**CDER Health IT Board Meeting Minutes**

**Date/Time:** November 7, 2017, 11:00am – 12:30pm EST
**Dial-in Information:** 301-796-7777 Participant code: 665107
**Adobe Connect:** https://collaboration.fda.gov/cderhealthit2017/ (For Slides only)

| | CDER Health IT Members | Office | |
|---|---|---|---|
| | Mary Ann Slack | CDER OSP | Co-lead |
| X | Mitra Rocca | CDER OTS | Lead |
| | ShaAvhrée Buckman-Garner | CDER OTS | |
| | Shahrukh Haider | CDER OTS | |
| X | Arzu Selen | CDER OPQ/Office of Testing and Research | |
| | Adam Kroetsch | CDER OSP | |
| | Carlene Randolph | CDER OGD | |
| X | Carol Pamer | CDER OSE | |
| X | Christine Lee | CDER OCD/PASES | |
| X | Cheryl Grandinetti | CDER OMP | |
| | Esther Zhou | CDER OSE | |
| | Henry (Skip) Francis | CDER OTS | |
| X | Jason Woo | CDER OGD | |
| | Kaveeta Vasisht | CDER OMP | |
| | Leonard Sacks | CDER OMP | |
| | Lilliam Rosario | CDER OTS/OCS | |
| | Mary Beth Clarke | CDER OEP | |
| | Mary Ghods | CDER OCD/PASES | |

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| X | Md Rashedul Hasan | CDER OTS | |
| X | Ni Aye Khin | CDER OC OSI | |
| | Norman Stockbridge | CDER OND | |
| | Paul Buckman | CDER OCOMM | |
| X | Robert Ball | CDER OSE | |
| X | Sanjay Sahoo | CDER OSE | |
| | Sean Kassim | CDER OTS/OSIS | |
| | Sean Khozin | CDER OND | |
| | Jill Adleberg | CDER OEP | |
| | Vaishali Popat | CDER OND | |
| | Scott Gordon | CDER OSP | |
| | Fatima Frye | CDER OSP | |
| X | Mitra Ahadpour | CDER OTS | |
| **Invited Speakers** | | | |
| X | Rakesh Maniar | Novartis | |
| X | Hugh Dai | Eli Lilly | |
| X | Donald Jennings | Eli Lilly | |
| X | Tesheia Johnson | Yale School of Medicine | |
| X | Alan Hsiao | Yale School of Medicine | |
| X | Rajesh Modi | Novartis | |
| X | Linda King | Eli Lilly | |
| X | Michael Buckley | Memorial Sloan Kettering Cancer Center | |

| Invited Guests | | | |
|---|---|---|---|
| X | Alec Petkoff | Engility (CDER), Project Manager | |
| X | Sara Meiselman | Engility (CDER) | |
| X | Abhivyakti Sawarkar | CDER OTS (Observer) | |
| X | Ana Szarfman | OMPT/CDER/OND/ODEI/DCRP | |
| X | Catherine Li | OMPT/CDER/OTS/OCS | |
| X | Jack Nebel | EPIC | |
| X | Nancy Smider | EPIC | |
| X | Patricia McGovern | Novartis | |
| X | James Wurdeman | Forte Research Systems, Inc. | |
| X | Mari Clovis | Bristol | |
| X | Timothy Joy | Pfizer | |
| X | Vikas Adlakha | Novartis | |
| X | Jung Lee | OMPT/CDER/OGD/CSSS | |
| X | Aruna Vattikola | Novartis | |
| X | Appalla Venkataprab | | |
| X | Brett Wilson | Pfizer | |
| X | Sherry Claxton | GW University | |
| X | Kassa Ayalew | OMPT/CDER/OC/OSI/DCCE/GCPAB | |

**Opening:**

Mitra opened the meeting and introduced the speakers.

**Meeting Minutes**:

| ACTION ITEMS | |
|---|---|
| **I = Information, A = Action, R = Risk, IS = Issue, D =Decision** | |
| **I** | The eSource Consortium has created a proof of concept and demonstrated a use case over the past year. The use case is local lab data and has been very successful. |
| **A** | FDA can help the eSource Consortium by becoming an advisory or steering committee member, and by keeping consortium members in the loop regarding the new EHR guidance, provide feedback on direction and traceability, and share experience in the realm of indication. |

- The consortium is discussing the joint proposal to leverage Electronic Health Records (EHR) as an eSource. Over the past year, much work has been done towards this goal, and the consortium can now prove out some real-life studies.
- The consortium is a good opportunity to form a group of scientific and academic groups. Previously, the timescale was longer to transfer and exchange data. The consortium is beneficial to enable efficient data exchange between sponsors and CDMS (Clinical Data Management Systems). This project merges investigative science with standards such as CDISC (Clinical Data Interchange Standards Consortium). FDA has given positive feedback.
- The value proposition is the platform to bring key stakeholders to enable EHR data to have faster submission to regulatory bodies. The faster transfer also defines best practices in a scalable way. Point to point testing is also scalable. Consortium members can share experiences and get input from FDA.
- Faster data exchange from sites to sponsor will bring faster decision making, and will help with patient monitoring for safety reporting and give faster access to sponsors and research data. Standardization and alliance with EHR vendors to double up standard templates in EHR, which are based on CFAST (Coalition For Accelerating Standards and Therapies), will also enable those standards quickly. The consortium is also leveraging exchange mechanisms through established standards. Members share outcomes at conferences and at presentations at central regulatory agencies.
- The consortium mission statement is a partnership between pharmaceutical companies, academic medical centers, and regulatory bodies to agree upon standardization of the clinical research data set to enable faster adoption of direct data transfers by academic sites and sponsors. The goal is to leverage standards for faster exchange, and to streamline the existing transfer process.
- Novartis and Eli Lilly made the scope available to technology partners as well, which will help projects get traction in applying global standards. Bristol has a similar engagement as well, and the consortium is currently working with Apple and Google.

- The eSource Consortium working group members include: Novartis, Eli Lilly, Bristol-Myers Squibb, Pfizer, Merck, Society for Clinical Data Management (SCDM), HL7 International, Memorial Sloan Kettering Cancer Center, Yale Medical School, Partners in Health, George Washington University, Duke Health, Forte, and Epic. Potential members include Verily, Apple, Allscripts, Cerner, and CDISC.
- The charter and governance structure include a steering committee and general membership. Face to face meetings occur bimonthly.
- The Chairs and steering committee members are from both academia and sponsor groups, and membership is open to all academic medical centers and regulatory agencies. The chairs govern on a rotating basis.
- The consortium is very keen on having a first group deliverable met, and then will move on to working groups.
- The governance structure includes a centralized repository of agendas and documents.
- The first project is a local lab core data set package, which is a good place to start as there is a lot of data in local labs. Data transfer in the local lab space is common so standards are necessary.
    - Question: Is the data functional, with ability to be managed and visualized at the other end, or will this be static regulatory data?
      Answer: This is a possibility once data sets are in.
- Part of the value proposition is the members of the consortium. The rich representation of members who are also part of other boards allows the group to leverage other work being done in this space.
- The round table discussion at the HL7 conference in September gave forth to some great synergies using FHIR standards.
- The first working group project, local lab data, completed the use case and proof of concept with partners over the summer.
    - Background: There is a high volume of local lab data, and 20-30% is of early stage oncology. Normally, the data does not need to be manually prescribed. It is a slow process, with about 8% data entry error rate. The goal is the same domain with a different approach.
    - Proof of concept: the flat file is sent in standard format, and an application in the cloud decides how to use it. On the right-hand side, it can load into an Oracle database.
    - Seven oncology studies were selected over the summer of 2017. 2,500 lab results were collected with three objectives: Connect sites with sponsors; improve efficiency; reduce human error.
    - Chart displayed shows latency, delay and transcription error. Sometimes the number is arbitrary due to data being sent and updated in durations. Looking over the results of the use case, the error percentage went down a lot.

  - Besides for efficiency and accuracy of data, another benefit is reduced time necessary to deal with data per patient per study (from 8 hours/patient/study to 2 hours/patient/study).
  - Because oncology studies were chosen first, there is a significant volume of lab results. This is also a huge win from a safety perspective, and causes an improvement in patient privacy because only very specific data is transferred as needed.
- Eli Lilly presented results of the use case: Data flow is faster, and transcription error rate is down to 0. Preliminary analysis shows significant savings of effort and a very prudent process.
  - The partners are moving forward carefully to ensure patient privacy is guarded and that organizational impact is positive.
  - This is the first step to using EHR data in clinical research. Care must be taken to ensure users will be on board. The method will be "build a little, test a lot". Issues will be dealt with while they are still small, before scaling up the model. Every EHR installation is a bit different. HL7 and FHIR (Fast Healthcare Interoperability Resources) is a way to have a single interface that a site can implement for EHR systems. One system to speak between sponsors and get scalability to EHR integration.
  - Question: With so many formats, how does FHIR handle and integrate them? FHIR will not be able to transform 20,000 different formats into functional data, as that will not be helpful. Is there a need to force a standard?
    Answer: HL7 FHIR actually addresses the system interoperability issue of different EHR systems. FHIR is vendor agnostic, so as long as the vendor supports FHIR technology, the data will come out with FHIR standards.
    The end product needs to be functional laboratory numbers. Local labs are notorious for picking their own names, so some standards are necessary. Logical Observation Identifiers Names and Codes (LOINC) has many to many mappings. This is a complex problem to solve.
- FHIR is not the end; there will be much work after FHIR is implemented. In 2018, the consortium will discuss data transfer specification guidelines. Because the consortium is made up of varied groups, the different perspectives will be helpful.
- Coming up with a clinical specification will lead to a goal of a graph standard specification as well as outcomes.
- Question: Is the expectation that insurance should move from EHR to sponsors?
  Answer: Activity using the tool for regulatory purposes should have that information. The tool needs to capture that. Electronically submitted data has more audit trail capability than paper.
- With data capture use case, query was reduced by 50%. eMonitoring started at Novartis with one monitor, and now there are 213 monitoring with a variety of sponsors. Other partners are going into EMR remotely. Tools are made available with transparency to varied academic centers.
- Working with the FDA has caused a lot of interest amongst partners. The consortium would like the FDA to become an advisory or steering committee member.

  - Question: Can FDA inspectors also be part of the eMonitoring?
    Answer: Yes. NIH members think this will also help with sponsored trials.
  - Question: How is data quality being increased through the sites and labs?
    Answer: Lab data is an area with high volume and high error rate. When doing investigative studies, sometimes information can be transferred from EHR to EDC, but with sponsors, local capabilities are lost. This will begin to address quality issues. Also, it will leverage medication in standard core domains.
  - After a review of MSKCC, 50% of data on eCRF could construct data available on MSKCC.
- This will be a journey starting with circuit data. These are all Natural Language Processing (NLP) tools to fix through radiology reports, but validation needs to be done first. The tool can already identify patients missed with well documented diseases such as diabetes, but there are a lot of missed patients for rare diseases. There is a lot of potential in applying technology to unstructured data that will be beneficial to FDA and sponsors.
- Question: There is an issue of written and unwritten rules in code which unnecessarily complicates submission of data to FDA, which in turn delays review.
  Answer: Each academic center or study participant needs to do legwork to insure properly mapped to LOINC, RX NORMS, and SNOMED codes. Once that system works once, they can send data to the different pharmaceutical companies easily. Names that local lab chose historically can be relied upon.
  Comment: Central labs are not using local names and not using LOINC. Try to avoid unnecessary transformation that doesn't add value.
- Question: What does the consortium need from the FDA- validation of acceptance, sponsors submitting information and FDA accepting it, etc.?
  Answer: Senior leadership at the pharmaceutical companies would like this to move forward. Now, the team is ensuring business partners are on board with the goals. The FDA being a part of this will get partners' interest. At a finer level, the consortium would like for the FDA to keep the partners in the loop, and let partners know when the new EHR guidance is coming out. Additionally, the consortium requests FDA feedback regarding traceability and whether the goals are on the right track. Moving into indication, the consortium would like the FDA to share experience.
- Mitra provided an overview to the CDER Real World Evidence Workgroup.
- Real world data is important to the FDA. Significant numbers of information about guidance and validation weren't clear on audit trails and guidance from EHR.
- Question: Are there comments from other regulators such as UK's Medicines and Healthcare Products Regulatory Agency (MHRA) or Japan's Pharmaceutical and Medical Devices Agency (PMDA)?
  Answer: No comments have been received as this has not been publicized to European colleagues.
- The CDER Health IT board, formed in 2014, is comprised of directors and deputy directors from different offices within CDER.

- The CDER Health IT members develop strategic priorities for Health IT, focusing on pre-market, post-market, and health IT enablers.