November 14, 2019: 5:00pm – 9:00pm  
Reception, Dinner and Keynote; University Club, Washington, DC  
Registration Opens: 4:00pm, Second Floor Meeting Room Foyer

5:00pm – 6:00pm  
Reception

6:00pm – 7:00pm  
Dinner

7:00pm – 9:00pm  
**Keynote: FDA’s Real-World Evidence Program**  
Speaker: Dr. John Concato, Deputy Director of Medical Policy Initiatives (OMPI), in the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA)

**Description:** In the context of real-world evidence, the session will address challenges in determining whether a) real-world data are fit for use, b) trial or study designs are adequate scientifically, and c) study conduct meets regulatory requirements.

November 15, 2019: 8:30am – 3:00pm  
Registration/Breakfast: 7:30am, University Club, Washington, DC

8:30am-8:45am  
**Welcome**  
Speaker: Daniel Ford, MD, MPH, Johns Hopkins University

8:45am – 9:45am  
**Clinical Researchers’ Perspective on Data**  
Moderator: Daniel Ford, MD, MPH, Johns Hopkins University  
Panelists: Stephen Davis, MD, University of Maryland; Naresh Punjabi, MD, PhD Johns Hopkins University; Andrew Williams, PhD, Tufts Medical Center

**Description:** We will discuss how clinical researchers view informatics support. What is the state of communication between clinical researchers and informatics specialists? How do clinical researchers view the current portfolio of informatics tools available to support their research? In what ways is the informatics community providing value to clinical researchers?

10:00am – 11:00am  
**Operationalizing Research IT Governance**  
Moderator: Jessica Chen, MD, University of Pennsylvania  
Panelists: Emma Meagher, MD, University of Pennsylvania; Kash Patel, Associate VP, Chief Digital Technology Corporate IS; Laura Fluharty, MPH, Senior Director, Clinical Research Operations, Office of Clinical Research
Description: A discussion on the importance of implementing an effective governance structure with operational and IT leadership in order to fully optimize the use of research IT applications and systems. This discussion will include perspectives from the leadership in clinical research as well as information technology on the importance of optimizing research technology for adoption and effective use, necessary to create a foundation for performing and sustaining research.

11:00am – 12:00pm **Clinical Data Sharing for Research (and Commercialization?!)**
Moderator: Curtis Cole, MD, Weill Cornell School of Medicine
Panelists: Rainu Kaushal, MD, Weill Cornell School of Medicine; David Vawdrey, MD, Geisinger

Description: This panel will explore the necessary uses of data sharing for clinical research, the need for new ethical frameworks and coherent policies across institutions to support such sharing, as well as the need for logical and consistent guidelines for the use of data across different purposes with varied risk. Issues of de-identification/re-identification, commercialization/licensing, product development and quality control, AI, and genomic data will be considered. Concrete policy recommendations will be proposed.

12:00pm – 1:00pm Lunch and Networking

1:00pm – 2:00pm **Synthetic Data in Research**
Moderator: Jeremy Harper, CRIO, Regenstrief Institute
Panelists: Albert Lai, PhD, Washington University School of Medicine in St. Louis; David Door, MD, MS, Oregon Health & Science University

Description: This panel will discuss the new approach of using synthetic data to generate realistic datasets that are statistically identical to the original. The panelists represent organizations who are releasing tools to use for the enterprise as well as how it has been used in an individual research project. We will discuss experiences and early wins in the space as well as challenges in implementation.

2:00pm – 3:00pm **Clinical Data Harmonization Efforts Across NCATS, NCI, FDA and CDC**
Christopher Chute, MD, Johns Hopkins University

Description: Several overlapping programs seek to align clinical data standards and interoperability, all aligning with the US Core Implementation Guide for HL7 FHIR at their core. Three will be featured: The NCATS/CTSA Center for Data to Health (CD2H), the NCI Cancer Commons Data Harmonization, and the HHS-wide Clinical Data Model Harmonization effort including NCATS, FDA, CDC, and CD2H.