



29 January 2016

Dear People,

We have several important messages to communicate to you regarding The AMP Study.

1. We have administratively separated The AMP Study into two regionally separate but otherwise comparable protocol versions. The MSM+TG protocol in the Americas is now called HVTN 704/HPTN 085. The sub-Saharan Africa women's protocol retains the original protocol number, HVTN 703/HPTN 081. There are no planned changes to the Protocol Team memberships or to the trial designs, and the two cohorts will be analyzed both separately and together, as in the original plan.
2. The South African Medicines Control Council (MCC) approved HVTN 703/HPTN 081 and upon completion of site training we will open in South Africa, likely in mid-April.
3. The North and South America MSM+TG protocol is under review by the FDA. We are submitting the revised version (HVTN 704/HPTN 085) to the Lead IRB as a modification to the original protocol. This series of events should allow us to open HVTN 704/HPTN 085 in mid-March pending any unexpected comments from the FDA. As we have had a recent face to face briefing with the FDA about the study, we are optimistic that these timelines will be firm.

Bottom line: get ready, all looks like a go.

There are, as always, some details to discuss so here goes:

**The HVTN 704/HPTN 085 AMP Study** mirrors the Americas portion of HVTN 703/HPTN 081 with few changes. Thus, the training that US sites received in November 2015 is still fully applicable, and we will be in touch with you soon regarding web-based refresher training that we will offer US sites in the coming weeks. Regulatory and operational staff from each Network will also be in touch with AMP North and South American sites regarding regulatory review processes and timelines for moving from HVTN 703/HPTN 081 to HVTN 704/HPTN 085.

**The HVTN 703/HPTN 081 AMP Study** will open in sub-Saharan Africa under version 1, which was approved by the MCC and is under review in other AMP sub-Saharan African countries. We are planning the first sub-Saharan Africa HVTN 703/ HPTN 081 protocol-specific training in early April. AMP





operational staff will be in touch with you very soon with more detail on that training. Later in 2016 we will distribute a full protocol amendment to AMP sub-Saharan Africa sites, removing the MSM+TG cohort from HVTN 703/HPTN 081. We do not anticipate substantive changes to the trial design in version 2. Regulatory and operational staff from each Network will be in touch with AMP sub-Saharan Africa sites regarding specific regulatory review processes and timelines for versions 1 and 2.

**Thank you.** We appreciate your patience and your tremendous effort to prepare for AMP study opening at your site. We look forward to the first AMP participants' enrollment in the HVTN 704/HPTN 085 and HVTN 703/HPTN 081 AMP studies in just a few months.

Best regards,

Larry Corey, Mike Cohen, & Shelly Karuna

***Contact information for any questions:***

- Kathy Hinson (KHinson@fhi360.org) if you are from an HPTN AMP site and have questions about fiscal matters.
- Kimberly Hitchcock (khitchco@fredhutch.org) if you are from an HVTN AMP site and have questions about fiscal matters.
- Gail Broder (gbroder@fredhutch.org) and Jonathan Lucas (jlucas@fhi360.org) if you are from any AMP site and have questions about community engagement.
- Rachael McClennen and Meg Brandon (vtn.core.reg@hvttn.org) if you are from any AMP site with questions about regulatory review processes and timelines.
- Phil Andrew, Liz Greene, and Carissa Karg (VTN703.PTN081.CTM.CRM@hvttn.org) if you are from any AMP site with questions about other implementation preparation impacts.

