Digital Health Technologies & Endpoints in Clinical Research

Driving Patient-Centered Medicines Development & Access

Ebony Dashiell-Aje, PhD
EuropaBio, BioMarin Pharmaceutical, Inc.

Digital Innovation is the Present & Future

505 digital endpoints

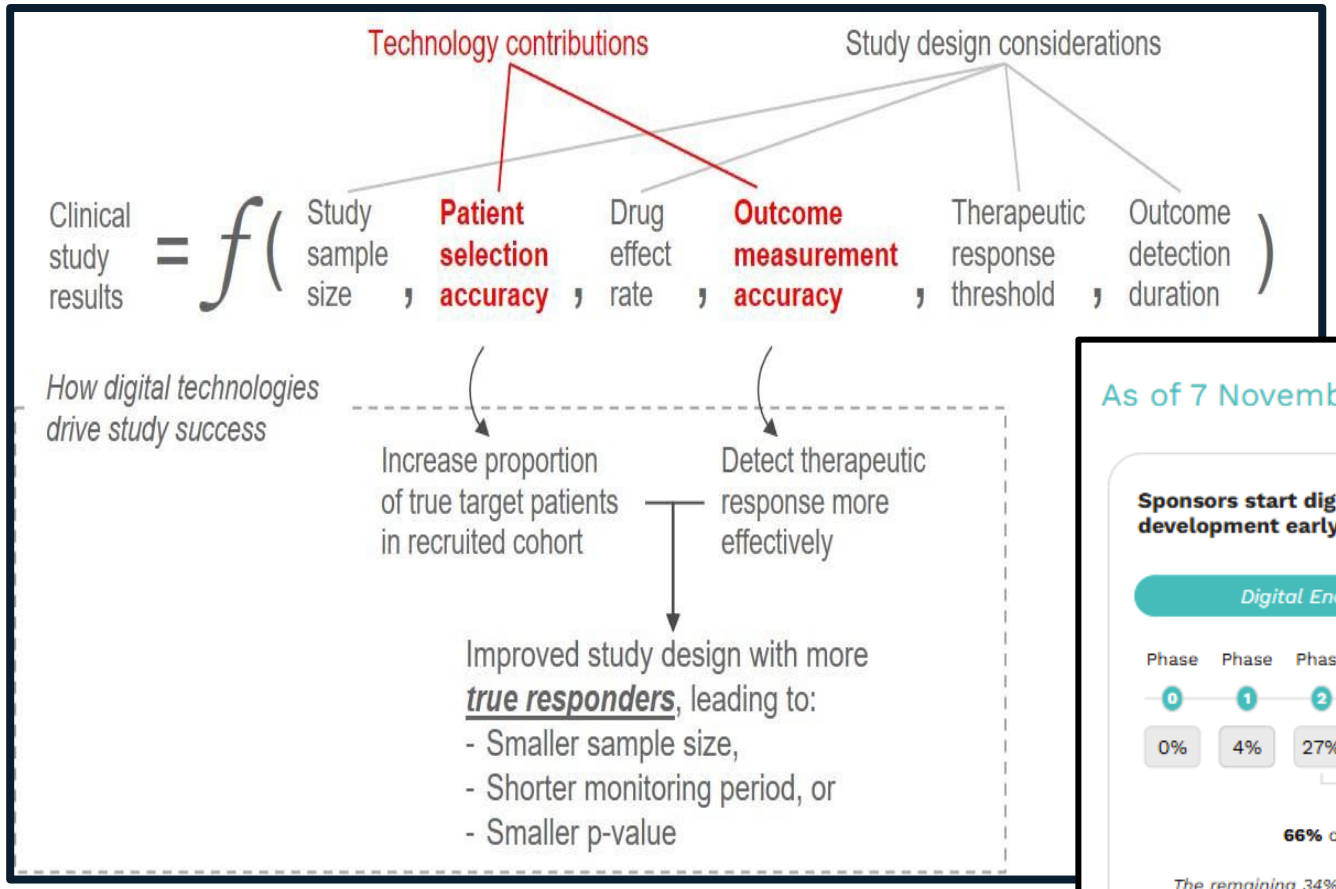
100+ research partners

3 global qualification programs

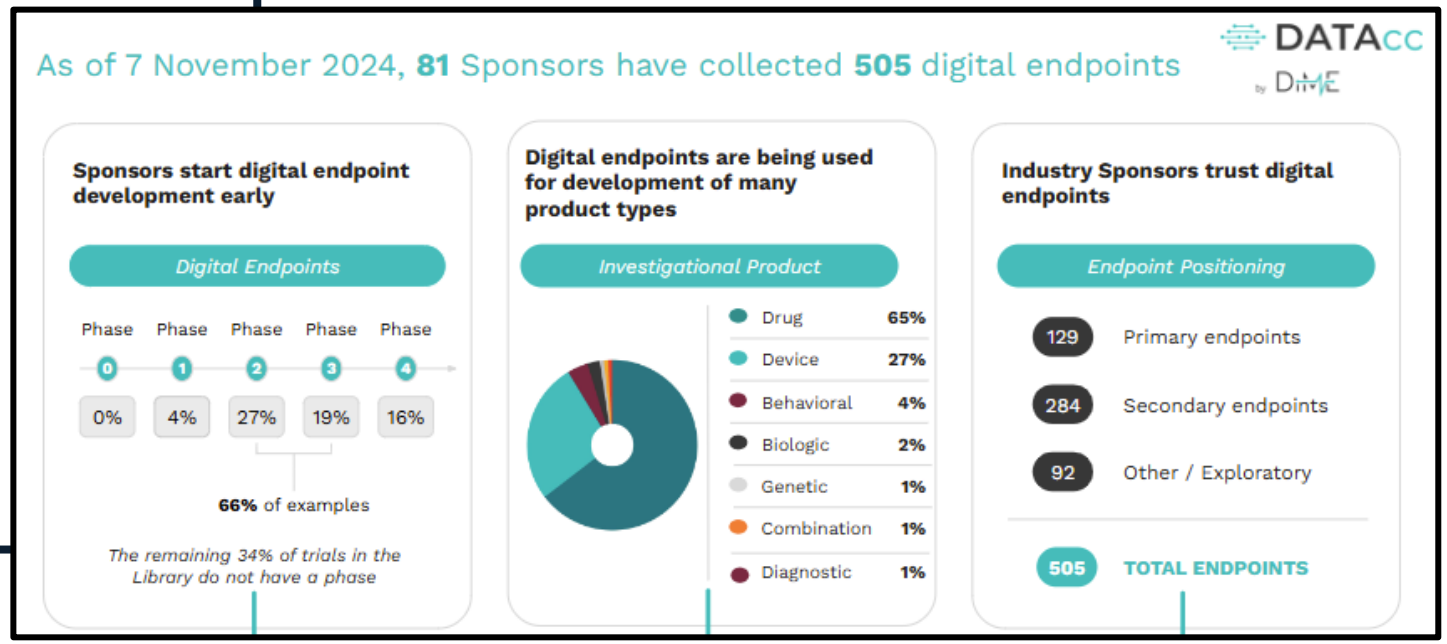
1 methodological guidance

2 regulatory frameworks

Digital health technologies & endpoints yield real-world, patient-relevant measurements that can be more sensitive, efficient, and provide representative data. This improves the quality and speed of evidence for regulatory and clinical decision-making.



Source: Mori et al., 2022 Project Moneyball publication, Figure 1 – https://karger.com/Article/FullText/525255



Source: Digital Medicine Society's Crowdsourced Library of Digital Endpoints; https://dimesociety.org/library-of-digital-endpoints/

We have the science, infrastructure, pathways, and global collaboration—now we must standardize, harmonize, and embed digital health technologies in research to deliver faster, precise, patient-centered clinical data and real-world evidence.

Present & Future Enablers

- Marked rise in collection of continuous information (actively or passively) in the real-world, making more convenient and accessible
- Increased interest/efforts to enable evidence generation in interventional and non-interventional studies
- Advances in technical validation efforts to drive precision and efficient operations worldwide
- Increased global collaboration (researchers, sponsors, regulators, developers) to advance the science in real-time