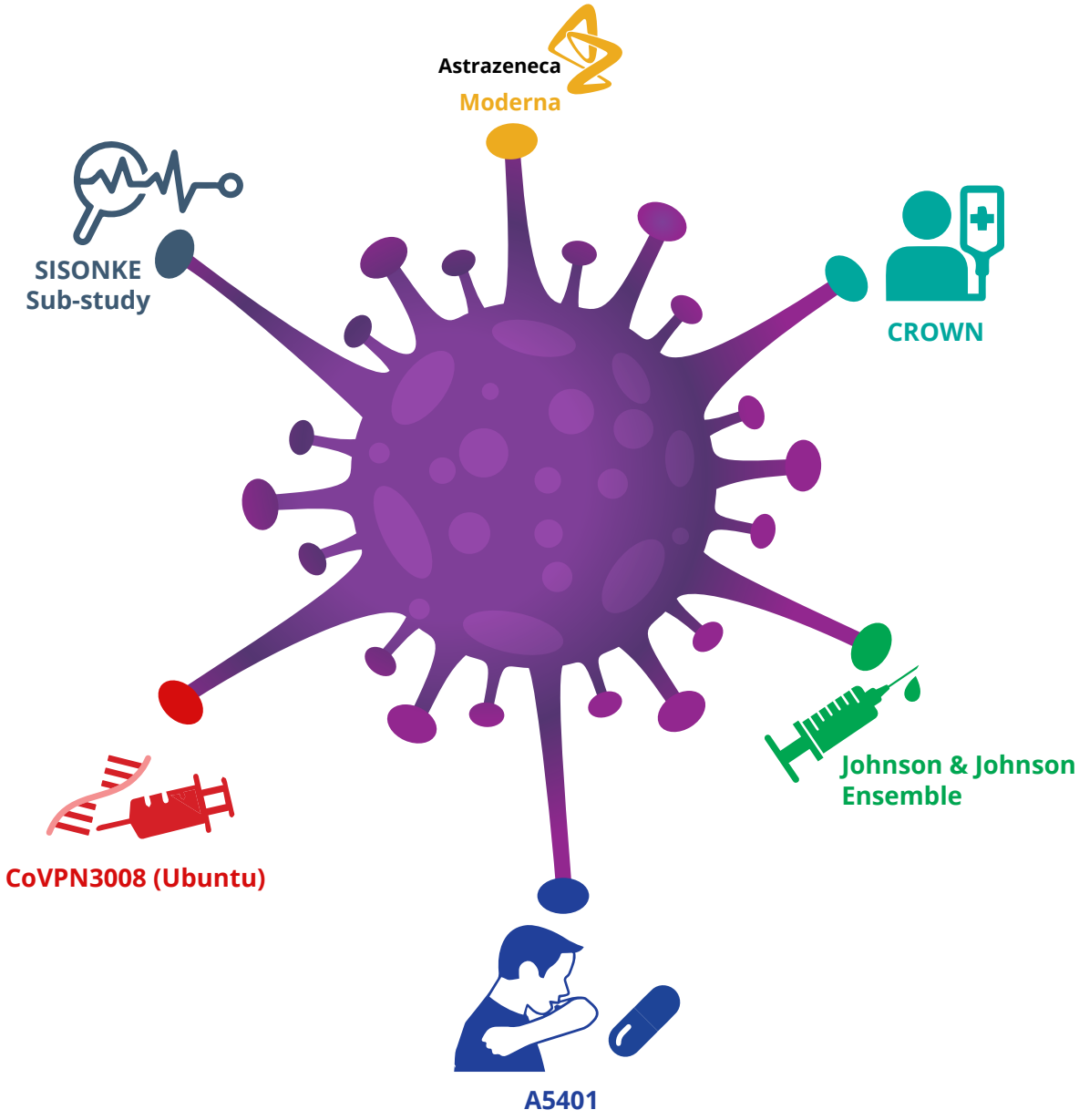
COVID-19 RESEARCH PROGRAMME



CROWN

CROWN CORONATION: Ambulatory Management of Moderate to High Risk COVID-19 (SARS-CoV-2) Patients - The Coronavirus Related Outpatient Work Navigators (CROWN) Protocol (CROWN).

Johnson & Johnson Ensemble

VAC31518COV3001/ENSEMBLE: Evaluate the efficacy of Ad26.COV2.S in the prevention of molecularly confirmed moderate to severe/critical COVID-19, as compared to placebo, in adult participants.

A5401

A master protocol to evaluate the safety and efficacy of investigational agents for the treatment of symptomatic non-hospitalized adults with COVID-19.

CoVPN3008 (Ubuntu)

Multi-Center, Randomized, Efficacy Study of COVID-19 mRNAVaccine in Regions with SARS-CoV-2 Variants of Concern.

SISONKE Sub-study

To monitor the effectiveness of the single dose Ad26.COV2.S COVID-19 vaccine among health care workers (HCW) as compared to the general unvaccinated population in South Africa.

MODERNA

AstraZeneca D7220C00001 study. A multinational, study in both previously vaccinated and unvaccinated adults to determine the safety and immunogenicity of AZD2816, a vaccine for the prevention of COVID-19 caused by variant strains of SARS-CoV-2.

WHO-ALIGNED HIV RESEARCH PROGRAMME

HPTN 052 Study – reduced HIV incidence in discordant couples

START - WHO and South Africa NDoH Treatment Guideliness premised on our START Study

REPRIEVE - caring for the heart of PLHIV

HPTN 052 - WHO HIV treatment guidelines for sero-discordant couples

CHRU together with PHRU represented South Africa as one of nine countries who conducted the Phase III randomized clinical trial HPTN 052, which determined that an early introduction of Antiretroviral Therapy (ART) can prevent HIV transmission of HIV-1 in HIV-1 sero-discordant couples. Following the interim results of this study, the WHO recommended that ART be offered to all people living with HIV who have uninfected partners.

START - WHO HIV-test and treat guidelines

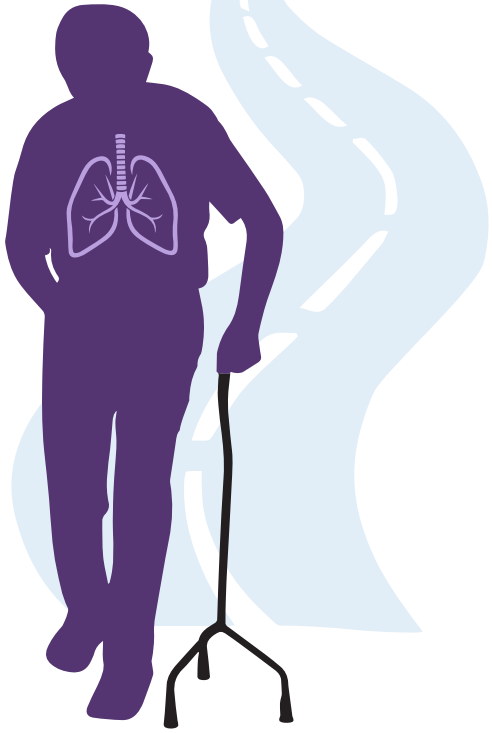
CHRU was one of the five South African sites that participated in the Strategic Timing of Antiretroviral Treatment (START) study aimed to establish whether earlier ART would prevent morbidity and mortality in HIV and to establish the correct time to start ARVs. A total of 218 research sites across 35 countries participated and the results showed that HIV –infected individuals have a lower risk of developing AIDS and co-infections with the early introduction of ART. The study laid the foundations for the WHO and the NDoH's test and treat approach to HIV.

REPRIEVE

The largest randomized trial to date in HIV with a total of 7557 participants accrued at multi-research sites across the globe. The results from REPRIEVE helped clinical researchers and clinical care providers to develop heart disease prevention and treatment guidelines, specifically for people living with HIV.

WHO-ALIGNED DRUG-RESISTANT TB RESEARCH PROGRAMME

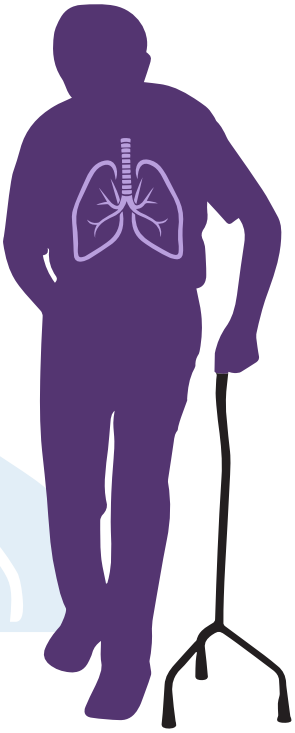
20 – 24 Months



STREAM I AND II

Phase 1 of the study showed that a 9 to 11 month treatment regimen is as effective in treating multidrug-resistant tuberculosis (MDR-TB) as the 20 to 24 month treatment regimen recommended in the 2011 WHO guidelines.

9 – 11 Months



Nix-TB – SAFE REDUCTION OF XDR-TB TREATMENT

The study evaluated the efficacy, safety, tolerability and pharmacokinetics of bedaquiline plus PA-824 plus linezolid after 6 months of treatment (option for 9 months for subjects who remain culture positive at month 4) in subjects with either pulmonary extensively drug resistant tuberculosis (XDR-TB), treatment intolerant or non-responsive multi-drug resistant tuberculosis (MDR-TB). The Nix-TB study was the first clinical trial to test a novel regimen that holds the potential to be a shorter, all-oral, and affordable treatment for XDR-TB.

Beat TB

Building Evidence for Advancing new Treatment for Drug Resistant TB Open-label, Single-Arm Stepped Study to Assess the Efficacy, Safety and Tolerability of Bedaquiline (BDQ), Delamanid (DLM), Linezolid (LNZ) and Clofazamine (CLZ), 6 to 9 month Regimen for the Treatment of Pulmonary Tuberculosis in Patients pre/XDR and MDR TB (USAID APPLICATION)

ZeNIX

A Phase 3 partially-blinded, randomized trial assessing the safety and efficacy of various doses and treatment durations of linezolid plus bedaquiline and pretomanid in participants with pulmonary infection of either extensively drug-resistant tuberculosis (XDRTB), pre-XDR-TB or treatment intolerant or non-responsive multidrug-resistant tuberculosis (MDR-TB).

CHRU Themba Lethu

CLINICAL HIV RESEARCH UNIT

CERVICAL CANCER PREVENTION PROGRAMME

UMSA

Cervical Dept: Innovations for screening and prognosis in HIV+ cancers including Kaposi sarcoma, cervical cancer, and lymphoma in Malawi and South Africa.

NIH ACTG A5282

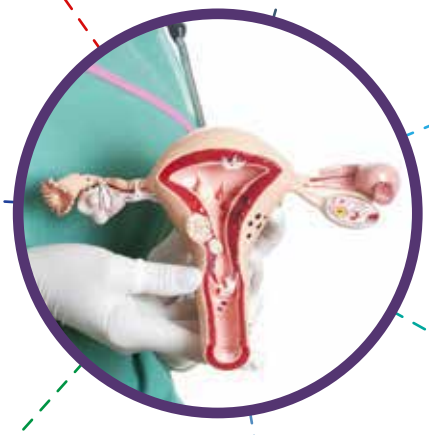
The study concluded that HPV Test and Treat potentially did not perform better due to worse responses to cryotherapy in this population and that more effective treatment options are needed to improve outcomes of cervical cancer screen-and-treat programs in high HIV burden countries with limited resources.

M-HAVE Study, HPV Vaccination vs placebo to reduce cervical dysplasia

The study did not support using q HPV Vaccine as adjuvant therapy and has shown that persistent HSIL occurred despite good CD4 and HIV Viral suppression. This study supported also that other treatment is needed in resources limited settings.

FIND Study

An implementation science approach to address multi-level barriers to cancer screening among women living with HIV in South Africa.



CIN 1 Study

A randomized, control trial of the treatment of cervical CIN1 dysplasia with cryotherapy vs non-treatment, to reduce progression of CIN1 in South African HIV infected. This study supports that treatment of CIN 1 with cryotherapy can be an adjuvant treatment to prevent cervical cancer in South African women.

ACT Study

Acceptability and feasibility of combination treatment for cervical precancer among South Africa women living with HIV.

COVENANT Study

AMC-099 A Randomized, Placebo-Controlled Trial of HPV Vaccination to Reduce Cervical High-Grade Squamous Intraepithelial Lesions Among HIV-Infected Women Participating in an HPV Test-and-Treat Program (COVENANT).

CLINICAL HIV RESEARCH UNIT