SCDM - Innovations/eSource Implementation Consortium Task Force Check-in

6/3/2022
10AM EDT

Type of meeting: Operations

Scribe: Mehdi Stambouli

Facilitator: Mehdi

Attendees:

1. Linda King – SCDM
2. Kenneth Milstead - Yale
3. Hugh Dai – Lilly
4. Meredith Zozus - Uthscsa
5. Michael Rauwerdink – Advarra
6. Aruna Vattikola – Novartis
7. Mehdi Stambouli- SCDM
8. Liat Modiano – Yale

Anti-trust statement:

ANTITRUST COMPLIANCE POLICY- for complete policy see SCDM website under policies and procedures or Appendix 1 to these meeting minutes.

The Society for Clinical Data Management ("SCDM") has adopted a policy of strict compliance with applicable antitrust laws. Certain topics that may be considered anticompetitive are not proper subjects for discussion or consideration at any SCDM meeting of members, officers, trustees, committees or taskforces, whether formal or informal. While it is entirely appropriate to meet as an association to discuss common problems and areas of interest, an agreement taken to eliminate, restrict, or limit competition, such as price-fixing, boycotts, or allocation of markets, can be a *per se* violation of antitrust laws and lead to severe civil or criminal penalties.

Minutes

Discussion:

Playbook Project Updates and Additional ideas on alternatives to augment/jump start the Playbook

- **Ken** introduced a rough draft of Table of contents for the playbook. (see below)
- **Ken** has volunteered to write first 3 topics- History, Definition and Journey of eSource. He will base these on TransCelerate white papers to start and then add updates from the last 4 years.
- **Ken & Liat** are in the process of writing about the Yale experience.
- **Denise** volunteered to write a chapter on Duke's experience with Yale and Advarra.
- Would like a chapter from MSKCC's experience- **Ken** reaching out to Mike Buckley.

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- **ALL--**We are looking for volunteers to help write other chapters on their experience w/ eSource implementation. Please reach out to Ken if you have any questions or have some experience to share.
- **Ken-** Will also reach out to others on the Consortium to gage their interest (Castor (Derek), UCSF etc.)
- **Meredith** shared some ideas and group brainstormed on 4 additional chapters for Playbook
    - 1) Meredith recommended reaching out Dr. Eric Eisenstein (Duke Clinical Research Institute DCRI) regarding his survey where preliminary data was presented recently at AMIA. The survey which was a written one with semi-structured interviews of the PI, Study Coordinator and Informatists at sites wasabout their readiness of implementing EHR to EDC. He may be interested to publish in JSCDM and we can to include in the Playbook.
    - 2) Another Chapter Topic idea – Methods for FHIR Mapping (a How-To for study mapping) –Maryam Garza (University of Arkansas)/Jan Wong have published results from a study mapping and can provide some content.
    - 3) Wake Forest Professor (Ask Meredith) has done work in 2010-2015 on automated AE detection while at Univ of Arkansas
    - 4) Meredith's team could write a site focused chapter on options for connecting FHIR servers to EDC etc. including what information is needed for hospital IRBs/ Institutional IT Data Governance to approve an external connection to their EHRs such as an App in the Epic App orchard. (This is Human in the Loop process.)
        - For use of abstraction tools, need to run past FDA (Mitra Rocca). There is a policy published by (Follow up with Meredith) that requires first 3 cases of proving re-abstraction works and mapping is correct.
        - Yale also has example to add about using EHR feed for medications which has manually entered assessment dates (Human in the loop)
    - Aruna reported that Novartis is starting a POC project for MSKCC and she will be able to provide content for writing groups. It would include site Data Governance, vendors, sponsor perspectives. May be a good basis for a TOOLKIT- list problems and solutions.
    - Discussed the possibility of having a living textbook that is live on the web and can publish one chapter at time. Can also update chapters as it's a live textbook- similar to GCDMP approach with each chapter published separately but difference is governance on content.
- Another idea to get content quicker was to interview subject matter experts in their respective field to discuss different topics- 30 min to 1 hour. Start with 4 to 5 people. Can publish in JSCDM as interview and follow-up with written document in future (like chapter for Playbook and/or article for JSCDM). May be able to use an SCDM writer from Innovation Committee. **Mehdi** to ask Triphine- also Mehdi to ask if SCDM is doing Podcasts.

- Meredith suggested she could begin working on the interview questions in June and have it reviewed by the group offline to get detailed question set to be discussed at next meeting Friday July 1st and then finalized in July for interviews to start in July/Aug. Post recorded interviews on SCDM website and write up for JSCDM and Playbook.
- **ALL-** Team should be thinking about who to interview either from Consortium or from external. One suggestion was MSKCC work to date with Novartis and Genetech/Roche.

Playbook Table of Content

History, Definition and Journey of eSource	**Yale - Ken**
Architectural Option	
Outcomes	
Implementations- and write an intro, discussion – include best practices and lessons learned, conclusion	
Advarra Chapter/how large sites can work with multiple sponsors efficiently	**Duke/Yale -**
Yale experience with REDCap	**Yale**
MSKCC/Pfizer Experience	
Pfizer/US, Pfizer/ex-US (focus on Japan, China and Europe)	
OneSource	**FDA**
Standards Development	
Lessons learned with our FHIR	**Advarra**
RWE Project	**Vulcan**

eSource Webinar Change to Awareness Slide deck with Voiceover

- Linda and Shannon to work on. Linda has started working on the draft PowerPoint for voiceover awareness slide deck on Consortium--what it is, what we are working on and how to join that will be posted on the SCDM website and promoted via LinkedIn (This is instead of the webinar for June).

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Project Vulcan: Updates on TransCelerate Local Labs Move to Vulcan and Volunteer for Project Vulcan Operations team

- Linda reported that she followed up with Rakesh post last meeting regarding the proposal to move TransCelerate/SCDM Local lab project to Vulcan. It is still in the process with TransCelerate evaluating the proposal.
- Rakesh to follow up on status of Local lab project transition on the next call. July 1st.
- **Interest in being SCDM lead on Vulcan Operations Team?** You would represent SCDM for voting and input to Vulcan Ops meetings
    - **Reach out to Ken if interested.**
    - Also looking for additional volunteers to participate on the Vulcan operations team and projects.
    - **Reach out to Ken if interested** in participating in projects. Note: Mike R. does attend the Ops meetings and can help bring back info to the team. Ken is currently representing SCDM as lead.

RWD Multi-Trial Project Update:

- Meredith shared that they have a final protocol for the RWD project and it's with the IRB. However in talking w/ Sponsors for this project, she discovered that some still would like evidence that SDV is not value add.
- Meredith and her colleague Dr. Mala will lead the evaluation and possible project on SDV.
- Dr. Mala's team started working on a systematic literature review on the quality add for doing SDV and hope to get the literature review complete in the next few weeks. If this doesn't uncover the evidence needed, then they will create a study to prove SDV is not a value add.
- **Meredith and Dr. Mala** will be looking for members to volunteer to conduct this study (i.e., Man vs Machine) Discussed conducting this project during the Fall SCDM Conference timeframe at her location. **For more information, contact Meredith.**
- **Meredith** also mentioned **if the study moves forward** to reach out to the CDER Health IT Board (Mitra Rocca) to share their intent and get feedback before starting. **Aruna** asked that Meredith work with her and Consortium ahead of that meeting to get questions together for FDA feedback (like a 'speed dating' meeting).

POST MEETING NOTE: Mike Buckley has a session at the SCDM Fall conference *Using HL7 FHIR to Automate Clinical Trial Data Transfers.* He is planning on having Genentech-Roche, FDA, and UCSF give presentations. **Could open up a spot for Meredith's project- more to follow.**

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POST MEETING NOTE: Survey Monkey for changing time- most liked the current time. 2nd best was moving to afternoon on Friday. Will keep as is.

Topic for Next Call on July 1st – Will eSource replace EDC?

July – **Will eSource replace EDC? –** Camila Matheny (out on the first week of June)
August – **RWD Project** – Meredith

September- TBD

Action items	Person responsible	Deadline
Finalize approach for Playbook (ie. Publish as we go in JSCDM)- also secure interest in writing chapters including 4 new chapter ideas from Meredith	**Ken, ALL (volunteer)**	**1 July**
Create interview questions; Follow up with Volunteers to do the interviews and volunteer SMEs for Interviews	**Ken, Meredith (start interview questions- Team completes)**	**1 July- first Draft questions, assignments for interviews**
Find SCDM tech writer and ask if SDCM doing Podcasts	**Mehdi**	**1 July**
Update on TcB/SCDM Local lab proposal to move to Vulcan	**Rakesh, Aruna**	**1 July**
Create PowerPoint Intro for eSource Voiceover	**Linda, Shannon**	**1 July**
Talk to SCDM on how to load Voiceover on website and also put on LinkedIn	**Mehdi**	**1 July**
Update on Man vs Machine study; lit search and if moving forward with study	**Meredith**	**1July**

Other Information

Observers:

None.

Resources:

Special notes:

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Appendix 1:

ANTITRUST COMPLIANCE POLICY

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It is essential, therefore, that all necessary steps be taken by SCDM trustees, officers, staff and members ("Participants") to prevent any SCDM meeting or activity from becoming a forum for the type of discussions which might lead to an understanding or agreement, expressed or implied, with respect to any essential element of competition. The following guidelines must be observed in connection with all SCDM meetings and activities:

1) Participants will adhere to competition rules, as applicable, prohibiting any discussion, understanding or agreement, however informal, or the exchange of information on:

    a) individual company prices, price changes, pricing strategies, terms of sales, price mark-ups, discounts, allowances, credit terms;
    b) costs of production or distribution, cost accounting formulae, methods of computing costs;
    c) individual company figures on or plans as to sources of supply, production, inventories, sales, marketing and promotion;
    d) any matters relating to individual suppliers or customers, including any attempted collective action that might have the effect of excluding suppliers or customers from the market;
    e) information as to future plans of individual companies concerning technology and investments;
    f) Confidential research and development projects, budgets, spend, or priorities, including early stage development targets, prioritization of targets or projects, R&D spend or forecasted spend on particular development projects or targets, and plans for future R&D projects;
    g) Avoiding or limiting research or development work or spend in certain areas or regarding certain targets, or limiting work or spend on R&D generally;
    h) A company's business strategies for identifying potential R&D targets and evaluating continued financial investment in the target throughout the R&D process;
    i) Refusals to do business with particular investigators, suppliers, vendors, licensors, customers, or competitors, or the suggestion that such a refusal or boycott might be appropriate or desirable;
    j) The amount that a specific company pays for goods or services;
    k) Future, current, or recent (i.e. within the last 90 days) prices, price changes, price quotations, pricing policies or philosophies, price differentials, markups, discounts, allowances, including any significant element of price, such as freight, credit, warranties, terms and conditions of sale;
    l) Future, current, or recent (i.e. within the last 90 days) output, capacity, inventory levels or costs (including production, down-time, inventory, distribution, or wage, salary or benefits cost);

m) The customers to whom a specific company does or does not sell, the territories in which a specific company does or does not sell, or the product categories which a specific company does or does not sell;
n) Plans concerning the future production, distribution, or marketing of particular products, or any other statistics or data pertaining to a particular company's business operations.

2) No member shall be compelled or coerced by SCDM or any other members into accepting or complying with any industry standard, guideline, procedure, or recommendation developed by SCDM or any of its committees or taskforces. No member is obligated to agree to accept or comply with any industry standard, guideline, procedure, or recommendation developed by SCDM or any of its committees or taskforces.

3) Any standard, guideline, procedure, or recommendation developed by SCDM, its committees and taskforces shall be solely and exclusively upon technical consideations and upon the merits of objective judgements and thorough procedures and shall in no way be based upon any effort, intention, or purpose of any of its members to reduce or eliminate competition in the sale, supply and finishing of products and services.

4) If information, materials, or reports of SCDM designed for the use of its members are significant to third parties or any others in the industry, then such information, materials, or reports will be made available by SCDM to all such persons, on such reasonable terms and conditions as it may prescribe, in order to carry out its purposes.

5) To the extent that the purpose of any SCDM committee or taskforce requires collaboration by two or more members or representatives of members in furthering those purposes, the members or representatives of members shall undertake such collaboration only to the extent necessary to achieve such purposes, and shall report the results of any such collaboration to the committee or taskforce chairs. Any such collaboration shall exclude:

    a) The exchange of information between or among members relating to any aspect of competition among the members, except to the extent that the exchange is reasonably required to accomplish the purposes of the committee or taskforce and is unlikely to have any impact on competition between or among members. In case of doubt, the collaborating members should consult legal counsel with regard to the proposed exchange or the format in which the exchange should take place.

    b) Any agreement or conduct restricting efforts to discover, develop, or produce any product by any member, limiting the manner in which any member markets or promotes any product, requiring the purchase or sale of any product by any member, limiting or discouraging members from engaging in any specific research and development project or reducing R&D generally; or limiting the sharing of intellectual property by, between, or among members. The collaborating members should consult legal counsel with respect to any limitation SCDM may desire to lawfully impose with respect to the result of the collaboration.

6) For all committee and taskforce meetings organized and attended there must be

    a) a written agenda circulated in advance of the meeting;

    b) written minutes, submitted for approval to chairs and posted for participants;

7) Working groups and participation criteria for meetings must be transparent and non-discriminatory.

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Committees and taskforces of SCDM may adopt additional guidelines or other policies as a means of mitigating any risk that could result from any meeting or activity of a committee or taskforce or be perceived as resulting in any reduction in competition between any members, whether intentionally or otherwise.

All SCDM meetings must be conducted in accordance with this Policy. Any questions should be addressed to legal counsel.

Adopted August 2018