

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

2/4/2022
10AM EDT

Type of meeting: Operations

Scribe: Mehdi Stambouli

Facilitator: Mehdi

Attendees:

1. Denise Snyder – Duke
2. Amy Cramer – Pfizer
3. Cory Ennis - Duke
4. Shannon Roznoski – Advarra
5. Kenneth Milstead – Yale
6. Meredith Zozus - UT
7. Linda King - SCDM
8. Michael Rauwerdink - Novartis
9. Mehdi Stambouli- SCDM
10. Hugh Dai – Lilly
11. Camila Matheny - medable

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 Proposal:

- Ken & Amy proposing a playbook that is less technical and focuses on the success & challenges of eSource.
- TOC Brainstorming – Using 4 TransCelerate buckets
 - Non-CRF (Central Labs, Etc.)
 - DDC
 - EHR
 - Apps (Split)

- Devices (split)
- Please look at the table below and see the current table of content for these projects. If you want to submit a proposal on a topic that is not listed below, please email [Mehdi Stambouli](#) or submit it on the [eSource Community page](#) by **February 15th**
- Broadening the scope – Ask experts at your company to participate
- Reach out to your organization if you think someone would be interested in working on any of the topics below.

Non-CRF- Central Labs	DDC	EHR	Apps-eCOA, ePRO	Device	Wearables
<ul style="list-style-type: none">• Pfizer• Merck• Yale	<ul style="list-style-type: none">• Novartis• Pfizer• Merck• Advarra (and friends)	<ul style="list-style-type: none">• Yale• UTHSA• Pfizer	<ul style="list-style-type: none">• Hard Coded• Apps		

Chapter Recommendations:
Advarra, Yale, Duke, potentially [FlatIron](#) Chapter on Site integrating with more than one product

- **eSource GCDMP Chapter** – JSMD is looking to add a chapter and have it posted on the journal. We are aiming to get this started in 3 months and need volunteers.
 - GCDMP is looking for volunteers from this group to be added to a chapter writing group to that will work on a chapter that will get published in the JSMD journal. If you are **interested** in being a part of the GDCMP eSource chapter, please reach out to [Mehdi Stambouli](#).
 - There are a few chapters currently in progress along with ePRO/eCoa and JSMD would love to have a chapter for this group to get published.
 - These are not mutually exclusive

Updates on TransCelerate/SCDM FHIR Local Lab Project:

- Rakesh report that they finished the last part of the proposal and have submitted to TransCelerate for review.
- Will have leadership for the consortium partner with TransCelerate team with the proposal that was put together.

Updates on RWD Multi-Trial Project:

- Meredith reported that she had an FDA meeting to review the research protocol before the holidays. Close to final protocol.
- Will be presenting Vulcan Operations on February 2nd
- First FHIR application went onto the Epic App orchard last month; it is for FHIR mapping. We are using it internally while undertaking the review process to make it freely available through Epic to other institutions.
- The 2nd FHIR application is not too far behind. Meredith will have meeting with colleagues at CDISC to review mapping to ODM and are working with collaborator to test the completeness of the mapping and context to insertion of data into an EDC system.

Topic for Next Call

Is eSource going to replace EDC? – Camila Matheny

Action items	Person responsible	Deadline
Send Kimberly Ho (Pfizer) invite to the group.	Mehdi	7 Feb
Work with Denise (Duke) re Duke, Yale, Advarra chapter on how large sites can work with multiple sponsors efficiently	Ken	4 March
Work with Shannon (Advarra) on April presentation on our lessons learned with our FHIR implementation	Ken	1 April
Reach out to Castor (Sebastian) – They have experience in a number of eSource areas that may be useful for the playbook	Ken	4 March
Submit your proposal on the community page	eSource Group	2/15/2022

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;

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- 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 considerations and upon the merits of objective judgments 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

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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