



World Health
Organization

INITIATIVE FOR VACCINE RESEARCH

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, 11 & 12 February 2010

Draft Objectives & Agenda

Preliminary

5th Draft

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Abbreviations and acronyms

AARSH	Agence Africaine de Recherche en Santé Humaine (Senegal)
AHRI	Armauer Hansen Research Institute (Ethiopia)
CVD-Mali	Centre pour le Développement des Vaccins-Mali (Mali)
IRD	Institut de Recherche pour le Développement (Senegal)
iGATE	iGATE Clinical Research International Pvt. Ltd. (India)
IRD	Institut de Recherche pour le Développement (Senegal)
Men	Meningococcal
MRC	Medical Research Council laboratories (The Gambia)
MVL/CDC	Meningitis Vaccine Laboratory, Centers for Disease Control and Prevention (U.S.A.)
MVP	Meningitis Vaccine Project
NIPH	Norwegian Institute of Public Health (Norway)
Nm	<i>Neisseria meningitidis</i>
PAG	Project Advisory Group
PATH	Program for Appropriate Technology in Health
SII	Serum Institute of India Limited (India)
VED/HPA	Vaccine Evaluation Department, Health Protection Agency, Manchester, U.K.
WHO	World Health Organization
WHO CC	World Health Organization Collaborating Centre
WHO/MDSC	World Health Organization Multi-Disease Surveillance Centre (Burkina Faso)

1. Background

Recurrent, severe epidemics of meningococcal disease strike the meningitis belt, an area of Sub-Saharan Africa extending from Senegal to Ethiopia. Annual incidences can reach 1,000/100,000 vs. 1/100,000 in developed countries. Over the last century, Group A meningococcus has remained unique in its ability to cause large epidemics. A vaccine, inducing long-lasting protection and herd immunity, is urgently needed. The Meningitis Vaccine Project (MVP), a partnership between the World Health Organization (WHO) and the Program for Appropriate Technology in Health (PATH), was created through core funding from the Bill and Melinda Gates Foundation to accelerate meningococcal conjugate vaccine development and introduction at an affordable cost for widespread use in Africa. MVP's goal is "to eliminate epidemic meningitis as a public health problem in sub-Saharan Africa through the development, testing, introduction, and widespread use of conjugate meningococcal vaccines" (<http://www.meningvax.org>).

Through innovative partnerships, MVP is developing a Men A conjugate vaccine specifically targeted for the prevention of meningococcal epidemics in sub-Saharan Africa. A consortium of manufacturers was created associating three entities: a company to produce the polysaccharide, a laboratory to develop and transfer the conjugation process, and a manufacturer to produce the vaccine for a target price of \$ 0.40 USD per dose. This new MenA conjugate vaccine, manufactured by Serum Institute of India limited (SIIL) was safe and immunogenic with long lasting immunity when tested in a Phase I study in healthy Indian adults in 2005 - 2006. Clinical studies in Africa began in 2006, initial phase II results showed that the conjugate vaccine elicited bactericidal antibody titres almost 20 fold higher than the current licensed tetravalent polysaccharide vaccine. This high response could be a good predictor of the ability of the conjugate vaccine to induce a long lasting immunity. The results of this phase II clinical study opened the prospect for the phase II/III studies in the older age-group (2 to 29 years of age) of the target population which started mid-2007, as well as for the Phase II study in infants, which are planned to start mid-2008. Licensure is expected to occur in 2009.

This meeting is intended to be a scientific forum to review all salient results from such a unique vaccine development model. Its primary aim is to bring together all partners in the pharmaceutical and clinical development to share results and experiences while building capacity and expertise among Indian and African investigators. It is expected that papers presented at the meeting will result in a journal supplement for publication.

2. Objectives of the meeting

To provide a unique forum for all MVP partners, but specifically African and Indian scientists, involved in the development of the MVP Men A conjugate vaccine:

- To review and discuss salient issues and results from this development;
- To gain knowledge and expertise in the area of vaccine development;
- To identify strengths and weaknesses that could benefit similar projects.

3. Expected outcomes

A. Partners and Expert discussions that will: (1) improve knowledge on MVP development model among participants; (2) foster further interactions and collaborations between all investigators and partners.

B. A compendium of papers presented covering issues and lessons learned in the areas of product development, clinical development, serology, regulatory strategies, partnership building, and vaccine introduction.

4. Preliminary Agenda

Day 1 Business Model & Pharmaceutical Development

Innovative Business Development Model

Vaccine Discovery and Preclinical Development

Vaccine Process Development and Characterization

Capacity-Building Aspects

Tour of the Manufacturing Facilities at SIIL, Pune

Day 2 Clinical Development

Vaccine Clinical Development: Phase I, II and III

Assays Development and Validation, Correlates of Protection

Capacity-Building Aspects

Day 3 Regulatory & Post-Licensure

Vaccine Clinical development: future steps

Regulatory Aspects

Post-Licensure Surveillance and Studies

Carriage studies

Vaccine Introduction Aspects

Action points and closure

