

PRODUCT: Booklet on AIDS vaccine FAQs

AIDS vaccines  
Frequently Asked Questions on AIDS vaccines

## I. Vaccines

AIDS VACCINE BASICS AND MORE.....

### 1. What is a vaccine and how does it work?

A vaccine is a preparation that stimulates an immune response that can prevent an infection or create resistance to an infection.

Millions of lives, across the world, are saved each year because of a small but powerful collection of 10-20 different vaccines. These protect both children and adults from a whole range of otherwise life-threatening diseases like diphtheria, tetanus, measles, rabies, hepatitis, influenza, meningitis and yellow fever. Without vaccines, we would still be battling polio on a global scale and would still be living in fear of small pox across the world. Vaccines are among the safest and most cost-effective public health tools that have shaped human well-being as we know it today.

A vaccine works in a seemingly simple manner. The human body has a built-in mechanism to fight disease, which is called the **immune system**. In normal course, an individual's immune system learns how to protect him/her against a disease only after the body is exposed to the disease or infection once. But a vaccine trains the immune system to recognise the disease/infection in advance, by teaching the immune cells to identify certain invaders, such as germs, that can cause a disease. These lessons of being able to distinguish invaders are then stored in the memory of the immune system, which quickly responds the next time the body is exposed to the same risk. To put it simply, vaccines prime the human body in advance to fight infection and keep dangerous diseases away.

Blurbs for FAQ 1...

#### 1. THE IMMUNE SYSTEM

The immune system consists mainly of a group of specialised blood cells and proteins. It has the ability to understand the difference between what belongs to your body and what does not. It can learn to recognise dangerous invaders such as germs responsible for diseases. Fever, swollen glands and rashes, for example, may be indicative of the fact that your immune system is learning to recognise and fight a new invader.

2. Most vaccines are not 100 percent effective (may not protect all those who are vaccinated or provide only some degree of protection that will not entirely eliminate the risk of infection) but give people a much better chance of fighting common infections.

### 2. Is there a vaccine against AIDS?

Currently, there is no effective AIDS vaccine available but the need for one is urgent because a vaccine remains the best long-term hope to bring an end to the AIDS epidemic. The scientific search for such a vaccine is almost as old as the discovery of HIV.

Several candidate AIDS vaccines are in various stages of being developed and tested in the laboratory, animals and humans. It is a long and tedious process but there is sufficient evidence to believe that an effective AIDS vaccine is a scientific possibility.

Many common vaccines are based on killed or weakened versions of the germ which causes the disease against which they build protection. No one is looking at vaccines of this type against HIV. All of the AIDS vaccines which are being tested in humans are based on a new way of making vaccines: tiny, harmless artificial components (parts) of HIV could be used on their own or inserted in a different virus which is usually harmless to the human body. This is done to help the AIDS vaccine enter the human cells more efficiently. There is no way that such vaccines can cause HIV infection. Researchers hope that the body will find the hidden fragments and then learn to recognise HIV if it tries to attack the body.

### **3. Can this vaccine be given to HIV infected individuals?)**

No. Most vaccines in use today are designed to protect humans from disease or infection i.e., they are preventive vaccines. Most scientific efforts in the search for an AIDS vaccine are also focused on finding a preventive AIDS vaccine. A preventive AIDS vaccine will be meant only for people who are not infected with HIV, for it will prepare the immune system to respond in case of exposure to the virus. All references in this document are to a preventive AIDS vaccine.

Blurbs for FAQ 2...

#### **1. ARE THERE ANY EFFECTIVE MEDICINES THAT CAN CURE AIDS?**

While there are still no drugs that can cure AIDS, many antiretroviral drugs (ARVs) are currently being used to check the speed of multiplication of HIV in the body. ARVs can also help decrease opportunistic infections and improve immune response. Babies born to HIV-positive mothers can be protected against HIV infection if the mother and baby receive ARVs during pregnancy and at the time of delivery. But these drugs do not offer a cure, have to be taken for life, are expensive and can sometimes cause toxicity in the body. Also, HIV can become resistant to ARVs over time.

2. An opportunistic infection (OIs) is an illness caused by an organism that usually does not cause disease in a person with a healthy immune system. People with advanced HIV infection are more likely to suffer from OIs such as pneumonia or tuberculosis.

3. Preventive AIDS vaccines are not like drugs or medicines against AIDS. It is hoped that an effective preventive AIDS vaccine will protect an individual from HIV infection.

4. An AIDS vaccine, once available, will be integrated into existing HIV/AIDS prevention programmes that encourage condom use, safe blood practices and behaviour change. An effective AIDS vaccine will always remain only one of the multiple options to fight HIV/AIDS. Over the long-term, as more and more people become vaccinated, a vaccine could help bring an end to the epidemic.

#### 5. WHAT ARE THERAPEUTIC AIDS VACCINES?

There are scientists who are working to develop therapeutic AIDS vaccines too. These are designed for people who are already infected with HIV. An ideal therapeutic vaccine will teach the immune system to control HIV in the body and prevent progression of infection to disease. Therapeutic vaccine research is still in its early stages of development.

#### 4. How is an AIDS vaccine developed?

As with other vaccines, AIDS vaccines are also tested in various stages over several years. Initial laboratory work is followed by animal studies and then human clinical trials. Many of the modern, licensed vaccines we use today have taken several decades before they cleared the many complicated stages of their development. Experts believe that a safe and effective AIDS vaccine may be found within the decade, but there are others who feel it may take much longer than that.

In keeping with international regulatory requirements, a vaccine clinical trial has three phases:

GRAPHIC: funnel diagram on Phases of AIDS vaccines. Please see attached file.

If the vaccine is found to be safe and effective, the Drugs Controller General of India will allow its licensing for widespread public use in India. Only then it will be available for use in the community.

#### 5. What are Prime-boost studies?

Prime-boost is a series of sequential immunisations meant to 'prime' or prepare the immune system with the first vaccination and 'boost' the immune system with the next vaccination(s). The same or different types of vaccine may be used for the prime and boost. The intent of the vaccination regimen is to induce stronger immune responses than those obtained by using either vaccine alone. The decision of a prime-boost study is taken on the basis of safety and immunogenicity data generated in Phase I clinical trials of each vaccine separately.

Blurbs for FAQ 3 & 4.

##### 1. A VACCINE CLINICAL TRIAL

A clinical trial is a scientific process in which a new vaccine is tested in volunteers to assess the human body's reactions to the vaccine and to be sure there are no side-effects. It also measures the level of immune response that the body is able to build up against the infection or disease.

##### 2. A TRIAL VACCINE

A trial vaccine is only a candidate that is being tested in a trial for which little is known about its ability to elicit an immune response against HIV. Receipt of trial vaccine candidate does not ensure protection from HIV/AIDS.

#### 6. Is it necessary to test an AIDS vaccine in humans?

Any vaccine has to be tested in humans to make sure that it does not cause side-effects and that it works. After initial laboratory work and animal testing, human trials provide conclusive results on whether the vaccine is successful in protecting against the infection or disease and poses no

danger to the human body. The necessity of testing AIDS vaccines in humans is even stronger because:

- HIV exclusively infects and causes disease in human beings
- There are no good animal models that can mimic what happens in the human body because our immune system is very different
- Although animal model data provide insights into vaccine concept and design, and reassurance about safety, only human clinical trials can determine whether the vaccine actually works the way it is supposed to (vaccine efficacy).

Blurb for FAQ 6...

#### **MORE CHALLENGING THAN THE REST**

AIDS vaccine development is proving to be scientifically much more challenging than vaccines for other diseases. A vaccine that is effective may be required to engage a whole complex of immune defenses. Also, HIV in itself is an enormous challenge to AIDS vaccine development, because of many subtypes of the virus, its ability to change its form rapidly and the fact that it attacks the immune system.

### **7. Why does India need to participate in AIDS vaccine trials?**

India today is a strong partner in the global search for a safe and effective AIDS vaccine. Indian scientists and top medical research institutions are collaborating with international partners to develop a preventive AIDS vaccine. Multiple vaccine candidates are being considered that are specifically designed for HIV-1, subtype C, the most prevalent HIV subtype in India. Development and deployment of an AIDS vaccine for India would require participation by the people in testing the vaccine. Clinical trials in humans are already underway in many other countries to test AIDS vaccine candidates.

Blurb for FAQ 7...

#### **WHO BENEFITS**

These vaccines, if effective, could protect millions of HIV-negative people from HIV/AIDS. Today, HIV has become a threat to all people since it is no longer restricted to those who live at risk of contracting the virus. HIV/AIDS is now a public health emergency and affects everybody. Experts believe that even a partially effective vaccine will have a significant impact in reducing the spread of the disease.

### **8. Are there other countries conducting AIDS vaccine trials?**

Since 1987, more than 40 different AIDS vaccines have already been tested in over a 100 clinical trials. These trials have taken place or are ongoing in many countries across the world including Australia, Belgium, Botswana, Brazil, Canada, China, Cuba, Finland, France, Germany, Haiti, Kenya, Malawi, Peru, Puerto Rico, Russia, South Africa, Switzerland, Thailand, the United Kingdom, Trinidad and Tobago, Uganda and USA.

More than 15,000 volunteers have participated in such clinical trials worldwide.

### **9. Have any AIDS vaccine trials been conducted in India?**

Yes. India's first ever Phase I trial was initiated in 2005 at the National AIDS Research Institute (NARI), Pune. The trial enrolled 30 volunteers and was completed in December 2006. A second

Phase I trial to test another vaccine candidate is underway at the Tuberculosis Research Centre (TRC), Chennai, where 32 volunteers have been enrolled. The planning for additional AIDS vaccine trials in India is underway.

**10. Has the Government of India approved these AIDS vaccine trials?**

Yes. This AIDS vaccine programme is governed by a Memorandum of Understanding (MoU) between the Government of India and the International AIDS Vaccine Initiative (IAVI). The Government of India is represented by the National AIDS Control Organization (NACO) in the Ministry of Health and Family Welfare and the Indian Council of Medical Research (ICMR). Approvals for the trial have been obtained from the office of the Drugs Controller General of India (which approves all clinical research with new drugs or vaccines) and the required ethical and regulatory committees.

Blurb for FAQ 10.....

**OTHER AIDS VACCINE TRIALS IN INDIA**

India is making multiple efforts to find a safe and effective AIDS vaccine for use in the country. In collaboration with IAVI, the Department of Biotechnology (DBT), under the Ministry of Science & Technology is pursuing efforts to design new vaccine candidates.

II. Participation in a Phase I AIDS vaccine trial  
**HELPING THE CAUSE .....**  
**.....WOULD YOU LIKE TO PARTICIPATE?**

**1. Can I participate in an AIDS vaccine trial?**

Yes, you can participate in a Phase I clinical trial if you are.....

- a man or woman between 18 and 50 years of age
- in good health
- HIV-uninfected
- a person who has no risk of an HIV infection (for more information refer to the booklet 'FAQs on HIV/AIDS')
- a resident of India and planning to live close to the trial sites (Pune or Chennai) for the next 18 months
- able to understand the process of the trial and give your 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.

If you have already participated in a previous AIDS vaccine trial, you do not qualify to volunteer for this Phase I AIDS vaccine clinical trial,

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

**2. Is the decision to participate entirely my choice?**

Yes. Participation in this trial is an entirely voluntary process. It is your free decision to accept or refuse to participate without any influence or pressure. Before you agree to volunteer, you must understand the purpose of the trial and the potential risks and benefits of participating in the trial. The counsellors will provide you with all the information and will attempt to explain all legal, ethical and medical issues of your participation in a user-friendly way. All the information that will be provided to you is meant to empower you to make a free, intelligent choice of whether you want to participate in the trial or not. Only after you have understood the informed consent process and have passed the **test of understanding**, will you be asked to provide written consent. No clinical procedures will be carried out as part of the trial without your informed consent.

Blurb for FAQ 2...

**WHAT IS INFORMED CONSENT?**

Any biomedical research that involves human beings is based on the informed consent of all those who participate in the study. The basic idea behind informed consent is that a person is making an entirely voluntary choice of participating in such research after having gained complete knowledge of all the risks and benefits of his/her participation. Informed consent is

considered incomplete without some form of **testing the understanding** of potential participants, which is the only way of assessing whether all the information has been accurately understood and imbibed by them or not. There are many methods of ensuring informed consent and several stages when it should be taken.

### **3. What if I decide to leave the trial after I have given my consent to participate?**

Although the researchers have your informed consent, you are free to leave the trial at any stage without having to explain the reasons. It is also your right to ask for any information you may require at any time during the clinical trial. However, you will only be told whether you received the vaccine or placebo (see question 4 below) at the end of the trial.

### **4. 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 typically used in any research design where scientists need 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. Commonly neither the trial team nor the volunteer 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.

### **5. What are my chances of receiving the vaccine compared to receiving the placebo and how is it decided?**

The assigning of the vaccine or placebo to each participant is a completely random process. According to chance, you have a higher probability of receiving the vaccine compared to receiving the placebo.

### **6. Who will be informed about my participation in this trial?**

Other than the research team, nobody will be informed about your participation in the trial. At the time of seeking consent, you 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 your identity will never be disclosed and your records will only have a code number without your name. However, it is entirely up to you whether you want to inform anybody about your decision to participate in the trial.

Blurb for FAQ 6

#### **CIRCLE OF CONFIDENTIALITY**

For many of us, confidentiality goes beyond just the self and includes either close family or friends. It is important to understand that defining this circle of confidentiality as a trial participant is entirely your free choice, although the trial team is strictly bound to keeping all records related to the trial completely confidential.

Illustration: Different communities that surround the AIDS vaccine trial participant.  
Please see attached file.

III Taking an informed decision  
**IT IS YOUR BODY...AND YOUR CHOICE.  
TAKE AN INFORMED DECISION**

### **1. Can this vaccine cause HIV infection or AIDS?**

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

### **2. 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. Although the tests in animals and in humans with the vaccine indicate that the vaccine is safe, there always remains a risk of unexpected side effects.

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.

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.

### **3. Will I test HIV-positive after receiving the vaccine?**

There is a small chance that you may test HIV-positive after receiving this vaccine. If you do test positive for HIV antibodies after the injections, this does not mean that you are 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 you are actually HIV-infected or you are only HIV antibody positive. If required, this test will be done free of cost. Upon your request, the investigator can provide you with 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 you are 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 only be a temporary condition.

#### **4. What happens if I become HIV-infected during the trial?**

As mentioned previously, the AIDS vaccine on its own cannot cause HIV infection. You will be counselled on prevention of HIV infection at every visit to the clinic and you will be repeatedly tested for HIV during the trial. Should you get infected with HIV from another source, for example, unprotected sexual intercourse or unsafe sharing of needles during drug use, you 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.

Should you 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 you are declared eligible for treatment. The sponsor will advocate with the Indian government to provide treatment beyond the covered period.

#### **5. What happens if I get pregnant during the trial?**

If you get pregnant during the trial, you will be followed up through your pregnancy and the health status of the baby will be checked. Considering the likelihood of harm to the foetus, the possibility of medical termination of pregnancy will be discussed with you.

#### **6. Will I receive family planning counselling?**

Yes. Both you and your partner will receive family planning counselling at screening and prior to enrolment in the trial. If you are a woman, at every visit you will be reminded of the importance of not becoming pregnant until four months after the last trial vaccination. Information on available family planning practices as well as potential side effects will be given. If you are a man, you will be expected to use condoms regularly from the day you get your first vaccination until the end of the trial. All temporary methods of contraception will be made available free of charge.

#### **7. How can counselling help?**

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

Blurb for FAQ 7...

Counselling provides the opportunity to both potential and enrolled volunteers for a confidential talk. A counsellor will be available throughout the trial.

**8. Can I continue with my normal daily life if I participate in the trial?**

Yes, you can and should continue with your normal daily life. If you have been selected to participate, you are a healthy individual. You can continue with a normal sexual life, but you will be counselled to practice safe sex and use condoms, a general precaution applicable to all, whether you are participating in this clinical trial or not.

**9. Can I donate blood if I participate in the trial?**

No, you cannot donate blood during the trial or until such time that your blood test is positive for HIV antibodies. You may report to the study team for advice on this matter.

**10. Will I receive compensation for participating in the trial?**

While no direct benefits will be provided for participating in the vaccine trial, you will receive compensation as outlined in the informed consent document. At a minimum, you will:

- receive information regarding HIV transmission and how it can be prevented
- receive compensation for time, transportation, food and other inconveniences caused due to your participation in the trial
- have regular and supportive contact with healthcare workers and counsellors throughout the course of the trial
- receive regular information about your 'health status' and the results of your blood tests, free of charge
- have access to a pre-agreed care and treatment package for HIV/AIDS if you become HIV-infected because of any behaviour that puts you at risk of HIV infection while enrolled in the trial
- receive free medical insurance for the duration of the trial period 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 you might experience as a result of participating in the trial.

**11. How can I be sure this trial is being conducted ethically?**

Ethics are sets of guidelines to ensure the protection of basic human rights of participants in biomedical research. These guidelines define the information that people have a right to and the choices people have the right to make in the context of the clinical trial. Before any 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. It has been ensured that this clinical trial has been approved by the national regulatory agencies in India and all the required ethics committees.

**12. 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. It will be conducted at 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.

### **13. Who can I turn to if something goes wrong?**

The trial is being conducted under strict government control, but also with strong community participation. The Principal Investigator conducting the trial, the ethics committees, an Arbitration Board comprising legal, social and medical experts and other existing redressal mechanisms will be available to resolve issues of concern that you may have regarding the trial

**END OF TEXT**

**Act  
NOW !**

Logo: NACO, ICMR, NARI, TRC, IAVI

Let us work together towards an AIDS vaccine