

# PSPT Project's Outcomes

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DCVMN

July 5<sup>th</sup>, 2022  
PSPT Final Meeting



# Key Milestone 1

## Establishment of Consortium

September 2020

- Established a of Consortium of 12 wP vaccine manufacturers (India, Indonesia, Bulgaria) and national control laboratories (India, Indonesia, Thailand) and a dedicated Steering Group for technical and scientific advice. *Within 2021, two laboratories left the project due to other priorities.*
- The Steering Group (5 members and 3 observers).
- Kick-off meeting held in September 2020.

### Manufacturers



### National Control Laboratories

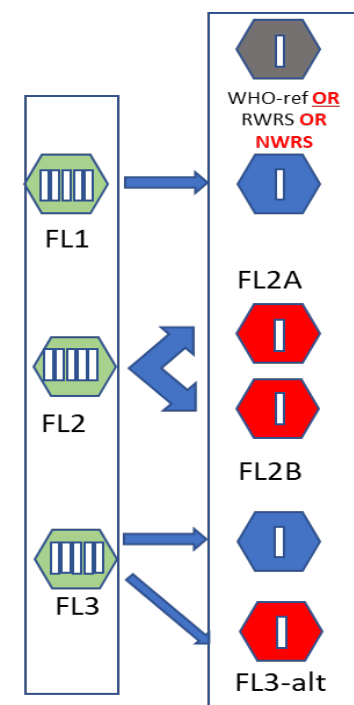


# Key Milestone 2

## Approval of Study design

January 2021

- Study design finalized after assessing all participants manufacturing capabilities and internal operations.
- All participating laboratories agreed to perform the PSPT on the batches of the final product (used by NCL and then released to the market).
- The approved study design could be carried out in two different experimental settings.



# Key Milestone 3

## Production of coating antigen

February 2021

- BioLyo, CMO successfully completed the production of coating antigen, using new method allowing for large scale production, of 2000 vials of lyophilized coating antigen material (whole-cell Pertussis strain 18323).
- Sample of vials were delivered to independent laboratory for characterization.
- Production protocol will be available in a dedicated publication
- DCVMN is exploring solutions for future long term management (storage and shipment) of coating antigen material (ongoing)

 **BIOLYO**

Version:  
Date:  
Project ID:  
Page:

1.0  
February 23, 2021  
Dolomite01  
1 of 1

### Certificate of Testing

Name	Manufacturing date	BioLyo n°	Storage conditions	Retest date
<i>Bordetella pertussis</i> 18323 coating antigen	15 Feb 2021	DP-21-008	Store 2-8 °C	15 Feb 2026

Test	Method	Result
Appearance lyophilized cake	Visual inspection	Off white cake
Residual moisture	Karl Fisher	1.16 % ± 0.24 %
Appearance upon reconstitution	Visual inspection	Opalescent
Plate count	Bordet Gengou Agar	No growth
pH upon reconstitution	Potentiometric	6.14
Microbial examination	SDA	No growth
Microbial examination	TSA	No growth

Approved by

Name	Role	Initials	Date
Mattias De Coster	Author	MDC	23 FEB 2021
Liesbeth Vercruyssen	Project Leader	L.V.	23 FEB 2021
Marcel Thalen	CEO	MTH	23 FEB 2021

History

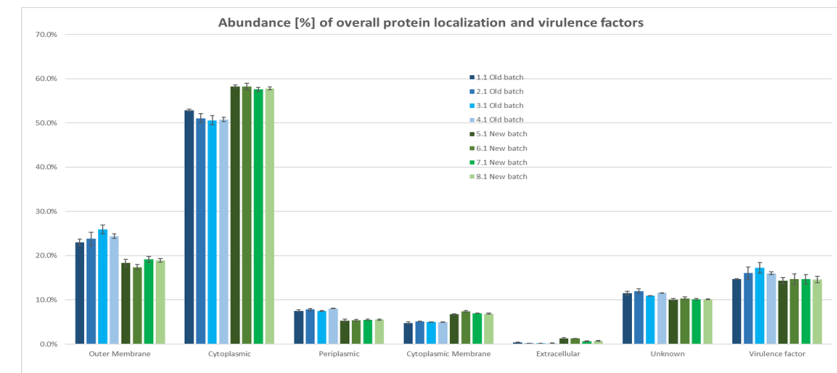
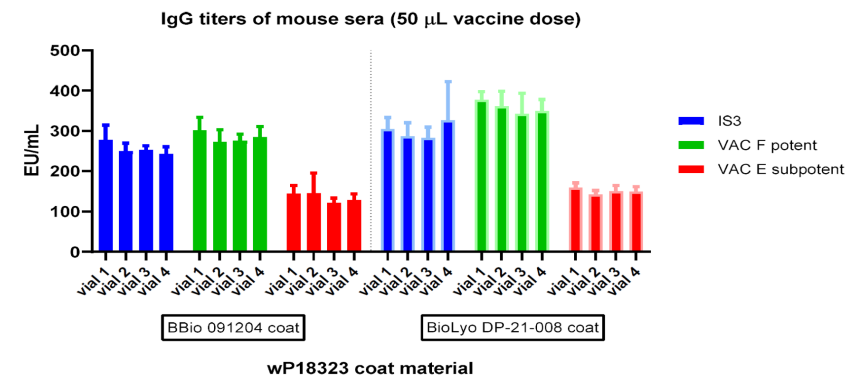
Version	Modification
1.0	New document

# Key Milestone 4

## Characterization of coating antigen

March 2021

- Intravacc performed characterization of coating antigen using ELISA and LC-MS and confirmed suitability of new antigen.
- Expression profiles of the new coating antigen production in comparison to reference material was highly similar with a 77% of the total proteins expressed being the same.



# Key Milestone 5

## Standard Operating Procedures and Data Collection Platform

April-August 2021

- PSPT-ELISA and *in vivo* Standard Operating Procedures revised and improved upon based on comments from Consortium and finalized study design.
- DCVMN created a dedicated anonymized data collection platform to capture results of study and study crucial information.
- The Steering Group created dedicated Spreadsheets for the collection of the raw testing data and laboratory journals templates for the laboratories.

The screenshot displays the 'PSPT Data Collection Platform' interface. At the top, the DCVMN logo and name are visible. Below the header, there are navigation tabs: 'Main', 'Before Testing', 'During Testing', 'PSPT Results', and 'Tutorial'. The 'PSPT Results' tab is currently selected, and the user ID 'PSPT 12345' is shown in the top right corner.

The main content area is divided into two columns. The left column contains a 'Registered contact' field with the email 'test@test.com' and a 'Logout' link. Below this is a table of vaccine information:

Type of vaccine tested	DTwP-HepB-IPV-Hib
Other type	N/A
Final bulk formulation	it is formulated by mixing bulks
Final bulk process	processed by xxx and 54 lots
Testing ability	No
Design component not implemented	FL2A and B
More tests than requirement	Yes
Additional lots origin	Different final bulk
Additional lots qty	3 additional lots - 2 unaltered (DTwP-HepB-Hib) + 1 Altered (DTwP-HepB-Hib) + Reference Standard
Reference standards	WHORegional
Reference vaccine potency	10

The right column contains 'Shipping Details' with the address: 'Street 56, 1222 Geneva, Suisse'. Below this is a 'Report shipping issue' link. Further down, there are 'DCVMN Announcements' and 'DCVMN Direct messages' sections. The announcements include a test announcement to all steering group members and a deadline notice for a survey by EOD July 5th. The direct messages section shows a message from 'Test to 12345' and a 'New message' input field.



# Key Milestone 6

## Coating Antigen Shipments

June 2021 and June 2022

- BioLyo in collaboration with DCVMN shipped to 10 Consortium members (4 countries) the vials of coating antigen material, based on signed MTAs for each shipment. This shipment allowed the laboratories to start the testing of the PSPT.
- A second shipment from BioLyo to all the participating laboratories with 98 vials has been successfully completed. This second round of shipment will allow laboratories to continue their pre- and validation work after the end of this project.



# Key Milestone 7

## PSPT Testing Phase Collaboration and Results

August 2021 and July 2022



- Laboratories performed the testing as per the agreed design and protocols, with minor changes, and shared their results with DCVMN
- After a preliminary assessment performed by the Steering Group, as hoc and laboratory specific communication took place aimed to provide recommendations on further testing improvements.
- **Overall, the work performed by the laboratories confirmed that the PSPT is suitable to detect sub-potent batches, although product-specific further refinement of the protocols might be needed.**



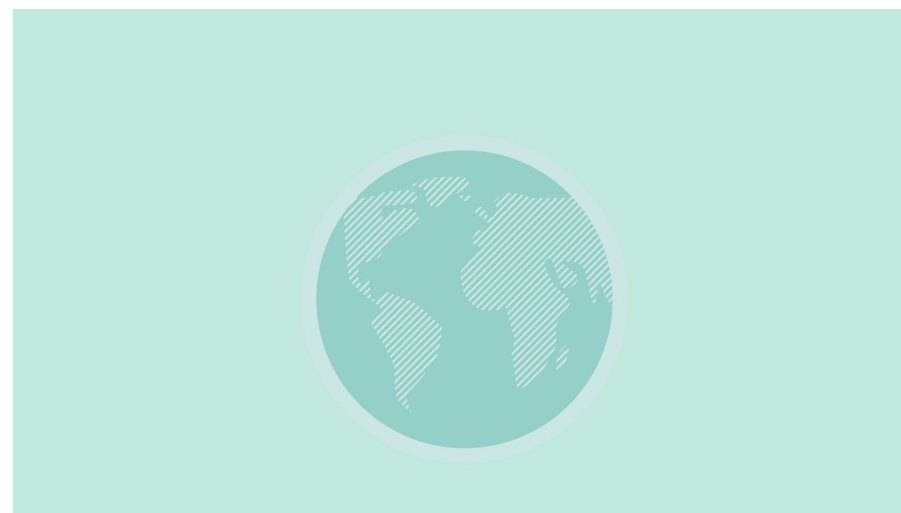


# Key Milestone 8

## PSPT Meetings, Documents and Publications

July 2022

- DCVMN offered 15 online Technical Workshop – thank you to the Steering Group and the Consortium Participants!
- 2 Scientific Publications will be available soon (coating antigen and project's results)
- SOPs and Spreadsheets (not validated) publicly available!



# Thank you!

For more information

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