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 Rauwerdink- 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.**

Action items	Person responsible	Deadline
Write up Data Flow protocol	TransCelerate, SCDM team	May 2021
Followup w/ Sue offline	Linda	4/2
Linda/Joe/Stacy/Maddie Schedule meeting to kick off writing of with Data Flow protocol	Linda/Joe/Stacy/Maddie	4/2
Send out Proposal/Schedule meeting with steering committee members	Meredith	4/2

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:

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.

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