

**Minutes of Society for Clinical Data Management (SCDM) eSource Implementation Consortium  
Face to Face Meeting**

Monday, October 14<sup>th</sup>, 7:30 AM – 12:00 PM, Hosted by Pfizer at Peapack, NJ

**Goals**

- Energize and continue to execute on leveraging our 2019 roadmap tracks using HL7 FHIR® for acquisition, exchange, and use of data for clinical research.
- 2020 roadmap planning



*From Left to right: Rakesh Maniar, Aruna Vattikola, Linda King, Susan Craft, Rhoda Arzoomanian, Mike Buckley, Shannon Roznoski, Amy Nordo, Prasann Mehta, Matthew Howard, Yi Zhang, Matt Koch, Hugh Dai, Abhijit Parab.*

**Agenda and Minutes**

**Welcome/Goal of the Meeting: Linda King, Astellas Inc., SCDM Chair and Board Liaison**

- Linda highlighted the existing Consortium members: Sponsors, Sites, Technology Vendors, and Standards Development Organizations.
  - CDISC and University of Manchester, UK are currently under discussion for joining us.
- Reviewed the Consortium vision and mission, and the new scope of SCDM.
  - SCDM has positioned itself to be a connector to other organizations through education, thought leadership, and advocacy. The Consortium fits well with SCDM's expanded scope, vision and mission.
- Highlighted the meeting goals:
  - Review landscape and align on Consortium's opportunity
  - Energize and continue to execute on leveraging our 2019 roadmap tracks using HL7 FHIR.
  - Plan our 2020 roadmap
- In line with SCDM's being a connector, Linda mentioned we might want to explore how we fit in with AMIA (American Medical Informatics Association) and Phuse (<https://www.phuse.eu/about>).

**Kick-Off: Demetris Zambas, Pfizer Inc., Global Head Data Monitoring and Management**

- Demetris welcomed everyone to Pfizer's Peapack Campus.

- Highlighted the importance of removing the data manager from the “swivel” of abstracting data from the EHR and entering that into the sponsor’s EDC.
- Noted the importance of how the Consortium is leading the way to help standardize nomenclature across systems in and out of clinical research.

**Introductions, Roles, Expectations: Mike Buckley, MSKCC, SCDM eSource Implementation Co- Chair**

- Mike noted that the Steering Committee members are the drivers and decision makers for our roadmap and deliverables. Thanked those members who have all appointed deputy decision makers and who can take a seat at the table to represent their site/company.
- Harmonizing across our other clinical research organizations.
- Encouraging everyone to be a recruitment champion for the Consortium and bring in new members.
- Highlighted deliverables for 2019, and 2020 succession planning for Chairs and the creation of two Vice Chair roles to further engage the Steering Committee members.
- For 2020: Rakesh to continue as Co-Chair, Linda to continue as SCDM Board Liaison, and Mike to continue as Co-Chair.

**Read out of HL7 9/15 eSource Thought Leader Meeting, Rakesh Maniar, Novartis, Inc., TransCelerate BioPharma, Inc. (TCB), eSource Initiative Co-Lead, SCDM eSource Implementation Co-Chair**

- Amy Nordo mentioned that the accelerator program, Vulcan, will have its first meeting Q1 2020.
- Vulcan will leverage shared community and collective resources to:
  - Bring FHIR resources to maturity to handle prioritized use cases
  - Communicate ROI/ROV
  - Provide recommendations to global regulators
- Attendee reflections
  - Meredith Zozus noted that Vulcan will be a key place to draft standards to implement and use standards before they are hardened.

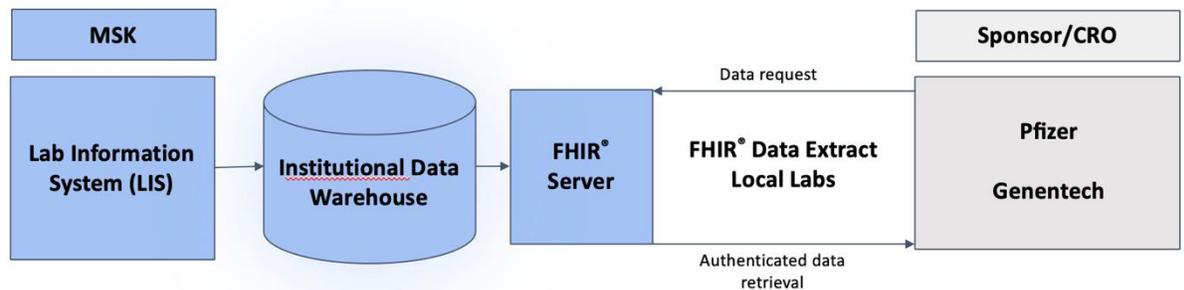
**Where Do We Fit? Review of Current and Planned Deliverables for TCB, Biomedical Research and Regulation Working Group (BR&R), Health Level Seven International (HL7), and SCDM**

- TCB Perspective: Rakesh Maniar
  - Rakesh gave an overview of the TCB eSource Workstream.
  - The group asked Rakesh to include site members of the Consortium to keep their awareness and allow for feedback for this workstream. Rakesh will follow up re: MOU for Consortium/academic sites.
- SCDM eSource Perspective: Mike Buckley
  - Mike gave an overview of the Consortium workstreams and also advocated for site representation/opportunity for input to TransCelerate workstreams.
- BR&R Perspective: Amy Nordo
  - Amy gave an overview of the HL7 BR&R work and mentioned the importance for creation of implementation guides to ensure resource maturity for clinical research and FHIR.

**10:00-11:00 2019 Three Tracks Review: Linda King, Astellas Inc., SCDM Chair**

- State 1A: eLabs White paper, Hugh Dai, Eli Lilly, Inc.
  - Hugh and Mike are finalizing first draft of the whitepaper.

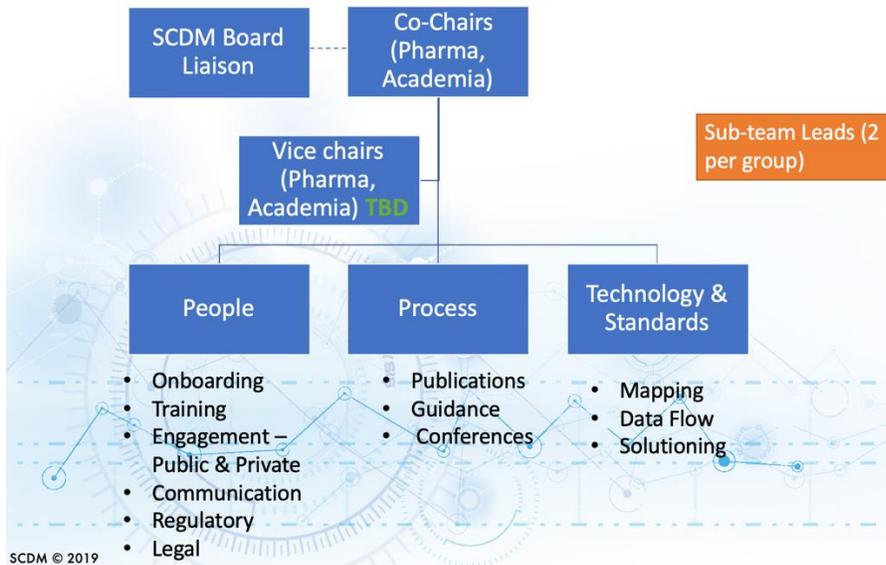
- Hugh will send manuscript draft to Aruna at Novartis for input of data/learnings and review (Japan sites), and then to Yale for their input/review. Will circulate to the other members of Steering Committee afterwards.
- Agreed to finalize by end of year.
- The group highlighted how the transfer of flat files is the manuscript's focus and will be useful as a site and industry best practices guide for other centers to reference and utilize the same transfer methods. The manuscript will allow them to see how other sites performed direct data extraction from source and shared that data securely with sponsors.
- The group agreed to highlight in the manuscript that we have pivoted to establishing a workflow for HL7-FHIR for creation of an interoperability standard. This removes the issues associated with flatfile transfers and chicken wire/duct tape point to point solutions. The HL7-FHIR interoperability standard will allow us to use the suitcase scenario to transfer data efficiently. The suitcase scenario (where HL7-FHIR is the suitcase that allows site/subject/protocol to harmonize with protocol/site/subject).
- Linda mentioned that we may want to consider publishing in Applied Clinical Trials, and Shannon mentioned that we could utilize the Forte blog to socialize the white paper when published.
- State 1B: Tech workstream: FHIR + MSKCC + Pfizer Amy Nordo, Pfizer, Inc., HL7 CIC Co-Chair
  - Matt Koch and Amy gave an update on where we stand with the MSK-Pfizer HL7-FHIR implementation. Matt highlighted the importance of the Consortium writing the implementation guide and increasing the maturity of the clinical research resources in HL7-FHIR.



- Amy mentioned the importance of tracking ROI and ROV for this workstream.
- Data domains beyond local labs, vitals, and demographics were discussed. There was consensus on furthering to response and concomitant medications, and the value of adverse events reporting.
- State 2: Future State Leveraging HL-7 BR&R Implementation Guide: All

**11:00-12:00 2020 Road Map, Wrap Up and Action Items, Rakesh Maniar, Novartis, Inc., TCB eSource Initiative Co-Lead, SCDM eSource Implementation Co-Chair**

- Rakesh introduced the Vice Chair structure (one from Pharma and one from Academia). The goal is to help distribute deliverables and create a solid annual succession plan.
- Creation of 3 workstreams: people, process, and technology.
- There was consensus among the group to have "Regulatory/Legal" be its own category given the high value audit items and nascent nature of eSource.



### **High Level Action Items**

1. Membership drive—action getting the word out and recruiting members. Utilize internal company blogs, promoting on social media, etc.
2. Have F2F meetings Quarterly throughout the year to better engage the team. Append them to existing society meetings/conferences.
3. Mike to reach out to EHR vendors for participation in the Consortium; Epic, Cerner, Allscripts.
4. More site participation with TransCelerate initiatives (SIP was offered as an example for how not to roll out in initiatives in future). Rakesh to action. The group asked Rakesh to include site members of the Consortium to keep their awareness and allow for feedback for this workstream. Rakesh will follow up re: MOU for Consortium/academic sites.
5. Rakesh to confirm participation of University of Manchester, UK and CDISC.