Project Brief: DAISY – Specific Aim 3

Full Title of Study/Programme	Delivery of Antiretrovirals via Implantable System for Young Children (DAISY) Specific Aim 3
Technical Focus Area/Key Words	HIV-infected children, antiretroviral treatment, long-acting treatment approaches, implant, acceptability
Rationale	SA reports one of the highest populations of HIV-infected young children and of the 55% of children that receive ART only 67% are virally suppressed. Adherence and retention in care are affected by multiple challenges with formulation and dosages for children, including poor palatability of drugs, high pill burden, and difficulty in swallowing. Simplified dosing regimens and long-acting (LA) ART formulations are needed to improve treatment success for children who face a lifetime of ART. Delivery of ART via implantable system for young children (DAISY) is one such formulation currently in development. Integrated research on product development and end-user preferences is critical for successful product development. For technology optimization and future implementation of the DAISY into clinical practice, research is needed on end-users' perspectives on (1) acceptability and preferred characteristics of the DAISY system for pediatric treatment, (2) considerations for future implementation within the existing health care system in SA, and (3) biodegradability of the inserted implants.
Primary Objectives	To measure acceptability of, and preferences for the DAISY drug delivery platform among two key end-user groups in South Africa (SA): caregivers of HIV-positive children receiving antiretroviral therapy (ART) and health care providers. These end-user perspectives are linked to the Target Product Profile (TPP) and will inform design of the DAISY, including device and applicator characteristics.
Secondary Objectives	N/A
Primary Endpoint/Outcome	N/A
Secondary Endpoint/Outcome	N/A
Study Design	Iterative qualitative study
Study arms	N/A
Study population	Health care providers serving pediatric HIV-infected populations and caregivers of HIV-infected children aged 2-5 who have been treated with antiretroviral treatment for at least 6 months.
Study sample size	24 Healthcare providers and 8 caregivers for in-depth interviews; ~64 caregivers for focus group discussions
Follow up/duration	No follow-up
Study/Programme sites	Hillbrow Community Health Centre, Yeoville Clinic, Harriet Shezi Children's Clinic and Tembisa Hospital Paediatric HIV Clinic
Study/Programme duration	Study completion expected end of 2021
Investigators	• Lee Fairlie, Wits RHI • Elizabeth Montgomery, RTI International • Ariane van der Straten, RTI International • Fiona Scorgie, Wits RHI

Other Partners & Collaborators	RTI
Sponsors/Donors	NIH
Linked Sub Studies and post grad projects	Nil
Publications/key presentations to date	None as yet
Progress Update as at 10/2030	Protocol approved by HREC Interview staff trained Study specific SOPs being finalised
Frequency of donor narrative report	
Overall Study/Project Contact	Lee Fairlie (lfairlie@wrhi.ac.za)
Briefing owner and date	Fiona Scorgie, 29/10/2020