

**Meningitis Vaccine Project Meeting: A Scientific Workshop
Vaccine Development from Bench to Licensure towards large scale Introduction
A Meningococcal A Conjugate Vaccine for the African Meningitis Belt**

*Pune, India
10 - 12 February 2010*

Tentative Agenda 21 January, 2010

WEDNESDAY 10 FEBRUARY 2010

Business Model & Pharmaceutical Development

9:00 - 9.15	Introduction and Welcome	Marie-Paule Kieny & Cyrus Poonawalla
9.15 – 9.30	A tribute to Dr. Charles Mérieux	Alain Mérieux (TBC by CD / Videocon)
9.30 - 10.00	The scope of the meningitis problem in Africa (political, public health and economic issues)	Francis Nkrumah
10.00 - 10.45	Meningitis in Africa: historic overview and current trends	Brian Greenwood, William Perea
10:45 - 11:00	Meningococcal meningitis in India	David Sinclair
<i>11.00 - 11.30</i>	<i>Coffee/tea break</i>	
11.30 - 12:00	How MVP came to be	Teresa Aguado, Luis Jodar
12:00 - 12.30	MenAfriVac as an example of a successful “push” business strategy to develop a needed vaccine	Marc LaForce
12.30 - 13.00	Discussions on morning presentations	Teresa Aguado, moderator
<i>13.00 - 14.00</i>	<i>Lunch</i>	
14.00 - 14.20	Evolution of conjugation techniques	Carl Frash
14.20 - 14.40	Men A conjugation technology	Robert Lee
14.40 - 15.00	Challenges in scaling up Men A conjugation and purification technology	Suresh Beri, Jayant Joshi
15.00 - 15.20	Fermentation technology	Hitesh Malviya
15.20 - 15.40	Lyophilization and spray-drying stabilization studies	Akshay Goel, Jean-Marie Préaud

15.40 - 16.00 Lessons learned in technology transfer Jean-Marie Préaud

16.00 - 16.30 Coffee/tea break

16:30 - 18:00 Tour of Serum Institute manufacturing facilities SIIL

THURSDAY 11 FEBRUARY 2009

Pharmaceutical Development

09.00 - 09.20 Results of vaccine stability studies K. Suresh

09.20 - 09.40 Characterization of *MenAfrivac* Ian Feavers

09.40 - 10.00 Lessons learned from the MVP/SIIL partnership Suresh Jadhav

10.00 - 10.30 Discussion on pharmaceutical development Subhash Kapre,
moderator

10.30 - 11.00 Coffee/tea break

Clinical Development

11.00 - 11.20 Introduction and historical overview Simonetta Viviani

11.20 - 11.40 Rationale and clinical plan to evaluate *MenAfriVac* Marie-Pierre Preziosi

11.40 - 12.00 Choice of assays Musa Hassan-King

12.00 - 12.40 Correlates of protection, assay development and validation Ray Borrow,
Cheryl Elie,
Margaret Bash
12.40 - 13.00 Discussion Musa Hassan-King,
moderator

13.00 - 14.00 Lunch

14.00 - 15.00 Results of Phase I, II and III studies Urmila Thatte,
Samba Sow,
Adebayo Akinsola,
Aldiouma Diallo,
Siddhivinayak Hirve,
Abraham Hodgson

15.00 - 15.20 Statistical methods YiJia Tang,
Brian Plikhaytis,
Varsha Parulekar

15.20 - 15.40 Capacity building at clinical trial sites Lionel Martellet,
Jacques Hervé,
Véronique Mazarin-
Diop, Manisha Ginde

16.00 - 16.30 Coffee/tea break

16.30 - 16.50 Tetanus control and *MenAfriVac*: a potentially important additional public health benefit Marc LaForce

16.50 - 17.20 Discussion and future plans Prasad Kulkarni,
moderator

FRIDAY 12 FEBRUARY 2009

Regulatory issues, vaccine introduction and impact assessment

9.00 - 9.50	The fight against epidemic meningitis in the African health agenda context: the AFRO perspective	Déo Nshimirimana
9:50 - 10.10	The <i>MenAfriVac</i> regulatory strategy	Graciela Spizzamiglio, Milind Javadekar, Muriel Socquet
10.10 - 10.30	Manufacturing capacity and harmonizing supply and demand	Subash Kapre, Carol Tevi-Benissan
10.30 - 11.00	Vaccine introduction and resource mobilization	Mamoudou Djingarey, Carol Tevi-Benissan
11.00 - 11.30	<i>Coffee/tea break</i>	
11.30 - 11.50	Pharmacovigilance	Katharina Hartmann
11:50 - 12.20	Impact assessment: surveillance and vaccine effectiveness studies	Mamoudou Djingarey, Nancy Messonnier
12.20 - 12.40	Impact assessment: carriage studies	Dominique Caugant, Brian Greenwood
12.40 - 13.00	Communication strategy	Monique Berlier
13.00 - 13.30	Discussion and lessons learned (regulatory, introduction and communication)	Francis Nkrumah, moderator
13.30 - 14.00	Final remarks and closure	Marc LaForce & Cyrus Poonawalla

Meeting Rapporteur: Valentina Picot

Meeting Responsible Officer: Marie-Pierre Préziosi

Administrative Officer: Maggie Ndowa

The workshop is co organized by Fondation Mérieux, PATH
and the World Health Organization.



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