

Digital Health Technologies & Endpoints in Clinical Research

**Driving Patient-Centered Medicines
Development & Access**

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE



European
Commission



ISPOR

Improving healthcare decisions

ISfTeH

International Society for
Telemedicine & eHealth

Your Global Partner in Digital Health



**CRITICAL PATH
INSTITUTE**

MDIC

MEDICAL DEVICE
INNOVATION CONSORTIUM



DIME

DIGITAL
MEDICINE
SOCIETY



innovative
health
initiative



**U.S. FOOD & DRUG
ADMINISTRATION**

Digital Innovation is the Present & Future

505 digital
endpoints

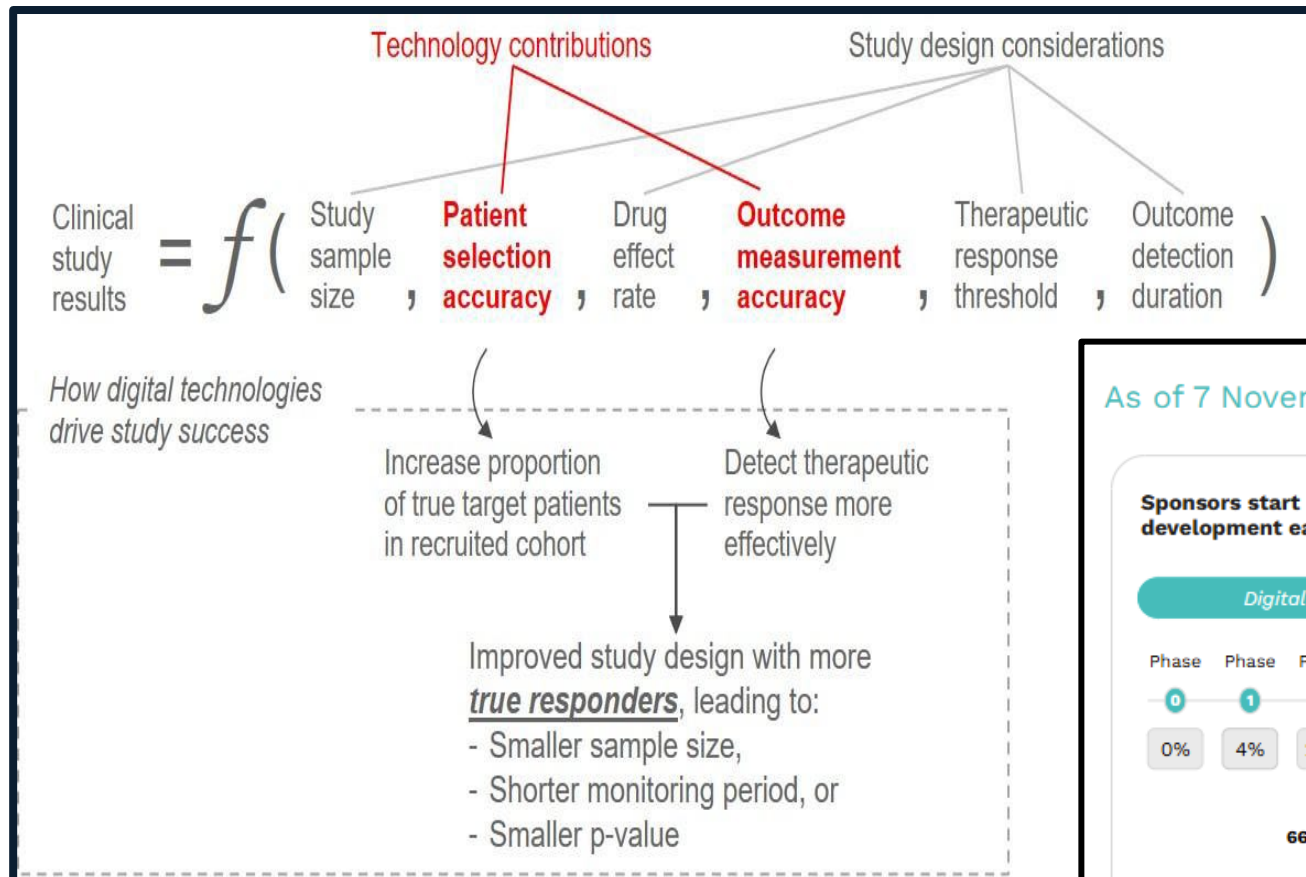
100+ research
partners

3 global qualification
programs

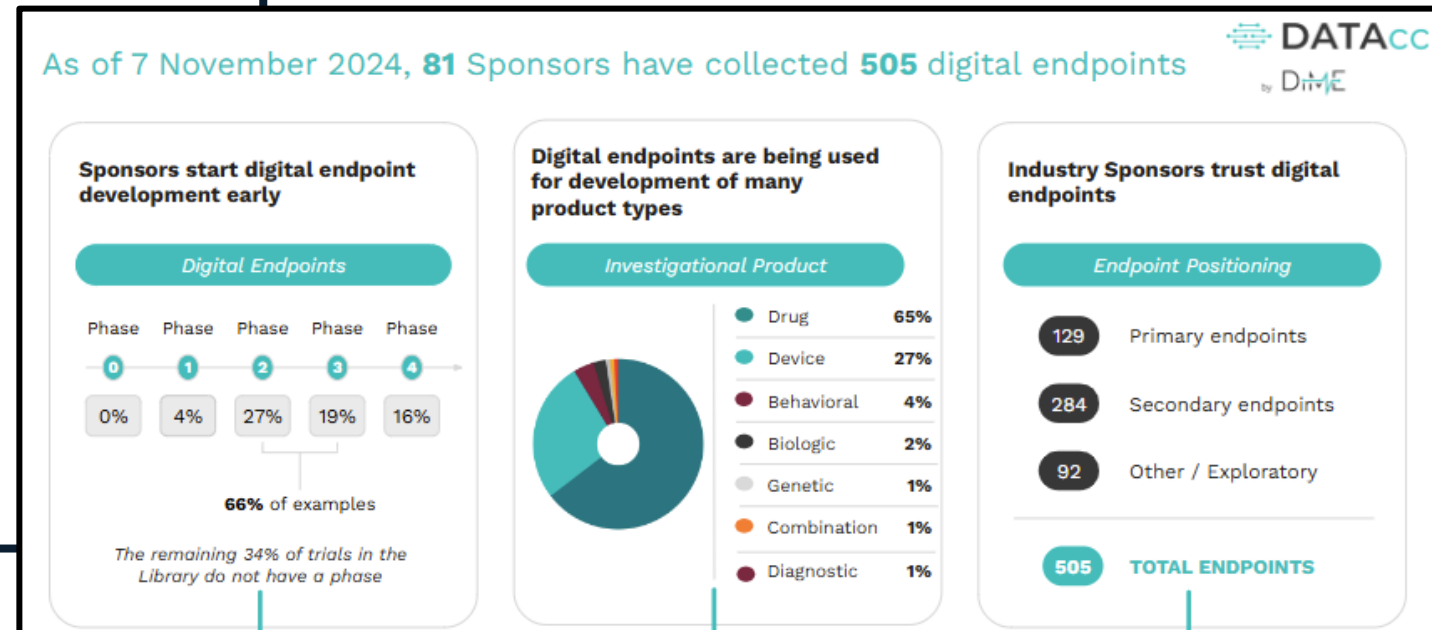
1 methodological
guidance

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