

Project Brief: PATH STUDY

Full Title of Study/Programme	A Phase 3b, open-label, multicenter, continued access study for participants transitioning from ViiV Healthcare-sponsored or ViiV Healthcare-collaborative parent studies for HIV treatment.
Full Title of Study/Programme (Parent study).	A multicentre, open-label, single-arm trial to evaluate the safety, pharmacokinetics and antiviral activity of fostemsavir in combination with optimized background therapy (OBT) in HIV-1 infected children and adolescents who are failing their current combination antiretroviral therapy (cART) and have dual- or triple-class antiretroviral (ARV) resistance .
Technical Focus Area/Key Words	Research in Children and Adolescents
Rationale	The purpose of this study is to provide continued treatment access and describe the continued use and safety of parent study intervention for eligible participants who continue to derive clinical benefit from ViiV Healthcare-sponsored or ViiV Healthcare-collaborative parent studies, and who do not have access to the locally available parent study intervention for continued treatment after completing the parent study.
Primary Objectives	To provide continued access to study interventions for participants who were enrolled and treated in ViiV Healthcare-sponsored or ViiV Healthcare-collaborative parent studies, and who, at the time of transition to this study, continue to experience clinical benefit from this treatment, and to describe the continued use and safety of the study intervention.
Primary Endpoint/Outcome	Reasons for discontinuation of study intervention. • Incidence and outcome of SAEs. • Incidence and outcome of AESIs (if collected in the applicable study appendix).
Investigators	Dr Faezah Patel, Principal Investigator Dr Lee Fairlie, Sub Investigator Dr Elizea Horne, Sub Investigator Dr Mrinmayee Dhar, Sub Investigator Dr Jeanne Coetzee , Sun Investigator
Sponsors/Donors	Fondazione Penta– for the treatment and care of children with HIV (and related diseases) – ONLUS
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Overall Study/Project Contact	Kabelo Mashaba Faezah Patel