DIGITAL HEALTH TRIALS

Recommendations for Developing Novel Endpoints

CTTI has defined a pathway for developing novel endpoints from digital health technologies. Using these recommendations and resources, you can develop novel endpoints that more objectively and accurately represent the patient experience and, therefore, may be more meaningful to patients, providers, and others than traditional endpoints.

RECOMMENDATIONS

1. Use a systematic approach to identify key novel endpoints
2. Focus on measures that are meaningful to patients
3. Engage patients, investigative site personnel, and regulators early and often when planning; involve biostatisticians and data scientists, as appropriate, in decisions regarding protocol design, data collection, analysis, and interpretation
4. Include novel endpoints as exploratory endpoints in existing interventional clinical trials and observational cohort studies
5. Remember that adaptive design considerations that inform trials using mobile technologies are the same as for traditional studies

RESOURCES

- Flowchart: Steps For Novel Endpoint Development
- Flowchart: Steps for Novel Endpoint Development with Suggested Approaches & Considerations
- CTTI Novel Endpoints Interactive Selection Tool
- Quick Reference Guide to Processes for Interacting with the FDA Regarding Novel Endpoint Development
- Case Study for Developing Novel Endpoints Generated Using Digital Health Technology: Duchenne Muscular Dystrophy
- Case Study: Developing Novel Endpoints Generated Using Digital Health Technology: Diabetes Mellitus
- Case Study: Developing Novel Endpoints Generated Using Digital Health Technology: Parkinson's Disease
- Case Study: Developing Novel Endpoints Generated Using Digital Health Technology: Heart Failure

For more information on CTTI’s Digital Health Trials work, please visit http://www.ctti-clinicaltrials.org/our-work/digital-health-trials