

HOW ARE MICROBICIDES TESTED?



1

Research idea

A scientist has an idea for a product that can prevent HIV.



2

Preclinical studies

The product is developed and first tested in a laboratory (and in animals) for safety and other information. These are called preclinical studies.



3

Clinical studies

After preclinical testing, the product is tested in humans in a process called clinical testing or clinical trials.

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THERE ARE TYPICALLY THREE PHASES OF CLINICAL TESTING:

Phase I

These are small safety trials in people to make sure the product does not cause harm. Safety trials take place over several days or weeks.



Tens

of participants over several days or weeks

Phase II

Phase II trials are tests for additional safety in people. These trials take place over a longer period of time and involve hundreds of volunteers.



Hundreds

of participants involved over several months or years

Phase III

Phase III (or efficacy) trials involve thousands of people in countries where there are high rates of new HIV infections. These trials determine whether or not the microbicide actually works to prevent HIV infection.

Thousands

of participants involved over several years



Once a microbicide has been shown to be safe, effective and acceptable to those who will use it, regulatory authorities in each country must approve the microbicide before it can be made available within that country.

WHY ARE MICROBICIDES IMPORTANT?

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- They offer hope of a new way to prevent HIV
- Would allow women to protect their own health
- Could save millions of women's lives: mothers, daughters, wives and sisters.

HOW CAN MEN GET INVOLVED?

Men play an important role in supporting the health of women they care about, by helping to protect them from HIV and by supporting their participation in clinical trials.



HOPE AGAINST HIV

- Clinical research is a long process. While medical products take years to develop, there is now new hope for HIV prevention: microbicides
- Research has shown that ARV-based microbicides products may reduce the risk of HIV in women. Scientists are conducting trials to see if gels used around the time of sex or other ARV-based microbicide products, like vaginal rings that could offer protection for a month or longer, can work to prevent HIV in women.
- When successful clinical trial results are confirmed and a microbicide is approved, millions of people could benefit, especially the women most in need of protection.

HOPE AGAINST HIV

Giving Women New Hope and Choice in HIV Prevention



Microbicides