



# **CLINICAL TRIALS**

Clinical trials and the people who participate in them play a vital and critical role in bringing new breakthroughs to society. Pfizer is committed to improving the effectiveness and efficiency of clinical trials, while protecting the safety, well-being and interests of clinical trial volunteers.



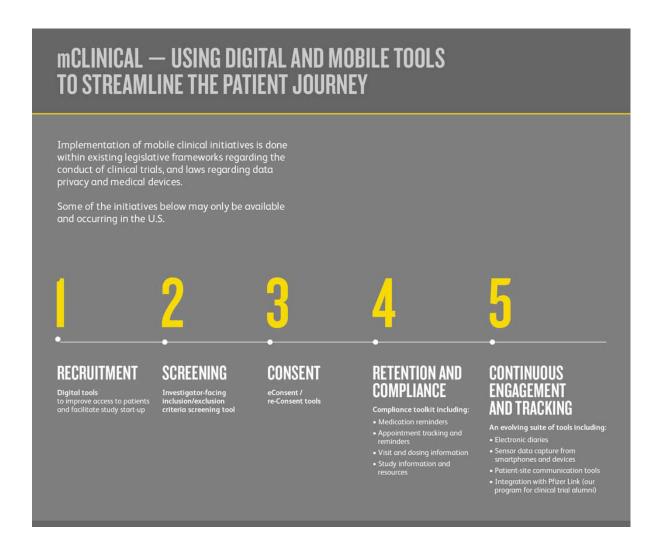
PHASE 1-4 INVOLVING 60,870 ACTIVE PATIENTS ACROSS 9,191 SITES IN 66 COUNTRIES AS OF DECEMBER 2015



## **RAPID UPTAKE OF MOBILE TOOLS**

Mobile health applications, social media and health information technology offer new ways to capture data and insights from patients, enhance the patient experience, and coordinate the clinical trials conducted in partnership with thousands of independent researchers. We are seeing a rapid uptake in the use of mobile tools that may support participation and facilitate a larger breadth of clinical data.

We continue to expand our digital toolkit. Pfizer mClinical initiatives seek to improve the patient experience and provide investigators with advanced tools that streamline information access and maintain compliance using a flexible and modular approach. Modular components may include electronic informed consent, sensors and wearable tools, retention and visit reminders, video and remote visits, bring-your-own-device applications, electronic labels, and digital tools for clinical study start-up activities.





#### ONE PARTICIPANT'S EXPERIENCE WITH PFIZER LINK

Pfizer Link is a unique online patient tool and "alumni program" for study participants who have completed participation in a Pfizer-sponsored clinical trial (available in the U.S.) which patients have the option of consenting to participate in. Pfizer Link provides information on diseases and conditions of interest, suggestions and tools for disease management, general information about clinical trials, and access to study results including the Pfizer Blue Button Project (launched by the U.S. Departments of Veterans Affairs and Health and Human Services) for select studies to access individual electronic data. A participant in a recent Pfizer clinical trial said this about the value of joining the Pfizer Link community: "I joined the trial out of a desire to advance diabetes research, and had a satisfying experience as a research participant. After I completed the study, I joined Pfizer Link and **Blue Button** because I was curious about my clinical trial data, and because I wanted to have a community where I can participate and share my experiences. I look forward to learning more from Pfizer about breakthroughs in medical research and to identify other opportunities to participate in research and clinical trials."

#### INVESTIGATING WITH INTEGRITY

We conduct all of our clinical trials to global standards for human subject research protection programs, comply with applicable laws and regulations, and fully protect the rights and welfare of trial participants. We integrate quality management principles into the clinical trial process, maintaining oversight over all trials, including those conducted for us by contract research organizations. To assure patient safety, data integrity, protocol adherence and good clinical practice regulatory compliance, clinical trial sites are monitored and subject to an audit program and the data generated in studies is subject to quality checks.

### TRANSCELERATE® COLLABORATION DRIVING IMPROVEMENTS IN CLINICAL TRIALS

TransCelerate Biopharma has been a great industry collaboration success story. Founded to generate industry-wide efficiencies with an initial focus on clinical trials, its supporting membership has grown in just three years from 10 global pharmaceutical companies (including Pfizer) to 20. Its original five workstreams have grown to 14. The initial work that TransCelerate has delivered is being used to improve efficiency in clinical trials across the industry and across the world. The nonprofit consortium has created a comparator drug sourcing network, new data standards for several disease areas, mutual recognition for good clinical practice (GCP) training for approximately 200,000 investigators, a shared investigator registry (helping study investigators find research opportunities with sponsors), a model approach for removing identifiers from individual patient data in clinical studies, and, most recently, the Shared Investigator Platform — a single web portal for investigators with single sign-on regardless of whether the investigator is working on a study with Pfizer or any industry peer members.

"TransCelerate is an unprecedented collaboration amongst some of the world's most successful biopharmaceutical companies," said Dalvir Gill, Ph.D., TransCelerate's CEO. "As one of TransCelerate's founding members, Pfizer is committed to finding solutions to common drug development inefficiencies. Through this collaboration, we believe we can help transform the R&D landscape and implement solutions to drive efficient, effective and high quality delivery of new medicines to patients around the world."

~200,000

INVESTIGATORS WORLDWIDE HAVE DECEMBED DECOGNITION ACROSS

RECEIVED RECOGNITION ACROSS
THE CONSORTIUM FOR THEIR GCP
TRAINING, REDUCING THE BURDEN
ON INVESTIGATORS AND GIVING
THEM BACK TIME TO SUPPORT
PATIENTS AND STUDY PARTICIPANTS.