PSPT Project’s Outcomes

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July 5th, 2022
PSPT Final Meeting
Key Milestone 1
Establishment of Consortium

September 2020

• Established a 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.
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)
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.
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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