

Vaccine and Immunization Research and Development News

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ONGOING VACCINE RESEARCH AND DEVELOPMENT AT PFIZER



Selected Publications from the Vaccine Research and Development Unit

A Phase 1 First-in-Human Study (B4901001) Evaluating a Novel Anti-IgE Vaccine in Adult Subjects with Allergic Rhinitis  The Journal of Allergy and Clinical Immunology Wong GY, Elfassi E, Girard G, Yang WH, Hebert J, Bugarini R, O'Connell MA, Champion B, Merson J, Davis H. February 2016

A Phase 1, Placebo-Controlled, Randomized Study of the Safety, Tolerability, and Immunogenicity of a Clostridium difficile Vaccine Administered With or Without Aluminum Hydroxide in Healthy Adults  VaccineSheldon E, Kitchin N, Peng Y, Eiden J, Gruber W, Johnson E, Jansen KU, Pride M, Pedneault L. April 19 2016

A Phase 3, Randomized, Active-Controlled Study to Assess the Safety and Tolerability of Meningococcal Serogroup B Vaccine Bivalent rLP2086 in Healthy Adolescents and Young Adults  VaccineOstergaard L, Lucksinger GH, Absalon J, Beeslaar J, Eiden J, Jansen KU, York LJ, Quinn A, Graversen ME, Perez JL. March 14 2016

A randomized phase 1 study of the safety and immunogenicity of three ascending dose levels of a 3-antigen Staphylococcus aureus vaccine (SA3Ag) in healthy adults  VaccineNissen M, Marshall H, Richmond P, Shakib S, Jiang Q, Cooper D, Rill D, Baber J, Eiden J, Gruber W, Jansen KU, Emini E, Anderson AS, Zito E, Girgenti D. April 8 2015

Cell Surface Antigen Manganese-Binding Protein MntC from Staphylococcus aureus  Encyclopedia of Inorganic and Bioinorganic ChemistryGribenko A, Liberator P, Anderson A, Matsuka Y, Mosyak L. September 14 2015

Demonstration of the preclinical correlate of protection for Staphylococcus aureus clumping factor A in a murine model of infection  VaccineScully IL, Timofeyeva Y, Keeney D, Matsuka Y, Severina E, McNeil L, Nanra J, Hu G, Liberator PA, Jansen KU, Anderson AS. October 5 2015

Comparison of Phenotypic and Genotypic Approaches to Capsule Typing Neisseria meningitidis Using Invasive and Carriage Strain Collections  Journal of Clinical MicrobiologyJones HC, Mohamed N, Rojas E, Andrew L, Hoyos J, Hawkins JC, McNeil LK, Jiang Q, Mayer LW, Wang X, Gilca R, De Wals P, Pedneault L, Eiden J, Jansen KU, Anderson AS. January 2016

Molecular attributes of conjugate antigen influence function of antibodies induced by anti-nicotine vaccine in mice and non-human primates  International ImmunotherapyMcCluskie MJ, Thorn J, Mehelic PR, Kolhe P, Bhattacharya K, Finneman JI, Stead DR, Bailey Piatchek M, Zhang N, Chikh G, Cartier J, Evans DM, Merson JR, Davis HLAugust 25 2015

Optimization of Molecular Approaches to Genogroup Neisseria meningitidis Carriage Isolates and Implications for Monitoring the Impact of New Serogroup B Vaccines  PLoS OneRojas E, Hoyos J, Oldfield N, Lee P, Flint M, Jones CH, Ala'Aldeen D, Jansen KU, Anderson AS. July 6 2015

Polysaccharide Conjugate Vaccine against Pneumococcal Pneumonia in Adults  The New England Journal of MedicineBonten MJM, Huijts SM, Bolkenbaas M, Webber C, Patterson S, Gault S, van Werkhoven H, van Deursen AMM, Sanders EAM, Verheij TM, Patton M, McDonough A, Moradoghli-Haftvani A, Smith H, Mellelieu T, Pride MW, Crowther G, Schmoele-Thoma B, Scott DA, Jansen KU, Lobatto R, Oosterman, B, Visser N, Caspers E, Smorenburg A, Emini EA, Gruber WC, Grobbee DE2015

Production and characterization of chemically inactivated genetically engineered *Clostridium difficile* toxoids  Journal of Pharmaceutical Sciences Vidunas E, Mathews A, Zi-rong Z, Weaver M, Cai P, Koh EH, Patel-Brown S, Yuan YH, Carriere M, Johnson EJ, Lotvin J, Moran J. July 2016

The Discovery and Development of a Novel Vaccine to Protect against *Neisseria meningitidis* Serogroup B Disease  Human Vaccines Zlotnick GW, Jones TR, Liberator P, Hao L, Harris S, McNeil LK, Zhu D, Perez J, Eiden J, Jansen KU, Anderson AS. November 1 2014

Vaccines are one of the greatest public health advancements of all time.

Vaccines are one of the greatest public health advancements of all time, resulting in the control, elimination, or near-elimination of numerous infectious diseases that were once pervasive and often fatal. Pfizer has a rich history in vaccine research and development. Over the years, we've played a pivotal role in eliminating or nearly eliminating deadly infectious diseases like smallpox and polio globally. We have designed novel vaccines based on new delivery systems and technologies that have resulted in vaccines to prevent bacterial infections, like those caused by *S. pneumoniae* and *N. meningitidis*.

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Today, more people benefit from safe and efficacious vaccines to prevent infectious diseases than ever before, and vaccines provide essential health benefits at all ages, from maternal and infant populations to seniors. However, our work is not done given the many infectious diseases remaining with a high unmet medical need and a growing list of vaccine preventable diseases.

Prevention is the Best Medicine



Watch Video At: <https://youtu.be/XB6fAyg0UJg>

Today is an exciting time in vaccine research and development, as scientific discoveries, technological advancements and regulatory paradigms are paving the way for novel vaccines. While Pfizer's Vaccine Research and Development scientists continue to extend our leadership position in pneumococcal and meningococcal disease prevention, they also work on vaccines against other major infectious diseases while striving to bring the benefits of vaccines into previously unexplored areas. We are at the forefront to usher in a new era of vaccine innovation, both to prevent and treat disease, with special focus on maternal/neonatal, hospital-acquired infections (HAI), and cancer.

We are the forefront to usher in a new era of vaccine innovation, both to prevent and treat disease...

We are optimistic about the broad potential to bring the benefits of vaccines to every age group, protecting a person throughout his or her entire life. Our vaccine research and development efforts are focused on three areas:



addressing_high_impact_infectious_diseases_infographic.p

Addressing high impact infectious diseases by supporting our vaccines against pneumococcal disease and meningitis and investigating vaccines against hospital-acquired infections, including those caused by *Staphylococcus aureus* and *Clostridium difficile*. The

burden of disease associated with these dangerous pathogens is increasing, particularly in healthcare settings but also in the community, making the need for effective vaccines even more urgent.

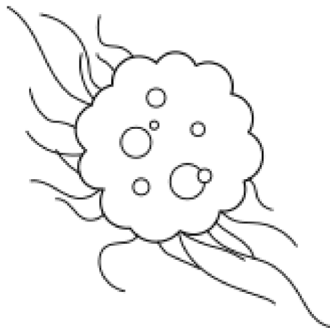
Learn more about our Staphylococcus Aureus research on this video »



expanding_the_benefits_of_maternal_immunization_infogr

Expanding the benefits of maternal immunization by discovering and developing vaccine candidates for neonatal infections such as those caused by respiratory syncytial virus (RSV), cytomegalovirus (CMV) and group B streptococcus (GBS). These infections can have severe negative consequences for the most vulnerable populations – the very young and older adults. Our strategy is to vaccinate pregnant women (or women who will become pregnant) so that lifesaving immunity will be passed on to newborns and protect them during those crucial first few days, weeks and months of life.

Watch a Video to Learn More about the Need for a Vaccine to Protect Against GBS »



Investigating cancer vaccines in combination with other immune system modifying agents will combine the science of vaccinology with recent or newly acquired knowledge in immune modulation to harness the body's immune system to elicit and maintain anti-tumor responses with vaccine based immunotherapy regimens and oncolytic viruses that should result in significant improvements in cancer treatment.

Leading Vaccine Design and Development Capabilities

End-to-End Product Development

Pfizer Vaccine R&D is a fully integrated, global operation that advances assets from discovery to registration and beyond, with talent and technical capabilities in Basic Research, early CMC Development, Clinical Development, Clinical Serology and Diagnostics and Operations.

Bioprocess Development

Pfizer Vaccine R&D employs an early focus on end-to-end planning of vaccine production processes, with experts considering both relevant biological attributes and sound engineering and manufacturing principals to develop scalable processes from program inception onward.

Antigen Presentation Technology

Pfizer continues to study novel conjugation and carrier systems in Vaccine R&D to generate a better immune response. We have significant expertise through the development of our pneumococcal and meningitis vaccines that we are now applying to a number of other programs.

Adjuvant Technologies

Adjuvants are added to vaccines to enhance their profile and sometimes increase the duration of effect.

Viral Vector Technology

We are expanding our expertise in viral vector design for optimized delivery of genetic material to specifically target cells and tissues.

Pathogen Surveillance

We incorporate rigorous epidemiologic surveillance into our vaccine R&D programs to enable the design of vaccines with the broadest possible coverage.

Antibody Technology

State of the art antibody technology is used to characterize immune responses and design vaccines that mimic the critical epitopes displayed by pathogens and cancer targets.

Novel Vaccine Delivery

Pfizer is exploring novel systems that may help the next generation vaccines provide added convenience for patients and doctors.

There is an urgent global health need for a vaccine that could protect pregnant women and their infants against GBS.



Human Vaccines Project In early 2016, Pfizer joined the Human Vaccines Project, a public-private consortium that aims to identify human immune responses associated with optimal vaccine protection. The project brings together leading academic research centers, industrial partners, nonprofits and governments to address the primary scientific barriers to developing

new vaccines and immunotherapies. The project has been endorsed by 35 of the world's leading vaccine scientists. Insights gained will guide the development of potentially improved vaccines against diseases such as influenza, dengue, HIV and other infectious illnesses as well as cancer.

[Learn more about Pfizer's work to help decode the immune system »](#)



Bill & Melinda Gates Foundation Pfizer received a grant from the Bill & Melinda Gates Foundation to conduct a Phase 1/2 clinical trial of Pfizer's vaccine candidate against group B streptococcus (GBS) infection in the developing world, a leading cause of neonatal sepsis, a serious life-threatening blood infection. The investigational vaccine would protect newborns via maternal immunization. There is an urgent global health need for a vaccine that could protect pregnant women and their infants against GBS, particularly in developing countries where prophylactic administration of antibiotics to prevent mother-to-child GBS transmission is not routine practice.

[Learn more about the need for a vaccine to protect against GBS »](#)

Meet Some of Pfizer's Vaccine Researchers



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nicholas_kitchin_

Nanette Cocero

Global President, Vaccines,
Pfizer Biopharmaceuticals Group

Nanette Cocero is the Global President of Pfizer Vaccines. In her role, Nanette oversees an international business and is responsible for the development and delivery of innovative vaccines that address serious and life-threatening conditions, helping to protect communities around the world.

Nanette leads a global team of 1,500 colleagues and manages a diverse vaccines portfolio aimed at protecting lives at all stages, from infants to older adults. She and her team also partner with governments, civic organizations, and others in the biopharmaceutical industry to accelerate global public health progress. She is Chair of the International Federation of Pharmaceuticals and Manufacturers Association (IFPMA) Vaccine CEO Steering Committee, advocating for policies and practices that will enable greater access and affordability to vaccines in low and middle-income countries. In addition, Nanette is a board member of the Americas Society/Council of the Americas (AS/COA).

Prior to her current position, Nanette was Regional President, Emerging Markets, for Pfizer's Innovative Health business. In this role, she led business operations in over 100 countries across Latin America, Africa, the Middle East, and Asia, spanning Pfizer's core therapeutic areas including vaccines, oncology, inflammation and immunology, internal medicine and rare disease. During her 15+ year tenure at Pfizer, Nanette has held numerous leadership positions in both developed and emerging markets, driving continuous growth for the businesses she managed and bringing novel medicines and access solutions to patients.

Before joining Pfizer, Nanette worked for 10 years as a management consultant and served as a Research Fellow for the University of Pennsylvania, Department of Pharmacology. Nanette earned a Bachelor of Science degree in chemistry from Cornell University; a Ph.D. in pharmacology from the University of Pennsylvania, and an MBA from The Wharton Business School. She has lived and worked in the continental United States, Puerto Rico, and Spain and she is bilingual in English and Spanish.

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