia Group B phase II study of sunitinib malate in patients with previously treated metastatic pancreatic adenocarcinoma (CALGB 80603)*. Oncologist. 15(12), 2010; 1310-1319.
151. Sugihara K, Ohtsu A, Shimada Y, Mizunuma N, Lee P, De Gramont A, **Goldberg RM**, Rothenberg ML, Andre T, Brienza S. *Analysis of Neurosensory adverse events (NSAES) induced by Folfex4 treatment in advanced/recurrent or adjuvant colorectal cancer in Asian and western patients (PTS)*. Annals of Oncology 21: Oct 2010 (suppl 8, page 202).
152. Raftery LL, Tepper JE, **Goldberg RM**, Blackstock AW, Aklilu M, Bernard SA, Sanoff HK, Ivanova B, O'Neil BH. *A phase I study of weekly oxaliplatin (OX) and gemcitabine (Gem) during radiotherapy (RT) for unresectable pancreatic or biliary carcinoma*. Proceedings 2010 Gastrointestinal Cancer Symposium. Abstract 220. Poster.
153. Alberts SR, Sargent DJ, Smyrk TC, Shields AF, Chan E, **Goldberg RM**, Gill S, Kahlenberg MS, Thibodeau SN, Nair S; Adjuvant mFOLFOX6 with or without cetuximab (Cmab) in KRAS wild-type (WT) patients (pts) with resected stage III colon cancer (CC): Results from NCCTG Intergroup phase III Trial N0147. J Clin Oncol 28:7s, 2010 (suppl; abstr CRA3507). Podium presentation.
154. **Goldberg RM**, Sargent DJ, Thibodeau SN, Mahoney MR, Shields AF, Chan E, Gill S, Kahlenberg MS, Nair S, Alberts SR; Adjuvant mFOLFOX6 plus or minus cetuximab (Cmab) in patients (pts) with KRAS mutant (m) resected stage III colon cancer (CC): NCCTG Intergroup Phase III Trial N0147. J Clin Oncol 28:7s, 2010 (suppl; abstr 3508), Podium presentation.
155. Blanke CD, Bot BM, Thomas DM, Bleyer A, Kohne C, Seymour MT, de Gramont A, **Goldberg RM**, Sargent DJ, LIVESTRONG Young Adult Alliance (LSYAA). *Impact of young (Y) age on efficacy and safety in advanced colorectal cancer (aCRC): A pooled analysis examining 6,286 patients (pts) from nine first-line phase III chemotherapy (CT) trials*. J Clin Oncol 28:7s, 2010 (suppl; abstr 3520). Poster/discussion presentation.
156. Sugihara K, Ohtsu A, Shimada Y, Mizunuma N, Lee P, de Gramont A, **Goldberg RM**, Rothenberg ML, Andre T, Brienza S. *Safety analysis of FOLFOX4 treatment in advanced/recurrent or adjuvant colorectal cancer in Asian and Western patients*. J Clin Oncol 28:7s, 2010 (suppl; abstr 3611). Poster presentation.
157. Enzinger PC, Burtness B, Hollis D, Niedzwiecki D, Ilson D, Benson AB, Mayer RJ, **Goldberg RM**. CALGB 80403/ECOG 1206: A randomized phase II study of three standard

- chemotherapy regimens (ECF, IC, FOLFOX) plus cetuximab in metastatic esophageal and GE junction cancer. *J Clin Oncol* 28:7s, 2010 (suppl; abstr 4006). Podium presentation.
158. Davies JM, Raftery LL, Sanoff HK, Triglianos T, Keller K, Ivanova A, Bernard SA, **Goldberg RM**, Dees EC, O'Neil BH. *Phase I study of the combination of everolimus (RAD001) with panitumumab in patients with refractory solid malignancies*. *J Clin Oncol* 28, 2010 (suppl; abstr e13085).
 159. Turja JH, Grothey A, Sargent DJ, Szydlo DW, Zhao X, Campbell ME, **Goldberg RM**, Sloan JA: Use of baseline quality of life (QOL) as compared to performance status (PS) as prognostic factors for overall survival (OS) in patients with metastatic colorectal cancer (CRC). *J Clin Oncol* 26, 15S, 182S. Poster discussion.
 160. O'Neil BH, Bernard SA, **Goldberg RM**, Moore D, Garcia R, Marroquin C, Morse MA, Woods L, Sanoff HK: *Phase II study of oxaliplatin, capecitabine and cetuximab in advanced hepatocellular carcinoma*. *J Clin Oncol* 26, 15S, 239S. Poster.
 161. Sanoff HK, Campbell ME, Pitot HC, **Goldberg RM**, Sargent DJ: Risk stratified analysis improves prediction of treatment (Rx) benefit over subgroup analysis: Findings from Intergroup N9741. *J Clin Oncol* 26, 15S, 182S. Poster discussion.
 162. Sloan JA, Grothey A, Green E, Zhao X, Campbell M, Szydlo D, Sargent DJ, **Goldberg RM**: *Tumor burden is not related to quality of life in patients with metastatic colorectal cancer*. Mayo Clinic. *J Clin Oncol* 26, 15S, 182S. Poster discussion.
 163. Bertagnolli MM, Niedzwiecki D, Hall M, Jewell SD, Mayer RJ, **Goldberg RM**, Colacchio TA, Warren RS, Redston M: Presence of 18q loss of heterozygosity (LOH) and disease-free and overall survival in stage II colon cancer: CALGB Protocol 9581. *J Clin Oncol* (Meeting Abstracts) May 2009, 27:15s, (suppl; abstr 4012). Poster Discussion.
 164. Meyerhardt JA, Jackson McCleary N, Niedzwiecki D, Hollis D, Venook A, Mayer R, **Goldberg R**: Impact of age and comorbidities on treatment effect, tolerance, and toxicity in metastatic colorectal cancer (mCRC) patients treated on CALGB 80203. *J Clin Oncol* (Meeting Abstracts) May 2009, 27:15s, (suppl; abstr 4038). Poster presentation.
 165. Schrag D, Naughton M, Kesselheim A, Archer L, Niedzwiedcki D, Romanus D, **Goldberg R**, Venook A: Cancer and Leukemia Group B. Clinical trial participants' strategies for coping with prescription drug costs: A companion study to CALGB 80405. *J Clin Oncol* 27:15s, 2009 (suppl; abstr 9503). Podium presentation.
 166. Meyers MO, Hollis DR, Mayer RJ, **Goldberg RM**, Benson AB, Cummings B, Gunderson LL, Martenson JA, Macdonald JS, O'Connell M, Tepper JE. *Ratio of Metastatic to Examined Lymph Nodes is Predictive of Local Recurrence in Rectal Cancer: Analysis of Data From Intergroup Trial 0114*. *Annals of Surgical Oncology* 16: Feb 2009 (suppl 1, page 90).
 167. McLeod HL, Owzar K, Kroetz D, Innocenti F, Das S, Friedman P, Giacomini K, **Goldberg R**, Venook A, Ratain M: *Cellular transporter pharmacogenetics in metastatic colorectal cancer: initial analysis of C80203*. *J Clin Oncol* (Meeting Abstracts) May 2008, 26:15S: 157S. Abstract 3513. Podium presentation.
 168. Ocean A, Niedzwiecki D, Lee J, Atkins J, Parker B, O'Neil B, Wadler S, **Goldberg RM**: *LE-SN38 for Metastatic Colorectal Cancer After Progression on Oxaliplatin; CALGB 80402*. Submitted to annual meeting ASCO. *J Clin Oncol* 26, 15S, 205S. Poster.
 169. O'Reilly EM, Hollis D, Niedzwiecki D, Bekaii-Saab T, Pluard T, Duffy A, Overcash F, Ivy P, **Goldberg RM**: *A Phase II Trial of Sunitinib (S) in Previously-Treated Pancreas Adenocarcinoma (PAC), CALGB 80603*. *J Clin Oncol* 26, 15S, 216S. Poster discussion.

170. Campbell ME, Mandrekar SJ, Hillman SL, **Goldberg RM**, Adjei AA, Pitot H, Morton R, Grothey A, Buckner J, Sargent DJ: *What is the added value of actual tumor measurements (TM) in predicting overall survival (OS)?* The North Central Cancer Treatment Group (NCCTG) Findings, J Clin Oncol 26, 15S, 342S. Poster discussion.
171. Mandrekar SJ, Hillman SL, Campbell M, Hobbs B, **Goldberg RM**, Adjei AA, Sargent DJ: Is continuous always better than categorical: actual tumor measurements versus categorical tumor response status in cancer clinical trials. Society for Clinical Trials. Podium presentation.
172. Grothey A, Sargent DJ, Szydlo DW, Zhao X, Campbell M, **Goldberg RM**, Sloan JA. Baseline quality of life (QOL) is a strong and performance status (PS)-independent prognostic factor for overall survival (OS) in patients with metastatic colorectal cancer (mCRC). Proc 2008 Gastrointestinal Canc Symp. Abs 334, p235, 2008. Poster presentation.
173. O'Neil BH, Bernard SA, **Goldberg RM**, Garcia R, Woods L, Sanoff HK. *Phase II study of oxaliplatin, capecitabine and cetuximab in advanced hepatocellular carcinoma*. Proc 2008 Gastrointestinal Canc Symp. Abs 228, p183, 2008. Poster presentation.
174. Sloan JA, Grothey A, Green EM, Campbell M, Zhao C, Szydlo D, Sargent DJ, **Goldberg RM**. *Tumor Burden is Not Related to Quality of Life in Patients with Metastatic Colorectal Cancer*. Submitted to GI Symposium. Proc 2008 Gastrointestinal Canc Symp. Abs 458, p296, 2008. Poster presentation.
175. Sargent DJ, Campbell M, Grothey A, **Goldberg RM**. Overall and 12 week tumor response (resp) versus actual tumor measurements (TM) as predictors of overall survival (OS) in advanced colorectal cancer (ACRC) - findings from NCCTG N9741. Proc 2008 Gastrointestinal Canc Symp. Abs 446, p290, 2008. Poster presentation.
176. Ramanathan RK, André T, Rothenberg ML, de Gramont A, Tournigand C, **Goldberg RM**, Gupta S. Diabetes mellitus (DM) and the incidence and time to onset of oxaliplatin induced peripheral sensory neurotoxicity (PSN) in patients with colorectal cancer. A pooled analysis of 3 randomized studies. GI Symposium. Proc 2008 Gastrointestinal Canc Symp. Abs 347, p242, 2008. Poster presentation.
177. Campbell ME, Grothey A, Sargent DJ, **Goldberg RM**. Waterfall plots provide detailed information on magnitude of response to conventional chemotherapy in advanced colorectal cancer (ACRC)- lessons learned from N9741. J Clin Oncol Proc Ann Meeting ASCO 25:183s, 2007. Poster presentation.
178. Allen RM, **Goldberg RM**, Berlin J, Spigel D, Stinchcombe TE, Sanoff HK, Hayes DN, Lin L, O'Neil BH. *Unusually high rates of hypersensitivity to cetuximab in the Middle Southern US; association with atopic phenotype*. J Clin Oncol Proc Ann Meeting ASCO 25:505s, 2007. Poster presentation.
179. O'Neil BH, Blackstock AW, **Goldberg RM**, Shearer H, Sanoff HK, Aklilu M, Bernard S, Martinie J, Kim HJ, Tepper JE. A phase I study of the addition of weekly oxaliplatin to weekly gemcitabine during radiotherapy for unresectable pancreatic or biliary malignancies. J Clin Oncol Proc Ann Meeting ASCO 25:634s, 2007.
180. Meyers MO, Hollis DR, Mayer RJ, Benson III AB, **Goldberg RM**, Cummings B, Gunderson LL, Martenson JA, Macdonald JS, O'Connell M, Tepper JE. *Ratio of metastatic to examined lymph nodes is a powerful predictor of overall survival in rectal cancer: An analysis of Intergroup 0114*. Proc Annu Meeting Amer Soc Clin Oncol. 25:165s, 2007. Podium presentation.
181. Sanoff HK, Sargent DJ, Campbell ME, Morton RF, Fuchs CS, Ramanathan RK, Williamson SK, Findlay BP, Pitot HC, **Goldberg RM**. N9741: 5 year survival update and

prognostic factor analysis of oxaliplatin (Ox) and irinotecan (Iri) combinations in metastatic colorectal cancer (MCRC). J Clin Oncol Proc Ann Meeting ASCO 25:180s, 2007. Poster presentation.

182. Yothers G, Blackstock AW, Wolmark N, **Goldberg RM**, O'Connell MJ, Benedetti J, Dignam J, Sargent DJ. *Outcomes in patients (Pts) African (A) descent and white (W) pts receiving adjuvant therapy for colon cancer (CC)*. J Clin Oncol Proc Ann Meeting ASCO 25:167s, 2007. Poster discussion.
183. Romanus D, Archer L, Wang X, **Goldberg RM**, Mulcahy M, Kindler H, Schrag D. Does health-related quality of life (HRQL) improve for patients who respond to chemotherapy? Analysis of patients with advanced pancreas cancer (APC) receiving gemcitabine on Cancer and Leukemia Group B (CALGB) study #80303. J Clin Oncol Proc Ann Meeting ASCO 25:495s, 2007. Podium presentation.
184. Schrag D, Archer L, Wang X, Romanus D, Mulcahy, M, **Goldberg RM**, Kindler H. Post-progression treatment among patients with advanced pancreas cancer (APC) after gemcitabine therapy on Cancer and Leukemia Group B (CALGB) Study #80303. J Clin Oncol Proc Ann Meeting ASCO 25:203s, 2007. Poster discussion.
185. Kindler HL, Niedzwiecki D, Hollis D, Sutherland S, Schrag D, Hurwitz H, McCleod H, Mulcahy M, Schilsky R, **Goldberg RM** for the CALGB. *A double-blind, placebo-controlled, randomized phase III trial of gemcitabine (G) plus bevacizumab (B) versus gemcitabine plus placebo (P) in patients (pts) with advanced pancreatic cancer (PC): A preliminary analysis of Cancer and Leukemia Group B (CALGB) 80303*. J Clin Oncol Proc Ann Meeting ASCO 25:199s, 2007. Podium presentation.
186. **Goldberg RM**, Köhne CH, Seymour MT, de Gramont A, Porschen R, Saltz L, Rougier P, Tournigand C, Grothey A, Sargent DJ. A pooled safety and efficacy analysis examining the effect of performance status (PS) on outcomes in 9 first line treatment (rx) trials (cts) of 6,286 patients (pts) with metastatic colorectal cancer (MCRC). J Clin Oncol Proc Ann Meeting ASCO 25:166s, 2007. Podium presentation.
187. Hoskins JM, **Goldberg RM**, McLeod HM. *UGT1A1*28 and irinotecan-induced neutropenia: does dose matter?* J Clin Oncol Proc Ann Meeting ASCO 25; 169s, 2007. Poster discussion.
188. Kindler HL, Niedzwiecki D, Hollis D, Sutherland S, Schrag D, Hurwitz H, McCleod H, Mulcahy M, Schilsky R, **Goldberg RM** for the CALGB. *A double-blind, placebo-controlled, randomized phase III trial of gemcitabine (G) plus bevacizumab (B) versus gemcitabine plus placebo (P) in patients (pts) with advanced pancreatic cancer (PC): A preliminary analysis of Cancer and Leukemia Group B (CALGB) 80303*. Programs/ Proceedings GI Canc Symposium 2007. Abstract 108, p139. Oral presentation.
189. Goetz MP, Reid JM, Safgren S, Mandrekar SJ, Erlichman C, Adjei AA, **Goldberg RM**, Grothey AF, McWilliams R, Ames MM. UGT1A1*28 genotype determines the maximally tolerated dose (MTD) of irinotecan (CPT-11)-based chemotherapy: a dose-escalation trial. Programs/ Proceedings GI Canc Symposium. Abstract 235, p 202. Oral presentation.
190. Grothey A, Sargent DJ, Campbell M, **Goldberg RM**. Waterfall plots provide detailed information on magnitude of response to conventional chemotherapy in advanced colorectal cancer (ACRC) - lessons learned from N9741. Programs/ Proceedings GI Canc Symposium 2007, Abstract 337, p 252. Poster.

191. O'Neil BH, Morse MA, Allen J, **Goldberg RM**, Bernard S, Lin L, Venook AP. *A phase II study of octreotide LAR in patients with advanced hepatocellular carcinoma and CLIP score ≥ 3 .* Programs/ Proceedings GI Canc Symposium 2007, abstract 161, p 166. Poster.
192. Grothey A, Hedrick EE, Mass RD, Sarkar S, Ramanathan RK, Hurwitz H, **Goldberg RM**, Sargent DJ. Response rate using conventional criteria is a poor surrogate for clinical benefit on progression-free (PFS) and overall survival (OS) in metastatic colorectal cancer (mCRC): A comparative analysis of N9741 and AVF2107. 2006 World GI Congress. Poster presentation.
193. Sinicrope FA, Rego RL, Halling KC, Foster NR, Sargent DJ, La Plant B, French A, Allegra CJ, Laurie JA, **Goldberg RM**, Thibodeau SN. *Microsatellite instability but not thymidylate synthase is a prognostic variable in primary colon cancers from patients treated in 5-FU-based adjuvant studies.* J Clin Oncol 2006 ASCO Meeting Proceedings Proc Ann Meeting ASCO 24:10019, 2006. Poster/discussion.
194. Sinicrope FA, Garrity M, Rego RL, French AJ, Foster NR, Sargent DJ, **Goldberg RM**, Laurie JA, Burgart LJ, Thibodeau SN, Witzig TE. *Alterations in cell proliferation and apoptosis in human colon cancers with microsatellite instability.* J Clin Oncol 2006 ASCO Meeting Proceedings Proc Ann Meeting ASCO 24:10022, 2006. Poster/discussion.
195. Bertagnolli MM, Compton CC, Niedzwiecki D, Warren RS, Jewell S, Bailey GP, Mayer RJ, **Goldberg R**, Saltz L, Redston M. Microsatellite instability predicts improved response to adjuvant therapy with irinotecan, 5-fluoruracil, and leucovorin in stage III colon cancer. J Clin Oncol 2006 ASCO Meeting Proceedings Proc Ann Meeting ASCO 24:10003, 2006. Oral presentation.
196. Tepper J, Krasna M, Niedzwiecki D, Hollis D, Reed C, **Goldberg R**, Rich T, Feins R, Mayer R. *Trimodality therapy is superior to surgery alone in esophageal cancer: Results of CALGB 9781.* J Clin Oncol 2006 ASCO Meeting Proceedings Proc Ann Meeting ASCO 24:4012, 2006. Oral presentation.
197. Grothey A, Hedrick EE, Mass RD, Sarkar S, Ramanathan RK, Hurwitz H, **Goldberg RM**, Sargent DJ. Response rate using conventional criteria is a poor surrogate for clinical benefit in metastatic colorectal cancer (mCRC): A comparative analysis of N9741 and AVF2107. J Clin Oncol 2006 ASCO Meeting Proceedings Proc Ann Meeting ASCO 24:3516, 2006. Poster/discussion.
198. Sargent D, **Goldberg RM**, Bleiberg H, de Gramont A, Tournigand C, Andre T, Rothenberg M, Mounedji-Boudiaf L, Tabah-Fisch I. A pooled safety and efficacy analysis of the FOLFOX4 regimen (bi-monthly oxaliplatin plus fluorouracil/ leucovorin) in elderly compared to younger patients with colorectal cancer. J Clin Oncol 2006 ASCO Meeting Proceedings Proc Ann Meeting ASCO 24:3517, 2006. Poster/discussion.
199. Venook A, Niedzwiecki D, Hollis D, Sutherland S, **Goldberg R**, Alberts S, Benson A, Wade J, Schilsky R, Mayer R. Phase III study of irinotecan/5FU/LV (FOLFIRI) or oxaliplatin/5FU/LV (FOLFOX) +/- cetuximab for patients (pts) with untreated metastatic adenocarcinoma of the colon or rectum (MCRC): CALGB 80203 preliminary results. J Clin Oncol 2006 ASCO Meeting Proceedings Proc Ann Meeting ASCO 24:3509, 2006. Oral presentation.
200. **Goldberg RM**, McLeod HL, Sargent DJ, Morton RF, Green EM, Fuchs C, Ramanathan RK, Williamson SK, Findlay BP, Pitot HC, Alberts SR. *African Americans (AA) with metastatic colorectal cancer (MCRC) had different polymorphisms, less toxicity, and a lower response rate than Caucasians (C) when treated with IFL, FOLFOX, or IROX in Intergroup N9741.* J Clin Oncol 2006 ASCO Meeting Proceedings Proc Ann Meeting ASCO 24:3503, 2006. Oral presentation.

201. Wong Y, Meropol NJ, Sargent D, **Goldberg R**, Beck JR. *Direct cost-survival analysis of therapies for metastatic colorectal cancer.* J Clin Oncol 2006 ASCO Meeting Proceedings Proc Ann Meeting ASCO 24:3515, 2006. Poster/discussion.
202. McLeod HL, Parodi L, Sargent DJ, Marsh S, Green E, Abreu P, Cisar LA, **Goldberg RM**. *UGT1A1*28, toxicity and outcome in advanced colorectal cancer: Results from Trial N9741.* J Clin Oncol 2006 ASCO Meeting Proceedings Proc Ann Meeting ASCO 24:3520, 2006. Poster/discussion.
203. French AJ, Mahoney MR, Sargent DJ, Burgart LJ, **Goldberg R**, Thibodeau SN. *Survival differences in patients with defective mismatch repair by BRAF mutational status.* Proc Amer Assoc Can Res. 47:390A, 2006. Poster presentation.
204. Sinicrope FA, Rego RL, Halling KC, Foster N, Sargent DJ, French A, Garrity M, **Goldberg RM**, Laurie JA, Burgart LJ, Thibodeau SN, Witzig TE. *Microsatellite instability is associated with reduced proliferative indices in human colorectal cancers.* Gastroenterology 130:4, Apr 2006 (suppl 2, page A719).
205. Sinicrope FA, Rego RL, Halling KC, Foster N, Sargent DJ, French A, Garrity M, **Goldberg RM**, Laurie JA, Burgart LJ, Thibodeau SN, Witzig TE. *Prognostic impact of DNA ploidy is stronger than and independent of microsatellite instability in human colon carcinoma patients.* Gastroenterology 130:4, Apr 2006 (suppl 2, page A470).
206. Krasna M, Tepper JE, Niedzwiecki D, Hollis D, Reed C, **Goldberg RM**, Kiel K, Rich T, Sugarbaker DJ, Mayer RJ. *Trimodality therapy is superior to surgery alone in esophageal cancer: Results of CALGB 9781.* Proc 2006 GI Canc Symposium. Abstract 4, page 86. Podium presentation.
207. **Goldberg RM**, Sargent D, Bleiberg H, de Gramont A, Tournigand C, Andre T, Rothenberg M, Mounedji-Boudiaf L, Tabah-Fisch I. *A pooled safety and efficacy analysis of the FOLFOX4 regimen (bi-monthly oxaliplatin plus fluorouracil/ leucovorin) in elderly compared to younger patients with colorectal cancer.* Proc 2006 GI Canc Symposium, Abstract 228, page 199. podium presentation.
208. Kim GP, Gornet MK, Rubin J, Mahoney MR, Nichols S, **Goldberg RM**, Alberts SR. *Premetrexed (Alimta) and oxaliplatin (OXAL) for metastatic colorectal cancer (mCRC): results of a phase I trial.* Proc 2006 GI Canc Symposium, Abstract 272, page 221. Poster presentation.
209. O'Neil BH, Calvo BF, Hawke NA, Kim HJ, Meyers M, Burns N, Threadgill DW, Caskey L, Tepper JE, **Goldberg RM**, Bernard SA, Baldwin AS, and Sartor CI. *Changes in NF-kappa B-related gene expression and global gene expression induced by therapeutic radiation in rectal adenocarcinoma.* 13th SPORE Investigator's Workshop, Washington, DC, July 9-12, 2005. Poster.
210. Mamon HJ, Niedzwiecki D, Hollis DR, Tan B, Smith J, Blackstoc AW, Tepper JE, **Goldberg RM**, Mayer RJ, Fuchs CS. *Preliminary analysis of Cancer and Leukemia Group B (CALGB) 80003: a phase II trial of gemcitabine, 5-fluorouracil (5FU), and radiation therapy in locally advanced non-metastatic pancreatic adenocarcinoma.* International Journal of Radiation Oncology, Biology, Physics - 1 October 2005 (Vol. 63, Issue (Supplement 1), Page S13).
211. Sargent D, **Goldberg R**, Bleiberg H, de Gramont A, Tournigand C, Andre T, Rothenberg ML, Green E, Mounedji-Boudiaf L, Tabah-Fisch I. *A pooled analysis to assess safety and efficacy of the FOLFOX4 regimen (bi-monthly oxaliplatin plus fluorouracil/leucovorin) in elderly patients with colorectal cancer.* World Congress on Gastrointestinal Cancer, Barcelona, June 2005.
212. Sinicrope FA, Halling KC, French A, Burgart LJ, Foster N, Sargent DJ, **Goldberg RM**, O'Connell MJ, Witzig TE, Thibodeau SN. *DNA ploidy is a stronger prognostic variable compared*

- to microsatellite instability or 18q allelic loss in patients with stages II and III colon cancer. Proc Ann Meeting ASCO 23: 842s, 2005. Poster discussion.
213. Erlichman C, **Goldberg RM**, Mahoney MR, Sargent DJ, Pitot HC, Kabat BF, Huntington JL, Sebo T J, Kaufmann SH. A phase II trial of CPT-11 in patients (pts) with advanced gastric or gastroesophageal (GE) junction adenocarcinoma ADCA): A clinical and pharmacodynamic evaluation. A North Central Cancer Treatment Group (NCCTG) Study. Proc Ann Meeting ASCO 23: 314s, 2005. Poster discussion.
 214. Grothey A, McLeod HL, Green EM, Sargent DJ, Fuchs C, Ramanathan RK, Williamson S, Findlay B, **Goldberg RM**. Glutathione S-transferase P1 I105V (GSTP1 I105V) polymorphism is associated with early onset of oxaliplatin-induced neurotoxicity. Proc Ann Meeting ASCO 23, 248s, 2005. Oral presentation.
 215. Pitot HC, Rowland KA, Sargent DJ, Philip PA, Mitchell EP, Mailliard JA, **Goldberg RM**, Alberts SR. N9841: A randomized phase III equivalence trial of irinotecan (CPT-11) versus oxaliplatin/5-fluorouracil (5FU)/leucovorin (FOLFOX4) in patients (pts) with advanced colorectal cancer (CRC) previously treated with 5FU. Proc Ann Meeting ASCO 23: 247s, 2005. Oral presentation.
 216. Hillner BE, Schrag D, Sargent DJ, Fuch CS, **Goldberg RM**. Cost-effectiveness projections of FOLFOX vs. IFL in first-line therapy of metastatic colorectal cancer in the context of the U.S. health care system. Proc Ann Meeting ASCO, 23: 253s, 2005. Poster discussion.
 217. Goetz MP, Safgren S, Reid JM, Mandrekar S, Furth A, Adjei AA, **Goldberg RM**, Grothey A, Erlichman C, Rubin J, Kuffel M, Ames MM. A phase I and dose escalation study of irinotecan, (CPT-11), oxaliplatin (Oxal), and capecitabine (Cap) within three UGT1A1 *28 genotype cohorts (6/6, 6/7 and 7/7). Proc Ann Meeting ASCO 23: 138s, 2005. Poster discussion.
 218. Rowland KA, Pitot HC, Sargent DJ, Philip PA, Mitchell EP, Mailliard JA, **Goldberg RM**, Alberts SR. Results of 3rd line therapy on N9841: a randomized phase III trial of oxaliplatin/5-fluorouracil (5FU)/leucovorin (FOLFOX4) versus irinotecan (CPT-11) in patients (pts) with advanced colorectal cancer (CRC) previously treated with prior 5FU chemotherapy. Proc Ann Meeting ASCO 23: 250s, 2005. Poster discussion.
 219. Johnston PG, Benson AB III, Catalano PJ, Eapen S, Sargent DJ, Wieand S, **Goldberg RM**, Allegra CJ. *The clinical significance of thymidylate synthase (TS) expression in primary colorectal cancer: an intergroup combined analysis*. Proc Ann Meeting ASCO, 23:248s, 2005. Oral presentation.
 220. Morton RF, Sloan JA. Grothey A, Sargent DJ, McLeod H, Green EM, Fuchs C, Ramanathan RK, Williamson SK, **Goldberg RM**. A comparison of simple single-item measures and the common toxicity criteria in detecting the onset of oxaliplatin-induced peripheral neuropathy in patients with colorectal cancer. Proc Ann Meeting ASCO 23: 750s, 2005. Poster.
 221. Hillner BE, Schrag D, Sargent DJ, **Goldberg RM**. *Cost-effectiveness projections of FOLFOX vs. IFL in first-line therapy of metastatic colorectal cancer*. Proc 2005 Gastrointestinal Ca Symp, 178, 2005. Poster presentation.
 222. Dy GK*, Krook J, Green E, Sargent D, Alberts S, Pitot H, Morton R, **Goldberg R**. Impact of complete response to chemotherapy on overall survival (OS) in advanced colorectal cancer (CRC): Results from Intergroup N9741. Proc 2005 Gastrointestinal Ca Symp, 176, 2005. Poster presentation.

223. Green EM, Sargent DJ, **Goldberg RM**, Grothey A. *Detailed analysis of oxaliplatin-associated neurotoxicity in intergroup trial N9741*. Proc 2005 Gastrointestinal Ca Symp, 175, 2005. Poster presentation.
224. Green EM, Sargent DJ, **Goldberg RM**, Morton R, Grothey A. *Detailed analysis of oxaliplatin-associated neurotoxicity in intergroup trial N9741*. ESMO annual meeting. Podium presentation.
225. Delaunoy T, Lymp JF, Limburg PJ, **Goldberg RM**, Smyrk TC, Loftus Jr EV. *Prognosis of inflammatory bowel disease-associated and sporadic colorectal cancer*. DDW (Digestive Disease Week), 2004.
226. Ahlquist DA, Sargent DJ, Loprinzi CL, **Goldberg RM**, Rex DK, Levin TR, Ahnen DJ, Knigge KL, Lance MP, Lawson MJ, Allison JE, Devens ME, Stella PJ, Hillman SL. *False-positive stool DNA results on colorectal cancer screening: Yield from supracolonic evaluation*. DDW (Digestive Disease Week), 2004.
227. Haddock MG, Swaminathan R, Alberts SR, Hauge MD, Foster NR, Martenson JA, **Goldberg RM**. Gemcitabine (Gem), cisplatin (CIS) and radiation therapy (RT) for patients with locally advanced pancreatic adenocarcinoma (ACA): A North Central Cancer Treatment Group (NCCCTG Phase II study. Proc Am Soc Clin Oncol 23: 343, 2004. Poster Colacchio TA, Niedzwiecki D, Compton C, Warren R, Benson AIB, Goldberg R, Kerr D, Fields A, Hollis D, Mayer R. Phase III trial of adjuvant immunotherapy with MOAB 17-1A following resection cor stage II adenocarcinoma of the colon (CALGB 9581). Proc Am Soc Clin Oncol 23: 251, 2004. Poster discussion.
228. Sargent DJ, Wieand S, Benedetti J, Labianca R, Haller D, Shepherd L, Seitz SF, Francini G, de Gramont A, **Goldberg R**. Disease-free survival (DFS) vs. overall survival (OS) as a primary endpoint for adjuvant colon cancer studies: individual patient data from 12,915 patients on 15 randomized trials. Proc Am Soc Clin Oncol 23: 246, 2004. Oral presentation.
229. **Goldberg RM**, Sargent DJ, Morton RF, Fuchs C, Ramanathan RK, Williamson SK, Findlay BP, Pitot HC, Alberts SR. N9741: FOLFOX (Oxaliplatin(Oxal)/ 5-Fluorouracil (5-FU)/ leucovorin (LV) or reduced dose R-IFL (CPT-11 + 5-FU/LV) in advanced colorectal cancer (CRC): final efficacy data from an intergroup study. Proc Am Soc Clin Oncol, 23:275, 2004. Poster.
230. Sloan JA, Mcleod H, Sargent D, Zhao X, Fuchs C, Ramanathan R, Williamson S, Findlay B, Morton R, **Goldberg RM** . *Preliminary evidence of relationship between genetic markers and oncology patient quality of life (QOL)*. Proc Am Soc Clin Oncol, 23: 2, 2004. Plenary session.
231. Fuchs CS, Pollak M, Sargent DJ, Meyerhardt J, Ramanathan RK, Williamson S, Findlay B, Green E, **Goldberg RM**. Insulin-like growth factor-I (IGF-1), IGF binding protein-3 (IGFBP-3), and outcome in metastatic colorectal cancer (CRC): Results from Intergroup Trial N9741. Proc Am Soc Clin Oncol, 23: 250, 2004. Poster discussion.
232. Saltz LB, Niedzwiecki D, Hollis D, **Goldberg R**, Hantel A, Thomas JP, Klaassen D, Carver G, Mayer RJ. Phase III trial of irinotecan plus fluorouracil/leucovorin (IFL) versus fluorouracil/leucovorin alone (FL) in stage III colon cancer (intergroup trial C89803). Proc Am Soc Clin Oncol, 23: 246, 2004. Oral presentation.
233. Delaunoy T, Lymp JF, Limburg PJ, **Goldberg RM**, Smyrk TC, Loftus EV. *Prognosis of inflammatory bowel disease-related and sporadic colorectal cancer*. Gastroenterology 126:4, Apr 2004 (suppl 2, page A471).

234. Ahlquist DA, Sargent DJ, Loprinzi CL, **Goldberg RM**, Rex DK, Levin TR, Ahnen DJ, Knigge KL, Lance MP, Lwson MJ, Allison JE, Devens ME, Stella PJ, Hillman SL. *False-positive stool DNA results on colorectal cancer screening: Yield from supracolonc evaluation*. Gastroenterology 126:4, Apr 2004 (suppl 2, page A58).
235. Green EM, Sargent DJ, **Goldberg RM**, Morton RF, Grothey A. *Detailed analysis of oxaliplatin-associated neurotoxicity in intergroup trial N9741*. Annals of Oncology 15: 2004 (suppl 3, page 70).
236. Alberts SR, Donohue JH, Mahoney MR, Horvath WL, Sternfeld WC, Dakhil SR, Levitt R, Rowland K, Sargent DJ, and **Goldberg RM**. Liver resection after 5-fluorouracil, leucovorin and oxaliplatin for patients with metastatic colorectal cancer (MCRC) limited to the liver: A North Central Cancer Treatment (NCCTG) phase II study. ECCO. Poster presentation.
237. Sargent D, Hillman S, An M, Kugler J, **Goldberg R**, Perez E, Jett J, Buckner J. *A critical evaluation of tumor response in solid tumor cancer clinical trials*. Society for Clinical Trials.
238. Gunderson LL, Sargent DJ, Tepper J, O'Connell MJ, Smalley S, Haller DG, Allmer C, Martenson JA, Mayer R, Rich T, Ajani J, Macdonald JS, Willett CG, **Goldberg RM**. *Impact of TN stage and treatment on survival and relapse in adjuvant rectal cancer pooled analysis*. Proc Am Soc Clin Oncol annual meeting 22: 1007, 2003. Podium presentation.
239. Hillman SL, Sargent DJ, An M-W, Buckner JC, **Goldberg RM**, Schaefer PL, O'Connell MJ. Evaluation of RECIST Criteria in determining the response to treatment in solid tumors: a North Central Cancer Treatment Group (NCCTG) investigation. Proc Am Soc Clin Oncol annual meeting 22: 521, 2003. Podium presentation.
240. McLeod HL, Sargent DJ, Marsh S, Fuchs CS, Ramanathan RK, Williamson SK, Findlay BP, Thibodeau SN, Petersen GM, **Goldberg RM**. Pharmacogenetic analysis of systemic toxicity and response after 5-fluorouracil (5FU)/CPT-11, 5FU/oxaliplatin (oxal), or CPT-11/oxal therapy for advanced colorectal cancer: Results from an intergroup trial. Proc Am Soc Clin Oncol annual meeting 22:253, 2003. Podium presentation.
241. Martenson J, Jatoi A, Mahoney M, Lair BS, Brindle JS, Nichols F, Caron N, Rowland K, Tschetter L, **Goldberg RM**. Use carboplatin AUC=4, not AUC=6, with carboplatin, 5-FU, paclitaxel, amifostine, and radiation for locally advanced esophageal cancer. Results of a planned interim toxicity analysis from the North Central Cancer Treatment Group. Proc Am Soc Clin Oncol annual meeting 22: 350, 2003.
242. **Goldberg RM**, Morton RF, Sargent DJ, Fuchs C, Ramanathan RK, Williamson S, Findlay B. N9741: Oxaliplatin (Oxal) or CPT-11 + 5-fluorouracil (5FU)/leucovorin (LV) or oxal + CPT-11 in advanced colorectal cancer (CRC): Efficacy and quality of life (QOL) data from a GI intergroup study. Proc Am Soc Clin Oncol annual meeting 22:252, 2003. Podium presentation.
243. Novotny PJ, Sloan JA, Guse L, Alberts S, **Goldberg R**, Gregory D, Hartmann L, Johnson M, Rummans T. A pilot study assessing social support among cancer patients enrolled on cancer clinical trials: A comparison of younger versus older adults. Proc Am Soc Clin Oncol annual meeting 22: 744, 2003. Poster presentation.
244. Hobday TJ, Rubin J, **Goldberg R**, Erlichman C, Lloyd R. *Molecular markers in metastatic gastrointestinal neuroendocrine tumors*. Proc Am Soc Clin Oncol annual meeting 22: 269, 2003. Poster presentation.
245. Fuchs C, Fitzgerald TJ, Mamon H, Haller D, Venook A, Enzinger P, **Goldberg R**, Gunderson L, Mayer R, Tepper J. Postoperative adjuvant chemoradiation for gastric or gastroesophageal adenocarcinoma using epirubicin, cisplatin, and infusional 5-fluorouracil (ECF)

- before and after 5-FU and radiotherapy: A multicenter pilot study. Proc Am Soc Clin Oncol annual meeting 22:257, 2003. Poster presentation.
246. Gill S*, Loprinzi CL, Sargent DJ, Haller DG, Benedetti J, Francini G, Shepherd L, Seitz JF, LaBianca R, **Goldberg RM**. *Using a pooled analysis to improve the understanding of adjuvant therapy (AT) benefit for colon cancer (CC)*. Proc Am Soc Clin Oncol annual meeting 22:253, 2003. Podium presentation.
 247. Alberts SR, Donohue JH, Mahoney MR, Horvath WL, Sternfeld WC, Dakhil SR, Levitt R, Rowland KM, Sargent DJ, and **Goldberg RM**. Liver resection after 5-fluorouracil, leucovorin and oxaliplatin for patients with metastatic colorectal cancer (MCRC) limited to the liver: A North Central Cancer Treatment Group (NCCTG) phase II study. Proc Am Soc Clin Oncol annual meeting 22: 263, 2003. Poster presentation.
 248. Jacobson S, Alberts SR, Mahoney MR, Green EM, Al-Khatib H, Burgart L, Cera PJ, Flynn PJ, Fitch TR, Levitt R, **Goldberg RM**. Phase II trial of gemcitabine (GEM), 5-fluorouracil (5FU), and leucovorin (lv) in patients with unresectable or metastatic biliary (BILI) and gallbladder (GB) carcinoma: A North Central Cancer Treatment Group (NCCTG) study. Proc Am Soc Clin Oncol annual meeting 22:275, 2003. Poster presentation.
 249. Burch PA, Alberts SR, Schroeder MT, Erlichman C, Steen PD Dakhil SR, Steen PD, Nair S, Cha S, Sargent DJ, **Goldberg RM**. Gemcitabine (GEM) and ISIS-2503 for patients with pancreatic adenocarcinoma (ACA): a North Central Cancer Treatment Group (NCCTG) phase II study. Proc Am Soc Clin Oncol annual meeting 22:259, 2003. Poster discussion presentation.
 250. Pitot HC, Wiesenfeld M, Mahoney MR, Alberts SR, Paul SL, Nair S, Mailliard JA, Kugler JW, **Goldberg RM**. A phase II trial of oxaliplatin (oxal), 5-fluorouracil (5FU), and leucovorin (lv) in patients (pts) with metastatic colon cancer (m-crc) refractory to irinotecan (cpt11) based therapy: a North Central Cancer Treatment Group (NCCTG) study. Proc Am Soc Clin Oncol annual meeting 22:261, 2003. Poster presentation.
 251. Gill S*, Smalley R, Burgart LJ, Lindor NM, **Goldberg RM**, Thibodeau SN. Analysis of hPMS2 expression in colorectal cancers (CRC) with microsatellite instability (MSI-H) and normal immunohistochemistry (IHC) for hMLH1, hMLH2 and hMSH6. Proceedings of Gastrointestinal Cancer Research Conference 2002, Abstract 10. Podium presentation.
 252. Gill S*, Kakar S, Burgart LJ, Thibodeau SN, **Goldberg RM**, Lindor NM, Smyrk TC. *E-cadherin expression in signet ring cell carcinoma of the colon*. American Association for Cancer Research Colon Cancer Genetics Workshop, March 2002.
 253. Morton R, **Goldberg RM**, Sargent DJ, Fuchs C, Ramanathan R, Williamson S. Oxaliplatin (oxa) or CPT-11 + 5-fluorouracil (5FU)/leucovorin (lv) or oxa + cpt-11 in advanced colorectal cancer (acrc). Efficacy and safety results from a North American gastrointestinal intergroup study (N9741). Proceedings of the Fourth International Conference: Perspectives in Colorectal Cancer, June 20-22, 2002 in Barcelona, Spain. Poster Presentation.
 254. Ribic C, Sargent DJ, Moore MJ, Thibodeau SN, **Goldberg RM**, Hamilton SR, Laurent-Puig P, Shepherd L, Dongsheng T, Redston M, Gallinger S. *Tumor microsatellite instability (MSI) and the benefit of 5-FU based chemotherapy in stage II & III Colon Cancer: A pooled molecular reanalysis of randomized chemotherapy trials*. NCI-EORTC joint symposium, 2002.
 255. Alberts SR, Schroeder M, Cha S, Erlichman C, Steen PD, Moore DF Jr, Sargent DJ, **Goldberg RM**, Holmlund J. Gemcitabine and ISIS-2503 for patients with pancreatic adenocarcinoma (ACA): A North Central Cancer Treatment Group (NCCTG) phase II study - interim analysis. Proc AACR. 2002 Poster presentation.

256. **Goldberg RM.** *New targets in the treatment of advanced colorectal cancer.* Tumori, Supplement, volume 1, number 2: S80-1, 2002. Podium presentation.
257. **Goldberg RM.** *The current status of clinical cancer research in the United States.* Tumori, Supplement, volume 1, number 2: S3-4, 2002. Podium presentation.
258. Alberts SR, Townley PM, Cha SS, Moore DF, Krook JE, Fitch TR, Sargent DJ, **Goldberg RM.** Oxaliplatin (Oxal) and gemcitabine (Gem) for patients with pancreatic adenocarcinoma (ACA): A North Central Cancer Treatment Group (NCCTG) phase II study. Proc Am Soc Clin Oncol annual meeting 21: 126a, 2002. Podium presentation.
259. Tria Tirona M, Jatoi A, Cha S, Alberts SA, Rubin J, Rowland K, Morton R, Nair S, Kardinal K, Stella P, Mailliard J, **Goldberg RM.** *Preliminary results of CPT-11 and taxotere for treatment of advanced esophageal cancer: A North Central Cancer Treatment Group study.* Proc Am Soc Clin Oncol annual meeting, 21: 152a, 2002. Poster presentation.
260. Martenson JA, Vigliotti APG, Pitot HC, Geeraerts LH, Sargent DJ, Haddock MG, Ghosh C, Windschitl HE, Fitch TR, **Goldberg RM.** Phase I study of twice weekly gemcitabine (Gem) and cisplatin (CDDP) during radiation therapy (RT) for locally advanced pancreas and gastric cancer. Proc Am Soc Clin Oncol annual meeting, 21: 146a, 2002. Poster presentation.
261. Mahoney MR, Sargent DJ, Furth AF, **Goldberg RM.** An assessment of routine adverse event (AE) data collected on North Central Cancer Treatment Group (NCCTG) clinical trials (CT). Society of Clinical Trials Annual meeting. 2002, Podium presentation.
262. Hobday TJ, Cha S, Buroker T, Sargent DJ, **Goldberg RM.** Long term survivors (LTS) of metastatic colorectal cancer (MCRC) treated with chemotherapy only: A North Central Cancer Treatment Group (NCCTG) review. Proc Am Soc Clin Oncol annual meeting 21: 174a, 2002. Poster presentation.
263. Mahoney MR, Sargent DJ, Furth AF, **Goldberg RM**, Buckner JC, Schaefer PL, O'Connell MJ. *An assessment of routine adverse event (AE) data collected on North Central Cancer Treatment Group (NCCTG) clinical trials (CT).* Proc Am Soc Clin Oncol annual meeting 21: 246a, 2002. Poster presentation.
264. Ribic C, Sargent DJ, Moore MJ, Thibodeau SN, **Goldberg RM**, Hamilton SR, Laurent-Puig P, Shepherd L, Redston M, Gallinger S. Tumor microsatellite instability (MSI) and the benefit of 5-FU based chemotherapy in stage II & III colon cancer: A pooled molecular re-analysis of randomized chemotherapy trials. Proc Am Soc Clin Oncol annual meeting, 21: 128a, 2002. Podium presentation.
265. Ribic C, Sargent DJ, Moore MJ, Thibodeau SN, **Goldberg RM**, Hamilton SR, Laurent-Puig P, Shepherd L, Redston M, Gallinger S. Tumor microsatellite instability (MSI) and the benefit of 5-FU based chemotherapy in stage II & III colon cancer: A pooled molecular re-analysis of randomized chemotherapy trials. Proc Am Soc Clin Oncol annual meeting, 21: 128a, 2002. Podium presentation.
266. **Goldberg RM**, Morton R, Sargent DJ, Fuchs C, Ramanathan R, Williamson S. N9741: Oxaliplatin (oxal) or CPT-11 + 5-fluorouracil (5FU)/ leucovorin (LV) or oxal + CPT-11 in advanced colorectal cancer (CRC). Initial toxicity and response data from a GI intergroup study. Proc Am Soc Clin Oncol annual meeting 21:128a, 2002. Podium presentation.
267. Garrity MM, Burgart LJ, Mahoney MR, Furth AF, Murphy LM, Hill EM, Riehle DL, Wiesenfeld M, Windschitl HE, Krook JE, Tria Tirona M, Michalak JC, Sargent DJ, **Goldberg RM**, O'Connell MJ, Meyers CH, Witzig TE. *Prognostic value of ploidy, proliferation and apoptosis markers, defective DNA mismatch repair (MMR) and p53 overexpression in*

patients(pts) with resected Dukes' B2 or C colon cancer: A North Central Cancer Treatment Group (NCCTG) study. Proc Am Soc Clin Oncol annual meeting 21:128a, 2002. Podium presentation.

268. French AJ, Halling KC, Burgart LJ, Furth AF, Sargent DJ, **Goldberg RM**, Thibodeau SN. Prognostic significance of microsatellite instability in the TGF- β IIR, BAX, and AXIN genes in colon cancer. American Association of Cancer Research annual meeting. 43:214, 2002. Poster presentation.
269. Lindor NM, Burgart LJ, Leontovich O, **Goldberg RM**, Cunningham JM, Walsh Vockley C, Petersen G, Redston M, Young J, Barker M, Walsh MD, Jass J, Leggett BA, Hopper J, Bapat B, Salliger S, Selander T, Thibodeau SN. Microsatellite instability versus immunohistochemistry testing in phenotyping colorectal tumors. Am J Hum Genetics 69(4) 262, 2001. Poster presentation.
270. Boardman LA, Petersen GM, Lindor NM, Nelson H, Schmidt SJ, **Goldberg RM**, Burgart LJ, de Andrade M, Thibodeau SN. Identification of novel regions of allelic imbalance (AI) in young onset colorectal cancer (CRC) with normal mismatch repair (MMR). Am J Hum Genetics 2001;69 (4):246. Poster presentation.
271. Reid JM, Adjei a, Sloan J, Diasio R, Smith DA, Pitot H, Rubin J, Alberts S, **Goldberg R**, Hanson L, Atherton P, Ames M, Erlichman C. A comparative pharmacokinetic study of continuous venous infusion (CVI) 5-fluorouracil and oral 5-fluorouracil with the dihydropyrimidine dehydrogenase (DPD) inactivator eniluracil in patients with advanced solid tumors. Proc Am Soc Clin Oncol 20:90a, 2001. Poster presentation.
272. Ackland S, Moore M, Jones M, Tu D, Simes J, Yuen J, Sargeant AM, Dhillon H, **Goldberg R**, Abdi E, Shepherd L. A meta-analysis of two randomized trials of early chemotherapy in asymptomatic metastatic colorectal cancer. Proc Am Soc Clin Oncol 20:132a, 2001 Poster/discussion.
273. Pitot HC, Adjei AA, Reid JM, Sloan JA, **Goldberg RM**, Rubin J, Alberts SR, Knight R, Schaaf LJ, Miller LL, Erlichman C. A phase I study to evaluate orally administered irinotecan HCL (CPT-11) given as a powder-filled capsule formulation daily for five days every three weeks in patients with advanced solid tumors. Proc Am Soc Clin Oncol 20: 102a, 2001. Poster presentation.
274. Alberts SR, Horvath W, Donohue JH, Sternfeld W, **Goldberg RM**, Mahoney MR, Nagorney DM, Levitt R, Dakhil S, Rowland K, Sargent DJ. Oxaliplatin (OXAL), 5-fluorouracil (5FU), and leucovorin (CF) for patients (PTS) with liver only metastases (METS) from colorectal cancer (CRC): a North Central Cancer Treatment Group (NCCTG) phase II study. Proc Am Soc Clin Oncol 20:129a, 2001. Poster/discussion.
275. Fishkin PA, Alberts SR, Mahoney MR, Sargent DJ, **Goldberg RM**. Irinotecan (CPT-11) in patients (PTS) with advanced gallbladder (GB) carcinoma (CA): a North Central Cancer Treatment Group (NCCTG) phase II study. Proc Am Soc Clin Oncol, 20:155a, 2001. Poster presentation.
276. Jacobson SD*, Cha S, Sargent DJ, O'Connell MJ, Poon M, Buroker T, Kugler J, **Goldberg RM**. Tolerability, dose intensity, and benefit of 5FU-based chemotherapy for advanced colorectal cancer (CRC) in the elderly. A North Central Cancer Treatment Group (NCCTG) study. Proc Am Soc Clin Oncol, 20:384a 2001. Podium presentation, winner ASCO Merit Award.
277. Schaaf LJ, Rothenberg ML, Hammond LA, **Goldberg RM**, Rushing DA, Goel R, Locker PK, Compton LD, Mc Govern JP, Knight RD, Miller LL. Phase I trial of weekly irinotecan (CPT-

- 11) in patients with hepatic dysfunction. Proc Am Soc Clin Oncol 20: 101a, 2001. Poster presentation.
278. Bolton J, O'Connell MJ, Mahoney MR, Nagorney DM, Mailliard JA, **Goldberg RM**. Phase II study of hepatic arterial infusion (HAI) plus systemic (SYS) chemotherapy (CH) after multiple metasectomy in patients (PTS) with colorectal carcinoma metastatic (M-CRC) to the liver. Proc Am Soc Clin Oncol 20:128a, 2001. Poster/discussion.
279. Morton R, **Goldberg RM**, Sargent DJ, Fuchs CS, O'Connell MJ. *Oxaliplatin (OXAL) or CPT-11 combined with 5FU/leucovorin (LV) in advanced colorectal cancer: An NCCTG/CALGB study*. Proc Am Soc Clin Oncol 20:125a, 2001. Podium presentation.
280. **Goldberg RM**, Langdon R, Sargent D, Pazdur R, Hantel A, Wieand S, O'Connell MJ, Kardinal C, Rowland K, Kugler J. Phase III trial of 5-fluorouracil (5FU), levamisole (LEV), +/- leucovorin (LV) as adjuvant treatment (ADJ) of resected metastatic colorectal cancer (M-CRC): An NCCTG/M.D. Anderson/ SWOG study. Proc Am Soc Clin Oncol 20: 133a, 2001. Poster/discussion.
281. Alberts SR, Mahoney MR, Fishkin PA, Burgart LJ, Cera PJ, Sargent DJ, Nair S, Pitot HC, **Goldberg RM**. Toxicity of irinotecan (CPT-11) in patients (PTS) with advanced gallbladder (GB) or biliary (Bili) tumors: A North Central Cancer Treatment Group (NCCTG) study. Proc Am Soc Clin Oncol 19:298a, 2000.
282. Poplin E, Benedetti J, Estes N, Haller D, Mayer R, **Goldberg R**, Macdonald J. Randomized trial of 5-FU/leucovorin/ levamisole versus 5-FU continuous infusion/levamisole as adjuvant therapy for high risk colon cancer (SWOG 9415: A phase III intergroup). Proc Am Soc Clin Oncol 2000, 19: 240a, 2000. Podium presentation.
283. **Goldberg RM**, Kugler JW, Mahoney MR, Fitch TR, Krook JE, Mailliard JA, Tria Tirona M, Tschetter LK, Schaefer PL, Braich TA, O'Connell MJ, Sargent DJ. *A phase II trial of 7 days of oral 776C85 plus 5 days of fluorouracil in patients (PTS) with metastatic colorectal cancer (M-CRC): A North Central Cancer Treatment Group study*. Proc Am Soc Clin Oncol 19: 245a, 2000. Poster/discussion.
284. Sloan JA, **Goldberg RM**, Sargent DJ, Cha S, Novotny P, Jatoi A, Loprinzi C. Women experience greater incidence and severity of 5-FU based chemotherapy induced stomatitis, leucopenia, and alopecia: A North Central Cancer Treatment Group meta-analysis. Proc Am Soc Clin Oncol 19: 599a, 2000. Podium presentation.
285. Sargent D, Chan V, **Goldberg R**. *A three outcome design for phase II clinical trials*. Society for Clinical Trials, April 16-19, 2000.
286. Sargent D, **Goldberg RM**, Macdonald J, Labianca R, Haller D, Shephard L, Seitz JF, Francini G. Adjuvant chemotherapy for colon cancer (CC) is beneficial without significantly increased toxicity in elderly patients (PTS): Results from a 3351 pt meta-analysis. Proc Am Soc Clin Oncol 19: 241a, 2000. Podium presentation.
287. Horgan A*, Nelson H, Sargent DJ, Gunderson LL, Hassan I, Dozois RR, **Goldberg RM**. *Curative potential of multimodality therapy for locally recurrent rectal cancer*. Proc Am Soc Clin Oncol 18:266a,1999. Poster presentation.
288. Sargent D, Mahoney M, Hillman D, McKeough T, Hamilton S, Darcy J Anderson V, **Goldberg R**. Increased incidence of a known toxicity: Experience and implications from a North Central Cancer Treatment Group (NCCTG) clinical trial. Controlled Clinical Trials 20: 38S-39S, 1999. Podium presentation.

289. Erlichman C, Adjei A, Sloan J, Pitot H, **Goldberg R**, Peethambaram P, Alberts S, Galanis E, Hanson L, Reid J, Rubin J, Burch P, Thornton D, Walling J. *A phase I trial of MTA (multitargeted antifol, LY231514) and gemcitabine (Gemzar) in patients with locally advanced or metastatic cancer.* Proc Am Soc Clin Oncol 18:172a, 1999. Poster presentation.
290. **Goldberg RM**, Sargent D, Mahoney MR, Wold LE, Windschitl H, Farr G, O'Connell MJ, Klein P, Behan K, Parr A, Allegra C. Limited prognostic importance of immunohistochemical parameters (IHP) [thymidylate synthase (TS), KI-67, and p53] in 465 patients (PTS) with Dukes' B2 and C colon cancer enrolled on North Central Cancer Treatment Group (NCCTG) trials. Proc Am Soc Clin Oncol 18:267a, 1999. Poster/discussion presentation.
291. Egner JR, **Goldberg RM**, Sargent DJ, Mahoney MM, Richardson RL, Miller LL. CPT-11 at 320 mg/m² caused excessive toxicity patients (pts) with advanced adenocarcinoma (ACA) of the stomach (S) or gastroesophageal Junction (GJ): A North Central Cancer Treatment Group Trial. Proc Am Soc Clin Oncol 18:282a, 1999.
292. Adjei AA, Erlichman C, Davis JN, Reid J, Sloan JA, Statkevich P, Zhu Y, Marks RS, Pitot HC, **Goldberg RM**, Hanson L, Alberts SR, Cutler D, Kaufmann SH. *A phase I and pharmacologic study of the farnesyl protein transferase (FPT) inhibitor SCH 66336 in patients with locally advanced or incurable cancer.* Proc Am Soc Clin Oncol 18:156a, 1999. Poster presentation.
293. Galanis E*, **Goldberg R**, Erlichman C, Sloan J, Reid J, Pitot H, Rubin J, Alberts S, Adjei A, Burch P, Safgren S, Atherton-Skaaf P, Witzig T, Ames MM. *Phase I trial of sequential administration of tomudex and 5-iodo-2'-deoxyuridine (IdUrd).* Proc Am Soc Clin Oncol 18:172a, 1999. Poster presentation.
294. Alberts S*, **Goldberg RM**, Fonseca R, Erlichman C, Sloan J, Kaufmann S, Rubin J, Pitot HC, Rubin J, Adjei A, Burch P, Miller II. *Phase I study of the combination of CPT-11+5-FU and Leucovorin.* Proc Am Soc Clin Oncol 18:202a, 1999.
295. Mowat RB, **Goldberg RM**, Sargent DJ, Cha SS, Adjei AA, Boulamwini J. A phase II evaluation of Fazarabine (FAZ) and G-CSF in patients with advanced pancreatic adenocarcinoma: A North Central Cancer Treatment Group study. Proc Am Soc Clin Oncol 18:293a, 1999.
296. Pitot HC IV, Erlichman C, Reid JM, Sloan JA, Ames MM, Bagniewski PG, Atherton-Skaaf P, Adjei AA, Rubin J, Rayson D, **Goldberg RM**. *A Phase I study of bizelesin (NSC615291) in solid tumors.* Proc Am Assoc Canc Res 40: A606, 1999. Podium Presentation.
297. Adjei AA, **Goldberg RM**, Rubin J, Kastrissious H, Sloan J, Reid J, Pitot H, Erlichman C. *A phase I study of sequential irinotecan (IRN) and docetaxol (DOC) in patients with advanced solid tumors.* Proc Am Assoc Canc Res 40:A603, 1999. Podium presentation.
298. Martenson J, Willett C, Sargent D, Donohue J, **Goldberg R**, Wasserman T, Gunderson L, Myerson R, Thomas P, Fisher B, Benson III A. *A phase III study of adjuvant radiation therapy (RT), 5-fluorouracil (5-FU), and levamisole (LEV) vs 5-FU and LEV in selected patients with resected high risk colon cancer: Initial results of INT-0130.* Proc Am Soc Clin Oncol, 18:235a, 1999. Podium presentation.
299. Adjei AA, Erlichman C, Thornton D, Alberts SR, Sloan JA, **Goldberg RM**, Pitot HC, Reid J. Synergistic cytotoxicity of MTA (LY231514) and gemcitabine in vitro and in vivo. 10th NCI-EORTC symposium on new drugs in cancer therapy. Ann Oncol 9:168, 1998.
300. **Goldberg RM**, Erlichman C, Pitot HC. *Beyond 5-fluorouracil: CPT- 11 in colorectal cancer (CRC).* Proceedings of the Ninth Conference on DNA Topoisomerases in Therapy. New York, NY. October 5-7, 1998, page 27. Podium presentation.

301. **Goldberg RM.** *Is the Mayo regimen of 5-FU + LD-LV still the control arm for Phase III trials in advanced colorectal cancer?* Proceedings of the Third International Conference on Biology, Prevention, and Treatment of Gastrointestinal Malignancies, Koln, Germany September 23-26, 1998, page 88. Podium presentation.
302. **Goldberg RM.** *Combined modality treatment of locally advanced gastric cancer.* Proceedings of the Fifth International Conference on Gastrointestinal Oncology, Bordeaux, France, September 16-18, 1998. Page 77. Podium presentation.
303. Fonseca R*, **Goldberg RM**, Erlichman C, Kaufman SH, Sloan JA, Miller L. *Phase I study of the combination of CPT-11/5-FU and leucovorin (lv).* Proc Am Soc Clin Oncol 17:203a, 1998. Poster presentation.
304. **Goldberg RM**, Kugler J, Sargent D, and Mahoney MR. A phase II trial of a seven day regimen of oral 5-ethanlyuracil (5-EU) plus a five day regimen of oral 5-fluorouracil (5-FU) in untreated patients with metastatic colorectal cancer (M-CRC): A North Central Cancer Treatment Group study. Proc Am Soc Clin Oncol 17:282a, 1998. Poster presentation.
305. Erlichman C, Adjei A, **Goldberg R**, Pitot H, Rubin J, Burch P, and Sloan J. *Phase I study of BAY 12-9566-A matrix metalloprotenase inhibitor (MMPI).* Proc Am Soc Clin Oncol 17:217a, 1998. Poster presentation.
306. Adjei AA, Kaufmann SH, Reid J, Sloan JA, Alberts SR, **Goldberg RM**, Erlichman C. *A phase I study of pyrazoloacridine (PZA) and carboplatin (CBDCA) in patients with advanced solid tumors.* Proc Am Assoc Canc Res, A2206, 1998. Poster presentation.
307. Galanis E*, **Goldberg RM**, Erlichman C, Rubin J, Pitot HC, Alberts SR, Burch PA, Reid JM, Witzig TE, Sloan JA, Ames MM. *Phase I trial of sequential administration of tomudex and 5-iodo-2'-deoxyuridine (IdUrd).* Proc Am Assoc Canc Res A2193, 1998. Winner Glaxo-Wellcome Oncology Trainee Award.
308. Alberts S, Erlichman C, Reid JM, Ames MM, Sloan JA, Richardson RL, **Goldberg RM.** *Phase I study of the synthetic duocarmycin derivative KW2189 given daily for 5 days every 6 weeks.* Proc Am Soc Clin Oncol 16, A748, 1997. Poster presentation.
309. **Goldberg RM**, Moertel CG, Fleming TR, Tangen C, Macdonald JS, Haller DG, Laurie, JA. Salvage surgery (s.s.) for recurrent colon cancer (c.c.) in patients(pts.) entered on INT 0035: An evaluation of levamisole alone or levamisole + 5-fluorouracil as surgical adjuvant treatment for resectable colon cancer. Proc Am Soc Clin Oncol 16: A992, 1997. Podium presentation.
310. **Goldberg RM**, Hatfield AK, O'Connell MJ, Mahoney M, Krook JE. Salvage 5-FU based chemotherapy for patients (pts) with advanced colorectal cancer (crc) who have relapsed following surgical adjuvant (adj) chemotherapy(ct): A North Central Cancer Treatment Group Trial. Proc Am Soc Clin Oncol 16, A960, 1997. Poster presentation.
311. Fonseca R*, **Goldberg RM**, Erlichman C, Kaufmann SH, Sloan JA, Miller L. *Phase I study of CPT-11/5-FU/CF.* Proc Am Assoc Clin Res 38:A513, 1997. Poster presentation.
312. Pitot IV HC, Erlichman C, **Goldberg RM**, Reid JM, Ames MM, Schaaf LJ, Dietz AJ. *Phase I trial of irinotecan (CPT-11) given once every three weeks to patients with advanced solid tumors.* Proc Am Soc Clin Oncol 15:A1581, 1996.
313. Okuno SH*, Kahn MJ, and **Goldberg RM.** Small bowel adenocarcinoma: A review of 106 consecutive cases from the Mayo Clinic 1985-1993. Proc Am Soc Clin Oncol 15:A552, 1996.
314. **Goldberg RM**, O'Connell MJ, Wieand HS, Hatfield AK, Moertel CG, Kahn MJ. A prospective randomized trial of intensive course 5-FU combined with A) the l-isomer of

intravenous leucovorin, B) oral (d,l) leucovorin, or C) intravenous (d,l) leucovorin for the treatment of advanced colorectal cancer: A North Central Cancer Treatment group trial. Proc Am Soc Clin Oncol 15:A471, 1996. Podium presentation.

315. **Goldberg RM**, Reid JM, Ames MM, Sloan JA, Rubin J, Erlichman C, Kuffel MJ, and Fitch TR. *Phase I clinical trial and pharmacokinetics of fazarabine*. Proc Am Assoc Clin Res 37:A1127, 1996. Podium presentation.
316. Schleusener J, Tazelaar H, Jung S, Cera P, Myers J, Creagan E, **Goldberg R**, Marschke R. *Neuroendocrine (NE) differentiation correlates with survival in chemotherapy treated non-small cell lung cancer (NSCLC)*. Proc United States and Canadian Soc Path. Podium presentation.
317. **Goldberg RM**, Loprinzi CL, Mailliard J, O'Fallon JR. A randomized, placebo-controlled evaluation of pentoxifylline in patients with cancer anorexia and cachexia: A North Central Cancer Treatment Group study. Proc Am Soc Clin Oncol 13:459, 1994. Poster presentation.
318. Erickson LD, Hartmann LD, Su J, Nielson SNJ, Pfeifle D, **Goldberg RM**, Levitt R, Stanhope CR. *Cyclophosphamide, cisplatin and leuprolide acetate in patients with debulked stage III-IV ovarian carcinoma*. Proc Soc Gynecol Invest 1993. Podium presentation.
319. **Goldberg RM**, Loprinzi CL, Mailliard J, O'Fallon JR. A randomized, placebo-controlled evaluation of pentoxifylline in patients with cancer anorexia and cachexia: A North Central Cancer Treatment Group study. Proc Am Soc Clin Oncol 13:459, 1994. Poster presentation.
320. Erickson LD, Hartmann LD, Su J, Nielson SNJ, Pfeifle D, **Goldberg RM**, Levitt R, Stanhope CR. *Cyclophosphamide, cisplatin and leuprolide acetate in patients with debulked stage III-IV ovarian carcinoma*. Proc Soc Gynecol Invest 1993. Podium presentation.
321. Krook J, **Goldberg RM**, Moertel CG, Wieand HS. A phase III evaluation of the somatostatin analogue octreotide in the therapy (Rx) of asymptomatic colon cancer (AACC): A North Central Group Trial. Proc Am Soc Clin Oncol 12:556, 1993. Podium presentation.
322. Loprinzi CL, **Goldberg RM**, Su JQ, Mailliard J, Maksymiuk A, Kugler J, Ghosh C, Pfeifle D, Wender D, Burch P, Jett J. Randomized double-blind, placebo-controlled trial evaluating hydrazine sulfate (HS) in patients with newly diagnosed non-small cell lung cancer. A North Central Cancer Treatment Group trial. Proc Am Soc Clin Oncol 12:337, 1993. Poster presentation.
323. Loprinzi CL, Quella S, O'Fallon J, **Goldberg RM**, Miser A, Dose AM, Mynderse L, Brown L, Tschetter L. Prospective trial of transdermal clonidine in men suffering from orchiectomy-induced hot flashes. A North Central Treatment Group Trial. Proc Am Soc Clin Oncol 12:464, 1993.
324. Loprinzi CL, Mailliard J, Schaid D, Krook J, **Goldberg RM**, Keppen M, Michalak J. Dose/response evaluation of megestrol acetate for the treatment of cancer anorexia/cachexia: A Mayo Clinic and North Central Cancer Treatment Group trial. Proc Am Soc Clin Oncol 11:378, 1992. Poster presentation.
325. **Goldberg RM**, Loprinzi CL, Gerstner J, Miser A, O'Fallon J, Mailliard J, Michalak J, Dose AM. Prospective trial of transdermal clonidine in breast cancer patients suffering from tamoxifen induced Hot flashes: A Mayo Clinic and North Central Cancer Treatment Group trial. Proc Am Soc Clin Oncol 11:378, 1992. Poster presentation.
326. **Goldberg RM**, Jett J, Therneau T. Etoposide and cisplatin (EP) via infusion or bolus therapy in patients with stage IV non-small cell lung cancer. Proc Am Soc Clin Oncol 8:C-851, 1989. Poster presentation.

327. **Goldberg RM**, Ahlgren JD. Continuous infusion 5-FU with weekly low dose cisplatin as second line therapy in patients with metastatic colorectal cancer who have failed 5-FU monotherapy. Proc 2nd International Conf on Gastrointestinal Cancer 2:14, 1989. Poster presentation.
328. **Goldberg R**, Smith F, Ueno W, Ahlgren J, Schein P. *Treatment of adenocarcinoma of unknown primary with fluorouracil, adriamycin and mitomycin C*. Proc Am Soc Clin Oncol 5:C-504, 1986. Poster presentation.
329. Kerr R, Ayoob M, **Goldberg R**, Byrne P, Smith F, Neeffe J. *Treatment of metastatic malignant melanoma with human leukocyte interferon: A profile of 5 complete responders*. Proc Am Soc Clin Oncol 4:C-899, 1985. Poster presentation.
330. Byrne P, Grady K, Smith F, **Goldberg R**, Goodman A. Phase II clinical trial of 2-N-methyl-9-hydroxy-elliptinium (elliptinium) in patients with advanced breast cancer. Proc Am Soc Clin Oncol 3:C-499, 1984. Poster presentation.
331. Harter K, **Goldberg R**, Byrne P, Lee T, Smith F, Dritschilo A. Local recurrence of breast cancer following lumpectomy in patients receiving adjuvant chemotherapy prior to definitive breast irradiation. Proc Am Soc Clin Oncol 3:C-491, 1984.
332. **Goldberg R**, Silgals R, Ayoob M, Smith F, Neeffe J. *A phase II trial of lymphoblastoid interferon (IF) in malignant melanoma (MM)*. Proc Am Soc Clin Oncol 3:C-289, 1984. Poster presentation.
333. **Goldberg R**, Byrne P, Feller W, Harter KW, Ueno W, Dritschilo A. *A comparison of adjuvant chemotherapy in lumpectomy - primary breast radiation and mastectomy patients*. Proc Am Soc Clin Oncol 3:C-492, 1984. Poster presentation.
334. Stefanik D, **Goldberg R**, Byrne PJ, Smith FP, Ueno W, Hill LT, Bachenheimer L, Beiser C, Dritschilo A. *Local-regional failure in patients treated with adjuvant chemotherapy for breast cancer*. Proc Annual San Antonio Breast Cancer Symposium 1984. Poster presentation.

BOOK REVIEWS

1. **Goldberg RM**. Review Gastrointestinal Cancers: Biology, Diagnosis, and Therapy, edited by Anil K. Rustgi, 663 pp, with illus, Philadelphia, Lippincott-Raven Publishers. Mayo Clin Proc 72: 94-95, 1997.
2. **Goldberg RM**. Review of Breast Cancer: Controversies in Management, edited by Leslie Wise and Houston Johnson, JR., 592 pp, with illus, Armonk, New York, Futura Publishing Company, 1994, Mayo Clin Proc 70:508-509, 1995.

TEACHING RECORD

Lectures:

To Students: Annual talk on Principles of Neoplasia to the UNC second year Hematology and Oncology course

To Residents: Annual talk on Advances in Colorectal Cancer Management to the Internal medicine noon lectur series

To Fellows: Annual talk on Advances in Colorectal Cancer Management to Hematology and Oncology fellows

LECTURES TO ALL SOURCES BY ACADEMIC YEAR:

2005-2006		
Jul 1	<i>Management of Advanced Colorectal Cancer</i>	Tokyo, Japan

Jul 3	<i>Management of Advanced Colorectal Cancer</i>	Japanese Society of Clinical Oncology - Osaka, Japan
Jul 15	<i>New Agents in the Management of Colorectal Cancer</i>	International Society of GI Oncology - Arlington, VA
Aug 5-7	Lecture: <i>Management of GI Cancers</i>	Director: Big Sky Oncology Course - Big Sky, MT
Aug 13	<i>Updates in GI Cancer Management</i>	NC Oncology Association - Greensboro, NC
Sep 3	Presentation on <i>Colorectal Cancer</i>	National Public Radio - Chapel Hill, NC
Sep 22-25	Lecture: <i>First-Line Therapy of Colorectal Cancer</i>	Course Director: Perspectives in Colorectal Cancer - Chicago, IL
Oct 1	<i>Management of Advanced Colorectal Cancer</i>	Falk Symposium - Berlin, Germany
Oct 14-16	Lecture: <i>New Agents in Colorectal Cancer as well as CALGB Studies</i>	Co-Director: Colorectal Cancer Symposium - Aventura, FL
Oct 24	Evening Lecture: <i>Management of Colorectal Cancer and Liver Resection for Colorectal Cancer</i>	Grand Rounds: Lehigh Valley Hospital - Reading, PA
Oct 29	<i>Adjuvant Therapy for Colorectal Cancer</i>	Atlanta, GA
Dec 2	<i>Targeted Therapies in the Management of Colorectal Cancer</i>	ASCO Media Event - New York, NY
Jan 27	<i>Use of FOLFOX in Elderly Patients with Colorectal Cancer</i>	2006 GI Symposium - San Francisco, CA
Feb 4	<i>Management of Colorectal Cancer</i>	Cowan Symposium - Salt Lake City, UT
Mar 4	<i>A Decade of Progress in Colorectal Cancer Management</i>	GI Cancer Summit - Warsaw, Poland
Apr 2	Session Chair & Lecturer: <i>Clinical Implications of Genetic Discoveries in Colorectal Cancer</i>	American Association for Cancer Research - Washington, DC
May 8	Oncology Grand Rounds: <i>Management of Colorectal Cancer</i>	Long Island Jewish Hospital - New Hyde Park, NY
May 20	<i>Challenging Cases in GI Cancer</i>	New York, NY
May 4-7	Session Chair/Oral Abstract Presenter/Poster Discussion Leader: <i>Differences in Outcomes and Polymorphisms in African American and Caucasians Treated for Advanced Colorectal Cancer</i>	American Society of Clinical Oncology Meeting Chicago, IL
Jun 24	<i>Challenging Cases in GI Cancer</i>	New York, NY
2006-2007		
Jul 7	Colorectal Cancer Think Tank for Research to Practice	Key Biscayne, FL
Aug 5-6	<i>Update on GI Cancer</i>	Course Director: Big Sky Oncology Course - Big Sky, MT
Aug 8	<i>Management of Advanced Colorectal Cancer</i>	Amgen Training Program - Miami, FL
Sep 16-17	Meeting Chairman: <i>Optimal Management of Advanced Colorectal Cancer</i>	Perspectives in Colorectal Cancer - Scottsdale, AZ
Sep 21-22	<i>Which Strategies will Lead to Progress in GI Cancer, Adjuvant Colorectal Cancer Trials in the US, Colorectal Cancer Cases</i>	Int'l Society of GI Oncology - Washington, DC (Installed as President)
Oct 7	Managing Advanced Colorectal Cancer	St. Louis University School of Medicine - St. Louis, MO

Nov 8	<i>UGT1a1 Testing with Irinotecan Therapy and Use of Fecal DNA for Colon Cancer Diagnosis</i>	Institute of Medicine - Washington, DC
Nov 17-18	Susan B. Lester Lectureship	University of Kentucky - Lexington, KY
Jan 9	Grand Rounds: <i>Advances in the Treatment of Colorectal Cancer</i>	AHEC, Moses Cone Hospital - Greensboro, NC
Jan 19-21	Panel Member: Colorectal Cancer Think Tank	ASCO GI Meeting - Orlando, FL
Jan 20-22	Session Chair & Program Committee Member	GI Cancer Symposium - Orlando, FL
Jan 25-26	<i>Management of Colorectal Cancer</i> (Public) - <i>Advances in the Management of Colorectal Cancer</i> (Med School)	Volkman Lectureship - Greenville, NC
Feb 7	<i>Managing Colorectal Cancer</i>	Sanofi-Aventis Training Program - Washington, DC
Feb 17	<i>Integrating Targeted Agents in the Management of Colorectal Cancer</i>	Las Vegas, NV
Mar 30-31	<i>Case Presentations and Recently Approved Agents for Treatment of GI Cancer, and Essentials for Excellence: Clinical Support</i>	ISGIO Fellows and Junior Practitioner's Meeting - Arlington, VA
Apr 13	<i>Targeted and Novel Therapies in Colorectal Cancer</i>	Gibbs Cancer Center - Spartanburg, SC
Apr 14-16	<i>Plenary Session Commentary: Cetuximab in Colon Cancer</i>	AACR Meeting - Los Angeles, CA
Apr 27	<i>Genetic and Pharmacogenetic Considerations in the Management of Colorectal Cancer</i>	OSU James Cancer Hospital Grand Rounds - Columbus, OH
May 2	<i>Genetic and Pharmacogenetic Considerations in the Management of Colorectal Cancer</i>	University of Chicago - Chicago, IL
May 3	<i>Genetic and Pharmacogenetic Considerations in the Management of Colorectal Cancer</i>	Rush Medical Center - Chicago, IL
May 9-11	<i>Cancer Control in Africa</i>	Sponsored by Oxford University - London, England
Jun 1-4	Program Committee: <i>Attributes of Successful Clinical Trials, GI Cancer Poster Discussion</i> Commentary: <i>A Pooled Safety & Efficacy Analysis Examining the Effect of Performance Status on Outcomes in 9 First-Line Treatment Trials of 6,286 Patients with Metastatic Colorectal Cancer</i>	Annual American Society of Clinical Oncology Chicago, IL
Jun 14-15	<i>Managing Older Patients and Symptomatic Patients with Colorectal Cancer; Meet the Professor</i>	Research to Practice - Miami, FL
Jun 22-24	<i>Molecular Marker Driven Studies</i>	CALGAB Symposium - Baltimore, MD
Jun 26	<i>Molecular Marker-Driven Studies</i>	CALGB Symposium - Baltimore, MD
Jun 28-30	Program Comm./Session Chair: <i>Optimal Management of Metastatic Colorectal Cancer in 2007</i>	World GI Cancer Congress - Barcelona, Spain
2007-2008		
Aug 7-9	Course Director: <i>New Developments in the Management of Gastrointestinal Cancers</i>	Big Sky Oncology Course - Big Sky, MT

Sep 7-9	Course Director and Lecturer: <i>First-Line Therapy of Metastatic Colorectal Cancer</i>	Perspectives in Colorectal Cancer - Miami, FL
Sep 28-30	Outgoing President/Meeting Coordinator/Session Chair/Supervised Present Fellow	International Society of GI Oncology - Philadelphia, PA
Oct 11-13	Session Chair: <i>Mgmt of Patients w/Untreated Advanced Colorectal Cancer & CALGB Update</i>	Colorectal Cancer Update - Aventura, FL
Oct 19	<i>Management of Esophageal Cancer</i>	Annual Fall Foliage Mtg - Asheville, NC (Sponsored by Wake Forest Univ)
Oct 22	<i>Management of Colorectal Cancer</i>	National Cancer Institute of Japan - Tokyo, Japan
Oct 23	<i>Management of Colorectal Cancer</i>	Japanese Society of Clinical Oncology - Osaka, Japan
Oct 24	<i>Management of Colorectal Cancer</i>	Nagoya, Japan
Oct 25	<i>Management of Colorectal Cancer</i>	Tokyo, Japan
Nov 2	<i>Management of Colorectal Cancer</i>	Wake Forest University - Winston-Salem, NC
Nov 17-18	<i>Managing in an Academic Setting and Advances in Treatment of Colorectal Cancer</i>	ISGIO Fellows Meeting - Washington, DC
Nv 31-Dec1	NCI Pancreatic Cancer State of the Science Meeting	Washington, DC
Jan 17-18	Keynote Speaker: <i>Advances in Colorectal Cancer Management</i>	South Carolina Colon Cancer Consortium - Charleston, SC
Jan 25-27	Symposium: <i>Colorectal Cancer Management</i>	ASCO GI Symposium - San Francisco, CA
Feb 8-9	<i>Adjuvant Therapy of Colon Cancer and Integrating Biologic Agents into the Management of Advanced Colorectal Cancer</i>	Perspectives in Colorectal Cancer - Charleston, SC
Mar 1	<i>Advances in Colorectal Cancer Management</i>	Wake Forest Nursing Conference - Greensboro, NC
Mar 10-11	Advocate Training and Keynote Speaker	Colon Cancer Coalition - Washington, DC
Mar 14-15	<i>Clinical Trials in Advanced Colon Cancer</i>	Sanofi-Aventis International Investigator's Meeting - Seville, Spain
Apr 26	<i>Adjuvant Therapy for Colon Cancer</i>	Rasco Symposium - Little Rock, AR
May 10	<i>Treating Metastatic Colorectal Cancer</i>	Hellenic Society of Clinical Oncology - Athens, Greece
May 29-Jn 4	Commentary on Adjuvant Matters. <i>GI Plenary Session and KRAS in Treatment Decisions</i>	ASCO Annual Meeting - Chicago, IL
Jun 13	<i>Genetic and Pharmacogenetic Considerations in the Management of Colorectal Cancer</i>	Roswell Park Memorial Cancer Institute - Buffalo, NY
Jun 20	<i>Genetics in Colorectal Cancer Management</i>	Myriad - Salt Lake City, UT
2008-2009		
Jul 12	<i>Colorectal Cancer</i>	Community Forum - Manteo, NC

Jul 24	Colorectal Cancer Think Tank Meeting	Miami, FL
Aug 15-17	Course Director: <i>Managing Colorectal Cancer in the Age of Molecular Markers</i>	Big Sky Oncology Course - Big Sky, MT
Sep 3	<i>Principles of Neoplasia</i>	UNCSOM 2 nd Year Class Oncology Course - Chapel Hill, NC
Sep 18	Colorectal Cancer Think Tank on Liver Metastases	Research to Practice - Miami, FL
Sep 19-20	Course Director: <i>Management of First-Line Therapy for Metastatic Colorectal Cancer</i>	Perspectives in Colorectal Cancer - Miami, FL
Oct 16-18	Co-Course Dir & Lecturer: <i>First Line Mgmt of Colon Cancer and Molecular Genetic Prognostic Markers in Adjuvant Therapy</i>	Perspectives in Colorectal Cancer - Aventura, FL
Oct 24	<i>Advances in the Management of Colorectal Cancer</i>	Medical Alumni Meeting - University of NC - Chapel Hill, NC
Oct 28	<i>Advances in the Management of Colorectal Cancer</i>	Fellows Didactic - University of NC - Chapel Hill, NC
Oct 31	<i>Update on Adjuvant Therapy of Liver Metastases</i>	South Bend, IN
Nov 3	<i>Leveraging Cooperative Group Clinical Trials in GI Cancer</i>	University of South Carolina - Columbia, SC
Nov 15	Plenary Talk: <i>Odyssey of a Clinical Researcher</i>	CALGB Meeting - Tampa, FL
Feb 24-25	2/24: <i>Advances in the Management of Colorectal Cancer & Managing Liver Metastases</i> 2/25: <i>Advances Related to Bevacizumab Use in Colorectal Cancer</i>	King Faisal Hospital Oncology Program Jeddah, Saudi Arabia
Apr 2	Magisterial Lecture: <i>Maximizing the Value of a Clinical Trial: US Intergroup Study N9741</i>	Italian Oncology Society - Florence, Italy
Apr 17	<i>A Colorectal Cancer Update</i>	Taipei, Taiwan
Apr 18	<i>A Colorectal Cancer Update</i>	Hong Kong
May 1	<i>Advances and Future Directions in Colorectal Cancer</i>	Grand Rounds, Lankenau Hosp - Philadelphia, PA
May 31	Chair and Lecturer of Educational Session: <i>Managing Colorectal Cancer in the Elderly</i>	American Society of Clinical Oncology - Orlando, FL
Jun 18	<i>Advances in GI Cancer</i>	Columbus CCOP CME Meeting - Columbus, OH
2009-2010		
Jul 7	Grand Rounds: <i>Leveraging Cooperative Group Clinical Trials in GI Cancer: Treatment, Biology, and Methodology</i>	Leo Jenkins Cancer Center, East Carolina University - Greenville, NC
Jul 16	Course Director: Colorectal Cancer Think Tank for Research to Practice	Colorectal Cancer Think Tank - Miami, FL
Aug 7-8	Course Director: <i>First-Line Therapy of Metastatic Colorectal Cancer</i>	Perspectives in Colorectal Cancer - Chicago, IL
Aug 14-16	Course Director: <i>GI Cancer Update</i>	Big Sky Oncology - Big Sky, MT

Oct 6	<i>Advances in the Management of Colorectal Cancer</i>	University of NC Fellow's Didactic Series - Chapel Hill, NC
Oct 15	<i>Leveraging Cooperative Group Clinical Trials in GI Cancer: Treatment, Biology, and Methodology</i>	Ann. Mtg of American Clinical & Climatological Assoc - Hot Springs, VA
Oct 22	<i>Elder Care: Managing Older Patients with Colorectal Cancer</i>	EC% Meeting - Montreal, Canada
Oct 30-31	<i>10/30: Debate: Antiangiogenic Therapy Should Be Included in First Line Regimens for All Patients With Metastatic CRC-Con Side; 10/31: Cooperative Group Trials in Colorectal Cancer</i>	7 th International Colorectal Cancer Congress - Washington, DC
Jan 21-25	Steering Committee Member - 1/23: Chair, <i>Young Investigators Program</i>	ASCO GI Cancers Symposium - San Francisco, CA
Feb 8	Visiting Professor and Oncology Grand Rounds	Sunnybrook Cancer Center - Toronto, Canada
Feb 8	<i>Managing Colorectal Cancer in the Elderly</i>	Toronto CME Event - Toronto, Canada
Feb 25	Plenary Lecture: <i>Management of Advanced Colorectal Cancer</i>	German Cancer Society Meeting - Berlin, Germany
Jun 5-9	Program Committee Member -6/6: Oral Research Presenter & Session Chair: <i>Managing Elderly Patients w/ Colorectal Cancer</i> - 6/7: Presenter and Session Chair: <i>Managing Conflict of Interest</i> -6/8: Presenter: Results of N0147 Adjuvant Study of FOLFOX +/- Cetuximab in Stage III Colon Canc	ASCO Meeting - Chicago, IL
2010-2011		
Jul 9	<i>Optimal Integration of Chemotherapy and Targeted Therapies in Managing Colorectal Cancer</i>	WIN Symposium - Paris, France
Aug 6-7	<i>Update on New Developments in GI Cancer</i>	Chair: Big Sky Oncology Course - Big Sky, MT
Aug 13	<i>Initial Management of Advanced Colorectal Cancer</i>	Natal, Brazil
Sep 26	<i>Managing Older Patients with Colorectal Cancer</i>	Cancer in the Elderly Symposium - Chicago, IL
Oct 11-12	- <i>Managing Older Patients with Colorectal Cancer</i> - <i>A Colorectal Cancer Update</i> - <i>Toward an Alaska Appropriate Screening Strategy for Colorectal Cancer</i>	Treadwell Visiting Scholar: Providence Hospital Anchorage, AK
Oct 16	<i>Management of Metastatic Colon Cancer</i>	University of Kansas Symposium - Kansas City, KA
Oct 27-30	<i>Managing the Interface Between Chemotherapy and Biologics in Patients with Colorectal Cancer</i>	Colorectal Cancer: Biology to Therapy - AACR Symposium - Philadelphia, PA
Jan 7-8	<i>Metastatic Disease</i>	NCI Colorectal Cancer Clinical Trials Planning Mtg - Washington, DC
Jan 20-23	Steering Committee and Session Chair	GI Cancers Symposium - San Francisco, CA
Jan 28-29	<i>Initial Management of Advanced Colorectal Cancer and Adjuvant Matters in Colorectal Cancer</i>	Perspectives in Colorectal and Pancreatic Cancer - Charleston, SC
Mar 8	<i>Managing Older Patients with Colorectal Cancer</i>	Grand Rounds - London Ontario

Mar 11-12	<i>Colorectal Cancer: Choosing Treatments in the Era of Molecular Genetics</i>	Charles William Rasco Symposium on Colorectal Cancer - Little Rock, AK
Apr 5	<i>Colorectal Cancer: Choosing Treatments in the Era of Molecular Genetics</i>	Cleveland Clinic Cancer Center Symposium - Cleveland, OH
Apr 29	<i>Update on Systemic Therapy for Colorectal Cancer</i>	3 rd Annual GI/HepatoPancreatoBiliary Symposium - Winston-Salem, NC
May 2	<i>Managing Older Patients with Colorectal Cancer</i>	Carolinas Medical Center Grand Rounds - Concord, NC
2011-2012		
Jul 7	<i>Predicting Clinical Efficacy: Molecular and Radiographic Markers as Harbinger of Drug Response</i>	WIN Symposium - Paris, France
Aug 15	<i>Managing Older Patients with Colorectal Cancer</i>	Oncology Grand Rds, British Columbia Cancer Agency - Vancouver, BC
Sep 9	<i>Maximizing the Harvest: A Parable Drawn from the Phase III NCCTG N9741 Study in Patients with Metastatic Colorectal Cancer</i>	Society for Translational Oncology - Belfast, Ireland
Oct 15	<i>Eldercare: Managing Older Patients with Metastatic Colorectal Cancer</i>	Oncology Congress 2011 - San Francisco, CA
Oct 26	<i>Cancer Patient's Quality of Life and Their Genes: Predestination or Predisposition?</i>	ISOQOL 18 th Annual Conference - Denver, CO
Nov 15	Fellows Presentation: <i>Management of Metastatic Colorectal Cancer</i>	The Ohio State University - Columbus, OH
Jan 20-22	<i>Strategies for Managing Resistant mCRC in an Era of Multiple Biologic Drugs</i> Session Chair: <i>Esophageal and Gastric Cancer Abstract Session</i> Session Chair: <i>GI Cancer Abstract Session</i>	ASCO GI Symposium San Francisco, CA
Feb 17-18	<i>Challenges and Choices When Treating Gastroesophageal Cancer: Initial Management of Advanced Colorectal Cancer</i>	FORCE Meeting - Ho Chi Minh City, Vietnam
Mar 12	<i>Maximizing the Harvest from a Phase III Colorectal Cancer Clinical Trial: NCCTG N9741</i>	James Cancer Center Oncology Grand Rounds - Columbus, OH
May 25	<i>New Developments in the Diagnosis and Treatment of Colorectal Cancer</i>	Geisinger Medical Center Grand Rounds - Danville, PA
Jun 16	Course Director: <i>Updates in Colorectal Cancer</i>	Ohio State's 2012 ASCO Review - Columbus, OH
Jun 21	<i>Updates in GI Cancers</i>	Columbus CCOP 2012 ASCO Review - Columbus, OH
2012-2013		
Jul 5-7	ASCO 2012 Update: <i>Emerging Drugs for the Treatment of Colorectal Cancer</i>	Japanese Society of Clinical Cancer Research Mtg (JSCCR)-Tokyo, Japan
Jul 6	Presenter: <i>Treatment for Unresectable Advanced Metastatic Colorectal Cancer</i>	JSCCR Meeting - Tokyo, Japan
Jul 7	Presenter: <i>Treatment for Unresectable Advanced Metastatic Colorectal Cancer</i>	JSCCR Meeting - Tokyo, Japan
Sep 21	Presenter: <i>After ASCO 2012: News in GI Cancers</i>	12 th Annual Cancer Conference - Aultman Cancer Center - Canton, OH
Oct 12	<i>Systematic Anti-Cancer Therapy for Elderly Patients with Colorectal Cancer</i>	1 st Ann. Symposium for Treatment & Management of Elderly Patients

		with Cancer - Los Angeles, CA
Oct 21	Presenter: <i>Screening for Colon Cancer: Impact, Disparities, and New Approaches</i>	Society of Translational Oncology /Lineberger UNC Fall Symposium University of North Carolina at Chapel Hill - Chapel Hill, NC
Dec 1	<i>Metastatic Colorectal Cancer w/ Liver-Only Metastases: Has the Optimal Approach Been Defined?</i>	Expert Practice in Colorectal Cancer Symposium New York, NY
Jan 24	<i>Regorafenib and Other New Agents in Colorectal Cancer</i>	Research To Practice Satellite Symposium on Advances in the Treatment of Colorectal Cancer - San Francisco, CA
Jan 25	Junior Faculty Mentorship Event	GI Cancer Symposium 2013 - San Francisco, CA
Jan 26	<i>Ten Years of Progress in the Management of Colorectal Cancer</i>	GI Cancer Symposium 2013 - San Francisco, CA
Apr 21	<i>Personalized Therapies in GI Cancer: Now and in the Future</i>	UPMC Multidisciplinary GI Cancer Symposium - Pittsburgh, PA
Apr 25	<i>Maximizing the Harvest from a Phase III Colorectal Cancer Clinical Trial: NCCTG N9741</i>	Karmanos Cancer Center Grand Rounds - Detroit, MI
Jun 1	<i>Adjuvant Therapy in the Elderly Patient with Colon Cancer</i>	American Society of Clinical Oncology Annual Meeting - Chicago, IL
Jun 15	Symposium Co-Chair: Review of Colorectal Cancer Presentations	OSU Annual ASCO Update - Columbus, OH
2013-2014		
Jul 5	Abstract Discussant. Scientific Organizing Committee Member and Session Co-Chair	World Congress on GI Cancer - Barcelona, Spain
Jul 9	- <i>Advances in the Management of Early Stage Colon Cancer</i> -Plenary Lecture: <i>Advances in the Management of GI Cancers</i>	Advances in Management of Colorectal Cancer 2013 Hanoi, Viet Nam
Jul 15	Symposium Co-Chair: <i>Targeted Therapies in the Management of Advanced Colorectal Cancer</i>	Asian Pacific Oncology Conference - Bangkok, Thailand
Sept 20	Gastrointestinal Cancer - Clinical Investigator Think Tank Meeting panel	GI Cancer - Clinical Investigator Think Tank Meeting - Miami, FL
Oct 9	Management of Peritoneal Carcinomatosis	Australian GI Tumor Study Group annual Meeting - Melbourne
Oct 10	Update on CRC Adjuvant Therapy: <i>Why have biological agents not succeeded?</i>	Australian GI Tumor Study Group annual Meeting - Melbourne
Oct 11	<i>Second Line Treatment of Colorectal Cancer and Beyond: 5, 4, 3, 2, 1, or 0 Drugs</i>	Australian GI Tumor Study Group annual Meeting - Melbourne
Dec 8	<i>Inclusion of African Americans in Cancer Clinical Trials: Potential Quality of Life, Comorbidity, and Pharmacogenetic-Related Barriers</i>	6th AACR Conference on The Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved - Atlanta, GA
Jan 16	<i>Making Good Choices: Second-Line Treatment for Metastatic Colorectal Cancer</i>	GI Cancer Symposium - San Francisco, CA
Jan 17	<i>Jumpstarting your Career: How to give a talk and write a paper</i>	GI Cancer Symposium - San Francisco, CA

Jan 18	<i>Chemotherapy for Stage II MSI: To treat or not to treat</i>	GI Cancer Symposium - San Francisco, CA
Feb 21	<i>Optimizing the Mgmt. of Liver Metastasis: Advances in the Neoadjuvant and Adjuvant Fronts</i>	International Cancer Conference - Madrid, Spain
Feb 22	<i>Challenging Cases in Metastatic Colorectal Cancer</i>	International Cancer Conference - Madrid, Spain
Mar 15	<i>Eldercare: Managing Older Patients with Metastatic Colorectal Cancer</i>	Oncology Outlook 2014 CME Conference - Point Clear, AL
Apr 10	<i>Tickets to Academic Success: Delivering Outstanding Oral Presentations & Publishing High-Impact Articles</i>	2014 Colorectal Cancer Meeting - Dublin, Ireland
Apr 11	<i>Moving Beyond RAS as a Predictive Biomarker in Colorectal Cancer</i>	2014 Colorectal Cancer Meeting - Dublin, Ireland
Apr 12	<i>Stage II Colon Cancer: To Treat or Not to Treat? That is the Question</i>	2014 Colorectal Cancer Meeting - Dublin, Ireland
Jun 26	<i>Co-Chair, Session VI: Cancer of the Liver</i>	ESMO 16 th World Congress on GI Cancer - Barcelona, Spain
Jun 27	<i>What are Resectable Liver Metastases?</i>	ESMO 16 th World Congress on GI Cancer - Barcelona, Spain
Jun 28	<i>Discussant, Session XVIII: Metastatic Colorectal Cancer</i>	ESMO 16 th World Congress on GI Cancer - Barcelona, Spain
Jun 28	<i>Perception of Metastatic Colorectal Cancer, Choice of Therapy & Treatment Challenges - Clinical Case 1: First-Line Therapy of de Novo mCRC</i>	ESMO 16 th World Congress on GI Cancer - Barcelona, Spain
Jun 28	<i>Perception of Metastatic Colorectal Cancer, Choice of Therapy & Treatment Challenges - Clinical Case 2: Second-Line Therapy of mCRC</i>	ESMO 16 th World Congress on GI Cancer - Barcelona, Spain
Jun 28	<i>Perception of Metastatic Colorectal Cancer, Choice of Therapy & Treatment Challenges - Clinical Case 3: First-Line Therapy for mCRC after Adjuvant Relapse <6 months</i>	ESMO 16 th World Congress on GI Cancer - Barcelona, Spain
2014-2015		
Oct 17	<i>Era of Molecular Risk Stratification in the Adjuvant Setting</i>	12 th Annual West Coast Colorectal Cancer Symposium - Seattle, WA
Jan 28	<i>Colorectal Liver Metastases Management</i>	Symposium on Hepatic Oncology at Whistler- Whistler, British Columbia
	<i>Case Reviews</i>	
	<i>What is the role of locoregional therapy in the setting of extrahepatic colorectal cancer</i>	
	<i>Keynote Lecture: Update and future direction of systemic and locoregional therapy in the liver</i>	
Apr 10-11	<i>Symposium Chair: Perspectives on Progress: Using Genomics to Guide Clinical Therapy</i>	Society for Translational Oncology, Columbus OH
	<i>Integrating pathologic & genomic factors to make treatment decisions in patients with GI cancers</i>	
	<i>Managing colorectal cancer: Second Line therapy and beyond</i>	Assessing recent data and future therapy for advanced gastric, pancreatic, and colorectal cancers
June 2	<i>Chair, Clinical Science Symposium: Targeted therapies: Does the disease matter?</i>	Annual Meeting of the American Society of Clinical Oncology

2015-2016		
Jul 3	<i>Presentation of selected abstracts</i>	ESMO World GI Cancer Symposium, Barcelona, Spain
Jul 4	<i>How to improve adjuvant therapy of colon cancer?</i>	ESMO World GI Cancer Symposium, Barcelona, Spain
Oct 18	<i>Talk: “Neoadjuvant and Adjuvant Chemotherapy for Rectal Cancer”</i>	ASTRO Presidential Symposium - San Antonio, TX

2016-2017		
Jan 19	<i>Drilling Down On Immunotherapy in CRC: What We Know and What We Need To Know</i>	Dawn of Immunotherapy in Gastric and Colorectal Cancers, Symposium San Francisco, CA
Feb 9	<i>Immunotherapy in GI Cancers</i>	University of Iceland, Reykjavik, Iceland
Mar 14	<i>In memorium to Daniel J Sargent Ph.D.</i>	Biometrics Society, Washinton DC
Apr 4	<i>Current and Emerging Mutation-based Treatment Strategies for Advanced Metastatic Colorectal Cancer</i>	Southside Regional Medical Center, Petersburg , VA
Apr 6	<i>Current and Emerging Mutation-based Treatment Strategies for Advanced Metastatic Colorectal Cancer</i>	Shadyside Hospital, Rockville, MD
May 8	<i>In memorium to Daniel J Sargent Ph.D.</i>	Society for Clinical Trials, Liverpool, England
Jun 27	<i>Pembrolizumab: A Recently Approved Treatment Option in the Management of Certain Advanced Cancers</i>	Webcast
Jul 11	<i>Pembrolizumab: A Recently Approved Treatment Option in the Management of Certain Advanced Cancers</i>	Webcast
Jul 19	<i>Pembrolizumab: A Recently Approved Treatment Option in the Management of Certain Advanced Cancers</i>	Webcast
Aug 18	<i>An Update on Progress in GI Cancers from ASCO 2017</i>	Oklahoma Society of Clinical Oncology Cancer Conference, Oklahoma City, OK
Nov 14	<i>Progress with Immuno-oncology agents in GI oncology</i>	European Society of Medical Oncology, Singapore
Dec 19	<i>Progress with Immuno-oncology agents in GI oncology</i>	Inova Schar Cancer Institute Grand Rounds, Fairfax, VA

2018-2019		
Feb 15	<i>A Case Study and Review of the Literature on PD-1 Inhibitors in GI Cancers</i>	21 st Annual TRCCC meeting, Seven Springs PA
Feb 21	<i>At Long Last: Immunologic Approaches to the Treatment of GI Cancers</i>	University of South Carolina, Columbia, SC
Mar 18	<i>Getting Behind a Cure: New and Noteworthy Information on Colorectal Cancer</i>	Fight Colorectal Cancer annual call on congress meeting, Washington DC

Jul 31	<i>A Career Punctuated by "C" Words</i>	Plenary lecture, Annual INBRE meeting, Morgantown, WV
	<i>The Utility of PD-1, PD-L1, and CTLA-4 Antibodies in Colorectal Cancer</i>	WVU Internal Medicine Grand Rounds, Morgantown, WV
Aug 25	<i>The Utility of PD-1, PD-L1, and CTLA-4 Antibodies in Colorectal Cancer</i>	Northside Hospital Cancer Institute Symposium, Atlanta, GA
Oct 26	<i>Colorectal Cancer ASCO Update 6/2018</i>	Plenary lecture Roger Maris Cancer Center Symposium, Fargo, ND

2019-2020		
Mar 18	<i>GI Cancers Update</i>	Cancer Cell Biology Course, Morgantown, WV
Apr 6	<i>Rechallenging Advanced Colorectal Cancer Patients with EGFR Targeted Monoclonal Antibodies</i>	Amgen Continuing Education Symposium, Cancun, MX
Nov 6	<i>At Long Last, Progress in the Immunotherapy of GI Cancers</i>	Garlove annual lecture, Lexington KY

Training Grant Director: A K12, A T32 and R25 (see below)						
Lab or Research Teaching/Mentorships:						
<i>Name</i>	<i>Dates Mentored</i>	<i>Degree</i>	<i>Grad Year</i>	<i>Graduated From:</i>	<i>Mentoring Assistance with:</i>	<i>Current Position</i>
Mohammed Salem MD	2016-present	MD	2008	University of Alexandria Medical School	Research	Attending Physician, Levine Cancer Institute
Hannah Hazard Jenkins	2017-present	MD	2011	West Virginia University	Career Development	Associate Professor, WVU School of Medicine
Narmin Talibova	2015-present	MD	2011	University of Azerbaijan	Career plans and research	Assistant Professor, University of Azerbaijan
Daniel Ahn	2015-2016	DO	2008	University of North Texas Health Science Center, University of North Texas	Research	Assistant Professor, Mayo Clinic
Macrae, Erin	2011-2015	MD	2005	Case Western Reserve Univ School of Med Cleveland, OH	Research	Attending Physician, OSU
Mrozek, Ewa	2011-Present	MD	1983	M.D. Medical Academy Gdańsk, Poland	Research	Assistant Professor, OSU
Mikhail, Sameh	2011-2015	MD	2006	American University of Beirut	Research	Assitant Professor, OSU
Ciombor, Kristen	2011-Present	MD	2005	Univ of Miami, FL Miller School of Med	Research	Assistant Professor, OSU
Haraldsdottir, Sigurdís	2012-2015	MD	2004	Univ of Iceland	Articles & Projects	Senior Fellow, OSU
Wu, Christina	2012-Present	MD	2002	Trinity College Dublin, OH	Articles & Projects	Asst Professor, OSU Div of Medical Oncology
Shapiro, Charles	2011-2014	MD	1984	State Univ of New York Buffalo, NY	Career Mentoring	Professor, OSU

McRee, Autumn	2009-2011	MD	2005	Univ of Texas	Articles & Projects	Sr Fellow, UNC-Chapel Hill
Davies, Janine (Post)	2008-2011	MD	2003	McMaster Univ	Articles & Projects	
Raftery, Laura (Post)	2007-2010	MD	2004	UNC-Chapel Hill	Articles & Projects	Fellow, UNC-Chapel Hill
Shah, Usman (Post)	2005-2008	MD	2003	Med College of Wisconsin	Case Studies	Fellow, UNC-Chapel Hill
Beaven, Anne (Post)	2004-2006	MD	1993	UNC-Chapel Hill	Review Articles in GI Cancer Trials	Fellow, UNC-Chapel Hill
Kelly-Sanoff, Hanna (Post)	2003-2006	MD	2000	Univ of PA School of Medicine	Developmental Therapeutics in GI Malignancies	Asst Prof, UNC Div of Hematology/Oncology
O'Neil, Bert (Post)	2003-2005	MD	1994	Univ of CA	Clinical Trials in GI Malignancies	Asst Professor, UNC-Chapel Hill
Penland, Shannon (Post)	2003-2006	MD	2000	Univ of Pittsburgh	Current strategies in Advanced Colon Cancer	Great Falls Clinic, Montana
Gill, Sharlene (Post)	2000-2003 (Mayo Med School)	MD	1996	Univ of British Columbia	Colorectal Chemotherapy	Asst Prof of Oncology, Univ of British Columbia, Vancouver
Alberts, Steven (Post)	1996-2003	MD	1996	Univ of Washington	GI Cancers	Professor of Oncology
Goetz, Matthew (Post)	2000-2003 (Mayo Med School)	MD	1999	Univ of North Dakota	Pharmacokinetics of Colorectal Chemotherapy	Asst Prof of Oncology, Mayo Medical School
Jacobson, Stacey (Post)	2000-2003 (Mayo Med School)	MD	1995	UC Davis	Adjuvant Chemotherapy in Elderly Patients with Colorectal Cancer	Asst Prof of Oncology, UC Davis
Hobday, Timothy (Post)	1996-2000 (Mayo Med School)	MD	1995	Mayo Med School	Molecular Markers in Metastatic GI Neuroendocrine Tumors	Asst Prof of Oncology, Mayo Medical School
Kumar, Shaji (Post)	1996-2000	MD	1995	India Institute of Medical Sciences	Adjuvant Chemotherapy for Colorectal Cancer	Asst Prof of Hematology, Mayo Medical School

	(Mayo Med School)					
Okuno, Scott (Post)	1996-2000 (Mayo Med School)	MD	1989	University of Illinois	Small Bowel Adeno-carcinoma: A Review of 106 Consecutive Cases from the Mayo Clinic 1985-1993	Assoc Prof of Oncology, Mayo Medical School
Fonseca, Rafael (Post)	1996-1999 (Mayo Med School)	MD	1991	Universidad Anahuac School of Medicine, Mexico	Phase I Study of the Combination of CPT-11/5-FU and Leucovorin	Assoc Prof of Hematology, Mayo Medical School
Galanis, Evanthia (Post)	1994-1997	MD	1990	University of Athens	Phase I Trial of Sequential Administration of Raltitrexed (Tomudex) and 5-iodo-2'-deoxyuridine (IdUrd)	Assoc Prof of Oncology, Mayo Medical School

GRANTS

Prior:

1U10CA180850-01 (Goldberg) 05/06/2014-02/28/2019 20% effort
NIH/NCI

National Clinical Trials Network - Network Lead Academic Participating Sites (U10)
This grant funds the OSU cooperative group academic participation and accrual program

5K12CA133250-07 (Byrd) 06/01/2015-05/31/2019 1% effort
NIH/NCI

Training grant for junior faculty in Hematology and Oncology

CA128590-01A1 (Goldberg) 09/01/2008-08/31/2013 10% effort
NIH/NCI

Academic Training in Oncology at the University of North Carolina at Chapel Hill
This T32 provides funds for training fellows interested in careers in academic oncology during their second and third fellowship years.

5R25CA116339-02 (Goldberg) 09/01/2008-08/31/2013 10% effort
NIH/NCI

National Cancer Institute (NCI) Cancer Education and Career Development Program
This R25 provides funds for training fellows and postdoctoral students interested in careers in public health.

1K12CA120780-01A1 (Goldberg)	09/12/2007-8/31/2012	10% effort
NIH/NCI		
UNC Oncology Clinical Translational Research training Program		
This K12 provides funds for training young investigators interested in cancer research for careers in that arena.		
P30 CA16086-30 (Earp)	12/01/2010-11/30/2011	20% effort
NIH/NCI		
Lineberger Comprehensive Cancer Center Support Grant		
The CCSG provides support for Cancer Center research programs, core facilities, administration, and related activities.		
No assignment # (Bertagnolli)	09/01/2004-open ended	10% effort#
Alliance for Clinical Trials in Oncology Foundation		
National Cancer Institute (NCI) Cancer Education and Career Development Program		
Funds position as Associate Group Chair for Intergroup Affairs for this national, NCI funded, cooperative oncology trials group		

PROFESSIONAL SERVICE

Administrative Experience:

WVU (WEST VIRGINIA UNIVERSITY)- MORGANTOWN, WV

- Director, WVU Cancer Institute
- Chair, Cancer Institute Executive Committee
- Member, School of Medicine Executive Council
- Member, Clinical Research Executive Council

OSU (THE OHIO STATE UNIVERSITY) - COLUMBUS, OHIO

- Chair, James Medical Staff Administration Committee (2012-
- Chair, James Executive Clinical Leadership Team (2012-
- Attendee, Wexner Medical Center Board of Trustees 2014-2016
- Member, Internal Medicine Board of Managers (2015-2016)
- Member, Patient Satisfaction Committee (2011-
- Chair, Hematology and Oncology Operations Council (2011-
- Member, Comprehensive Cancer Center Associate Directors (2011-
- Member, Resource Utilization Committee (2011-
- Member, Wexner Medical Center Chief Medical Officers Council (2011-
- Member, Teletracking Steering Committee (2015-
- Member, James Medical Staff Bylaws Committee (2011-
- Member, Leadership Council for Clinical Quality Safety & Service (2012-
- Member, James Network Steering Committee (2011-
- Member, Health System Quality and Professional Affairs Committee (2011-
- Member, James Clinical Quality Review Committee (2011-
- Member, G-5 Leaders Group (2011 -
- Member, Value-Based Clinical Integration Steering Committee (2011-
- Member, OSU Wexner Medical Center Board (2012-2014)
- Member, OSU Wexner Patient Experience Council (2012-
- Member, James Cancer Hospital Board (2012 -2014)
- Member, James Foundation Board (2012 -
- Member, OSU Wexner Medical Center Professional Evaluation Committee (2012-

- Member, OSU Wexner Medical Center Schwartz Rounds Steering Committee (2013-
- Member, OSU Wexner Medical Director's Forum, (2013-
- Member, OSU Wexner Critical Care Executive Committee (2012-
- Executive Sponsor, James Expansion Transition Steering Committee (2012-2014)
- Chair, James Service Line Advisory Committee (2014-
- Chair, Palliative Medicine Division Chief Search Committee (2013-2014)
- Member, Wexner Medical Center Chief Medical Officer Council (2013-
- Member, Ex-Officio, Wexner Medical Center Practitioner Evaluation Committee
- Member, Wexner Medical Center Credentialing Committee (2012-
- Member, Wexner Medical Center Clinical Resource Utilization Committee (2013-
- Member, Wexner Medical Center Clinical Hematology and Oncology Operations Committee (2012-
- Member, Wexner Medical Center Digestive Disease Executive Steering Committee (2013-
- Member, Wexner Medical Center Clinical Operations Working Group (2013-

UNC (UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL) - CHAPEL HILL, NORTH CAROLINA

- Member, Ambulatory Operations Group, 2004-2011
- Member, Dean's Executive Council
- Attendee, UNC Health System Board of Trustees
- Member, Steering Committee for UNC Clinical Trials Office, 2005-2011
- Member, Hospital Building Projects Oversight Group, 2004-2011
- Chair, Lineberger Clinical Cancer Center Executive Committee, 2004-2011
- Chair, North Carolina Cancer Hospital Executive Committee, 2006-2011
- Chair, Oncology Process Improvement Group, 2004-2011
- Member, GI SPORE Executive Committee, 2005-2011
- Member, Lineberger Comprehensive Cancer Center GI Cancer Tumor Group, 2004-2011
- Member, Lineberger Comprehensive Cancer Center Executive Committee, 2004-2011
- Member, Lineberger Comprehensive Cancer Center Program Leaders Group, 2004-2011
- Director, Clinical Protocol Office, 2005-2007
- Chair, Clinical Protocol Office Executive Committee, 2005-2011
- Member, Oncology Advisory Council, 2004-2011
- Member, Radiation Oncology Chair Search Committee

MAYO CLINIC - ROCHESTER, MINNESOTA

- Member, Cancer Center Clinical Research Committee, 1994-1997
- Member, Mayo Clinic Public Affairs Committee, State, 1997-2001
- Member, Cancer Center Planning Task Force
- Member, Oncology Clinical Guidelines Group
- Initiator and Coordinator, Oncology, New Patient Gastrointestinal Cancer Clinic
- Member, Medical Management Group for Mayo Medical Services Incorporated (MMSI), the Mayo HMO, 1997-2000
- Member, Mayo Medical Services Incorporated Medical Management Executive Committee, 1998-2000
- Member, Mayo Clinic Web Site Task Force, 1994-1996
- Member, Editorial Board, Mayo Clinical Updates, 1995-1999
- Member, Zumbro Valley Medical Society Legislation Committee
- Member, Cancer Center Industry Interaction Task Force

- Member, Mayo Clinic Marketing Committee
- Co-chair, Cancer Center Multidisciplinary GI cancer planning effort
- Chair, Multidisciplinary GI practice integration effort

GEISINGER PHYSICIAN'S ELECTED REPRESENTATIVE

- Member, Geisinger Clinic Board of Governors, 1988-1990
- Member, Combined Medical Center and Clinic Governance Committee, 1989-1990
- Member, Geisinger Medical Center Finance Committee, 1988-1991
- President of Medical Staff, 1989-1990
- Vice-President of Medical Staff, 1988-1989

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

- Member, Board of Directors for Alliance for Clinical Trials in Oncology (3/2014- present)
- Member, Board of Directors for the Alliance Foundation (2/2012- present)
- Member, Executive Committee for Alliance for Clinical Trials in Oncology (3/2012- present)
- Member, Gastrointestinal Cancer Committee for Alliance for Clinical Trials in Oncology (3/2012-present)
- Member, Cancer in the Elderly Committee for Alliance for Clinical Trials in Oncology (3/2012-present)
- Chair, Gastrointestinal Cancer Committee Cancer and Leukemia Group B (CALGB) (2007-2011)

NATIONAL MEMBERSHIPS AND INTERNATIONAL OFFICES OR COMMITTEES

- Alpha Omega Alpha Honor Medical Society
 - American Association of Cancer Research
 - American Clinical and Climatological Association
 - American College of Physicians (Fellow)
 - NCI Colorectal Task Force, 2000-
 - American Joint Committee on Cancer
 - Co-Chair Colorectal and Anal Cancer Staging Committee 2013- present
 - Board of Directors 2005-2013
 - Finance Committee 2008-2013
 - Promotions Committee 2008-2013
 - Co-Chair, Colorectal Cancer Staging Working Group for the 8th Edition of Cancer Staging - 2014
 - American Medical Association
 - American Society of Clinical Oncology (ASCO):
 - Member, Annual meeting Program Committee, 1991-1992, 2000-2002, 2007-2011
 - Member, Education Committee, 1997-2000
 - Member, Publications Committee 2003-2006
 - Member, Program Committee for the GI Cancer Symposium 2006-2007
 - Member, Steering Committee for the GI Cancers Symposium 2010 and 2011
 - Chair, Steering Committee for the GI Cancers Symposium 2012
 - Editorial Board, GI cancer editor, Cancer.Net 2005-2014
 - Editorial Board, Journal of Clinical Oncology 2001-2003
 - Member, Ethics Committee, 2007-2010
- Mentor, ASCO International Development and Education Program (IDEA), 2007-10
 Recipient, ASCO Statesman Award, 2011
 Fellow, American Society of Clinical Oncology, 2013

Member, Governmental Affairs Committee, 2013-

- Member, Dana Farber/ Harvard Cancer Center External Advisory Board, 2010
- Society for Translational Oncology, Board of Directors, 2009-
- Zumbro Valley Medical Society, 1996-2003
- Minnesota Medical Society Annual meeting, Delegate, 1999
- Association of Program Directors of Internal Medicine, 1992-94
- American College of Physician Executives, 1992-94
- ASCO Representative to the American Society for Radiology Oncology (ASTRO) Rectal Cancer Best Practice Expert Panel Meeting - Washington, DC - 2014

LEGAL CONSULTING

- Patent law expert witness for Genentech, Taiho 2019-20

INVITED REVIEWER

- Annals of Gastroenterology and Hepatology
- Anti-Cancer Drugs
- British Journal of Cancer
- CA, A Cancer Journal for Clinicians
- Cancer
- Cancer Chemotherapy and Pharmacology
- The Cancer Journal, Scientific American
- Cell
- Clinical Cancer Research
- Clinical Colorectal Cancer
- Clinical Drug Investigation
- Diseases of the Colon and Rectum
- Drug Safety
- Expert Review of Anticancer Therapy
- Expert Review of Pharmacology
- Expert Review of Vaccines
- Gastroenterology
- Gastrointestinal Cancer Research
- Health Policy
- Investigational New Drugs
- JAMA
- JAMA Oncology
- Journal of Clinical Gastroenterology
- Journal of Clinical Oncology
- Journal of Oncology Practice
- The European Journal of Cancer
- The European Journal of Oncology
- European Journal of Cancer and Clinical Oncology
- International Journal of Cancer
- International Journal of Gastrointestinal Cancer
- Italian Journal of Gastroenterology and Hepatology
- International Journal of Metabolic, Molecular and Laboratory Medicine

- Journal of the National Cancer Institute
- The Lancet
- The Lancet, Oncology
- Mayo Clinic Proceedings
- Nature Clinical Practice Oncology
- The New England Journal of Medicine
- Oncology
- Clinical Pharmacokinetics
- Pharmacogenetics

GRANT REVIEWS

- European Commission on Cancer, Quality of Life grants 2001
- Italian Association of Cancer Research, grants 2001, 2006, 2008
- Canadian Institutes of Health Research grant 2006
- Cancer Research UK grant 2006
- Cancer Research UK grant 2007
- Cancer Research UK grants 2008
- Dana Farber/Harvard Cancer Center External Advisory Board 2010
- Cancer Research UK grant 2014
- American Society of Clinical Oncology Foundation 2018-19
- NIH National Center for Advancing Translational Sciences (NCATS) Special Emphasis Panel/ Scientific Review Group 2019/05 ZTRI RD-8 (01) for Rare Disease Clinical Research Consortia for the Rare Diseases Clinical Research Network

EDITORIAL BOARDS

- Physician Data Query (PDQ) Adult Treatment Editorial Board, 1998-2000
- Physician Data Query (PDQ) Adult Treatment Advisory Board, 1996 - Present
- Journal of Clinical Oncology, 2001-2003
- Clinical Colorectal Cancer, 2001 - Present
- European Journal of Clinical and Medical Oncology 2010-2014
- The Oncologist, Section Editor for GI Cancer 2006-2016
- The Oncologist, Senior Editor 2014-2016
- ONCOLOGY, 2002-2007
- Oncology Business Review, 2011- Present
- Clinical Advances in Hematology & Oncology, 2002- 2009
- Mayo Clinic Proceedings, 2005-2015
- Gastrointestinal Cancer Research, 2005 - Present
- UpToDate Gastrointestinal Cancer, Section editor, 2006-Present
- Targeted Therapies in Oncology, 2013-2015
- Oncology Payers, Policy Makers and Prescribers, 2013-2015
- Cancer.Net: Associate Editor for GI Oncology 2005-2011