Clinical trial results:
Efficacy of BIC/F/TAF versus standard of care in the treatment of new HIV infection diagnoses in the context of 'test and treat'

Summary

EudraCT number	2019-003208-11
Trial protocol	GB
Global end of trial date	31 July 2023

Results information

Result version number	v1 (current)
This version publication date	12 March 2025
First version publication date	12 March 2025

Trial information

Trial identification

Sponsor protocol code	CRF002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04653194
WHO universal trial number (UTN)	-
Other trial identifiers	IRAS: 271361, EudraCT: 2019-003208-11, REC Reference : 19/LO/1953

Notes:

Sponsors

Sponsor organisation name	Chelsea and Westminster Hospital NHS Foundation Trust
Sponsor organisation address	Unit G3, Harbour Yard, Chelsea Harbour, London, United Kingdom, SW10 0XD
Public contact	CI: Marta Boffito / marta.boffito@nhs.net, Chelsea and Westminster Hospital NHS Foundation Trust, 0044 02033156685, marta.boffito@nhs.net
Scientific contact	CI: Marta Boffito / marta.boffito@nhs.net, Chelsea and Westminster Hospital NHS Foundation Trust, 0044 02033156685, marta.boffito@nhs.net

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	26 August 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 June 2023
Global end of trial reached?	Yes
Global end of trial date	31 July 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to compare virological response in newly diagnosed HIV patients at week 12 when administering TAF/FTC/BIC (Biktarvy) versus TAF/FTC/DRV/c (Symtuza) in the context of 'test and treat'.

Protection of trial subjects:

Thorough informed consent process where the participant is made aware of study in detail risk benefits and given opportunity to answer any questions.
The possibility to withdraw the trial at any point.
Review of medical history and physical exam and other paraments as part of baseline visits to ensure participant is eligible and fit for the the study.
Data protection paraments to ensure the patient data is de-identified and only those who should have the access to the data.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 March 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 36
Worldwide total number of subjects	36
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	36

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Start of recruitment: 30/07/2020
End of recruitment : 31/07/2022
Study Finished follow up: 30/07/2023

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	36
Number of subjects completed	36

Period 1

Period 1 title	Study Visits (week 1 to week 48 & EOS vi (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm 1

Arm description:

Product: Biktarvy (B)
Dose: one tablet
Frequency: OD

Arm type	Active comparator
Investigational medicinal product name	Biktarvy
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

50 mg/200 mg/25 mg film-coated tablets
1 table
OD

Arm title	Arm 2

Arm description:

Product: Symtuza (S)
Dose: one tablet
Frequency: OD

Arm type	Active comparator
Investigational medicinal product name	Symtuza
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

800 mg/150 mg/200 mg/10 mg film coated tablets
1 tablet
OD

Number of subjects in period 1	Arm 1	Arm 2
Started	19	17
Completed	17	13
Not completed	2	4
Lost to follow-up	1	4
Moved to different country	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Study Visits (week 1 to week 48 & EOS vi

Reporting group description: -

Reporting group values	Study Visits (week 1 to week 48 & EOS vi	Total	
Number of subjects	36	36	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	36	36	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	2	2	
Male	34	34	

End points

End points reporting groups

Reporting group title	Arm 1
Reporting group description:	
Product: Biktarvy (B) Dose: one tablet Frequency: OD	
Reporting group title	Arm 2
Reporting group description:	
Product: Symtuza (S) Dose: one tablet Frequency: OD	
Subject analysis set title	Primary Objective
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Primary objectiveTime weighted average change from baseline in log10 HIV RNA level recorded in viral load assays from initiation of treatment to week 12. Secondary objectivesAbsolute efficacy of study treatments: Proportion of patients treated with Biktarvy and Symtuza with HIV viral load less than 20 copies/ml and less than 50 copies/ml at week 2, 4, 12, 24, and 48	

Primary: The primary endpoint is the virological response (HIV RNA<50copies/mL) at week 12 by time-weighted average change in log10 HIV RNA recorded in viral load assays from treatment initiation to week 12, using two-sample Wilcoxon rank-sum test.

End point title	The primary endpoint is the virological response (HIV RNA<50copies/mL) at week 12 by time-weighted average change in log10 HIV RNA recorded in viral load assays from treatment initiation to week 12, using two-sample Wilcoxon rank-sum test.
End point description:	
The time-weighted mean decrease in log10 HIV RNA from treatment initiation to week 12 was significantly greater in B in comparison to D (3.1 vs. 2.6 log10 copies/mL, p<0.001).	
End point type	Primary
End point timeframe:	
Baseline to 12 weeks	

End point values	Arm 1	Arm 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	17		
Units: small decimals	19	17		

Statistical analyses

Statistical analysis title	Two-sample, Wilcoxon rank-sum test.
Statistical analysis description:	
The primary endpoint is the virological response (HIV RNA<50copies/mL) at week 12 by time-weighted average change in log10 HIV RNA recorded in viral load assays from treatment initiation to week 12,	

using two-sample Wilcoxon rank-sum test.

Comparison groups	Arm 1 v Arm 2
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.001 [1]
Method	two-sample, Wilcoxon rank-sum test.

Notes:

[1] - The time-weighted mean decrease in log10 HIV RNA from treatment initiation to week 12 was significantly greater in B in comparison to D (3.1 vs. 2.6 log10 copies/mL, p<0.001).

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 30 July 2020 to 31 July 2023	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	5.0
Reporting groups	
Reporting group title	Biktarvy
Reporting group description: -	
Reporting group title	Symtuza
Reporting group description: -	

Serious adverse events	Biktarvy	Symtuza	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 19 (5.26%)	1 / 17 (5.88%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Skin and subcutaneous tissue disorders			
Dressler's syndrome			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Latent Tuberculosis	Additional description: n		
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Biktarvy	Symtuza	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 19 (100.00%)	15 / 17 (88.24%)	
Vascular disorders			

AAA			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			
Bichectomy			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Circumcision			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Neck liposuction			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Pacemaker insertion			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Root canal left upper molar			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Root canal repair			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Surgery on left testicle for mass extraction			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
fatigue			
subjects affected / exposed	1 / 19 (5.26%)	1 / 17 (5.88%)	
occurrences (all)	1	1	
Fever			
subjects affected / exposed	2 / 19 (10.53%)	0 / 17 (0.00%)	
occurrences (all)	4	0	
Reproductive system and breast disorders			
Purple plaque lesion on neck of penis			

subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 19 (15.79%)	2 / 17 (11.76%)	
occurrences (all)	3	2	
Pharyngeal mucus			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Phlegm			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Shortness of breath			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Sore throat			
subjects affected / exposed	1 / 19 (5.26%)	1 / 17 (5.88%)	
occurrences (all)	1	1	
Psychiatric disorders			
vivid dreams			
subjects affected / exposed	3 / 19 (15.79%)	1 / 17 (5.88%)	
occurrences (all)	3	1	
Anxiety			
subjects affected / exposed	2 / 19 (10.53%)	1 / 17 (5.88%)	
occurrences (all)	2	1	
Depression			
subjects affected / exposed	1 / 19 (5.26%)	1 / 17 (5.88%)	
occurrences (all)	1	1	
Insomnia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Worsening of insomnia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Nightmares			

subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Sleep disturbance			
subjects affected / exposed	2 / 19 (10.53%)	1 / 17 (5.88%)	
occurrences (all)	2	1	
Suicidal ideation			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Investigations			
Colonoscopy			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Creatinine increased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Endoscopy			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Low neutrophils			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Weight gain of more than 10%			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Weight loss			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Heatstroke			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Squirrel bite			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Nervous system disorders			

Dizziness			
subjects affected / exposed	1 / 19 (5.26%)	1 / 17 (5.88%)	
occurrences (all)	1	1	
Facialis on right side			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Headache			
subjects affected / exposed	1 / 19 (5.26%)	2 / 17 (11.76%)	
occurrences (all)	1	2	
Memory impaired			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Somnolence			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 19 (0.00%)	3 / 17 (17.65%)	
occurrences (all)	0	3	
Swollen neck lymph nodes			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
Irritated eyes			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Keratoconus			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Sore left eye / blurry vision			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	2	0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 19 (10.53%)	0 / 17 (0.00%)	
occurrences (all)	2	0	
Abdominal ultrasound			

subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Acid reflux			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Constipation			
subjects affected / exposed	1 / 19 (5.26%)	1 / 17 (5.88%)	
occurrences (all)	1	1	
Diarrhoea			
subjects affected / exposed	3 / 19 (15.79%)	2 / 17 (11.76%)	
occurrences (all)	3	2	
Gastritis			
subjects affected / exposed	4 / 19 (21.05%)	0 / 17 (0.00%)	
occurrences (all)	4	0	
Gum lesion			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
IBS/Gastritis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Nausea			
subjects affected / exposed	2 / 19 (10.53%)	2 / 17 (11.76%)	
occurrences (all)	3	2	
Nausea + vomiting			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Worsening of nausea			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Pruritus Ani			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
stomach pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Vomiting			

subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Hepatic steanosis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
dry skin			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
eczema on upper back			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Rash			
subjects affected / exposed	4 / 19 (21.05%)	4 / 17 (23.53%)	
occurrences (all)	7	4	
Night sweats			
subjects affected / exposed	2 / 19 (10.53%)	0 / 17 (0.00%)	
occurrences (all)	2	0	
Renal and urinary disorders			
Dysuria and penile discharge			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Left shoulder pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Muscular pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
lower back pain			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	

Right hip/pelvic area pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Infections and infestations			
Athletes foot			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Chest infection			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	2	0	
Cold			
subjects affected / exposed	3 / 19 (15.79%)	2 / 17 (11.76%)	
occurrences (all)	3	3	
Cold sore			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Coryzal symptoms			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Covid-19			
subjects affected / exposed	5 / 19 (26.32%)	2 / 17 (11.76%)	
occurrences (all)	6	2	
Early syphilis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Folliculitis on back			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Gonorrhoea			
subjects affected / exposed	4 / 19 (21.05%)	3 / 17 (17.65%)	
occurrences (all)	4	3	
Helicobacter pylori infection			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Hepatitis C			

subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Human papilloma virus infection			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Monkeypox			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Otitis media			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Rectal chlamydia			
subjects affected / exposed	3 / 19 (15.79%)	1 / 17 (5.88%)	
occurrences (all)	3	1	
Sinusitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Syphilis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Tonsillitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
UTI			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Urine infection			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Vaginal thrush			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Hyperlipidemia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 March 2020	SA01 MHRA Notice of non-acceptance and response 1. The exclusion criteria do not address all contraindications for both investigational medicinal products (IMPs). The protocol needs to be updated to exclude patients with any contraindication to either of the IMPs. The exclusion criterion has been revised to list all contraindications and the full list of contraindications have been added to the protocol as appendix 4 for reference. 2. The statement in Section 4.4.3 of the protocol that investigators who opt to discontinue study drugs for an individual subject should discuss with the Chief Investigator prior to study drug discontinuation is not acceptable and needs to be removed. The statement has been removed as requested. 3. The listed methods of contraception in Appendix 3 are acceptable for this protocol but are not highly effective methods with a failure rate of less than 1% per year as described in the Clinical Trial Facilitation Group document for clarification of effective contraception in clinical trials: http://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2014_09_HMA_CTFG_Contraception.pdf . Highly effective needs to be removed from the title of Appendix 3 and the first paragraph needs to describe acceptable methods rather than highly effective methods. In addition, the appendix titles and references should be corrected as Appendix 3 is described and referenced as "Sample collection, processing and shipping" in some sections of the protocol. 'Highly effective methods…' title revised to 'Acceptable methods for avoiding pregnancy in females of child bearing potential'. Statement about failure rates less than 1% removed. Sample collection, processing and shipping references have been removed from the protocol and replaced with 'refer to lab manual'. 4. Section 4.4.1 of the protocol lists pregnancy as one of the reasons an investigator may discontinue study treatment.
13 April 2021	SA02 Changes have been proposed in the protocol specifically in the update of the most recent SmPCs available for both the treatment arms.
27 September 2021	SA03 The primary reasons for this substantial amendment are as follows:• The section on safety information within the study protocol has been updated to bring it in line with the current approved SmPCs for the trial.• Extension to the planned recruitment and study end date (Last patient last visit) • Addition of a new PI• Modification to the PIS (Patient Information Sheet) to bring it in line with current approved SmPC for IMPs • Modification to the Informed Consent Form (ICF) to bring it in line with trial requirements• Supply chain verification of trial labelled stock • Specific risk assessment
21 June 2022	SA04 An annual update to the current approved SmPCs for the trialSymtuza SmPC dated 20 October 2021 Biktarvy SmPC dated 24 February 2022• Change to the HIV viral load minimum detection from <20 copies to <50 copies in line with standard of care in the secondary endpoint section of the protocol.• Removal of the metabolomics laboratory details in the protocol.
29 July 2022	SA05 Site missed updated PIS from previews amendment (SA04). Annual updates to SmPC documents, which includes additional Special warnings and precautions for use, leading to changes to PIS which were not submitted as part of the SA 04 submission. Updated PIS forms will be submitted as part of this amendment to be reviewed.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/39244669