

# THE SATULAB IN TB VACCINE RESEARCH







VACCINES TO STOP TB

The Liquid Nitrogen Container is state-of-the-art laboratory equipment that plays a critical role in our TB vaccine studies. Each container can store hundreds of thousands of blood samples which are taken from our study participants. These samples are prepared and frozen at temperatures of up to -195°C and stored in our Biobank.

Results are determined after many years of research, and this sample bank enables our scientists or immunologists to access the samples for various studies. This enables researchers to get a better understanding of the body's immune responses to TB and novel TB vaccines.

> The Liquid Nitrogen Container is state-of-the-art laboratory equipment

# AN EFFECTIVE VACCINE IS A KEY TOOL IN PREVENTING TB

**South Africa has the** second highest rate of tuberculosis (TB) in the world. A striking 1% of our population develops TB disease every year! World-wide, 1 person dies every 20 seconds from the disease. Experts agree that an effective TB vaccine is one of the key tools needed to prevent TB. The only TB vaccine currently available (known as BCG) is given to babies soon after birth, but is effective only in protecting children against serious TB, and not lung TB.



### SATVI IS THE LARGEST DEDICATED TB VACCINE RESEARCH GROUP IN AFRICA

**Established in 2001, SATVI's** aim is the development of a new and effective TB vaccine. We are part of worldwide research that, if successful, has the potential to save hundreds of thousands of lives. We have a clinical field site in Worcester, 110km outside of Cape Town, where the rate of TB is amongst the highest in the world. This site spans the entire Boland-Overberg region of the Western Cape, covering an area of about 12,000 square kilometers with a population of 350,000.

SATVI has enrolled more than 20,000 participants in various research projects. Our state-of-the-art immunology laboratories are located within the Institute of Infectious Diseases and Molecular Medicine of the University of Cape Town, and at the Worcester Project Office.

Our growing success as the premier TB vaccine research site in the world is evident from the ongoing support of international funding agencies, presentations of our research at international conferences, representation on international bodies, as well as high-impact articles documenting research findings published in international medical journals.

(For access to our publications, visit the SAT VI publications page on our website at http://www.satvi.uct.ac.za/publications/latest-satvi-publications.html)

# SATVI IS TESTING NOVEL TB BOOSTER VACCINES

- SATVI is the only site in the world testing multiple new TB vaccines
- All clinical trials carried out at the SATVI site are compliant with international ethical and scientific standards known as Good Clinical Practice (GCP)
- Four Phase I studies are being conducted which evaluates the safety and immunogenicity in small groups of participants
- The Phase IIb clinical vaccine trial being conducted amongst 3000 participants is the most advanced study of a TB vaccine in infants in the world
- SATVI will be starting two additional Phase II trials in 2011 and 2012, which may lead to Phase III trials to determine the efficacy of vaccines in thousands of participants

## QUESTIONS WE ARE ASKING IN OUR RESEARCH

- Whether any measurable markers or indicators of infection/disease can be identified. This is essential for the selection of a vaccine that protects against TB.
- Current studies in infants are investigating:
  - •• What happens over time to the immune response to BCG vaccination
  - •• What is the right time for BCG vaccination in HIV infected infants
  - •• Whether there is a 'genetic link' in the way BCG works to protect against TB.
- In adults we are investigating:
  - •• The body's immune responses to TB disease
  - •• Whether there are measurable markers or indicators for TB infection compared to TB disease. This work contributes to the development of a post-exposure TB vaccine, which could be given to adults or adolescents.



# SATVI is a world leader in TB vaccine research

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SATVI is a world leader in TB vaccine research, having conducted a number of large-scale studies. The study that established SATVI as a prime site for testing novel TB vaccines compared the incidence of TB over two years in 11,680 infants vaccinated at birth using two different methods of administration.

### SATVI IS A WORLD LEADER IN TB VACCINE RESEARCH

**SATVI laboratories are accredited** by the South African National Accreditation System (SANAS), and comply with the highest international standards. They comprise of academic research and clinical trials components, immunology and molecular processing areas, a flow cytometry area and a Biobank.

SATVI's Biobank has eight -80°C freezers and thirteen liquid nitrogen tanks and currently stores more than 600,000 samples from various tuberculosis study-related cohorts. This is an invaluable resource for the scientific community.

BIOBANK 13

Best Biobanking practices are followed at all times. This means that the integrity of all stored samples is under continuous internal review and monitoring, and is subject to strict quality control procedures.

### THE SATVI TEAM

**SATVI consists of a** research team comprising highly trained study clinicians, epidemiologists, infectious disease specialists, immunologists, technologists, a laboratory assistant and a number of PhD and Masters students, all supported by dedicated administrative, communications, IT and regulatory affairs teams. All members of the SATVI team are trained in Good Clinical Practice and Good Laboratory Practice.

### SATVI AIMS TO BECOME A CENTRE OF EXCELLENCE FOR TRAINING IN CLINICAL, EPIDEMIOLOGICAL AND LABORATORY ASPECTS OF TB BY:

- Scientific development and capacity building through the Honours in Vaccinology, Masters programmes, PhDs and postdoctoral fellowships
- Capacity building of SATVI technical, nursing, administrative and support staff through our very own Siyantinga Professional Development Programme (PDP)
- Refresher courses covering all aspects of clinical research, such as epidemiology, biostatistics, ethics and project management, at the Fogarty, National Institutes of Health (NIH) USA supported Summer Institute
- Continuing Medical Education (CME) through active participation with service providers



### SATVI ACTIVELY SUPPORTS DEVELOPMENT OF ADDITIONAL TB VACCINE TRIAL SITES IN AFRICA

**SATVI is an active member** of TBVACSIN (TB Vaccine Clinical Trial Sites Network), an initiative to build TB vaccine clinical trial capacity in countries hardest hit by the TB epidemic. Members are from Kenya, Uganda, Mocambique and Tanzania.

Activities are funded by the European Developing Countries Trials Partnership (EDCTP) and Aeras, and involve multiple European collaborators.

SATVI works closely in partnerships with international and local institutions, researchers and commercial sponsors, notably:

- Multiple local investigators at UCT and University of Stellenbosch
- Regional and provincial health departments in the Western Cape and the Boland
- Aeras Global TB Vaccine Foundation
- European Developing Countries Trials Partnership (EDCTP)
- The University of Oxford
- University of Washington
- The Public Health Research Institute of UMDNJ (USA)
- The Bill and Melinda Gates Foundation
- Large consortiums such as IMPAACT, which involve multiple sites in the US (Miami), Africa (South Africa, Zimbabawe, Tanzania and Uganda) and India (Pune)
- Tuberculosis Research Unit (TBRU), Case Western Reserve University (US)
- Vodacom Foundation

SATVI actively supports development of additional TB vaccine trial sites in Africa



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### SOUTH AFRICAN TUBERCULOSIS VACCINE INITIATIVE (SATVI)

Institute of Infectious Disease and Molecular Medicine (IIDMM), Health Sciences Faculty, University of Cape Town Rm S2.01, Level 2, Werhner Beit North Building, Anzio Road, Observatory, 7925 T 021 - 4066014 F 086-6134778 W www.satvi.uct.ac.za

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