



# RESEARCH & DEVELOPMENT

**HIGHLIGHTS**

Signed an agreement with Medicines for Malaria Venture (MMV) to provide MMV with access to the Pfizer library of novel chemical entities to screen for compounds that could be developed into new treatments for malaria.

Obtained first accreditation in the pharmaceutical industry by the Association for the Accreditation of Human Research Protection Program (AAHRP) for protection of human rights in clinical research.

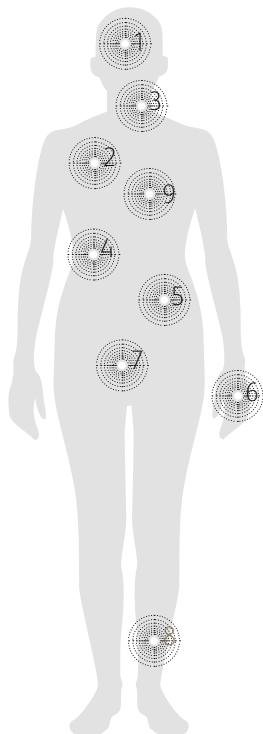
Registered over 1,183 trials to [www.clinicaltrials.gov](http://www.clinicaltrials.gov). In addition, 885 summaries of trial results have been posted on [www.clinicalstudyresults.org](http://www.clinicalstudyresults.org).

As advances in medical care help more and more people live longer lives, the need for new medicines to keep people healthy continues to grow. Pfizer researchers and scientists are working to discover and develop new ways to treat and prevent life-threatening and debilitating illnesses like Alzheimer’s disease and cancer, as well as to improve wellness and quality of life across a range of therapeutic areas. At Pfizer, we are focusing on developing treatments for unmet medical needs inspired by a single goal: patient health. This is why we are dedicated to developing promising new medicines to prevent and treat the world’s most serious diseases. We believe that from progress comes hope, and the promise of a healthier world.

Pfizer’s research & development teams are focused on nine therapeutic and disease areas that span a broad range of medical needs. Our current pipeline reflects a therapeutic-area focus with 100 programs in Phase I through Phase III. From March 2008 to September 2008, 21 programs advanced in the pipeline—12 of them in the identified high-priority disease areas of diabetes, oncology, inflammation/immunology, Alzheimer’s disease, psychoses and pain.

Pfizer’s recently established business units—for Primary Care, Specialty, Oncology, Established Products, and Emerging Markets—are designed to respond to customers’ and patients’ changing needs and to ensure the alignment of research and development activities with these needs.

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**PFIZER DISEASE RESEARCH AREAS**

**1 NEUROSCIENCE**  
Alzheimer’s disease  
Schizophrenia  
Bipolar disorder  
Autism

**2 ALLERGY/ RESPIRATORY**  
Allergic Rhinitis  
Asthma  
COPD

**3 INFECTIOUS DISEASE**  
ANTIBACTERIAL  
Antibiotics, focused and broad-spectrum

**4 INFECTIOUS DISEASE**  
ANTIVIRAL  
Hepatitis C  
HIV

**5 ONCOLOGY**  
Anti-angiogenesis agents  
Cytotoxic agents  
Immunotherapy/  
Vaccines  
Signal transduction agents

**6 INFLAMMATION**  
General  
Anti-Inflammation agents  
Rheumatoid Arthritis  
Osteoarthritis  
Super  
Anti-Inflammation

**7 GENITOURINARY SEXUAL HEALTH**  
Gynecology  
Urology

**8 PAIN**  
Inflammatory pain  
Neuropathic pain  
Nociceptive pain  
Osteoarthritis pain  
Severe chronic pain

**9 CARDIOVASCULAR METABOLIC ENDOCRINE DISORDERS**  
Diabetes

Please note that the designation “Disease Research Area” does not include programs that are continuing in clinical trials through in-licensed or co-development collaborations but do not have corresponding active discovery research programs. Furthermore, Pfizer may initiate new programs as necessary in response to new discoveries and unmet medical needs.

Pfizer is committed to the discovery, investigation and development of innovative treatment options for cancer patients worldwide, including the use of targeted agents in specific patient populations in several advanced and difficult-to-treat cancers. Our robust pipeline consists of 21 biologics and small molecules in clinical development and over 200 clinical trials, including a robust Phase III clinical trial program for Sutent. By working collaboratively with academic institutions, researchers, governments and licensing partners, Pfizer strives to transform treatment by targeting the right drug for the right patient at the right time.

## Expanding Research for Neglected Diseases

We have a shared responsibility to conduct research about diseases that disproportionately affect people in the developing world and will continue our efforts to help meet this global health challenge. As one company, however, we are limited in our ability to solve such universal health problems and recognize that multisector solutions are needed. We believe that public-private partnerships are essential to making progress on this front, with each partner contributing unique assets and expertise toward common goals.

### EFFORTS TO COMBAT MALARIA

Malaria continues to be an endemic disease in sub-Saharan Africa and is one of the leading causes of infant mortality. The World Health Organization estimates that in 2006, 247 million people worldwide had malaria and 881,000 died from the disease.<sup>1</sup> Ninety percent of these deaths occurred in Africa. In addition to our Mobilize Against Malaria initiative described in the *Access to Medicines* section of this report, Pfizer has significant ongoing research programs to develop new antimalarial drugs. The following are examples of research where Pfizer is advancing the fight against malaria:

- **EXPLORATORY RESEARCH PARTNERSHIPS**

Pfizer is collaborating with the World Health Organization's Special Programme for Research in Tropical Diseases (WHO-TDR) to target malaria and other neglected diseases by giving TDR access to Pfizer's library of medicinal compounds and bringing scientists from developing countries into Pfizer's laboratories for training in drug discovery techniques. This collaboration, based at Pfizer's Sandwich, U.K. site, has identified a number of novel compounds with antimalarial activity.

Pfizer scientists and three WHO-TDR Fellows are now working together to modify these compounds to have improved pharmaceutical properties. If successful, this effort will feed potential new therapies into our malaria pipeline while providing state-of-the-art training in drug discovery for the WHO-TDR Fellows.

Pfizer will be hosting two developing world clinical researchers as part of the new TDR program of Clinical R&D career development fellowships, funded by the Bill and Melinda Gates Foundation. During the 12-month program, each Fellow will receive specialized in-house training and acquire experience in clinical project management, regulatory compliance and good practices while assisting with clinical trials on new therapies for malaria and tuberculosis.

Pfizer has also agreed to provide Medicines for Malaria Venture (MMV) with access to Pfizer's chemical library to screen for compounds that have potential to be developed into novel treatments for malaria.

While these are early-stage research efforts, with effective new treatments still years away, public-private collaborations starting at the beginning of the drug discovery process are vital to ensure a pipeline of potential new medicines to combat the emergence of resistance.

- **AZITHROMYCIN/CHLOROQUINE**

Pfizer has identified, in consultation with global stakeholders, that the combination of azithromycin and chloroquine (AZCQ) could be a safe and effective option for Intermittent Preventive Therapy (IPTp) in pregnant

women in sub-Saharan Africa. This is significant in that there is a high unmet medical need due to increased resistance and/or safety concerns with existing drugs and a shortage of drugs for IPTp in the global malaria R&D pipeline. The findings are based on the results from two clinical trials for the treatment of symptomatic uncomplicated malaria in adults in sub-Saharan Africa. The clinical development of AZCQ for IPTp in sub-Saharan Africa is being planned in consultation with Medicines for Malaria Venture (MMV) and the London School of Hygiene and Tropical Medicines.

- **EURARTESIM®** Pfizer and the Italian firm Sigma-Tau have a license and supply agreement for the companies to market Eurartesim®, a novel fixed-dose artemisinin-based combination therapy (ACT), in Africa. The drug, which is currently in clinical trials, aims to treat uncomplicated malaria in adults and children, while reducing the potential for re-infection. The product candidate, developed jointly by Medicines for Malaria Venture and Sigma-Tau, is expected to be filed for registration in 2009, and has already been granted orphan drug status by both the European and U.S. regulatory authorities.

Through this partnership, Pfizer is advancing global health and strengthening our business in emerging markets. While Sigma-Tau will have the rights to sell this drug to governments and other public entities, Pfizer will have general commercial rights to this medicine in Africa. This arrangement will allow Pfizer to expand access for underserved populations to this medicine while realizing a commercial return, an approach we believe will prove sustainable for our business and for society.

<sup>1</sup> World Health Organization. "World Malaria Report 2008." Available online at: <http://apps.who.int/malaria/wmr2008/>.

## SHARING AN INNOVATIVE NEW HIV MEDICINE

In January 2008 Pfizer signed a royalty-free agreement with the International Partnership for Microbicides (IPM) to allow IPM to develop maraviroc, Pfizer's HIV treatment, as a microbicide for the prevention of HIV infection. Microbicides are products, such as gels and films, which could be applied vaginally to prevent transmission of HIV. Under this agreement, Pfizer will provide assistance to IPM to develop maraviroc as a vaginal microbicide. IPM has the rights to develop, manufacture and distribute the microbicide in developing countries.

## Opportunities in New Technology

Pfizer is also investing in technology to improve the clinical benefit of our products and to deliver better patient management through tools that can predict and diagnose diseases, research patient outcomes, or assist in patient compliance and post-treatment monitoring.

We are also in search of physician-directed and patient-managed diagnostic tools for better patient monitoring. For doctors, these include simple-to-use office-based tools that quickly provide information to aid physicians in providing better diagnosis, treatment and ultimately better patient management. For patients these include portable devices that measure heart function, glucose level or blood pressure.

## Clinical Trials

Clinical trials are one of the most important steps in the research process. Pfizer is committed to the safety of patients who take part in our clinical trials and to upholding the highest ethical standards. By establishing and following rigorous clinical trial, pharmacovigilance, and regulatory policies, we strive to maintain the highest ethical, scientific and clinical standards in all our clinical research around the world. We regularly review these policies to align them with Pfizer's vision, values and goals, and with our stakeholders' expectations, and have

posted our key policies for ensuring human subject protection on [www.pfizer.com/clinicaltrials](http://www.pfizer.com/clinicaltrials). We take great care to ensure that all of our sponsored clinical studies are conducted in accordance with local laws and regulations, as well as with established international standards.

In early 2009, Pfizer became the first pharmaceutical company to be accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) for ensuring the protection of human subjects taking part in early-stage clinical trials. This accreditation was awarded to our Phase I clinical research units in the U.S., Belgium and Singapore. To earn the accreditation, Pfizer participated in a rigorous, 15-month examination of the clinical research practices at these units.

We are also a leader in making the results of our trials available to the public and to our stakeholders. We publicly post clinical trial summary results of all our clinical trials, including those where further development has been discontinued. Summaries of 885 trial results have been posted thus far on [www.clinicalstudyresults.org](http://www.clinicalstudyresults.org) and more than 1,183 trials have been registered and posted on [www.clinicaltrials.gov](http://www.clinicaltrials.gov). This year, Pfizer began a pilot for distribution of information to participants in clinical trials from the Medical Heroes Program, sponsored by the Center for Information & Study on Clinical Research Participation.

## COMPENSATION TO INVESTIGATORS IN CLINICAL TRIALS

Over the past few years, there has been a growing concern over how patients are recruited for clinical trials and about payments and bonuses to physicians who enroll patients in trials sponsored by pharmaceutical companies.

In 2008, Pfizer collaborated with almost 8,000 clinical investigators to conduct more than 280 studies to better understand how our medicines can be safely and effectively used to the benefit of patients. Pfizer compensates outside investigators for their work in conducting Pfizer-sponsored clinical studies and for providing services to Pfizer related to those studies. Financial compensation for conducting clinical trials for us, for consulting advice, or other services related to our studies and research programs, are only made for bona fide services rendered to Pfizer. Compensation is documented and must adhere to the

*Pfizer Global Policy on Interactions with Healthcare Professionals* and our policies for compensation of investigators.

As part of our new policy on compensation to investigators, Pfizer will begin posting information, in 2010, about payments made to those primary investigators and their institutions for Pfizer studies run in the U.S.

## THE GLOBALIZATION OF CLINICAL TRIALS

Clinical trials of pharmaceuticals are expanding globally, in part to ensure that the intended demographic for medicine is the same demographic that participates in trials. We run trials in more than 60 countries and continue to identify new, qualified physician-investigators and research sites. In addition, we only place studies in those markets where the medicine will be made available (commercialized) if it is proven to be safe and effective. During 2009, Pfizer offered compassionate use or expanded access programs to patients who participated in our trials.

Pfizer trials are increasingly moving into countries in the developing world. Pfizer's research is done to international standards, including the *International Conference of Harmonization (ICH) Good Clinical Practices (GCP) Guidelines* (1996) and the principles in the *Declaration of Helsinki* (2008), regardless of where the trial site is located around the world. While our trials often offer health benefits to the patients who enroll, we do not pay patients to enroll in these trials. We also are careful in using placebos in our studies as controls, and do not use placebos, or withhold life-saving medicine, in any study where doing so would harm study participants. Additional information on our standard for multi-regional trials and how we respect the rights of participants are also posted on [www.pfizer.com/globalizationoftrials](http://www.pfizer.com/globalizationoftrials).

As the number of our clinical trials in emerging countries continues to increase so does our reliance on qualified and highly competent local investigators. Training has become an essential activity. Training needs to include (and indeed may be more effective), if ethics committee members, regulators and others, in addition to investigators, all participate. Last year, Pfizer worked to establish investigator and study staff training pilots in India

and Korea that engaged experts outside of the investigators themselves. We are extending this outreach and training to other nations where we are expanding clinical trials, including Turkey, China, Brazil, India, Mexico and in Africa.

To improve the way that clinical trials are conducted, we have developed a series of case studies, focusing on challenges that Pfizer has faced in the developing world. These are intended to be used as discussion pieces with new partners in developing markets, and in internal training, and are posted at [www.pfizer.com](http://www.pfizer.com). In addition, Pfizer has made a grant to the Clinical Trial Centre of the University of Hong Kong for the development of a manual for ethics committee and IRB members that is intended to improve local capabilities, especially with regard to the review of multi-regional trials that involve the developing world.

## Stem Cells

For more than a decade, Pfizer has been using animal or adult stem cells in its laboratories to help screen new compounds and identify safer and more effective medicines. We acknowledge the sensitive ethical issues surrounding stem cell use, and strongly oppose cloning, but we believe that stem cell research, conducted in accord with laws and regulations, is an important tool in the search for innovative new medicines.

With compelling evidence from this research, Pfizer has begun to explore accessing drug development technology from leading academic, biotechnology and pharmaceutical partners around the world, who also have experience with currently-available, human embryonic stem cell lines that meet the highest ethical standards set by leading scientific authorities. Pfizer's *Stem Cell Policy* ([www.pfizer.com](http://www.pfizer.com)) guides the company's research activities and its exploration of new external partnerships.

Pfizer recently launched a new Regenerative Medicine Unit, whose mission is to build upon recent scientific progress in understanding the biology of all types of stem cells, and to leverage these opportunities to discover and develop a new generation of regenerative medicines for major medical needs. Through our work with strategic alliance partners, academic researchers and patient advocate groups, Pfizer seeks to further develop these technologies and provide new therapies for patients around the world.

## Animal Care and Use

Pfizer's *Animal Care and Use Policy* ([www.pfizer.com](http://www.pfizer.com)) reflects our absolute commitment that animals used in research are treated humanely. This means that any research involving animals is conducted only after appropriate ethical consideration and review. This review ensures that we provide a high level of care to experimental animals, and that there is

no scientifically appropriate and validated alternative to the use of animals that is acceptable to regulators, where relevant. For as long as it remains necessary to use animals in biomedical research for the discovery, development and evaluation of new medicines, we commit to maintaining the highest standards in the humane treatment of these animals.

### STAKEHOLDER COMMENTARY

“Pfizer, as the world's largest pharmaceutical company, would be expected to have a dominant position in its corporate responsibility efforts related to diseases of the developing world but this was not always the case.

Recently this began to change dramatically at Pfizer, and a real sense of catch up with the leaders in this area (as for example tabulated in the *Access to Medicines Index*) now permeates Pfizer's actions and communications. Pfizer also now clearly has a partnership mindset, a key to successful execution in this space. In April 2009 Pfizer and the Medicines for Malaria Venture (MMV) signed an agreement designed to facilitate advancements in the battle against malaria. MMV will have access to the Pfizer library of novel chemical entities, in order to screen it for compounds with potential to be developed into new malaria treatments. Our partnership extends to collaborating on the Phase III clinical development of a novel intermittent preventive treatment for malaria in pregnant women. Such partnerships are key to building a strong antimalarial pipeline to ultimately reach the goal of malaria eradication.”

**DR. CHRIS HENTSCHEL**

CEO, MEDICINES FOR MALARIA VENTURE (MMV)

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## LOOKING FORWARD

Given the enormous potential benefits that our drug portfolio brings to patients and their caregivers, Pfizer is focusing on remaining a top tier health care company and a recognized leader in the development of innovative drugs and treatments for disease. The recent scientific advances that have been made in biologics therapies, stem cells, and new disease models, have tremendous potential, even against feared conditions such as paralysis. However, the cost of research and development to get a new drug approved and into the hands of doctors now exceeds \$1 billion, with only one in 10 drugs in clinical trials gaining regulatory clearance. Other issues also remain with the clinical trial process, including the increasing number of trials required in developing countries.

It is clear that today's regulatory and economic challenges need to be addressed in ways that preserve our ability to innovate for the benefit of millions of patients who depend upon us to live healthier lives. This will require a working partnership involving the industry, government regulators, academia, physicians, pharmacists, patient advocate groups and drug benefit payers. Pfizer is collaborating with all of these parties in order to achieve a common goal of providing safe, effective, high value therapies to patients in need. It will truly take a global effort and the contributions of everyone to successfully address these challenges.