

Aurum Institute (AI) – Clinical Research Division



Translating science
into global health impact

A proudly African, health impact organization dedicated to researching, supporting, and implementing innovative, integrated approaches to global health



The Aurum Institute (AI), founded by current CEO Professor Gavin Churchyard, has been in existence for almost 21 years as a South African public-benefit organization with extensive experience in leading the response, treatment, and research efforts to eradicate tuberculosis (TB) and HIV in South Africa. AI works with government, the mining industry, NGOs, and communities to better understand the epidemic and to provide innovative solutions that will improve the health of communities. Aurum's headquarters are in Johannesburg, South Africa, with a staff presence in the U.S., as well as operations in Ghana, Lesotho, and Mozambique.

Aurum's projects and programs cover a wide range of activities including programmatic implementation and technical assistance for HIV/AIDS and TB prevention, care and treatment services throughout the health system in South Africa, HIV prevention clinical research studies, TB and HIV vaccine studies, and voluntary medical male circumcision to large-scale TB prevention programs, to name a few.

The AI – Clinical Research Division is experienced in running clinical trials ranging from large-scale public health studies to highly regulated clinical trials of new medications. The Institute has extensive experience in conducting randomized clinical trials of HIV vaccines, treatment, prevention (oral, topical, and long-acting injectable pre-exposure prophylaxis), and TB treatment, host-directed therapy, vaccines, preventative therapy, diagnostics, and socio-behavioral studies. AI has demonstrated success in identifying, recruiting, and retaining a wide range of volunteer populations including groups at high risk of HIV such as men, young women, men who have sex with men, and sex workers.

The administrative office is based in Parktown, Johannesburg. It houses centralized institutional support services (i.e., human resources, information technology, finance, and operations) and technical support personnel.

AI has well established the Division of AIDS (part of the U.S. National Institute of Allergy and Infectious Diseases of the U.S. National Institutes of Health)-approved infrastructure, and demonstrated in-house expertise in managing multiple grants, enhancing cost-effectiveness and efficiencies, and implementing innovative operational and oversight strategies around recruitment, retention, data quality, and prevention of co-enrollment in multiple clinical studies.

AI maintains strong relationships with local and national regulators and policymakers. Additionally, the over 300 staff employed in the Clinical Research Division possess multiple years of experience in the field of clinical research and are highly skilled and trained in Good Clinical Practice (GCP). The infrastructure and resources available to the Aurum Institute Clinical Research Sites (CRSs) – Klerksdorp, Rustenburg, and Tembisa – include an adult clinic, adolescent youth-friendly services clinic, CRS pharmacy, CRS laboratory, data management office, and referral systems.



The Aurum Institute – Rustenburg Clinical Research Centre

Laboratory capacity

The CRS on-site access-controlled laboratory consists of a receiving area for receipt and logging of all samples, sample testing areas, and separate areas for peripheral blood mononuclear cells (PBMC) and plasma/serum processing, storage area, and administration area. The laboratory area and equipment are two automated temperature monitoring systems.

The laboratory consists of equipment for storage of samples, blood count testing, and viral load testing. On-site testing and processing include: serology; endocrinology (urine pregnancy); microbiology (urine

microscopy); rapid testing for sexually transmitted infections (such as trichomonas vaginalis and bacterial vaginosis); and immunology (enzyme-linked immunosorbent assay [Elisa], PBMC, plasma, and serum processing). The laboratory staff are PBMC proficient and follow the six-monthly clinical laboratory services and HIV Vaccine Trials Network PBMC proficiency programs.

People

Aurum Institute is comprised of an experienced team of scientists and research staff with abilities needed to ensure the successful conduct of complex, multi-site clinical trials. The team has been involved in clinical research for over two decades with experience in HIV and TB prevention and treatment trials among high- and low-risk individuals. The staff are trained on sponsor, network, regulatory, GCP, and individual protocol requirements, and cross-trained to work on multiple protocols within the CRS.

Each CRS is led by experienced clinical trialists and investigators: James Craig Innes, GP, MBChB, (Klerksdorp CRS); William Brumskine, MBChB, Dip HIV Man (Rustenburg CRS); and Modulakgotla Anthony Sebe, M.D. (Tembisa CRS). Each CRS leader is supported at site level by a CRS coordinator, study-specific coordinators, research pharmacists, doctors, and nurses, laboratory, data, quality, regulatory and administrative teams, community recruitment and retention teams, and counselors.

Additional support is provided by project, program, and department managers, the managing director of the

clinical research division, chief operating officer, and institutional support teams.

Community engagement

CRS community advisory boards (CABs) are trained to advise across networks/sponsors and studies. Each study has an individual recruitment and enrollment plan, customized for the specific trial population and per network/sponsor requirements. Each CRS has deep roots in their communities, including strong relationships with community stakeholders, health providers, and experienced CABs with representation from populations of interest.

IAVI-supported activities

- Early infections and clinical outcomes cohort (Protocol C) – study to evaluate clinical, laboratory, immunologic, and viral markers of disease progression in volunteers with recent HIV infection to prepare for activities relevant to the execution of preventive HIV vaccine efficacy trials. The USAID-supported Protocol C study¹ has provided a much better understanding of HIV in Africa, revealing differences in how the infection progresses and the distribution of the many HIV variants across regions or countries.
- Adolescent research (enrollment and follow up of adolescents)
- Research preparedness (engaging communities and cohorts)
- T-cell immunogen design and assessment
- International training program

¹ <https://www.iavi.org/our-work/clinical-epidemiology-research/hiv-epidemiology/?view=article&id=415:protocol-c&catid=60>

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