INNOVATION

AT THE SOUTH AFRICAN MEDICAL RESEARCH COUNCIL

saMRC
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CONTENTS

THE SOUTH AFRICAN MEDICAL RESEARCH COUNCIL – A GATEWAY TO HEALTH RESEARCH AND INNOVATION IN SOUTH AFRICA AND BEYOND

The South African Medical Research Council (SAMRC) is a parastatal organization established through Act No. 19 of 1969, which was later replaced by the SAMRC Act No. 58 of 1991. It is the largest local funder of health research in Africa, with total annual revenue of around R1,3 billion (~US$72 million), of which approximately 58% is from a baseline government grant and 41% from contract income. More than 80% of the total income is invested in research, innovation and capacity development.

The SAMRC's Mission is to improve the nation's health and quality of life by conducting and funding relevant and responsive health research, development, innovation and research translation.

The core functions of the SAMRC towards achieving its mission are depicted in Figure 1 below.

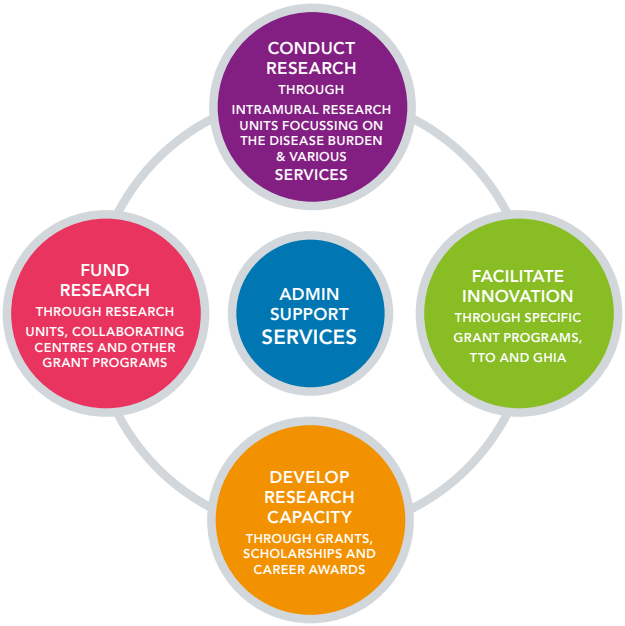


Figure 1: Core functions of the SAMRC

The SAMRC has a long track record of funding high quality health research, innovation and capacity development programs, including large, multi-institutional and multi-disciplinary programs, some of which are described in the following sections. We implement sound financial governance in accordance with the standards of generally recognized Accounting Practice (GRAP), Good Financial Grant Practice (GFGP) and the requirements of the South African Public Finance Management Act 1 of 1999, and consistently achieve clean audits from the Auditor General of South Africa as well various international funders. As a result, a number of organizations have entrusted the SAMRC to manage funding for health research and innovation in South Africa and beyond on their behalf, including the SA National Department of Science and Innovation, the Bill & Melinda Gates Foundation, the Newton Fund, GSK, Novartis and various philanthropic foundations.

In addition to sound financial management, the SAMRC has a national footprint with a vast network of local and international research and innovation partners. We can also co-fund programs and leverage existing investments and partnerships to ensure maximum value and impact of any funding programs. The SAMRC also has full end-to-end capability to plan, implement and manage small, medium and large, multi-centre clinical trials. Our innovation programs include a range of grant types from seed fund grants to full-scale product development and testing grants, hands-on support to drive innovation and commercialization and broader health innovation ecosystem support.

The SAMRC is an ideal partner for international funders, academic institutions, philanthropies and private sector stakeholders seeking to implement health research and innovation programs on the African continent.

GRANT AND INNOVATION PROGRAMS AT THE SOUTH AFRICAN MEDICAL RESEARCH COUNCIL

The sections below provide details on a selection of grant and innovation programs managed by the SAMRC. They involve a range of different funding and partnering models that are tailored to the needs of the strategic partners involved.

Global Health Innovation Accelerator (GHIA)

In August 2014, the SAMRC and US-based product development partnership, PATH, formed the Global Health Innovation Accelerator (GHIA) as a partnership to address the gaps and barriers in the health innovation ecosystem in South Africa and to enhance the ability of both organizations to meet their respective mandates. GHIA is aimed at facilitating the late stage development and introduction of affordable and appropriate global health technologies in South Africa and Africa more broadly.

GHIA combines the local context experience and networks, human and financial resources and research and development project portfolio of the SAMRC with PATH's in-house product development and commercialization expertise, network of international health technology companies, international footprint in developing countries and global funding and advocacy network. GHIA's value proposition is thus the combination of offerings from two reputable organizations with demonstrated success in utilizing resources to drive health impact and commercialization. The ultimate goal of GHIA's work is to strengthen the health innovation ecosystem in South Africa, to deliver new health solutions, and to drive positive social health impact through its programs and projects. This is achieved through the project and ecosystem support activities of MeDDIC, as described in the next section, as well as hands-on support for global health product development, testing, commercialization and scale up.

For funders, GHIA offers the potential to de-risk projects and to enhance the probability of success by presenting projects that have been through a thorough due diligence process, that respond to a clear market need, that are technically sound and backed by strong academic networks, and that are rigorously managed by experienced project managers to deliver on defined milestones. GHIA also addresses social imperatives by focusing on technologies aimed at improving health outcomes for vulnerable populations.

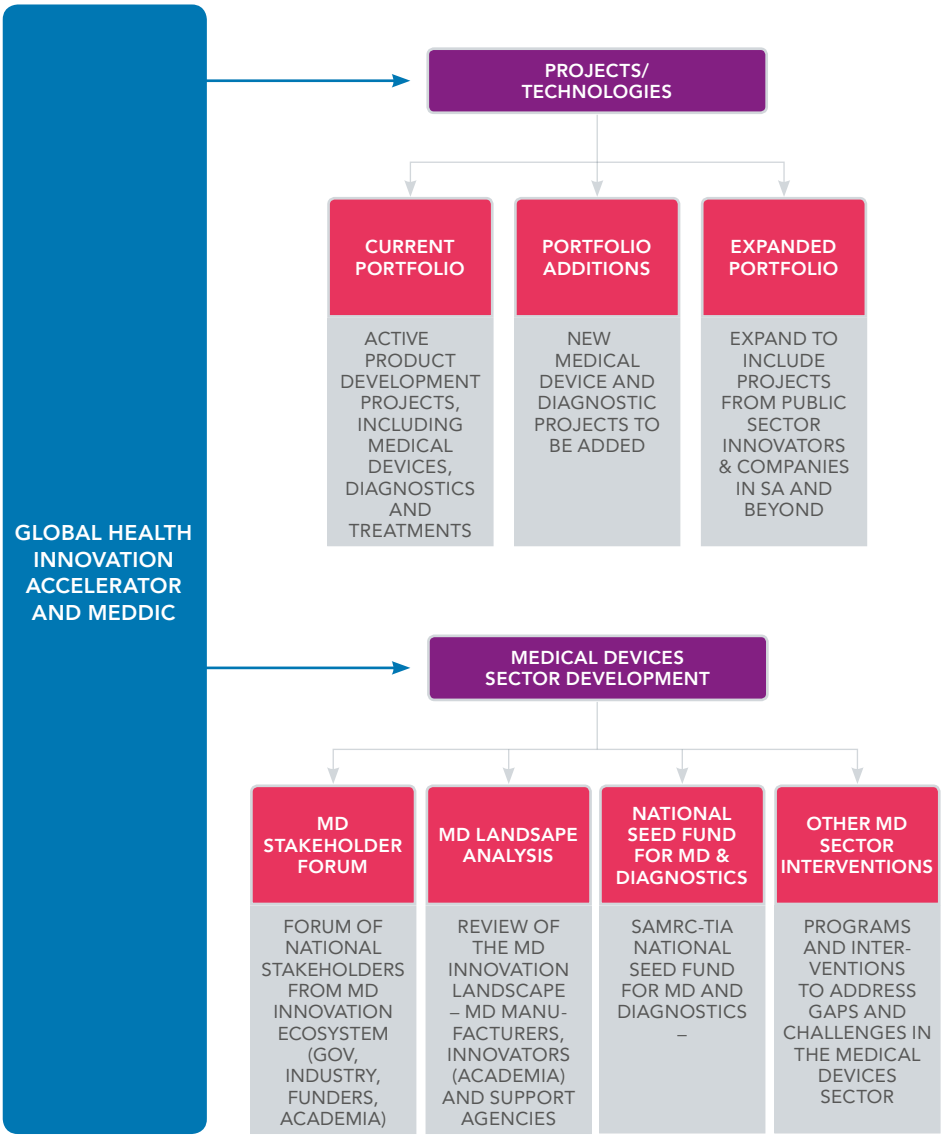


Figure 2: Activities of the Global Health Innovation Accelerator

Medical Device and Diagnostic Innovation Cluster

The Medical Device and Diagnostic Innovation Cluster (MeDDIC) is a national program aimed at increasing innovation and manufacturing in the medical devices and diagnostics sector in South Africa. It is funded by the Technology Innovation Agency (TIA) and the Department of Science and Innovation (DSI) and hosted by the SAMRC under the Global Health Innovation Accelerator program.

MeDDIC was created to exploit a high concentration of skills, expertise, infrastructure and companies across South Africa within the medical devices field. The initiative is aimed at stimulating and intensifying technology innovation within the sector as well as encouraging an integrated ecosystem in support of increasing the competitiveness of the industry.

VISION	***"To stimulate and advance the creation of a sustainable, dynamic and internationally competitive South African medical device and diagnostic ecosystem in which ideas can become realities that positively impact healthcare and outcomes in Africa".***
MISSION	***"To develop a vibrant, cohesive ecosystem in which stakeholders co-operate and collaborate pre-competitively to seamlessly design, develop, manufacture and commercialize medical devices with a significantly increased local content, thereby contributing to the sector and broader economic development".***

The primary goal of MeDDIC is to facilitate, coordinate and support key initiatives that will grow the medical device innovation and manufacturing ecosystem through the following objectives:

CO1: INTEGRATED AND COHESIVE ECOSYSTEM	• Policy and Regulatory Support • Strengthening the Ecosystem • Leveraging Funding
CO2: LOCALISATION AND RAPID PRODUCT DEVELOPMENT	• Establish a Technology Product Development and Manufacturing Pipeline • Support Regulatory Compliance • Increase Utilisation of Key Technologies, Platforms and Capabilities
CO3: HUMAN CAPITAL DEVELOPMENT	• Development of Regulatory Knowledge and Expertise • Key Skills Training

MEDICAL DEVICES STAKEHOLDER FORUM (MDSF)

MeDDIC hosts the secretariat for the MDSF, which is aimed at providing a platform for increased cooperation and information sharing amongst key stakeholders in the medical devices ecosystem.

SUPPORT FOR REGULATORY COMPLIANCE

MeDDIC has teamed up with the Council for Scientific and Industrial Research (CSIR) to offer regulatory support to those in the sector developing new or improved medical devices.

SEED FUNDING FOR PRODUCT DEVELOPMENT

MeDDIC is supporting several projects to develop novel medical devices and diagnostics and to localize the production of currently imported devices.

MEDICAL DEVICES INNOVATION BRIDGE PORTAL

The CSIR has developed a dedicated medical devices section within the national Innovation Bridge Portal on behalf of MeDDIC.

CAPACITY DEVELOPMENT FOR MEDICAL DEVICE INNOVATION

MeDDIC is working with academia and industry to capacitate medical device innovators and industry personnel for product development, registration and commercialization.

FUND RAISING AND ADVOCACY

MeDDIC is facilitating fund raising for the sector and provides a platform for advocacy and collective response to sector challenges.

mRNA Technology Transfer Hub

The mRNA Technology Transfer Hub was established at Afrigen Biologics in 2021 by the World Health Organization (WHO), with support from Medicines Patent Pool (MPP), and is aimed at building capacity in low- and middle-income countries to produce mRNA vaccines through a centre of excellence and training. The mRNA Hub will share technology and technical know-how with local and international vaccine producers to enable rapid response to vaccine needs during pandemics.

In order to ensure sustainability, the SAMRC is driving a product development pipeline for the mRNA Technology Transfer Hub. The SAMRC is funding and coordinating a network of institutions involved in the development and testing of mRNA-based candidates for a variety of priority diseases, including COVID, HIV and TB. The development program is also looking at improved, locally developed carriers, manufacturing processes and raw materials for manufacture. The Hub is seeking partners with a common goal and vision to work together to develop vaccines for priority pathogens in Africa.

Strategic Health Innovation Partnerships (SHIP)

Launched in 2013, the Strategic Health Innovation Partnerships (SHIP) program is a partnership between the SAMRC and the South African National Department of Science and Innovation (DSI). The goal of SHIP is to strengthen the research and development ecosystem and advance health innovation to address the health priorities of South Africa and other low-resource settings. SHIP funds, co-ordinates and actively manages multi-disciplinary, multi-institutional product research, development and innovation programmes from discovery to proof of concept.

Informed by national health innovation priorities in digital health, precision medicine, and new treatment and prevention technologies, SHIP's investments are targeted at addressing the following disease areas:

Focus	HIV	TB	NCD	MCH	AMR	MALARIA	COVID-19
Treatment	●	●	●	●		●	●
Diagnosis	●	●	●	●	●		●
Prevention	●	●	●	●	●		●
Digital Health	●	●	●	●	●	●	●
Precision Medicine			●	●			●

HIV

The SHIP HIV program supports the development of solutions spanning prevention, treatment, diagnostics, platforms, and HIV cure.

TB

The SHIP TB program supports projects that are aimed at the discovery and development of novel, shorter TB drug regimens as well as point-of-care diagnostic tests.

Malaria

The focus of the SHIP malaria program is to identify and progress novel compounds to drug candidates for the treatment of malaria.

Non-communicable diseases

The program has focused on diagnostics, therapeutics and platforms to address various disease areas including diabetes, cancer, and cardiovascular disease.

Maternal and Child Health

The goal of the program is to support development of innovative solutions to address the key drivers of deaths in neonates, children under-5, and pregnant women in low-resource settings.

Antimicrobial Resistance

The SHIP programme is aimed at the development of innovative solutions for surveillance, diagnosis, and digital health solutions to inform decision-making in the treatment of drug resistant bacteria in various health settings.

SHIP was established as a mechanism to coordinate relevant partners with an interest in investing in health innovation in South Africa. To date, SHIP has worked with funders such as the Bill & Melinda Gates Foundation, the Medicines for Malaria Venture, Grand Challenges Canada, Newton Fund, Joint Programming Initiative on AMR (JPIAMR), and the South African Technology Innovation Agency. SHIP has also co-funded programmes with the private sector, including Anglo-American Platinum, Novartis, GSK, and has recently concluded a Memorandum of Understanding with the Innovative Pharmaceutical Association of South Africa. Total funding secured from various partners to date (expended and committed) is over USD $70 million, with at least half provided by the South African government through various funding streams.

Some examples of successful SHIP investments include:

Exatype:
a cloud-based method for detecting mutations in high-throughput sequencing data.

GIFT:
an affordable and easy-to-use test to detect sexually transmitted infections in asymptomatic women.

Uterine Balloon Tamponade (UBT):
an affordable, easy to use device for treating postpartum hemorrhage.

UmbiFlow:
a simple-to-use, cost-effective, portable ultrasound device for antenatal screening of placental function during pregnancy to prevent stillbirths.

GKnowmix
A diagnostic test kit and pharmacogenomics algorithm for breast cancer.

H3D
Establishment of local drug discovery capability.

The SAMRC is seeking partners who are interested in working together on any of the local priority areas described here, as well as the intersection of climate and health.

The South African Precision Medicine Program

Precision medicine (PM) is an emerging field that utilizes advanced technologies and data analysis to tailor medical treatment and prevention strategies to individual patients based on their unique genetic, environmental, and lifestyle factors. Since, 2016, The SAMRC, in collaboration with the DSTI, has been driving the genomic/ precision medicine initiative in South Africa. Furthermore, the SAMRC as the secretariat of the South African Precision Medicine Think Tank and active participant of the EU Africa PerMed Consortium, has been involved in developing an interdisciplinary research and innovation programme to catalyse precision medicine in South Africa. This is aimed at addressing the significant healthcare challenges faced by South Africa, with a rising prevalence of non-communicable diseases such as cardiovascular diseases, diabetes, and cancer as well as looking at host genomic influences on susceptibility for infectious diseases (HIV/ TB).

Key objectives of the South African Precision Medicine Program include:

Genomic Research: The program emphasizes research to identify genetic variations and biomarkers associated with various diseases prevalent in the South African population. This research is crucial for understanding disease susceptibility, treatment response, and drug interactions specific to different genetic backgrounds. Africa is the most genetically diverse continent, with a wide range of ethnic groups and genetic variations. However, there is a lack of representation of African populations in genetic studies and databases, hindering the development of personalized medicine approaches tailored to the unique genetic profiles of Africans.

Data Infrastructure: The program aims to establish a robust data infrastructure to collect, store, and analyze large-scale genomic and clinical data to facilitate the integration of genomic information into routine healthcare practices, enable data sharing and collaboration among researchers and healthcare providers, and support the development of predictive models and algorithms for precision/ personalized medicine.

Clinical Implementation: The ultimate goal is to translate genomic research findings into clinical practice. This involves developing guidelines and protocols for healthcare professionals to effectively use genomic information in patient diagnosis, treatment selection, and monitoring. A core component is to educate and train healthcare providers to ensure they have the necessary knowledge and skills to utilize precision medicine approaches in their practice.

Ethical and Legal Considerations: The program is addressing ethical, legal, and social implications associated with precision/ personalized medicine, including privacy and data protection, informed consent, and equitable access to genomic technologies.

Collaborations and Partnerships: Establishing links with academic institutions, research organizations, industry stakeholders, and international initiatives to leverage expertise, resources, and knowledge sharing, has played a crucial and successful role in establishing the South African PM ecosystem. Collaboration has enabled access to cutting-edge technologies, facilitates research collaborations, and promotes capacity building in precision/ personalized medicine.

The vision for the South African PM Program is to revolutionize healthcare delivery, enable targeted therapies, and improve the overall health and well-being of the South African population. We are actively seeking program partners to drive this agenda, including to develop population-specific genomic studies to move Africa forward; and to incorporate the latest technologies in the healthcare sector on the continent in order to provide quality care and precision medicine options to African patients.

Grand Challenges South Africa

Launched in 2003 by the Bill & Melinda Gates Foundation as Grand Challenges in Global Health, this initiative initially focused on 14 major scientific challenges that, if solved, could lead to key advances in preventing, treating, and curing the diseases and health conditions contributing most to global health inequity. It was relaunched in 2014 as Grand Challenges and has grown into a family of global initiatives aimed at fostering innovation to solve key health and development problems.

Grand Challenges South Africa was launched in 2014 as a partnership framework for the South African Medical Research Council, the South African Department of Science and Innovation, and the Bill & Melinda Gates Foundation to launch joint challenges aimed at catalyzing innovative health research within South Africa to address the country's health priorities. To date, Grand Challenges South Africa has supported projects aimed at addressing the following priorities:

Maternal, neonatal and child health: Announced in 2014, this call sought new measurement tools and new combinations of approaches targeting healthy birth, growth, and neurodevelopment to ensure all children thrive, and was co-funded by the SAMRC and the Bill and Melinda Gates Foundation. This call was launched in parallel with Grand Challenges Brazil and Grand Challenges India, in addition to a global call. A second request for proposals was announced in 2017, in partnership with Grand Challenges Africa and the Bill and Melinda Gates Foundation. This call was based on the Grand Challenges Explorations approach launched by the Bill and Melinda Gates Foundation and sought to engage more of the world's innovators. The goal of the initiative was to identify high-risk, high-reward ideas to address maternal and neonatal health challenges in Africa, which would be supported with budgets ranging up to $100 000 over a period of 18 – 24 months.

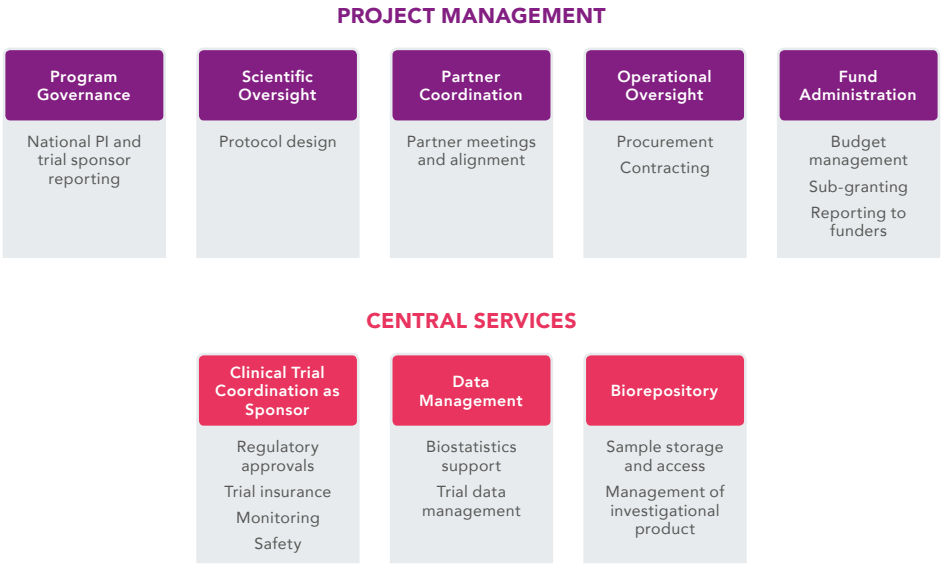
Antimicrobial Resistance: Launched in 2018, this call was aimed at the identification and development of new approaches to characterize the global burden of antimicrobial resistance. It was co-designed and launched together with Grand Challenges Africa, Grand Challenges Brazil, Grand Challenges India, with support from the Bill and Melinda Gates Foundation.

Grand Challenges South Africa has also worked with Grand Challenges Africa and Grand Challenges Canada to identify and provide transition-to-scale support to promising maternal and neonatal health projects led by South African innovators. One of the key successes from this endeavour is the development of a simple to use Protein-to-Creatine (PrCr) radiometric urine dipstick test, which detects concentrations of protein and creatinine in urine, providing a colorimetric read-out as an indicator of preeclampsia. The test is simple enough to use by health care providers across the health care system in developing countries including at the community level where most women receive routine antenatal care. The test has been successfully commercialized in Ghana, South Africa and Kenya, and has been procured for use in Pakistan, Philippines, Indonesia, and Egypt.

Together with AUDA-NEPAD and Grand Challenges Africa, Grand Challenges South Africa is supporting the establishment of country Grand Challenges programmes on the African continent. Through the SAMRC's Global Health Innovation Accelerator (GHIA) program, the SAMRC will drive the establishment of an innovation network where Grand Challenges national programs can work together to provide pre-commercialization and support to projects, and fill innovation skills gaps through capacity development.

SAMRC'S CLINICAL TRIAL CAPABILITY

The SAMRC has established the capability to offer end-to-end clinical trial management in South Africa and beyond for infectious diseases, with a focus on vaccine trials, as depicted in the figure below.



The SAMRC's Clinical Trial Unit (SAMRC CTU) is headed by Professor Glenda Gray, a National Research Foundation A1-rated scientist, world-renowned for her research in HIV and COVID vaccines, and interventions to prevent mother to child transmission of HIV. She is co-Principal Investigator of the National Institutes of Health-funded HIV Vaccine Trials Network (HVTN) and directs the program in Africa. She is supported by a program management team that offers a full clinical trial service to companies or academic institutions wishing to test their products on the African continent, including the following.

Protocol Development

Under Prof Gray's leadership, the SAMRC CTU provides guidance to internal and external collaborators on protocol development for prevention, screening, diagnostic and treatment trials. The SAMRC CTU team has experience with protocol development and implementation of first in human dose finding (Phase 1) trials to Phase 2 and Phase 3 (safety and efficacy / effectiveness) trials. The team has also successfully executed a large-scale emergency national roll out study, known as SISONKE, which saw the vaccination of 500,000 healthcare workers across more than 30 sites in South Africa.

The SAMRC CTU is supported by the SAMRC Research Integrity Office and the SAMRC Bioethics Advisory panel, who ensure that all study designs, informed consents, and study material developed by the team comply with local and international guidelines for research, based on ethics and human rights.

Regulatory Support

The SAMRC CTU offers regulatory support to internal and external, local, and international collaborators and ensures that the trials are run in compliance with the Declaration of Helsinki, the US Food and Drug Association Code of Federal Regulations, and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP). The Regulatory team submits initial applications, amendments to protocols and ongoing study communications on behalf of partners conducting trials in South Africa to the local regulator, the South African Health Products Regulatory Authority (SAHPRA) and to local ethics committees. The team also facilitates consultative meetings with the local regulator to keep them abreast of clinical trial activities, and to seek guidance on study design and research questions being posed. This collaborative process provides clarity to the regulator and assists to expedite timelines for approvals of the clinical trials in South Africa.

Sponsors are required to register their trials on a clinical trial registry in South Africa. The South African National Clinical Trials Register (SANCTR) provides the public with updated information on clinical trials on human participants being conducted in South Africa, while the Pan African Clinical Trials Registry (PACTR) is the only African Primary Registry in the World Health Organization's Registry Network, and it fulfils the International Committee of Medical Journal Editors (ICMJE) mandate for prospective registration of all trials prior to publication. Both the SANCTR and PACTR registries are hosted and managed by the SAMRC, on behalf of the South African Department of Health. The SAMRC CTU team registers clinical trials on behalf of sponsors on both these platforms.

Clinical Research Site Selection

The SAMRC CTU has 6 of its own clinical research sites in KwaZulu Natal and has access to a network of >30 other clinical research sites across South Africa and in other sub-Saharan African countries. This national and regional presence ensures that there is adequate representation of different populations and geographies in the trials. The team assists sponsors with site selection and site Principal Investigator selection.

Statistical Support and Data Management

The SAMRC's Biostatistics Research Unit provides biostatistics expertise, statistical support and data management for trials. They assist with the clinical trial design and sample size, development of statistical analysis plans, analysis of clinical trial data, development of hard copy and electronic case results forms (CRFs), database set-up, and data management.

Biobanking

The SAMRC has a centralized NIH approved, DAIDS Good Clinical Laboratory Practices (GCLP) compliant sample archive facility located at the SAMRC Peter Mokaba Ridge campus. The biorepository has the capacity to store approximately 1,140,000 samples. Samples currently in storage originated from ethics approved local and international clinical trials.

The biorepository team applies for the import and export permits, and other documents required for international shipments. The biorepository manager works together with the SAMRC legal department, local ethics committees and collaborators to ensure that material transfer agreements and specimen storage informed consents are in place prior to shipments. The SAMRC biorepository is currently storing and shipping regularly to neighboring African countries and to the USA for NIH funded clinical trials.

The SAMRC biorepository uses the NIH supported Frontier Science and Technology Research Foundation, web based, Version 10.1 LDMS system to electronically manage samples in storage. This data management system is FDA, 21 CFR Part 11 compliant and meets National Institute of Standards and Technology (NIST) and Federal Information Security Management Act (FISMA) guidelines.

This web-based, password protected, data management system, allows approved internal and external users to view samples in storage, and samples that have been shipped, thus supporting local and international sample sharing, and enhancing scientific collaboration.

Community

Clinical trial activities are further supported by experienced community teams who have forged good relationships with community leaders and councilors. They provide community education and explain research activities, thus reducing misconceptions and misinformation around clinical trials and encouraging enrolment. The team also assists with recruitment plans.

Laboratory

The SAMRC CTU has 5 SANAS accredited, DAIDS GCLP compliant onsite laboratories in KwaZulu Natal. They partner with local research laboratories and private and government diagnostic laboratories to conduct safety testing and specialized study specific tests. They have collaborative agreements in place with the University of Cape Town, the National Institute of Communicable Diseases (NICD), KwaZulu-Natal Research Innovation and Sequencing Platform (KRISP), Africa Health Research Institute (AHRI) and Centre for Epidemic Response & Innovation (CERI) at Stellenbosch University. CERI is a specialized genomics facility of the Africa CDC and WHO AFRO in Africa and leads the Network for Genomic Surveillance-SA. The SAMRC also has a Genomics Platform that was established in July 2019 through a partnership between the SAMRC and the Beijing Genomics Institute (BGI) to provide next generation sequencing (NGS) to African scientists.

Pharmacy

The SAMRC CTU has 5 pharmacies registered with the South African Pharmacy Council (SAPC). The Pharmacy team aids and provides guidance on the regulatory clearance required for the importation of investigational product into South Africa and provides pharmacy support for clinical trials.

IT Infrastructure

SAMRC's network connectivity is provided by TENET (The Tertiary Education and Research Network of South Africa). Multiple levels of data and physical security are in place. All network links are protected by enterprise grade Palo Alto layer seven firewalls and all shared resources on the network are restricted by an active directory username/password. Physical access to datacenters is limited to selective senior IT server support staff via biometric access with full audit logs. Datasets can be stored securely on SAMRC servers and accessed selectively based on agreed data governance protocols. The robust IT infrastructure allows for the safe transfer of large data sets to local and international collaborators. Full video and teleconferencing facilities enable staff to effectively communicate with local and international collaborators via both video

and audio platforms.

BCEPS - Biometric Co-enrolment Prevention System

The SAMRC Biometric Co-enrolment Prevention System (BCEPS) is used to check for the participation of volunteers in other clinical trials and to assist with eligibility confirmation. The BCEPS is a web-based application using biometrics to prevent participant co-enrolment between clinical research trials and sites. This application checks and captures the participant's South African Identity number/ Passport number and fingerprints. BCEPS is used to determine if a volunteer has screened and/or enrolled in another research study within research organizations that are listed in the co-enrolment database. The BECPS system was developed and is maintained by the SAMRC. Memoranda of Agreement (MoA) are in place between the SAMRC and other research organizations in South Africa to utilize the system. This is currently the only database controlling for co-enrollment into clinical trials in South Africa.

Training and Mentorship

Transformation remains an integral part of building sustainable health research capacity in South Africa. The SAMRC CTU provides training and mentorship to up and coming clinical trialists. They also providing training required for the operational implementation of the clinical trials at a site level.

Financial Management

The SAMRC's Grants Innovation and Product Development Unit manages the internal and external funding for research and innovation, including large, multi-source grants for clinical trials. The unit manages all sub-contracting and procurement for the studies, including the clinical trial insurance.

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Medical Devices Innovation Bridge Portal
Visit the Medical Devices and Diagnostics Innovation Bridge platform on this link:
https://www.innovationbridge.info/ibportal/meddic

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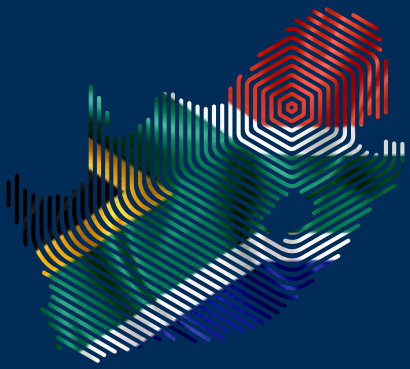

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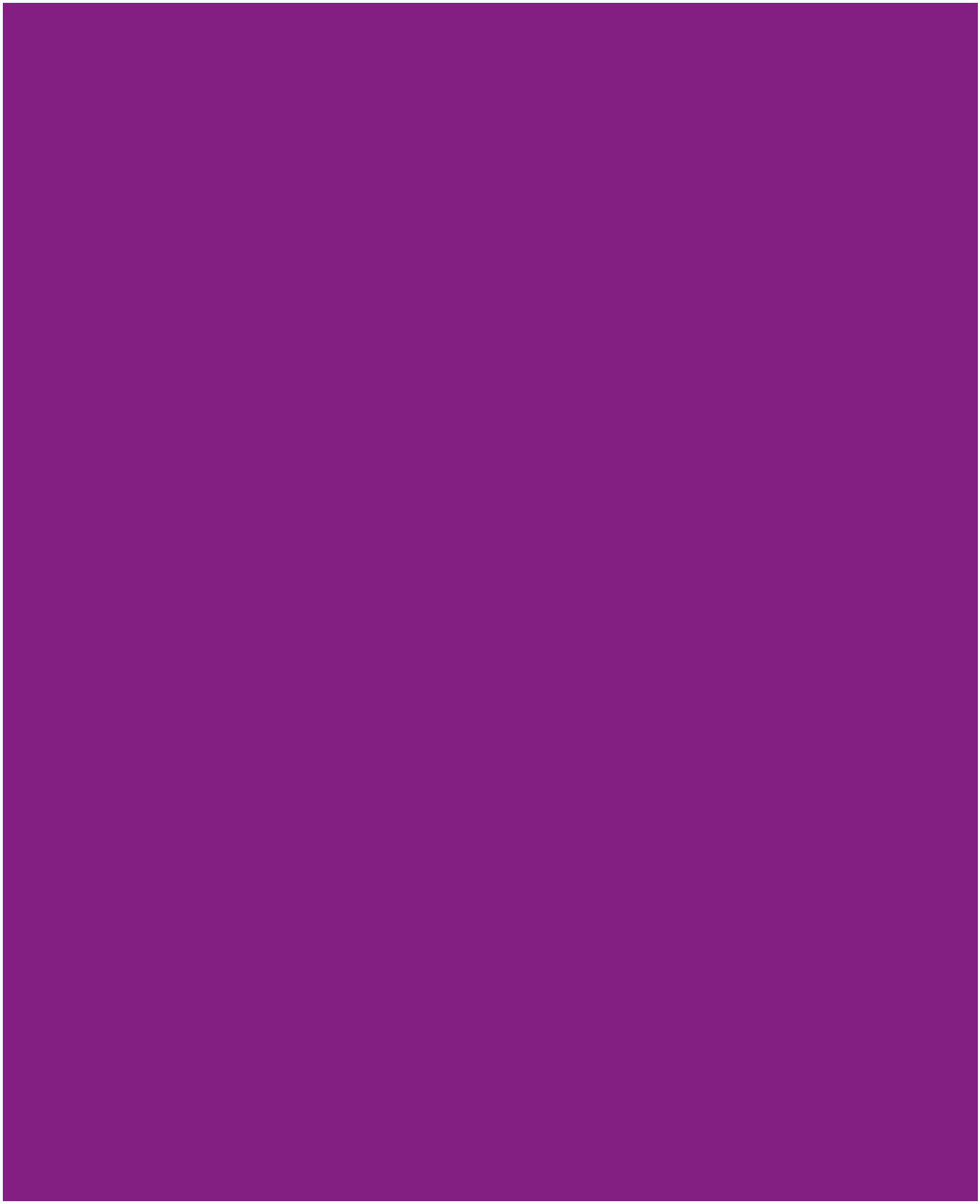

DIAGNOSTICS

PILOT SCALE PRODUCTION PROCESS FOR A BST POLYMERASE

TECHNOLOGY DESCRIPTION

Bst polymerase is a key component for accurate, affordable, field-deployable DNA-based diagnostics. Bst polymerase fits these criteria as the basis for loop-mediated isothermal amplification (LAMP), a nucleic acid amplification technique (NAAT) that is becoming increasingly popular globally as a more accessible alternative to PCR in a variety of applications. Compared to other nucleic acid amplification techniques, LAMP can be 10 to 100-fold more sensitive than PCR, showing a higher specificity with an amplification time usually less than 1 h at 60–65°C. Additional advantages include not requiring an initial template denaturation step at 95°C and being less prone to inhibitory substances often present in biological samples. Perhaps one of the most interesting benefits is that LAMP output may be visualized by the naked eye (e.g., turbidimetry), making it ideal for low resource settings and point-of-care applications.

LAMP has been used for the detection of pathogens such as Adenoviral keratoconjunctivitis and cancer diagnostics such as detecting metastasis of gastric cancer. More recently, LAMP has been applied to the molecular detection of SARS-CoV-2 due to the rapidity and specificity of its amplification mechanisms. Additionally, LAMP has played an important role in the quality control of food and dietary products, such as rapid detection of Salmonella, Staphylococcus aureus, and E. coli.

The enhanced Bst polymerase developed by DHS Healthcare is envisaged to be incorporated into diagnostic kits and used in point-of-care medical devices.

BENEFITS/VALUE PROPOSITION

- A locally developed and produced reagent to stimulate the growth of the diagnostics and reagents industry in Africa.
- Offers a solution for accurate, affordable, field-deployable DNA-based diagnostics.
- No instrumentation required for visualization, allowing use in low resource settings and point-of-care applications.

CURRENT STATUS

- Plasmid of interest successfully transformed into competent cells and established a master cell bank.
- Successfully produced Bst polymerase at laboratory scale
- The team are preparing for pilot scale production using an automated Chi.Bio platform.

OPPORTUNITIES

The team is seeking the following:

- Active engagement with potential funders and partners to open new sales and distribution networks and assist in obtaining regulatory certifications.
- Expert guidance and collaborations with clinicians and consultants.
- In addition, DHS Healthcare has a pipeline of enzymes, reagents and associated equipment in various stages of development, and welcomes engagement with potential funders and partners to explore these.

FOR MORE INFORMATION PLEASE CONTACT:
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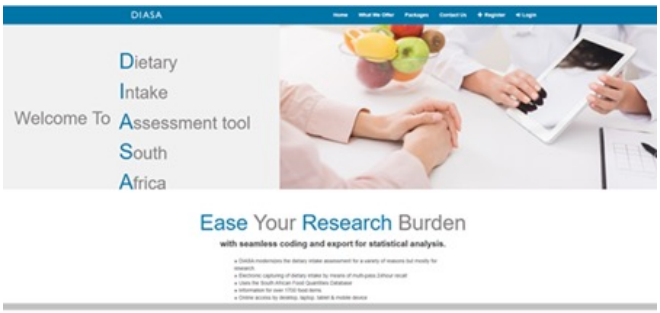
www.samrc.ac.za/content/innovation-samrc

HEALTH INTERVENTIONS

THE DIETARY INTAKE ASSESSMENT TOOL FOR SOUTH AFRICA (DIASA)



TECHNOLOGY DESCRIPTION

The foundation of sound nutrition research and practice starts with sound dietary intake assessment. However, the collection of this important data comes with many challenges. The global need for more effective methods has led to the development of many digital automated methodologies and tools across the globe. The absence of such an automated digital tool for South Africa highlighted the need to develop an application which could be used broadly across all practices in the nutrition research fraternity. The newly developed DIASA app is a web-based, android driven mobile application which employs multi-pass 24-hour dietary intake assessment methodology, linking the South African food identity and food quantity databases for automated quantification and coding with the aim to assist in dietary intake assessment research.

VALUE PROPOSITION

A multi-pass 24-hour recall dietary intake assessment mobile application utilizing the South African validated food quantities database and food identification system of the national South African food composition database (SAFoods).

BENEFITS

The DIASA is a mobile application developed to assist with research by enabling guided multi-pass intake methodology and submission of collected intake data to a research manager for real time quality assurance, data approval or rejection with in-app notifications. The application facilitates automated communication between fieldworkers collecting data and research managers/PIs responsible for dietary intake assessments. DIASA enables food code linking, portion size auto-calculation, and coding for multi- export modalities. It also allows the option of collecting additional individualized information and data to facilitate flexibility.

OPPORTUNITIES

The DIASA application is available for subscription through the SAMRC for those involved in clinical and other research in South Africa that requires dietary intake assessment.

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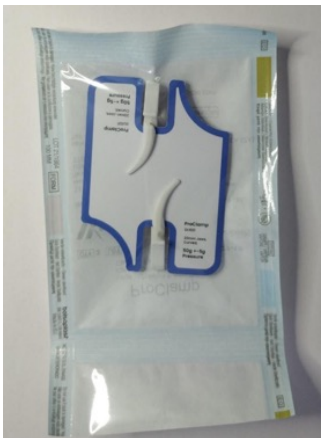
MEDICAL DEVICES

LIGHTWEIGHT, COST-EFFECTIVE, SINGLE USE POLYMER SURGICAL BULLDOG CLAMPS



BACKGROUND/TECHNOLOGY DESCRIPTION

Coba Manufacturing has developed a disposable, sterile bulldog clamp with a soft textured foam jaw liner that provides constant and consistent atraumatic clamping pressure. A surgical bulldog clamp is a medical device used during surgical procedures to control or temporarily stop blood flow in blood vessels. It is a clamp with a scissor-like structure that is used to compress a blood vessel to prevent or reduce blood flow to that area. The bulldog clamp is designed to be placed on an artery or vein to restrict the flow of blood to a specific area of the body during surgery. The clamp can be used in a wide range of surgical procedures, including cardiovascular surgery, plastic surgery, and orthopedic surgery. The surgical bulldog clamp comes in different sizes and shapes, depending on the specific surgical procedure and the size of the blood vessel that needs to be clamped. With traditional, reusable metal bull clamps, the pressure degrades over time, resulting in inconsistent and unreliable clamping force. Additionally, the hard metal surface of traditional clamps damages the outer wall of the vessel which leads to complications. COBA Manufacturing's affordable single-use polymer bulldog clamps offer consistent and safe clamping pressure. The soft textured foam jaws result in safe and secure atraumatic clamping of the vessels. Additionally, the use of injection moulding technology has made the manufacturing process more cost-effective to ensure an affordable disposable device. They are lightweight, cost-effective, and offer consistent atraumatic clamping pressure with each use. Having constant clamping pressure ensures that the bulldog clamp maintains a secure and stable occlusion of the blood vessel during a surgical procedure, reducing the risk of complications. The soft textured foam jaws of COBA Manufacturing's bulldog clamps also provide atraumatic occlusion of the blood vessel, resulting in less tissue damage and faster healing time for the patient.

CURRENT STATUS

The technology has been fully developed.

- All clamp variants have been tested and validated.
- The team has partnered with an international distributor of surgical instruments.
- The developed bulldog clamps have been used in surgeries with great success.
- The products are FDA registered.

INTELLECTUAL PROPERTY AND PUBLICATIONS

- Know-how – cost effective injection molding manufacturing process developed in-house.
- Proprietary clamp designs informed by surgeons.

OPPORTUNITIES

To further the technology development and commercialization of these single-use plastic bulldog clamps, COBA Manufacturing is seeking international partners to increase the distribution of the device worldwide. Additionally, funding is needed to obtain the CE mark for the device, as it is currently only registered with the FDA. The company is also looking for investors, funders, and regulatory assistance to help bring this innovative technology to more surgical procedures and patients worldwide.

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THERAPEUTICS

GREEN ROOIBOS EXTRACT

TECHNOLOGY DESCRIPTION

Rooibos and its biologically active phenolic compound, aspalathin, have been shown to possess a number of beneficial effects relevant to the management of Type 2 Diabetes and Cardiovascular disease. The aspalathin content of the rooibos plant, however, varies depending on a number of factors, and its level in the plant material drops even further during the oxidation process used to produce fermented rooibos, the product commonly prepared as a herbal tea. The South African Medical Research Council (SAMRC) and the Agricultural Research Council (ARC) have developed a method for the production of aspalathin-rich unfermented green rooibos extract (GRT Extract), containing a minimum of 12% aspalathin, and having a number of beneficial effects in the management of conditions linked to glucose and lipid metabolism. These include a glucose lowering effect, ameliorated insulin resistance in vitro, protection of pancreatic beta cells against oxidative stress, protection of heart cells and lowering of cardiovascular risk factors.

VALUE PROPOSITION

Aspalathin-rich green rooibos extract (GRT Extract) has potential for incorporation in novel therapeutic preparations for the treatment and management of metabolic disease in humans and animals.

BENEFITS

Aspalathin-rich green rooibos extract (GRT Extract) can be utilized in novel therapeutic preparations for the treatment and management of metabolic dysfunction, including the modulation of glucose and cholesterol, thereby lowering cardiovascular risk. The products have application in the complementary medicine, nutritional supplement and veterinary markets.

OPPORTUNITIES

The SAMRC is seeking international partners for the formulation and sale of GRT Extract into novel products for a variety of markets.

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