|  |  |
| --- | --- |
| *Society for Clinical Data Management*  eSource Implementation Consortium- *Operations* | February 16, 201811a ESTTeleconference |

|  |  |  |  |
| --- | --- | --- | --- |
| Co-chairs: | Mike Buckley MSKCC, Rakesh Maniar Novartis | Type of meeting: | Operations |
| Facilitator: | Linda King, SCDM | Note taker: | Linda King, SCDM |
|  |  |  |  |

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

# Minutes

|  |  |  |  |
| --- | --- | --- | --- |
| Agenda item: | Update on SCDM Annual conference (AC), DIA AC | Presenter: | Mike Buckley and Rakesh Maniar |

#### Discussion:

Linda shared background on the SCDM AC- it will be in Seattle-Bellevue in September. It has a data management focus but attracts other disciplines. There are usually approx. 800 attendees. Mike and Rakesh announced that their abstract for an eSource session was accepted for the AC and is on Monday Sept 23 in the afternoon (90 minutes). They described the panel discussion format. The session will have reps from academia, pharma, vendor (2), and regulatory. Mike and Rakesh will be the moderators and also provide slides on our Consortium and the local lab success. Others will provide a few slides as well and will take questions from audience. Mitra Rocca from the FDA has been invited (pending acceptance). If we focus on local labs as implementation success and talk about new domains for 2018, it was suggested that Lilly could be the pharma and Yale Tesheia would be the academic. Shannon volunteered Forte to talk about their experience with labs and other interoperability examples. A suggestion was made to see if Google/Verily might be available to talk about wearables/sensors or Apple to talk about their FHIR application in their research kit (EHR data to mobile). Another suggestion was an EHR vendor such as Cerner, Epic or Allscripts. Decisions on speakers will need to be made by 2Q; Mike and Rakesh will flush out an agenda and followup w/ folks by April Operations meeting.

Mike and Rakesh are also presenting on the SCDM eSource Implementation Consortium – how we were formed, our charter etc at a DIA eSource session chaired by Jennifer Price. DIA is in Boston in June. More details to follow.

Other conferences worth pursuing? SCOPE was mentioned if we have implementation success stories to share. August is when abstracts are due for Feb 2019 meeting.

| Action items | Person responsible | Deadline |
| --- | --- | --- |
| * Decide on agenda or content focus for panel discussion at SCDM AC | Mike and Rakesh | Goal is by April Operations meeting |
| * Secure speakers for SCDM AC * Presentation for DIA * Linda to populate Basecamp calendar w/ conference dates and abstract deadlines- suggest to focus on SCDM, DIA and SCOPE for now- taking suggestions for future conferences | Mike and Rakesh  Mike and Rakesh  Linda | Goal is by May Operations meeting  Due to Jennifer by ?  End of February |
|  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Agenda item: | Announcement and charter feedback | Presenter: | Mike Buckley |

#### Discussion:

The draft announcement and updated charter (new) is posted on Basecamp. While Rakesh is working on MOU/CDA, pls socialize these 2 documents within your companies so when MOU/CDA is available for review, your approvers have background on the request and a heads up.

#### Conclusions:

#### Please review the revised charter as additional clarifying information was added about governance and structure.

| Action items | Person responsible | Deadline |
| --- | --- | --- |
| * Review revised charter * Socialize the draft announcement and revised charter w/in your organization. | ALL  ALL | Week of Feb 19  Week of Feb 19 |
| . |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Agenda item: | MOU/CDA for consortium members | Presenter: | Rakesh Maniar |

#### Discussion:

Rakesh provided an update- delays due to charter updates and rounds of updates but are now stable. Novartis and Pfizer Legal have added wording wrt Anti-trust guidance and requirements plus information sharing guidance. Rakesh has asked the Novartis legal folks to send it around so all the bases on the agreement are covered. Novartis is close to a full draft 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 provided input, any modifications have been made and all have signed (goal by March 31), 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, it was suggested that member organizations take both the MOU/CDA and press release to their Legal department for a joint approval.

MOUs for other consortiums will follow SCDM MOU policies but will not be pursued until the member companies have all signed MOU/CDAs. Also we can create areas of ‘watch’ for overlap of activities if member companies are on multiple consortium.

| Action items | Person responsible | Deadline |
| --- | --- | --- |
| * Finalize draft MOU/CDA language and send to SCDM and member organizations | Rakesh | Goal is week of Feb 19 |
| * Finalize announcement | Mike, Rakesh, Brett, Linda | In conjunction with MOU/CDA- goal- March 31 |
| * 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 | Draft announcement- now, feedback by mid March, sign off by March 31  As soon as possible after all orgs have signed off |

|  |  |  |  |
| --- | --- | --- | --- |
| **Agenda item:** | Additional members- followup from Jan 19 meeting | **Presenter:** | Mike Buckley |

**Discussion:**

**January 19 meeting minutes:** 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 |
| --- | --- | --- |
| * On-board Merck | Mike, Rakesh | After NDAs/CDAs signed |
| * Contact Apple (Don’s contact) | Mike | **DONE- regional approval- waiting on global approval** |
| * Contact Cerner, Allscripts- resend email out; Linda to provide Cerner contact if needed * Contact Medidata, Oracle * Contact 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  TBD  SCDM | By EOM  TBD  Forte on board  1Q18 |

|  |  |  |
| --- | --- | --- |
|  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Agenda item:** | UPDATE FROM JAN 19…SCDM Board update | **Presenter:** | Linda King |

**Discussion:**

**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** |
| --- | --- | --- |
| * Create page off of the SCDM website; * Add button for visitors to the site to reach out to us | John (SCDM), Linda  John | DONE- Page is there w/ limited info  By March 31 |
| * 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- include Twitter, LinkedIn, Facebook etc | Linda  John (SCDM), Linda | DONE- approved- pending naming a person  Pending- due by March 31 |

# Other Information

#### Observers:

n/a

#### Resources:

n/a

#### Special notes:

Jan 19 meeting: 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.-

***Followup as of Feb 16: Linda, Mike and Rakesh worked on answering FDA’s 8 questions as an application for our consortium to be added to FDA volunteer approved consortium list. Mitra confirmed she received the responses and is sending them on internally to the next step in the process. She will let us know when we are accepted and she can join as an At-large member.***