Meeting Minutes: DP Workshop

27 of July 2020


A recording of the workshop can be found at the following link: https://web.microsoftstream.com/video/7cc8a130-9942-44d2-b06a-f4a9e596f761

Actions:

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<tr>
<th>Action</th>
<th>Responsible</th>
<th>Date</th>
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<tbody>
<tr>
<td>Send 1:1 meeting requests and Aug. 3rd meeting interest to Julia Kuhn (<a href="mailto:Julia.kuhn@gatesfoundation.org">Julia.kuhn@gatesfoundation.org</a>)</td>
<td>All</td>
<td>July 27</td>
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<td>Follow up with Ingrid and Nicolas to organize 1:1 with Inovio and CEPI CMC lead</td>
<td>Rob Juba</td>
<td>July 27</td>
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<td>Discuss the need to understand the presentations to assess the delivery guidelines as well as the CCE needs in countries. Align on decision maker and harmonization efforts.</td>
<td>Jim R. / Karan Sagar</td>
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Decisions:

- Final DP Workshop presentation can be shared with attendee organizations
- Those who expressed interest in CEPI OMPI vials: Clover, Imperial, CSL, PATH/IMMS, Biological E, AZ (as backup supply), Walvax will confirm interest after consulting with local NRA (NMPA)
- Those who expressed interest in using DP Network: PATH/ISMMS has sufficient f/f capacity but may need vial/stopper supply
- Those who expressed interest in attending Aug. 3rd follow up meeting: AAVCOVAX/MEEI/Novartis, Biological E, BioFarma, Clover, CSL, Novavax, PATH/ISMMS, Walvax

Questions for follow up agenda topics:
User needs and preferences:
- CEPI (working on this) F/u:
  - Secondary packaging design - What is the desired multi-pack of the vials one filled -10 vials/carton or tray, 20 per tray, etc.?
- RAG F/u:
  - How do we harmonize requirements for single dose presentation mandated by home country regulatory agency and MDV presented at DP Workshop today? - (Andrew Wong, Walvax)
Lead Presentation

- RAG F/u:
  - Will WHO get alignment with regional HA/regulatory agencies for COVID pandemic?
  - Can WHO-PQ indicate what kind of data is needed for programmatic suitability (LMICs)?

- Delivery f/u:
  - Syringe supply (to be bundled with Vx. supply?)

- PATH F/u: Do you have a manufacturer of thiomersal?

Examples of Alternative Backup Presentation

- RAG F/u
  - What is the current experience with Luer lock based needle and auto-disable/AD syringes, as may be required for the 200-d-bag; are any Luer Lock based injection devices pre-qualified by WHO? (Jean-Pierre, UNICEF)
  - Discuss labeling requirements for BFS given the potentially limited space for labelling in the BFS designs that minimize the cold chain storage volume required. (Kim Duffy, Merck/IAVI)

DP Network

- RAG F/u:
  - Discuss limiting label versions for efficiency (Kim Duffy Merck/IAVI)
  - Need to reduce the number of countries requiring repeat testing on importation by the MAH and/or the health authority. (Kim Duffy Merck/IAVI)

Stability Shelf-life and cold chain requirements

- RAG F/u:
  - How will regulators review policy with VVM considering stability time of vaccine
  - Suggestion to use modeling data to support the shelf-life in lieu of real time data. Will RAG work with NRA to justify novel approaches (such as platform Vx. stability data) to assign shelf-life for new vaccines?
  - Supply chain working group F/u: What is the need to secure VVM stocks?

Closing and next steps

- Future agenda items for Vx. Dev Workshops
  - RAG F/u:
    - Discuss potential science and risk based regulatory approaches to ensure acceleration while still safe/efficacious
    - Discuss barcode, VVM, BFS network progress (Ranjit Deshmukh)
  - Aug 3 meeting potential topics: DP network, vials, stoppers, MEDInstill bags and BFS