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| Type of meeting: | Operations  |
| Scribe:Facilitator: | Mehdi StambouliMehdi |

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| Attendees: | 1. Linda King – SCDM
2. Camilla Matheny – Medable
3. Michael Buckley – MSKCC
4. Amy Cramer -Pfizer
5. Kenneth Milstead - Yale
6. Hugh Dai – Lilly
7. Shannon Roznoski - Advarra
8. Meredith Zozus - Uthscsa
9. Michael Rauwerdink – Advarra
10. Mehdi Stambouli- SCDM
11. Liat Modiano – Yale
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| *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 Updates and Additional ideas on alternatives to augment/jump start the Playbook**

* Scheduled call to discuss Topics and create interview Questions (Merdith/Group) If you have topic ideas that you want to consider, reach out to Mehdi Stambouli or Ken
* **ALL--**We are looking for volunteers to help write other chapters on their experience w/ eSource implementation. Please reach out to Ken if you have any questions or have some experience to share.
* **Ken-** Will also reach out to others on the Consortium to gage their interest (Castor (Derek), UCSF etc.)

**eSource Webinar Change to Awareness Slide deck with Voiceover**

* Slide Deck is complete and consist of 3 sections (Intro, HL7/Vuclan, playbook) Presentation will be posted on SCDM website and promoted via LinkedIn.
* Presentation scheduled for 8/10
* Opportunities to participate on multiple projects being conducted by the University of Texas Health Science Center – San Antonio under Dr. Merdith Zozus : There are long term projects and short term projects.
* If anyone interested to get on invite list for CEDAR Meeting on Sep. 29 contact Meredith
* Camilla to assist in the video editing/MP4 Format

**Vulcan: Updates on TransCelerate Local Labs Move to Vulcan and Volunteer for Vulcan Operations team**

* Linda reported that she followed up with Rakesh post last meeting regarding the proposal to move TransCelerate/SCDM Local lab project to Vulcan. It is still in the process with TransCelerate evaluating the proposal.
* Waiting for Materials from Aruna & Rakesh and Linda will connect with Hugh and Amy for next steps.
* Rakesh and Linda to work on proposal for the operations group.
* **Interest in being SCDM lead on Vulcan Operations Team?** You would represent SCDM for voting and input to Vulcan Ops meetings
	+ **Reach out to Ken if interested.**
	+ Also looking for additional volunteers to participate on the Vulcan operations team and projects.
	+ **Reach out to Ken if interested** in participating in projects. Note: Mike R. does attend the Ops meetings and can help bring back info to the team. Ken is currently representing SCDM as lead.

**eConsent and Telemedicine Research Presentation (slides attached) - Mike**

**September- TBD**

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| Action items | Person responsible | Deadline |
| Finalize approach for Playbook (ie. Publish as we go in JSCDM)- also secure interest in writing chapters including 4 new chapter ideas from Meredith  | Ken, ALL (volunteer) | 1 September |
| Create interview questions; Follow up with Volunteers to do the interviews and volunteer SMEs for Interviews | Ken, Meredith (start interview questions- Team completes) | 1 September- first Draft questions, assignments for interviews |
| Find SCDM tech writer and ask if SDCM doing Podcasts | Mehdi | 1 September |
| Update on TcB/SCDM Local lab proposal to move to Vulcan | Rakesh, Aruna | 1 September |
| Present Voice overpowerpoint  | Linda, Shannon | 10 August |
| Update on Man vs Machine study; lit search and if moving forward with study | Meredith | 1 September |

# 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:
	1. individual company prices, price changes, pricing strategies, terms of sales, price mark-ups, discounts, allowances, credit terms;
	2. costs of production or distribution, cost accounting formulae, methods of computing costs;
	3. individual company figures on or plans as to sources of supply, production, inventories, sales, marketing and promotion;
	4. 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;
	5. information as to future plans of individual companies concerning technology and investments;
	6. 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;
	7. 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;
	8. A company’s business strategies for identifying potential R&D targets and evaluating continued financial investment in the target throughout the R&D process;
	9. 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;
	10. The amount that a specific company pays for goods or services;
	11. 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;
	12. 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);
	13. 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;
	14. 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:
	1. 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.
	2. 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
	1. a written agenda circulated in advance of the meeting;
	2. 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