Project Brief: IMPAACT 2028

Full Title of Study/Programme	Long-Term Clinical, Immunologic, and Virologic Profiles of Children who Received Early Treatment for HIV
Technical Focus Area/Key Words	Pediatrics
Rationale	Early treatment of infants living with HIV offers a unique population in which to investigate long-term clinical, immunologic, and virologic outcomes and to better characterize how early ART impacts HIV infection over time. The overarching goals of IMPAACT 2028 are to establish long-term follow-up of participants who received early treatment for future interventional cure and/or remission trials and to establish a unique biorepository from which additional scientific questions can be answered. In lower and middle-income settings, where the majority of these trial participants live, the significant mobility of enrolled participants may reduce access for future studies, particularly if they are currently not receiving care at a clinical research site. The durability of early treatment, the effect of acquired co-infections on reservoir dynamics, the longterm effects of ART and/or bNAbs on a maturing immune system and on the evolution of HIVspecific neutralizing antibodies, cell-mediated immunity, systemic immune activation, inflammation, and the predictive value of biomarkers associated with increased morbidity and mortality in adults are poorly understood in children. It is thus anticipated that IMPAACT 2028 will longitudinally track these participants while simultaneously advancing our understanding of the long-term effects of early ART and/or bNAb initiation through establishing a biorepository to address scientific questions and promote innovation in this field
Primary Objectives	To characterize the long-term clinical, immunologic, and virologic profiles of children who received early treatment for perinatally-acquired HIV
Study Design (R)	Observational prospective cohort study
Study population (R)	Children living with perinatally-acquired HIV who received early treatment in IMPAACT network studies or other research studies sponsored by the United States National Institutes of Health. Early treatment is defined as treatment with at least three antiretroviral agents from at least two classes of antiretroviral therapy initiated within 12 weeks of birth. Early treatment regimens may also include broadly neutralizing antibodies (in addition to at least three antiretroviral agents). Within the overall study population, children who initiated treatment within 48 hours of birth will be classified as having received very early treatment.
Study sample size (R)	Up to approximately 250 participants
Follow up/duration	Approximately seven years
Study/Programme sites	12701, Gaborone Clinical Research Site

	12702, Molepolole Clinical Research Site 5071, Instituto de Puericultura e Pediatria Martagao Gesteira Clinical Research Site 5073, School of Medicine Federal University Minas Gerais Clinical Research Site 5074, University of Sao Paulo Clinical Research Site 5097, Hospital Geral De Nova Igaucu Clinical Research Site 30022, Les Centres GHESKIO Clinical Research Site 5121, Kenya Medical Research Institute/Walter Reed Project Clinical Research Center 12001, Malawi Clinical Research Site 30301, Blantyre Clinical Research Site 8051, Wits RHI Shandukani Research Centre Clinical Research Site 8950, FAMCRU Clinical Research Site 30300, Umlazi Clinical Research Site 5118, Kilimanjaro Christian Medical Centre Clinical Research Site 5115, Siriraj Hospital Mahidol University Clinical Research Site 5116, Chiangrai Prachanukroh Hospital Clinical Research Site 31798, Baylor-Uganda Clinical Research Site 3801, Texas Children's Hospital Clinical Research Site 4001, Lurie Children's Hospital of Chicago Clinical Research Site 4201, Pediatric Perinatal HIV Clinical Trials Unit Clinical Research Site 4601, University of California, San Diego Clinical Research Site 5048, University of Southern California Clinical Research Site 5051, University of Florida, Jacksonville Clinical Research Site 5052, University of Colorado, Denver Clinical Research Site 5055, South Florida CDTC Fort Lauderdale Clinical Research Site 5092, Johns Hopkins Clinical Research Site 5112, David Geffen School of Medicine at UCLA Clinical Research Site 5114, Bronx Lebanon Hospital Center Clinical Research Site 6501, St Jude Children's Research Hospital Clinical Research Site 30303, Saint Mary's Clinical Research Site 31890, Harare Family Care Clinical Research Site
Intervention (R)	No intervention is provided in this study
Operations	Study Specific
Investigators	• Dr Faeezah Patel, Principal Investigator • Prof Lee Fairlie • Dr Mrinmayee Dhar • Dr Muneerah Khan • Dr Jeanne Coetzee • Dr Elizea Horne • Othusitse Segal • Tiffany Seef
Other Partners & Collaborators	National Institute of Allergy and Infectious Diseases Eunice Kennedy Shriver National Institute of Child Health and Human Development National Institute of Mental Health
Sponsors/Donors	IMPAACT 2028
Linked Sub Studies and post grad projects	LEOPARD TIES CHERS P2008 P1115
Publications/key presentations to date	None yet

Progress Update	• Site has been activated • Participant to be recruited from the Leorpard study • 10 Participants screened and enrolled • 1 Screening Failure. • 8 Participants completed their Q24 visits
Frequency of donor narrative report	Monthly
Overall Study/Project Contact	Dr Faeezah Patel Dr Hermien Gous
Briefing owner and date	Kabelo Mashaba 19 Mar 2024