

PRODUCT: Booklet on GETTING TO KNOW THE TRIAL ORGANISERS

A Memorandum of Understanding (MoU) was signed between the National AIDS Control Organization (NACO) through the Ministry of Health and Family Welfare, the Indian Council of Medical Research (ICMR) and the International AIDS Vaccine Initiative (IAVI) in December 2000 to develop a safe, effective and accessible preventive AIDS vaccine for India. NACO is the nodal agency of the AIDS vaccine programme, facilitating all permits and permissions for the programme. The ICMR, through its state-level research institutions, is the main agency in charge of the research and development aspects of the programme. IAVI is expected to establish partnerships to design, develop and evaluate candidate AIDS vaccines appropriate for use in India.

The first Phase I trial under this programme was conducted by the National AIDS Research Institute (NARI), as the ICMR's representative state-level research institution in Pune, Maharashtra. A second Phase I trial is currently underway at the Tuberculosis Research Centre (TRC), Chennai, Tamil Nadu, which is also an ICMR research institute. It is planned to initiate a third Phase I trial at NARI and TRC.

The National AIDS Control Organization

NACO is the nodal organisation for formulation of policy and implementation of programmes for the prevention and control of HIV/AIDS in India. The National AIDS Control Programme was launched in 1987, soon after the first few cases of HIV/ AIDS were reported in the country. It has since been decentralised and State AIDS Societies have been set up in all the states and Union Territories to manage state-level efforts for HIV/AIDS prevention and control, including management of NGO collaboration. NACO's activities include information, education, communication (IEC) campaigns and social mobilisation; condom promotion, blood safety and control of sexually transmitted infections. As part of its prevention programme, NACO is also exploring new medical technologies such as vaccines and microbicides as potentially powerful tools that may be the best hope for ending the AIDS epidemic.

The Indian Council of Medical Research

ICMR is the apex body in India for the formulation, coordination and promotion of biomedical research. It was founded in 1911 and is one of the oldest medical research bodies in the world. The Council promotes research in the country through 21 Permanent Research Centres. These are mission-oriented institutes located in different parts of India undertaking research on major diseases like tuberculosis, leprosy, cholera and diarrhoeal diseases, viral diseases, AIDS and malaria, among others. ICMR has put in place systems and guidelines to ensure ethical biomedical research in the country. In addition, ICMR has six Regional Medical Research Centres which address regional health problems and

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aim to build research capacity in different geographic areas of the country. ICMR also supports extramural research in non-ICMR research institutes, medical colleges and universities located in different parts of the country. All these efforts aim to reduce the total burden of disease and to promote health and well-being of the population.

The National AIDS Research Institute

NARI is one of the national research institutes dedicated to HIV/ AIDS. Headquartered in Pune, Maharashtra, NARI was set up in 1992 by the ICMR to provide leadership in biomedical research in India and to complement the National AIDS Control Programme. The institution has one of India's best and most experienced multidisciplinary teams of scientists and some of the best-equipped laboratories for tuberculosis and HIV/AIDS research in the country. Research at NARI initially focused on understanding the epidemiology of HIV/AIDS, but this mandate has broadened considerably in the last few years. NARI's ongoing research includes:

- Epidemiology and preventive research:
 - Dynamics of HIV infection and transmission in various sub-populations, prevention and control strategies including field-based prevention.

- Social and behavioural intervention research:
 - The social relevance of infection in society, behavioural patterns associated with HIV and provision of counselling services, studies on stigma and discrimination.

- Developmental research:
 - Characterisation of HIV, immunological correlates, research on candidate vaccines, diagnostics and in vitro testing of drugs.
- Patient care and management strategies:
 - Clinical research and therapeutic trials for HIV disease, chemoprophylaxis, treatment algorithms in case management in India.

NARI complements the National AIDS Control Programme by contributing to national efforts for preventing and controlling HIV/AIDS in the country and providing care and support to people living with HIV/AIDS.

NARI is the trial site for the first Phase I preventive AIDS vaccine trial in India

The Tuberculosis Research Centre

TRC is one of the national research institutes dedicated to HIV/AIDS. Headquartered in Chennai, Tamil Nadu, TRC was set up in 1956 by the ICMR to provide leadership in biomedical research in India and to complete the National Tuberculosis Control

Programme. More recently, in view of the close interaction between tuberculosis and HIV, the TRC has also involved itself with research into HIV. The institution has one of India's best and most experienced multidisciplinary teams of scientists and some of the best-equipped laboratories for tuberculosis and HIV/AIDS research in the country. Research at TRC in HIV/AIDS includes:

- Epidemiology and preventive research:
 - Dynamics of HIV infection and transmission in various sub-populations prevention and control strategies including field-based prevention
- Social and behavioural intervention research:
 - The social relevance of infection in society, behavioural patterns associated with HIV and provision of counselling services, studies on stigma and discrimination.
- Developmental research:
 - Characterisation of HIV, immunological correlates research on candidate vaccines, diagnostics and in vitro testing of drugs.
 - Patient care and management strategies:
 - Clinical research and therapeutic trials for HIV disease, chemoprophylaxis, treatment algorithms in case management in India.

TRC complements the National AIDS Control Programme by contributing to national efforts for preventing and controlling HIV/AIDS in the country and providing care and support to people living with HIV/AIDS. TRC is the trial site for the second Phase I preventive AIDS vaccine trial in India.

Y R Gaitonde Centre for AIDS Research and Education

YRG Care is a premier non-profit HIV referral centre in Chennai, Tamil Nadu. Its mission is to ensure that people living with HIV and AIDS, and their families, live with dignity; and that there is no further transmission of the infection. It was founded in 1993 by Dr. Suniti Solomon, who documented the first evidence of HIV infection in India in 1986, at the Madras Medical College, with which she was then associated as a Professor of Microbiology. YRG CARE offers an unusually broad array of services along the entire spectrum of prevention to care.

The organisation is widely recognised for the AIDS care and support services it provides to over six thousand registered patients. YRG CARE has developed capacity to conduct ethically and scientifically rigorous community, clinic and laboratory based research. It has extensive experience in community based research, in particular, spanning structured ethnography, focus groups, in-depth interviews, quantitative surveys, mapping and enumeration and cohort location and retention. Research undertaken by the organisation is first approved by an Institutional Review Board and guided by a Community Advisory Board.

TRC and YRG CARE are collaborating on the second Phase I AIDS vaccine clinical trial in Chennai, Tamil Nadu for community mobilisation and recruitment of volunteers.

The International AIDS Vaccine Initiative

IAVI is a global not-for-profit organisation founded in 1996. IAVI works in 23 countries to accelerate the search for a preventive AIDS vaccine. It is IAVI's mandate to ensure an effective AIDS vaccine, once available, is globally accessible and affordable to those who need it the most, especially in developing countries. IAVI works with organisations worldwide to advocate with political leaders, community groups and others about the need to be involved in the search for an AIDS vaccine. In the ten years since it was founded, IAVI and its international partners have advanced six preventive AIDS vaccine candidates from the concept stage to human trials. It is the second largest supporter of AIDS vaccine research and development in the world.

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Logos of NACO, ICMR, NARI and TRC.