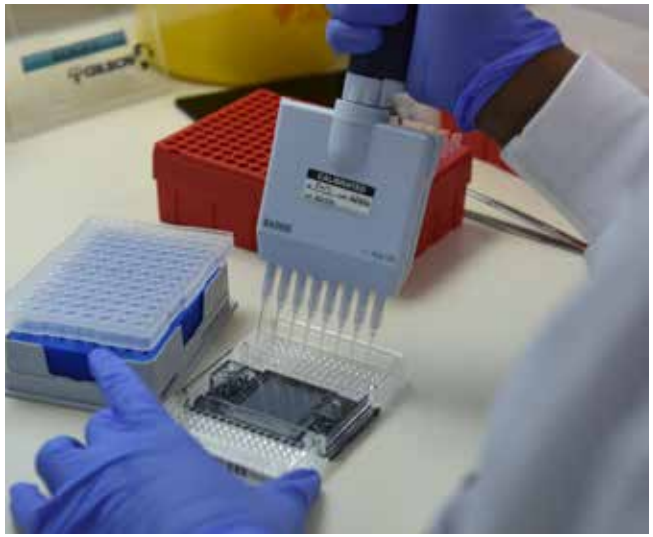
satvi

SOUTH AFRICAN
TUBERCULOSIS VACCINE INITIATIVE

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

ANNUAL REPORT 2017



vision and mission

Our Vision

A World Without TB

Our Mission

Innovative and High Quality TB Vaccine Research to Impact the Global Epidemic

Our Values

Innovation | Respect | Employee Recognition | Accountability | Communication | Commitment | Honesty

contents

directors foreword

It is a pleasure to present the 2017 Annual Report of the South African Tuberculosis Vaccine Initiative. The past year has been marked by the end of trial follow-up for three infant trials of candidate TB vaccines (MTBVAC, VPM, and H4:IC31); and the successful completion of the landmark proof-of-concept 040 trial, which tested H4:IC31 and BCG revaccination for Prevention of *M. tuberculosis* Infection (POI), defined by Interferon-Gamma Release Assay (IGRA) conversion, among adolescents in a high transmission area. The 040 trial results, which are expected in early 2018, may have important implications for discovery of immune correlates of risk and protection for TB; and will show whether the POI design has potential utility to select candidate vaccines to advance into disease efficacy trials. New projects starting in 2017 included PREDICT, a multicentre biomarker-targeted TB treatment-shortening trial, and successful grants included a Phase 2 trial of the MTBVAC candidate vaccine in adults, funded by the US Government; and three new TB vaccine trials funded by the European & Developing Countries Clinical Trials Partnership (EDCTP): an infant Phase 2 trial of MTBVAC; an efficacy trial of VPM in infants; and a Prevention of Recurrence (POR) trial of H56:IC31 in treated TB patients.

The diversification of our TB research portfolio remains a priority and it was business-as-usual for our large ongoing TB therapeutic studies. Enrolment in the multi-centre CORTIS trial of biomarker-targeted preventive therapy is approaching the half-way mark and, in a tremendous effort, the SATVI laboratory processed more than 9,000 RNA biomarker screening samples for the CORTIS trial in the last year. The AIDS Clinical Trials Group (ACTG) treatment-shortening trial A 5349 continues to enrol rapidly and is expected to reach its recruitment target in early 2018.

Our clinical and immunology research program continues to produce high quality outputs, with 24 SATVI co-authored papers in 2017. Key papers described the sequential inflammatory processes during progression to TB disease (Scriba et al, PloS Pathogens) and the dynamics of serial IGRA testing and TB disease risk in young children (Andrews et al, Lancet Respiratory Medicine).

We remain grateful for the continued support of our local and international funders, collaborators and public health stakeholders and, in particular, the strong commitment of the Boland community to the SATVI TB research programme. We are committed to engagement with the Worcester community to advance TB awareness and control, for which the drama production “Lienkie se Longe” (“Lienkie’s Lungs”) and the “Kick TB” schools programme have been stand-out examples. Our bursary scheme for local school leavers to attend university-bridging courses has seen the first four graduates and we hope to see the TB scientists of the future coming from this community.

We look forward to 2018 and the several new and exciting projects that provide welcome impetus to clinical TB vaccine development efforts in the years ahead.

Professor Mark Hatherill - Director

about SATVI

WHO WE ARE

The South African Tuberculosis Vaccine Initiative (SATVI) is a tuberculosis (TB) research group with a research scope that spans several disciplines including paediatrics, infectious diseases, epidemiology, public health, immunology, systems biology and clinical sciences. Our research focus is understanding the risk for, and protection against, *M. tuberculosis* infection and TB disease, in order to develop more effective vaccines and preventive strategies.

SATVI has a large and well-developed clinical field site in the Boland Overberg region, with the core facility on the premises of the Brewelskloof TB Hospital in Worcester, from where most clinical/epidemiological studies and clinical trials are conducted. The clinical trials research is led by SATVI Director, Professor Mark Hatherill, and the immunology and laboratory-based research is led by SATVI Deputy Director, Associate Professor Tom Scriba.

OUR RESEARCH

SATVI was established in 2001 at the University of Cape Town (UCT) and has developed into a sophisticated, world-class TB clinical research centre with state of the art immunology laboratories located within the Institute of Infectious Disease and Molecular Medicine (IDM) of the University of Cape Town. SATVI is regarded as a leader in TB vaccine and prevention research worldwide and is the largest dedicated TB vaccine research group on the African continent. Our laboratories are accredited and adhere to the highest international standards. In addition to our track record in TB vaccine development, our recent work builds on discovery of prognostic biomarkers for TB disease to test screen & treat strategies, based on biomarker-targeted TB preventive therapy.

OUR OUTPUTS

Our clinical trial programme has been extraordinarily productive over the past 16 years. SATVI has conducted 22 Phase I–IV trials of BCG and 9 novel TB vaccine candidates among more than 25,000 research participants. During 2017 our research publication output included 24 peer-reviewed papers and our cumulative publications over the last 10 years include 275 papers, the majority of these with a SATVI first or senior author. Our active postgraduate student programme has also produced 10 PhD graduates and several Masters graduates during the same period.

governance

Executive Committee

From left to right: Professor Mark Hatherill, Mrs Marwou de Kock, Associate Professor Tom Scriba, Dr Masooda Kaskar

The Executive Committee is comprised of:

Director: Professor Mark Hatherill

Deputy Director: Associate Professor Tom Scriba

Chief Operations Officer: Dr Masooda Kaskar

Field Site Manager: Mrs Marwou de Kock

EXECUTIVE COMMITTEE:

PROFESSOR MARK HATHERILL, DIRECTOR

Dr Mark Hatherill (MD, FCPaed) is a specialist paediatrician and clinical trialist who is active in the design and implementation of innovative trials of new TB vaccines and TB preventive therapy strategies, through several consortia. His current academic focus includes development and evaluation of biomarker-targeted interventions and several clinical trials of novel TB vaccine candidates.

He is a Full Member of the Institute of Infectious Disease & Molecular Medicine (IDM) at the University of Cape Town; member of the WHO SAGE Working Group on BCG Vaccine, the WHO IVR Working Group on TB Vaccines and Co-Chair of the Regional Prospective Observational Research in Tuberculosis (RePORT) South Africa consortium. Dr Hatherill is funded by institutional research grants from the Bill & Melinda Gates Foundation, SA Medical Research Council, US National Institutes of Health (DAIDS, AIDS Clinical Trials Group), the European & Developing Countries Clinical Trials Partnership and Aeras.

ASSOCIATE PROFESSOR TOM SCRIBA, DEPUTY DIRECTOR IMMUNOLOGY

Dr Tom Scriba (PhD) directs the clinical immunology laboratory at SATVI. He was trained in biological sciences at Stellenbosch University and obtained a DPhil (PhD) in T-cell Immunology at Oxford University. He returned to South Africa in 2006 to complete a postdoctoral fellowship in paediatric and clinical immunology in TB and vaccinology at the IDM, University of Cape Town.

Dr Scriba is a Full Member of the IDM, member of the STOP TB Partnership Working Group for New Diagnostics Biomarkers Taskforce and the Collaboration for TB Vaccine Discovery of the Bill and Melinda Gates Foundation (BMGF). He is funded by competitive grants from the BMGF, the National Research Foundation, SA Medical Research Council, US National Institutes of Health and the European Union.

DR MASOODA KASKAR, CHIEF OPERATIONS OFFICER

Dr Masooda Kaskar joined SATVI's senior leadership team in 2016 to advance organisational excellence and drive innovation and growth. Her leadership experience spans corporate, public and philanthropic sectors with a focus on strategic business development, governance and operations. In her current role she is a key driver of SATVI's transformation efforts and risk management plans to ensure growth and long-term sustainability of the organisation. Dr Kaskar previously occupied several senior leadership positions within the Pharmaceutical Industry. At Novartis she was instrumental in developing and implementing Transformational Growth Plans that resulted in establishing Novartis's leadership position within the industry. She holds an MBChB degree from the University of Cape Town and an MBA degree from the University of Cape Town Graduate School of Business.

MARWOU DE KOCK, FIELD SITE MANAGER

Marwou de Kock holds a Master's degree in Clinical Research Administration from the University of Cape Town, as well as degrees in biomedical science and laboratory management. She has worked at SATVI since 2002 and has intricate knowledge of the site, the people and procedures in the laboratory, clinical operations and community engagement. She helped establish the SATVI Field Site laboratory and developed it into a world class facility that received SANAS accreditation in 2010. She is currently responsible for managing the SATVI Field Site, overseeing and managing service delivery for all operations, as well as coordinating and implementing multiple research projects.

senior research team

DR MICHELE TAMERIS, INVESTIGATOR

Dr Michele Tameris graduated from the University of Cape Town with an MBChB degree in 1980. She worked for many years in the public health sector in Cape Town and in Worcester. In 2003 she joined SATVI as a clinical researcher and since 2005 has been Sub-Investigator on 15 vaccine trials, 6 as Principal Investigator, including trials of 9 novel TB vaccines and the first Phase 2b infant efficacy trial of a new TB vaccine (MVA85A). She has been awarded two Wellcome Trust International Engagement awards (2012 and 2014) for projects using drama to improve community understanding of TB clinical research. She is a member of the Stop TB Working Group on New Vaccines.

DR ANGELIQUE LUABEYA, INVESTIGATOR

Dr Angelique Kany Kany Luabeya graduated as a medical doctor in 1996 from the University of Kinshasa (DR Congo) and holds a Master's degree in Epidemiology from the London School of Tropical Medicine (LSHTM). She joined SATVI in 2009 as a clinical investigator from the Africa Centre for Health and Population Studies at University of KwaZulu-Natal and has been involved as Principal Investigator in the implementation and conduct of clinical trials of new TB vaccines (AERAS C035-456, IDRI-TBVPx-203, and VPM1002-ZA-2.13TB) in healthy adults, TB patients and newborns, respectively. She has produced a number of scientific publications and has a particular research interest in the design and conduct of TB diagnostic studies (TB case finding by oral swab PCR) and health systems operational research in the area of TB prevention in young children.

DR JUSTIN SHENJE, INVESTIGATOR

Dr Justin Shenje graduated as a Medical doctor in 2004 from the University of Zimbabwe and holds a Master's degree in Clinical Epidemiology from the University of Pretoria. He joined SATVI in 2015 as a clinical investigator and has served as Principal Investigator for the A5300, A5349 (also known as Study 31) and the Tuberculosis Case Finding by Oral Swab PCR studies. He has experience with TB prevention, diagnostic and treatment studies, but has a special interest in the application of Geographic Informational Systems (GIS) in mapping local TB incidence rates.

DR HENNIE GELDENHUYS, INVESTIGATOR

Dr Hennie Geldenhuys trained in Family Medicine and joined SATVI in 2007. He has fulfilled the role of Principal Investigator on a number of clinical trials. His current focus is coaching and training in private practice, but he remains associated with SATVI as a sessional Sub-Investigator, based at the field site in Worcester, and as clinical quality management consultant for clinical trials.

DR SIMON MENDELSOHN, INVESTIGATOR

Dr Simon Mendelsohn graduated from the University of Cape Town as a medical doctor in 2011, completing his internship training and community service in Mpumalanga. Thereafter he read for two Master's degrees at the University of Oxford on a Rhodes scholarship; in Integrated Immunology (2015) and in International Health and Tropical Medicine (2016) with a Diploma in Tropical Medicine and Hygiene from the Royal College of Physicians (London). Simon joined SATVI on a PhD Fellowship in 2017 and also works as a clinical trial sub-investigator. He has experience in HIV and TB clinical medicine, most recently with Médecins Sans Frontières implementing an HIV and TB programme in Malawi prisons. Simon's research interests lie in HIV/TB co-infection from immunological, clinical, and public health perspectives, specifically with developing practical tools for clinical practice.

DR ELISA NEMES, INVESTIGATOR

Dr Elisa Nemes completed her PhD in HIV-specific T-cell Immunology in Italy and France in 2008. She then worked on paediatric immune responses to HIV and TB in Cameroon. She joined SATVI in 2011, where she has been involved in basic immunology studies, immuno-diagnostics, clinical trials of new TB vaccines and studies of host correlates of risk of TB disease in BCG-vaccinated infants and of BCG/TB immune reconstitution inflammatory syndrome in HIV+ children. She is funded by competitive grants from the Center for AIDS Research (CFAR) and the US National Institutes of Health.

DR ADAM PENN-NICHOLSON, INVESTIGATOR

After receiving his PhD in the USA, Dr Adam Penn-Nicholson worked in industry on the development and manufacture of vaccines. He joined SATVI in 2011. Adam's main focus is the discovery of blood-based biomarkers that prospectively predict TB disease risk, and understanding the biology involved in progression from *M. tuberculosis* infection to active TB disease. He also provides scientific oversight of immunology for several clinical TB vaccine trials currently being conducted at SATVI.

research highlights

SELECTED CLINICAL TRIALS AND STUDIES IN 2017

Clinical Systems Immunology	7
Vaccine Trials	5
Diagnostic Studies	1
Drug Trials	4
Total	17

1. PROGRESSION FROM INFECTION TO PULMONARY TUBERCULOSIS FOLLOWS DISTINCT TIMELINE

A research highlight in 2017 was the publication of findings which describe the sequence of biological processes that occur in healthy humans infected with *M. tuberculosis* as the infection progresses to pulmonary TB disease, appearing in *PLOS Pathogens*.

The purpose of the study was to create an understanding of the mechanisms that underlie progression to TB. During the study 150 adolescents infected with *M. tuberculosis* were observed over several years, with 106 remaining healthy and 44 developing pulmonary TB within a few years of initial infection.

For the duration of the study, blood samples were studied to compare the immune system activity of individuals who remained healthy with those who eventually fell ill. Some signs of progression, in particular very specific inflammatory signals, were detectable as early as one to two years before disease diagnosis, while others were only detectable just before manifestation of active disease.

Eighteen months prior to diagnosis, those who ultimately developed TB displayed elevated levels of the immune system signaling molecules, known as interferons, which aid in fighting infection. They also had elevated activity of the complement system, another immune system component.

The study is ground-breaking, because it reveals a timeline to the progression from infection to disease and provides important new information about the processes that occur during this transition. A better understanding of these sequential inflammatory responses informs how and to whom preventive antibiotic treatment should be given to prevent TB before the disease manifests.

2. A RANDOMIZED, PLACEBO CONTROLLED, PARTIALLY BLINDED PHASE II STUDY TO EVALUATE SAFETY, IMMUNOGENICITY, AND PREVENTION OF INFECTION WITH *MYCOBACTERIUM TUBERCULOSIS* OF AERAS-404 AND BCG REVACCINATION IN HEALTHY ADOLESCENTS (CLINICAL TRIALS GOV: NCT02075203)

SATVI Principal Investigator: Mark Hatherill
Funder: Aeras

This landmark first proof-of-concept trial (040) for the prevention of *M. tuberculosis* Infection (POI) approach to the up/down-selection of candidate TB vaccines for further clinical development, was successfully completed in 2017. The trial demanded a huge collaborative effort from the clinical team, who achieved 96% participant retention, and from the laboratory team, who processed more than 6,000 IGRA assays.

The 040 trial will show whether BCG revaccination or the novel TB vaccine candidate H4:IC31 (AERAS-404) can protect adolescents against *M. tuberculosis* infection, defined by Interferon-Gamma Release Assay (IGRA) conversion, in a high transmission area.

Results, which will be available in early 2018, may impact clinical development of new vaccines that are preparing to enter large trials to test efficacy against TB disease; may help identify immune correlates of risk or vaccine-mediated protection for TB; and will provide insight into the potential utility of the POI trial design as a tool for clinical vaccine development.

3. THE CORRELATE OF RISK TARGETED INTERVENTION STUDY (CORTIS)

A Randomized, partially-blinded, clinical trial of Isoniazid and Rifapentine (3HP) therapy to prevent Pulmonary Tuberculosis in High-Risk individuals identified by a Transcriptomic Correlate of Risk

National Principal Investigator: Mark Hatherill
SATVI Principal Investigator: Michele Tameris
Funders: Bill and Melinda Gates Foundation; SAMRC

CORTIS builds on a decade-long project to develop a host blood RNA biomarker that predicts whether a person is at risk of developing TB, based on the human immune response (Zak et al, Lancet 2016). In this large clinical trial we are evaluating whether targeted preventive therapy for people with a positive RNA biomarker test can stop them from developing TB. This international collaboration is led by SATVI in partnership with the Aurum Institute, the Stellenbosch University Immunology Research Group, the Centre for the AIDS Programme of Research in South Africa (CAPRISA), the London School of Hygiene and Tropical Medicine (LSHTM), and the Fred Hutchinson Cancer Research Center (FHCRC).

The trial is recruiting 3,200 HIV-uninfected adult volunteers, from communities with high TB burden at 5 sites in South Africa, who are randomised to either preventive therapy or active surveillance based on their RNA biomarker test result. All participants are screened for TB disease at baseline, and through 15 months of follow-up, to evaluate the biomarker for diagnosis of prevalent TB and prognosis of incident TB. Efficacy of preventive therapy (3 months of once-weekly, high dose Isoniazid and Rifapentine) for protection against incident TB will be evaluated in sub-groups of RNA biomarker positive participants in the preventive therapy and active surveillance arms. If successful, CORTIS would provide proof of concept for a strategy of biomarker-targeted TB preventive therapy. Mass campaigns using a ‘TB screen & treat’ strategy have the potential for major impact on the global epidemic.

With CORTIS enrolment approaching the half-way mark, our laboratory has processed more than 13,000 RNA samples on the Fluidigm RT-PCR platform in the last year, which demonstrates that high-throughput host blood RNA biomarker screening is possible in a TB endemic country. Preliminary indications suggest a very high prevalence of TB disease in this study population, which is enriched for RNA biomarker-positive persons. Data remain blinded and results are expected in 2019.

CORTIS has also provided an extraordinary opportunity for related studies to advance our understanding of the RNA biomarker of TB, including: a parallel prognostic study among HIV-infected people; a sub-study of the dynamics of the RNA biomarker during and after preventive therapy; a sub-study of the relationship between other respiratory pathogens and RNA biomarker expression; a sub-study comparing RNA biomarker expression between HIV-infected and uninfected people; and a biorepository project to store samples for the analysis of future novel biomarkers in the same CORTIS cohort.

overview of clinical & immunology research

Correlates of Risk Targeted Intervention Study - High Risk (CORTIS-HR).

National Principal Investigator: Mark Hatherill
SATVI Principal Investigator: Michele Tameris
Funder: Bill and Melinda Gates Foundation; SAMRC

CORTIS-HR is an observational study of the diagnostic and prognostic performance of the host blood RNA biomarker of TB in HIV-infected persons. This multi-site study aims to enrol 860 participants and follow them up over a 15 month period, to determine if the transcriptomic signature can identify prevalent and incident TB in this population. We have completed the enrolment of the SATVI-allocated 150 participants and follow-up is still ongoing. We anticipate results will be available early in 2019.

A Phase IIb, double-blinded, randomized, placebo-controlled study to evaluate the efficacy, safety and immunogenicity of GSK Biologicals candidate Tuberculosis (TB) vaccine GSK 692342 against TB disease, in adults aged 18-50 years, living in a TB endemic region.

Principal Investigator: Mark Hatherill
Funders: Aeras, GSK

The 018 trial is an efficacy trial of the novel M72:ASO1E candidate vaccine to establish whether M72:ASO1E protects HIV uninfected, *M. tuberculosis* infected, previously BCG vaccinated adults against TB disease over 3 years of follow-up. The trial is fully enrolled and follow-up is ongoing. A primary analysis will be conducted in the first quarter of 2018.

Clinical Trials gov: NCT01755598

Using Biomarkers to Predict TB treatment duration (PREDICT).

Principal Investigator: Michele Tameris
Funding: Bill and Melinda Gates Foundation; EDCTP; ICIDR; RePORT South Africa

This is a prospective, randomized, Phase 2b non-inferiority trial in pulmonary drug-sensitive TB participants. Eligible participants initially receive Isoniazid (H), Rifampin (R), Pyrazinamide (Z), Ethambutol (E) for 8 weeks, then switch to Isoniazid and Rifampicin (HR). Early treatment completion criteria will be evaluated for each participant using all available data at Week 16. Those who do not meet the early treatment completion criteria will be put into Arm A (2HRZE/4HR) and those who meet early treatment completion criteria, will be randomised at week 16, either to continue therapy to week 24 (Arm B) or to complete therapy early at week 16 (Arm C). All participants will be followed until approximately 18 months from the start of the study, with the primary endpoint evaluated at 18 months.

Rifapentine-containing treatment shortening regimens for Pulmonary Tuberculosis: A randomized, open-label, controlled phase 3 clinical trial (ACTG Study A5349).

Principal Investigator: Justin Shenje
Funders: ACTG, DAIDS, TBTC

A5349/S31 is a multi-centre randomized controlled TB drug trial, led by ACTG and the Tuberculosis Trials Consortium (TBTC), which seeks to enrol 2,500 participants to compare standard treatment for drug-sensitive TB with novel shortened regimens which contain Rifapentine and Moxifloxacin. Outcome measures of the study include microbiological and clinical treatment success and non-recurrence of disease, as well as safety parameters. The study started in July 2016 and has thus far successfully enrolled 99 participants.

Tolerability, and Pharmacokinetics of Bedaquilline and Delamanid, alone and in combination, among patients taking Multidrug Treatment for Drug-Resistant Pulmonary Tuberculosis (ACTG 5343).

Principal Investigator: Justin Shenje
Funders: ACTG, DAIDS

Bedaquiline and Delamanid are novel experimental drugs for the treatment of Multi-drug resistant TB. The safety of the combination of these two drugs with standard MDR treatment has not been investigated, especially for their known effect on the heart. This trial, for which SATVI is one of 3 global sites, tests each drug alone or together in addition to standard MDR-TB treatment, with intensive monitoring for electrocardiogram (ECG) changes and other safety events. The participants are treated as in-patients for at least the first 8 weeks of treatment in co-operation with Brewelskloof Hospital, a local TB referral facility. Recruitment for the trial commenced in November 2016 and to date, six participants have been enrolled.

Clinical Trials gov NCT02583048

Phase II double-blind, randomized, controlled study to evaluate the safety and immunogenicity of VPM1002 in comparison with BCG in HIV-exposed and HIV-unexposed, BCG-naive newborn infants.

Principal Investigator: Michele Tameris
Funder: Serum Institute of India, Ltd

BCG is currently the only licensed TB vaccine, but it provides incomplete protection against pulmonary TB in children and variable protection in adults. It is also contraindicated for HIV-positive persons due to the high risk of adverse events. This multi-site trial of 416 infants evaluated the safety and immunogenicity of the candidate recombinant BCG vaccine VPM1002, in HIV exposed and unexposed neonates, compared with BCG. Enrolment and follow up at all sites is now complete. We anticipate the results of this trial will be made available in the first quarter of 2018.

Clinical Trials gov: NCT02391415

Phase I/II, safety and immunogenicity study of a recombinant protein tuberculosis vaccine (H4:IC31) in BCG-primed infants (P1113, Aeras C-015-404).

Principal Investigator: Dr Michele Tameris
Funders / Sponsors: Aeras, NIAID, NICHD, IMPAACT

This multisite study of 211 participants will evaluate the H4:IC31 vaccine, designed as a booster to BCG to provide protection against *M. tuberculosis* infection and/or TB disease early in life. The trial compares different doses and number of administrations of the vaccine, in infants of different ages. Enrolment and follow up is complete at all sites and the database was locked at the end of 2017. We anticipate the results of this trial will be made available in 2018.

Clinical Trials gov: NCT01861730

A randomized, double-blind, dose-escalation clinical trial of the safety, reactogenicity and immunogenicity of MTBVAC compared to BCG Vaccine SSI in newborns living in a tuberculosis endemic region with a safety arm in adults.

Principal Investigator: Dr Michele Tameris
Funder: Biofabri

The novel vaccine, MTBVAC, is the first recombinant live, whole cell *M. tuberculosis* vaccine in clinical testing, intended as a BCG replacement vaccine in newborns, or a booster to BCG in older individuals. In this trial we first tested the safety of MTBVAC in 18 BCG vaccinated, TB uninfected adults. After establishing safety in adults, the safety and immunogenicity of 3 doses of MTBVAC was tested in 36 BCG-naïve newborns, compared against BCG. Enrolment and follow up has been completed and results are expected to be available in the first quarter of 2018.

Clinical Trials gov NCT02729571

Tuberculosis case-finding by Oral Swab PCR.

Principal Investigators: Angelique Luabeya and Jerry Cangelosi
Funders: University of Washington, NIH, Bill and Melinda Gates Foundation

This study tests the buccal swab method to collect DNA from the inner surface of the mouth for amplification of DNA from *M. tuberculosis* by polymerase chain reaction (PCR) technology, thus allowing highly specific diagnosis of TB. The study aims to evaluate the performance of the buccal swab test in comparison with conventional sputum-based diagnostic methods. The study has recruited 175 individuals presenting with TB symptoms and 70 healthy controls. Preliminary results indicate that *M. tuberculosis* cells and DNA accumulate in diagnostically useful amounts within the oral cavity of patients with TB.

Study of multi-drug resistant (MDR) tuberculosis (TB) cases and their household contacts: Operational feasibility to inform protecting household contacts on exposure to newly diagnosed index MDR TB cases (PHOENIx) trial design.

Principal Investigator: Justin Shenje
Funders: ACTG, DAIDS

The PHOENix study evaluated the feasibility of recruiting household MDR-TB contacts, their willingness to take medication to prevent transmission of TB and to identify the proportion of high risk household contacts. In the first phase, the PHOENIx study recruited a total of 64 participants for the period November 2015 to February 2016. This was followed by a one-year extended follow-up period of a subset of these household contacts. Thirty seven of the initial household contacts were followed up. Study enrolment and follow up have now come to an end and data analysis is in progress.

Immunological significance of QuantiFERON TB Gold in-tube reversions in settings with high burden of tuberculosis.

Principal Investigator: Elisa Nemes
Project Scientist: Cheleka Mpande
Funder: National Institutes of Health (NIH)

This project set out to identify adaptive and innate Immune responses associated with spontaneous reversion of the QuantiFERON In Tube assay (QFT), used to determine if a person is infected with *M. tuberculosis*. Our study will contribute to the interpretation of QFT serial testing, develop novel and more robust immunological assays to diagnose *M. tuberculosis* infection and monitor vaccine-induced immune responses. Results will also generate hypotheses about immune protection from *M. tuberculosis* infection.

Proteomic correlates of risk of TB disease.

Principal Investigator: Thomas Scriba
Project Scientist: Adam Penn-Nicholson
Funder: Bill and Melinda Gates Foundation (PI: Urs Ochsner)

The aim of this project is to discover and validate a blood protein biomarker, or signature, that identifies healthy, asymptomatic individuals with *M. tuberculosis* infection and who are at risk of progression to active TB disease. Such a test would allow targeted preventive treatment before the onset of TB disease, presenting an opportunity to prevent transmission.

In collaboration with Dan Zak and colleagues at the Center for Infectious Disease Research in Seattle and Urs Ochsner and Mary-Ann de Groote and colleagues at SomaLogic in Boulder, Colorado, we used the aptamer-based SOMAscan proteomic platform to simultaneously quantify more than 3,000 different proteins in plasma samples from *M. tuberculosis*-infected adolescents who remained healthy (controls) or developed TB disease (progressors) during two years of follow-up. We identified two proteomic signatures that identify individuals at risk of developing TB, one comprising of 3 proteins and the other of 5 proteins. Both proteomic signatures validated in an independent cohort of household contacts of TB patients from The Gambia (from the GC6-74 study), who either progressed to active disease or remained healthy. Our vision is to develop a novel point-of-care device that can easily, accurately and rapidly determine an individual's risk of TB progression using small volumes of blood, such as a finger prick.

A head to head comparison of T cell responses induced by six novel TB vaccine candidates.

Principal Investigator: Thomas Scriba
Project Scientists: Miguel Rodo, Virginie Rozot, Francesca Little
Funder: SACEMA (studentship to Miguel Rodo)

We have conducted Phase I/II safety and immunogenicity trials of 9 novel TB vaccine candidates at SATVI. In all these trials, vaccine-induced immune responses were measured using a qualified whole blood intracellular cytokine staining (WB-ICS)/flow cytometry assay. Results from each clinical trial are typically analysed and published separately, which makes the comparison of vaccine-induced immune responses difficult. In this statistical study we leveraged the extensive WB-ICS datasets to perform direct "head-to-head" comparison of CD4 and CD8 T cell responses induced by six vaccines that include different antigens delivered in viral vectors, as fusion proteins in adjuvant formulations or in live, whole bacterial vaccines.

In collaboration with Francesca Little at the Department of Statistical Sciences, we developed statistical approaches, including longitudinal response models and multivariate dimensionality reduction techniques, to compare antigen-specific T cell responses from healthy participants vaccinated with MVA85A, Aeras402, M72:ASO1E, H1:IC31, H56:IC31, ID93:GLA-SE, as well as BCG. Our aim is to identify which vaccines induce immune responses that are either very similar or those that induce unique responses, to inform selection of vaccine candidates for down-stream vaccine efficacy testing.

Age-associated inflammatory determinants of risk of tuberculosis disease.

Principal Investigators: Thomas Scriba
Project Scientists: Richard Baguma, Adam Penn-Nicholson
Funder: European and Developing Countries Clinical Trials Partnership (EDCTP)

On average, approximately 10% of *M. tuberculosis*-infected individuals progress to active Pulmonary TB disease. Despite relatively consistent acquisition rates of new *M. tuberculosis* infection, TB disease incidence is much lower in pre-adolescent children in the so-called "Golden Age" (between 4 and 12 years), compared to adolescents or adults. This differential risk presents an opportunity to identify the immune mechanisms of *M. tuberculosis* control, or of risk of progression from infection to active TB disease.

We have identified inflammatory molecules that are inherently expressed at lower levels in pre-adolescent children than in young adults, which we hypothesize are involved in age-associated inflammatory determinants of risk of TB disease. We are currently validating our results using an alternative approach and determining if *M. tuberculosis* infection modulates these inflammatory responses to different degrees in the different age groups.

planned studies

MTBVAC Phase 1b/2a randomized, double-blind, active-controlled, safety, immunogenicity, and dose-escalation study in adults with and without latent tuberculosis infection in South Africa.

Investigator: Angelique Luabeya
Funders: NIH, CDMRP
Sponsor: Aeras

MTBVAC is a live-attenuated TB vaccine based on deletion of the genes encoding two major virulence factors, the transcription factor regulator PhoP (phoP) and the virulence associated cell-wall lipids PDIM (fadD26), from a clinical isolate of the Euro-American Mtb lineage, which is the most widespread lineage commonly transmitted between humans by the aerosol route. We aim to evaluate safety and reactogenicity of MTBVAC at escalating dose levels compared to BCG vaccine in 144 adults aged 18-50 years with and without latent tuberculosis infection. The participants will be followed for 12 months after vaccination and the estimated study duration (from first participant vaccinated to completion of data collection) is approximately 24 months.

A Phase 2a randomised controlled dose-defining trial of the safety and Immunogenicity of MTBVAC in healthy, BCG naïve, HIV unexposed, South African newborns.

Investigator: Michele Tameris
Funders: Biofabri, EDCTP

This planned Phase 2a randomized controlled, dose defining trial of the safety and immunogenicity of MTBVAC in 99 newborns is planned to start in the third quarter of 2018. Infants will be enrolled sequentially into one of three cohorts to receive a single intradermal dose of MTBVAC 2.5×10^4, 2.5×10^5 and either 2.5×10^3 or 2.5×10^6 CFU, compared to the BCG vaccine (24 BCG; 75 MTBVAC).

The primary objectives of this study are to evaluate the safety, reactogenicity and immunogenicity of MTBVAC at escalating dose levels compared to the BCG vaccine in healthy, BCG naïve, HIV unexposed, South African newborns. The secondary objectives of this study are to evaluate the immunogenicity of MTBVAC at escalating dose levels as compared to BCG and to evaluate QuantiFERON conversion and reversion rates in these neonates.

A multicenter Phase III double-blind, randomized, controlled study to evaluate the efficacy and safety of VPM1002 in comparison to BCG.

Investigator: Angelique Luabeya
Funder: EDCTP
Sponsor: VPM

The VPM1002 (Hyg-)-BCG-derivative is a new putative Vaccine against *M. tuberculosis*. We aim to evaluate the safety and tolerability and efficacy of VPM1002 compared with BCG Vaccine SII, as assessed by the difference in incidence of adverse reactions related to lymphadenopathy, other systemic reactions, and protection against TB disease in infants vaccinated with BCG Vaccine SII or VPM1002.

Protecting households on exposure to newly diagnosed index multidrug-resistant tuberculosis patients (PHOENIx MDR-TB).

Investigator: Justin Shenje
Funders: DAIDS, ACTG

The PHOENIx MDR-TB study is a Phase III, open-label, cluster-randomized, multi-center trial which aims to compare the efficacy and safety of Delaminid versus Isoniazid for preventing active TB disease among high-risk household contacts (HHC) of adults with MDR-TB. The study seeks to recruit 3,452 HHC from multiple sites and follow them for 96 weeks for TB disease.

A double blind phase II randomised control trial evaluating the safety and efficacy of a novel tuberculosis vaccine H56:IC31 in prevention of recurrence of tuberculosis in patients who have successfully completed six months of tuberculosis treatment.

Investigator: Justin Shenje
Funders: EDCTP

The study seeks to evaluate the safety and efficacy of H56:IC31 in the prevention of recurrence of TB in individuals who have recently successfully completed 6 months of TB treatment. The prevention of recurrence study design reduces the required sample size and follow-up period to evaluate vaccine efficacy by targeting individuals with a high incidence of TB, in this case individuals who have recently completed TB treatment. The study is a multi-centre, double blind, randomized clinical trial which aims to recruit 900 participants and follow them up for a period of twelve months.

Transmission of tuberculosis in high schools students in Worcester, South Africa.

Principal Investigator: Mark Hatherill & Erick Bunyasi (PhD student)
Funder: Stanford University (PI Andrews)

We aim to investigate whether room air sampling and testing indoor air quality can identify high risk classrooms for TB transmission. We will determine whether these findings can inform a screening strategy that will enable the earlier and faster identification of TB patients in schools and reduce risk of spread of TB to fellow learners and teachers. This observational study, which will involve approximately 3,000 learners, will commence in 2018.

awards, honours & accreditations

1. Professor Mark Hatherill was selected as a member of the World Health Organisation Initiative for Vaccine Research Working Group (IVR) on TB Vaccines.

2. Dr Michele Tameris was awarded C1 accreditation as an Established Researcher by the National Research Foundation (NRF) and selected as member of the Stop TB Working Group on New Vaccines.

3. Dr Munyaradzi Musvosvi was awarded a Postdoctoral Fellowship under the new Carnegie Corporation Developing Emerging Academic Leaders (DEAL) in Africa programme.

4. Dr Adam Penn-Nicholson was awarded an Early Scientist Award by the Collaboration for TB Vaccine Discovery (CTVD)

research outputs

1. **A novel blood test for tuberculosis prevention and treatment.** Penn-Nicholson A, Scriba TJ, Hatherill M, White RG, Summer T. South African Medical Journal. 2017; 107(1):4-5.

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8. **The CSF immune response in HIV-1-associated cryptococcal meningitis: macrophage activation, correlates of disease severity, and effect of antiretroviral therapy.** Scriven JE, Graham LM, Schutz C, Scriba TJ, Wilkinson KA, Wilkinson RJ, Boulware DR, Urban BC, Meintjes G, Lalloo DG. Journal of Acquired Immune Deficiency Syndrome. 2017; 1; 75(3):299-307.

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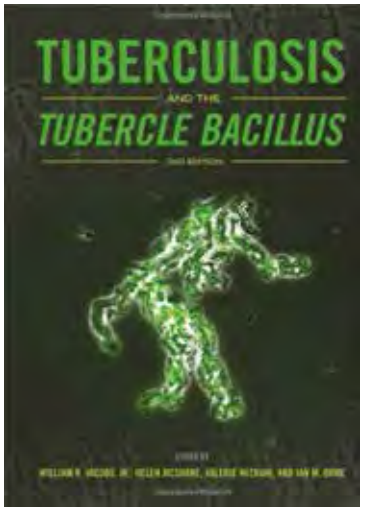
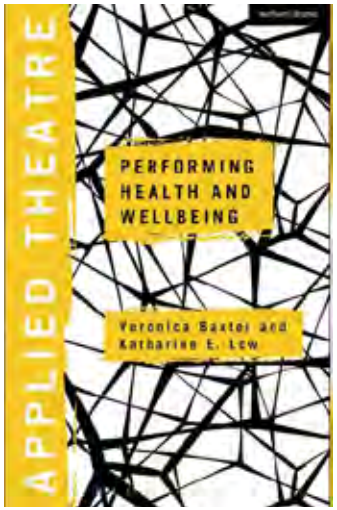
Book Chapters





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our staff

SATVI says farewell to Dr Hennie Geldenhuys

In June 2017 we said farewell to Dr Hennie Geldenhuys, who after a clinical research career of ten years at SATVI, spanning across a number of TB research areas, decided to pursue his interests in coaching and training.

CASUAL DAY

Casual Day has become an annual fixture on our calendar through which our staff get involved with the Casual Day Non-profit Organisation, which benefits organisations working with people with disabilities.

WELLNESS DAY

Staff Wellness Wellness Day, 10 November 2017

STAFF TRAINING

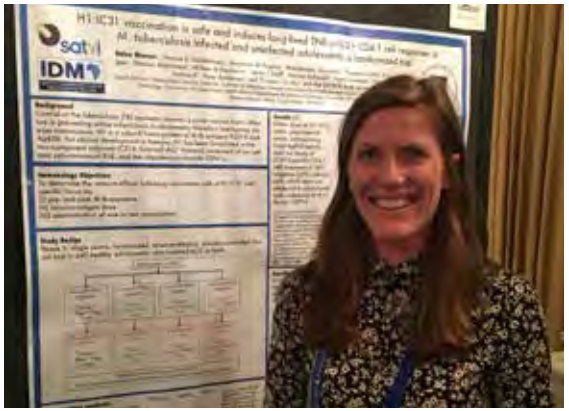
Staff Training; Good Clinical Practice, HIV and Communications

postgraduate students

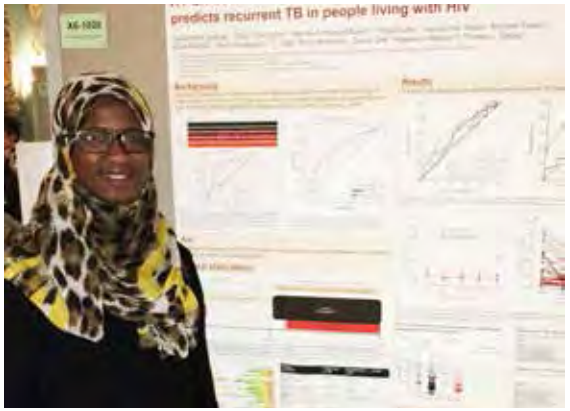
During the year under review we hosted two Masters students, seven PhD students and 6 Postdoctoral Fellows.

& postdoctoral fellows

Justin Dixon, a visiting student graduated with a PhD from the University of Durham with a thesis titled: "Disease, morality and Bio-Ethics: An Ethnographic Study of a TB Vaccine Trial in South Africa", which was based on his work at SATVI.



Dr Helen Mearns, Postdoctoral Fellow presenting a poster titled "H1:IC31 induces long-lived TNF-α+IL-2+ CD4 Tcell responses in M. Tuberculosis infected and uninfected adolescents" at the Keystone Symposia on Molecular and Cellular Biology.



Fatoumatta Darboe PhD student who has been selected as a grant recipient from Margaret McNamara Education Grants.

our community

LIENKIE'S LUNGS DRAMA

During 2017 Lienkie's Lungs, a locally produced drama which aims to raise awareness about TB, featured on Hectic Nine 9, a national youth television programing reaching an estimated two million viewers. The drama cast performed an extract from the play to a live audience on this youth TV program.

During the program Dr Michele Tameris, SATVI Investigator, who conceptualised the drama and secured funding from the Wellcome Trust through an engagement program, spoke about the prevalence, signs and symptoms and treatment of TB, as well as the work that the SATVI.

BEAT TB GRAFFITI WALL

During 2017 the Beat TB Graffiti Wall and Stories of Engagement was displayed at the "Art of Medicine" exhibit convened by the Hatter Institute and the UCT Health Sciences Faculty.

COMMUNITY ADVISORY BOARD

In April 2017 the SATVI and the Community Advisory Board hosted Allegra Cermak, CAB Coordinator from ACTG.

In June 2017, Belinda Ameterra, the CAB chairperson was awarded the Bridget Murtagh and Sharon Maxwell Community Impact Awards for her involvement in the AIDS Clinical Trials Group (ACTG) network.

During the year the CAB has been extremely busy with engaging SATVI researchers. The Youth CAB has been involved with participatory activities to better understand study protocols, through roleplay and media work.

During December the CAB participated in a training program conducted by the SATVI laboratory to better understand the clinicial research process, with a focus on biobanking.

In December 2017 the CAB participated in the “TB Under the Microscope” Art/Science Exhibit, a collaborative exhibition held in Cape Town between scientists and social scientists aimed at sharing scientific research on TB with the broader public. This initiative was funded by the Wellcome Trust.

KICK TB POSTER COMPETITION

In February 2017, we announced the winners of the 2016 Kick TB Poster Competition which was held amongst local schools in the Cape Winelands district. The competition attracted one hundred and six entries from learners. Adjudication was done by a panel comprising of SATV, Kick TB & HIV, Aeras and the UCT Michaelis Art School. During October 2017 we have launched a second competition in October, also expanding to other art forms, such poetry and songs.

UNIVERSITY BRIDGING BURSARY PROGRAMME

In 2017 we supported 4 learners from the Cape Winelands district with the registration fees for the SciMathUS program, a university preparation program offered by the University of Stellenbosch. All have improved on their Grade 12 results and have been accepted for first year studies at tertiary institutions, including one student who will study for a BSc Pharmacy degree.

SOCIAL RESPONSIBILITY

During 2017 we have supported numerous social organisations working in the Cape Winelands ranging from old age homes, to community-based soup kitchens and community agriculture initiatives.

SCHOOL & COMMUNITY TB AWARENESS PROGRAM

During 2017 we have conducted several community based talks within the community ranging from schools, youth centres, places of safety, workplaces, to community events, reaching in excess of one thousand people.

BEAT TB THROUGH BEADMAKING

During SATVI partnered with Ikamva Lethu, a arts and crafts womens project to teach beading skills to children.

EHWOZA WELLCOME TRUST-FUNDED COMMUNITY ENGAGEMENT PROJECT

Cheleka Mpande and Pia Steigler facilitated a TB vaccinology workshop, during EH!WOZA, a Wellcome Trust funded community engagement project.

This Wellcome Trust-funded community engagement project, which aims to engage Grade 10 and 11 pupils from Khayelitsha-based is coordinated by Dr Anastasia Koch, a Postdoctoral Research Fellow at the Clinical Infectious Diseases Research Initiative (CIDRI) within the IDM.

RESEARCH AND POLICY DEVELOPMENT

Dr Michele Tameris, SATVI Principal Investigator presented an oral paper titled “Building a portfolio of Community Engagement Projects to enhance TB knowledge” at the Ukwanda Rural Research Day of the University of Stellenbosch (May 2017).

Kelvin Vollenhoven presented an oral abstract titled “Community Engagement in TB Research and Development” at the Union World Conference on Lung Health (October 2017), as well as 2 poster abstracts titled respectively “Leveraging libraries in raising awareness about TB on World TB day in the Worcester community” and “Drama as community engagement tool to raise TB awareness” at the Provincial Research Day (October 2017) of the Department of Health (Western Cape).

SATVI staff Dr Michele Tameris, Marwou de Kock, Linda van der Merwe and Kelvin Vollenhoven contributed towards the development of the “Good Participatory Practice Guidelines for TB Vaccine Research” which was tabled at the Union World Conference on Lung Health (October 2017).

funders

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SOUTH AFRICAN
TUBERCULOSIS VACCINE INITIATIVE

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

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