Library of Digital Endpoints: Overview of methods and endpoint eligibility

The Library of Digital Endpoints, hosted by the Digital Health Measurement Collaborative Community (DATAcc) by the Digital Medicine Society (DiMe), is an open-access resource that catalogs industry-sponsored clinical trials using sensor-derived endpoints. Continued innovation in digital measurement requires that clinical researchers can readily access the data necessary to track trends in the field and build on what's been done without recreating the wheel. Recognizing that, DATAcc is dedicated to updating this resource. Below, we have outlined the eligibility criteria and methodology for populating the Library of Digital Endpoints.

Methodology

Endpoints are identified for inclusion in the library from one of two sources:

- DATAcc completes a periodic search of clinicaltrials.gov;
- DATAcc reviews the eligibility of crowdsourced submissions.

Eligibility criteria

Endpoints are eligible for inclusion if they meet the following criteria:

1. The trial is listed on a reputable registry;
2. The trial is industry-funded;
3. The trial assesses a regulated intervention designed for screening, diagnosis, treatment, or disease prevention;
4. The trial includes one or more safety and/or efficacy/effectiveness endpoints captured by a sensor-based digital health technology product.

Endpoints are eligible if the trial:	Description
Is registered on a public clinical trials registry	The registry must be on the World Health Organization International Trials Registry Platform (WHO ICTRP) list of primary registries[1] or ClinicalTrials.Gov which is a data provider to the World Health Organization.[2]

[1] https://www.who.int/clinical-trials-registry-platform/network/primary-registries
[2] This entire definition has been adopted by the International Committee of Medical Journal Editors

Endpoints are eligible if the trial:	Description
Is funded by industry	Industry is defined as a for-profit entity, excluding government agencies, individuals, universities or other educational organizations, and registered non-profits.
Is interventional, with the intervention being a drug, biologic, genetic intervention, regulated diagnostic test, regulated medical device, regulated combination product, regulated behavioral intervention, regulated procedural/surgical intervention, or regulated radiation intervention	Interventional studies are defined as those in which participants are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect of the intervention(s) on biomedical or other health-related outcomes.[3] A complete list of intervention types is available at ClinicalTrials.Gov.[4]
Have a primary purpose listed as one of the following: treatment, prevention, diagnostic, or screening	A complete list of intervention types is available at ClinicalTrials.Gov.[5]
Include at least one safety or efficacy/effectiveness endpoint captured by a sensor-based digital health technology	Safety endpoints are those reflecting side effects of the intervention[6] Efficacy and effectiveness endpoints are those reflecting the performance of the intervention under controlled and real-world conditions, respectively. Sensor-based DHTs are defined as: Connected digital medicine products that process data captured by mobile sensors using algorithms to generate measures of behavioral and/or physiological function.[7]

Note: The endpoints captured by the sensor-based digital health technology must assess the trial intervention's safety or efficacy/effectiveness **and not the digital health technology itself.*

[3] 42 CFR 11.10(a) "Interventional"
[4] See Section 8: https://prsinfo.clinicaltrials.gov/definitions.html
[5] See Section 7: https://prsinfo.clinicaltrials.gov/definitions.html
[6] DiMe Glossary definition, referencing the FDA Clinical Trials for Patient Engagement Advisory Committee: https://www.fda.gov/media/108378/download
[7] Per the V3 Framework: https://pubmed.ncbi.nlm.nih.gov/32337371/