

**DCVMN PSPT Project
13th Technical Workshop
December 2nd 2021**

Attendees and excused: Arjen Sloots (AS), Arun Bhardwaj (AB), Christina Von Hunolstein (CVH), Deepak Mahajan (DM), Elizabeth Ika Prawahju (EP), Gopal Singh (GSH), Gautam Sanyal (GSL), Irma Riyanti (IR), Pavel Mitrenga (PM), Pavlinka Stoyanova (PS), Pradip Das (PD) excused, Sreenivasulu Reddy B (SR), Muhammad Erdiansyah (ME), Sunil Gairola (SG), Tim Schofield (TS), Weryarmarst Jaroenkunathum (WJ), Zulfa Noerhidayati (ZN), Sonia Pagliusi (SP), Coenraad Hendriksen (CH) excused, Maya Ramdas (MR), Brunda Ganneru (BG), Namrata Raman (NR), Laura Viviani (LV), Sonia Villaseñor (SV), Sivashen Cunden (SC), Rajinder Suri (RS) Supaporn Phumiamorn (SPh), Ute Roszkopf (UR).

Welcome and AOB

CVH welcomed all the participants and opened the 13th Technical Workshop, the last of 2021. The agenda was approved, without addition of other issues to discuss.

1. Current project status and update

LV informed the participants on the status of the project, where a delay in the testing phase was confirmed which would result in a delay of the statistical analysis. However, the submitted spreadsheets have been shared with the designated statistician for a brief review of the results. As mentioned during the 12th Technical Workshop, DCVMN is preparing the request for a no-cost extension to be submitted to NIIMBL before the end of the year. LV acknowledged the key milestones and achievements met so far by the Consortium.

Ten laboratories from both industry and National Control Laboratories (2 laboratories left before testing phase due to COVID19 priorities) participated to the study.

The ELISA coating antigen (inactivated *B. pertussis* 18323), critical and strictly necessary material to perform the PSPT study, was *ad hoc* produced by BioLyo with the support of Intravacc. The coating antigen was then characterized by Intravacc to assure its quality and suitability for the study (consistency with the material used in the previous studies). About 2000 vials of the ELISA coating antigen were produced and a part of it was distributed to the participants after signing an MTA.

SOPs for immunization of animals as well as for performing the ELISA were distributed to the participants.

A dedicated platform for data collection was created.

13 Technical workshops were held over a period of 1 year and 4 months.

LV shared again the proposed activities that can be carried out if the no-cost extension is going to be approved by NIIMBL (see the Gantt chart below).

It was agreed to have, in case, a minimum of 3 TW: one to discuss within the PSPT Consortium the statistical analysis results, and two dedicated to the validation studies that laboratories might initiate once the current project is completed.

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	Gantt Chart					
	Month					
	2022					
	Feb	Mar	Apr	May	Jun	Jul
Project Scientific Publication Prepared and Submitted						
Management of the coating antigen (final decision)						
Technical workshop(s) dedicated to validation. Aim: support laboratories to plan full validation studies						
Creation of content to be shared publicly to advertise the project outcomes						
PSPT Video						
Final Workshop (face to face or hybrid or virtual) with key international regulatory and industry stakeholders, and other 3Rs organizations						

DCVMN foresees an additional donation (including shipment to the laboratories) of coating antigen to perform full validation studies.

LV reported that DCVMN wishes to know how many laboratories plan further PSPT validation studies. SG commented that, based on the 12th Technical Workshop feedback, the majority of the participating laboratories are interested in planning full validation studies. WJ asked when DCVMN will provide the additional coating antigen material. LV informed that the shipment should be done within the first part of 2022 and DCVMN is currently assessing how many vials might be needed to complete these validation studies. SR asked whether the coating antigen material production process is going to be shared. LV confirmed that all the production's protocols will be shared. All participating laboratories are invited to contact DCVMN in case of any questions about the 2022 activities, while DCVMN will inform the participating laboratories and Steering Group about NIIMBL feedback on the no-cost extension request.

2. Update from each participant on project status and request of support

LV called up the participating laboratories to confirm the status of their testing activities:

- NCL/India: testing completed; documentation submitted (spreadsheet)
- Biological E: testing completed; documentation submitted (spreadsheet)
- BulBio: requested technical support from the Steering Group (support not received – Post meeting note: request received and recommendation provided on the same day); completion of the testing is ongoing;
- Bharat Biotech: testing completed; documentation submitted (spreadsheet)
- BioFarma: testing completed; documentation submitted (spreadsheet)

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- Department of Medical Sciences Thailand: testing completed; waiting for updated spreadsheet to facilitate data copy
- NCL Indonesia: testing completed; documentation submitted (spreadsheet)
- Panacea Biotec: testing completed; documentation submitted (spreadsheet)
- Sanofi Pasteur: testing completed; documentation to be submitted shortly (spreadsheet)
- Serum Institute of India: testing completed; documentation submitted (spreadsheet)

LV reminded to all laboratories to submit also their laboratory's journal and if possible, the results of the potency calculated with the routine software (e.g. Combistats). LV recommended all laboratories to contact DCVMN in case of any unexpected results and to not postpone documentation submission: in case of questions about the submitted data, DCVMN will contact the laboratory. DCVMN will follow up with an email on the documentation submission.

CVH closed the event reminding laboratories to complete their data submission and to be waiting for DCVMN communications with regard to no-cost extension and statistical analysis. CVH thanked all participants for their fruitful participation to the study and wished all a happy 2022 and to meet in February.

3. Next steps

- ❖ DCVMN communication on data submission
- ❖ DCVMN to inform participants about the PSPT results
- ❖ DCVMN to complete no-cost extension submission to NIIMBL
- ❖ DCVMN to communicate 2022 planning once finalized

Meeting closed at*Notes taken by LV*C. v. **Signed**