

New Smartphone App May Enable Lupus Patients to Report Symptoms More Easily and Accurately

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App developed by Lupus Research Alliance, Pfizer Inc. and Tata to be tested through noninterventional clinical trial called VALUE

The Lupus Research Alliance, the world's largest private funder of lupus research, and Pfizer Inc., the global biopharmaceutical company, announced the start of a noninterventional clinical study that will test a custom smartphone app enabling lupus patients to report on their fatigue and other symptoms in real time. Incorporating feedback from people with lupus, the new app will be evaluated through a noninterventional clinical study called VALUE (VAlidation in LUpus of an Electronic Patient Reported Outcomes Tool), scheduled to begin at the end of this month. If successful, this new app will permit patients to use their smartphones to report on symptoms of lupus such as pain and fatigue. These reports are now obtained largely through paper surveys during visits to physicians' offices.

Pfizer Inc., the Lupus Research Alliance and Tata Consultancy Services Ltd. jointly developed the new mobile app, using the Apple ResearchKit platform and building on existing research tools that have been validated in lupus.

"This is an important step in demonstrating that mobile technology can improve how and what patients report to their care teams about subjective but serious symptoms of lupus, such as debilitating fatigue," said Kenneth M. Farber, co-CEO and co-President of the Lupus Research Alliance. "This app may enable more frequent and consistent reporting from patients, thus providing better information for care teams and empowering patients to take a larger role in developing future therapies."

Patients enrolled in VALUE will use an iPhone with the app installed, submitting selfassessments of symptoms over a two-month period. This data will be compared with standard questionnaire data collected by traditional methods such as written surveys in physicians' offices. VALUE will help determine if information reported by patients through the new app is sufficiently complete and accurate to be used in future studies of new lupus therapies.

"The current paper methods of collecting patient-reported data can be cumbersome and inconvenient, and often depend on memory. VALUE holds promise for 'in the moment' reporting of symptoms and may open the door to similar tools being used in Pfizersponsored clinical studies for lupus and other diseases," said Freda Lewis-Hall, MD, Pfizer Executive Vice President and Chief Medical Officer.

VALUE is being conducted through the Lupus Clinical Investigators Network (LuCIN), an alliance of independent investigators focusing on clinical trials for therapies that may be important to lupus patients. LuCIN was launched and is funded by the Lupus Research Alliance. VALUE is slated to launch this month, with results expected in December 2017.

About Lupus Lupus is a chronic, complex autoimmune disease that affects millions of people worldwide. Most lupus sufferers are women, between the ages of 15 and 44. Women of color are especially at risk. In lupus, the immune system, which enables protection against infection, creates antibodies that attack the body's own tissues and organs. Lupus can affect many parts of the body and is characterized by unpredictable periods of illness, called flares, followed by periods of remission. Symptoms often include pain and fatigue. Lupus can damage internal organs, degrade quality of life and lead to premature death.

Lupus currently has no cure but can often be managed through lifestyle changes and therapies to reduce inflammation and infection, control flares and fevers, and protect against organ damage. Pfizer and the Lupus Research Alliance are collaborating to develop new therapies for patients with lupus, jointly supporting research projects driven by leading academic medical centers that are members of Pfizer's Centers for Therapeutic Innovation.

About the Lupus Research Alliance (www.lupusresearch.org) The Lupus Research Alliance unites the global lupus community in bold determination to free the world of lupus through the power of science. The organization will transform the lives of people affected by lupus as it welcomes and embraces a new scientific era, pioneers innovation, pushes the frontiers of knowledge, enlists diverse new scientific talent, and leads the drive to new treatments, prevention and cure. Because the Lupus Research Alliance Board of Directors funds all administrative and fundraising costs, 100% of all donations goes to support lupus research programs.

About Pfizer Inc. (www.pfizer.com) Pfizer applies global resources to bring people therapies that extend and significantly improve their lives. For more than 165 years, Pfizer has worked to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes branded and established medicines, vaccines and consumer health products.

About Tata Consultancy Services Ltd. (www.tcs.com)

A member company of the Tata group, India's largest conglomerate, Tata Consultancy Services delivers results to global businesses through a consulting-led, integrated portfolio of information technology, business process, infrastructure, engineering and quality assurance services. Tata Consultancy Services has more than 370,000 consultants based in 45 countries.