

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMGEN INC.,
Petitioner,

v.

BRISTOL-MYERS SQUIBB COMPANY,
Patent Owner.

Case No. IPR2025-00602
Patent No. 10,174,113

DECLARATION OF PRESCOTT LASSMAN

Amgen Exhibit 1031 Amgen v. BMS

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I, Prescott (“Scott”) M. Lassman, declare:

1. I have been retained by Wolf, Greenfield & Sacks, P.C., counsel for Petitioner Amgen Inc., to assess certain prior art references pertaining to claims 1-20 (the “’113 challenged claims”) of U.S. Patent No. 10,174,113 (“the ’113 patent”). I am being compensated for my time at my standard rate, plus actual expenses. My compensation is not dependent in any way upon the outcome of the inter partes review of the ’113 patent.

2. This declaration sets forth my opinions regarding the public availability and public accessibility of certain documents on ClinicalTrials.gov.

3. As set forth more fully below, it is my opinion that the ClinicalTrials.gov posting for Clinical Study No. NCT01844505, Version 1, was publicly available and publicly accessible prior to April 28, 2014, more than a year before the earliest alleged priority date of the ’113 patent.

4. In addition, it is my opinion that the ClinicalTrials.gov posting for Clinical Study No. NCT01968109, Version 1, was also publicly available and publicly accessible prior to April 28, 2014, more than a year before the earliest alleged priority date of the ’113 patent.

5. Finally, it is my opinion that ClinicalTrials.gov posting for Clinical Study No. NCT02713867, Version 2, was publicly available and publicly accessible prior to April 28, 2016.

I. PERSONAL AND PROFESSIONAL BACKGROUND

6. I am a Principal at Lassman Law+Policy, a Washington, D.C. boutique firm that I founded in 2019 and that specializes in FDA regulatory practices and policy. Among my areas of expertise are clinical trials and clinical trial postings, drug approval, drug lifecycle management, and FDA policy and legislation. I have over 32 years of experience advising clients, including pharmaceutical and biotechnology companies, on FDA requirements applicable to pharmaceuticals, biological products, and medical devices. I retired from the active practice of law in 2025.

7. From 2003-2007, I was Assistant General Counsel, and then Senior Assistant General Counsel, at the Pharmaceutical Research and Manufacturers of America (“PhRMA”), a trade organization that represents research-based pharmaceutical companies. While at PhRMA, I handled a wide variety of FDA regulatory and legislative issues affecting the pharmaceutical and biotechnology industries, including industry initiatives regarding clinical trial transparency. I helped develop principles adopted in 2005 by trade associations representing research-based pharmaceutical companies in the United States, Europe, and Japan regarding disclosure of information about ongoing clinical trials (clinical trial registries), and I helped establish ClinicalStudyResults.org, a publicly available database where PhRMA members and others could post the results of completed

clinical studies (results database). During my time at PhRMA, I also worked on legislative changes to the clinical trial transparency requirements under the Food and Drug Administration Amendments Act of 2007 (“FDAAA”), which expanded the requirements to report and publish information about ongoing and completed clinical trials on ClinicalTrials.gov. In 2007, I received the PhRMA Board of Directors Exceptional Service Award for my work on FDAAA.

8. I have received numerous accolades for my work in the FDA regulatory law space. I received the LMG Life Sciences Star award every year from 2016-2024, including being shortlisted for FDA Regulatory Attorney of the Year in 2017 and 2018, and Lassman Law+Policy was shortlisted for Regulatory Firm to Watch in 2019.

9. In my practice, I routinely accessed and relied upon the information available on ClinicalTrials.gov. In addition, I have assisted companies’ compliance with the clinical trial disclosure requirements of FDAAA and ClinicalTrials.gov, for example, by helping them draft compliant Standard Operating Procedures (“SOPs”) for clinical trial posting and providing advice on the requirements and deadlines for submitting information about specific clinical trials.

10. I have been a frequent speaker at conferences regarding FDA regulatory requirements, including the FDAAA clinical trial disclosure

requirements, and I have authored numerous publications and book chapters concerning FDA law and practice. I am the lead author of the 2017 publication “Clinical Trial Transparency: A Reassessment of Industry Compliance with Clinical Trial Registration and Reporting Requirements in the United States,” published in BMJ Open, a peer-reviewed, open access medical journal published by the British Medical Journal. This article analyzes the pharmaceutical industry’s compliance with statutory and regulatory requirements regarding disclosure of clinical trial information on ClinicalTrials.gov, based upon my collection and analysis of historical data about such compliance.

11. Prior to founding Lassman Law+Policy, I was a Partner in the FDA Practice Group at Goodwin Procter LLP from 2016-2019. My practice focused on FDA regulatory practices, including strategic advice, counseling, administrative advocacy, and litigation on civil matters concerning pharmaceuticals, biological products, and medical devices. Before joining Goodwin, I practiced as a Partner at WilmerHale, where I was Co-Chair of the FDA practice group, and at Kleinfeld, Kaplan, and Becker, where my practice focused on FDA regulatory law involving pharmaceuticals, biologics, and medical devices.

12. I have been a member of several professional organizations, including the Food and Drug Law Institute (“FDLI”), a non-profit membership organization

offering education, training, publications, and professional networking opportunities in the food and drug law field.

13. My curriculum vitae is provided as Exhibit 1032, and includes a list of my publications, and additional information about me.

II. LEGAL BACKGROUND

14. I understand that the “prior art” includes patents and printed publications that were “publicly available” prior to a patent’s priority date. In order for a printed publication to be “publicly available,” it needs to have been disseminated or otherwise accessible to the public interested in the art before the priority date. It is my understanding that whether a reference counts as a printed publication is a legal conclusion based on underlying factual determinations and is decided on a case-by-case inquiry looking into the facts and circumstances surrounding the reference’s disclosure and its accessibility to the public.

15. I have been informed that the earliest-claimed priority date for the ’113 patent is April 28, 2015 and that to be indisputable prior art against the ’113 patent, a prior art reference must be dated and publicly available and accessible as of April 28, 2014 (one year prior to the earliest claimed priority date). I have also been informed that the application for the ’113 patent itself was filed on April 28, 2016—meaning that a reference dated and publicly available and accessible prior to that date (but after April 28, 2014) is presumptively prior art unless the patent

owner carries its burden of production to come forward with evidence to the contrary. I have assessed the public availability and accessibility of the prior art discussed in this declaration relative to these dates.

III. MATERIALS REVIEWED AND CONSIDERED

16. My findings, as explained below, are based on my use of and work with ClinicalTrials.gov, my years of education, research, experience, and background in the field of food and drug law and policy, as well as my investigation and study of relevant materials for this declaration. In forming my opinions, I have studied and considered the materials identified in the list below.

Exhibit	Description
EX1007	NCT01968109 Version 1, Brief Title: “Safety Study of Anti-LAG-3 With and Without Anti-PD-1 in the Treatment of Solid Tumors” (Last Update Posted to clinicaltrials.gov: October 23, 2013).
EX1013	NCT02713867 Version 2, Brief Title: “A Dose Frequency Optimization, Trial of Nivolumab 240 mg Every 2 Weeks vs Nivolumab 480 mg Every 4 Weeks in Subjects With Advanced or Metastatic Non-small Cell Lung Cancer Who Received 4 Months of Nivolumab at 3 mg/kg or 240 mg Every 2 Weeks” (Last Update Posted to clinicaltrials.gov: March 22, 2016).
EX1014	NCT01844505 Version 1, Brief Title: “Phase 3 Study of Nivolumab or Nivolumab Plus Ipilimumab Versus Ipilimumab Alone in Previously Untreated Advanced Melanoma” (Last Update Posted to clinicaltrials.gov: May 1, 2013).
EX1019	U.S. National Library of Medicine, National Institutes of Health, ClinicalTrials.gov, Glossary of Common Site Terms, https://clinicaltrials.gov/ct2/about-studies/glossary (“ <i>ClinicalTrials.Gov Glossary</i> ”)
EX1043	U.S. National Library of Medicine, National Institutes of

	Health <i>Food and Drug Administration Modernization Act of 1997 (FDAMA)</i> , available at https://clinicaltrials.gov/policy/reporting-requirements
EX1044	U.S. National Library of Medicine, National Institutes of Health, Press Release: National Institutes of Health Launches “ClinicalTrials.gov” (February 29, 2000), https://www.nlm.nih.gov/archive/20040831/news/press_releases/clntrlpr00.html (“ <i>Press Release: National Institutes of Health Launches “ClinicalTrials.gov”</i> ”)
EX1045	U.S. National Library of Medicine, National Institutes of Health, ClinicalTrials.gov, How to Edit Your Study Record, https://clinicaltrials.gov/ct2/manage-recs/how-edit (“ <i>ClinicalTrials.gov, How to Edit Your Study Record</i> ”)
EX1046	Deborah A. Zarin et al., “Reporting ‘Basic Results’ in ClinicalTrials.gov,” CHEST 136(1), 295-303 (July, 2009) (“ <i>Zarin</i> ”)
EX1047	U.S. National Library of Medicine, National Center for Biotechnology Information, <i>About ClinicalTrials.gov</i> : Major milestones related to ClinicalTrials.gov and how information in the database has changed over time, available at https://clinicaltrials.gov/about-site/about-ctg (“ <i>About ClinicalTrials.gov</i> ”)
EX1048	National Library of Medicine, National Center for Biotechnology Information, ClinicalTrials.gov, <i>Trends and Charts on Registered Studies</i> , available at https://clinicaltrials.gov/about-site/trends-charts (“ <i>ClinicalTrials.gov Trends & Charts</i> ”)
EX1049	Affidavit of Nathaniel E. Frank-White (Internet Archive) (“ <i>Frank White Aff.</i> ”)

IV. BACKGROUND

A. ClinicalTrials.gov

17. ClinicalTrials.gov is a government website run by the National Library of Medicine (“NLM”) at the National Institutes of Health (“NIH”) that

provides information concerning not-yet initiated, ongoing, and completed clinical studies. The website was established and continues to be maintained in response to a series of federal laws requiring NIH to collect and publicly disseminate information concerning clinical studies.

18. While subject matter experts, clinicians, and researchers certainly can access the ClinicalTrials.gov website, the site was designed to be used by members of the public or lay persons.

19. On November 21, 1997, Congress enacted the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115 (1997) (“FDAMA”). Section 113 of FDAMA, entitled “Information program on clinical trials for serious or life-threatening diseases,” required NIH to create a publicly accessible databank to assist individuals with serious or life-threatening diseases and conditions to gain access to experimental treatments. The databank eventually created was called ClinicalTrials.gov. According to the “Clinical Trial Reporting Requirements” section of the ClinicalTrials.gov website, “FDAMA 113 required that the registry include information about federally or privately funded clinical trials conducted under investigational new drug applications to test the effectiveness of experimental drugs for patients with serious or life-threatening diseases or conditions.” *See* EX1043 (*Food and Drug Administration Modernization Act of 1997 (FDAMA)*), available at

<https://clinicaltrials.gov/policy/reporting-requirements>), 3. ClinicalTrials.gov explains that “[t]he information in the registry was intended for a wide audience, including individuals with serious or life-threatening diseases or conditions, members of the public, health care providers, and researchers.” *Id.*

20. On February 29, 2000, ClinicalTrials.gov was launched by NIH in fulfillment of the above-described statutory requirement for a clinical trials registry. *See* EX1044 (*Press Release: National Institutes of Health Launches “ClinicalTrials.gov,”* available at https://www.nlm.nih.gov/archive/20040831/news/press_releases/clntrlpr00.html). When it was launched, the site was described by NIH as “a consumer-friendly database...with information on more than 4,000 federal and private medical studies involving patients and others at more than 47,000 locations nationwide.” *Id.*, 1. NIH confirmed that the site was intended to “provide[] patients, families and members of the public easy access to information about the location of clinical trials, their design and purpose, criteria for participation, and, in many cases, further information about the disease and treatment under study.” *Id.*

21. Following enactment of FDAMA and the creation of ClinicalTrials.gov, efforts intensified among stakeholders to increase clinical trial transparency even further. For instance, in 2005 the International Committee of Medical Journal Editors (“ICJME”), a group of editors from various leading

medical journals (*e.g.*, New England Journal of Medicine), implemented a new policy requiring registration of clinical trials in a public trials registry (such as ClinicalTrials.gov) as a condition for publication of the trial results in any of the member medical journals.

22. In addition, in 2005, the global, research-based pharmaceutical industry represented by PhRMA, the European Federation of Pharmaceutical Industries and Associations (“EFPIA”), the International Federation of Pharmaceutical Manufacturers and Associations (“IFPMA”), and the Japanese Pharmaceutical Manufacturers Association (“JPMA”) adopted a Joint Position on the Disclosure of Clinical Trial Information Via Clinical Trial Registries and Databases (“Joint Position”). These organizations and their members agreed, among other things, to register all clinical trials (other than exploratory trials) on a free, publicly accessible clinical trial registry like ClinicalTrials.gov within 21 days of the initiation of patient enrollment using a minimum dataset that included: brief title of the study; trial description in lay terminology; trial phase; trial type (*e.g.*, interventional); trial status; trial purpose (*e.g.*, treatment, diagnosis, prevention); intervention type (*e.g.*, drug, vaccine); condition or disease; key eligibility criteria, including gender and age; the location of the trial and contact information. Moreover, in 2006, the World Health Organization (“WHO”) stated that all clinical trials should be registered with a database like ClinicalTrials.gov, and it identified

a minimum trial registration dataset. *See* EX1043, 2. I was personally involved in shaping PhRMA's response to these developments discussed in this paragraph and paragraph 7 above, including helping to draft the 2005 Joint Position on the Disclosure of Clinical Trial Information Via Clinical Trial Registries and Databases.

23. Consistent with these trends for increased transparency, Congress enacted FDAAA in 2007 to, among other things, expand the requirements for submission and public dissemination of clinical trial information on ClinicalTrials.gov. FDAAA, Pub.L.No. 110-85, § 801 (2007) (codified at 42 U.S.C. § 282(j)). While at PhRMA, I was directly involved in formulating the pharmaceutical industry's position regarding this legislation and proposing revisions to the draft bill, some of which were incorporated into the final legislation.

24. Among other things, the law required responsible parties to submit the following "descriptive information" about each applicable clinical trial to ClinicalTrials.gov: (a) a brief title, intended for the lay public; (b) a brief summary, intended for the lay public; (c) the primary purpose; (d) the study design; (e) for an applicable drug clinical trial, the study phase; (f) study type; (g) the primary disease or condition being studied, or the focus of the study; (h) the intervention name and intervention type; (i) the study start date; (j) the expected completion

date; (k) the target number of subjects; and (l) outcomes, including primary and secondary outcome measures. 42 U.S.C. § 282(j)(2)(A)(ii)(I).

25. Furthermore, the law required that the “Format and structure” of the ClinicalTrials.gov database provide for “[s]earchable categories” to ensure that “the public” be able to search the database both by keyword and by one of several criteria, including, among other things, the disease studied, and the drug or device studied. 42 U.S.C. § 282(j)(2)(B)(i). The law also required the Director of the NIH to “ensure that the registry data bank is easily used by the public, and that entries are easily compared.” 42 U.S.C. § 282(j)(2)(B)(iv).

26. As of August 2009, ClinicalTrials.gov offered two ways to search its database—a “Basic Search” and an “Advanced Search.” *See* EX1049 (*Frank White Aff.*), Ex. A, pp. 7, 28, 30. The basic search function allowed for keyword searching, which would include, for example, the name of a medical condition, or intervention, or the location of a clinical trial. *Id.*, 7, 30. The basic search function also allowed for the use of the operator “AND” to combine terms. *Id.* For example, a basic search could search for clinical trials located in Los Angeles that dealt with treatment for heart attacks by searching “Heart Attack AND Los Angeles.” *Id.* ClinicalTrials.gov also included an advanced search function. *Id.*, 28. This advanced search had the same functionality of the basic search but allowed the public to filter search results by more categories, such as, conditions,

interventions, outcome measures, sponsors, study IDs, gender, age group, phase, and funders, among others. *Id.* The site also had a help dialog box that explained the various categories and filters that could be applied. *Id.*, 25-26 (explaining, inter alia, what the “conditions,” “interventions,” “Lead Sponsors,” and “Study ID” search fields refer to). Accordingly, the lay public was able to search ClinicalTrials.gov in various ways, for example, by condition (*i.e.*, a disease such as rheumatoid arthritis), or by intervention (*i.e.*, a drug, such as tocilizumab) in order to locate a specific clinical trial. The help document also explained how to use search expressions to connect terms, and while it stated that the use of some of these terms can be confusing, “[f]ortunately, search will do a pretty good job of finding the right studies either way.” *Id.*, 26. I have personally used the search functionality on ClinicalTrials.gov many times, even as far back as 2009, in the course of my work, in order to locate specific clinical trials.

27. In September 2008, as required by FDAAA, the “ClinicalTrials.gov results database launched for the public.” EX1047 (*About ClinicalTrials.gov*), 8. At this time, “sponsors or investigators could begin submitting results for their registered studies.” EX1048 (*ClinicalTrials.gov Trends & Charts*), 6. By October 2008, the ClinicalTrials.gov website stated that it provided “up-to-date information” on federally and privately supported clinical trials, and noted that it contained information on 63,054 trials, in the US and 158 countries. *See* EX1049

(*Frank-White Aff., About ClinicalTrials.gov*), Ex. A, 23. At the time, the site was receiving over 40,000,000 page views per month and 50,000 visitors daily. *Id.*

28. When a clinical trial is initiated and registered with ClinicalTrials.gov, the “responsible person” (either the sponsor or clinical investigator) must provide several required data elements in order to comply with FDAAA and the ClinicalTrials.gov website. *See* EX1049 (*Frank-White Aff., ClinicalTrials.gov Protocol Data Element Definitions*), Ex. A, 11-18. These include, among other things, a “brief title” that is “intended for the lay public,” the study type, board approval status, sponsor information, a “brief summary” of the trial intended “for the lay public,” information on the study’s status and design, information on the arms, groups, and interventions used, information on the conditions of focus of the study, information on eligibility for the study, information on the location and recruitment status, and contact information for the facility or individual(s) responsible for the study. *Id.* All information submitted to ClinicalTrials.gov is reviewed by the National Library of Medicine, and the ClinicalTrials.gov database is updated daily. *See id.*, 9. Information is submitted to ClinicalTrials.gov through a “Protocol Registration System” (“PRS”), and all data submitted is reviewed by a PRS administrator before being published on the ClinicalTrials.gov website. *See id.*, Ex. B, 33-34; *see also* EX1045 (*How to Edit Your Study Record*, available at <https://clinicaltrials.gov/ct2/manage-recs/how-edit>); EX1046 (*Zarin*), 296-7.

29. A Responsible Party (i.e., the study sponsor, or the principal investigator, if designated by the sponsor) is required to update the clinical trial record on ClinicalTrials.gov within 30 days of a change to Recruitment Status, Overall Recruitment Status, and Completion Date. 42 U.S.C. § 282(j)(4)(C)(i)(III), (IV); *see also* 42 C.F.R. § 11.64(a)(1)(ii)(B)-(L), (O). Other changes or updates to the record, such as protocol amendments, must be made at least every 12 months. 42 U.S.C. § 282(j)(4)(C)(i)(I); EX1045 (*How to Edit Your Study Record*), 1; EX1046 (*Zarin*), 296; *see also* 42 C.F.R. § 11.64(a)(2)(i). The records on ClinicalTrials.gov are required to be made “easily search[able]” and “easily used by the public.” 42 U.S.C. § 282(j)(5)(E)(vi); 42 U.S.C. § 282(j)(2)(B)(iv). In particular, ClinicalTrials.gov is required to provide keyword searching and additional search categories for the public to access records. 42 U.S.C. § 282(j)(2)(B)(i)-(iii).

30. Below I detail several searching strategies and screenshots from my recent manipulation of ClinicalTrials.gov to demonstrate the public accessibility and availability of the study record versions of, for example NCT-505. In view of the disclosure, functionality, and searchability requirements discussed above and imposed by regulation, an interested researcher would have interacted with similar searching and version selection functionality going back to 2009.

31. One way in which clinical trial records are organized is by “record history.” For a given clinical trial, all submissions are assigned a version number and each historical version can be accessed by clicking on the version number. In order to do that a member of the public could take the following steps:

- a. On the ClinicalTrials.gov webpage (Home | ClinicalTrials.gov, annotated below), one could search the publicly accessible documents by navigating to the “Focus Your Search” section and could search by the clinical trial number (e.g., by entering “NCT01844505” in “Other terms”).

The screenshot displays the ClinicalTrials.gov homepage. At the top, the header includes the site name and navigation links: Find Studies, Study Basics, Submit Studies, Data and API, Policy, and About. A link for My Saved Studies (0) is also present. Below the header, a banner states: "ClinicalTrials.gov is a place to learn about clinical studies from around the world." A prominent yellow warning box contains a triangle icon and the text: "The U.S. government does not review or approve the safety and science of all studies listed on this website. Read our full disclaimer for details." The main search section is titled "Focus Your Search (all filters optional)" and includes a link to "Expert Search". It features several input fields: "Condition/disease", "Other terms" (which contains the text "NCT01844505"), "Intervention/treatment", and "Location" (with a subtext: "Search by address, city, state, or country and select from the dropdown list"). Below these fields is a "Study Status" section with two radio button options: "All studies" (selected) and "Recruiting and not yet recruiting studies". A "More Filters" link with a plus icon is located at the bottom of the filter section. A dark blue "Search" button is positioned at the bottom right of the search area.

- b. After selecting the one trial result that comes up (annotated below), a member of the public could select “Record History” which is one of 4 tabs that appears (annotated below).

Search Results

Viewing 1 result

Showing results for: Other terms: NCT01844505

Card View

Table View

Focus Your Search
(all filters optional)

Hide

Condition/disease ⓘ

Other terms ⓘ

NCT01844505

Intervention/treatment ⓘ

Location

Search by address, city, state, or country and select from the dropdown list

Study Status ⓘ

Looking for participants

☐ Not yet recruiting (0)

☐ Recruiting (0)

No longer looking for participants

☐ Active, not recruiting (0)

☐ Completed (1)

☐ Terminated (0)

Other

☐ Enrolling by invitation (0)

☐ Suspended (0)

☐ Withdrawn (0)

☐ Unknown (0)

Expanded access ⓘ

+

More Filters

—

Eligibility Criteria ⓘ

Sex

☒ All (1)

Clear Filters (1)

Apply Filters

None Selected

RSS

☐ NCT01844505

Completed

WITH RESULTS

Phase 3 Study of Nivolumab or Nivolumab Plus Ipilimumab Versus Ipilimumab Alone in Previously Untreated Advanced Melanoma (CheckMate 067)

Conditions

Unresectable or Metastatic Melanoma

Locations

Gilbert, Arizona, United States

Tucson, Arizona, United States

La Jolla, California, United States

Los Angeles, California, United States (2)

Show all 150 locations

10

studies per page

Completed

Phase 3 Study of Nivolumab or Nivolumab Plus Ipilimumab Versus Ipilimumab Alone in Previously Untreated Advanced Melanoma (CheckMate 067)

ClinicalTrials.gov ID
NCT01844505

Sponsor
Bristol-Myers Squibb

Information provided by
Bristol-Myers Squibb (Responsible Party)

Last Update Posted
2024-07-03

Download

Bookmark

Study Details

Researcher View

Results Posted

Record History

Study Record Versions

- This table shows all the versions of this study record arranged in order by submitted date.
- To view one version of the study record, click the submitted date.
- To compare two versions, select them using the check boxes and click "Compare" at the bottom of the list.

	Version	Date submitted (YYYY-MM-DD)	Changes
☐	1	2013-04-30	None (earliest version on record)
☐	2	2013-06-25	- Recruitment Status - Study Status - Contacts/Locations
☐	3	2013-08-12	- Study Status - Contacts/Locations - References
☐	4	2013-08-30	- Study Status - Contacts/Locations
☐	5	2013-09-17	Study Status
☐	6	2013-09-30	- Study Status - Contacts/Locations
☐	7	2013-10-31	- Study Status - Contacts/Locations - Study Identification
☐	8	2013-11-28	- Study Status - Contacts/Locations
☐	9	2013-12-31	Study Status

Compare

- c. From there an interested member of the public could see a list of every version and date of submission and could select specific versions to view and/or download.
- d. If an interested member of the public did not know or have access to the specific clinical trial number, that person could

alternatively use various keyword searches to locate a clinical trial involving both anti-PD-1 and anti-CTLA-4 antibodies. For example, an interested person could search ClinicalTrials.gov by entering “Untreated Unresectable or Metastatic Melanoma” as the “Condition/disease” with Nivolumab as the “Intervention/treatment.”

The screenshot displays the ClinicalTrials.gov homepage. At the top, the navigation bar includes links for 'Find Studies', 'Study Basics', 'Submit Studies', 'Data and API', 'Policy', and 'About', along with a 'My Saved Studies (0)' link. A prominent disclaimer states: 'The U.S. government does not review or approve the safety and science of all studies listed on this website. Read our full disclaimer for details.' Below this, the 'Focus Your Search' section is active, showing search criteria: 'Condition/disease' as 'Untreated Unresectable or Metastatic Melanoma' and 'Intervention/treatment' as 'Nivolumab'. Other fields for 'Other terms', 'Location', and 'Study Status' (set to 'All studies') are also visible. A 'Search' button is located at the bottom right of the search form.

ClinicalTrials.gov

Find Studies ▾ Study Basics ▾ Submit Studies ▾ Data and API ▾ Policy ▾ About ▾

My Saved Studies (0) →

ClinicalTrials.gov is a place to learn about clinical studies from around the world.

 The U.S. government does not review or approve the safety and science of all studies listed on this website. [Read our full disclaimer](#) for details. +

Focus Your Search (all filters optional) [Expert Search](#)

Condition/disease ⓘ

Untreated Unresectable or Metastatic Melanoma

Other terms ⓘ

Intervention/treatment ⓘ

Nivolumab

Location

Search by address, city, state, or country and select from the dropdown list

Study Status ⓘ

☒ All studies

☐ Recruiting and not yet recruiting studies

More Filters +

Search

- e. If such person sorted the resulting hits by “Relevance,” NCT01844505 appears as Entry 1 as shown in the screen capture below (annotated).

Search Results
Viewing 1-9 out of 9 studies

Showing results for: **Untreated Unresectable or Metastatic Melanoma | Nivolumab**

+ [Synonyms of conditions or disease \(1\)](#)

Focus Your Search
(all filters optional)

Condition/disease
Untreated Unresectable or Mete

Other terms

Intervention/treatment
Nivolumab

Location
Search by address, city, state, or country and select from the dropdown list

Study Status

Looking for participants

☐ Not yet recruiting (0)

☐ Recruiting (1)

No longer looking for participants

☐ Active, not recruiting (1)

☐ Completed (7)

☐ Terminated (0)

Other

☐ Enrolling by invitation (0)

☐ Suspended (0)

☐ Withdrawn (0)

☐ Unknown (0)

Expanded access

More Filters

Eligibility Criteria

None Selected [Download] [Bookmark] [RSS]

☐ **NCT01844505** **Completed** [WITH RESULTS](#)

Phase 3 Study of Nivolumab or Nivolumab Plus Ipilimumab Versus Ipilimumab Alone in Previously Untreated Advanced Melanoma (CheckMate 067)

Conditions
Unresectable or Metastatic Melanoma

Locations

Gilbert, Arizona, United States
Tucson, Arizona, United States
La Jolla, California, United States
Los Angeles, California, United States (2)

[Show all 150 locations](#)

☐ **NCT01927419** **Completed** [WITH RESULTS](#)

Study of Nivolumab (BMS-936558) Plus Ipilimumab Compared With Ipilimumab Alone in the Treatment of Previously Untreated, Unresectable, or Metastatic Melanoma

Conditions
Metastatic Melanoma **Unresectable Melanoma**

Locations

San Francisco, California, United States
Orlando, Florida, United States
Louisville, Kentucky, United States
Boston, Massachusetts, United States (3)

[Show all 21 locations](#)

☐ **NCT05625399** **Recruiting**

A Study of Subcutaneous Nivolumab + Relatlimab Fixed-dose Combination (FDC) in Previously Untreated Metastatic or Unresectable Melanoma

Conditions
Melanoma

Locations

Phoenix, Arizona, United States
Springdale, Arkansas, United States
Los Angeles, California, United States
Orange, California, United States

[Show all 190 locations](#)

- f. Alternatively, when searching ClinicalTrials.gov for clinical trials involving treatment of “metastatic melanoma” (in the

“Condition/disease” search box) with “nivolumab/ipilimumab” and “PD-L1” as the other terms, NCT-505 is the fifth study returned in the search results.

NIH An official website of the United States government [Learn how we keep you safe](#)

NIH National Library of Medicine
National Center for Biotechnology Information

PRS Login

ClinicalTrials.gov

Find Studies Study Basics Submit Studies Data and API Policy About

My Saved Studies (0) >

Home > Search Results

 The U.S. government does not review or approve the safety and science of all studies listed on this website.
Read our full [disclaimer](#) for details.

Search Results

Viewing 1-10 out of 21 studies

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Study Title	NCT Number	Status	Conditions	Interventions	Sponsor	Study Type
☐ Phase 1 Biomarker Study of Nivolumab and Ipilimumab and Nivolumab in Combination With Ipilimumab in Advanced Melanoma	NCT01621490	Completed View results	- Advanced Melanoma - Metastatic Melanoma	- Biological: Nivolumab - Drug: Ipilimumab	Bristol-Myers Squibb	Interventional
☐ SABR Plus Ipilimumab Plus Nivolumab in Metastatic Melanoma Patients	NCT03126461	Withdrawn	- Melanoma - Metastatic Melanoma	- Radiation: SABR - Drug: Ipilimumab - Drug: Nivolumab	University of Texas Southwestern Medical Center	Interventional
☐ A Comparison of Nivolumab-based Treatments in a Real-world PD-L1 Positive Metastatic Melanoma Population in the US	NCT03732560	Completed	Melanoma	Other: Non-Interventional	Bristol-Myers Squibb	Observational
☐ Anti-PD-1 Brain Collaboration + Radiotherapy Extension (ABC-X Study)	NCT03340129	Recruiting	Melanoma Stage Iiv	- Drug: Ipilimumab - Drug: Nivolumab - Radiation: Stereotactic Radiotherapy 1 more	Melanoma Institute Australia	Interventional
☐ Phase 3 Study of Nivolumab or Nivolumab Plus Ipilimumab Versus Ipilimumab Alone in Previously Untreated Advanced Melanoma (CheckMate 067)	NCT01844505	Completed View results	Unresectable or Metastatic Melanoma	- Biological: Nivolumab - Biological: Ipilimumab - Biological: Placebo for Nivolumab 1 more	Bristol-Myers Squibb	Interventional

V. ANALYSIS

A. The Treatment Protocol for NCT01844505 was Publicly Available

32. I accessed the ClinicalTrials.gov website and located the record for Clinical Study No. NCT01844505 (Protocol CA209-067) Version 1, with the Brief Title “Phase 3 Study of Nivolumab or Nivolumab Plus Ipilimumab Versus Ipilimumab Alone in Previously Untreated Advanced Melanoma,” and Last Update Posted to clinicaltrials.gov as of May 1, 2013 (“hereafter, “NCT-505”). EX1014, 3.

33. NCT-505 describes a Phase 3 clinical study protocol to show that Nivolumab and/or Nivolumab in combination with Ipilimumab will extend survival compared to Ipilimumab alone. EX1014, 4.

34. NCT-505 also provides “Study Details” including “Study Status.” EX1014, 3. These details indicate that the “Last Update Posted” was May 1, 2013. The “Last Update Posted” date is the “most recent date on which changes to a study record were made available on ClinicalTrials.gov.” EX1019 (*Clinicaltrials.gov Glossary*, available at <https://clinicaltrials.gov/ct2/about-studies/glossary>), 10.

35. While the ClinicalTrials.gov website indicates that the “Last Update Posted” date is an estimate (*see* EX1014, 3) this “estimate” accounts for any “delay between when the changes were submitted to ClinicalTrials.gov by the study’s

sponsor or investigator (the last submitted date) and the last update posted date.”

EX1019 (*ClinicalTrials.gov Glossary*, available at <https://clinicaltrials.gov/ct2/about-studies/glossary>), 10.

36. NCT-505 also indicates that the “Last Update Submitted that Met QC Criteria” was April 30, 2013. EX1014, 3. The “Last Update Submitted that Met QC criteria” is defined as “[t]he most recent date on which the study sponsor or investigator submitted changes to a study record that are consistent with National Library of Medicine (NLM) quality control (QC) review criteria.” EX1019 (*ClinicalTrials.gov Glossary*, available at <https://clinicaltrials.gov/ct2/about-studies/glossary>), 10.

37. The May 1, 2013 “Last Update Posted” date is consistent with the April 30, 2013 “Last Update Submitted that Met QC Criteria” date, and in my experience, the estimated posting date is typically accurate to within a few days.

38. Based on my extensive experience with ClinicalTrials.gov and my recent manipulation of that website to access NCT-505, and based on the statutory posting and searchability requirements for ClinicalTrials.gov that I describe above, in my opinion, an interested member of the public would have been able to search, locate, and access NCT-505 in the year 2013.

39. In my opinion, NCT-505 was publicly available and accessible to interested members of the public on or about May 1, 2013, and certainly within a few days thereafter, *i.e.* well prior to April 28, 2014.

40. The ClinicalTrials.gov website is updated daily. *See, supra*, ¶28.

41. As can be seen from these records, NCT-505, which would have been publicly available and accessible to interested members of the public as of the May 1, 2013 “Last Update Posted” date, contained a detailed description of a protocol to evaluate whether Nivolumab and/or Nivolumab in combination with Ipilimumab will extend survival compared to Ipilimumab alone. EX1014, 3. More specifically, NCT-505 discloses a two-stage treatment regime—(1) co-administration of nivolumab and ipilimumab followed by (2) administration of nivolumab alone:

a. In one arm of the co-administration phase, “Nivolumab 1 mg/kg solution” was “combined with Ipilimumab 3 mg/kg” and administered “intravenously every 3 weeks for 4 doses.”

EX1014, 4.

b. In the subsequent anti-PD-1 monotherapy stage, nivolumab was given at a dose of “3 mg/kg solution intravenously every 2 weeks.” *Id.*

42. For the foregoing reasons, it is my opinion that the NCT-505 (EX1014) publicly disclosed details of a protocol to evaluate whether Nivolumab

and/or Nivolumab in combination with Ipilimumab will extend survival compared to Ipilimumab alone, per the above-noted dosing regimens, prior to April 28, 2014.

B. The Treatment Protocol for NCT01968109 was Publicly Available

43. I accessed the ClinicalTrials.gov website and located the record for Clinical Study No. NCT01968109 (Protocol CA224-020) Version 1, with the Brief Title “Safety Study of Anti-LAG-3 With and Without Anti-PD-1 in the Treatment of Solid Tumors,” and Last Update Posted to clinicaltrials.gov as of October 23, 2013 (hereinafter, “NCT-109”). EX1007, 4.

44. NCT-109 describes a Phase 1 clinical study protocol “[t]o assess the safety and tolerability, characterize the dose-limiting toxicities, and identify the maximum tolerated dose of BMS-986016 alone and in combination with Nivolumab in subjects with select advanced (metastatic and/or unresectable) solid tumors and to provide preliminary information on the clinical benefits of the combination. *Id.*, 4.

45. NCT-109 also provides “Study Details” including “Study Status.” *Id.* These details indicate that the “Last Update Posted” was October 23, 2013. The “Last Update Posted” date is the “most recent date on which changes to a study record were made available on ClinicalTrials.gov.” EX1019 (*ClinicalTrials.gov Glossary*, available at <https://clinicaltrials.gov/ct2/about-studies/glossary>), 10.

46. While the ClinicalTrials.gov website indicates that the “Last Update Posted” date is an estimate (*see* EX1007, 4) this “estimate” accounts for any “delay between when the changes were submitted to ClinicalTrials.gov by the study’s sponsor or investigator (the last submitted date) and the last update posted date.” EX1019 (*Clinicaltrials.gov Glossary*, available at <https://clinicaltrials.gov/ct2/about-studies/glossary>), 10.

47. NCT-109 also indicates that the “Last Update Submitted that Met QC Criteria” was October 18, 2013. EX1007, 4. The “Last Update Submitted that Met QC criteria” is defined as “[t]he most recent date on which the study sponsor or investigator submitted changes to a study record that are consistent with National Library of Medicine (NLM) quality control (QC) review criteria.” EX1019 (*Clinicaltrials.gov Glossary*, available at <https://clinicaltrials.gov/ct2/about-studies/glossary>), 10.

48. The October 23, 2013 “Last Update Posted” date is consistent with the October 18, 2013 “Last Update Submitted that Met QC Criteria” date, and in my experience, the estimated posting date is typically accurate to within a few days.

49. Based on my extensive experience with ClinicalTrials.gov and my recent manipulation of that website to access NCT-109, and based on the statutory posting and searchability requirements for ClinicalTrials.gov that I describe above,

in my opinion, an interested member of the public would have been able to search, locate, and access NCT-109 in the year 2013.

50. In my opinion, NCT-109 was publicly available and accessible to interested members of the public on or about October 23, 2013, and certainly within a few days thereafter, *i.e.* well prior to April 28, 2014.

51. The ClinicalTrials.gov website is updated daily. *See, supra*, ¶28.

52. As can be seen from these records, NCT-109, which would have been publicly available and accessible to interested members of the public as of the October 23, 2013 “Last Update Posted” date, contained a detailed description of a protocol to assess the safety and tolerability, characterize the dose-limiting toxicities, and identify the maximum tolerated dose of BMS-986016 alone and in combination with Nivolumab in subjects with select advanced (metastatic and/or unresectable) solid tumors and to provide preliminary information on the clinical benefits of the combination. EX1007, 4. Specifically, NCT-109 discloses administering BMS-93655” (a.k.a. nivolumab) “240 mg solution intravenously” “every 2 weeks” to treat “incurable melanoma.” EX1007, 5-6.

53. For the foregoing reasons, it is my opinion that the NCT-109 (EX1007) publicly disclosed details of a protocol to assess the safety and tolerability, characterize the dose-limiting toxicities, and identify the maximum tolerated dose of BMS-986016 alone and in combination with Nivolumab in

subjects with select advanced (metastatic and/or unresectable) solid tumors and to provide preliminary information on the clinical benefits of the combination, prior to April 28, 2014.

C. The Treatment Protocol for NCT02713867 was Publicly Available

54. I accessed the ClinicalTrials.gov website and located the record for Clinical Study No. NCT02713867 (Protocol CA209-384) Version 2, with the Brief Title “A Dose Frequency Optimization, Trial of Nivolumab 240 mg Every 2 Weeks vs Nivolumab 480 mg Every 4 Weeks in Subjects With Advanced or Metastatic Non-small Cell Lung Cancer Who Received 4 Months of Nivolumab at 3 mg/kg or 240 mg Every 2 Weeks,” and Last Update Posted to ClinicalTrials.gov as of March 22, 2016 (hereinafter, “NCT-867”). EX1013, 3.

55. NCT-867 describes a Phase IIIB/IV clinical study protocol “[t]o show that PFS (progress-free survival) rate at 6 months and at 1 year after randomization, of Nivolumab 480 mg every 4 weeks is non-inferior to nivolumab 240 mg every 2 weeks in subjects with advanced/metastatic (Stage IIIb/IV) NSCLC (non-Sq and Sq).” *Id.*, 3.

56. NCT-867 also provides “Study Details” including “Study Status.” *Id.* These details indicate that the “Last Update Posted” was March 22, 2016. The “Last Update Posted” date is the “most recent date on which changes to a study

record were made available on ClinicalTrials.gov.” EX1019 (*Clinicaltrials.gov Glossary*, available at <https://clinicaltrials.gov/ct2/about-studies/glossary>), 10.

57. While the ClinicalTrials.gov website indicates that the “Last Update Posted” date is an estimate (*see* EX1013, 3) this “estimate” accounts for any “delay between when the changes were submitted to ClinicalTrials.gov by the study’s sponsor or investigator (the last submitted date) and the last update posted date.” EX1019 (*Clinicaltrials.gov Glossary*, available at <https://clinicaltrials.gov/ct2/about-studies/glossary>), 10.

58. NCT-867 also indicates that the “Last Update Submitted that Met QC Criteria” was March 21, 2016. *Id.* The “Last Update Submitted that Met QC criteria” is defined as “[t]he most recent date on which the study sponsor or investigator submitted changes to a study record that are consistent with National Library of Medicine (NLM) quality control (QC) review criteria.” EX1019 (*Clinicaltrials.gov Glossary*, available at <https://clinicaltrials.gov/ct2/about-studies/glossary>), 10.

59. The March 22, 2016 “Last Update Posted” date is consistent with the March 21, 2016 “Last Update Submitted that Met QC Criteria” date, and in my experience, the estimated posting date is typically accurate to within a few days.

60. Based on my extensive experience with ClinicalTrials.gov and my recent manipulation of that website to access NCT-867, and based on the statutory

posting and searchability requirements for ClinicalTrials.gov that I describe above, in my opinion, an interested member of the public would have been able to search, locate, and access NCT-867 in the year 2016.

61. In my opinion, NCT-867 was most likely publicly available and accessible to interested members of the public on or about March 22, 2016, and certainly within a few days thereafter, *i.e.* well prior to April 28, 2016.

62. The ClinicalTrials.gov website is updated daily. *See, supra*, ¶28.

63. As can be seen from these records, NCT-867, which would have been publicly available and accessible to interested members of the public as of the March 22, 2016 “Last Update Posted” date, contained a detailed description of a protocol to demonstrate that PFS rate at 6 months and at 1 year after randomization of Nivolumab 480 mg every 4 weeks is non-inferior to nivolumab 240 mg every 2 weeks in subjects with advanced/metastatic (Stage IIIb/IV) NSCLC (non-Sq and Sq). Specifically, NCT-867 discloses using 480 mg nivolumab once every four weeks to treat cancer. EX1013, 4.

64. For the foregoing reasons, it is my opinion that the NCT-867 (EX1013) publicly disclosed details of a protocol to demonstrate that PFS rate at 6 months and at 1 year after randomization of Nivolumab 480 mg every 4 weeks is non-inferior to Nivolumab 240 mg every 2 weeks in subjects with

advanced/metastatic (Stage IIIb/IV) NSCLC (non-Sq and Sq), prior to April 28, 2016.

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

I declare under penalty of perjury that the foregoing is true and correct.

Dated: February 24, 2025

____/Prescott Lassman/_____
Prescott Lassman