Advancing meningitis research worldwide



MVP Access Program open to researchers

History

Until recently, more than 80 percent of sub-Saharan Africa's epidemic meningitis cases were caused by *Neisseria meningitidis* group A, a highly transmissible bacterial form of the disease that mainly affects infants, children, and young adults, and is also a cause of life-threatening bloodstream infections. After a particularly devastating group A meningococcal meningitis epidemic in 1996-1997 sickened more than 250,000 people and killed more than 25,000, the World Health Organization and PATH launched the Meningitis Vaccine Project (MVP), an initiative dedicated to developing a low-cost vaccine that would permanently end group A meningococcal meningitis epidemics in Africa.

In 2003, MVP enlisted Serum Institute of India Pvt. Ltd. (SIIPL) to develop a group A meningococcal meningitis conjugate vaccine. Known as MenAfriVac®, the vaccine was subsequently manufactured, tested, licensed, and introduced in people 1 to 29 years of age across the meningitis belt (an area that stretches across 26 countries from Senegal in the west to Ethiopia in the east, and has an at-risk population of 430 million). Since 2010, the vaccine has been delivered to more than 270 million people, virtually eliminating group A meningococcal meningitis wherever it's been used.

The MVP Access Program

The impact of MenAfriVac® continues. During the clinical trials for MenAfriVac® licensure and pre-qualification, more than 70,000 vials of frozen serum were collected from 11,100 volunteers of all ages. Having generated key evidence to support the development of MenAfrivac®, these specimens and their associated clinical data have the potential to contribute even more to public health. In 2008 the MVP team established a biobank at the University of Siena in Italy to store the specimens. To facilitate researcher access to these samples, PATH and SIIPL established the MVP Access Program. Launched in 2016, the MVP Access Program provides researchers conducting studies related to meningococcal disease and other vaccine-preventable diseases access to the MenAfriVac® clinical study serum collection and data sets.

Clinical data sets include anonymized records of demographic information, physical examinations, concomitant medications, medical histories, and immunogenicity results for



Data and frozen serum samples from the MenAfriVac® clinical trials are available for use for researchers working on vaccine-preventable diseases. Photo: PATH/Lionel Martellet

MenAfriVac® and other vaccines given throughout the course of the studies.

All serum samples stored in the biobank were collected between 2006 and 2013 at the following locations:

- Centre pour les vaccins en développement, Bamako, Mali (CVD-Mali)
- Medical Research Council, Basse, The Gambia (MRC-LSHTM)
- Institut de recherché pour les développement, Niakhar, Senegal (IRD)
- Navrongo Health Research Centre, Navrongo, Ghana (NHRC)

Fostering Research

By providing external researchers and qualified investigators with access to sera and data, the MVP Access Program offers them an opportunity to perform invaluable research in the interest of public health.

In 2017, more than 2,000 samples were shared with researchers from diverse institutions and research areas. With numerous proposals submitted to the program, the biobank has proven its unique worth in assisting researchers with global health concerns.

Accessing the biobank

When qualified project proposals come in, a small team at PATH works with the researchers to help them gain access. This ranges from supporting initial proposal development, establishing collaborations among requestors, confirming sample availability, obtaining ethics committee approvals, and coordinating transfer of requested samples.

Specimen extractions and shipments are handled by a small, dedicated team at the University of Siena.

Requested data sets are prepared by PATH's biostatistician.

Submitting a proposal

Researchers studying vaccine-preventable diseases can submit proposals for access to the MVP sera and/or data, provided that:

- The proposed research is in the public health interest and does not include genetic research; and
- Researchers agree to comply with the laws, regulations, research standards, and ethical standards governing the MVP clinical study protocols and informed consents.

Currently, both the sera and the clinical trial data sets are jointly owned by PATH and SIIPL. Research requests undergo a joint scientific review by qualified representatives from PATH.

To find out more about the available data and sera, including how to submit a proposal, please contact us at: meningitisresearch@path.org.

To learn more about the MVP Access Program, and see a list of approved research proposals, please visit: https://www.path.org/programs/center-for-vaccine-innovation-and-access/advancing-meningitis-research/.

