

Explaining STEP Study Results to your Community

- On September 21, 2007, Merck & Co. Inc., the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, and the NIAID-funded HIV Vaccine Trials Network (HVTN) announced vaccinations and enrollment in the HIV vaccine clinical trial known as the STEP study (one of two phase II trials) had been discontinued.
- Although the results were disappointing, the STEP trial itself was successful, since it asked valid scientific questions about the potential efficacy of one vaccine candidate and answered those questions as quickly, efficiently, and safely as possible. Thanks to the participants and study staff, retention rates and adherence were at the highest levels of trial conduct.

Why the study was discontinued

- The Merck HIV vaccine candidate was not effective at preventing infection in participants not previously infected with HIV, or at lowering the amount of HIV in the body of those who became infected with HIV during the study.

Current Data Analyses from the STEP study

- Volunteers were recruited for this trial with both high and low levels of pre-existing immunity to adenovirus (a common cold virus). This is important because a disabled adenovirus was used as a carrier for synthetic HIV genes in the vaccine.
- Particularly among participants with a higher pre-existing level of immunity to adenovirus, there were more infections in those who received the vaccine than in those who received the placebo. The reasons for the increased number of infections among those who received the vaccine are still not known. The causes could be biological, behavioral or simply chance.
- The data are complex and answers to these questions may require months and possibly years of further research.
- The possibility of greatest concern is that those who received the vaccine might have an increased susceptibility to acquiring HIV infection. The safety of the study participants has been and continues to be the top priority. Participants have been informed of the findings and counseled on the need to avoid exposure to HIV. Investigators are working to ensure that all who became infected with HIV during the study are being provided with appropriate care and treatment.

Did the vaccine cause HIV?

- The participants did not get HIV from the vaccine.
- It is currently unknown whether the vaccine caused increased susceptibility to HIV infection among the participants.

Unanswered Questions

- Further data collection and analysis could help scientists understand:
 - why more infections occurred among the volunteers who received the vaccine candidate versus the placebo ,
 - whether variation in the HIV virus contributed to the failure of the HIV vaccine candidate, and
 - what association exists (if any) between the participants pre-existing immunity to the adenovirus and the body's response to the HIV vaccine candidate.

What will happen next?

- All study participants are asked to return to the clinical trial sites for ongoing counseling and protocol-specified visits.
- Community representatives and clinical investigators are involved in ongoing discussions this week about the continued follow-up that will occur with the STEP study volunteers.
- In consultation with community representatives, a decision will be made within a few days as to when the STEP trial participants will be told whether they received the vaccine or placebo. Participants can be unblinded upon request.
- Further analyses are being conducted and the trial partners will share additional results as they become available with the broader scientific community. A presentation is currently scheduled at the Conference on Retroviruses and Opportunistic Infections in Boston in February 2008.

HIV vaccine research must continue.

- Every day, another 12,000 people become infected with HIV with an estimated 4.3 million new HIV infections occurring worldwide in 2006.
- Our best hope for a long-term solution is an HIV vaccine.
- The failure of one vaccine candidate does not mean the search is over. Our world's best researchers and scientists remain committed to the discovery of a successful vaccine.