



News digest 21
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Dear partners, friends, and colleagues:

The following is a summary of recent, current, and upcoming activities at the Meningitis Vaccine Project (MVP). We welcome your comments and suggestions at info@meningvax.org and encourage you to forward this update to friends or colleagues who might be interested in learning about MVP's progress.

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Vaccine Development Activities

- Between June 8–10 MVP convened a meeting in the PATH office in Ferney-Voltaire, France, to conduct a formal review of the clinical part of the regulatory file before its submission to the Drugs Controller General of India (DCGI) for Indian licensure. Following this meeting the dossier was finalized and submitted to DCGI on July 6. This completes the initial submission process to the Indian regulatory authorities; some queries can be expected.
- MVP is assisting Serum Institute of India Ltd. with the preparations of the prequalification dossier for submission to the World Health Organization (WHO).

Clinical Activities

- The PsA-TT-001 clinical study in India has officially ended. The official report on this Phase 1 study is part of the regulatory dossier submitted to DCGI.
- The PsA-TT-002 clinical study in Mali and The Gambia has been closed. The clinical study report up to visit 7 was completed and is part of the regulatory dossier. This two-year-long pivotal Phase 2 study looked at safety and immunogenicity of the meningococcal A (MenA) conjugate vaccine in 600 12- to 23-month-olds (the younger age-group targeted by the mass vaccination campaigns).
- The MVP clinical team completed the closeout activities for the PsA-TT-003 clinical study in Mali, Senegal, and The Gambia. PsA-TT-003a clinical study in India has also been closed. Both these Phase 2/3 studies looked at safety and immunogenicity of the MenA conjugate vaccine in the age-groups targeted by the mass vaccination campaigns (2–29 years). The clinical study reports are also part of the regulatory dossier.
- The PsA-TT-004 clinical study at the Navrongo Health Research Centre, Ghana, is going well. So far over 1,100 infants have been enrolled and immunized. Screening and enrollment is proceeding according to timelines and will continue until a total of 1,200 subjects have been recruited. This Phase 2 study evaluates the safety and immunogenicity of three different schedules using the MenA conjugate vaccine in healthy infants.
- Preparations for PsA-TT-005 in India are complete. An investigators' meeting, including a workshop on good clinical practice in clinical trials, took place in Lavasa, India, on May 21–22. PsA-TT-005 is a Phase 3 study that will evaluate the safety and consistency of consecutive lots of the MenA conjugate vaccine administered as a single dose to healthy children ages 5 to 10 years. The MVP clinical team awaits the final study approval from the DCGI to begin the study.
- The draft protocol for PsA-TT-006 has been sent out to reviewers, and their comments have been included in the document. The MVP clinical team is now finalizing the informed consent form for this large Phase 3 safety study that is scheduled to start later this year in Africa.

Surveillance and Epidemic Preparedness Activities

- Between January 1 and June 21, 2009, a total of 78,890 cases and 4,243 deaths from meningitis were reported in the 14 countries under enhanced surveillance. The countries hit hardest were Nigeria (55,739 cases; 2,448 deaths) and Niger (12,629 cases; 510 deaths). Group A *Neisseria meningitidis* was the principal cause of disease in epidemic districts.
- As the 2008–2009 meningitis season winds down in sub-Saharan Africa, Médecins sans Frontières (MSF) reported on the unusual amplitude and duration of the epidemic. In this largest mass vaccination campaign ever organized by the humanitarian organization, MSF and ministries of health from Nigeria, Niger, and Chad deployed up to 400 emergency vaccination teams to vaccinate 7.5 million people in these three countries alone. MSF teams have trained local staff on emergency case management, and tens of thousands of patients have received medical care in West Africa. Stopping the epidemic in the countries mobilized no less than 200 international staff (mostly doctors, nurses, and logisticians), 7,500 local staff, and staff employed at ministries of health, both nationally and locally.
- The WHO Multi-Disease Surveillance Center (MDSC) team in Ouagadougou, Burkina Faso, has been relocated and is now part of the WHO Intercountry Support Team (IST) in Ouagadougou.
- On July 2–4, the IST organized a workshop in Bobo Dioulasso, Burkina Faso, to further plan the new case-based surveillance system. The old system reported *suspected* meningococcal cases, the new system reports *confirmed* cases only, with complete epidemiological and laboratory data.
- A new data management software for epidemiological surveillance and laboratory testing has been installed in five districts in Burkina Faso. The new case-based surveillance system will be piloted in these five districts after the MenA conjugate vaccine (MenAfriVac™) is introduced.
- The IST participated in a RESAO-LAB workshop on June 22–26 in Bamako, Mali. Funded by Fondation Mérieux and the French government development agency Agence Française de Développement, RESAO-LAB is a regional project that seeks to reinforce laboratory capacity in Burkina Faso, Mali, and Senegal through four activities: (a) ongoing training of laboratory staff, (b) strengthening of laboratory quality assurance, (c) enhancing epidemiological surveillance, and (d) creation of a subregional laboratory network.

Vaccine Introduction Strategy and Communication

- MVP and partners are working with the Ministry of Health from Burkina Faso to draw up detailed plans for vaccine introduction in the country. Bearing in mind the timetable for Indian licensure and WHO prequalification, vaccine introduction originally planned for the last quarter of 2009 has now been rescheduled for the first semester of 2010 as a country-wide immunization campaign targeting 1–29 year olds who will receive a single dose of MenAfriVac. A linked safety study will be done by Burkina Faso with the help of WHO and the Agence de Médecine Préventive. Similar introduction strategies for Mali and Niger are being developed for late 2010.

Miscellaneous

MVP is very pleased to welcome Jacques Hervé as the the new Clinical Operations Manager. Jacques has over 13 years of experience working in clinical trials. Most recently he worked for ORION Clinical Services managing their office in Melbourne, Australia. Jacques started his work on July 5 setting off with Dr. Préziosi on a visit to the PsA-TT-004 clinical study site at the Navrongo Health Research Centre, Ghana.

That's all for now from the MVP team. Stay tuned for our next news digest in three months' time.

We look forward to receiving your comments at info@meningvax.org.

Created in 2001, the Meningitis Vaccine Project is a partnership between WHO and PATH. The mission of MVP 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.

For more information on MVP, please visit our website at <http://www.meningvax.org>.