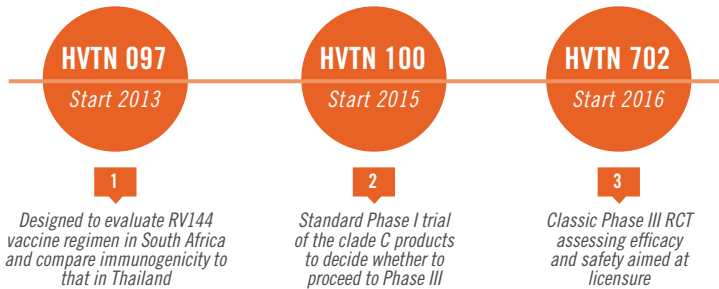


An Advocate's Guide to Tracking the P5 Development Tracks

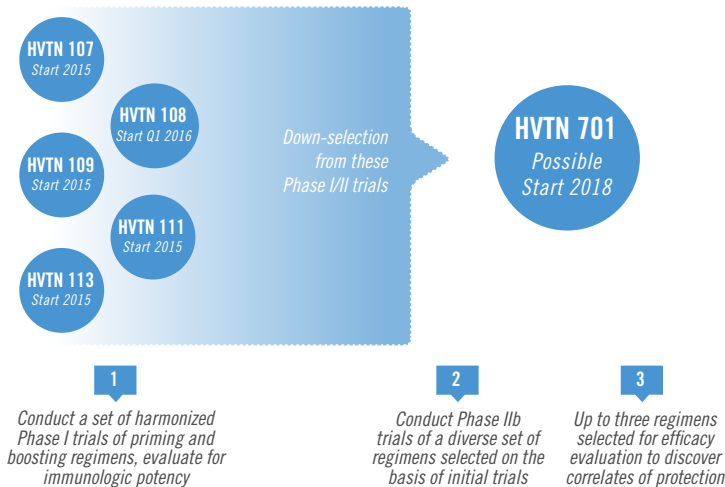
Strategy for the Development Track



What's a development track?

This refers to a series of trials that are designed, as a whole, to lead to a product submitted for regulatory approval and eventual public health introduction. The trial designs—from numbers of participants, to the types of data collected—are set with the ultimate licensure goal in mind. Of course, licensure depends on evidence of efficacy from the Phase III trial.

Strategy for the Research Track



What's a research track?

The term research track is being used to refer to a series of trials designed to add to scientific information about components of an effective vaccine strategy. The trials are designed to identify potent regimens but not to bring any specific regimen to market. An immune correlate is a vaccine-induced immune response such as an antibody or specific type of T cell that is linked to protection from HIV. Finding an immune correlate for an AIDS vaccine could guide strategies to improve this protection. Finding a correlate could also help shorten trials, bring down costs and guide regulatory and policy decisions in the future.

What's the difference?

The P5 development and research track trials will take place in many of the same countries and communities. Both tracks will test regimens that might turn out to reduce the risk of HIV infection. The development track trials follow a traditional design. The research track is more flexible or “adaptive”; one regimen might be ruled out sooner than other regimens, and participants may be moved from one trial arm to another. One track is focused on developing a product that could be licensed when the trials are completed. The other aims to advance science—and might have valuable information about how to build an even better vaccine than the one in the licensure track.

There are many questions for advocates to consider as trials on both tracks advance: whether participants in both research tracks would get early access to any product that proved effective; how funding will be allocated across the tracks and what will happen if there is a budgetary shortfall; and what this work, based in southern Africa, means for other regions of the continent and the world.