Session I: Selecting Mobile Technologies for Data Capture in Clinical Trials

SUMMARY OF CTTI RECOMMENDATIONS ON TECHNOLOGY SELECTION

- Know what you want to measure before selecting the mobile technology.
- Mobile technology selection should be specification-driven and collaborative.
- A technology’s regulatory status should not be the sole driver in sponsors’ decisions about which mobile technology to use.
- The appropriateness of the selected mobile technology should be justified through verification and validation processes.
- Feasibility studies conducted before full implementation in a large study reduce risk.

CTTI RESOURCES TO SUPPORT TECHNOLOGY SELECTION

- Mobile technology selection framework
- Two case studies:
  1. Verification and Validation Processes in Practice
  2. Feasibility Testing to Promote Successful Inclusion of Mobile Technologies for Data Capture
- Glossary defining key terms, including verification and validation

TAKE ACTION: Visit https://www.ctti-clinicaltrials.org/projects/mobile-technologies to access CTTI’s Mobile Technologies recommendations and resources

TERMS USED IN THIS SESSION

Accuracy – The agreement between the measurement made by a single mobile technology and a known standard.

Calibration – The process of evaluating and adjusting the mobile technology to ensure the accuracy and precision of the raw data it generates.

Consistency – The agreement between multiple measurements made by a single mobile technology over a long period of time (tests performed over days, weeks, or months).

Consumer Products – Consumer grade mobile technologies are generally considered Class I devices and are not FDA-cleared. As consumer products, these mobile technologies tend to be appealing in style, functionality and price point to consumers. Many have a consumer-facing app paired with the mobile technology.

Firmware – Permanent software programmed into the mobile technology that serves as its operating system.

Medical Device – Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. Medical devices are regulated and subject to FDA’s laws and regulations.

Mobile Technologies – Mobile applications and other wearables, ingestibles, implantables, and portable technologies containing sensors for the capture of outcomes data.

Outcome Assessment – An assessment (interpretation or evaluation of the measurement) of an outcome (measurable characteristic that is influenced or affected by an individuals’ baseline state, or an intervention as in a clinical trial or other exposure) that results in recorded data point(s).

Precision – The agreement among multiple measurements made by a single mobile technology over a period of time that is short enough so that the quantity being measured can be assumed constant and the variability of the measurements is due solely to the variability in the measuring technology.

Uniformity – The agreement between measurements made by multiple mobile technologies, either simultaneously or over a short period of time (tests performed back-to-back).
Validation – The process of ensuring that the mobile technology is meeting its intended use by generating objective data that accurately represents the outcome assessment it purports to be measuring.

Verification – The assessment of accuracy (which may include routine calibration), precision, consistency across time, uniformity across mobile technologies, and possibly also across different environmental conditions. Verification also provides assurance that the relevant firmware/software that generates processed data is accurate, precise, consistent, and uniform.

A complete listing of all terms and definitions are listed in the glossary available at https://bit.ly/2uj5ZoW

SESSION SPEAKERS

Aaron Coleman
CEO and Founder, Fitabase
Mr. Coleman is Founder and CEO of Fitabase where he leads the company in its mission to help health and medical researchers discover new insights and treatments using wearable devices. Fitabase emerged from Mr. Coleman’s years of software experience at UC San Diego, where he saw the limitations of existing objective measure tools and began thinking through the potential for consumer wearables in research. In 2012, Mr. Coleman left academic software development, formed a partnership with Fitbit, and founded Fitabase. Today Fitabase is the industry-leading platform for researchers all around the world using Fitbits. Mr. Coleman and his company have enabled over 450 research studies and trials using Fitbit devices, many adopting innovative ways to monitor participants, give feedback, and improve patient care. Fitabase was represented on the CTTI MCT Mobile Technologies project team by Ernesto Ramirez.

John Hubbard, Ph.D., FCP
Strategic Advisory Board, Genstar Capital
Dr. Hubbard was the Chief Executive Officer and President of BioClinica, Inc. from January 5, 2015 to January 1, 2018. He is a leader in the Clinical Services and Biopharmaceutical R&D industries, with over three decades of experience including executive level positions at Pfizer, ICON, Parexel, and Hoechst Marion Roussel Pharmaceuticals. Prior to joining BioClinica, Dr. Hubbard served as Senior Vice President and Worldwide Head of Development Operations for Pfizer Inc. Dr. Hubbard sits on CTTI’s Executive Committee and is the Executive Committee Champion for the MCT Mobile Technologies project.

Barry Peterson, Ph.D
Independent Consultant
Dr. Peterson is currently an independent consultant on the use of wearable devices in clinical trials. He recently retired from Philips Respironics where he was Senior Manager for Clinical Affairs. Prior to his six years at Philips, he spent 11 years developing and validating technologies for Pfizer in their Clinical Technology group. This was proceeded by 20 years in academia as a Professor of Physiology at the Universities of Texas and Rochester where he developed technologies for investigating the pathogenesis of acute lung injury. Dr. Peterson is a member of the CTTI MCT Mobile Technologies project team.

Linda Ricci
Associate Director for Digital Health Programs, CDRH, FDA
Ms. Ricci began her career developing artificial intelligence solutions in the defense industry before moving to the medical device industry as a software engineer. She helped to develop several diagnostic cardiology devices and has participated in all phases of product life cycle development. Ms. Ricci moved to the FDA in 2005 and has had several roles including scientific reviewer and branch chief within the Division of Cardiovascular devices. Currently Ms. Ricci is the Associate Director for Digital Health within the Office of Device Evaluation. In this role, she leads the development and implementation of digital health policy within the Office of Device Evaluation.
Drew Schiller  
**CEO and Co-founder, Validic**

Mr. Schiller is CEO and co-founder at Validic and serves on the Board of Directors. He is a Board Member of the Consumer Technology Association (CTA) Health & Fitness Technology Division and contributes to moving the industry forward through his work with CTA Health & Fitness Standards. Mr. Schiller serves on the Leadership Council for the eHealth Initiative (eHI) and participates in the eHI Interoperability Workgroup. He is also an advisor for CTTI’s Mobile Devices Project to advance the use of mobile devices in clinical trials. Mr. Schiller previously served on the Federal Advisory Committee joint HITPC/HITSC API Task Force on Meaningful Use Stage 3. He is a member of the CTTI MCT Mobile Technologies project team.

Jeremy Wyatt, MBA  
**Chief Technology Officer and Senior VP of Product Development, ActiGraph**

Mr. Wyatt is the Chief Technology Officer and Senior VP of Product Development for ActiGraph, an industry-leading provider of wearable physical activity monitoring solutions for global clinical drug trials and academic research centers in over 85 countries. Mr. Wyatt’s 15 years of experience in working with low-power micro-electro-mechanical systems and related cloud technology have given him a unique perspective on the challenges and opportunities of deploying wearable technology to produce meaningful patient data. Mr. Wyatt was a member of the Recommendations Advisory Committee that provided feedback on drafts of the CTTI MCT Mobile Technologies recommendations and resources.

### A GUIDE TO USING MOBILE TECHNOLOGIES FOR DATA CAPTURE

- **Executive Summary**
- **Selecting Your Mobile Technology**
  - **Recommendations**
  - **Related Resources**
    - **Mobile Technology Selection Framework**
    - **Related Case Studies**
      - **Verification & Validation Processes in Practice**
      - **Feasibility Testing to Promote Successful Inclusion of Mobile Technologies for Data Capture**
- **Glossary: Definition Technical & Regulatory Terms**

### CTTI’S JULY 16 MOBILE TECHNOLOGIES EVENT

- Access the [recommendations and resources](#) (zip file)
- Download the [presentation](#)
- View related [July 16 event materials](#)