

Digital Health Topics for StEM

Mobile Health Overview

Digital Health: "Use of mobile and wireless devices to improve health outcomes, healthcare services and health research."

- National Institute of Health

Clinical Trial Accelerators



- ▶ EMR Integration
- ▶ Patient Recruitment
- ▶ eConsent
- ▶ eEnrollment
- ▶ eSource
- ▶ Patient Retention
- ▶ Gamification

Telemedicine



- ▶ Virtual Face to Face Visits
- ▶ Secure Messaging
- ▶ Home Healthcare
- ▶ Point of Care Testing
- ▶ Door to Door Transportation

Wearable Devices



- ▶ Heart rate, HRV
- ▶ Respiration
- ▶ ECG
- ▶ EEG
- ▶ PPG
- ▶ Glucose
- ▶ Activity, Movement
- ▶ Sleep
- ▶ Sweat Analytes

Mobile Apps



- ▶ eCOAs (ePROs, obsROs, clinROs, etc)
- ▶ Visit Reminders
- ▶ Medication Compliance
- ▶ Patient Education
- ▶ Health Reporting

Mobile Health Experience (CRO & Pharmaceutical)

	Study Phase(s)	Services	TA/Indications
eConsent	Commercial	<ul style="list-style-type: none"> eConsent implemented on virtual study eConsent implemented alongside other technologies eConsent being used in mega-trial 	<ul style="list-style-type: none"> RWE – tobacco Diabetes Balance and ENT
ABPM & Holter	Phase I - Ph IIIb		<ul style="list-style-type: none"> Advanced Hematologic Disorders Advanced Hematologic Malignancies Asthma A-Fib COPD Diabetes Hypertension Kidney Disease Pancreatic Cancer
Home Nursing Services	Ph II-III	<ul style="list-style-type: none"> Vital signs, IMP administration Completion of scales AE and Con Med review Blood work Photography imaging Monitoring data 	<ul style="list-style-type: none"> Acromegaly Amyloidosis Epidermolysis Bullosa Heart Failure Hypertension Pancreatic Cancer T2DM/NAFLD
Wearable Devices / Connected Sensors	Phase III, Commercial Exploratory in a CT	<ul style="list-style-type: none"> Continuous Glucose Monitors Smart Diaper Smart Pill Cardiac sensor patch Gait & balance 	<ul style="list-style-type: none"> Diabetes GI Incontinence Osteoarthritis Arrhythmia Balance and ENT

Mobile Health Experience (cont.)

	Study Phase(s)	Services	TA/Indications
ePRO	Ph 1-Ph IV, Commercial	<ul style="list-style-type: none"> • Patient diaries • Blood glucose monitoring • Peak flow meter • Digital Pen • Site based ClinRO and ePRO • Diagnostic scales 	Adult & Pediatric Asthma, ADHD, Cardiovascular, COPD, Colorectal Cancer, Contraception, Depression, Diabetes, Electronic Cigarette Delivery Systems, Endometriosis, Fabry's Disease, Hemophilia, Hereditary angioedema, Hypogonadism, Kidney Disease, Musculoskeletal, Myelofibrosis, Neuropathy, NASH, Ophthalmology, Opioid-induced Constipation, Overactive Bladder, Pain, Parkinson's Disease, Pediatric Vaccine, Perennial Allergic Rhinitis, Prostate Cancer, Raynaud's Disease, RA, Adult & Pediatric Schizophrenia, SAR, Ulcerative Colitis, Urology

Discussion Points

- Guidance and legislation
 - Are there any new guidance/ legislation on the horizon? (eSignature, eConsent, BYOD etc.)
 - Will device and traditional pharmaceutical legislation become more aligned?
- Recent experiences with digital studies
 - How many digital/virtual studies have been inspected?
 - How did the inspection technique differ and what was the focus?
 - With regard to sponsor inspections could you provide:
 - Level of focus on digital technologies
 - Lessons learned & suggestions on handling digital technology
- Level of 'quality' in digital health
 - Can you describe any observations/trends regarding quality and digital health
 - What have been the barriers to inspecting the technical aspects?
 - What influence has ICH E6 R2 had on how you inspect/reference?