

**DCVMN PSPT Project  
Technical Workshop 7  
Thursday May 27<sup>th</sup> 2021**

**Attendees:** Anissa Wari Murti (AWM), Apichai Supasanatorn (ASP), Arjen Sloots (AS), Arun Bhardwaj (AB), Christina Von Hunolstein (CVH), Deepak Mahajan (DM), Dewi Sulanjari (DS), Dini Hiayati (DH), Dionne David (DD), Elizabeth Ika Prawahju (EP), Gautam Sanyal (GSL), Gopal Singh (GSH), Irma Riyanti (IR), Muhammad Erdiansyah (ME), Pavel Mitrenga (PM), Pavlinka Stoyanova (PS), Pradip Das (PD), Rajinder Suri (RS), Sreenivasulu Reddy B (SR), Sunil Gairola (SG), Surender Reddy (SRR), Tim Schofield (TS), Ute Roskopf (UR), Weyerarmarst Jaroenkunathum (WJ), Zulfa Noerhidayati (ZN), Laura Viviani (LV), Sonia Villaseñor (SV), Sivashen Cunden (SC)

**Apologies:** Coenraad Hendriksen (CH), Jim Saylor (JS), Sivakumar Sakthivel (SS), Supaporn Phumiamorn (SPh), Sekar Thangaraj (ST), Sonia Pagliusi (SP),

**Welcome and AOB**

**CVH**

CVH introduced agenda and asked participants to raise any other business not captured in the agenda. No other business was raised by participants.

**1. PSPT Project Update**

**LV/SC/AS**

*Shipping*

DCVMN and BioLyo have received 10 MTAs and are currently awaiting the final MTA. DCVMN have confirmed that 5 labs have received the coating antigen with no issue. DCVMN are currently aware that 3 shipments are currently in transit and the involved laboratories are expected to receive the package in first week of June. A singular shipment will require air transport and is being arranged with a suitable courier. Delays of antigen delivery due to Covid have only minorly impacted project timeline.

*Future management of the coating antigen material*

DCVMN are awaiting NIBSC feedback on next steps for future management of coating antigen. However, DCVMN are exploring other opportunities for the management and is identifying the manufacturers and control laboratories that may be interested in using the antigen after the study has concluded.

*Getting ready for testing*

LV asked all participating laboratories when they will initiate the testing phase. Biological E Limited indicated that testing would begin after arrival of the antigen in the 2<sup>nd</sup> week of June. Panacea Biotec have already begun initial phases of testing. Serum institute of India have also begun testing phase and commenced the immunization and the sentinel program.

*Data Collection Platform*

Deployment has currently been put on hold as bugs have been identified on the platform preventing changing of passwords and upload of files. Debugging and beta testing will take place between 27<sup>th</sup> May- 4<sup>th</sup> June and members will receive account details by the 7<sup>th</sup> of June. Additionally, after discussion with Intravacc's team a tutorial video for the PSPT results Excel spreadsheet will now be featured on the platform.

*PSPT results Excel spreadsheet*

AS explained that the Excel spreadsheet for data collection is in the final stage of development and due to some discovered bugs cannot be distributed for use at this point. AS also updated the consortium that Bilthoven Biologicals have approved the use of the potency calculation spreadsheet and that both the final PSPT spreadsheet and the Bilthoven Biologicals spreadsheet will be shared with the statistician for review. Post meeting note: a sample dataset and associated outputs will be included so a laboratory can validate their use of the spreadsheet.

**Consortium comments**

Regarding the testing of sentinel mice, to exclude the presence of infection/antibodies against *B.pertussis*, *B.parapertussis* and *B.bronchiseptica* SG made the following observation: "about testing of *B.parapertussis* and *B.bronchiseptica*, previously I had shared in MS-PSPT work protocol Version-5 that absence of infection against *B.pertussis*, *B.parapertussis* and *B.bronchiseptica* in mice colony needs to be confirmed by appropriate method (cultural or serological assay) or by commercial kits in case they are available. At our end, we are performing culture method for *B.bronchiseptica*. For general information, kits for *B.bronchiseptica* are available from B.XpressBio and for *B.papapertussis* available from TestLine Clinical Diagnostics".

In case an animal results positive for any *Bordetella*, that animal cohort cannot be used.

The PSPT ELISA can also be used to exclude reactivity against the coating antigen in the cohort of animal available for the study.

**2. In vivo and ELISA SOP Update**

- Both *in vivo* and ELISA SOP were updated during the meeting and will be finalized and redistributed after CvH, CH and AS approval.
- SG will also provide more clarification regarding the ELISA assay method and provide manufacturers which could be used.

**5. Next steps**

- ❖ SOPs to be finalized based on comments received during meeting.
- ❖ Intravacc to integrate Bilthoven spreadsheet into final PSPT spreadsheet.
- ❖ DCMVN to prepare and circulate suggested metadata to be collected excel.
- ❖ DCVMN to finalize Data collection platform and add video to platform.

**Meeting closed at 14:00**

*Notes taken by SC.*

C. v. J. A.

**Signed**