

Project Brief: TMC278LAHTX4002

Full Title of Study/Programme	A Phase 3b, Open-Label, Rollover Study to Provide Continued Access to Cabotegravir Long-acting Injection and Rilpivirine Long-acting Injection to Participants Living with Human Immunodeficiency Virus Type 1 (HIV-1) Infection Who Participated in Long-acting Combination Therapy Studies
Technical Focus Area/Key Words	Research in Paediatrics
Rationale	This study enables continued access to CAB LA + RPV LA and allows for the evaluation of the long-term safety and tolerability in participants upon completion of the following studies: TMC278LAHTX3002 (CARES), TMC278LAHTX3005 (IMPALA), IMPAACT 2017 (MOCHA), IMPAACT 2036 (CRAYON), IMPAACT 2040 (CREATE) (referred to as the parent studies in the following sections). Eligible participants will include those who, at the time of rollover, experience and are expected to continue to experience clinical benefit from the regimen but have no access to locally available CAB LA + RPV LA to continue the treatment. The rollover study will be reviewed periodically by the Sponsor to evaluate other access options.
Primary Objectives	The primary objective of the study is to provide continued CAB LA + RPV LA access to participants who were enrolled and treated with CAB LA + RPV LA in the parent studies, and who, at the time of roll-over, experience and are expected to continue to experience clinical benefit from this treatment.
Secondary Objectives	The secondary objective is to assess the long-term safety and tolerability of CAB LA + RPV LA by evaluating the incidence of serious adverse events (SAEs), pregnancies, adverse events (AEs) leading to discontinuation of CABLA +RPV LA, and AEs considered to be related to the study intervention.
Study Design (R)	This is a Phase 4, open-label, non-randomized, multicenter, multicountry, rollover study in participants living with HIV-1 infection who were treated in the parent studies with CAB LA + RPV LA given intramuscularly on a Q4W or Q8W dosing schedule.
Study arms (R)	This is a rollover study and the arms are dependent on the parent study.

Study population (R)	Children from the IMPAACT 2017 and IMPAACT 2036 study that completed the study and require access to the injectable ART that is not yet registered for use in standard of care in South Africa.
Study sample size (R)	Dependant on the parent study enrolment - 15 expected at Shandukani
Follow up/duration	Access to CAB LA + RPV LA will continue for up to 48 months (end of study).
Study/Programme sites	Wits RHI Shandukani Research Centre (SRC)
Study/Programme duration	Access to CAB LA + RPV LA will continue for up to 48 months (end of study).
Intervention (R)	CAB LA + RPV LA
Operations	Study specific
Investigators	Dr Faezah Patel, Principal Investigator Dr Lee Fairlie, Sub Investigator Dr Elizea Horne, Sub Investigator Dr Mrinmayee Dhar, Sub Investigator Dr Jeanne Coetzee, Sub Investigator
Other Partners & Collaborators	Janssen
Sponsors/Donors	Janssen
Linked Sub Studies and post grad projects	IMPAACT 2017 and IMPAACT 2036
Publications/key presentations to date	Nil expected
Progress Update as at Jun 2025	• Currently on protocol version 2 dated 29 Jul 2025. • Enrolled:14 • Withdrawn:1 • Active participants:13 • 10 IMPAACT 2017 participants enrolled on the study. • 4 IMPAACT 2036 participants enrolled on the study. • ZA100040005 withdrew consent due to relocation. • New CRA is Kamogelo Seloane
Frequency of donor narrative report	3 Monthly
Overall Study/Project Contact	Kabelo Mashaba Faezah Patel
Briefing owner and date	Kabelo Mashaba 14 Jul 2026