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.”

- 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)

<table>
<thead>
<tr>
<th>Study Phase(s)</th>
<th>Services</th>
<th>TA/Indications</th>
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| eConsent       | Commercial | eConsent implemented on virtual study  
|                |           | eConsent implemented alongside other technologies  
|                |           | eConsent being used in mega-trial |
|                |           | RWE – tobacco  
|                |           | Diabetes  
|                |           | Balance and ENT |
| ABPM & Holter  | Phase I - Ph IIIb | Vital signs,  
|                |           | IMP administration  
|                |           | Completion of scales AE and Con Med review  
|                |           | Blood work  
|                |           | Photography imaging  
|                |           | Monitoring data  
|                |           | Advanced Hematologic Disorders  
|                |           | Advanced Hematologic Malignancies  
|                |           | Asthma  
|                |           | A-Fib  
|                |           | COPD  
|                |           | Diabetes  
|                |           | Hypertension  
|                |           | Kidney Disease  
|                |           | Pancreatic Cancer |
| Home Nursing Services | Ph II-III | Continuous Glucose Monitors  
|                |           | Smart Diaper  
|                |           | Smart Pill  
|                |           | Cardiac sensor patch  
|                |           | Gait & balance  
|                |           | Acromegaly  
|                |           | Amyloidosis  
|                |           | Epidermolysis Bullosa  
|                |           | Heart Failure  
|                |           | Hypertension  
|                |           | Pancreatic Cancer  
|                |           | T2DM/NAFLD |
| Wearable Devices / Connected Sensors | Phase III, Commercial Exploratory in a CT | Diabetes  
|                |           | GI  
|                |           | Incontinence  
|                |           | Osteoarthritis  
|                |           | Arrhythmia  
<p>|                |           | Balance and ENT |</p>
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| ePRO Ph 1-Ph IV, Commercial | • 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?