SOUTH AFRICA'S TB AND HIV RESEARCH AT RISK:
A CALL TO CATALYZE URGENT ACTION BY FUNDERS

May 2025

Since January 2025, a series of United States (U.S.) executive orders, funding suspensions, and grant terminations have thrown South Africa's tuberculosis (TB) and HIV programs into crisis, threatening lifesaving research, prevention, and treatment programs. The stop-work order issued on January 24, 2025 affected all projects funded by the U.S. Agency for International Development (USAID), the Centers for Disease Control and Prevention (CDC), and the President's Emergency Plan for AIDS Relief (PEPFAR). South Africa had been one of the largest beneficiaries of PEPFAR, which contributes approximately 17% to the national HIV/AIDS response, supporting access to antiretroviral therapy (ART) for 5.5 million people.[1] Along with USAID, PEPFAR also contributes 14% to the national TB response, including essential National TB Program and community-based services in South Africa.[2] Research conducted in South Africa — much of it led by South African scientists supported with funding from the U.S. National Institutes of Health (NIH), and, to a lesser extent, CDC and USAID — has helped to bring forward most of the innovations introduced globally in the last two decades and shaped global health policies that have revolutionized TB and HIV prevention, diagnosis, treatment and care, benefiting both the local population and communities worldwide, including people who live in the United States.

This issue brief provides information about TB and HIV clinical trials and research programs impacted by U.S. government funding disruptions, and proposes urgent actions that donor agencies, governments, and philanthropies can take to preserve scientific advances underway and prevent the collapse of TB and HIV medical research in South Africa.

According to the latest data, over 8 million, or 12.8% of South Africa's 63 million people are living with HIV.[3] Of these, about 6.2 million are receiving ART, at least prior to the recent USAID/PEPFAR program cuts. In 2023/2024 there were an estimated 178,000 new HIV infections and 105,000 deaths among people with HIV.[4] TB is the leading cause of death among people with HIV, but also affects people without HIV. According to the World Health Organization (WHO), in 2023 there were 270,000 new cases of TB in South Africa, 145,000 of them (53%) among people living with HIV. Thirteen thousand cases of rifampicin-resistant and multidrug-resistant TB were reported, and 56,000 deaths from TB overall, 31,000 of them (55%) among people with HIV.[5]

South African research institutions have played a central role in advancing global TB treatment, prevention, diagnostics, and vaccine development. Contributions include key trials that led to the registration and defined the optimal use of new medicines for drug-resistant TB (bedaquiline, pretomanid, delamanid), and introduced short-course regimens for the prevention (3HP, 1HP, 6L) and treatment of both drug-sensitive and drug-resistant TB (4HPMZ, 6BPaLM). South Africa has led pediatric investigations for nearly all TB medicines and generated most of the available dosing and safety data for TB prevention and treatment during pregnancy. Diagnostic breakthroughs, including validation of rapid TB tests like GeneXpert and urine LAM, relied heavily on South African study populations. Furthermore, the country has contributed to every major TB vaccine trial over the past 25 years, including the first infant efficacy trial of a novel TB vaccine candidate (MVA85A) and other ongoing trials of candidates including: M72/AS01E, BCG revaccination, MTBVAC, ID93/GLA-SE, and the first mRNA TB vaccines.

The country has played an equally critical role in the development and implementation of innovative HIV treatment, service delivery, and prevention strategies that have advanced global HIV care. This includes differentiated service delivery models to improve treatment access and retention, the use of dolutegravir as a preferred cornerstone medication (with lamivudine and tenofovir disoproxil fumarate [TDF]) for HIV treatment, studies demonstrating the efficacy of long-acting injectables for HIV prevention in cisgender women, and efforts to expand the use of oral self-testing as a means to increase early diagnosis. South Africa has made — and continues to make — vital contributions to HIV vaccine research, including conducting an intensive, essential assessment of whether the marginal efficacy reported in the RV144 vaccine trial in Thailand could be translated to other higher HIV incidence settings. South Africa is also participating in the first studies to be conducted on the continent pursuing the development of an HIV cure, including two Advancing Clinical Therapeutics Globally for HIV/AIDS and Other Infections (ACTG) trials and a protocol investigating the potential for HIV remission in early-treated infants.

U.S. FUNDING CUTS JEOPARDIZE A WIDE RANGE OF TB AND HIV SCIENTIFIC ADVANCES

Since the start of 2025, several critical research initiatives funded by USAID and NIH have either received cancellation letters already or are expecting them soon — putting millions of dollars and decades of investments in research infrastructure and cooperation between South African and U.S. universities and research institutions at risk. A survey administered to 31 organizations that make up the South African TB Think Tank identified eight organizations and 14 TB research grants affected to date, ranging from US$50,000 to $5 million per organization for 2025 alone.

Notices of Awards (NOAs) to the NIH-funded Division of HIV/AIDS (DAIDS) Clinical Trials Networks (ACTG, International Maternal Pediatric Adolescent AIDS Clinical Trials Network [IMPAACT], HIV Vaccine Trials Network [HVTN], HIV Prevention Trials Network [HPTN]) have been delayed or renewed at reduced levels, affecting enrollment across clinical trials, including at South African sites. The NOAs issued indicate that all activities at South African sites will be discontinued at the end of the current NOA term in November 2025.

The BRILLIANT Consortium, an initiative led by the South African Medical Research Council (SAMRC) and dedicated to advancing HIV vaccine research in Africa, led by African scientists, for African communities, lost USAID support on March 3, 2025.[7] The Wits Health Consortium at the University of the Witwatersrand, which oversees multiple HIV and TB trials, received a termination letter for all components of its $2.5 million NIH grant.[8] Closing clinical trials early without a scientific or safety justification violates the moral and ethical standards of beneficent research. Further, NIH cuts have targeted research funding that includes vulnerable communities such as LGBTQ+ people and sex workers, citing an executive order issued by the U.S. government that forbids diversity, equity, and inclusion (DEI) initiatives.[9] These communities have historically been underrepresented in research yet are disproportionately affected by HIV and TB, which is the leading cause of death among people with HIV. This clearly contradicts the right to science and right to health, as recognized in international human rights frameworks, that assert that everyone should benefit from scientific advancements and health without discrimination.

With as much as 70% of the country's HIV and TB research funded through the NIH,[10] already executed and further anticipated terminations of NIH funding for TB and HIV research puts a wide range of scientific advances at risk, including critical studies focused on the prevention, diagnosis, treatment, and care of HIV and TB.

FINDINGS FROM TREATMENT ACTION GROUP AND MÉDECINS SANS FRONTIÈRES ANALYSIS

An analysis by Treatment Action Group (TAG) and Médecins Sans Frontières (MSF) finds that 39 South African TB and HIV clinical research sites are under threat due to potential NIH funding cuts, placing at least 24 HIV trials and 20 TB trials at risk (see Annex for more details). For TB, these include trials of new drugs and shorter, safer regimens for treatment and prevention, an optimized regimen for TB meningitis, and therapeutic and preventive vaccines. Also at risk are trials necessary to expand access among children and pregnant women to life-saving TB innovations – such as pretomanid and rifapentine-based short-course regimens for TB prevention and treatment.

Terminating awards to South African sites could affect up to 30% of participants enrolled in TB trials sponsored by internationally run trials networks including ACTG, HVTN, and IMPAACT. The proportion is even higher for TB trials focused on pediatric and pregnant populations (50–90% of participants).

For HIV, trials at risk include cure-related protocols involving broadly neutralizing antibodies (bNAbs) and analytical interruptions of antiretroviral therapy (for both adults and infants), studies to promote treatment adherence for youth, and trials of innovative preventive vaccine modalities designed to induce bNab production.

If South African sites are prohibited from participating in enrollment, follow-up, study completion, and data collection and analysis, then ongoing and planned trials will likely be underpowered to produce meaningful results, wasting years of work and hundreds of millions of dollars in previous investment. Trials no longer able to continue enrollment in South Africa will face delays and increased costs as they seek new sites and study participants elsewhere.

The Annex provides a detailed overview of South African TB and HIV research sites in the DAIDS HIV/AIDS Clinical Trials Networks and the extent of disruptions caused by actual and threatened USG funding terminations.

IMPACTS OF U.S. FUNDING CUTS ON TB AND HIV RESEARCH AND PROGRAMS IN SOUTH AFRICA AND BEYOND

NIH funding cuts place the overall TB and HIV research and development (R&D) infrastructure in South Africa at risk, as trials sponsored by other research funders build on top of core and other funding provided to clinical trials units and research sites through NIH awards. For TB, anticipated ripple effects on trials sponsored by non-U.S. government R&D funders could affect studies focused on advancing vaccine candidates MTBVAC and M72/AS01E; new TB drugs, including ganfeborole, DprE1 inhibitors quabodepistat and BTZ-043, and next-generation diarylquinolones and oxazolidinones; and registrational pediatric pharmacokinetic (PK) and safety work for bedaquiline.

TABLE 1. PRIORITY TB INNOVATIONS AT RISK

PREVENTIVES	THERAPEUTICS	SPECIAL POPULATIONS
• Shorter, safer regimens for TB prevention (6-month delamanid and 1-month bedaquiline regimens) • TB vaccines MTBVAC and M72/AS01E and next-generation TB vaccine candidates at earlier stages of clinical testing	• New drugs, including ganfeborole, DprE1 inhibitors (quabodepistat and BTZ-043), and next generation diarylquinolones (TBAJ-876) and oxazolidinones (TBI-223) • Shorter, safer treatment regimens, including for TB meningitis and XDR-TB • Therapeutic vaccine ID93 + GLA-SE	• Pretomanid and 6BPaLM for treating children with drug-resistant TB • 4HPMZ for treating drug-sensitive TB during pregnancy • 1HP for preventing TB among children exposed to drug-sensitive TB

South African academic and research institutes could lose about 30% of their annual income and may be forced to lay off hundreds of staff as a result of U.S. funding cuts. There is growing concern about the potential collapse of TB and HIV R&D capacity in South Africa with direct implications for people living with HIV and TB in South Africa — and globally, given the substantial contributions of South African research centers to advancements in TB and HIV prevention, treatment, and care worldwide.

The critical medical research that is now at risk of being completely halted or significantly limited would delay access to new medical tools that are essential for reducing HIV and TB transmission and shortening treatment duration, tools expected to ease the financial and human resource burden on already strained health systems in South Africa and many other countries facing high burdens of TB and HIV or acute outbreaks of TB and HIV, including communities across the United States.

URGENT CALL FOR ALTERNATIVE FUNDING TO SUSTAIN TB AND HIV RESEARCH IN SOUTH AFRICA

Considering the significant U.S. funding cuts and growing concerns of complete withdrawal of funding for South African researchers and institutions, there is an urgent need for other donors to step in and prevent the collapse of TB and HIV medical research in South Africa.

We therefore call on donor agencies, governments, and philanthropies to:

- Provide immediate support to clinical research sites to ensure continuity of care and follow-up for South African study participants. South African trial participants must be supported to complete treatments safely and, in cases of treatment failure, be offered appropriate alternatives, and research sites must be supported to complete data collection and analysis.
- Offer South Africa TB and HIV research sites emergency funding to complete enrollment, follow up, and data collection and analysis for existing studies that have only been partially enrolled.
- Address research gaps vital for advancing innovations in prevention, diagnostics, and treatment, including by investing in TB and HIV trials that were planned or suspended just as they were about to begin.
- Make long-term investments necessary to secure South Africa's unique and globally recognized research infrastructure, that has not only served the needs of the South African population, which bears a heavy burden of TB and HIV, but has also played a pivotal role in contributing to global health evidence and solutions.
- Ensure full transparency and greater coordination among R&D funders and other stakeholders to maximize limited financial resources by avoiding duplication of studies, and secure sustained funding for priority TB and HIV medical tools (see Annex).

ANNEX. TB AND HIV TRIALS AND RESEARCH INFRASTRUCTURE AT RISK IN SOUTH AFRICA

Background

Critically important TB research projects have already been terminated by the U.S. government (USG). The current USG administration's position toward South Africa puts additional research projects and the work of the NIH-funded HIV Clinical Trials Networks and TB and HIV R&D infrastructure overall in South Africa at risk. The following tables present a mapping of:

1. TB and HIV studies sponsored by NIH via ACTG, IMPAACT, HVTN, and HPTN that will be affected should the USG terminate research awards to South African institutions (Tables 2 and 3);
2. NIH-funded clinical trials units (CTUs) and clinical research sites (CRSs) in South Africa (Table 4); and
3. other USG-proposed or -funded TB studies with sites in South Africa (Table 5).

At risk are 39 clinical research sites and at least 20 TB trials and 24 HIV trials. The TB trials at risk are designed to advance new drugs and shorter, safer regimens for treatment and prevention, an optimized regimen for TB meningitis, and therapeutic and preventive vaccines; and to expand access to life-saving TB innovations to children and pregnant women (i.e., pretomanid as a core component of the BPaLM regimen for drug-resistant TB and rifapentine-based short-course regimens for TB prevention and treatment). The HIV trials at risk are designed to evaluate bNAbs and analytical interruptions of ART for both adults and infants, test preventive innovative vaccine modalities designed to induce bNab production, and promote treatment adherence for youth. Not captured in the tables are anticipated ripple effects on TB and HIV trials sponsored by non-USG R&D funders that rely on sites that are at risk of losing core support and other funding from NIH awards. TB trials funded by other donors include studies focused on advancing vaccine candidates MTBVAC and M72/AS01E; testing new TB drugs, including ganfeborole, DprE1 inhibitors quabodepistat and BTZ-043, and next generation diarylquinolones and oxazolidinones; and completing registrational pediatric PK and safety work for bedaquiline.

Limitations of the Analysis

This analysis is primarily focused on NIH-funded/DAIDS HIV Clinical Trials Network studies and research infrastructure — trials funded by other governments or donors that may be put at risk by withdrawal of USG funding are not captured in the tables below. Additionally, the list of other USG-proposed or -funded TB studies with sites in South Africa in Table 5 is not comprehensive as it doesn't capture trials or studies supported through other extramural NIH funding mechanisms, and only includes one TB diagnostic trial; an analysis of TB diagnostic trials funded by USG with South African sites was not performed. Not included here, but potentially helpful for donors to have access to, is information regarding capabilities, core costs, and costs per participant per site.

To help us capture a more complete picture of affected TB and HIV trials, please consider sharing information about USG grants that have been terminated or that are under active threat using the secure form accessible at the following link and QR code: https://cryptpad.fr/form/#/2/form/view/Q4Luco0lx+Rszmc5P+hwKOa0EtGAu3SXvdeOWZO7Mok/.

TABLE 2. DAIDS HIV CLINICAL TRIALS NETWORK TB STUDIES WITH SITES IN SOUTH AFRICA

STUDY	CONTRIBUTION TO THE FIELD	STATUS	SITES IN SOUTH AFRICA	% OF PARTICIPANTS FROM SOUTH AFRICA
A5409, RAD-TB NCT06192160 A Phase 2 Adaptive, Dose-Ranging Trial of Novel Regimens for the Treatment of Pulmonary Tuberculosis	Will advance next generation oxazolidinones (e.g., sutezolid, TBI-223) as safer alternatives to linezolid.	Opened to accrual February 2025; temporarily paused as of April 2025. [3/315 enrolled]	Durban - eThekwini CRS (CAPRISA) Durban International CRS Aurum Institute - Rustenburg CRS South African Tuberculosis Vaccine Initiative (SATVI) CRS - Worcester + Cape Town PHRU - Soweto CRS - Baragwaneth Hospital University of Cape Town Lung Institute (UCTLI) CRS University of the Witwatersrand Helen Joseph (WITS HJH) CRS	32%
A5384, IMAGINE-TBM NCT05383742 A Phase 2 Trial of a 6-Month Regimen of High-dose Rifampicin, High-dose Isoniazid, Linezolid, and Pyrazinamide versus a Standard 9-Month Regimen for the Treatment of Adults and Adolescents with Tuberculous Meningitis	Will evaluate optimized, shorter treatment regimen for TB meningitis.	Opened to accrual December 2023; temporarily paused as of April 2025. [45/330 enrolled]	Durban International CRS University of the Witwatersrand Helen Joseph (WITS HJH) CRS	10%
A5300B/I2003B, PHOENIx NCT03568383 A Phase 3 Trial Protecting Households On Exposure to Newly Diagnosed Index Multidrug-Resistant Tuberculosis Patients	Will evaluate TB preventive treatment (6 months of delamanid) for contacts of drug-resistant TB.	Active, not recruiting; estimated completion date 7/30/27. [3,902/3,834 enrolled]	Durban - eThekiwini CRS (CAPRISA) PHRU - Soweto CRS - Baragwaneth Hospital	32%

STUDY	CONTRIBUTION TO THE FIELD	STATUS	SITES IN SOUTH AFRICA	% OF PARTICIPANTS FROM SOUTH AFRICA
			University of the Witwatersrand Helen Joseph (WITS HJH) CRS	
			Durban International CRS	
			Klerksdorp - PHRU Matlosana CRS	
			Aurum Institute - Rustenburg CRS	
			TASK Applied Science CRS - Brooklyn Chest Hospital	
			University of Cape Town Lung Institute (UCTLI) CRS	
			South African Tuberculosis Vaccine Initiative (SATVI) CRS - Worcester + Cape Town	
			Stellenbosch - Desmond Tutu TB Centre CRS	
A5414, SPECTRA-TB A Phase 2c Trial of Stratified Patient-Centered Treatment Regimens for Active TB	Will evaluate shorter treatment with HPMZ for drug-sensitive TB; 2–6 months depending on disease severity.	Protocol in development. N = 900	Aurum Institute - Rustenburg CRS	36%
			University of Cape Town Lung Institute (UCTLI) CRS	
A5397/HVTN603 NCT06205589 A Phase 2a/2b Study Evaluating Safety, Immunogenicity, and Therapeutic Efficacy of ID93 + GLA-SE Vaccination in Participants with Rifampicin-Susceptible Pulmonary TB	Will evaluate a therapeutic vaccine to improve rates of recurrence following treatment for drug-sensitive TB.	Projected to open to accrual May 2025. N = 1,500 Phase 2a = 400 Phase 2b = 1,100	PHRU - Soweto CRS - Baragwaneth Hospital	Phase 2a = 100% Phase 2b = 30%
			South African Tuberculosis Vaccine Initiative (SATVI) CRS - Worcester + Cape Town	
			Aurum Institute Rustenburg CRS	
			Durban - Isipingo CRS (MRC)	
			Durban - eThekwini CRS (CAPRISA)	

STUDY	CONTRIBUTION TO THE FIELD	STATUS	SITES IN SOUTH AFRICA	% OF PARTICIPANTS FROM SOUTH AFRICA
			Cape Town - Emavundleni	
			Aurum Institute - Klerksdorp CRS	
			Durban International CRS	
			University of the Witwatersrand Helen Joseph (WITS HJH) CRS	
HVTN605/A5421 NCT05947890 Evaluating the Safety and Immunogenicity of MTBVAC in Adolescents and Adults Living With and Without HIV in South Africa	Will generate safety and immunogenicity data necessary for inclusion of PLHIV in late-stage studies of TB vaccine candidate, MTBVAC.	Recruiting; opened to accrual January 2024. [184/276 enrolled]	Cape Town - Emavundleni	100%
			Cape Town - Groote Schuur CRS	
			Khayelitsha CIDRI-Africa	
			University of Cape Town Lung Institute (UCTLI) CRS	
			Durban - Botha's Hill CRS (MRC)	
			Durban - Chatsworth CRS (MRC)	
			Durban - eThekwini CRS (CAPRISA)	
			Durban - Isipingo CRS (MRC)	
			Durban - Wentworth	
			Johannesburg - CHRU	
			Aurum Institute - Klerksdorp CRS	
			Ladysmith CRS	
			Aurum Institute - Rustenburg CRS	
			Soshanguve	
			PHRU - Soweto CRS - Baragwaneth Hospital	
			South African Tuberculosis Vaccine Initiative (SATVI) CRS - Worcester + Cape Town	

STUDY	CONTRIBUTION TO THE FIELD	STATUS	SITES IN SOUTH AFRICA	% OF PARTICIPANTS FROM SOUTH AFRICA
IMPAACT 2005 NCT03141060 A Phase 1/2 Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of Delamanid in Combination with Optimized Multidrug Background Regimen in Children with MDR-TB with and without HIV	Will generate PK and safety data necessary to refine delamanid dosing in young children.	Closed to accrual; estimated completion date 7/20/26. [37/48 enrolled]	Stellenbosch - Desmond Tutu TB Centre CRS Klerksdorp - PHRU Matlosana CRS Johannesburg - Sizwe CRS	70%
IMPAACT 2026 NCT04518228 Pharmacokinetic Properties of Antiretroviral and Anti-Tuberculosis Drugs During Pregnancy and Postpartum	Will generate opportunistic PK and safety data to inform the use of key first- and second-line TB drugs during pregnancy and the postpartum period.	Closed to accrual early - March 2025. [102/325 enrolled] DS-TB = 23/25 DR-TB = 7/25	Stellenbosch - Desmond Tutu TB Centre CRS Johannesburg - Sizwe CRS Stellenbosch University - FAMCRU CRS Wits RHI Shandukani Maternal and Child CRS	48%
IMPAACT 2034 NCT05586230 Phase 1 Study of the Pharmacokinetics, Safety, and Acceptability of a Single Dose of Pretomanid Added to an Optimized Background Regimen in Children with Rifampicin-Resistant Tuberculosis	Will generate PK and safety data necessary for children to benefit from access to pretomanid-based regimens for drug-resistant TB.	Recruiting; opened to accrual October 2023. [27/72 enrolled]	Stellenbosch - Desmond Tutu TB Centre CRS Klerksdorp - PHRU Matlosana CRS Johannesburg - Sizwe CRS	93%
IMPAACT 2024 Phase 1/2 Dose Finding, Safety and Tolerability Study of Daily Rifapentine Combined with Isoniazid (1HP) for Tuberculosis Prevention in Children Less Than 13 Years of Age with and without HIV	Will generate PK and safety data necessary for children to benefit from access to the one-month TB preventive treatment regimen, 1HP.	Projected to open to accrual September 2025. N = 144	Umlazi CRS (Women's Health and HIV Research Unit) Stellenbosch - Desmond Tutu TB Centre CRS	30% South African sites are especially important for recruiting young HIV-negative children (< 10 kg) and children living with HIV.

STUDY	CONTRIBUTION TO THE FIELD	STATUS	SITES IN SOUTH AFRICA	% OF PARTICIPANTS FROM SOUTH AFRICA
IMPAACT 2020 Phase 2 Study of Shortened Oral Treatment for Rifampicin-Resistant Tuberculosis in Children	Will evaluate a six-month, all-oral treatment regimen optimized for use in children.	Protocol in development.	N/A	N/A
IMPAACT 2047 Phase 2 Randomized Study of the Pharmacokinetics, Safety and Tolerability of High Dose Rifapentine given with Moxifloxacin for Tuberculosis during Pregnancy	Will generate PK and safety data necessary for pregnant women to benefit from access to the four-month HPMZ regimen for drug-sensitive TB.	Protocol in development.	N/A	N/A

TABLE 3. DAIDS HIV CLINICAL TRIALS NETWORK HIV STUDIES WITH SITES IN SOUTH AFRICA

STUDY	CONTRIBUTION TO THE FIELD	STATUS	SITES IN SOUTH AFRICA	% OF PARTICIPANTS FROM SOUTH AFRICA
ACTG				
A5417 NCT06205602 Randomized, Double-Blind, Placebo-Controlled Phase 2 Study of the Combination of two Long-Acting Broadly Neutralizing Antibodies at ART Initiation in Adults Living with HIV-1 in sub-Saharan Africa	Will assess whether the administration of two bNAbs (10-1074-LS and 3BNC117-LS) at ART initiation can promote control of viral load during analytical treatment interruption (ATI).	Opened to accrual January 2025; temporarily paused as of April 2025. N = 135 [41/44 enrolled at South African sites still in follow up]	Durban - eThekwini CRS (CAPRISA) University of the Witwatersrand Helen Joseph (WITS HJH) CRS Durban International CRS PHRU - Soweto CRS - Baragwaneth Hospital Aurum Institute - Rustenburg CRS	56%
A5416/ HVTN 806/ HPTN 108 NCT06031272 Pausing Antiretroviral Treatment Under Structured Evaluation (PAUSE)	Will assess whether the administration of two bNAbs (3BNC117-LS-J and 10-1074-LS-J) to people on long-term ART can promote control of viral load during ATI.	Closed to accrual. [29/48 enrolled; recruitment stopped early due to futility]	Wits RHI Hillbrow Health Precinct Ward 21 CRS PHRU - Soweto CRS - Baragwaneth Hospital	100%

STUDY	CONTRIBUTION TO THE FIELD	STATUS	SITES IN SOUTH AFRICA	% OF PARTICIPANTS FROM SOUTH AFRICA
ACTG				
			Durban - eThekwini CRS (CAPRISA)	
			Aurum Institute - Klerksdorp CRS	
			Aurum Institute - Rustenburg CRS	
			Cape Town - Groote Schuur CRS	
A5394 **NCT05551273** Phase 2 Safety, Tolerability, and Impact of Oral TLR8 Agonist Selgantolimod on HBsAg in Participants with Both Chronic Hepatitis B and HIV	Will assess oral TLR8 agonist selgantolimod in people with HBV/ HIV.	Opened to accrual May 2024; temporarily paused as of April 2025. N = 48	Durban International CRS	4%
			PHRU - Soweto CRS - Baragwaneth Hospital	
A5418 **NCT05534984** A Randomized, Placebo-Controlled, Double-Blinded Phase 3 Trial of the Safety and Efficacy of Tecovirimat for the Treatment of Human Mpox Disease	Assessment of the efficacy of tecovirimat for treating mpox.	Active, not recruiting; estimated completion date 9/30/25. N = 719	PHRU - Soweto CRS - Baragwaneth Hospital	N/A
			University of the Witwatersrand Helen Joseph (WITS HJH) CRS	
A5403 **NCT06005610** Giving Standardized Estradiol Therapy In Transgender Women to Research Interactions with HIV Therapy: the GET IT RIgHT Study	Will assess whether transgender women continue to achieve therapeutic concentrations of ART while receiving female hormone therapy for 48 weeks.	Active, not recruiting; estimated completion date 8/5/27. N = 93	PHRU -Soweto CRS - Baragwaneth Hospital	N/A
A5402 **NCT06705478** An Open-Label, Randomized Controlled Phase 2 Trial of Pramipexole versus Escitalopram to Treat Major Depressive Disorder (MDD) and Comorbid MDD with Mild Neurocognitive Disorder (MND) in Persons with HIV: COPE	Will compare pramipexole to escitalopram in the treatment of major depressive disorder in PWH.	Not yet recruiting. N = 186	Durban International CRS	N/A

STUDY	CONTRIBUTION TO THE FIELD	STATUS	SITES IN SOUTH AFRICA	% OF PARTICIPANTS FROM SOUTH AFRICA
ACTG				
A5424 **NCT06856174** Menopausal HT for Women Living With HIV (HoT)	Will determine the effects of hormone therapy on vasomotor symptoms in women living with HIV in late menopausal transition or early postmenopause.	Not yet recruiting. N = 345 Step 1 = 240 Step 2 = 105	Durban International CRS	N/A
HPTN				
HPTN 083 **NCT02720094** Injectable Cabotegravir Compared to TDF/FTC For PrEP in HIV-Uninfected Men and Transgender Women Who Have Sex With Men	Evaluation of the safety and efficacy of injectable cabotegravir for pre-exposure prophylaxis in HIV-uninfected cisgender men and transgender women who have sex with men.	Active, not recruiting; estimated completion date 4/30/25. N = 4,570	Cape Town - Groote Schuur CRS	3.3%
HPTN 084 **NCT03164564** Evaluating the Safety and Efficacy of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women	Evaluation of the safety and efficacy of injectable cabotegravir for pre-exposure prophylaxis in HIV-uninfected women.	Active, not recruiting; estimated completion date 11/30/24. N = 3,224	PHRU - Soweto CRS - Baragwaneth Hospital Wits RHI Hillbrow Health Precinct Ward 21 CRS Durban - Botha's Hill CRS (MRC) Durban - Isipingo CRS (MRC) Durban - Verulam CRS Stellenbosch Desmond Tutu TB Centre CRS Cape Town - Emavundleni CRS	41%
HVTN				
HVTN 206/HPTN 114 **NCT06812494** A Study of VRC07-523LS, PGT121.414. LS, and PGDM1400LS Broadly Neutralizing Monoclonal Antibodies Given Intravenously in Adult Participants Without HIV	Will assess three bNAbs administered to HIV-negative participants as possible preparation for a prevention efficacy trial.	Recruiting; opened to accrual March 2025. N = 200	PHRU - Soweto CRS - Baragwaneth Hospital Durban - Chatsworth CRS (MRC) PHRU - Setshaba Research Centre / Soshanguve CRS Cape Town - Groote Schuur CRS	25%* *Originally planned to recruit 25% of participants from South Africa; enrollment is now being shifted to non-South African sites.

STUDY	CONTRIBUTION TO THE FIELD	STATUS	SITES IN SOUTH AFRICA	% OF PARTICIPANTS FROM SOUTH AFRICA
HVTN				
HVTN 139 **NCT05182125** Phase 1 Clinical Trial to Evaluate the Safety and Immunogenicity of HIV-1 Chimp Adenovirus Vaccines Expressing Clade C gp140 & CH505TF gp120 Protein Boost in HIV-uninfected Adult.	Will assess the safety, tolerability, and ability to induce HIV-specific immune responses of vaccines based on chimpanzee serotypes of adenovirus expressing HIV clade C gp140 and a CH505TF gp120 protein boost in HIV-negative adults.	Active, not recruiting; estimated completion date 11/6/25. N = 34	Cape Town - Emavundleni CRS Durban - eThekwini CRS (CAPRISA) Durban - Isipingo CRS (MRC) PHRU - Soweto CRS - Baragwaneth Hospital Aurum Institute - Klerksdorp CRS PHRU - Setshaba Research Centre / Shoshanguve CRS	100%
HVTN 305 **NCT05781542** Phase 1 Clinical Trial to Evaluate the Safety and Immunogenicity of Synthetic DNAs Encoding NP-GT8 and IL-12, With or Without a TLR-agonist-Adjuvanted HIV Env Trimer 4571 Boost, in Adults Without HIV	Will evaluate an experimental prime-boost vaccine regimen for safety and ability to induce immune responses against HIV.	Active, not recruiting; estimated completion date 8/31/25. N = 45	PHRU - Soweto CRS - Baragwaneth Hospital Durban - eThekwini CRS (CAPRISA) Durban Adult HIV CRS Cape Town - Groote Schuur CRS	53%
HVTN 805/HPTN 093 **NCT04860323** Analytical Treatment Interruption (ATI) to Assess the Immune System's Ability to Control HIV in Participants Who Became HIV-infected During the HVTN 703/HPTN 081 AMP Study	Will evaluate the viral and immune system responses in an ATI in participants who received antibody VRC01 or placebo and got HIV while enrolled in HVTN 703/HPTN 081 (NCT02568215).	Active, not recruiting; estimated completion date 2/28/25. N = 13	Durban - eThekwini CRS (CAPRISA) Vulindlela CRS (CAPRISA) PHRU - Soweto Kliptown CRS Wits RHI Hillbrow Health Precinct Ward 21 CRS Aurum Institute - Rustenburg CRS	31%
HVTN 317 **NCT06694753** Safety and Immunogenicity of MRNAs Encoding HIV Immunogens (eOD-GT8 60mer, Core-g28v2 60mer, N332-GT5 Gp151) in Adult Participants Without HIV and in Overall Good Health in South Africa	Will evaluate the safety and immunogenicity of 3 experimental HIV vaccines (mRNA-1645-eODGT8, mRNA-1645-CoreG28v2 and mRNA-1645-N332GT5) in adult participants without HIV and in overall good health.	Not yet recruiting. N = 96	PHRU - Setshaba Research Centre / Shoshanguve CRS	100%* *Originally planned to recruit only in South Africa; protocol now retracted by DAIDS and potential for other funding/ sponsorship being investigated.

STUDY	CONTRIBUTION TO THE FIELD	STATUS	SITES IN SOUTH AFRICA	% OF PARTICIPANTS FROM SOUTH AFRICA
HVTN				
			PHRU - Soweto CRS - Baragwaneth Hospital	
			Durban - Chatsworth CRS (MRC)	
			Durban - eThekwini CRS (CAPRISA)	
			Durban - Isipingo CRS (MRC)	
			Aurum Institute - Klerksdorp CRS	
			Cape Town - Emavundleni CRS	
			Cape Town - Groote Schuur CRS	
HVTN 316 **NCT06613789** Phase 1 Safety & Immunogenicity of 426c.Mod.Core-C4b Vaccine With 3M-052-AF+Alum in Infants Perinatally Exposed to HIV But Uninfected	Will evaluate the safety and immunogenicity of an experimental HIV vaccine (426c. Mod.Core-C4b) in infants with perinatal HIV exposure who are without HIV at birth.	Not yet recruiting. N = 22	PHRU - Soweto CRS - Baragwaneth Hospital	100%* *Originally planned to recruit only in South Africa; protocol development now on hold.
IMPAACT				
IMPAACT P1115 **NCT02140255** Very Early Intensive Treatment of Infants Living With HIV to Achieve HIV Remission	Investigation of whether very early treatment of newborns with HIV can allow for later extended interruption of therapy without viral load rebound.	Recruiting; opened to accrual January 2015. N = 1,120	Umlazi CRS (Women's Health and HIV Research Unit)	87%
			Stellenbosch University - FAMCRU CRS	
			PHRU - Soweto CRS - Baragwaneth Hospital	
			Wits RHI Shandukani Maternal and Child CRS	
IMPAACT 2023 **NCT05406583** A Phase 1 Study of the Safety, Tolerability, and Pharmacokinetics of Dolutegravir in Neonates Exposed to HIV-1	Will evaluate dolutegravir in neonates exposed to HIV-1.	Recruiting; opened to accrual October 2022. N = 36	Wits RHI Shandukani Maternal and Child CRS	50%
			Umlazi CRS (Women's Health and HIV Research Unit)	
			Stellenbosch University - FAMCRU CRS	
			PHRU - Soweto CRS - Baragwaneth Hospital	

STUDY	CONTRIBUTION TO THE FIELD	STATUS	SITES IN SOUTH AFRICA	% OF PARTICIPANTS FROM SOUTH AFRICA
IMPAACT				
IMPAACT 2026 **NCT04518228** Pharmacokinetic Properties of Antiretroviral and Anti-Tuberculosis Drugs During Pregnancy and Postpartum	Will evaluate the PK properties of ARV and anti-TB drugs administered during pregnancy and postpartum.	Active, not recruiting; estimated completion date 3/11/26. N = 205	Stellenbosch Desmond Tutu TB Centre CRS Johannesburg - Sizwe CRS Stellenbosch University - FAMCRU CRS Wits RHI Shandukani Maternal and Child CRS	
IMPAACT 2028 **NCT05154513** Long-Term Clinical, Immunologic, and Virologic Profiles of Children Who Received Early Treatment for HIV	Will characterize a cohort of early treated children with HIV who may participate in future research related to HIV remission or cure.	Recruiting; opened to accrual February 2022. N = 250	Umlazi CRS (Women's Health and HIV Research Unit) Wits RHI Shandukani Maternal and Child CRS Family Clinical Research Unit (FAM-CRU) CRS PHRU - Soweto CRS - Baragwaneth Hospital	
IMPAACT 2036 **NCT05660980** Phase 1/2 Study of Oral and Long-Acting Injectable Cabotegravir and Rilpivirine in Virologically Suppressed Children Living With HIV-1, Two to Less Than 12 Years of Age	Will evaluate the PK, safety, tolerability, and acceptability of a long-acting injectable cabotegravir and rilpivirine in children.	Recruiting; opened to accrual January 2024. N = 90	Wits RHI Shandukani Maternal and Child CRS PHRU - Soweto CRS - Baragwaneth Hospital Umlazi CRS (Women's Health and HIV Research Unit)	~25%
IMPAACT 2016 **NCT04024488** Group-Based Intervention to Improve Mental Health and Adherence Among Youth Living With HIV in Low Resource Settings	Will evaluate whether an Indigenous Leader Outreach Model (ILOM) of trauma-informed cognitive behavioral therapy (TI-CBT) delivered by Indigenous Youth Leaders (IYL) is associated with improved mental health outcomes and ART adherence among youth living with HIV in resource-limited settings.	Active, not recruiting; estimated completion date 10/15/25. N = 256	PHRU - Soweto CRS - Baragwaneth Hospital	8%

STUDY	CONTRIBUTION TO THE FIELD	STATUS	SITES IN SOUTH AFRICA	% OF PARTICIPANTS FROM SOUTH AFRICA
IMPAACT				
IMPAACT 2017 NCT03497676 More Options for Children and Adolescents (MOCHA): Oral and Long-Acting Injectable Cabotegravir and Rilpivirine in HIV-Infected Children and Adolescents	Will determine the dosage for oral cabotegravir and long-acting cabotegravir and long-acting rilpivirine and evaluate the safety, acceptability, tolerability, and PK of oral CAB, CAB LA, and RPV LA in virologically suppressed children and adolescents living with HIV.	Active, not recruiting; estimated completion date 6/17/25. N = 144	Wits RHI Shandukani Maternal and Child CRS PHRU - Soweto CRS - Baragwaneth Hospital Umlazi CRS (Women's Health and HIV Research Unit) Stellenbosch University - FAMCRU CRS	30%
IMPAACT 2037 NCT06517693 Phase 1 Safety and Pharmacokinetics Study of PGT121.414.LS Alone and in Combination With VRC07-523LS in Infants Exposed to HIV-1	Will evaluate the safety and PK of the bNAbs PGT121.414.LS alone and in combination with VRC07-523LS soon after birth in infants exposed to HIV-1.	Not yet recruiting. N = 48	Stellenbosch University - FAMCRU CRS	~30%
IMPAACT 2040 NCT06336434 CREATE - Cabotegravir & Rilpivirine Antiretroviral Therapy in Pregnancy	Will characterize the PK and safety of cabotegravir and rilpivirine long-acting injectable during pregnancy and postpartum among people with HIV-1 viral suppression and their infants.	Not yet recruiting. N = 45	Wits RHI Shandukani Maternal and Child CRS PHRU - Soweto CRS - Baragwaneth Hospital Stellenbosch University - FAMCRU CRS Umlazi CRS (Women's Health and HIV Research Unit)	75%* *Study is divided into switch and continuation groups; anticipated that >75% of participants in the switch group would be enrolled in South Africa

TABLE 4. DAIDS-FUNDED CLINICAL TRIALS UNITS AND CLINICAL RESEARCH SITES IN SOUTH AFRICA

CLINICAL TRIAL UNIT (CTU)	ANNUAL CORE FUNDING FROM DAIDS (USD; FY25)	CLINICAL RESEARCH SITE (CRS)	TYPE, FUNDER, AND NUMBER OF TRIALS	DAIDS-FUNDED TB & HIV STUDIES
University of Cape Town CTU	$1,594,012	Cape Town - Emavundleni CRS	TB DAIDS: 2 HIV DAIDS: 3	A5397/HVTN603, HVTN605/A5421, HPTN084, HVTN139, HVTN317
		Cape Town - Gugulethu CRS		
		Cape Town - Groote Schuur	TB DAIDS: 1 HIV DAIDS: 5	HVTN605/A5421, A5416/HVTN806/ HPTN108, HPTN083, HVTN206/HPTN114, HVTN305, HVTN317
		University of Cape Town Lung Institute (UCTLI) CRS	TB DAIDS: 4 TB other USG: 2	A5409, A5300/ I2003B, A5414, HVTN605/A5421
		South African Tuberculosis Vaccine Initiative (SATVI) CRS - Worcester + Cape Town	TB DAIDS: 4	A5409, A5300/I2003B, HVTN605/A5421, A5397/HVTN603
Wits HIV Research Group CTU	$943,730	Johannesburg CHRU / University of the Witwatersrand Helen Joseph (WITS HJH) CRS	TB DAIDS: 5 HIV DAIDS: 2	A5409, A5384, A5300/I2003B, A5397/HVTN603, HVTN605/A5421, A5417, A5418
		Johannesburg - Sizwe CRS	TB DAIDS: 3 TB other USG: 1 HIV DAIDS: 1	P2034, P2005, P2026
		Wits RHI Shandukani Maternal and Child CRS	TB DAIDS: 1 HIV DAIDS: 7	P1115, P2023, P2026, P2028, P2036, P2017, P2040
		Wits RHI Research Centre CRS		
		Wits RHI Hillbrow Health Precinct Ward 21 CRS	HIV DAIDS: 3	A5416/HVTN806/ HPTN108, HVTN805/ HPTN093, HPTN084

CLINICAL TRIAL UNIT (CTU)	ANNUAL CORE FUNDING FROM DAIDS (USD; FY25)	CLINICAL RESEARCH SITE (CRS)	TYPE, FUNDER, AND NUMBER OF TRIALS	DAIDS-FUNDED TB & HIV STUDIES
PHRU/Setchabe Clinical Trials Unit (Soweto/ Soshanguve)	$1,559,790	PHRU - Setshaba Research Centre / Soshanguve CRS	TB DAIDS: 1 HIV DAIDS: 3	HVTN206/HPTN114, HVTN605/A5421
		PHRU - Soweto CRS - Baragwaneth Hospital	TB DAIDS: 4 HIV DAIDS: 18	A5409, A5300/ I2003B, A5397/ HVTN603, HVTN605/A5421, A5417, A5416/ HVTN806/HPTN108, A5394, A5403, A5418, HPTN084, HVTN206/HPTN 114, HVTN139, HVTN305, HVTN316, HVTN317, P1115, P2023, P2028, P2036, P2016, P2017, P2040
		Klerksdorp - PHRU Matlosana CRS	TB DAIDS: 3 TB other USG: 2 HIV DAIDS: 1	A5300B/I2003B, P2005, P2034, HVTN206/HPTN114
		PHRU - Soweto Kliptown CRS	HIV DAIDS: 1	HVTN805/HPTN093
Stellenbosch University CTU	$747,752	Stellenbosch University -Desmond Tutu TB Centre CRS	TB DAIDS: 5 HIV DAIDS: 2	A5300B/I2003B, P2034, P2024, P2005, P2026, HPTN084
		Stellenbosch University -FAMCRU CRS	TB DAIDS: 1 HIV DAIDS: 7	P1115, P2023, P2026, P2028, P2017, P2037, P2040
		TASK Applied Science CRS - Brooklyn Chest Hospital	TB DAIDS: 1 TB other USG: 1	A5300B/I2003B
Aurum South and East African CTU	$795,942	Aurum Institute - Rustenburg CRS	TB DAIDS: 5 HIV DAIDS: 3	A5409, A5414, A5300B/I2003B, HVTN605/A5421, A5397/HVTN603, A5417, A5416/ HVTN806/HPTN10, HVTN805/HPTN093
		Aurum Institute - Klerksdorp CRS	TB DAIDS: 2 TB other USG: 1 HIV DAIDS: 3	HVTN605/A5421, A5397/HVTN603, A5416/HVTN806/ HPTN10, HVTN139, HVTN317
		Aurum Institute - Johannesburg - Tembisa CRS	TB other USG: 1	
		Tembisa Serurubele		

CLINICAL TRIAL UNIT (CTU)	ANNUAL CORE FUNDING FROM DAIDS (USD; FY25)	CLINICAL RESEARCH SITE (CRS)	TYPE, FUNDER, AND NUMBER OF TRIALS	DAIDS-FUNDED TB & HIV STUDIES
KwaZulu-Natal CTU	$1,043,933	Durban – Verulam CRS	HIV DAIDS: 1	HPTN084
		Durban - Botha's Hill CRS (MRC)	TB DAIDS: 1 HIV DAIDS: 1	HVTN605/A5421, HPTN084
		Durban - Chatsworth CRS (MRC)	TB DAIDS: 1 HIV DAIDS: 2	HVTN605/A5421, HVTN206/HPTN114, HVTN317
		Durban - Isipingo CRS (MRC)s	TB DAIDS: 2 HIV DAIDS: 3	HVTN605/A5421, A5397/HVTN603, HPTN084, HVTN139, HVTN317
		Durban - eThekwini CRS (CAPRISA)	TB DAIDS: 4 HIV DAIDS: 6	A5409, A5300B/ I2003B, A5397/ HVTN603, HVTN605/ A5421, HVTN139, HVTN305, HVTN 317, HVTN805/ HPTN093, A5417, A5416/HVTN806/ HPTN108
		Vulindlela CRS (CAPRISA)	HIV DAIDS: 1	HVTN805/HPTN093
		Springfield CRS (CAPRISA; King Dinuzulu Hospital)	TB other USG: 2	
		Umlazi CRS (Women's Health and HIV Research Unit)	TB DAIDS: 1 HIV DAIDS: 6	P2024, P1115, P2023, P2028, P2036, P2017, P2040
Protocol-Specific or non-DAIDS-Network Sites	NA	Ladysmith CRS	TB DAIDS: 1	HVTN605/A5421
		Port Elizabeth - Dora Nginza Hospital	TB other USG: 1	
		Port Elizabeth - Isango Lethemba TB Research Unit - Jose Pearson TB Hospital	TB other USG: 1	
		Joshua Bloemfontein		
		Khayelitsha CIDRI-Africa	TB DAIDS: 1	HVTN605/A5421
		Durban - Africa Health Research Institute - Nelson R. Mandela School of Medicine	TB other USG: 1	
		Think - Durban		

CLINICAL TRIAL UNIT (CTU)	ANNUAL CORE FUNDING FROM DAIDS (USD; FY25)	CLINICAL RESEARCH SITE (CRS)	TYPE, FUNDER, AND NUMBER OF TRIALS	DAIDS-FUNDED TB & HIV STUDIES
		Durban Adult HIV CRS	TB DAIDS: 1	HVTN305
		Durban - Wentworth	TB DAIDS: 1	HVTN605/A5421
		Durban International CRS	TB DAIDS: 4 HIV DAIDS: 4	A5409, A5384, A5300B/I2003B, A5397/HVTN603, A5417, A5394, A5402, A5424

TABLE 5. OTHER USG-PROPOSED OR -FUNDED STUDIES WITH SITES IN SOUTH AFRICA

STUDY	CONTRIBUTION TO THE FIELD	STATUS	SITES IN SOUTH AFRICA
CRUSH-TB / TBTC Study 38 **NCT05766267** Phase 2C trial of the efficacy and safety of Combination Regimens for Shortening Tuberculosis Treatment Funded by CDC	Will evaluate effectiveness and safety of new 4-month bedaquiline, moxifloxacin, and pyrazinamide-based regimens for the treatment of drug-sensitive TB.	Recruiting; opened to accrual November 2023. [194/288 enrolled]	University of Cape Town Lung Institute (UCTLI) CRS
PRESCIENT **NCT05556746** Phase 2c trial of an ultra-short course regimen of bedaquiline, clofazimine, pyrazinamide, and delamanid for DS-TB (NIH)	Will evaluate a 3-month, bedaquiline- and delamanid-containing regimen for the treatment of drug-sensitive TB.	Recruiting; opened to accrual November 2023. [89/156 enrolled]	University of Cape Town Lung Institute (UCTLI) CRS
CLOBBER-TB Phase 3 randomized trial to evaluate an optimized regimen for extensively drug-resistant tuberculosis (XDR-TB) Submitted to NIH	Will evaluate 6–9-month, all-oral regimen containing multiple novel compounds for the treatment of XDR-TB (current treatment is 18+ months containing injectable and IV agents).	Submitted to DMID; awaiting council review. N = 120	Springfield CRS (CAPRISA; King Dinuzulu Hospital) TASK Applied Science CRS - Brooklyn Chest Hospital Johannesburg - Sizwe CRS
BREACH-TB **NCT06568484** Bedaquiline Roll-out Evidence in Contacts and People Living With HIV to Prevent TB Funded by USAID	Will evaluate 1-month of bedaquiline as TPT for contacts of drug-sensitive and drug-resistant TB.	Protocol developed. N = 2,530	Aurum Institute - Klerksdorp CRS Aurum Institute - Johannesburg Tembisa CRS Klerksdorp - PHRU Matlosana CRS

STUDY	CONTRIBUTION TO THE FIELD	STATUS	SITES IN SOUTH AFRICA
SMILE-TB **NCT06253715** Shortened Regimen for Drug-susceptible TB in Children Funded by USAID	Will evaluate if treatment can be shortened to 2 months for children with HPMZ.	Active, not recruiting; temporarily paused as of February 2025. [3/860 enrolled]	Durban - Africa Health Research Institute - Nelson R. Mandela School of Medicine
PRISM-TB **NCT06441006** Program for Rifampicin-resistant disease with Stratified Medicine for TB Funded by USAID	Will evaluate shorter treatment with BPaLM for drug-resistant TB; 3–6 months depending on disease severity.	Protocol in development. N = 690	Port Elizabeth - Isango Lethemba TB Research Unit - Jose Pearson TB Hospital Springfield CRS (CAPRISA; King Dinuzulu Hospital) Klerksdorp - PHRU Matlosana CRS
PRISM-Kids Program for Rifampicin-Resistant Disease with Stratified Medicine for Tuberculosis in Children Funded by USAID	Will evaluate shorter treatment with BDLxLz for drug-resistant TB in children; 4–6 months depending on disease severity.	Protocol in development. N = 200	
ADAPT for Kids **NCT05989802** Rapid Research in Diagnostics Development for TB Network (R2D2 Kids) and Assessing Diagnostics At POC for TB in Children Funded by USAID	Will evaluate the accuracy and usability of novel tests for TB in children (e.g., tongue swab samples on Xpert and Truenat).	Recruiting; opened to accrual January 2024. N = 2,100	Port Elizabeth - Dora Nginza Hospital

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