

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

4/2/2021  
10AM EDT

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**Type of meeting:** Operations

**Scribe:** Mehdi Stambouli

**Facilitator:** Rakesh/Linda/

**Apologies:** Amy Cramer, Mike Buckley

**Attendees:**

1. Linda King- SCDM
2. Rakesh Maniar - SCDM
3. Meredith Zozus-UT-SA
4. Demetris Zambas – Pfizer
5. Mitra Rocca -FDA
6. Nagree Verma - Pfizer
7. Kenneth Milstead- SCDM
8. Joe Dustin- BMS
9. Mehdi Stambouli- SCDM
10. Hugh Dai- Lilly
11. Shannon Roznoski- Advarra-
12. Sebastiaan Knijnenburg- Castor
13. Aruna Vattikola - Novartis

**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.

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## Minutes

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**Discussion:**

1. eSource related processes: Sharon shared that Advarra recently acquired Bio electronics, clinical trial suite software (CTMS). This software is for sites to enable their own eSource (i.e., digitize their operations). Key to EMA needs.
2. Updates on TransCelerate/SCDM FHIR Local Lab Project – Group looking to meet on the week of the 12<sup>th</sup> as a kick-starter to discuss the charter and the data flow protocol that will define local lab data exchange with

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FHIR. Rakesh also reported that there is a [FHIR boot camp hosted by HL7 in April 13-15](#) After meeting note: The SCDM TransCelerate KOM was April 15<sup>th</sup>. More meetings for subteams being scheduled for May.

3. Rajesh Modi from Merck & Co. will be joining this team.
4. Updates on Project Vulcan –
  - Shannon Labout has been working with Mike Ward who is leading the Schedule of Assessments for Vulcan. Shannon will work with the group to bring her expertise in data collection.
  - Discussed onboarding to the different projects for Vulcan. If interested, reach out to Shannon R. - There is an onboarding process that is required, and Shannon will be able to direct you.
  - Mitra- FDA's concomitant meds project (part of RWD project) has started and was part of the January connectathon. They are looking to progress it more at the May connectathon- focus on 4 resources in FHIR on where to get conomed data. Multiple EHR vendors involved (incl. Cerner, Epic). In September, looking to expand to add AE's.
  - Joe (BMS) asked a question about moving the needle on eSource to build that 'last mile' to get the data into sponsor data lakes- suggest sponsors work w/ site networks and dedicated research sites w/o EMRs- can this be tied back to RWD project in Vulcan?
  - Rakesh- smaller sites like bigger sites still need e capabilities to enter data, still need to have structured data, is there an opportunity to collect data on a shared Cloud network or common eSource platform?
  - Meredith- there is a PCOR Network (10 networks, ~12 sites each, <https://pcornet.org/network/>) using the PCORnet common data model. The network has done multiple pragmatic, prospective trials that include a batch data pull for baseline data and outcomes. There are limited study-specific visits (if any) after recruitment. Example trials include ADAPTABLE (<https://theaspirinstudy.org/>) and PREVENTABLE (<https://preventabletrial.org/home.cfm>). there is an NIH funded Collaboratory, the Healthcare Systems Research Collaboratory that does nothing but pragmatic, prospective randomized controlled trials embedded within health systems, for more information and a web textbook about pragmatic trials with multiple data-related chapters, see <https://commonfund.nih.gov/hcscollaboratory>.
  - Demetris- the use of the data or intended purpose matters here- RWD/retrospective vs prospective clinical trials data. For RWD to be used prospectively, how does DM normalize and structure data (like controlled process)?
5. Multi -Trial EHR-to-eCRF Project – Meredith reported that we are waiting to hear back from the grant application that would cover the coordination and administration of the multi-Sponsor, multi-trial, multi-site project to evaluate the quality of EHR and claims RWD. We don't expect to have an answer till May. Post meeting note: Meredith is a finalist for the grant and needs sponsors to commit to improve chances to get the award. Interview is scheduled for early June.
  - CDISC is working with Meredith to find additional sponsors/Site to participate. We will need 3 sites/2 trials, sponsors would do the trial analysis, the site would compare the EHR data to traditional data. The sponsors would provide the discrepancies for the analysis. The studies can be retrospective or prospective. Goal is to test whether EHR data is reliable and good enough for FDA to use in regulatory decision-making.
6. SCDM Annual Conference Update – Ken reported that the proposal was accepted and will be virtual this year in August. Each project should be presented during the Annual Conference. We are need a Co-Lead to present

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for the SCDM Projects. Ken to reach out- suggested presenters: Mitra, NIH, sponsors, academia, examples for local lab data via FHIR and how it relates to our SCDM TcB Local Lab FHIR project

7. Community Page updates – SCDM changing communication platforms that will be launching a new community page for SCDM members to interact and work on projects seamlessly. More updates coming soon!

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
Community Page	Mehdi	April 2021
TransCelerate Kick Start	TransCelerate, SCDM team	April 12 <sup>th</sup> – April 16 <sup>th</sup> – Done April 15 <sup>th</sup>
Send team links and specs on pragmatic trials	Meredith	May 2021

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## *Other Information*

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**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;

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- 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 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.

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

Adopted August 2018