

Sample Questions to Include in an Internal Q&A for Trial Results, Based on Three Outcome Scenarios

Below are examples of questions that might be included in an internal Q&A, for each of three possible outcome scenarios. Preparing answers for these questions allows you to think through in advance how to respond to challenging questions.

Positive effect

- When did researchers first observe positive results (such as a protective effect) with use of this product, and why did they not immediately halt the study and begin making it available to all of the study participants?
- Are you now providing all study participants with the product at no cost? If not, when?
- How can you be sure that your results are accurate, especially since they contradict the results of a similar study completed earlier by another research group?
- Is this study conclusive or are more studies needed to confirm the results?
- What are you doing to help the participants who may have acquired HIV during their participation in this study?
- Now that you have positive results, what are you doing to ensure that public health authorities can quickly begin to develop policies and implement strategies that support widespread distribution and use of the product?
- Can enough of the product be manufactured fast enough to meet the demand?
- What are you doing to ensure that persons who can benefit from use of the product have easy access to it free or at low cost?

Minimal or no effect

- Why did researchers continue this study after results from a similar study showed that the use of the product did not reduce the risk of someone becoming infected with HIV?
- Given that a higher dose of the product might have reduced the risk of participants becoming infected with HIV, are you going to provide them with a free supply of the appropriate dose?
- What are you doing to help the participants who may have acquired HIV because of their participation in this study?
- Why should donors continue to fund studies of products that do not work?
- What more must researchers do to ensure that all studies are well designed and no study becomes a missed opportunity to prevent the spread of HIV?
- What impact do you think the failure of these studies to find effectiveness will have on how public and private donors evaluate research proposals?

Negative effect

- When did researchers first observe negative results and why did they not immediately halt the study to protect study participants?
- What are you doing to get the word out about these findings and prevent harm to all persons taking this product who may be at risk of becoming infected with HIV?
- What caused the negative results?
- If you do not know definitively what caused the negative results, what are you doing to find out?
- What are you doing to help the participants who may have acquired HIV because of their participation in this study?
- Are there other studies under way of use of this product for HIV prevention that should be halted?
- Who is to blame for what happened?
- Why was this study conducted on humans in the first place? Why in developing countries?
- Why should donors continue to fund HIV prevention studies?
- How can you expect anyone to participate in HIV prevention studies if they know that such participation may harm them?
- Are these negative trial outcomes having a negative impact on recruitment for HIV prevention studies?
- Why did you do this study here and harm our people?
- Did you have any indications from other research that the product is harmful?