Study Report to DSMC

CTN Study Number	CTNPT 038
Study Title	Fecal microbiota transplantation to reduce immune activation in ART-treated people living with HIV with low CD4/CD8 ratio: The Gutsy study
CTN+ Services	Database/data management, Statistical analysis, Communications and KT, Regulatory Support (to a maximum of 2 protocol amendments, DSMC)
Study Status	☒ Enrolling ☐ Enrolment suspended ☐ Ongoing (Visits ongoing but closed to enrolment) ☐ LPLV completed
Target Enrolment	20 participants completing the study
Total Enrolment to date	**23** (8 participants completed study: 3 FMT, 5 Placebo) **6** participants withdrawn (to be replaced)
Date of FPFV	31 Jul 2024
Date of LPLV / Projected date of LPLV	Est: 31 Jul 2025
Description of issues (e.g. study delays, low enrolment; enrolment suspended)	1. Disproportionate distribution of participants in each arm due to withdrawals. Participants are randomized 1:1 to FMT:Placebo • 6 participants withdrawn (4 FMT arm, 2 Placebo arm) <u>Reason for withdrawals:</u> 3 – Participant request 2 – Antibiotic use 1 – AE/antibiotic use, withdrawn prior to treatment • 5 participants were withdrawn prior to treatment o Note: Randomization is done right after the screening visit once eligibility is confirmed rather than at the first treatment visit (Visit 3- Baseline 2). The reason for early randomization is because FMT capsules need to be requested/manufactured and be onsite prior to Visit 3 (Baseline 2 – treatment visit). It may take up to 3 weeks to obtain the FMT capsules after a participant is randomized. • Issue discussed at the February 2025 risk management meeting

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	○ Decision to continue enrolment until 10 FMT participants complete the study.
SAEs (additional information)	None reported
Other Comments	

ATTACHMENTS

Highlight Sheet	☒ YES ☐ NO If No, Reason not attached:
Annual Study Report	☐ YES ☒ NO The first study annual report will be requested in April 2025. The study was in start-up at the time of the 2024 annual report request.
Stats Report	☐ YES ☒ NO If No, Reason not attached: Comment: to be provided by the stats team