Session III: Data Management

SUMMARY OF CTTI RECOMMENDATIONS ON DATA MANAGEMENT

- Ensure the authenticity, integrity, and confidentiality of data over its entire lifecycle.
- Optimize data accessibility while preventing data access from unauthorized users.
- Ensure that access to data meets your needs prior to contracting an electronic service vendor.
- Apply an end-to-end, risk-based approach to data security.
- Monitor the quality of data captured by mobile technologies centrally through automated processes.
- Ensure that site investigators have access to data generated by their participants.

CTTI RESOURCES TO SUPPORT DATA MANAGEMENT

- Data flow diagram
- Strategies for promoting and protecting data integrity
- Case example – secondary data use
  - “Using Remote, Smartphone-Based Data Collection to Broadly Share Health Insights”
- Appendix of approaches to securing data generated by mobile technologies

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

TERMS USED IN THIS SESSION

**Application Programming Interface (API)** – The means by which one piece of software is able to communicate with a second piece of software, typically used for passing data between these two software components.

**Confidentiality** – A principle that ensures data from study participants will not be shared with people or organizations beyond those whom the subjects have agreed to in the process of providing consent.

**Data Authenticity** – A term describing a property of data saying that it is what the originator claims it to be, or what it is claimed to be by the data originator/processor.

**Data Integrity** – Data that is not modified or corrupted in an undetectable and/or unauthorized way during its generation and flow.

**End-to-End Data Security** – End-to-end security relies on protocols and mechanisms that are implemented on the endpoints of a data connection.

**Principle of Least Privilege** – The practice of limiting access rights for users to the bare minimum permissions they need to perform their work.

**Principle of Need to Know** – A principle that, when applied, grants access to covered data only when strictly necessary for specific processes associated with the clinical study.

**Risk-Based Approach** – With respect to data security, the process of identifying potential high risks and focusing security solutions toward these high-risk areas.

**Source Data** – All information in original records and certified copies of original records detailing clinical findings, observations, or other activities in a clinical investigation used for reconstructing and evaluating the investigation.

**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 measure.

**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](https://bit.ly/2uj5ZoW)*
SESSION SPEAKERS

Bill Bates  
SVP, Engineering, Validic  
Mr. Bates has been Senior Vice President of Engineering at Validic since October 2016, building the technology used to acquire health, wellness and biometric data from individuals outside of the four walls of the hospital. From Mr. Bates’ prior experience in other industries, he brings the know-how of securely moving and processing large volumes of data for the purpose of analytics and building scalable technology to aid in data-driven decision making. Mr. Bates provided expertise throughout the CTTI MCT Mobile Technologies project, participating as a key informant during evidence gathering and attending the expert meeting.

Andrea Coravos, MBA  
CEO and Co-founder, Elektra Labs  
Ms. Coravos is a software engineer and the CEO and Co-founder of Elektra Labs, which is building a pre-competitive digital biomarker consortium, and a Fellow at Boston Children's Computation Health Informatics Program. Ms. Coravos worked as a software engineer at Akili Interactive Labs, a leader in digital medicine and digital biomarkers while in graduate school. Before graduate school, she worked at KKR, a private equity firm, and at McKinsey & Company where she focused on the healthcare industry. Ms. Coravos was an expert advisor to the CTTI MCT Mobile Technologies project team.

Philip Coran, JD, CISA, CIPP/US  
Principal, Global Compliance & Strategy, Medidata Solutions  
Mr. Coran is Principal in Global Compliance & Strategy at Medidata Solutions Inc. He has had numerous interactions with regulatory authorities including the FDA and the EMA. Prior to joining Medidata, Mr. Coran was at Pfizer for 12 years in Medical Quality Assurance where he conducted dozens of GCP site audits (worldwide) and technology compliance audits. He is a Certified Information Systems Auditor (CISA) & Privacy Professional (CIPP/US), a Fordham School of Law JD, and University of Washington MBA. He is a member of the New York and California Bar and a frequent speaker on clinical trial related topics including GCP and emerging technologies. Mr. Coran is a Team Lead on the CTTI MCT Mobile Technologies project.

Cheryl Grandinetti, PharmD  
Health Science Policy Analyst, Office of Medical Policy, Center for Drug Evaluation and Research, FDA  
Dr. Grandinetti has been with the Center for Drug Evaluation and Research since 2009 and most recently on detail in the Office of Scientific Investigation (OSI), in the Good Clinical Practice Assessment Branch. Before OSI, Dr. Grandinetti worked in the Office of Medical Policy where she was the lead on a number of guidance documents related to integrating electronic technologies in clinical trials. Dr. Grandinetti is a team lead on the CTTI MCT Mobile Technologies project.

Ashish Narayan, MS, MBA  
Associate Dean of Research Technology, Icahn School of Medicine, Mount Sinai Health System  
Mr. Narayan is the Associate Dean of Research Technology at Icahn School of Medicine at Mount Sinai Health System in New York. He brings over 18 years of experience as an IT professional, as well as over 13 years of working within the research community. Prior to joining Mount Sinai, he was the founding Director of Research Informatics and Information Systems at Northwell Health and oversaw Clinical Research Informatics, Research Analytics, IT Security & Compliance, and Research Innovation. Mr. Narayan is a member of the CTTI MCT Mobile Technologies project team.
A GUIDE TO USING MOBILE TECHNOLOGIES FOR DATA CAPTURE

Managing Your Data

• **Recommendations**

• **Related Resources**
  - Data Flow Diagram
  - Strategies for Promoting & Protecting Data Integrity
  - Approaches to Securing Data Generated by Mobile Technologies

• **Related Case Study**
  - Using Remote, Smartphone-Based Data Collection to Broadly Share Health Insights

• **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