Meeting Minutes: DP Workshop

27 of July 2020

Attendees: AAVCOVID/MEEI/Novartis, University of Oxford/AstraZeneca, Biological E, BioFarma, BMGF, CEPI, Clover, CureVac, GAVI, Icosavax, IFPMA, Imperial College, Inovio, Merck/ IAVI, Merck/ Themis, MSF, Novavax, PATH, PATH/ISMMS, Serum Institute of India, SK Biosciences, UNICEF, U. Queensland/CSL, Vaccines Europe, Walvax, WHO, Zhifei

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

Actions:

Action	Responsible	Date
Send 1:1 meeting requests and Aug. 3rd meeting interest to Julia Kuhn (Julia.kuhn@gatesfoundation.org)	All	July 27
Follow up with Ingrid and Nicolas to organize 1:1 with Inovio and CEPI CMC lead	Rob Juba	July 27
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.	Jim R. / Karan Sagar	

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