



# "I investigate."

"There is great beauty in science and in the research we do. When we find or make a compound with a novel mechanism of action for a disease that affects millions, and our compound shows a tolerability and efficacy profile that could lead to a best-in-class therapy, it is breathtaking. And the greatest reward, if we can help bring this new medicine to the world, is knowing you've improved the lives of the people suffering from this disease, compared to what was previously possible."

> Neeta B. Amin, Pharm.D. Clinical Lead, CVMED Research Unit, Pfizer Worldwide R&D

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# Strengthening Our Innovative Core R&D Priorities

#### We continue to transform our R&D approach and capabilities to position Pfizer for sustainable innovation and productivity.



Three years after launching a comprehensive R&D turnaround effort, we are working toward a future where R&D is delivering value, both for our shareholders and for the patients who are counting on us. By collaborating with a range of partners in new ways, instilling greater business discipline, end-to-end portfolio management, and leveraging emerging technology platforms, we are advancing our purpose of innovating to bring new therapies to patients.

From discovery through commercialization, Pfizer is focused on aligning our portfolio with priority therapeutic areas where we bring cutting-edge capabilities in medicine and vaccine design and development.

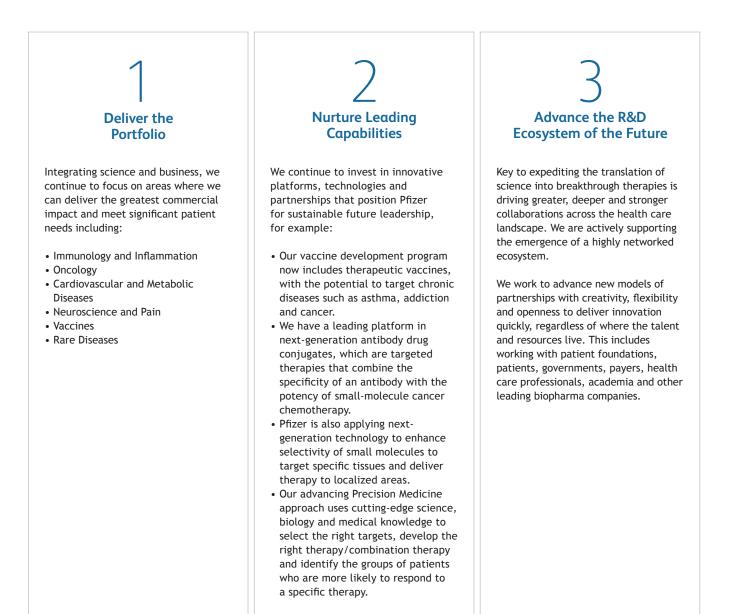




Pre-Proof of Concept:

## Inventing the Highest Potential Candidate Medicines and Vaccines

In the pre-Proof of Concept/invention phase, we have three key R&D priorities:





#### Post-Proof of Concept:

## Developing Medicines for Maximum Value and Impact in the Real World

A critical part in the process of bringing new therapies to patients is clinical development — the study of potential new therapies in humans. Pfizer is committed to enhanced clinical and regulatory quality, and compliance to build trust among key stakeholders, including patients and payers. We work with payer organizations to ensure our medicines are valued and reimbursed appropriately, and with regulatory authorities around the word to meet and maintain their standards.

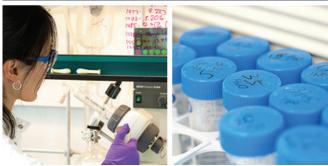
#### **Clinical Innovation**

Pfizer has taken an early leadership position in creating a discipline around Clinical Innovation, ensuring we are taking advantage of cutting-edge tools, approaches and partnerships to ensure our clinical trials are executed with optimal quality, speed and agility. Pfizer's Clinical Innovation investments and initiatives are focused on patient engagement, making work easy for sites and leveraging real world data.

#### Integrated Regulatory & Safety

Patient safety is a paramount concern for Pfizer, from the moment a new compound is discovered, and for as long as a medicine is prescribed. It is our ethical and regulatory responsibility to monitor the safety of our medicines everywhere they are marketed. Once a drug compound is approved, we continue to monitor its safety and work with governments and others to secure the supply chain and prevent counterfeiting.





#### Key Programs in Registration / Phase 3

- Xeljanz® (tofacitinib): Ulcerative Colitis, Psoriasis (oral), Psoriatic Arthritis
- Palbociclib: Advanced Breast Cancer (1st Line & Recurrent), High Risk Early Breast Cancer
- Prophylactic Vaccine for Meningococcal Serogroup B
- PCSK9 Inhibitor (bococizumab/RN316): Hyperlipidemia
- Ertugliflozin: Type 2 Diabetes (in collaboration w/ Merck)
- Trastuzumab: Breast Cancer

#### Key Programs in Phase 2

- Xeljanz® (tofacitinib): Crohn's Disease, Ankylosing Spondylitis, Psoriasis (topical), Atopic Dermatitis
- Anti-IL-6 Antibody: Crohn's Disease, Lupus
- Anti MadCAM: Crohn's Disease, Ulcerative Colitis
- PDE5 Inhibitor: Diabetic Nephropathy
- CCR2/5 Antagonist: Diabetic Nephropathy
- Inlyta®: Hepatocellular Carcinoma
- PI3K/mTOR Inhibitor: Colorectal Cancer
- ALK-1 Inhibitor mAb:
- Hepatocellular Carcinoma • SMO Inhibitor:
- Acute Myeloid Leukemia
  Prophylactic Vaccine for Staphylococcus Aureus
- GMI-1070 (Rivipansel): Sickle Cell Disease
- PDE10 Inhibitor: Huntington's Disease, Adjunctive Treatment for Schizophrenia

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# Advancing Our Pipeline

We prioritize our R&D efforts in areas with the greatest scientific and commercial promise: immunology and inflammation, oncology, cardiovascular and metabolic diseases, neuroscience and pain, vaccines, rare diseases and biosimilars. Through major research efforts across multiple modalities — including small molecules, biologics and vaccines — Pfizer is developing the medical solutions that will matter most to the people we serve.

View the latest pipeline on pfizer.com



Programs in Clinical Trial or Registration as of February 28, 2014







# Improving Clinical Trials

Much of the cost of developing a new medicine or vaccine is found in clinical development the long, highly regulated process, managed by independent experts, of determining if a proposed product is safe and effective. Clinical trials may run from the tens of millions of dollars to one billion dollars or more. Pfizer is committed to improving the effectiveness and efficiency of clinical trials, while protecting the safety and interests of clinical trial volunteers. We recognize that clinical trials and those involved in them play a vital and heroic role in bringing new breakthroughs to patients.

## Broadening Access to Information from Clinical Trials

Recently, we simplified and broadened access to information gathered in Pfizersponsored clinical trials, expanding upon our established methods of clinical trial information sharing. Qualified researchers now have access to anonymized patientlevel data upon request via our INSPIIRE (Integrated System for Pfizer Investigator Initiated Research) public web portal for investigator-initiated research (<u>iirsubmission.pfizer.com</u>). An external Independent Review Panel will rule on any denied requests. We also are publishing, on pfizer.com, anonymized synopses of clinical study reports filed with regulatory

agencies for approved products. Overall, we are working hard to protect patient privacy while allowing qualified researchers to access data for further research.

New trial participants can receive laylanguage summaries of clinical trial results in countries where regulations permit. Pfizer is also piloting the use of "Blue Button®" technology (launched by the U.S. Departments of Veterans Affairs and Health and Human Services), to enable trial participants to download their own electronic clinical data. Pfizer's updated policy on clinical trials meets or exceeds the "Principles for Responsible Data Sharing" issued by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) in July 2013.

The full version of Pfizer's updated clinical data access policy and related information, including the data request portal, are available at <a href="http://www.pfizer.com/trialdataandresults">http://www.pfizer.com/trialdataandresults</a>.



### Clinical Innovation

Pfizer has created a discipline around Clinical Innovation, focused on making research participation easier for patients and health care providers. We are using new approaches and partnerships for clinical trial recruitment, particularly in the drive to increase the diversity of such trials. We are also using mobile health, social media and health information technology to ensure that clinical trials can be conducted most effectively by the thousands of independent researchers we rely on for expertise. To enhance these efforts, we also participate in key industry collaborations that seek to improve the clinical trial process. For example, Pfizer is a founding member of TransCelerate BioPharma Inc., a novel non-profit partnership of 10 major biopharmaceutical companies working to develop shared solutions to common research and development challenges.

# Investigating with Integrity

We conduct our clinical trials, wherever they take place, to the same ethical standards and comply with applicable laws and regulations to ensure we fully protect the rights and welfare of our clinical trial participants around the world. In 2012, we completely re-engineered our clinical trial processes. Our new process integrates wellknown quality management principles such as "quality by design" into the process. We have also narrowed the number of contract research organizations we use, so that we can increase vigilant oversight. As part of this quality process, we routinely conduct thorough inspections of clinical trial sites and audit the data generated in studies, to assure patient safety, data integrity, protocol adherence and regulatory compliance.