cbas Fact Sheet

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Frequently Asked Questions *about* Clinical Trials of HIV/STI Prevention Methods

In the U.S., every new health technology or treatment has to pass through a series of rigorous tests before it can be approved by regulatory authorities and made available for widespread use.

About CBAS

The Cervical Barrier Advancement Society (CBAS) aims to raise the profile of cervical barrier methods both for preventing pregnancy and potentially HIV and other sexually transmitted infections.

CBAS membership is free and open to all who are interested in joining. Sign up on the CBAS website.

www.cervicalbarriers.org

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What is the clinical trial process?

Tests on HIV/STI prevention methods begin in the laboratory, where researchers determine whether a treatment prevents HIV and STI infection, first in test tubes, and then in animals. If the data from these trials show that the product is 1) effective against pathogens and 2) safe (non-irritating), then clinical (human) trials can begin.

What are the different phases of clinical trials?

Clinical trials are traditionally divided into different phases. Each phase is designed to gather specific information about the treatment (prevention method, drug, or device) being studied.

- **Phase I trials**: These trials are the first human tests of new treatments. They typically involve small numbers of healthy participants and are designed to check for any side effects.
- **Phase II trials**: If a treatment is shown to be safe and well tolerated in Phase I, it moves on to Phase II trials. These trials involve many more volunteers and are designed to study safety in an expanded population and to explore acceptability of the treatment.
- **Phase III trials**: If the treatment is safe and acceptable in Phase II trials, it moves on to Phase III trials. Hundreds or even thousands of people may participate in these studies. They are aimed at testing how well the treatment works. Many Phase III trials compare the new treatment to an existing standard treatment.
- **Phase IV trials**: Once a treatment has been approved by a regulatory authority and is available on the market, Phase IV trials can begin. Phase IV trials typically involve a very large number of participants and are designed to evaluate real world use of the treatment or to detect rare side effects that were not documented during Phase III studies.

	Number of Participants	Length	Purpose
Phase I	20-100	Several months	Safety
Phase II	~200	6 months – 1 year	Expanded safety and acceptability
Phase III	3000-5000	1 – 4 years	Effectiveness
Phase IV	3000-5000	1 – 4 years	After approval, real world use or rare side effects

How are clinical trials conducted?

The doctors and researchers running a clinical trial develop a written plan detailing exactly how the trial will be conducted. This plan, also called a protocol, explains how the trial will be managed, what information will be gathered, and what new things the researchers hope to learn.

Many clinical trials compare a new treatment to a standard treatment. In these trials, participants are divided into two groups. One group receives the new treatment and the other group (the "control" group) receives the standard treatment. Information is gathered from participants, and researchers compare how well each group responds to the two kinds of treatment to see if the new treatment is safe, acceptable and effective.

In order to prevent biased results or interpretation, many trials assign participants by chance to one of these two groups. This process, known as randomization, is used to make sure the study participants in the two groups are similar, so that any differences in study findings can be attributed to the treatment being tested.