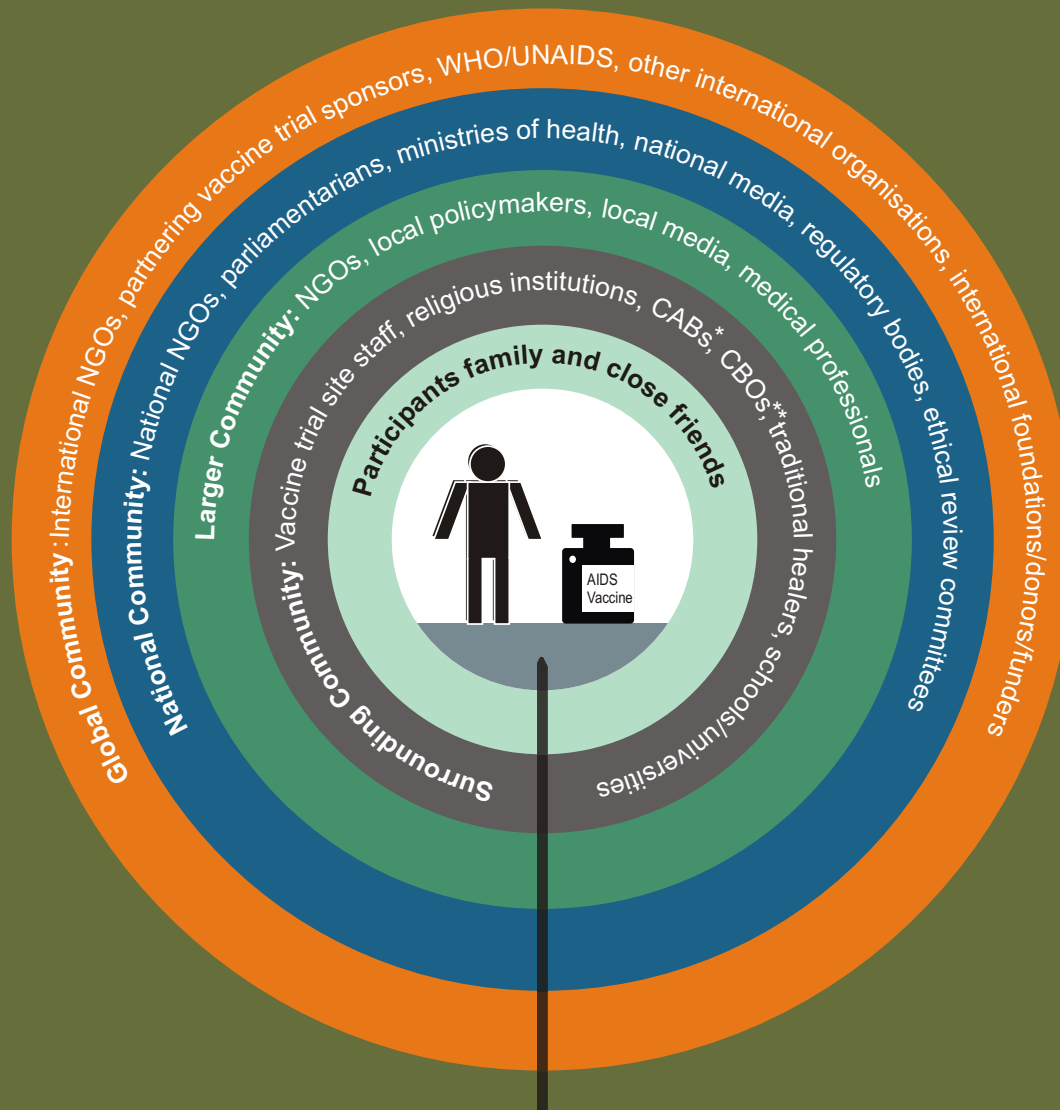


The following diagram illustrates the different communities that surround an AIDS vaccine trial participant, starting from the closest layer (a participant's family and close friends) to the broadest layer (the global/international level), the diagram shows that there is a vast range of external influences on one individual trial participant. Note that these are external influences, and the diagram is not meant to imply that each of these 'communities' is aware of the individual's trial participation.



**Trial participant**

\*CABs: Community Advisory Boards

\*\*CBOs: Community Based Organisations

Source: AIDS Vaccine Literacy Toolkit, IAVI



**FAQs about  
Participation in a clinical trial**

# Participation in a clinical trial

## Who can participate in these Phase I trials being conducted in India?

Individuals can participate in a Phase I clinical trial if they are

- men or women between 18-50 years of age
- in good health
- HIV-uninfected
- persons who stand a very low chance of contracting HIV
- residents of India and are planning to live close to the trial site for the entire duration of the Phase I trial
- able to understand the process of the trial and give their signed informed consent to participate
- willing to come for all scheduled visits for clinical examination and blood draws. These visits are designed to intensively monitor the effects of the vaccine.

Women who are pregnant, lactating or planning to become pregnant within four months after the last vaccination has been administered for the trial do not qualify to participate in these Phase I clinical trials.

It is important for women to be involved in AIDS vaccine trials to detect trends in the effect of the vaccine on men and women.

## Why is it important to ensure equitable numbers of women and men are enrolled in trials?

- Equitable numbers of women and men should ideally be enrolled in trials to determine whether a vaccine has the same efficacy and/or side effects in women and men;
- A vaccine must be tested in sufficient numbers of women and men to ensure licensure;
- Principles of health equity require that both women and men have access to the benefits of participation, i.e., education, counselling and care.

AIDS vaccines are one method among a range of technologies that have the potential to meet women's HIV prevention needs and offer women real choices.

## Is the decision to participate entirely voluntary?

Yes. Participation in a trial is an entirely voluntary process. It is an individual's free decision to accept or refuse to participate without any influence or pressure. Before a person agrees to volunteer, s/he must understand the purpose of the trial and the potential risks and benefits of

participating in the trial. The counsellors will provide the individual with all the information and will attempt to explain all legal, ethical and medical issues of his/her participation in a user-friendly way.

All the information that will be provided is designed to empower the individual to make a free, intelligent choice of whether s/he wants to participate in the trial or not. Only after the person has understood the process and has passed the **test of understanding**, will s/he be asked to provide written consent. This procedure is known as **informed consent** and no clinical procedures will be carried out as part of the trial without an individual's informed consent.

AIDS vaccines are one method among a range of technologies that have the potential to meet women's HIV prevention needs and offer women real choices.

## Can a person decide to leave the trial after giving his/her consent to participate?

Although the researchers have a person's informed consent, the individual is free to leave the trial at any stage without having to explain the reasons. It is also the individual's right to ask for any information s/he may require at any time

during the clinical trial. However, the person will only be told whether s/he received the vaccine or placebo (see FAQ below) at the end of the trial

## Will all participants in a Phase I clinical trial receive the vaccine?

All participants in a Phase I clinical trial will not receive the vaccine. Some participants will receive an inactive and harmless substance called a **placebo**. This is typical to any research design where scientists need to be able to differentiate between effects related to the vaccine and those due to other, extraneous factors.

The assignment to receive the vaccine or placebo is made by a computer in order to avoid any bias in judgment. This procedure is called '**randomisation**'. It is very useful because it helps the research team compare the vaccine group and the placebo group to find out whether a potential side effect is caused by the vaccine or not and to evaluate the immune response of trial participants without any bias in the interpretation of the results. Neither the trial team nor the volunteer will know whether the vaccine or placebo has been administered. Since both parties are 'blind' to this information, it is called a '**double-blind**' study. The blinding is maintained until the end of the trial.

# Participation in a clinical trial

## Who will be informed about volunteers' participation in these trials?

Other than the research team, nobody will be informed about volunteers' participation in the trials. At the time of seeking consent, they will be assured of complete privacy and confidentiality. The entire team is bound to keep all medical information collected from participants confidential. This means that a volunteer's identity will never be disclosed and his/her records will only have a code number without the name. However, it is entirely up to the person whether s/he wants to inform anybody about his/her decision to participate in the trial.

## Can this vaccine cause HIV infection or AIDS?

There is no risk at all of getting infected with HIV due to this vaccine because the virus is never used in its natural, active and infectious form to make the vaccine. Scientists create synthetic copies of a small part of HIV's genetic material in the laboratory and use them for the vaccine. It is impossible for the experimental vaccine to cause HIV infection or AIDS.

## Can this vaccine cause any physical side effects?

The vaccine is a new substance given to the body and for it to be effective, the body must recognise it. This process of recognition may cause some reaction in the body. Additionally, individuals may react differently to the same vaccine.

It is likely that some participants may experience side effects such as tenderness, swelling or redness at the injection site, or mild flu-like symptoms such as headache and fever. All participants will be asked to come to the clinic to review any side effects. They will also be given telephone numbers to call in case there are any problems.

## Can a participant test HIV-positive after receiving the vaccine?

A participant is not likely to test HIV-positive after receiving this vaccine. If a participant does test positive for HIV antibodies after the injections, this does not mean that s/he is actually HIV-infected. This just means that the vaccine has stimulated the immune system to produce HIV antibodies and can therefore potentially show a positive result in an HIV antibody test, the most commonly used test to check for HIV.

There are very reliable additional tests to differentiate whether a participant is actually HIV-infected or s/he is only HIV antibody positive. If required, this test will be done free of cost.

Upon the participant's request, the investigator can provide a certificate of participation in an AIDS vaccine trial. This certificate would state that the HIV antibody positive test result is due to participating in an AIDS vaccine trial and that the participant is not HIV-infected. It would also mention the results of additional tests, if required. It is not known how long this HIV antibody positivity will persist but it is likely to be only a temporary condition.

## **What happens if a participant becomes HIV-infected during the trial?**

As mentioned previously, the AIDS vaccine on its own cannot cause HIV infection. All participants will be counselled on prevention of HIV infection at every visit to the clinic and they will be repeatedly tested for HIV during the trial. Should a participant get infected with HIV from another source, for example, unprotected sexual intercourse or unsafe sharing of needles during drug use, s/he will receive counselling and will be referred by the trial

team for free HIV care and treatment in keeping with the Government of India (NACO) guidelines.

Medical insurance will be provided to the study participants for vaccine-unrelated medical events (not covering HIV infection and vaccine-related events) for the duration of the trial period. Should a participant become HIV-infected during the course of the trial, the study sponsor will support access to care, support and treatment, including free of cost anti-retroviral therapy (ART) as and when medically recommended by existing national treatment guidelines. This will be for a period of five years from the time s/he is declared eligible for treatment. The sponsor will advocate with the Indian government to provide treatment beyond the covered period. If a participant suffers from any adverse events or disabilities directly due to the trial vaccine, the study sponsor will ensure the provision of comprehensive care, support, treatment and if required, appropriate compensation to the trial participant.

## **What happens if a volunteer gets pregnant during the trial?**

If a volunteer gets pregnant during the trial, she will be followed up through her pregnancy and the health status of the baby will be checked. Considering the likelihood of harm

# Participation in a clinical trial

to the foetus, the possibility of medical termination of pregnancy will be discussed with the participant.

## Can participants continue with their normal daily life if they participate in this trial?

Yes, participants can and should continue with their normal daily life. Only healthy individuals are selected to participate. They can continue with a normal sexual life but they will be counselled to practice safe sex and use condoms, a general precaution applicable to all, whether people are participating in these clinical trials or not.

## Can participants donate blood if they participate in the trial?

No, participants cannot donate blood during the trial or until such time that their test is positive for HIV antibodies.

Before any clinical trial can begin, the relevant ethics committees must approve the protocol in order to verify that international guidelines are respected and that the confidentiality, safety and liberty of the participants in the trial are not compromised. The AIDS vaccine trials in India have been approved by all the required Ethics Committees and regulatory authorities including the Drugs Controller General of India.

## Will family planning counselling be provided to participants?

Yes. All participants and their respective partners will receive family planning counselling at screening and prior to enrolment in the trial. At every visit, female volunteers will be reminded of the importance of not becoming pregnant until four months after the injection. Information on available family planning practices as well as potential side effects will be given. Male volunteers will be expected to use condoms regularly from the day they get vaccinated until the end of the trial. All temporary methods of contraception will be made available free of charge.

## How can counselling help?

During the clinical procedures, volunteers will be counselled every time before blood is taken for an HIV test. This is called pre-test counselling. It consists of informing participants that blood is taken for an HIV test, conducting a risk assessment, whether individuals are at-risk for getting infected with HIV, and if so, counselling them on how risky behaviour can be reduced or even avoided. The counsellor will inform participants about the result of each test afterwards. This is called post-test counselling. Volunteers will also be provided information on the implications of a positive or a negative result.

## Will volunteers receive compensation and benefits for participating in the trial?

Volunteers will receive compensation for participating in the vaccine trial as outlined in the informed consent document. At a minimum, they will:

- receive information regarding HIV transmission and how it can be prevented
- receive compensation for time, transportation, food, and other inconveniences caused due to their participation in the trial
- have regular and supportive contact with healthcare workers and counsellors throughout the course of the
- receive regular information about their 'health status' and the results of their blood tests, free of charge
- have access to a pre-agreed care and treatment package for HIV/AIDS if they become HIV-infected because of any behaviour that puts them at risk of HIV infection while enrolled in the trial;
- receive free medical insurance that will cover any medical costs for illnesses not related to participation in the vaccine trial (such as pneumonia)
- receive free treatment for any adverse effects they might experience as a result of participating in the trial.

## What will the research team do to protect participants' safety and rights?

The trial will be conducted by research scientists who are well trained in Good Clinical Practice and ethical conduct of research. Both NARI and TRC are government institutes with many years of experience of conducting clinical research that conforms to highest international ethical and scientific standards. Similarly, IAVI has sponsored and supported AIDS vaccine development and trials in several countries in the world.

An appropriate written informed consent will be obtained after providing detailed information about study participation including the benefits and risks of participation and compensation. Participation will be entirely voluntary and the investigators will be available for discussion with the participant or his/her family members when required. The investigators will maintain confidentiality regarding the participant's identification details. Efforts will be made to provide best possible medical care during the trial period.

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