GPP Case Study
MTN-017: Global civil society consultations

November 2012

MTN-017 is a Phase II rectal safety and adherence study of a reformulated version of tenofovir gel and oral Truvada®. It includes approximately 186 men who have sex with men (MSM) and transgender women (TG) in the U.S., Peru, South Africa and Thailand. It is sponsored and coordinated by the Microbicide Trials Network (MTN).

MTN-017, although not yet looking for efficacy, is a ground-breaking study in a number of ways. The first Phase II study of a rectal microbicide, it is designed to give an indication of whether the product can be moved forward into an efficacy study. Rectal microbicide research is further behind in the pipeline of HIV-prevention research than other modalities, but is extremely important because a large proportion of HIV transmission occurs through unprotected anal sex. Additionally, MTN-017 will be the first rectal microbicide trial outside the U.S. The trial will involve sensitive issues that many people are uncomfortable or not used to discussing. Participants in the trial will need to undergo rectal exams, and some will undergo biopsies. Finally, populations that are highly stigmatized and vulnerable to HIV infection are being sought for participation. Click here for a backgrounder on the trial and key issues.

As part of protocol development, the MTN, partnering with trial sites and advocacy organizations (including AVAC), undertook a series of civil society consultations at planned trial sites. Consultations took place in Cape Town, South Africa, in October 2011; Pittsburgh, Pennsylvania, in December 2011; Bangkok and Chiang Mai, Thailand, in January 2012; and Lima, Peru, in March 2012.

At the time of the Thai consultations, investigators were still questioning whether to enrol TG women in addition to MSM. Researchers were uncertain whether to focus on TG women, given their status as a highly stigmatized group, which could hinder recruitment and retention in the study. Civil society and other community representatives at both Thai consultations, however, advocated strongly for their inclusion. The Thai community members informed the researchers that, in Thai society, there is a great deal of fluidity between sexes; that is, some MSM may become TG women, even during the course of the trial. Similarly, some individuals who identify as TG women may not have had gender-reassignment surgery. They assured investigators that recruiting and retaining TG in the trial would not be prohibitively challenging, and that many TG women would most likely be willing to participate. Investigators listened and agreed to include TG women in the protocol.

This case shows the importance of the research team obtaining the unique insight of the community about social norms, practices, and perceptions to develop the protocol in a thoughtful way and, in the process, enhancing the efficiency of the overall trial.

It also highlights how research networks can embrace and implement GPP. Especially in the case of efficacy or larger-scale studies that involve multiple sites, protocols are most often developed at network or sponsor level, and are received at trial sites in final form. No matter where a protocol is developed, it is the responsibility of the research group to consider and facilitate stakeholder input, whether it is on the entire trial design and protocol, or on key aspects. The case of MTN-017 provides an exemplary model for stakeholder engagement in protocol development.