Clinical trial results:
A Phase 3B, Randomized, Open-label Study to Evaluate the Safety and Efficacy of a Single Tablet Regimen of Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate Compared With a Single Tablet Regimen of Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naive Adults

Summary

EudraCT number	2010-024007-27
Trial protocol	GB DE PT BE ES AT IT
Global end of trial date	03 February 2014

Results information

Result version number	v1 (current)
This version publication date	22 March 2016
First version publication date	06 August 2015

Trial information

Trial identification

Sponsor protocol code	GS-US-264-0110

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01309243
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Gilead Sciences, Inc.
Sponsor organisation address	333 Lakeside Drive, Foster City, CA, United States, 94404
Public contact	Clinical Trial Mailbox, Gilead Sciences International Ltd, ClinicalTrialDisclosures@gilead.com
Scientific contact	Clinical Trial Mailbox, Gilead Sciences International Ltd, ClinicalTrialDisclosures@gilead.com

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	03 February 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 February 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of the study was to evaluate the safety and efficacy of the emtricitabine (FTC)/rilpivirine (RPV)/tenofovir disoproxil fumarate (TDF) single-tablet regimen (STR) compared with the efavirenz (EFV)/FTC/TDF STR in HIV-1 infected adults who had not previously received treatment with antiretroviral medications.

Participants were randomized in a 1:1 ratio to receive one of the study treatments. Randomization was stratified by HIV-1 RNA level (≤ 100,000 copies/mL or > 100,000 copies/mL) at screening. A treatment duration of 96 weeks was planned, with the option for subjects in FTC/RPV/TDF STR arm to receive treatment following the Week 96 visit until FTC/RPV/TDF STR is commercially available or until Gilead Sciences elects to terminate development in that country.

Protection of trial subjects:

The protocol and consent/assent forms were submitted by each investigator to a duly constituted Independent Ethics Committee (IEC) or Institutional Review Board (IRB) for review and approval before study initiation. All revisions to the consent/assent forms (if applicable) after initial IEC/IRB approval were submitted by the investigator to the IEC/IRB for review and approval before implementation in accordance with regulatory requirements.

This study was conducted in accordance with recognized international scientific and ethical standards, including but not limited to the International Conference on Harmonization guideline for Good Clinical Practice (ICH GCP) and the original principles embodied in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 February 2011
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	Portugal: 7
Country: Number of subjects enrolled	Spain: 15
Country: Number of subjects enrolled	United Kingdom: 20
Country: Number of subjects enrolled	Austria: 13
Country: Number of subjects enrolled	Belgium: 9
Country: Number of subjects enrolled	France: 23
Country: Number of subjects enrolled	Germany: 47
Country: Number of subjects enrolled	Italy: 13
Country: Number of subjects enrolled	United States: 541
Country: Number of subjects enrolled	Canada: 48

Country: Number of subjects enrolled	Australia: 40
Country: Number of subjects enrolled	Puerto Rico: 18
Country: Number of subjects enrolled	Switzerland: 5
Worldwide total number of subjects	799
EEA total number of subjects	147

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)	792
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were enrolled in a total of 121 study sites in North America, Europe, and Australia. The first participant was screened on 23 February 2011. The last participant observation was on 03 February 2014.

Pre-assignment

Screening details:

991 participants were screened.

Period 1

Period 1 title	Randomized Phase through Week 96
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	FTC/RPV/TDF

Arm description:

FTC/RPV/TDF STR administered orally once daily

Arm type	Experimental
Investigational medicinal product name	FTC/RPV/TDF
Investigational medicinal product code	
Other name	Eviplera®, Complera®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Emtricitabine (FTC) 200 mg/rilpivirine (RPV) 25 mg/tenofovir disoproxil fumarate (TDF) 300 mg single-tablet regimen (STR) administered orally once daily

Arm title	EFV/FTC/TDF

Arm description:

EFV/TFC/TDF STR administered orally once daily

Arm type	Active comparator
Investigational medicinal product name	EFV/FTC/TDF
Investigational medicinal product code	
Other name	Atripla®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Efavirenz (EFV) 600 mg/emtricitabine (FTC) 200 mg/tenofovir disoproxil fumarate (TDF) 300 mg STR administered orally once daily

Number of subjects in period 1[1]	FTC/RPV/TDF	EFV/FTC/TDF
Started	394	392
Randomized and Treated	394	392
Completed	325	313
Not completed	69	79
Adverse event, serious fatal	-	1
Adverse event, non-fatal	7	17
Death	-	1
Investigators Discretion	5	6
Protocol Violation	1	-
Lost to follow-up	25	26
Withdrew consent	15	22
Participant noncompliance	7	5
Lack of efficacy	9	1

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 13 participants who were enrolled but not treated are not included in the subject disposition table.

Period 2

Period 2 title	Extension Phase
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	FTC/RPV/TDF

Arm description:

FTC/RPV/TDF STR administered orally once daily

Arm type	Experimental
Investigational medicinal product name	FTC/RPV/TDF
Investigational medicinal product code	
Other name	Eviplera®, Complera®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

FTC 200 mg/RPV 25 mg/TDF 300 mg STR administered orally once daily

Arm title	EFV/FTC/TDF

Arm description:

EFV/FTC/TDF STR administered orally once daily

Arm type	Active comparator

Investigational medicinal product name	EFV/FTC/TDF
Investigational medicinal product code	
Other name	Atripla®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

EFV 600 mg/FTC 200 mg/TDF 300 mg STR administered orally once daily

Number of subjects in period 2[2]	FTC/RPV/TDF	EFV/FTC/TDF
Started	40	117
Completed	34	117
Not completed	6	0
Lost to follow-up	6	-

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Of those who completed the Randomized Phase (FTC/RPV/TDF: n = 316; EFV/FTC/TDF: n = 290), 40 participants randomized to FTC/RPV/TDF and 117 participants randomized to EFV/FTC/TDF entered the Extension Phase.

Baseline characteristics

Reporting groups	
Reporting group title	FTC/RPV/TDF
Reporting group description: FTC/RPV/TDF STR administered orally once daily	
Reporting group title	EFV/FTC/TDF
Reporting group description: EFV/TFC/TDF STR administered orally once daily	

Reporting group values	FTC/RPV/TDF	EFV/FTC/TDF	Total
Number of subjects	394	392	786
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	37	37	
standard deviation	± 10.4	± 11	-
Gender, Male/Female Units: participants			
Female	28	28	56
Male	366	364	730
Race Units: Subjects			
American Indian or Alaska Native	3	1	4
Asian	8	13	21
Black or African Heritage	98	94	192
Native Hawaiian or Pacific Islander	4	3	7
White	266	262	528
Other	13	19	32
Not Permitted	1	0	1
Not Reported	1	0	1
Ethnicity Units: Subjects			
Hispanic/Latino	59	75	134
Non-Hispanic/Latino	331	315	646
Not Permitted	3	2	5
Not Reported	1	0	1
HIV-1 RNA Category Units: Subjects			
≤ 100,000 copies/mL	260	250	510
> 100,000 copies/mL	134	142	276
Use of lipid-lowering agent Units: Subjects			
Yes	4	1	5
No	390	391	781

HIV-1 RNA			
Units: log10 copies/mL			
arithmetic mean	4.8	4.8	
standard deviation	± 0.65	± 0.61	-
Cluster of differentiation 4 (CD4) Cell Count			
Units: cells/µL			
arithmetic mean	395.7	385.2	
standard deviation	± 179.64	± 186.82	-

End points

End points reporting groups	
Reporting group title	FTC/RPV/TDF
Reporting group description: FTC/RPV/TDF STR administered orally once daily	
Reporting group title	EFV/FTC/TDF
Reporting group description: EFV/TFC/TDF STR administered orally once daily	
Reporting group title	FTC/RPV/TDF
Reporting group description: FTC/RPV/TDF STR administered orally once daily	
Reporting group title	EFV/FTC/TDF
Reporting group description: EFV/FTC/TDF STR administered orally once daily	

Primary: Percentage of participants with HIV-1 RNA < 50 copies/mL at Week 48	
End point title	Percentage of participants with HIV-1 RNA < 50 copies/mL at Week 48

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 48 was analyzed using the US FDA snapshot algorithm.

The snapshot algorithm defines a patient's virologic response status using only the viral load at the predefined time point within an allowed window of time.

Full Analysis Set: participants who were randomized into the study and received at least 1 dose of study drug

End point type	Primary

End point timeframe:

Week 48

End point values	FTC/RPV/TDF	EFV/FTC/TDF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	394	392		
Units: percentage of participants				
number (not applicable)	85.8	81.6		

Statistical analyses

Statistical analysis title	Difference in percentage

Statistical analysis description:

The analysis was to assess the noninferiority of FTC/RPV/TDF versus EFV/FTC/TDF using a 95% confidence interval (CI) approach, with a noninferiority margin of 12% (lower bound of CI > -12%).

700 subjects allocated 1:1 to either treatment arm was predicted to give > 95% power when the

proportion of responders in both treatment groups for the primary endpoint is 80% at Week 48.

Comparison groups	FTC/RPV/TDF v EFV/FTC/TDF
Number of subjects included in analysis	786
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Parameter estimate	Difference in the response rates
Point estimate	4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	9.2

Notes:

[1] - Null hypothesis: The FTC/RPV/TDF group was at least 12% worse than the EFV/FTC/TDF group with respect to the percentage of subjects achieving HIV-1 RNA < 50 copies/mL ("response rate," as defined by the snapshot analysis algorithm) at Week 48.

Alternative hypothesis: The FTC/RPV/TDF group was less than 12% worse than the EFV/FTC/TDF group with respect to the percentage of subjects achieving HIV-1 RNA 50 copies/mL at Week 48.

Secondary: Percentage of Participants With HIV-1 RNA < 50 Copies/mL at Week 96

End point title	Percentage of Participants With HIV-1 RNA < 50 Copies/mL at Week 96

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 96 was analyzed using the US FDA snapshot algorithm.

Full Analysis Set

End point type	Secondary

End point timeframe:

Baseline to Week 96

End point values	FTC/RPV/TDF	EFV/FTC/TDF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	394	392		
Units: percentage of participants				
number (not applicable)	77.9	72.4		

Statistical analyses

Statistical analysis title	Difference in percentage
Comparison groups	FTC/RPV/TDF v EFV/FTC/TDF
Number of subjects included in analysis	786
Analysis specification	Pre-specified
Analysis type	other[2]
Parameter estimate	Difference in the response rates
Point estimate	5.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.6
upper limit	11.5

Notes:

[2] - Comparative analysis

Secondary: Change from baseline in CD4 cell count at Week 48

End point title	Change from baseline in CD4 cell count at Week 48

End point description:

Participants in the Full Analysis Set with available data were analyzed; the missing = excluded method was used in which all participants with missing data were excluded from analysis.

End point type	Secondary

End point timeframe:

Baseline to Week 48

End point values	FTC/RPV/TDF	EFV/FTC/TDF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	357	346		
Units: cells/µL				
arithmetic mean (standard deviation)	200 (± 158.6)	191 (± 144.3)		

Statistical analyses

Statistical analysis title	Difference in change from baseline
Comparison groups	FTC/RPV/TDF v EFV/FTC/TDF
Number of subjects included in analysis	703
Analysis specification	Pre-specified
Analysis type	other[3]
P-value	= 0.34 [4]
Method	ANOVA
Parameter estimate	Difference in LSM
Point estimate	11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11
upper limit	32

Notes:

[3] - Comparative analysis

[4] - The p-value, and difference in least square means (LSM) and its 95% CI are from analysis of variance (ANOVA) with treatment and baseline HIV-1 RNA levels (≤ 100,000, > 100,000 copies/mL) as fixed effect.

Secondary: Change From Baseline in CD4 Cell Count at Week 96

End point title	Change From Baseline in CD4 Cell Count at Week 96

End point description:

Participants in the Full Analysis Set with available data were analyzed; the missing = excluded method was used in which all participants with missing data were excluded from analysis.

End point type	Secondary

End point timeframe:

Baseline to Week 96

End point values	FTC/RPV/TDF	EFV/FTC/TDF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	327	319		
Units: cells/µL				
arithmetic mean (standard deviation)	278 (± 186.6)	259 (± 191.4)		

Statistical analyses

Statistical analysis title	STATISTICAL_ANALYSIS_TITLE
Comparison groups	FTC/RPV/TDF v EFV/FTC/TDF
Number of subjects included in analysis	646
Analysis specification	Pre-specified
Analysis type	other[5]
P-value	= 0.17 [6]
Method	ANOVA
Parameter estimate	Difference in LSM
Point estimate	20
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9
upper limit	49

Notes:

[5] - Comparative analysis

[6] - The p-value, and difference in LSM and its 95% CI are from ANOVA with treatment and baseline HIV-1 RNA levels (≤ 100,000, > 100,000 copies/mL) as fixed effect.

Secondary: Change from baseline in Fasting Total Cholesterol at Week 48

End point title	Change from baseline in Fasting Total Cholesterol at Week 48

End point description:

Participants in the Safety Analysis Set with available data were analyzed using the missing = excluded method.

End point type	Secondary

End point timeframe:

Baseline to Week 48

End point values	FTC/RPV/TDF	EFV/FTC/TDF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	322	305		
Units: mg/dL				
arithmetic mean (standard deviation)	1 (± 28.1)	22 (± 31.3)		

Statistical analyses

Statistical analysis title	Difference in change from baseline
Comparison groups	FTC/RPV/TDF v EFV/FTC/TDF
Number of subjects included in analysis	627
Analysis specification	Pre-specified
Analysis type	other[7]
P-value	< 0.001 [8]
Method	ANOVA

Notes:

[7] - Comparative analysis

[8] - P-value for the difference in change from baseline at Week 48 is from ANOVA with treatment as fixed effect.

Secondary: Change from baseline in Fasting high-density lipoprotein (HDL) Cholesterol at Week 48

End point title	Change from baseline in Fasting high-density lipoprotein (HDL) Cholesterol at Week 48

End point description:

Participants in the Safety Analysis Set with available data were analyzed using the missing = excluded method.

End point type	Secondary

End point timeframe:

Baseline to Week 48

End point values	FTC/RPV/TDF	EFV/FTC/TDF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	322	305		
Units: mg/dL				
arithmetic mean (standard deviation)	2 (± 8.7)	8 (± 10.3)		

Statistical analyses

Statistical analysis title	Difference in change from baseline
Comparison groups	FTC/RPV/TDF v EFV/FTC/TDF

Number of subjects included in analysis	627
Analysis specification	Pre-specified
Analysis type	other[9]
P-value	< 0.001 [10]
Method	ANOVA

Notes:

[9] - Comparative analysis

[10] - P-value for the difference in change from baseline at Week 48 is from ANOVA with treatment as fixed effect.

Secondary: Change from baseline in Fasting low-density lipoprotein (LDL) Cholesterol at Week 48

End point title	Change from baseline in Fasting low-density lipoprotein (LDL) Cholesterol at Week 48

End point description:

Participants in the Safety Analysis Set with available data were analyzed using the missing = excluded method.

End point type	Secondary

End point timeframe:

Baseline to Week 48

End point values	FTC/RPV/TDF	EFV/FTC/TDF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	322	303		
Units: mg/dL				
arithmetic mean (standard deviation)	1 (± 24.4)	14 (± 28.2)		

Statistical analyses

Statistical analysis title	Difference in change from baseline
Comparison groups	FTC/RPV/TDF v EFV/FTC/TDF
Number of subjects included in analysis	625
Analysis specification	Pre-specified
Analysis type	other[11]
P-value	< 0.001 [12]
Method	ANOVA

Notes:

[11] - Comparative analysis

[12] - P-value for the difference in change from baseline at Week 48 is from ANOVA with treatment as fixed effect.

Secondary: Change from baseline in Fasting triglycerides at Week 48

End point title	Change from baseline in Fasting triglycerides at Week 48

End point description:

Participants in the Safety Analysis Set with available data were analyzed using the missing = excluded method.

End point type	Secondary

End point timeframe: Baseline to Week 48

End point values	FTC/RPV/TDF	EFV/FTC/TDF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	322	305		
Units: mg/dL				
arithmetic mean (standard deviation)	-8 (± 68.9)	8 (± 103)		

Statistical analyses

Statistical analysis title	Difference in change from baseline
Comparison groups	EFV/FTC/TDF v FTC/RPV/TDF
Number of subjects included in analysis	627
Analysis specification	Pre-specified
Analysis type	other[13]
P-value	< 0.001 [14]
Method	ANOVA

Notes:

[13] - Comparative analysis

[14] - P-value for the difference in change from baseline at Week 48 is from ANOVA with treatment as fixed effect.

Secondary: Development of HIV-1 Drug Resistance through Week 96, All Participants

End point title	Development of HIV-1 Drug Resistance through Week 96, All Participants

End point description:

Full Analysis Set: participants with either suboptimal virologic response or virologic rebound were considered to have virologic failure and were analyzed for resistance. Suboptimal virologic response was assessed at Week 8 and was defined as having HIV-1 RNA ≥50 copies/mL and <1 log10 reduction from baseline at the Week 8 visit, which was confirmed at the subsequent visit. Virologic rebound was defined as having 2 consecutive visits with HIV-1 RNA ≥400 copies/mL after achieving HIV-1 RNA <50 copies/mL, or as having 2 consecutive visits with >1 log10 increase in HIV-1 RNA from their nadir. In addition, subjects who were on study drugs, had not been analyzed previously, and who had HIV-1 RNA ≥400 copies/mL at Week 48, Week 96, or their last visit (at or after Week 8) were also analyzed for resistance at their last visit. Subsequent to the first resistance testing, subjects experiencing repeated confirmed virologic failure were assessed for resistance retesting on a case-by-case basis

End point type	Secondary

End point timeframe:

Baseline to Week 96

End point values	FTC/RPV/TDF	EFV/FTC/TDF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	394	392		
Units: percentage of participants				
number (not applicable)				
Baseline through Week 48	4.3	0.8		
Week 48 through Week 96	1	0.3		
Baseline through Week 96	5.3	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Development of HIV-1 Drug Resistance through Week 96, Participants with Viral Resistance

End point title	Development of HIV-1 Drug Resistance through Week 96, Participants with Viral Resistance

End point description:

Resistance Analysis Set: participants with either suboptimal virologic response or virologic rebound were considered to have virologic failure and were analyzed. Suboptimal virologic response was assessed at Week 8 and was defined as having HIV-1 RNA ≥50 copies/mL and <1 log10 reduction from baseline at the Week 8 visit, which was confirmed at the subsequent visit. Virologic rebound was defined as having 2 consecutive visits with HIV-1 RNA ≥400 copies/mL after achieving HIV-1 RNA <50 copies/mL, or as having 2 consecutive visits with >1 log10 increase in HIV-1 RNA from their nadir. In addition, subjects who were on study drugs, had not been analyzed previously, and who had HIV-1 RNA ≥400 copies/mL at Week 48, Week 96, or their last visit (at or after Week 8) were also analyzed for resistance at their last visit. Subsequent to the first resistance testing, subjects experiencing repeated confirmed virologic failure were assessed for resistance retesting on a case-by-case basis.

End point type	Secondary

End point timeframe:

Baseline to Week 96

End point values	FTC/RPV/TDF	EFV/FTC/TDF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	9		
Units: participants				
number (not applicable)				
Baseline through Week 48	17	3		
Week 48 through Week 96	4	1		
Baseline through Week 96	21	4		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Baseline through Week 96 (Randomized Phase), and Week 96 up to a maximum of 954 days (Extension Phase)	
Adverse event reporting additional description:	
Safety Analysis Set: participants who were randomized and received at least 1 dose of study drug	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	16.1

Reporting groups	
Reporting group title	FTC/RPV/TDF
Reporting group description:	
FTC/RPV/TDF STR administered orally once daily	
Reporting group title	EFV/FTC/TDF
Reporting group description:	
EFV/FTC/TDF STR administered orally once daily	

Serious adverse events	FTC/RPV/TDF	EFV/FTC/TDF	
Total subjects affected by serious adverse events			
subjects affected / exposed	36 / 394 (9.14%)	48 / 392 (12.24%)	
number of deaths (all causes)	0	2	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Burkitt's lymphoma			
subjects affected / exposed	1 / 394 (0.25%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal squamous cell carcinoma			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anogenital warts			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniopharyngioma			

subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gliosarcoma			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer stage 0			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular germ cell cancer			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Behcet's syndrome			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			

subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	2 / 394 (0.51%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 394 (0.00%)	2 / 392 (0.51%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Cervical dysplasia			

subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asphyxia			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Epistaxis			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Depression			
subjects affected / exposed	2 / 394 (0.51%)	2 / 392 (0.51%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	1 / 394 (0.25%)	3 / 392 (0.77%)	
occurrences causally related to treatment / all	0 / 1	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	2 / 394 (0.51%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	1 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Suicidal ideation			
subjects affected / exposed	2 / 394 (0.51%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	1 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar I disorder			
subjects affected / exposed	1 / 394 (0.25%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol abuse			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Delirium tremens			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	2 / 394 (0.51%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Ankle fracture			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			

subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	1 / 394 (0.25%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Convulsion			
subjects affected / exposed	0 / 394 (0.00%)	2 / 392 (0.51%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	1 / 394 (0.25%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	1 / 394 (0.25%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			

subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Haemolytic anaemia			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Rectal haemorrhage			
subjects affected / exposed	0 / 394 (0.00%)	2 / 392 (0.51%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Gastritis			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			

Leukocytoclastic vasculitis			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	2 / 394 (0.51%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthritis reactive			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			

subjects affected / exposed	2 / 394 (0.51%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	1 / 394 (0.25%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 394 (0.25%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurosyphilis			
subjects affected / exposed	0 / 394 (0.00%)	2 / 392 (0.51%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ophthalmic herpes zoster			
subjects affected / exposed	1 / 394 (0.25%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical pneumonia			

subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye infection syphilitic			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Furuncle			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis shigella			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis aseptic			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis viral			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal abscess			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Secondary syphilis			

subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	1 / 394 (0.25%)	0 / 392 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 394 (0.00%)	1 / 392 (0.26%)	
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	FTC/RPV/TDF	EFV/FTC/TDF	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	300 / 394 (76.14%)	322 / 392 (82.14%)	
Nervous system disorders			
Dizziness			
subjects affected / exposed	27 / 394 (6.85%)	90 / 392 (22.96%)	
occurrences (all)	30	93	
Headache			

subjects affected / exposed	56 / 394 (14.21%)	61 / 392 (15.56%)	
occurrences (all)	64	67	
Somnolence			
subjects affected / exposed	9 / 394 (2.28%)	30 / 392 (7.65%)	
occurrences (all)	9	30	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	42 / 394 (10.66%)	54 / 392 (13.78%)	
occurrences (all)	45	58	
Pyrexia			
subjects affected / exposed	16 / 394 (4.06%)	22 / 392 (5.61%)	
occurrences (all)	19	22	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	69 / 394 (17.51%)	78 / 392 (19.90%)	
occurrences (all)	83	89	
Nausea			
subjects affected / exposed	65 / 394 (16.50%)	65 / 392 (16.58%)	
occurrences (all)	71	70	
Vomiting			
subjects affected / exposed	20 / 394 (5.08%)	21 / 392 (5.36%)	
occurrences (all)	23	27	
Flatulence			
subjects affected / exposed	24 / 394 (6.09%)	9 / 392 (2.30%)	
occurrences (all)	25	9	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	38 / 394 (9.64%)	27 / 392 (6.89%)	
occurrences (all)	42	28	
Oropharyngeal pain			
subjects affected / exposed	23 / 394 (5.84%)	15 / 392 (3.83%)	
occurrences (all)	29	17	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	31 / 394 (7.87%)	51 / 392 (13.01%)	
occurrences (all)	33	55	

Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	23 / 394 (5.84%)	101 / 392 (25.77%)	
occurrences (all)	23	104	
Insomnia			
subjects affected / exposed	45 / 394 (11.42%)	60 / 392 (15.31%)	
occurrences (all)	46	68	
Depression			
subjects affected / exposed	34 / 394 (8.63%)	47 / 392 (11.99%)	
occurrences (all)	34	50	
Anxiety			
subjects affected / exposed	28 / 394 (7.11%)	37 / 392 (9.44%)	
occurrences (all)	29	37	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	28 / 394 (7.11%)	23 / 392 (5.87%)	
occurrences (all)	29	25	
Back pain			
subjects affected / exposed	20 / 394 (5.08%)	25 / 392 (6.38%)	
occurrences (all)	22	27	
Myalgia			
subjects affected / exposed	20 / 394 (5.08%)	13 / 392 (3.32%)	
occurrences (all)	21	14	
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	57 / 394 (14.47%)	72 / 392 (18.37%)	
occurrences (all)	75	98	
Nasopharyngitis			
subjects affected / exposed	33 / 394 (8.38%)	39 / 392 (9.95%)	
occurrences (all)	46	49	
Bronchitis			
subjects affected / exposed	34 / 394 (8.63%)	29 / 392 (7.40%)	
occurrences (all)	37	38	
Sinusitis			
subjects affected / exposed	28 / 394 (7.11%)	19 / 392 (4.85%)	
occurrences (all)	34	21	

Syphilis			
subjects affected / exposed	26 / 394 (6.60%)	18 / 392 (4.59%)	
occurrences (all)	29	20	
Folliculitis			
subjects affected / exposed	27 / 394 (6.85%)	8 / 392 (2.04%)	
occurrences (all)	28	8	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	10 / 394 (2.54%)	20 / 392 (5.10%)	
occurrences (all)	10	20	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 November 2010	The use of HIV Treatment Satisfaction Questionnaire (HIVTSQ[c]) was changed to HIVTSQ(s), and HIVTSQ(s) was removed from the Screening Visit since the subjects in this study were ARV treatment naive; inclusion criteria were revised so that subjects who had received the Gilead Sciences investigational product tenofovir alafenamide (TAF; formerly known as GS-7340) and participated in Gilead Study GS-US-120-0104 were no longer eligible for the study; management of suboptimal virologic response was clarified.
05 April 2011	Inclusion of food examples to ensure proper dosing of FTC/RPV/TDF STR; removal of 'life expectancy ≥ 1 year' and allowance of pre-exposure prophylaxis (PrEP) from the inclusion criteria; removal of 'history of liver disease including Gilbert's Disease' from the exclusion criteria.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

There were no limitations affecting the analysis or results.

Notes: