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| *Society for Clinical Data Management*  eSource Implementation Consortium- *Operations* | January 19, 201811a ESTTeleconference |

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| Co-chairs: | Mike Buckley MSKCC, Rakesh Maniar Novartis | Type of meeting: | Operations |
| Facilitator: | Linda King, SCDM | Note taker: | Linda King, SCDM |
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| Attendees: | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Org | Name | Attendance |  | Org | Name | Attendance | | MSKCC | Mike Buckley | X |  | MSKCC | Matt Koch |  | | Novartis | Rakesh Maniar |  |  | MSKCC | Joe Lengfellner |  | | SCDM | Linda King | X |  | BMS | Mari Clovis | X | | Pfizer | Brett Wilson | X |  | Novartis | Rajesh Modi |  | | Partners | Chris Custer |  |  | Lilly | Ed Rausch |  | | Duke | Cory Ennis |  |  | Yale | Rhoda Arzoomanian |  | | Lilly | Hugh Dai | X |  | Novartis | Saurin Mehta |  | | Duke | Denise Snyder | X |  | Partners | S Movin |  | | Pfizer | Demetris Zambas |  |  | Yale | Tesheia Johnson | X | | Lilly | Einav Leberknight |  |  | Pfizer | Tim Joy | X | | BMS | Elsie Mathews |  |  | HL7 | Wayne Kubick | X | | Lilly | Begona Gonzalez | X |  | Lilly | Aileen Ilaria |  | | Partners | H Barrvermilya |  |  | Partners | Jeanhee Chung | X | | Lilly | Don Jennings | X |  | Yale | Tesheia Johnson | X | | Lilly | Jeremy Keeton |  |  |  |  |  | |
| Please read: | Agenda |
| Please bring: | n/a |

# Minutes

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| Agenda item: | Update on eSource Implementation Consortium NDA/CDA | Presenter: | Brett Wilson |

#### Discussion:

Brett provided an update for Rakesh. There are 4 agreements/sections that Rakesh is working on packaging up. Novartis and Pfizer Legal have added wording wrt Anti-trust guidance and requirements plus information sharing guidance. Rakesh and Brett are close to a full agreement that can be shared with member organizations for their Legal input. The goal is to send out to organizations some time next week. Once all organizations have signed, a press release can be issued by SCDM and organizations are free to post internally and externally about the Consortium (note- MSKCC and Yale have plans in place to post). To expedite the announcement, Brett suggested that member organizations take both the NDA/CDA and press release to their Legal department for a joint approval. To help, Mike will post the draft announcement to Basecamp so members can socialize the announcement w/in their organizations now.

| Action items | Person responsible | Deadline |
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| * Finalize NDA/CDA language and send to SCDM and member organizations | Rakesh | Goal is week of Jan 22 |
| * Post draft announcement on Basecamp * Finalize announcement | Mike  Mike, Rakesh, Brett, Linda | Week of Jan 22  In conjunction with NDA/CDA |
| * Socialize draft announcement now and take NDA/CDA and final announcement to your Legal group for approval and Management for sign off * Press release and internal/external posting- social media | All member organizations  SCDM Communication lead (John), member organizations | As soon as possible after receipt  As soon as possible after all orgs have signed off |

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| Agenda item: | Tech updates- FHIR progress report back from members | Presenter: | Mike Buckley |

#### Discussion:

To facilitate work and ensure the right folks are at the meetings, Mike suggested to have 2 meetings of the eSource IC per month: one for Operations and one for Technical work. The technical work meeting would be focused on sharing best practices and collaboration on identified and agreed to technical projects (e.g., Local Lab now and next domains etc). Co-chairs would continue leading the Operations meetings and Technical Leaders would lead the Technical team(s). Don Jennings and Hugh Dai (Lilly) volunteered to continue w/ leading the technical team.

#### Conclusions:

It was agreed to hold 2 meetings/month. The next call for the eSource IC will be the Technical call.

| Action items | Person responsible | Deadline |
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| * Update the invitees to the Operational and Technical meetings; include SCDM for the Technical invitation to facilitate. | Mike Buckley | Week of Jan 22 |
| * Technical meeting minutes will be posted to BaseCamp and outcomes/topics to be added as updates to Operational meeting as appropriate. | Don Jennings, Hugh Dai | W/in 1 week of the Tech meetings |

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| Agenda item: | Onboarding updates/discussion : New members | Presenter: | Mike Buckley |

#### Discussion:

Mike reviewed the proposed on-boarding waves (note- Onboarding meeting is conducted by Co-chairs and first wave will begin after the core team (5 sponsors/5 academia) has signed NDA/CDAs)

* First wave: Merck, Apple, Verily
* Second wave: Medidata, Oracle
* Third wave: Academia/Sponsors/Tech Vendors (general membership)

#### Conclusions:

Team agreed to first wave with the addition of Epic. Cerner and Allscripts were also discussed as needing to be added to the first wave. Discussions have occurred w/ Epic. Team needs to reach out to Cerner and Allscripts again. Linda offered to provide a contact for Cerner if needed. Additionally, it was suggested to talk to the EHR companies at the HL7 connectathon in New Orleans next week (Don Jennings). For Apple, Don Jennings provided Lilly’s contact info to Mike Buckley.

For second wave, it was agreed that Medidata and Oracle need to be at the table. Additionally, Forte was added.

For the third wave of general membership, this will be facilitated by a button on the SCDM website (eSource IC to have its own page initially and microsite later in the year (proposal)- see SCDM Board update below)

| Action items | Person responsible | Deadline |
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| * On-board Merck | Mike, Rakesh | After NDAs/CDAs signed |
| * Contact Apple (Don’s contact) | Mike | By EOM |
| * Contact Cerner, Allscripts- resend email out; Linda to provide Cerner contact if needed * Contact Medidata, Oracle, Forte * Third wave – see action item below for SCDM Board agenda topic on adding a button to website to enable visitors to the site to contact us if interested | Mike, Linda (if needed)  TBD  SCDM | By EOM  TBD  1Q18 |

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| **Agenda item:** | SCDM Annual Conference Session Planning Potential | **Presenter:** | Mike Buckley |

**Discussion:**

Mike and Rakesh met w/ Linda and talked through options for an eSource session at the SCDM Annual Conference in September (Seattle-Bellevue). Mike and Rakesh submitted a session abstract and request. Linda to discuss and promote at SCDM Board meeting this weekend.

**Conclusions:**

Team agreed it was good timing.

| **Action items** | **Person responsible** | **Deadline** |
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| * Keep team updated on session and speakers etc. | Mike, Rakesh | As receive updates from SCDM |

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| **Agenda item:** | SCDM Board update | **Presenter:** | Linda King |

**Discussion:**

Linda updated the team on her discussion w/ the SCDM Communications lead wrt the options for an eSource Implementation Consortium communication plan. SCDM suggested to start w/ adding a page to the SCDM website dedicated to the eSource IC- this could be done as soon as the press release goes out. It was also recommended to put money in the 2018 SCDM budget to create a microsite for us which would be linked to the SCDM main website. This could be accomplished by 3Q18. (Linda to add proposed dollars to budget) SCDM also suggested to maximize the use of social media (Twitter, LinkedIn etc) and to optimize Google Search to find the eSource IC easily.

Linda also shared that dollars have been proposed to support a Project Manager for the Consortium. Linda to advocate for this at this weekend’s Board meeting. When approved, Linda will introduce PM that will help her w/ admin activities.

**Conclusions:**

Team agreed on approach and will partner w/ SCDM communications team to design initial page and subsequent microsite. Content for the site will be approved by Co-chairs so we post information ready for a wide distribution. Additionally, having a website will improve our visibility and transparency- key to enabling the FDA and other health authorities to participate on the eSource IC. It was noted that we need a button on the page or microsite for visitors to the site to contact us for interest in joining or learning more about the eSource IC.

| **Action items** | **Person responsible** | **Deadline** |
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| * Create page off of the SCDM website; include button for visitors to the site to reach out to us | John (SCDM), Linda | As soon as press release goes out |
| * Design eSource IC microsite (if approved) | John (SCDM), Linda, TBD | End of 3Q18 |
| * Followup on PM request at Board meeting * Create a communication plan and get approval by Co-chairs | Linda  John (SCDM), Linda | January 23, 2018  By EOM |

# Other Information

#### Observers:

n/a

#### Resources:

n/a

#### Special notes:

Linda to followup again w/ Mitra Rocca at FDA to find out how if there’s been any progress in Mitra being able to join our Consortium and calls.