

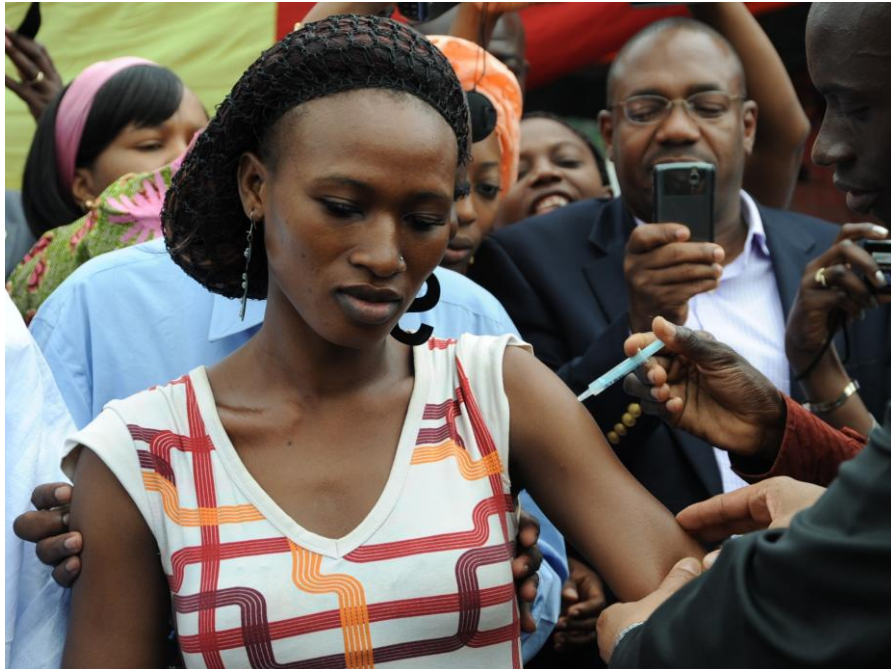
Dear partners, friends, and colleagues:

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 Introduction and Communication Activities

- District-level introduction of MenAfriVac™, the meningococcal A (MenA) conjugate vaccine developed through the MVP, took place in September in Burkina Faso, Niger, and Mali, with the last being the first African country to introduce the vaccine, on September 13, in the districts of Fana and Dioïla. In the picture below, principal investigator Professor Samba Sow from Center for Vaccine Development (CVD)-Mali—a site that hosted several MVP clinical studies—trades his stethoscope for a phone camera to document a moment that CVD staff have been waiting for since the start of the Phase 2 study in 2006: the administration of MenAfriVac™ outside a clinical trial environment.



By the end of September 1,042,514 people in Mali, Burkina Faso (Kaya district), and Niger (Filingué district) had been immunized with MenAfriVac™, with provisional vaccine coverage rates reaching respectively 98%, 98.63%, and 86%. Mop-up vaccination will continue until vaccine coverage nears 100% in all three countries. In each country, people queued patiently, sometimes under heavy rain, to have their children vaccinated or be vaccinated themselves.

Overall these vaccination campaigns went very well. Lessons learned from these district-level immunization campaigns will be critical for implementing country-wide introduction of the vaccine in these three countries in December of this year. Pharmacovigilance conducted thus far in the

vaccinated districts continues to indicate that MenAfriVac™ is a very safe vaccine. All safety-related data will be reviewed by national committees and by a World Health Organization (WHO) Global Advisory Committee on Vaccine Safety.

- The WHO Inter Country Support Team (IST) in Ouagadougou, Burkina Faso, started issuing a richly illustrated weekly bulletin on the introduction of MenAfriVac™ in Africa. *MenAfriVac Hebdo* summarizes vaccine introduction activities in Burkina Faso, Mali, and Niger with regard to logistics and cold chain, waste disposal, communication and social mobilization, and case-based surveillance. Of particular note is the impressive number of partnerships established in the field among a variety of stakeholders, including WHO and UNICEF, ministries of health, national introduction committees, community leaders, traditional communicators, and the populations themselves. View [MenAfriVac Hebdo](#) on the MVP website (in French).
- The official country-wide launch of MenAfriVac™ will take place in Ouagadougou, Burkina Faso, in early December. Preparations are ongoing to make this event a memorable one not only for the populations who will benefit from the vaccine, but also for organizations that have been instrumental in developing MenAfriVac™. The launch will be the start of mass vaccination campaigns in Burkina Faso, Mali, and Niger that will continue into 2011 and aim to protect 33 million 1- to 29-year-olds from group A meningococcal meningitis.

Vaccine Development Activities

- Serum Institute of India Ltd. (SIIL) completed vaccine production for the first mass campaigns in Africa.

Clinical Activities

- The Phase 1 [PsA-TT-001](#) clinical study in India has officially ended.
- The Phase 2 [PsA-TT-002](#) clinical study in Mali and the Gambia has officially ended.
- The Phase 2/3 [PsA-TT-003](#) clinical study in Mali, Senegal, and the Gambia, and the Phase 2/3 [PsA-TT-003a](#) clinical study in India have officially ended.
- The clinical team is working on the database lock for the dose-ranging component of [PsA-TT-004](#)—a Phase 2 study that evaluates the safety and immunogenicity of different dosages and schedules of the MenA conjugate vaccine in 1,200 healthy infants when administered concomitantly with EPI vaccines. PsA-TT-004 is conducted at the Navrongo Health Research Centre in Ghana.
- The clinical team is also working on the database lock of [PsA-TT-005](#)—a Phase 3 study that evaluates the consistency of consecutive lots of MenA conjugate vaccine administered as a single dose to 830 healthy Indian children ages 5 to 10 years. This trial is taking place at Vadu's Shirdi Sai Baba Rural Hospital, a rural division of the King Edward Memorial Hospital in Pune.
- The Phase 3 [PsA-TT-006](#) clinical study conducted at CVD-Mali in Bamako is proceeding well and according to schedule. Over 5,500 subjects had been enrolled by the end of September, and the total number of enrolment of 6,000 is likely to be achieved by the end of October. The study looks at potential rare side effects related to the administration of one dose of the MenA conjugate vaccine in healthy subjects aged between 1 and 29 years. Like in all other MVP clinical studies conducted since 2005, no safety concerns have been identified thus far.

Surveillance and Epidemic Preparedness Activities

- The WHO/IST reports 23,241 suspected cases of meningitis so far this year in the 14 countries under enhanced meningitis surveillance. Burkina Faso is the hardest-hit country with 6,307 cases and 865 deaths (case-fatality rate: 14 %).
- Over the course of the summer, the WHO/IST continued to provide training on case-based surveillance to personnel in Burkina Faso, Mali, and Niger.

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>.