Digital health technologies hold key to new Parkinson's treatments

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The use of digital health technologies across health care and drug development has accelerated. A new paper titled "Digital Progression Biomarkers as Novel Endpoints in Clinical Trials: A Multistakeholder

Perspective," co-authored by experts across diverse disciplines, highlights how new remote monitoring technologies present a tremendous opportunity to advance digital medicine in health care even further, specifically in Parkinson's disease. This perspective paper is co-authored by the academic leader of the largest funded project for digital technologies in Europe, Professor Lynn Rochester, University of Newcastle; European Medicines Agency (EMA) scientific leader, Dr. Maria Tome; young investigator and Ph.D. candidate Reham Badawy; physician and Parkinson's patient, Dr. Soania Mathur; and Dr. Diane Stephenson, Executive Director of the Critical Path for Parkinson's (CPP) Consortium.

Global collaborative efforts are underway with the goal of advancing the use of digital health technologies for use in Parkinson's clinical research and therapeutic trials—yet several gaps and barriers stand in the way of success. These include data security issues, the rapidly evolving nature of the technology, lack of consensus on data standards, vast diversity of distinct studies carried out on different devices and the need for open science.

CPP's Digital Drug Development Tool team at Critical Path Institute consists of industry members, scientific academic advisors, patient research organizations and people living with Parkinson's all collaborating across the globe to seek advice early and often from regulatory agencies. Companies advancing innovative therapies for the treatment of Parkinson's see the promise of digital technologies, yet they also recognize that there are gaps that are too challenging to overcome on their own. CPP's focus on the voice of people living with Parkinson's aligns with the U.S. Food and Drug Administration (FDA) and EMA's vision for patient-focused drug development. Sharing costs, risks and knowledge will streamline a more efficient runway for regulatory endorsement in the future.

"We felt it was imperative to come together on this paper, at this moment, to bring attention to how existing digital health technologies can complement traditional modalities and transform and accelerate clinical research and therapeutic development," said Rochester.

Dr. Mathur, who has lived with Parkinson's for 22 years, inspired the team of five women leaders to work on this paper across different countries during the pandemic. "It is vital to include the patient voice to drive the sense of urgency when it comes to Parkinson's research. As patients, we fully experience the unrelenting progression of this disease, the ongoing daily challenges that we live with. From the direction of research to identifying the tools that can estimate relevant outcome measures in the search for new therapeutics that are directed towards disease modification or improved quality of life, patient input is absolutely integral to its success. This collaboration kept that sense of urgency at the forefront."

"EMA works with the FDA to assure that digital technologies are aligned with what is important to patients," said Dr. Tome. "The pace of progress is going to be accelerated by applying principles of what it took the world to tackle the COVID-19 pandemic," Stephenson added. "True collaborations amongst all stakeholders are urgently needed to make efficient progress, avoid duplication of effort, share costs and risks and advance with warp speed."

Professor Bas Bloem, editor-in-chief of the *Journal of Parkinson's Disease* and author of the book "Ending Parkinson's Disease," said, "We are very excited to publish this very important paper in our journal, as it provides a clear and visionary glimpse into the future of better care and innovative research approaches in the field of Parkinson's disease."

More information: Diane Stephenson et al, Digital Progression Biomarkers as Novel Endpoints in Clinical Trials: A Multistakeholder

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