



Chelsea and Westminster Hospital NHS Foundation Trust
Research and Development Office
Unit G2, Harbour Yard
Chelsea Harbour
London
SW10 0XD

29 April 2024

To whom it may concern,

Protocol number: CRF005

EUDRACT number: 2020-001070-29

IRAS: 302393

RE: Early termination of trial

**Trans BIC: Efficacy, tolerability and acceptability of the single tablet regimen (STR) Biktarvy®
by trans people living with HIV (TPLWH)**

On behalf of the Sponsor, Chelsea and Westminster Hospital NHS Foundation Trust, we confirm that the study opened to recruitment in the UK only (Spain was not activated) to recruitment in March 2023. Following the recruitment of one patient, the IMP manufacturer and study funder, Gilead Sciences Inc, met with the Chief Investigator in May 2023 to discuss the continuation of the trial.

Following on from this discussion, a request to stop recruitment and terminate the study was submitted to ethics committees and competent authorities in May 2023. At the time of termination, there was one patient on treatment, recruited from the UK. This patient attended for an early termination visit (ETV) on 18 May 2023 and has subsequently continued their Biktarvy regimen as per standard care. Following the ETV the patient came off the study, with the last patient last visit taking place on 18 May 2023.

As only one patient was recruited in the study the Sponsor will not proceed with data analysis. No results are therefore available.

Yours sincerely,

Tess Cheetham
Research Project Manager

Cc:

Dr Marta Boffito
Chief Investigator