

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

2/5/2021

10AM EDT

Meeting called by: Mike Buckley

Type of meeting: Operations

Facilitator: Mike, Rakesh and Linda
Apologies: Mike B.

Scribe: Mehdi Stambouli

Attendees:

1. Linda King- SCDM
2. Rakesh Maniar- Merck
3. Meredith Zozus-UT-SA
4. Mehdi Stambouli- SCDM
5. Hugh Dai- Lilly
6. Muzafar Mirza- Pfizer
7. Shannon Roznoski- Advarra
8. Sue Dubman- UCSF
9. Aruna Vattikola- Novartis
10. Cory Ennis- Duke
11. Amy Cramer (Nordo)- Pfizer

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 SCDM Annual Conference in September 2021.
 - Topics for separate standalone eSource session: Real World Data Quality (Meredith's CDER presentation this week), Project Vulcan (Amy), TransCelerate (Rakesh), Upscaling Skillset in partnership w/ Education group (Meredith), and potentially additional use cases in Project Vulcan (Anita Walden, Mitra R. and Scott Gordan)
 - Topic for Innovation Committee session- provide updates on eSource Consortium projects (Ken and Amy)
 - Potential opportunity to work w/ PhUSE on the SoA topic but would need to connect with them prior to conference- Is there an MOU w/ PhUSE for SCDM? Ask Triphine.
2. Recap of the 3 SCDM Projects and identifying volunteers that could lead SCDM projects. Will need to establish leads/Co Leads.

- **TranCelerate FHIR Local Lab Project –Hugh is interested in being a lead to coordinate with PMs at TransCelerate as soon as possible- Hugh to verify.** They have tentative timelines and actions needed for defining the protocol to conducting the FHIR Local Lab exercise. First activity is to write the ‘how’ or protocol that the data should be exchanged (includes KRIs). Next is to identify 3-5 Sponsor/Sites to execute the protocol and report back. Helping the 3-5 Sponsor/Sites as needed along the way. Final activity is to report out all the data from the exercises and combine it for publishing.
- **Project Vulcan- Post Meeting update: Shannon** sent email out to team asking for names of folks interested in Vulcan so we can share w/ Maddie for Vulcan onboarding. **Rakesh is identifying someone from Merck. Others interest?**
- **Multi Trial Evaluations of EHR-to-eCRF Technology-** Meredith has a possible fund to use to offset the ~\$40K per Sponsor to participate. (Meredith sent budget estimates to team Feb 5, 2021). Could also be less if did exercise retrospectively (need FDA okay). This project’s objective is to show that RWD can be used for regulatory decision making for efficacy (not just safety). Note: EU is also planning some field work in this space this year so opportunities to compare.
- **Sue (UCSF) is interested in participating in any of the projects above-** she will look for which Sponsors are already doing research w/ UCSF from our Steering Committee (Novartis, Merck, Lilly, Pfizer and BMS) to see if there are any opportunities to apply to one or more of the above projects.

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
✓ Submitting topics/proposals to SCDM	Shannon R.	2/8/2021- Done
✓ Email to everyone who voted for Project Vulcan and TransCelerate/SCDM FHIR Local Lab project to get a name to participate or volunteer as Lead .	Shannon All Sue	2/8/2021 2/19/2021 2/19/2021
✓ Team to respond to Shannon’s email	Meredith	3/5/2021
✓ Sue to get back to Shannon on names from UCSF if interested	Meredith	3/5/2021
✓ Team to respond to Meredith if interested in Multi study project	Mehdi	2/19/2021
✓ Provide FDA CDER Health IT Board RWD Summary on Next Call		
✓ MOU w/ PhUSE? Ask Triphine		

Action items

Person responsible

Deadline

Other Information

Observers:

None.

Resources:

Special notes:

Appendix 1:

ANTITRUST COMPLIANCE POLICY

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.

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;
 - 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 considerations 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