Meeting Minutes: WHO presentation of NRL

2 of September 2020

Attendees: David Robinson, Ajoy Chakrabarti, Julia Kuhn, Steve Hadley, Mike King, John Hennessey (BMGF), Ingrid Kromann, Nicolas Havelange, Jim Robinson, Svein Rune Andersen, Raafat Fahim, Anna Särnefält, Renske Hesselink, Gamal Aberra, Mauro Bernuzzi, Diletta Magini, Debra Yeskey (CEPI), Dominique Maugeais (GAVI), Michael Thien (IFPMA), Diane Wilkinson (Vaccines Europe), Carmen Rodriguez-Hernandez, Ute Rosskopf (WHO)

Actions:

Action	Responsible	Date
Develop a forecast/ simulation of # batches and samples to determine testing capacity and needs	Mfg. SWAT	Discuss at Sept. 8 Core Team meeting
Survey developers on types of methods and # of samples per assay	Mfg. SWAT	Discuss at Sept. 8 Core Team meeting
Submit prioritized questions to RAG on template and include suggested response	All	September 8 COB
WHO Share information on established testing methodologies that is stored on WHO NCL network SharePoint site	Ute	September 8
Ask the OMCL to share the information with the developers	Co-leads	

Decisions:

- WHO slides presented by Ute may be shared with developers

ITEM 1iii: [Notes]

WHO prequalification of vaccines, WHO vaccines testing, monitoring and the WHO-National Control Laboratory Network for Biologicals

Ute Rosskopf shared a presentation which was broken into four topic areas: 1) WHO prequalification (PQ), 2) WHO vaccines testing, 3) Challenges, 4) WHO- Nation Control Laboratory Network and Biologicals. The presentation included many specifics which can be referenced in the attached document. A few additional notes:

- All laboratories have ISO 17025 qualification and are audited by Ute and other WHO colleagues
- Information sharing agreements are in place with manufacturers
- Ute shared feedback from network members that emphasized the importance of the membership and benefit of sharing information among the network

Discussions/Questions

- WHO does not repeat testing by laboratories in the network and the network is not intending to reproduce COVID vaccine testing
- There was considerable conversation on the increased demand of COVID vaccine testing. The amount of testing will depend upon the number of batches and samples to be tested, as well as the testing methods. The magnitude of the lots that will be produced will be significant compared to existing vaccines. Timing will also be an important element. (For example, timeline to transition assays may be reduced from 1 year to a few months. Multiple DS/DP sites and inspection burden are also concern.
- Carmen emphasized the importance of trending consistency in the production process which Ute noted will be difficult to manage as COVID vaccines will be new products in the market.
- In vitro vs. in vivo testing – there was consensus that in vitro potency testing would be more reproduceable, easier and reduce burden/complexity of animal testing.
- For EUL – Share with CMC leads that the NRA of record must be prepared to assume the responsibility of releasing batches – early discussion with the relevant NRA and the WHO PQ team is advised.
- Sample logistics – the group discussed the possibility of running a simulation to understand the number of lots that will be produced and the batches that would need to be tested. (Estimated to be ~200 batches/month, for comparison the current workload for the OMCL ~1600 batches/year)
    - Should also assess the number of labs and samples to see if any materials need to be secured if there are concerns of limited availability.

Next steps: Inform grantees/developers

- Next steps: Communicate with developers and ensure that they are aware of the network. If there are additional questions reach out to Ute Rosskopf (rosskopfu@who.int)