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

6/5/2021
10AM EDT

Type of meeting: Operations

Scribe: Mehdi Stambouli

Facilitator: Linda/Mehdi

Apologies: Mike Buckley

Attendees:

1. Linda King- SCDM
2. Meredith Zozus-UT-SA
3. Rakesh Maniar - Merck
4. Amy Nordo – Pfizer
5. Prasann Mehta - Merck
6. Michael Rauwerdink - Novartis
7. Mehdi Stambouli- SCDM
8. Hugh Dai- Lilly
9. Aruna Vattikola – Novartis
10. Abhijit Parab- BMS
11. Cory Ennis- Duke

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:

- **Updates on TransCelerate/SCDM FHIR Local Lab Project –FHIR – Hugh Reported the following from his meeting on 5/24:** *Opportunities are still available for this project – Contact Linda for more info*

Pilot participants:

- At least two sponsors, each brings one protocol with reasonable *safety* local lab collections
- At least two study sites, each is capable to stand up an external-facing FHIR server
- Would like one site to multiple sponsors if possible

FHIR standard and related technologies

- FHIR V4.x is preferred and should be agreed upon by all study sites
- Post meeting note: Sponsors/sites will need to do their own FHIR API client coding

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Pilot data collection

- Each and every sponsor will apply their own API client to connect the purpose is to demonstrate sponsor/site/study agnostic nature of FHIR standard
- Data collection should be scheduled at least once per day in fully automatic fashion
- Collection duration: minimum of 8 weeks (?) and minimum of 1000 test results per study (?)

Sponsor data repository

- Each sponsor make decision where to store the lab data once transmitted via API
- Integration with sponsor's choice of EDC is preferred but not required

Protocol selection and participating subjects

- Select ongoing studies will be ideal to measure latency (see endpoint comparison section)
- Studies should have at least one site from participating sites, the more the better
- Actual lab results should be BLINDED for privacy protection
- Actual study subjects should be used in this pilot

Pilot endpoint comparison

- Primary endpoints (this could only be performed by the sponsor company)
    - Latency: compare the actual EDC with the FHIR API (assuming every 24 hours)
    - Accuracy: compare the EDC data entry errors (by % against overall volume) with the FHIR API (assuming 0%)
- Secondary endpoints
    - Sponsor effort saving (data/query management, data monitoring/SDV, etc.), estimate either via actual hours or via interviews; suggest to have same mechanism to track effort for each study (TcB/SCDM tool)
    - Study site effort saving: estimate time saving from data entry and query resolution via interviews

- **SCDM Annual Conference Update – Working to add additional abstracts.**

    - Aiming to have preliminary results to share at SCDM conference.

    - A couple of sites/sponsors that have started exchanging work with local lab- may be able to share this experience in addition to the TransCelerate/SCDM Local Lab project plans.

    - Genetech/Yale/Pfizer – Working on a project that is allowing us to move Data so we can compare using the evaluation outcome metrics. Opportunity to include this work in the SCDM AC.

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- **Updates on Connectathon/Project Vulcan**
    - Amy reported that Shannon Labout has been working a lot on the Schedule of activities.
    - Adverse event piece is the next big hurdle – The challenge is finding out what's possible and maximizing resources. Members can check out the Vulcan Confluence page to see a graphic on AEs
    - Hired Michael VanKapen as new eSource Program Manager.
    - Mike R. shared that Advarra is participating on the AE Round Table too
- **FHIR and DDE Security Documents and Assessments:**
    - As a side note, Meredith reported that JSCDM is happy to consider design manuscripts. For example, the TcB/SCDM Local Lab Project. She suggests we submit once we have completed the onboarding packet.
    - More info to come soon on Security document idea from Mike Buckley at MSKCC
- **Multi-Trial Project Update:**
    - 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. Post meeting note: Grant was awarded to project!!
    - Meredith shared that we are shortlisted and there are 15/37 applications on the shortlist/Deadline to interview shortlist is the week of June 8th. Meredith/CDISC proposed to recruit sponsors ahead of the interview meeting. Post meeting: A sponsor information session was held in May.
    - CDISC is working with Meredith to find additional sponsors/Site to participate. She needs 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. EHR to EDC is focus. Timing is set for 1st year collection of baseline data- by March 2022.

- **Community Page Updates**
  - The community page is up, and running/Members are encouraged to sign in
  - If you are having trouble signing in, please reach to Mehdi.

Conclusions: We need to fill these projects with leads/volunteers and have projects ready to present in Annual Conference

Action items	Person responsible	Deadline
Write up Data Flow protocol	TransCelerate, SCDM team	June 2021- in progress
Send team links and specs on pragmatic trials	Meredith	June 2021

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:

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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