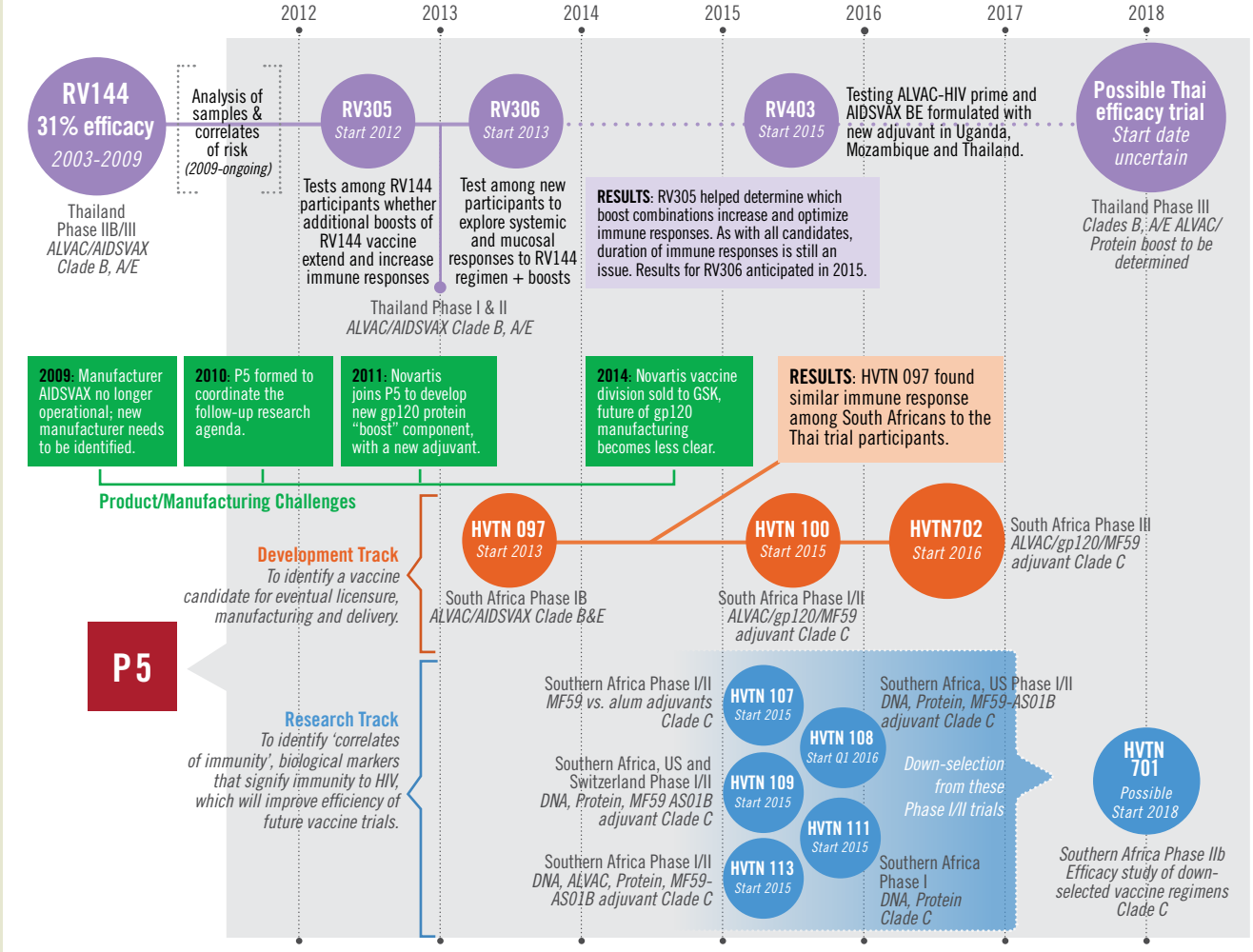
Intervention Update

What's Next for AIDS Vaccines and the Pox-Protein Public-Private Partnership?

It's been more than five years since the news broke that the Thai trial known as RV144 had found evidence of efficacy. RV144 tested a vaccine strategy that used a poxvirus-vectored vaccine to "prime" the immune system, and a different, protein vaccine to "boost" it. The overall protection was modest, but the implications were not. RV144 was the first proof-of-concept that an AIDS vaccine could reduce risk of HIV acquisition in humans. As such, it demanded follow-up. While there has indeed been a lot of work and significant scientific analysis over the past five years, the progress to launch additional trials in humans has been slow (see *www.avac.org/vaccines* for background). But activity is finally starting to ramp up in Southern Africa. Figuring out what's happening where, when and why isn't easy. These two graphics are designed to help.

What's Next for the Pox-Protein Public-Private Partnership (P5)?

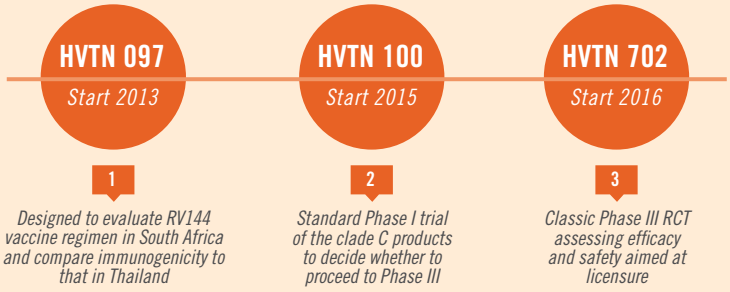


For up-to-date information on the vaccine pipeline, visit the HIV Prevention Research Database at *www.avac.org/pxrd*.

To understand the research that's emerged from RV144, you need to have a two-track mind. Most vaccines and indeed most products are developed via a suite of trials designed to bring a product to licensure. That's one track of post-RV144 research. The other track has a set of scientific questions that it seeks to answer. Both are going forward in the many of the same places, so it's especially important for advocates to begin to track the tracks.

An Advocate's Guide to Tracking the P5 Development Tracks

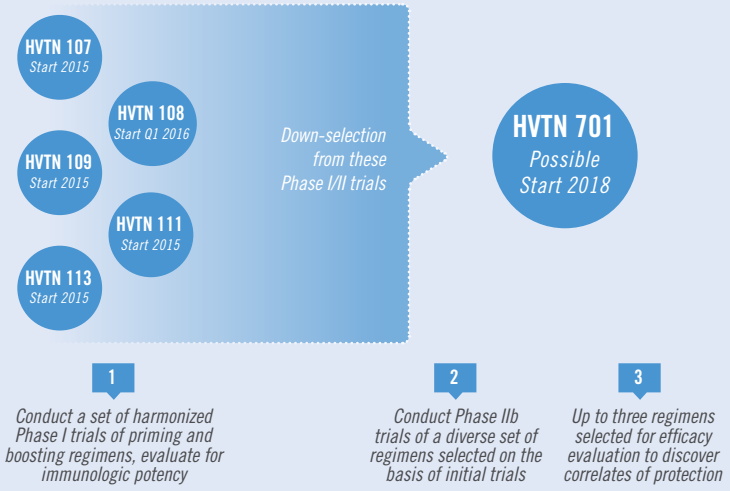
Strategy for the Development Track



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.