Pfizer

Pfizer is a leading research-based biopharmaceutical company that applies science and global resources to deliver innovative therapies that extend and significantly improve lives.

The Problem

- Digital biomarkers* can revolutionize the way we conduct future clinical trials.
- Researchers from Pfizer worked on a project to identify digital medicine studies and characterize trends over time.

> *A complete catalog of digital medicine studies (ideally linked to ClinicalTrials.gov study record) has a potential to advance regulator's view of digital medicine. DiMe's Library of Digital Endpoints can greatly contribute to creation of such a catalog.*
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> **— Vojtech Huser,** Pfizer

The Resources

- The authors first leveraged ClinicalTrials.gov – a registry of clinical studies, which is mandatory or optional, depending on the study type - to analyze study device intervention, title, description, and declared outcomes.
- Next, the authors used DiMe's crowdsourced Library of Digital Endpoints. The authors used the 178 studies (as of April 2022) in the library registered on ClinicalTrials.gov to create a study set of digital medicine studies.
- Based on the Endpoints Library study set, the authors developed a list of keywords comprising manufacturers, product names, and model numbers of the digital technologies utilized in clinical studies. The keywords were used to arrive at a computationally derived set of digital medicine trials.
- From the ClinicalTrials.gov and DiMe endpoints library study sets, the authors characterized temporal trends in the use of wearable sensors and found that there was variability in how studies reported the use of digital technologies.

The Impact

- Identifying digital medicine studies on ClinicalTrials.gov proved to be difficult due to the high variability in how sponsors utilize structured fields within ClinicalTrials.gov. Thus, DiMe's Endpoint library provided Pfizer with another reference set of digital medicine studies to use in the trend analysis.

*The FDA defines a digital biomarker to be a characteristic or set of characteristics, collected from digital health technologies, that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention.