PAEDIATRIC ONGOING STUDIES

STUDY	SPONSOR / FUNDER	STUDY SUMMARY		Projected start / end date
(ii) Protocol 0106	**Sponsor:** Gilead Sciences	It is a Phase 2/3, Open-Label Study to confirm the dose of elvitegravir/cobicistat/emtricitabine/tenofoviralafenamide (E/C/F/TAF) single tablet regimen (STR) in HIV-1 infected, antiretroviral (ARV) treatment naive adolescents and evaluate the pharmacokinetics, safety, tolerability, and antiviral activity of E/C/F/TAF STR in HIV-1 infected, ART naive adolescents and virologically suppressed HIV-1 infected children. Antiviral activity is determined by the achievement of HIV-1 RNA < 50 copies/mL at Weeks 24 and 48.	Are in follow-up, the first participant reached their 360 week visit, the last participant is in the week 60 visit. The last participant will exit at least in their 96 week visit.	Started in 2013, **Projected to end in January 2022**
Protocol GS-US-380-1474	**Sponsor:** Gilead Sciences.	**T**he Pharmacokinetics, Safety, and Antiviral Activity of the (GS-9883/F/TAF) Fixed Dose Combination (FDC) in HIV-1 Infected Virologically Suppressed Adolescents and Children	Study is still recruiting. Amendment to the study make it hard to estimate exit dates.	
PAINT	***Source of funding:*** *TIBOTEC, Johnson and Johnson.*	A Study to Evaluate the Pharmacokinetics, Safety, Tolerability, and Antiviral Efficacy of TMC278 in Human Immunodeficiency Virus Infected Adolescents.	Is still recruiting though the site has been paused but it is about to start recruiting again. End date is not known.	Started 2009, ongoing. **End date not clear**
ODESSY (PENTA 20),	**Funder: ViiV through PENTA**	Dolutegravir (DTG) based Antiretroviral Therapy vs Standard of Care (SOC) in Children with HIV infection starting First-line or Switching to Second-line ART	Participants above 14kgs exited the main trial, those less than 14kgs are still being followed up until January 2021. They will all be followed up in the extended follow-up for long term phase	Started November 2016, **Projected to end in in 2023**
DRIBS STUDY	*Funder:* ***EDCTP*** ***Sponsor: JCRC***	Aims to assess the importance of an HIV baseline drug resistance test in HIV positive infants born to HIV positive mothers who were on ART during pregnancy. (Low frequent HIV drug resistant polymorphisms in infants born to HIV sero-positive mothers: Implications on response to therapy)	Has exited about 8 participants. It is also still recruiting. Follow-up of participants is for 2 years	Started in May 2018, **May end in 2023 or take longer than that**

CHAPAS 4	***Funder: EDCTP Sponsor: MRC-CTU***	Children with HIV in Africa – Pharmacokinetic and acceptability of simple second line Antiretroviral regimen.	Started exiting, 11 have been exited. Are in the process of submitting an amendment for long-term follow-up for 3 years. Still also enrolling.	Started January 2019, **will end in 2022 plus the three year follow-up once approved**
K23 (paediatrics)	***Funder: NIH Sponsor: University hospital Cleveland medical centre***	Predictors of cardiovascular diseases and inflammation in Ugandan children with HIV.	Are in follow-up visit until June 2021	Started in 2018, **ended in June 2021**
The Iron study	***Funder: NIH Sponosr: UNiv. of Minnesota - GHU***	The role of Iron Deficiency in the Neurodevelopment of Children Perinatally exposed to HIV	Participants attend only one visit, 57 participants have attended their only visit. The study needs to recruit 153 other participants for their only visit.	Started in July 2020 The study duration is two years however a lot of time has been lost due to COVID, the study team is planning to meet in March to see how they can adjust study duration.
Another PAINT Follow on study **(TMC278HTX2002)**	**Janssen Research and Development**	A Phase 2, Open-label, Single-arm, Multicenter Study to Evaluate the Pharmacokinetics, Safety, Tolerability, and Efficacy of Switching to RPV Plus Other ARVs in HIV-1-infected Children (Aged 2 to <12 years) who are Virologically Suppressed	Pending REC, and regulatory approval	
HEADS UP	***Royal Holloway University - UK***	Study on HIV disclosure among adolescents and young adults born with HIV	On hold in the U.K however it is preparing to start recruitment into phase in Uganda. Training the therapist and the peer worker are ongoing	Started in September 2019, **proposed end date is March 2022**

PAEDIATRIC STUDIES TO START IN 2021

Study	Funder / Sponsor	Study Summary	Comment	Projected start / end date
Breather Plus:	**Funded by EDCTP**	A randomised open-label 2-arm, 96-week trial evaluating the efficacy, safety and acceptability of short cycle therapy (five days on, two days off) dolutegravir-based antiretroviral therapy (ART) compared to daily dolutegravir-based ART in virologically suppressed HIV-infected adolescents aged 12-<20 years of age in sub-Saharan Africa.	Awaits Sponsor's final decision to start the regulatory review process. Will need IRB/REC, UNCST and NDA	**projected to start in Jan 2022**

LATA	**JANSSEN / MRC-CTU**	A randomised open-label 2-arm, 96-week trial evaluating the efficacy, safety and acceptability of 8-weekly dual long-acting injectable antiretroviral therapy (ART) compared to daily dolutegravir-based triple ART in virologically suppressed HIV-infected adolescents aged 12-<20 years in sub-Saharan Africa.	Awaits Sponsor's final decision to start the regulatory review process. Will need IRB/REC, UNCST and NDA.	**projected to start in April 2022**
D3 (PENTA) 21	**ViiV / PENTA/ MRC-CTU**	A randomised non-inferiority trial with nested PK to assess DTG/3TC fixed dose formulations for the maintenance of virological suppression in children with HIV infection aged 2 to <15 years old	In the process of responding to REC review comments	**Projected to start in April 2021**
PAINT follow on (TMC2781FD3004)	**Janssen Research and Development**	Follow on study / role over from the Original paint study	Received REC approval, pending UNCST, NDA approval.	
ODYSSEY long term follow up	**ViiV/PENTA/MRC-CTU**	Dolutegravir (DTG) based Antiretroviral Therapy vs Standard of Care (SOC) in Children with HIV infection starting First-line or Switching to Second-line ART: A longer time follow up was approved	Not yet submitted to REC, UNCST,NDA	
CHAPAS 4 long term follow up	**Funded by EDCTP**	Children with HIV in Africa – Pharmacokinetic and acceptability of simple second line Antiretroviral regimen.	Not yet submitted to REC, UNCST,NDA	
IMARA study	**IMARA Inc.**	A Phase 2b/3 Study to Evaluate the Safety and Efficacy of IMR-687 in Subjects with Sickle Cell Disease. Primary Objectives • To evaluate the foetal haemoglobin (HbF) response to IMR-687 versus placebo • To evaluate the safety of IMR-687 versus placebo.	Completed IRB/REC. Now at UNCST then will move to NDA	**started in May 2021**
GUT study (HS 1036ES)	**NIH/ CWRU**	Gut Integrity and Metabolic Complications in Youth Living with HIV in Uganda – A cross sectional study	Completed IRB/REC. Now at UNCST, Doesn't require NDA	**started in March 2021**
CARMA-GLOBAL	**PENTA**	A cross-sectional study of children with perinatally-acquired HIV infection who started ART at a young age, four or more years ago, and who are currently in care on ART. The aim is to describe the size and profile of the persisting viral reservoir and associated immunological parameters after several years of ART after	Yet to start the regulatory review process. Awaits Sponsor's final decision	

		initiation of treatment at a young age.		
UNIVERSAL	**EDCTP**	Pharmacokinetic and safety studies of new antiretroviral formulations: expediting UNIVERSAL first and second line regimens for all children living in Africa.	Protocol is yet to be completed. Not yet to started the regulatory review process	