Breakout Session 1 - 2:30-3:30

Terminology and Modeling

Discussion Leaders: Stan Huff and John Gennari **Room:** C123 A
Description: The goal is to discuss and share information about terminology and modeling as it relates to HL7 FHIR Resources. A key part of making FHIR truly interoperable is making the references to codes/terms in the models explicit, which treads the slippery slope between terminology models and information models. We intend to show a few slides to introduce some current topics, and then pursue the items that are of most interest to the group. Some topics that may be of interest include, models for HL7 FHIR resources, HL7 Clinical Information Modeling Initiative, SOLOR (SNOMED, LOINC, and RxNorm), The Clinical Information Interoperability Council – clinicians driving model content, International modeling efforts: openEHR, and FHIR resource profiles from the Argonauts.

Standards Development: How do we actually get the standards we need?

Discussion Leaders: Bob Freimuth and Ken Kawamoto **Room:** C123 B
Description: This break will out will help attendees gain an understanding of the standards development process, including the scope and workings of standard development organizations. Dr. Kawamoto will share experiences from the HITAC and Dr. Freimuth will share experiences HL7 Clinical Genomics and how it relates to GA4GH and xSDO. The facilitators will describe the role of this work to HSPC, CIMI, Argonaut, US Core FHIR profiles and other initiatives and how attendees can become active participants in the standards development process.

Patient Engagement

Discussion Leaders: Andrea Hartzler and Donna Berry **Room:** Lounge
Description: This break will out will bring together attendees to share interests and experiences with patient engagement and FHIR apps. Drs. Berry and Hartzler will share examples for their own engagement work with patient-facing technologies and examples of patient-facing FHIR apps others have built. Attendees will engage in group discussion to share their own experiences and exchange ideas on patient engagement and FHIR --How can FHIR help patients engage in health care? How can patients help guide the design and use of FHIR apps?

App Showcase

Leader: Tim Bergquist **Room:** Orin Auditorium
Description: Applications that have been developed locally by attendees will be showcased and discussed. Volunteers for the showcase include an EMR results review application, and the TrueNTH portal described in the morning "examples" session. If you have an app you can demo, or screenshots to share, bring them with you and show up!

"Stage" is available for an ad-hoc breakout session

Breakout Session 2 - 3:45-4:45

FDA Law

Discussion Leaders: Cindy Jacobs and Erik Van Eaton/David Stone **Room:** C123 A
Description: The FDA is the primary agency regulating "medical devices," which has an extremely broad definition. There are three device classes, assigned by increasing risk, and the FDA process is governed by statutes, regulations, and a veritable ocean of guidance documents. In recent years, the FDA has turned its attention to the general category of software and medical devices, which includes 1) internal, medical device-operating software; 2) software related to data collected/stored by a medical device; and 3) "just plain old software" that happens to analyze healthcare data. In this breakout session, we will briefly review the FDA's device regulation scheme, and then discuss the baseline question of when software becomes a medical device regulated by the FDA. We will cover the current status of regulation related to "mobile medical apps," and the effect of the 2016 21st Century Cures Act on the FDA's jurisdiction over the regulation of software, including the concept of "black box medicine." We will specifically look at four FDA guidance documents: 1) Software as a Medical Device Guidance (December 2017); 2) Clinical and Patient Decision Support Software Guidance (December 2017); 3) Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act Guidance (December 2017); and 4)Mobile Medical Applications Guidance (February 2015).

Enterprise FHIR

Discussion Leader: Kevin Swank **Room:** C123 B
Description: What does it take to "SMART-enable" the healthcare enterprise. From API Management Platforms to Identity and Master Data Management, there are many issues that enterprises must consider to truly support a SMART on FHIR future. Kevin Swank, UW Medicine Enterprise Integration Architect, will discuss what they are doing to prepare for the SMART-enabled healthcare enterprise of the future and how you can help. He will also discuss in-production examples of what Mayo Clinic and a for-profit pharmacogenomics startup are doing to bring technical innovation to their providers and patients.

Population Health and Aggregated Statistics with FHIR

Discussion Leader: Harold Solbrig **Room:** Orin Auditorium
Description: In this breakout, Harold Solbrig from Johns Hopkins University will lead a discussion around the work JHU has done developing FHIR resources for aggregated statistics. These tools and resources have implications in population health, study populations, and cohorts.

"Stage" and "Lounge" are available for ad-hoc breakout sessions