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

3/5/2021
10AM EDT

Meeting called by: Mike Buckley
Type of meeting: Operations
Facilitator: Rakesh/Linda
Scribe: Mehdi Stambouli

Attendees:
1. Linda King- SCDM
2. Meredith Zozus-UT-SA
3. Rebecca Kush- Learning Health
4. Kenneth Milstead-
5. Ed Rausch- Lilly
6. Kim O’Day – Lilly
7. Joe Dustin- BMS
8. Mehdi Stambouli- SCDM
9. Hugh Dai- Lilly
10. Muzafar Mirza- Pfizer
11. Shannon Roznoski- Advarra
12. Sue Dubman- UCSF
13. Cory Ennis- Duke
14. Mike Rauerdink- Advarra

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:

1. Discussed Projects/Job descriptions. TransCelerate/SCDM FHIR Local Lab/Project Vulcan
   - TransCelerate: First activity is to write the ‘how’ or protocol that the data should be exchanged (includes KRIs). Next step is to run the protocols with 3-5 pairs of sponsors/sites to prove out the IG to generate data so we do ROI.
   - Implementing FHIR integration project – Hugh expressed interest in co-leading the project, representing SCDM. Focus should be on 2 gates- site side and Pharma side. Also, possible additional help from Ken with FHIR implementation. More people volunteered for this topic to work on deliverables/scope/key gaps for this project (see names provided to Maddie at TransCelerate below). There is room for a possible Co-Lead for this project with
TransCelerate (Value Lead from Roche, Co-Execution Lead at TransCelerate?). Meredith mentioned that an external source Maryam Garza that would be willing to help with experimental design and FHIR to SDTM mapping.

- Sue (UCSF) is interested in participating in any of the projects above/Linda to follow up offline.
- Post meeting update: Provided these names to Maddie at TransCelerate March 29 for KOM in April:
  - Hugh Dai dai_hugh@lilly.com
  - Milstead, Kenneth kenneth.milstead@yale.edu
  - Sebastiaan Knijnenburg <sebastiaan@castoredc.com>
  - Verma, Nagree Singh Nagree.Verma@pfizer.com

2. Updates on Project Vulcan
- Shannon L. began her onboarding and attended her first meeting and she saw room for opportunities and interesting projects.
- Mike R. from Advarra reported on AE ramp up, SOA/ODM mapping discussions with HL7 BR&R team
- If you’re interested in Project Vulcan, reach out to Shannon R to get situated with the onboarding.

3. Multi-Trial EHR-to-eCRF Technology Project
- Looking for Pharma’s to complete two trials, three sites per trial- retrospective is okay. This will provide enough data for pooled analysis on discrepancies. No trial data will leave the sponsor. Meredith’s team does metadata analysis- looking for error rate as KEY outcome.
- Determining site budget- estimated approx. $26K to sites to facilitate extraction of data

Conclusions: We need to fill these projects with leads/volunteers and create a team structure to begin working on SCDM Projects.

<table>
<thead>
<tr>
<th>Action items</th>
<th>Person responsible</th>
<th>Deadline</th>
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<tbody>
<tr>
<td>Write up Data Flow protocol</td>
<td>TransCelerate, SCDM team</td>
<td>May 2021</td>
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<tr>
<td>Followup w/ Sue offline</td>
<td>Linda</td>
<td>4/2</td>
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<tr>
<td>Linda/Joe/Stacy/Maddie Schedule meeting to kick off writing of with Data Flow protocol</td>
<td>Linda/Joe/Stacy/Maddie</td>
<td>4/2</td>
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<tr>
<td>Send out Proposal/Schedule meeting with steering committee members</td>
<td>Meredith</td>
<td>4/2</td>
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</tbody>
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**Other Information**

Observers:
None.

Resources:

Special notes:
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:
Plans concerning the future production, distribution, or marketing of particular products, or any other
information, materials, or reports will be made available by SCDM to all
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.

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