

RV144 Follow-on Trials: Lagging timelines

The next scheduled efficacy trials in the AIDS vaccine field are meant to build on the results of the Thai RV144 trial that showed modest efficacy in 2009. As one next step, a consortium known as the Pox-Protein Public-Private Partnership (P5) was formed to move an RV144-like vaccine strategy into additional trials in Southern Africa and Thailand.

While there is now clarity, particularly about the regimens that will be evaluated in Southern Africa, the timelines for trial launch continue to be pushed back. It has taken longer than expected to select and manufacture the protein boost that will be used in the trials. Novartis, the P5 partner developing the boost, has finally begun manufacture of the clade C boost for the South African licensure trial, which is scheduled to begin in 2016.

A proposed Southern African “correlates” clinical study will gather information on other RV144-like vaccines, but is not designed to lead to licensure. There are still questions about when the Thai trial might begin, since the clade B/E boost that would be used in that trial hasn’t been finalized. As the Thai trial timeline slips, there is discussion about whether an additional industry partner should step in to work on a different protein boost.

Regarding these delays, some stakeholders say that the science of developing and manufacturing a new candidate can’t be rushed; others argue that industry hasn’t treated the project with sufficient urgency. The truth almost certainly lies somewhere in between.

AVAC thinks it is useful to look at the current coordinating structures and make sure that they are still adding efficiency. Is there a different approach to coordination that could allow the Southern African and Thai trials to proceed more quickly? We also look for the current timelines to hold. RV144 provided the proof of concept that an HIV vaccine is, in fact, possible. However, the continued delays in launching trials designed to build on this result make it harder to maintain the optimism.