SATVI is a world leader in TB vaccine clinical research

The mission of SATVI, which is based at the University of Cape Town (UCT), is the development of new and effective vaccination strategies against tuberculosis (TB). A new, effective TB vaccine has the potential to save hundreds of thousands of lives world-wide.

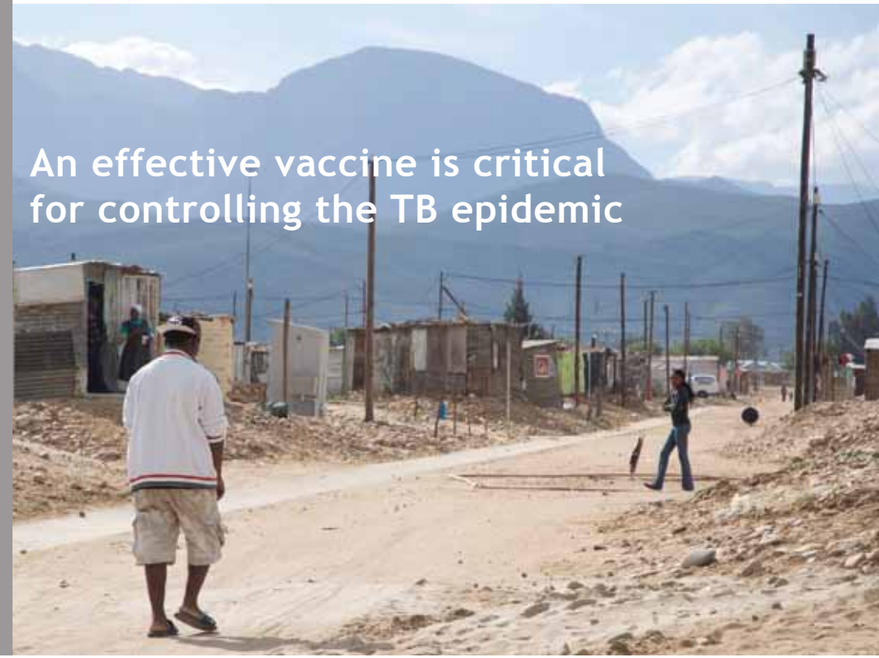
We are testing multiple new TB vaccine candidates in clinical trials. We are also completing projects to address critical clinical, epidemiological, immunological and human genetic questions in TB vaccine development. Our activities occur within an academic context and thus include the training of postgraduate students. In addition, we have an active Professional Development Programme (PDP) to develop the skills of all our research workers.

The SATVI field site is located in the Boland region, 110km outside of Cape Town, where the rate of TB is amongst the highest recorded in the world. This rural area of about 12,000 square kilometers has a population of about 350,000, of whom more than 20,000 have participated in our studies to date. The SATVI leadership is based In Cape Town, at UCT's Health Sciences Faculty, with state of the art laboratory facilities.

Our success as a clinical TB vaccine research site is evident from manuscripts published in high impact journals, funding support from multiple international funding agencies, invited presentations at international conferences and representation on international policy bodies.(For more detail: www.satvi.uct.ac.za)

Many of SATVI's activities are conducted within large consortia that involve investigators from other parts of Africa, Europe, the US and Asia. We are also leading the Vaccines for Africa (VACFA) initiative on the continent (www.vacfa.com).

South Africa has amongst the highest rates of 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 would be the most effective tool to interrupt the TB epidemic. The only TB vaccine currently available, BCG, is given to babies soon after birth. Whilst it is effective in protecting children against severe forms of TB, it does not protect well against lung TB, the more common form of the disease.

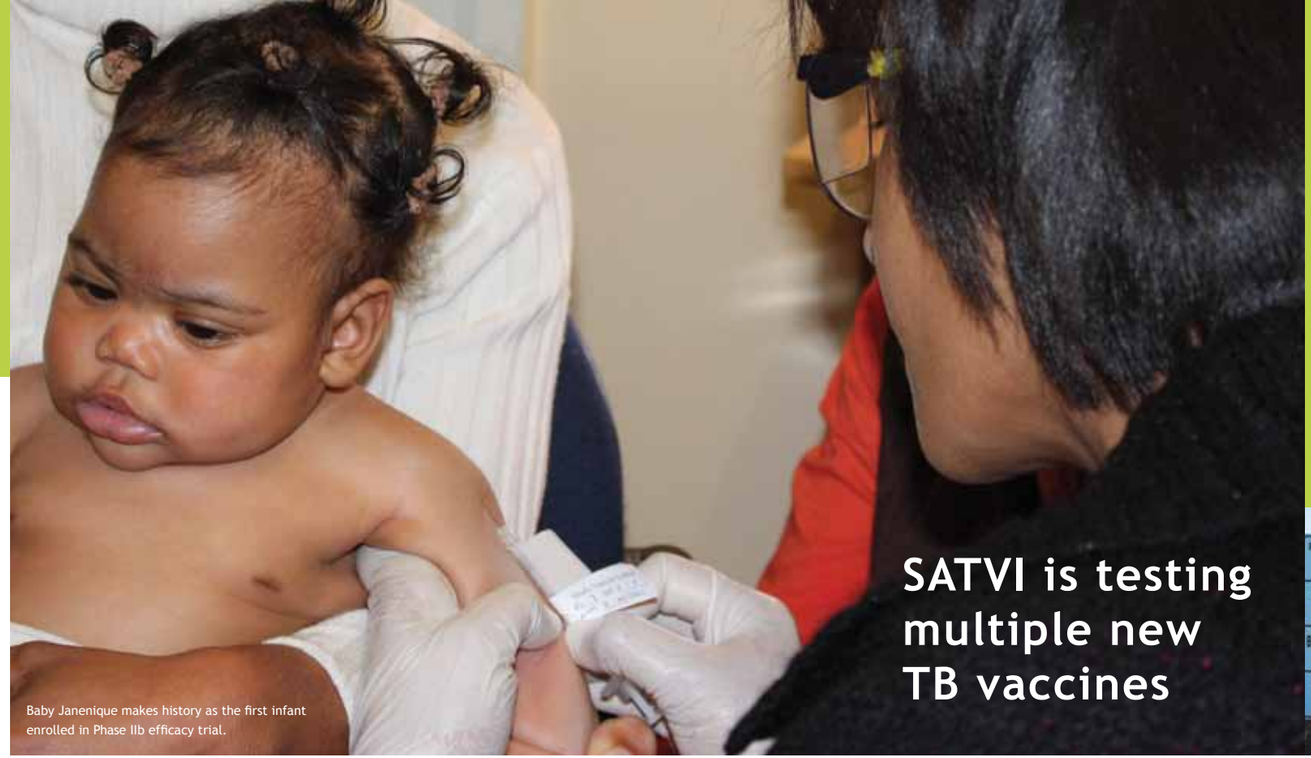


SATVI IS TESTING NEW TB VACCINES

- SATVI has tested four new TB vaccines, and the current TB vaccine, BCG.
- Safety and immunogenicity of the new vaccines are tested in multiple population groups (Phase I/IIa trials), involving small numbers of participants.
- We are currently conducting the first efficacy trial (Phase IIb) of a new TB vaccine since BCG, involving about 2,784 infants. We will be starting two additional Phase II trials in the near future, which may lead to Phase lll trials.
- All clinical trials carried out at the SATVI site are compliant with international ethical and scientific quality standards, known as Good Clinical Practice (GCP).

SOME QUESTIONS WE ARE ASKING IN OUR RESEARCH

- Are new TB vaccines entirely safe?
- Do these vaccines stimulate our immune systems in a manner that is likely to protect us against TB?
- Do the new vaccines actually prevent TB disease?
- What is the best way to diagnose TB in trials of new vaccines?
- What are the best markers that can be measured in blood of vaccinated persons to tell us they will be protected against TB?
- How can the current TB vaccine, BCG, best be used?
- Can the vaccines be given to HIV-infected persons, who are at high risk of developing TB disease?

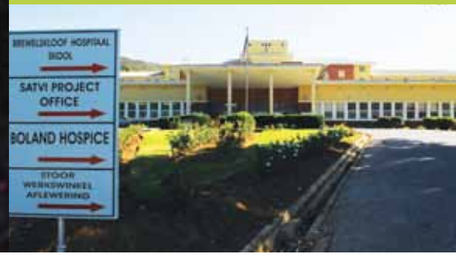


Baby Janenique makes history as the first infant enrolled in Phase IIb efficacy trial.

SATVI is testing multiple new TB vaccines

SATVI'S FIELD SITE

SATVI conducts its TB studies in the Boland region of the Western Cape, centred around the town of Worcester. The field site base is located on the premises of Brewelskloof Hospital, the regional TB hospital in the Boland. Facilities include a vaccine trials clinic, a 15 bed Case Verification ward in the hospital for TB investigations in children, a world class laboratory, and support services. Additionally, the two satellite offices in the towns of Ceres and Robertson, approximately 30 minutes drive from Worcester, provide access to the surrounding rural areas to its north and south.



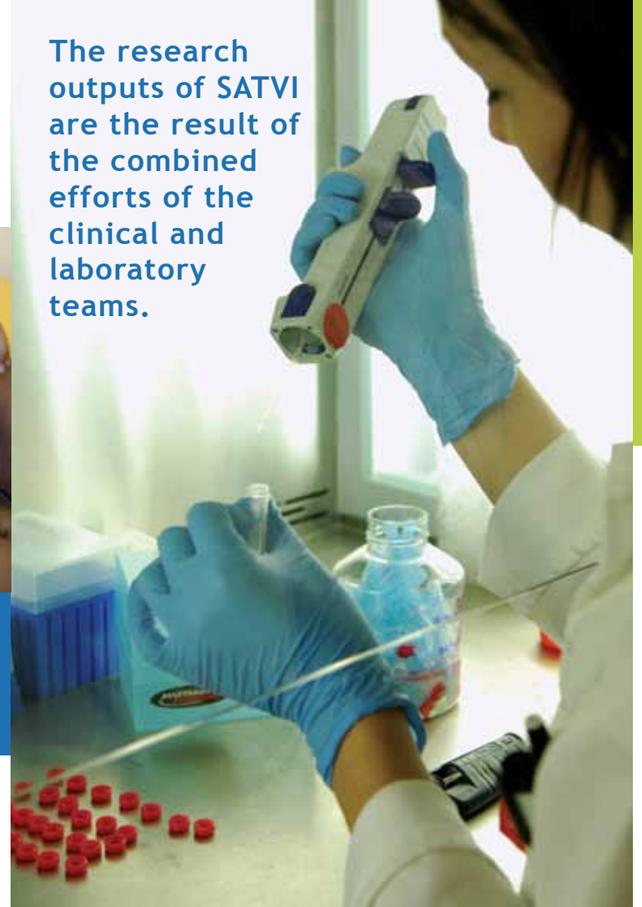
THE SATVI TEAM

The SATVI research team is led by highly trained clinicians, public health specialists and immunologists overseeing a multi-disciplinary team comprising technologists, pharmacists, nursing professionals, clinical research workers, and a number of PhD and Masters students. Key support services are provided through professional development, quality assurance, surveillance, data management, administrative, communications, IT, logistics and regulatory affairs teams.

Of these, medical doctors at the field site oversee a team of 160 personnel, at a central project office and various satellite offices, to complete recruitment, enrolment and follow up of participants.

We believe that the success of a trial lies in the quality of its team members.

The research outputs of SATVI are the result of the combined efforts of the clinical and laboratory teams.

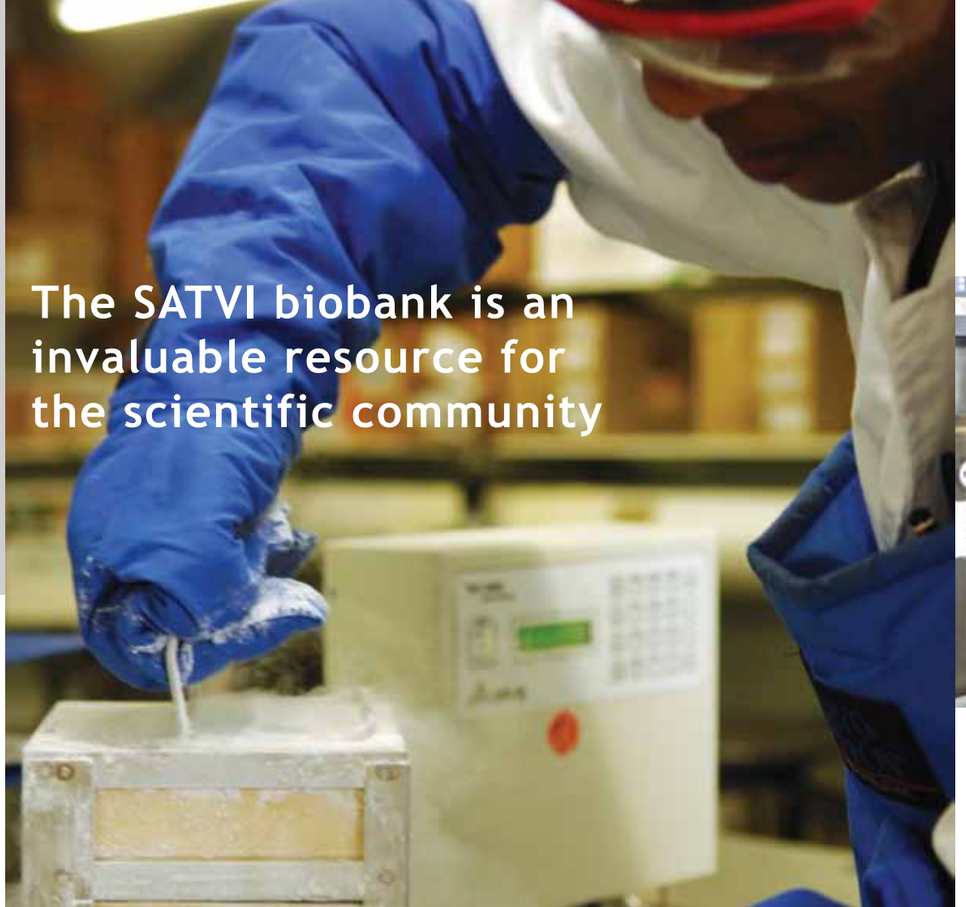


SATVI IS COMMITTED TO HIGH ETHICAL STANDARDS FOR CONDUCTING RESEARCH

SATVI is committed to high ethical standards necessary for conducting research involving human participants. We ensure that the safety of study participants comes first, and make sure that all are well informed of their rights before, during and after trials. A dedicated Regulatory Team ensures we comply with local, national and international standards. In addition, all personnel receive rigorous training in Good Clinical Practice (GCP) and/or Good Laboratory Practice (GLP), which includes consenting of and appropriate communication with study participants. Our activities are overseen by the University of Cape Town's Faculty of Health Sciences Human Research Ethics Committee.

SATVI HAS WORLD-CLASS LABORATORY FACILITIES

Our state of the art immunology laboratories are located within the Institute of Infectious Disease and Molecular Medicine of the University of Cape Town, and at the Worcester field site. In addition to testing whether new TB vaccines have stimulated the immune system, we are trying to understand how our bodies protect us against TB. This knowledge is important for the development of even better TB vaccines. We also aim to find the best blood marker after vaccination to determine whether a person is protected against TB or not. Our laboratories are accredited, which means adherence to the highest international standards.



The SATVI biobank is an invaluable resource for the scientific community

SATVI has a large biobank for cold storage of blood collected from our study participants. The blood is separated into different components and stored in one of eight -80ºC freezers or thirteen liquid nitrogen tanks. We currently have more than 800,000 samples in storage. Storage of samples is important for later access to complete tests that will inform scientists of how vaccines stimulate our immune system to protect against TB.

SATVI AIMS TO BECOME A CENTRE OF EXCELLENCE FOR TRAINING IN CLINICAL, EPIDEMIOLOGICAL, IMMUNOLOGICAL AND HUMAN GENETIC ASPECTS OF TB BY:

- Offering Honours in Vaccinology, Masters and PhD student programmes, and postdoctoral fellowships
- Capacity building of SATVI technical, nursing, administrative and support staff through our Siyantinga Professional Development Programme (PDP)
- Refresher courses covering a wide range of topics in 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

World TB Day with Department of Health and **loveLife**


Community Advisory Board

SATVI WORKS WITH MANY PARTNERS TO FIND A NEW TB VACCINE

SATVI has established a strong partnership with the regional Department of Health, on whose premises our project site is located. Our Community Advisory Board (CAB) represents the interests of our local community and allows SATVI to engage with people from the research site area. SATVI's current CAB represents a mixed constituency of TB workers, farm workers, community activists, and health workers.

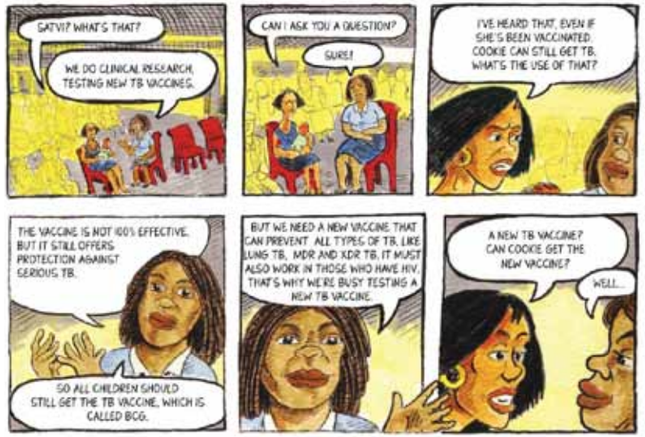
SATVI keeps the community informed about its work through a range of communication vehicles such as posters, pamphlets, newsletters, edutainment and local media (weekly print and community radio). In conjunction with the CAB and other partners, we engage the community through various outreach activities such as World TB day awareness events, public meetings and local arts and cultural activities relating to TB education, many involving schools in the region.

'This TB vaccine research affects the Boland community, so it is important that we as a community know what it is about and have a voice in this research.' Bosch Willemse, Chairperson of the Community Advisory Board (2009-2011)

SATVI WORKS IN CLOSE PARTNERSHIP WITH INTERNATIONAL AND LOCAL INSTITUTIONS, RESEARCHERS AND COMMERCIAL SPONSORS, NOTABLY:

- Multiple investigators at our University, the University of Stellenbosch and other universities in South Africa
- Department of Health at national, provincial and local levels
- Aeras Global TB Vaccine Foundation
- European and Developing Countries Trials Partnership (EDCTP) and other EU funded initiatives
- The Bill and Melinda Gates Foundation, through individual and consortium-funded projects
- NIH-funded consortia such as IMPAACT and the Tuberculosis Research Unit (TBRU)
- KNCV Tuberculosis Foundation
- Commercial and academia-based vaccine developers, such as GSK Bio, the Statens Serum Institute and the University of Oxford, Crucell, Emergent Bio Solutions, Sanofi Pasteur
- Multiple US, African and European university-based investigators
- Vodacom Foundation
- StopTB Partnership of the World Health Organisation

SATVI comic funded by Stop TB Partnership/WHO



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

SATVI is a founding 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. Member sites are situated in South Africa, Kenya, Uganda, Mozambique and Tanzania. Activities are funded by the European Developing Countries Trials Partnership (EDCTP) and the Aeras Global TB Vaccine Foundation, and involve multiple collaborators.

TBVACSIN
Tuberculosis Vaccine Trial Sites Network

CO-DIRECTORS
Associate Professor Willem Hanekom
Dr. Hassan Mahomed

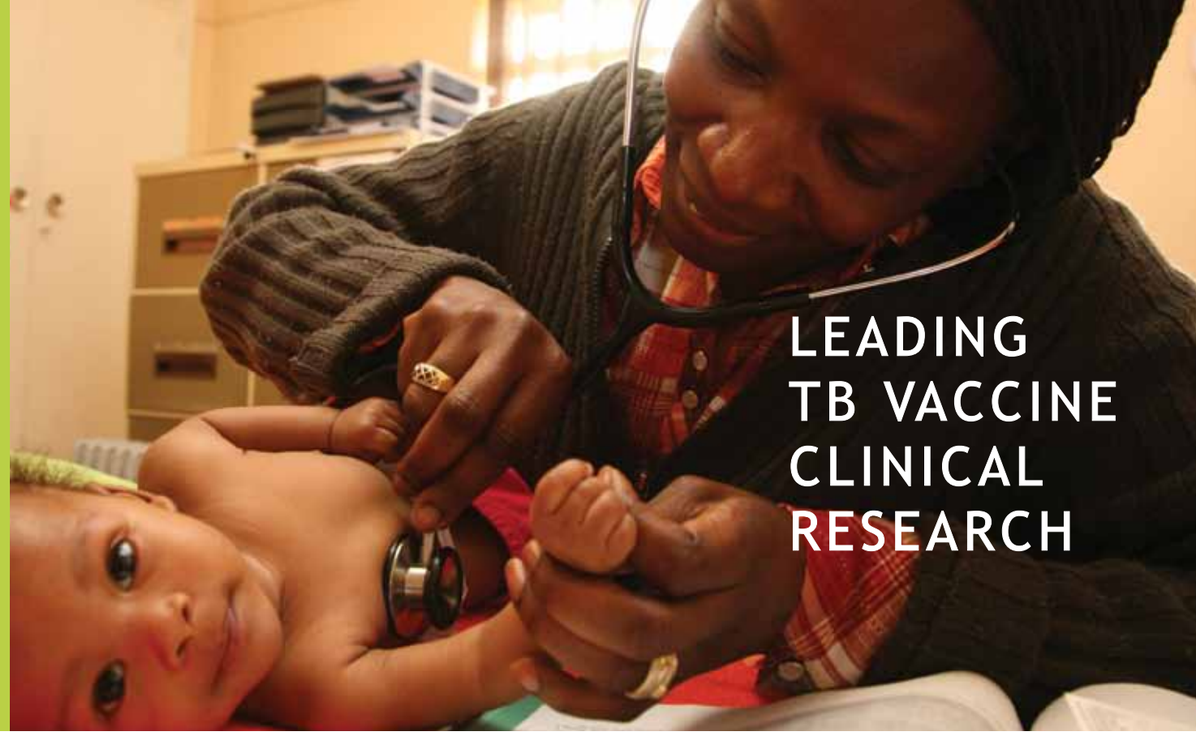
FOUNDING DIRECTOR:
Professor Gregory Hussey

SOUTH AFRICAN TUBERCULOSIS VACCINE INITIATIVE (SATVI)
Institute of Infectious Disease and Molecular Medicine (IIDMM),
Health Sciences Faculty, University of Cape Town
Rm 52.01, Level 2, Werhner Beit North Building, Anzio Road, Observatory, 7925
T +27 021 406 6014 **F** 086 613 4778 **W** www.satvi.uct.ac.za **E** satvi-info@uct.ac.za

DESIGN & LAYOUT: Laurian Miles, Mantaray Design Studio www.mantaraydesign.co.za
PHOTOGRAPHS: Courtesy of Jordi Matas, David Miles, Matthew Wilman and Lieve Vanleeuw

satvi SOUTH AFRICAN TUBERCULOSIS VACCINE INITIATIVE

VACCINES TO STOP TB



LEADING TB VACCINE CLINICAL RESEARCH

satvi SOUTH AFRICAN TUBERCULOSIS VACCINE INITIATIVE

VACCINES TO STOP TB