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Dolutegravir plus Abacavir–Lamivudine for the Treatment of HIV-1 Infection

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Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

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Supplementary Appendix

Table of Contents

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Table S1. Protocol Inclusion/Exclusion Criteria.

Eligible subjects must:

- Be able to understand and comply with protocol requirements, instructions, and restrictions;
- Be likely to complete the study as planned;
- Be considered appropriate candidates for participation in an investigative clinical trial with oral medication (e.g., no active substance abuse, acute major organ disease).

Subjects eligible for enrollment in this study **must** meet all of the following:

1. HIV-1 infected adults ≥18 years of age.
2. A female, may be eligible to enter and participate in the study if she:
   a. Is of non-child-bearing potential defined as either post-menopausal (12 months of spontaneous amenorrhea and ≥45 years of age) or physically incapable of becoming pregnant with documented tubal ligation, hysterectomy, or bilateral oophorectomy, or
   b. Is of child-bearing potential with a negative pregnancy test at both Screening and Day 1 and agrees to use one of the following methods of contraception to avoid pregnancy:
      - Complete abstinence from intercourse from 2 weeks prior to administration of investigational product (IP), throughout the study, and for at least 2 weeks after discontinuation of all study medications.
      - Double barrier method (male condom/spermicide, male condom/diaphragm, diaphragm/spermicide).

- Any intrauterine device (IUD) with published data showing that the expected failure rate is <1% per year (not all IUDs meet this criterion; see the study procedure manual for an example listing of approved IUDs).
- Any other method with published data showing that the expected failure rate is <1% per year.
- Hormonal contraception plus a barrier method. Hormonal contraception alone will not be considered adequate for inclusion into or participation in this study (due to potential receipt of blinded efavirenz in this trial).

3. HIV-1 infection as documented by Screening plasma HIV-1 RNA ≥1000 copies/mL.
4. Antiretroviral-naive (≤10 days of prior therapy with any antiretroviral agent following a diagnosis of HIV-1 infection).
5. A negative HLA-B*5701 allele screening assessment.
6. Signed and dated written informed consent is obtained from the subject or the subject's legal representative prior to screening.
7. **For subjects enrolled in France:** a subject will be eligible for inclusion in this study only if either affiliated with or a beneficiary of a social security category.

Exclusionary Medical Conditions

1. Women who are breastfeeding.
2. Any evidence of an active Center for Disease Control and Prevention (CDC) Category C disease, except cutaneous Kaposi's sarcoma not requiring systemic therapy. Historical or current CD4 cell counts <200 cells/mm^3 are not exclusionary.
3. Subjects with any degree of hepatic impairment.

4. Positive for Hepatitis B at screening (+HbsAg), or anticipated need for Hepatitis C virus therapy during the study.
5. Recent history (≤3 months) of any upper or lower gastrointestinal bleed, with the exception of anal or rectal bleeding.
6. History or presence of allergy or intolerance to the study drugs, their components, or drugs of their class.
7. History of malignancy within the past 5 years or ongoing malignancy other than cutaneous Kaposi's sarcoma, basal cell carcinoma, or resected, non-invasive cutaneous squamous cell carcinoma; other localized malignancies require agreement between the investigator and Study medical monitor for inclusion of the subject.

Exclusionary Treatments prior to Screening or Day 1

8. Treatment with an HIV-1 immunotherapeutic vaccine within 90 days of Screening.
9. Treatment with any of the following agents within 28 days of Screening:
    i. Radiation therapy
    ii. Cytotoxic chemotherapeutic agents
    iii. Any immunomodulator
10. Treatment with any agent, except recognized antiretroviral therapy as allowed above, with documented activity against HIV-1 *in vitro* within 28 days of first dose of IP. Allowed antiretroviral therapy cannot be given within 28 days of first dose.
11. Exposure to an experimental drug or experimental vaccine within either 28 days, 5 half-lives of the test agent, or twice the duration of the biological effect of the test agent, whichever is longer, prior to the first dose of IP.

12. French subjects recruited at sites in France will be excluded if the subject has participated in any study using an investigational agent during the previous 60 days or 5 half-lives, or twice the duration of the biological effect of the experimental drug or vaccine, whichever is longer, prior to screening for the study or if the subject will participate simultaneously in another clinical study.

Exclusionary Laboratory or Clinical Assessments at Screening

13. Any evidence of primary viral resistance in the Screening result or, if known, any historical resistance test result; Note: retests of Screening genotypes are not allowed.
14. Any verified Grade 4 laboratory abnormality (a single repeat test is allowed during the Screening period); any acute laboratory abnormality at Screening, which, in the opinion of the Investigator, would preclude the subject's participation in the study of an investigational compound is exclusionary.
15. Alanine aminotransferase (ALT) >5 times the upper limit of normal (ULN).
16. ALT ≥3xULN **and** bilirubin ≥1.5xULN (with >35% direct bilirubin).
17. Subject has creatinine clearance of <50 mL/min via Cockroft-Gault method.

Table S2. Supplementary Statistical Methodology.

Section/Topic	Description
Randomization Sequence generation, allocation concealment mechanism, and implementation	The study statistician generated the randomization schedule with GlaxoSmithKline-validated randomization software RANDALL. Care providers enrolled participants and used an automated phone system to retrieve container numbers from the randomization system as well as a randomization number from the randomization schedule.
Blinding	The sponsor central study team (including CG, KP, BW, SM, and GN) remained blinded until the last subject's week 48 visit for the primary analysis. Participants, sponsor study site staff, and care providers will remain blinded until each subject's week 96 visit. The sponsor clinical trial supplies group was unblinded in order to package and label the clinical trials supplies. The care providers may unblind a subject's treatment assignment only in the case of an emergency. The sponsor global clinical safety and pharmacovigilance group was partially unblinded, as required by various country regulations, in order to process reports of serious, related, and unexpected adverse events.
Primary endpoint definition	Subjects' responses (<50 copies/mL) were calculated according to the US Food and Drug Administration's Snapshot algorithm. It is intended to be primarily a virologic assessment of the endpoint, and as such follows a

(Snapshot)	"virology first" hierarchy. Virologic success (<50 copies/mL) or virologic failure is typically determined by the last available HIV-1 RNA measurement within the visit window of interest (48 weeks ± 6 weeks) while the subject is on treatment. When no HIV-1 RNA data are available within a window, a subject is considered a non-responder. Depending on the reason for the lack of data, the subject will be classified as a virologic failure or reported as "no virologic data at week 48"; in the latter case, the algorithm further classifies the nature of the missing data. Typically, a subject withdrawn (1) due to AE or, (2) for another reason yet was suppressed at the time, will be counted as "no virologic data at week 48." Should a subject withdraw for reasons other than adverse events and were not suppressed at the time, they would be classified a virologic failure. A subject may also be considered a virologic failure if they make changes to their background regimen. Since changes in antiretroviral therapy are not permitted in this protocol, all such subjects who change antiretroviral therapy are considered non-responders. To view a graphical representation of this algorithm, see Figure S1.
Pre-specified subgroup analyses	All subgroup analyses (for stratification factors and other subject characteristics) were pre-specified and unadjusted for multiplicity. <u>Stratification factors:</u> For the statistical analysis of the primary endpoint, 4 subgroups were formed according to the combinations of levels of the stratification factors:

Baseline plasma HIV-1 RNA (≤ vs. >100,000 c/mL) and baseline CD4 cell count (≤ vs. >200 cells/mm^3). For these strata, in addition to the proportion of responders by treatment arm and subgroup (with 95% CI), the P value from the test of homogeneity was also reported for each categorical variable. Tests of homogeneity were assessed at the 1-sided 10% level of significance. These results were used to assess the statistical assumption underlying the Cochran Mantel Haenszel stratified analysis procedure—namely the assumption on a common difference in unadjusted proportions across strata.

Other subject characteristics:

A simple analysis of the primary endpoint for all the subgroups listed below was performed. This showed the proportion of responders by treatment and subgroup, and a 95% CI for the (unadjusted) treatment difference in each subgroup. These analyses were exploratory and likely underpowered so that interpretation may therefore focus on point estimates as well as the lower bounds of 95% CIs for the treatment differences and response rates. Additionally, multiple comparisons were being made, which inflates the risk of false-positive findings. Therefore, if consistent findings across the multiple comparisons were observed, then these analyses would still be suggestive of a generalizable finding of non-inferiority. For brevity, only baseline HIV-1 RNA (≤100,000 or >100,000 copies/mL), baseline CD4 cell count (≤200 or >200 cells/mm^3), gender, race (white or non-white), and age (<50 or ≥50 years) are presented in this manuscript.

- Baseline plasma HIV-1 RNA:

a. ≤100,000 or >100,000 copies/mL;

b. <1000; 1000 to <10,000; 10,000 to <50,000; 50,000 to 100,000; >100,000 copies/mL.

- Baseline CD4 cell count:

  a. ≤200 or >200 cells/mm^3;

  b. <50; 50 to <200; 200 to <350; 350 to <500; ≥500 cells/mm^3.

- Baseline CDC category (CDC Category A, CDC Category B, or CDC Category C)
- Race (white or non-white) and race 2 (African American/African heritage or non–African American/African heritage)
- Gender (female or male)
- Age:

  a. <36 or ≥36 years (i.e., baseline median cutoff);

  b. <65 or ≥65 years;

  c. <50 or ≥50 years; this post hoc category was added after review of the data, as the number of subjects in the ≥65 years category (n=1 in the DTG+ABC/3TC arm and n=6 in the Atripla arm) planned in the protocol to look at response in the elderly population was too small for any meaningful interpretation.

- Country
- Known HIV risk factors or mode of transmission (injectable drug

	user, homosexual contact and not injectable drug user, or no homosexual contact and not injectable drug user)

CDC denotes Centers for Disease Control and Prevention, CI confidence interval.

Table S3. Summary of Protocol Deviations Leading to Exclusion From the Per-Protocol Population (ITT-E Population) Through Week 48.

	DTG 50 mg + ABC/3TC QD N=414	EFV/TDF/FTC QD N=419	Total N=833
Protocol deviations*	**n (%)**	**n (%)**	**n (%)**
Any deviation	11 (3)	7 (2)	18 (2)
Inclusion/exclusion criteria	1 (<1)	1 (<1)	2 (<1)
Subject took/received incorrect study drug >10% of total treatment time	1 (<1)	0	1 (<1)
Study drug interruption for >10% of total treatment time	2 (<1)	1 (<1)	3 (<1)
Use of prohibited medication†	2 (<1)	3 (<1)	5 (<1)
Permanent discontinuation of study drug due to protocol deviation	6 (1)	4 (<1)	10 (1)

*Some subjects may have multiple deviations leading to exclusion from the per-protocol population; deviations may appear in more than one category. †Prohibited medications included prednisone, methylprednisolone, methotrexate, and infliximab. ABC denotes abacavir, CI confidence interval, DTG dolutegravir, EFV efavirenz, FTC emtricitabine, ITT-E denotes intention-to-treat exposed, QD once daily, 3TC lamivudine, and TDF tenofovir disoproxil fumarate.

Table S4. Summary of Demographic Characteristics (ITT-E Population).

	DTG 50 mg + ABC/3TC QD N=414 n (%)	EFV/TDF/FTC QD N=419 n (%)	Total N=833 n (%)
Age in years, median (range)	36.0 (18-68)	35.0 (18-85)	35.0 (18-85)
Sex			
Male	347 (84)	356 (85)	703 (84)
Female	67 (16)	63 (15)	130 (16)
Ethnicity			
Hispanic/Latino	56 (14)	56 (13)	112 (13)
Not Hispanic/Latino	358 (86)	363 (87)	721 (87)
Race			
African American/African heritage	98 (24)	99 (24)	197 (24)
American Indian or Alaska native	13 (3)	17 (4)	30 (4)
Asian	9 (2)	9 (2)	18 (2)
Central/South Asian heritage	2 (<1)	3 (<1)	5 (<1)
Japanese/East Asian heritage/ Southeast Asian heritage	7 (2)	6 (1)	13 (2)
Native Hawaiian or other Pacific Islander	0	0	0
White – White/Caucasian/European heritage	284 (69)	285 (68)	569 (68)
Other	10 (2)	6 (1)	16 (2)

	DTG 50 mg + ABC/3TC QD N=414 n (%)	EFV/TDF/FTC QD N=419 n (%)	Total N=833 n (%)
Baseline HIV-1 RNA (log_{10} copies/mL)			
≤100,000	280 (68)	288 (69)	568 (68)
>100,000	134 (32)	131 (31)	265 (32)
Median	4.67	4.70	4.68
Baseline CD4 (cells/mm^3)			
<50	13 (3)	14 (3)	27 (3)
50 to <200	44 (11)	48 (11)	92 (11)
200 to <350	163 (39)	159 (38)	322 (39)
350 to <500	131 (32)	128 (31)	259 (31)
≥500	63 (15)	70 (17)	133 (16)
Median	334.5	339.0	338.0
Hepatitis C positive*	27 (7)	29 (7)	56 (7)
CDC category			
A: Asymptomatic or lymphadenopathy or acute HIV	343 (83)	350 (84)	693 (83)
B: Symptomatic, not AIDS	53 (13)	52 (12)	105 (13)
C: AIDS	18 (4)	17 (4)	35 (4)
HIV risk factors known			
Yes	403 (97)	408 (97)	811 (97)

	DTG 50 mg + ABC/3TC QD N=414 n (%)	EFV/TDF/FTC QD N=419 n (%)	Total N=833 n (%)
Homosexual contact	268 (67)	289 (71)	557 (69)
Heterosexual contact	133 (33)	111 (27)	244 (30)
Injectable drug use	20 (5)	9 (2)	29 (4)
Transfusion	2 (<1)	1 (<1)	3 (<1)
Hemophilia-associated injections	0	2 (<1)	2 (<1)
Occupational exposure	0	0	0
Vertical/Perinatal transmission	0	1 (<1)	1 (<1)
Other	5 (1)	12 (3)	17 (2)

*Hepatitis C status was determined using antibody (IgM or IgG) and/or hepatitis C virus RNA assessments performed during screening or during the conduct of the study. If both antibody and virus RNA assessments were available, then the latter took precedence and positive/negative status was based on whether hepatitis C virus RNA was detectable. ABC denotes abacavir, CI confidence interval, DTG dolutegravir, EFV efavirenz, FTC emtricitabine, ITT-E denotes intention-to-treat exposed, QD once daily, 3TC lamivudine, and TDF tenofovir disoproxil fumarate.

Table S5. Summary of All Adverse Events by System Organ Class and Maximum Toxicity.

Protocol: ING114467
Population: Safety
Summary of All Adverse Events by System Organ Class and Maximum Toxicity

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
ANY EVENT	169 (41%)	157 (38%)	39 (9%)	4 (<1%)	369 (89%)
Infections and infestations					
Any Event	131 (32%)	88 (21%)	13 (3%)	0	232 (56%)
Nasopharyngitis	57 (14%)	5 (1%)	0	0	62 (15%)
Upper respiratory tract infection	27 (7%)	9 (2%)	0	0	36 (9%)
Bronchitis	12 (3%)	6 (1%)	2 (<1%)	0	20 (5%)
Gastroenteritis	12 (3%)	3 (<1%)	0	0	15 (4%)
Sinusitis	10 (2%)	4 (<1%)	1 (<1%)	0	15 (4%)
Influenza	8 (2%)	6 (1%)	0	0	14 (3%)
Syphilis	6 (1%)	6 (1%)	1 (<1%)	0	13 (3%)
Pharyngitis	5 (1%)	4 (<1%)	0	0	9 (2%)
Pneumonia	2 (<1%)	6 (1%)	1 (<1%)	0	9 (2%)
Tonsillitis	5 (1%)	3 (<1%)	0	0	8 (2%)
Cellulitis	2 (<1%)	5 (1%)	0	0	7 (2%)
Folliculitis	6 (1%)	1 (<1%)	0	0	7 (2%)
Urethritis	4 (<1%)	3 (<1%)	0	0	7 (2%)
Gonorrhoea	4 (<1%)	2 (<1%)	0	0	6 (1%)
Tooth abscess	1 (<1%)	5 (1%)	0	0	6 (1%)
Urinary tract infection	4 (<1%)	2 (<1%)	0	0	6 (1%)
Chlamydial infection	3 (<1%)	2 (<1%)	0	0	5 (1%)
Otitis media	1 (<1%)	4 (<1%)	0	0	5 (1%)

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Respiratory tract infection	4 (<1%)	1 (<1%)	0	0	5 (1%)
Tinea pedis	3 (<1%)	2 (<1%)	0	0	5 (1%)
Oral herpes	4 (<1%)	0	0	0	4 (<1%)
Rhinitis	4 (<1%)	0	0	0	4 (<1%)
Abscess	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Acarodermatitis	1 (<1%)	2 (<1%)	0	0	3 (<1%)
Acute sinusitis	0	3 (<1%)	0	0	3 (<1%)
Herpes simplex	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Otitis externa	1 (<1%)	2 (<1%)	0	0	3 (<1%)
Subcutaneous abscess	1 (<1%)	1 (<1%)	1 (<1%)	0	3 (<1%)
Tinea cruris	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Acute tonsillitis	2 (<1%)	0	0	0	2 (<1%)
Body tinea	2 (<1%)	0	0	0	2 (<1%)
Ear infection	2 (<1%)	0	0	0	2 (<1%)
Furuncle	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Genital herpes	2 (<1%)	0	0	0	2 (<1%)
Giardiasis	2 (<1%)	0	0	0	2 (<1%)
Gingival infection	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Herpes virus infection	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Herpes zoster	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Infectious mononucleosis	2 (<1%)	0	0	0	2 (<1%)
Molluscum contagiosum	2 (<1%)	0	0	0	2 (<1%)
Orchitis	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Pharyngitis streptococcal	0	2 (<1%)	0	0	2 (<1%)
Pharyngotonsillitis	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Tinea versicolour	2 (<1%)	0	0	0	2 (<1%)
Vaginitis bacterial	2 (<1%)	0	0	0	2 (<1%)
Viral upper respiratory tract infection	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Wound infection	2 (<1%)	0	0	0	2 (<1%)
Abscess limb	0	1 (<1%)	0	0	1 (<1%)

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Anal chlamydia infection	1 (<1%)	0	0	0	1 (<1%)
Anorectal infection	0	1 (<1%)	0	0	1 (<1%)
Appendicitis	0	0	1 (<1%)	0	1 (<1%)
Balanitis candida	1 (<1%)	0	0	0	1 (<1%)
Blastocystis infection	0	1 (<1%)	0	0	1 (<1%)
Conjunctivitis infective	1 (<1%)	0	0	0	1 (<1%)
Cryptosporidiosis infection	0	1 (<1%)	0	0	1 (<1%)
Cystitis	0	0	1 (<1%)	0	1 (<1%)
Enterobiasis	1 (<1%)	0	0	0	1 (<1%)
Eye infection	1 (<1%)	0	0	0	1 (<1%)
Fungal skin infection	0	1 (<1%)	0	0	1 (<1%)
Genital candidiasis	1 (<1%)	0	0	0	1 (<1%)
Genitourinary chlamydia infection	1 (<1%)	0	0	0	1 (<1%)
Helicobacter gastritis	0	1 (<1%)	0	0	1 (<1%)
Infected dermal cyst	0	0	1 (<1%)	0	1 (<1%)
Laryngitis	0	1 (<1%)	0	0	1 (<1%)
Latent tuberculosis	1 (<1%)	0	0	0	1 (<1%)
Localised infection	1 (<1%)	0	0	0	1 (<1%)
Lower respiratory tract infection	0	1 (<1%)	0	0	1 (<1%)
Lung infection	1 (<1%)	0	0	0	1 (<1%)
Lymphogranuloma venereum	1 (<1%)	0	0	0	1 (<1%)
Meningitis	0	1 (<1%)	0	0	1 (<1%)
Mycobacterium avium complex infection	0	1 (<1%)	0	0	1 (<1%)
Neurosyphilis	0	0	1 (<1%)	0	1 (<1%)
Onychomycosis	1 (<1%)	0	0	0	1 (<1%)
Oral infection	1 (<1%)	0	0	0	1 (<1%)
Oropharyngeal gonococcal infection	1 (<1%)	0	0	0	1 (<1%)
Papilloma viral infection	0	0	1 (<1%)	0	1 (<1%)
Parasitic gastroenteritis	0	1 (<1%)	0	0	1 (<1%)
Parotitis	1 (<1%)	0	0	0	1 (<1%)

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Pharyngitis bacterial	0	1 (<1%)	0	0	1 (<1%)
Post procedural cellulitis	0	1 (<1%)	0	0	1 (<1%)
Post procedural infection	0	0	1 (<1%)	0	1 (<1%)
Postoperative wound infection	0	0	1 (<1%)	0	1 (<1%)
Proctitis gonococcal	1 (<1%)	0	0	0	1 (<1%)
Pyelonephritis	0	0	1 (<1%)	0	1 (<1%)
Sialoadenitis	0	1 (<1%)	0	0	1 (<1%)
Skin infection	0	1 (<1%)	0	0	1 (<1%)
Staphylococcal abscess	0	1 (<1%)	0	0	1 (<1%)
Staphylococcal infection	0	1 (<1%)	0	0	1 (<1%)
Staphylococcal skin infection	1 (<1%)	0	0	0	1 (<1%)
Tinea infection	0	1 (<1%)	0	0	1 (<1%)
Toxoplasmosis	0	1 (<1%)	0	0	1 (<1%)
Tracheitis	1 (<1%)	0	0	0	1 (<1%)
Tracheobronchitis	0	1 (<1%)	0	0	1 (<1%)
Tuberculosis	0	0	1 (<1%)	0	1 (<1%)
Viral infection	1 (<1%)	0	0	0	1 (<1%)
Vulval abscess	1 (<1%)	0	0	0	1 (<1%)
Vulvovaginal candidiasis	1 (<1%)	0	0	0	1 (<1%)
Vulvovaginal mycotic infection	0	1 (<1%)	0	0	1 (<1%)
Gastrointestinal disorders					
Any Event	133 (32%)	43 (10%)	4 (<1%)	0	180 (43%)
Diarrhoea	51 (12%)	20 (5%)	1 (<1%)	0	72 (17%)
Nausea	52 (13%)	7 (2%)	0	0	59 (14%)
Vomiting	16 (4%)	4 (<1%)	0	0	20 (5%)
Abdominal pain upper	11 (3%)	2 (<1%)	0	0	13 (3%)
Abdominal pain	10 (2%)	2 (<1%)	0	0	12 (3%)
Constipation	10 (2%)	2 (<1%)	0	0	12 (3%)

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Flatulence	8 (2%)	4 (<1%)	0	0	12 (3%)
Abdominal distension	10 (2%)	1 (<1%)	0	0	11 (3%)
Dyspepsia	9 (2%)	1 (<1%)	0	0	10 (2%)
Gastrooesophageal reflux disease	6 (1%)	3 (<1%)	1 (<1%)	0	10 (2%)
Haemorrhoids	7 (2%)	1 (<1%)	0	0	8 (2%)
Toothache	6 (1%)	1 (<1%)	1 (<1%)	0	8 (2%)
Abdominal discomfort	4 (<1%)	1 (<1%)	0	0	5 (1%)
Gastritis	3 (<1%)	2 (<1%)	0	0	5 (1%)
Anogenital dysplasia	3 (<1%)	1 (<1%)	0	0	4 (<1%)
Food poisoning	2 (<1%)	1 (<1%)	1 (<1%)	0	4 (<1%)
Gingivitis	2 (<1%)	2 (<1%)	0	0	4 (<1%)
Enteritis	3 (<1%)	0	0	0	3 (<1%)
Gastric disorder	3 (<1%)	0	0	0	3 (<1%)
Gingival bleeding	3 (<1%)	0	0	0	3 (<1%)
Anal fissure	2 (<1%)	0	0	0	2 (<1%)
Anorectal disorder	2 (<1%)	0	0	0	2 (<1%)
Dental caries	2 (<1%)	0	0	0	2 (<1%)
Frequent bowel movements	2 (<1%)	0	0	0	2 (<1%)
Haematochezia	2 (<1%)	0	0	0	2 (<1%)
Inguinal hernia	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Mouth ulceration	2 (<1%)	0	0	0	2 (<1%)
Odynophagia	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Paraesthesia oral	2 (<1%)	0	0	0	2 (<1%)
Anal ulcer	0	1 (<1%)	0	0	1 (<1%)
Aphthous stomatitis	1 (<1%)	0	0	0	1 (<1%)
Cheilitis	0	1 (<1%)	0	0	1 (<1%)
Diarrhoea haemorrhagic	0	1 (<1%)	0	0	1 (<1%)
Dry mouth	1 (<1%)	0	0	0	1 (<1%)
Duodenitis	1 (<1%)	0	0	0	1 (<1%)
Dysphagia	1 (<1%)	0	0	0	1 (<1%)

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Eructation	1 (<1%)	0	0	0	1 (<1%)
Faecal incontinence	0	1 (<1%)	0	0	1 (<1%)
Faeces discoloured	1 (<1%)	0	0	0	1 (<1%)
Gastrointestinal disorder	1 (<1%)	0	0	0	1 (<1%)
Hiatus hernia	1 (<1%)	0	0	0	1 (<1%)
Lip dry	1 (<1%)	0	0	0	1 (<1%)
Mallory-Weiss syndrome	0	1 (<1%)	0	0	1 (<1%)
Oral disorder	1 (<1%)	0	0	0	1 (<1%)
Perianal erythema	1 (<1%)	0	0	0	1 (<1%)
Proctalgia	0	1 (<1%)	0	0	1 (<1%)
Proctitis	0	1 (<1%)	0	0	1 (<1%)
Rectal discharge	1 (<1%)	0	0	0	1 (<1%)
Rectal haemorrhage	1 (<1%)	0	0	0	1 (<1%)
Rectal prolapse	1 (<1%)	0	0	0	1 (<1%)
Sensitivity of teeth	1 (<1%)	0	0	0	1 (<1%)
Tongue coated	1 (<1%)	0	0	0	1 (<1%)
Tongue disorder	1 (<1%)	0	0	0	1 (<1%)
Tooth disorder	1 (<1%)	0	0	0	1 (<1%)
Nervous system disorders					
Any Event	82 (20%)	28 (7%)	1 (<1%)	0	111 (27%)
Headache	43 (10%)	11 (3%)	1 (<1%)	0	55 (13%)
Dizziness	35 (8%)	2 (<1%)	0	0	37 (9%)
Paraesthesia	9 (2%)	1 (<1%)	0	0	10 (2%)
Somnolence	6 (1%)	3 (<1%)	0	0	9 (2%)
Memory impairment	1 (<1%)	3 (<1%)	0	0	4 (<1%)
Disturbance in attention	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Dysgeusia	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Hypoaesthesia	3 (<1%)	0	0	0	3 (<1%)

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Lethargy	3 (<1%)	0	0	0	3 (<1%)
Sinus headache	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Syncope	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Carpal tunnel syndrome	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Migraine	2 (<1%)	0	0	0	2 (<1%)
Poor quality sleep	1 (<1%)	1 (<1%)	0	0	2 (<1%)
VIIth nerve paralysis	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Amnesia	1 (<1%)	0	0	0	1 (<1%)
Aphonia	1 (<1%)	0	0	0	1 (<1%)
Cerebrovascular accident	0	1 (<1%)	0	0	1 (<1%)
Depressed level of consciousness	0	1 (<1%)	0	0	1 (<1%)
Dysaesthesia	0	1 (<1%)	0	0	1 (<1%)
Formication	1 (<1%)	0	0	0	1 (<1%)
Grand mal convulsion	0	1 (<1%)	0	0	1 (<1%)
Meralgia paraesthetica	1 (<1%)	0	0	0	1 (<1%)
Myoclonus	1 (<1%)	0	0	0	1 (<1%)
Neuralgia	1 (<1%)	0	0	0	1 (<1%)
Neuropathy peripheral	0	1 (<1%)	0	0	1 (<1%)
Post herpetic neuralgia	1 (<1%)	0	0	0	1 (<1%)
Sleep paralysis	1 (<1%)	0	0	0	1 (<1%)
Trigeminal neuralgia	0	1 (<1%)	0	0	1 (<1%)
Psychiatric disorders					
Any Event	86 (21%)	33 (8%)	4 (<1%)	2 (<1%)	125 (30%)
Insomnia	47 (11%)	14 (3%)	3 (<1%)	0	64 (15%)
Abnormal dreams	28 (7%)	2 (<1%)	0	0	30 (7%)
Depression	16 (4%)	5 (1%)	2 (<1%)	0	23 (6%)
Anxiety	5 (1%)	9 (2%)	0	0	14 (3%)
Nightmare	8 (2%)	1 (<1%)	0	0	9 (2%)

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Libido decreased	5 (1%)	1 (<1%)	0	0	6 (1%)
Sleep disorder	5 (1%)	1 (<1%)	0	0	6 (1%)
Depressed mood	3 (<1%)	0	0	0	3 (<1%)
Initial insomnia	3 (<1%)	0	0	0	3 (<1%)
Nervousness	2 (<1%)	0	0	0	2 (<1%)
Suicide attempt	1 (<1%)	0	0	1 (<1%)	2 (<1%)
Adjustment disorder	1 (<1%)	0	0	0	1 (<1%)
Adjustment disorder with depressed mood	0	1 (<1%)	0	0	1 (<1%)
Agitation	1 (<1%)	0	0	0	1 (<1%)
Anger	0	1 (<1%)	0	0	1 (<1%)
Antisocial personality disorder	1 (<1%)	0	0	0	1 (<1%)
Anxiety disorder	1 (<1%)	0	0	0	1 (<1%)
Binge eating	1 (<1%)	0	0	0	1 (<1%)
Bipolar disorder	0	1 (<1%)	0	0	1 (<1%)
Depressive symptom	1 (<1%)	0	0	0	1 (<1%)
Dysthymic disorder	0	1 (<1%)	0	0	1 (<1%)
Euphoric mood	1 (<1%)	0	0	0	1 (<1%)
Homicidal ideation	0	0	0	1 (<1%)	1 (<1%)
Libido increased	1 (<1%)	0	0	0	1 (<1%)
Mood swings	0	1 (<1%)	0	0	1 (<1%)
Panic attack	1 (<1%)	0	0	0	1 (<1%)
Premature ejaculation	1 (<1%)	0	0	0	1 (<1%)
Restlessness	0	1 (<1%)	0	0	1 (<1%)
Social phobia	0	1 (<1%)	0	0	1 (<1%)
Substance abuse	0	1 (<1%)	0	0	1 (<1%)
Suicidal ideation	0	0	0	1 (<1%)	1 (<1%)
Withdrawal syndrome	1 (<1%)	0	0	0	1 (<1%)
Skin and subcutaneous tissue disorders					
Any Event	70 (17%)	13 (3%)	1 (<1%)	0	84 (20%)

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Rash	11 (3%)	3 (<1%)	0	0	14 (3%)
Pruritus	13 (3%)	0	0	0	13 (3%)
Night sweats	8 (2%)	3 (<1%)	0	0	11 (3%)
Alopecia	8 (2%)	1 (<1%)	0	0	9 (2%)
Acne	7 (2%)	1 (<1%)	0	0	8 (2%)
Eczema	5 (1%)	1 (<1%)	0	0	6 (1%)
Dry skin	4 (<1%)	0	0	0	4 (<1%)
Hyperhidrosis	1 (<1%)	2 (<1%)	0	0	3 (<1%)
Rash pruritic	3 (<1%)	0	0	0	3 (<1%)
Dermatitis	2 (<1%)	0	0	0	2 (<1%)
Increased tendency to bruise	2 (<1%)	0	0	0	2 (<1%)
Rash maculo-papular	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Rash papular	2 (<1%)	0	0	0	2 (<1%)
Seborrhoeic dermatitis	2 (<1%)	0	0	0	2 (<1%)
Skin irritation	2 (<1%)	0	0	0	2 (<1%)
Angioedema	0	0	1 (<1%)	0	1 (<1%)
Chloasma	1 (<1%)	0	0	0	1 (<1%)
Dermatitis contact	0	1 (<1%)	0	0	1 (<1%)
Dyshidrosis	1 (<1%)	0	0	0	1 (<1%)
Eosinophilic pustular folliculitis	1 (<1%)	0	0	0	1 (<1%)
Erythema	1 (<1%)	0	0	0	1 (<1%)
Erythema nodosum	1 (<1%)	0	0	0	1 (<1%)
Hidradenitis	0	1 (<1%)	0	0	1 (<1%)
Hyperkeratosis	1 (<1%)	0	0	0	1 (<1%)
Pigmentation disorder	1 (<1%)	0	0	0	1 (<1%)
Pityriasis rosea	1 (<1%)	0	0	0	1 (<1%)
Psoriasis	1 (<1%)	0	0	0	1 (<1%)
Purpura	1 (<1%)	0	0	0	1 (<1%)
Rash macular	1 (<1%)	0	0	0	1 (<1%)
Seborrhoea	1 (<1%)	0	0	0	1 (<1%)

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Skin disorder	1 (<1%)	0	0	0	1 (<1%)
Skin lesion	1 (<1%)	0	0	0	1 (<1%)
Solar dermatitis	1 (<1%)	0	0	0	1 (<1%)
Spider naevus	1 (<1%)	0	0	0	1 (<1%)
Swelling face	0	1 (<1%)	0	0	1 (<1%)
General disorders and administration site conditions					
Any Event	85 (21%)	15 (4%)	8 (2%)	0	108 (26%)
Fatigue	44 (11%)	8 (2%)	2 (<1%)	0	54 (13%)
Pyrexia	18 (4%)	2 (<1%)	3 (<1%)	0	23 (6%)
Asthenia	11 (3%)	1 (<1%)	0	0	12 (3%)
Chest pain	8 (2%)	1 (<1%)	1 (<1%)	0	10 (2%)
Chills	6 (1%)	0	0	0	6 (1%)
Influenza like illness	5 (1%)	1 (<1%)	0	0	6 (1%)
Oedema peripheral	5 (1%)	1 (<1%)	0	0	6 (1%)
Pain	6 (1%)	0	0	0	6 (1%)
Feeling hot	3 (<1%)	0	0	0	3 (<1%)
Cyst	2 (<1%)	0	0	0	2 (<1%)
Facial pain	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Adverse drug reaction	0	0	1 (<1%)	0	1 (<1%)
Axillary pain	1 (<1%)	0	0	0	1 (<1%)
Discomfort	1 (<1%)	0	0	0	1 (<1%)
Feeling drunk	1 (<1%)	0	0	0	1 (<1%)
Irritability	1 (<1%)	0	0	0	1 (<1%)
Malaise	1 (<1%)	0	0	0	1 (<1%)
Non-cardiac chest pain	0	0	1 (<1%)	0	1 (<1%)
Papillitis	1 (<1%)	0	0	0	1 (<1%)

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Musculoskeletal and connective tissue disorders					
Any Event	56 (14%)	26 (6%)	2 (<1%)	0	84 (20%)
Back pain	13 (3%)	10 (2%)	0	0	23 (6%)
Arthralgia	10 (2%)	2 (<1%)	1 (<1%)	0	13 (3%)
Pain in extremity	9 (2%)	4 (<1%)	0	0	13 (3%)
Muscle spasms	8 (2%)	2 (<1%)	0	0	10 (2%)
Myalgia	3 (<1%)	3 (<1%)	0	0	6 (1%)
Musculoskeletal pain	4 (<1%)	1 (<1%)	0	0	5 (1%)
Neck pain	4 (<1%)	1 (<1%)	0	0	5 (1%)
Bone pain	3 (<1%)	0	0	0	3 (<1%)
Musculoskeletal chest pain	3 (<1%)	0	0	0	3 (<1%)
Flank pain	1 (<1%)	0	1 (<1%)	0	2 (<1%)
Joint swelling	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Musculoskeletal stiffness	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Osteoarthritis	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Rotator cuff syndrome	2 (<1%)	0	0	0	2 (<1%)
Tendon disorder	0	2 (<1%)	0	0	2 (<1%)
Tendonitis	2 (<1%)	0	0	0	2 (<1%)
Bursitis	0	1 (<1%)	0	0	1 (<1%)
Costochondritis	0	1 (<1%)	0	0	1 (<1%)
Fasciitis	1 (<1%)	0	0	0	1 (<1%)
Foot deformity	1 (<1%)	0	0	0	1 (<1%)
Groin pain	0	1 (<1%)	0	0	1 (<1%)
Muscle fatigue	1 (<1%)	0	0	0	1 (<1%)
Osteopenia	1 (<1%)	0	0	0	1 (<1%)
Plantar fasciitis	1 (<1%)	0	0	0	1 (<1%)
Sjogren's syndrome	1 (<1%)	0	0	0	1 (<1%)
Synovial cyst	1 (<1%)	0	0	0	1 (<1%)
Temporomandibular joint syndrome	1 (<1%)	0	0	0	1 (<1%)

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Tenosynovitis	0	1 (<1%)	0	0	1 (<1%)
Respiratory, thoracic and mediastinal disorders					
Any Event	63 (15%)	15 (4%)	2 (<1%)	0	80 (19%)
Cough	22 (5%)	2 (<1%)	0	0	24 (6%)
Oropharyngeal pain	16 (4%)	4 (<1%)	0	0	20 (5%)
Nasal congestion	8 (2%)	0	0	0	8 (2%)
Rhinorrhoea	7 (2%)	0	0	0	7 (2%)
Sinus congestion	7 (2%)	0	0	0	7 (2%)
Rhinitis allergic	4 (<1%)	1 (<1%)	0	0	5 (1%)
Asthma	1 (<1%)	3 (<1%)	0	0	4 (<1%)
Dyspnoea	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Epistaxis	3 (<1%)	0	0	0	3 (<1%)
Productive cough	1 (<1%)	2 (<1%)	0	0	3 (<1%)
Respiratory tract congestion	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Wheezing	3 (<1%)	0	0	0	3 (<1%)
Hiccups	2 (<1%)	0	0	0	2 (<1%)
Rhinitis seasonal	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Throat irritation	2 (<1%)	0	0	0	2 (<1%)
Allergic sinusitis	1 (<1%)	0	0	0	1 (<1%)
Apnoea	1 (<1%)	0	0	0	1 (<1%)
Chronic obstructive pulmonary disease	0	1 (<1%)	0	0	1 (<1%)
Dry throat	1 (<1%)	0	0	0	1 (<1%)
Dysphonia	1 (<1%)	0	0	0	1 (<1%)
Nasal ulcer	1 (<1%)	0	0	0	1 (<1%)
Paranasal sinus hypersecretion	1 (<1%)	0	0	0	1 (<1%)
Pleural effusion	0	0	1 (<1%)	0	1 (<1%)
Pulmonary congestion	1 (<1%)	0	0	0	1 (<1%)
Sneezing	1 (<1%)	0	0	0	1 (<1%)

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Tonsillar disorder	0	0	1 (<1%)	0	1 (<1%)
Tonsillar hypertrophy	1 (<1%)	0	0	0	1 (<1%)
Upper-airway cough syndrome	1 (<1%)	0	0	0	1 (<1%)
Injury, poisoning and procedural complications					
Any Event	26 (6%)	14 (3%)	5 (1%)	2 (<1%)	47 (11%)
Arthropod bite	4 (<1%)	1 (<1%)	0	0	5 (1%)
Muscle strain	3 (<1%)	2 (<1%)	0	0	5 (1%)
Procedural pain	2 (<1%)	3 (<1%)	0	0	5 (1%)
Laceration	3 (<1%)	1 (<1%)	0	0	4 (<1%)
Ligament sprain	2 (<1%)	2 (<1%)	0	0	4 (<1%)
Foot fracture	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Road traffic accident	1 (<1%)	0	2 (<1%)	0	3 (<1%)
Exposure to communicable disease	2 (<1%)	0	0	0	2 (<1%)
Intentional overdose	0	1 (<1%)	0	1 (<1%)	2 (<1%)
Lip injury	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Skeletal injury	2 (<1%)	0	0	0	2 (<1%)
Tooth fracture	2 (<1%)	0	0	0	2 (<1%)
Animal scratch	1 (<1%)	0	0	0	1 (<1%)
Comminuted fracture	0	0	1 (<1%)	0	1 (<1%)
Contusion	0	1 (<1%)	0	0	1 (<1%)
Epicondylitis	1 (<1%)	0	0	0	1 (<1%)
Head injury	0	0	1 (<1%)	0	1 (<1%)
Heat stroke	1 (<1%)	0	0	0	1 (<1%)
Humerus fracture	0	1 (<1%)	0	0	1 (<1%)
Injury	1 (<1%)	0	0	0	1 (<1%)
Jaw fracture	0	0	1 (<1%)	0	1 (<1%)
Overdose	0	0	1 (<1%)	0	1 (<1%)
Splinter	1 (<1%)	0	0	0	1 (<1%)

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Subdural haematoma	0	0	0	1 (<1%)	1 (<1%)
Suture rupture	1 (<1%)	0	0	0	1 (<1%)
Traumatic haematoma	0	1 (<1%)	0	0	1 (<1%)
Metabolism and nutrition disorders					
Any Event	13 (3%)	5 (1%)	4 (<1%)	0	22 (5%)
Decreased appetite	7 (2%)	0	0	0	7 (2%)
Vitamin D deficiency	3 (<1%)	1 (<1%)	0	0	4 (<1%)
Hypercholesterolaemia	1 (<1%)	0	1 (<1%)	0	2 (<1%)
Hypertriglyceridaemia	0	0	2 (<1%)	0	2 (<1%)
Cow's milk intolerance	1 (<1%)	0	0	0	1 (<1%)
Dehydration	0	1 (<1%)	0	0	1 (<1%)
Diabetes mellitus	1 (<1%)	0	0	0	1 (<1%)
Dyslipidaemia	0	1 (<1%)	0	0	1 (<1%)
Gout	0	1 (<1%)	0	0	1 (<1%)
Hyperglycaemia	0	0	1 (<1%)	0	1 (<1%)
Lactose intolerance	1 (<1%)	0	0	0	1 (<1%)
Type 2 diabetes mellitus	0	1 (<1%)	0	0	1 (<1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Any Event	16 (4%)	8 (2%)	0	0	24 (6%)
Anogenital warts	9 (2%)	5 (1%)	0	0	14 (3%)
Skin papilloma	5 (1%)	2 (<1%)	0	0	7 (2%)
Lipoma	2 (<1%)	0	0	0	2 (<1%)
Basal cell carcinoma	0	1 (<1%)	0	0	1 (<1%)
Degeneration of uterine leiomyoma	1 (<1%)	0	0	0	1 (<1%)
Dysplastic naevus	1 (<1%)	0	0	0	1 (<1%)
Reproductive system and breast disorders					

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Any Event	18 (4%)	7 (2%)	1 (<1%)	1 (<1%)	27 (7%)
Erectile dysfunction	4 (<1%)	2 (<1%)	0	0	6 (1%)
Balanitis	2 (<1%)	0	0	0	2 (<1%)
Benign prostatic hyperplasia	2 (<1%)	0	0	0	2 (<1%)
Balanoposthitis	1 (<1%)	0	0	0	1 (<1%)
Bartholin's cyst	0	1 (<1%)	0	0	1 (<1%)
Breast induration	1 (<1%)	0	0	0	1 (<1%)
Breast mass	1 (<1%)	0	0	0	1 (<1%)
Breast tenderness	1 (<1%)	0	0	0	1 (<1%)
Cervix disorder	0	1 (<1%)	0	0	1 (<1%)
Dysmenorrhoea	1 (<1%)	0	0	0	1 (<1%)
Erection increased	1 (<1%)	0	0	0	1 (<1%)
Genital lesion	0	1 (<1%)	0	0	1 (<1%)
Gynaecomastia	1 (<1%)	0	0	0	1 (<1%)
Menometrorrhagia	0	1 (<1%)	0	0	1 (<1%)
Menorrhagia	1 (<1%)	0	0	0	1 (<1%)
Penile discharge	0	1 (<1%)	0	0	1 (<1%)
Priapism	0	0	0	1 (<1%)	1 (<1%)
Sexual dysfunction	1 (<1%)	0	0	0	1 (<1%)
Uterine prolapse	0	1 (<1%)	0	0	1 (<1%)
Vaginal discharge	0	1 (<1%)	0	0	1 (<1%)
Vaginal haemorrhage	1 (<1%)	0	0	0	1 (<1%)
Vulvovaginal swelling	0	0	1 (<1%)	0	1 (<1%)
Investigations					
Any Event	10 (2%)	10 (2%)	2 (<1%)	0	22 (5%)
Weight increased	5 (1%)	1 (<1%)	0	0	6 (1%)
Blood pressure increased	1 (<1%)	3 (<1%)	0	0	4 (<1%)
Blood creatine phosphokinase increased	0	2 (<1%)	0	0	2 (<1%)
Hepatic enzyme increased	1 (<1%)	1 (<1%)	0	0	2 (<1%)

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Blood creatinine increased	0	1 (<1%)	0	0	1 (<1%)
Blood glucose increased	0	1 (<1%)	0	0	1 (<1%)
Blood testosterone decreased	1 (<1%)	0	0	0	1 (<1%)
Blood triglycerides increased	0	1 (<1%)	0	0	1 (<1%)
Lipase increased	0	0	1 (<1%)	0	1 (<1%)
Liver palpable subcostal	1 (<1%)	0	0	0	1 (<1%)
Mycobacterium tuberculosis complex test positive	1 (<1%)	0	0	0	1 (<1%)
Neutrophil count decreased	0	0	1 (<1%)	0	1 (<1%)
Spleen palpable	1 (<1%)	0	0	0	1 (<1%)
Weight decreased	1 (<1%)	0	0	0	1 (<1%)
Eye disorders					
Any Event	22 (5%)	1 (<1%)	0	0	23 (6%)
Conjunctivitis	13 (3%)	1 (<1%)	0	0	14 (3%)
Blepharitis	2 (<1%)	0	0	0	2 (<1%)
Dry eye	1 (<1%)	0	0	0	1 (<1%)
Eye swelling	1 (<1%)	0	0	0	1 (<1%)
Eyelid oedema	1 (<1%)	0	0	0	1 (<1%)
Ocular hyperaemia	1 (<1%)	0	0	0	1 (<1%)
Photopsia	1 (<1%)	0	0	0	1 (<1%)
Scleritis	1 (<1%)	0	0	0	1 (<1%)
Vision blurred	1 (<1%)	0	0	0	1 (<1%)
Visual acuity reduced	1 (<1%)	0	0	0	1 (<1%)
Ear and labyrinth disorders					
Any Event	8 (2%)	4 (<1%)	0	0	12 (3%)
Tinnitus	3 (<1%)	1 (<1%)	0	0	4 (<1%)
Cerumen impaction	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Ear discomfort	2 (<1%)	0	0	0	2 (<1%)

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Vertigo	2 (<1%)	0	0	0	2 (<1%)
Deafness bilateral	1 (<1%)	0	0	0	1 (<1%)
Ear pain	0	1 (<1%)	0	0	1 (<1%)
Tympanic membrane perforation	0	1 (<1%)	0	0	1 (<1%)
Renal and urinary disorders					
Any Event	13 (3%)	3 (<1%)	1 (<1%)	0	17 (4%)
Dysuria	4 (<1%)	0	0	0	4 (<1%)
Haematuria	2 (<1%)	0	0	0	2 (<1%)
Nephrolithiasis	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Choluria	1 (<1%)	0	0	0	1 (<1%)
Chromaturia	1 (<1%)	0	0	0	1 (<1%)
Micturition urgency	1 (<1%)	0	0	0	1 (<1%)
Polyuria	1 (<1%)	0	0	0	1 (<1%)
Renal cyst	0	0	1 (<1%)	0	1 (<1%)
Renal failure	1 (<1%)	0	0	0	1 (<1%)
Renal pain	1 (<1%)	0	0	0	1 (<1%)
Urethral discharge	0	1 (<1%)	0	0	1 (<1%)
Urinary incontinence	0	1 (<1%)	0	0	1 (<1%)
Urinary retention	1 (<1%)	0	0	0	1 (<1%)
Immune system disorders					
Any Event	10 (2%)	5 (1%)	1 (<1%)	0	16 (4%)
Seasonal allergy	7 (2%)	3 (<1%)	0	0	10 (2%)
Hypersensitivity	2 (<1%)	0	1 (<1%)	0	3 (<1%)
Allergy to arthropod bite	1 (<1%)	0	0	0	1 (<1%)
Drug hypersensitivity	0	1 (<1%)	0	0	1 (<1%)
Immune reconstitution syndrome	0	1 (<1%)	0	0	1 (<1%)
Vascular disorders					

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Any Event	9 (2%)	5 (1%)	0	0	14 (3%)
Hypertension	3 (<1%)	2 (<1%)	0	0	5 (1%)
Flushing	2 (<1%)	0	0	0	2 (<1%)
Arterial disorder	0	1 (<1%)	0	0	1 (<1%)
Essential hypertension	0	1 (<1%)	0	0	1 (<1%)
Haematoma	1 (<1%)	0	0	0	1 (<1%)
Hot flush	1 (<1%)	0	0	0	1 (<1%)
Orthostatic hypotension	0	1 (<1%)	0	0	1 (<1%)
Peripheral coldness	1 (<1%)	0	0	0	1 (<1%)
Peripheral vascular disorder	1 (<1%)	0	0	0	1 (<1%)
Blood and lymphatic system disorders					
Any Event	11 (3%)	6 (1%)	1 (<1%)	0	18 (4%)
Lymphadenopathy	9 (2%)	2 (<1%)	0	0	11 (3%)
Neutropenia	0	2 (<1%)	0	0	2 (<1%)
Anaemia	1 (<1%)	0	0	0	1 (<1%)
Febrile neutropenia	0	0	1 (<1%)	0	1 (<1%)
Iron deficiency anaemia	0	1 (<1%)	0	0	1 (<1%)
Splenic cyst	0	1 (<1%)	0	0	1 (<1%)
Splenomegaly	1 (<1%)	0	0	0	1 (<1%)
Cardiac disorders					
Any Event	5 (1%)	3 (<1%)	1 (<1%)	0	9 (2%)
Tachycardia	4 (<1%)	0	0	0	4 (<1%)
Palpitations	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Cardiac disorder	0	1 (<1%)	0	0	1 (<1%)
Cardiac failure congestive	0	0	1 (<1%)	0	1 (<1%)
Supraventricular tachycardia	0	1 (<1%)	0	0	1 (<1%)
Endocrine disorders					

Treatment: DTG 50 mg +ABC/3TC QD (N=414)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Any Event	3 (<1%)	0	0	0	3 (<1%)
Testicular failure	2 (<1%)	0	0	0	2 (<1%)
Hyperthyroidism	1 (<1%)	0	0	0	1 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
ANY EVENT	159 (38%)	160 (38%)	58 (14%)	10 (2%)	387 (92%)
Infections and infestations					
Any Event	127 (30%)	77 (18%)	5 (1%)	2 (<1%)	211 (50%)
Nasopharyngitis	52 (12%)	8 (2%)	0	0	60 (14%)
Upper respiratory tract infection	34 (8%)	9 (2%)	0	0	43 (10%)
Syphilis	11 (3%)	6 (1%)	0	0	17 (4%)
Bronchitis	4 (<1%)	10 (2%)	1 (<1%)	0	15 (4%)
Gastroenteritis	10 (2%)	2 (<1%)	0	0	12 (3%)
Urinary tract infection	9 (2%)	3 (<1%)	0	0	12 (3%)
Sinusitis	8 (2%)	3 (<1%)	0	0	11 (3%)
Folliculitis	8 (2%)	2 (<1%)	0	0	10 (2%)
Herpes zoster	4 (<1%)	4 (<1%)	0	0	8 (2%)
Pharyngitis	8 (2%)	0	0	0	8 (2%)
Cellulitis	3 (<1%)	3 (<1%)	0	0	6 (1%)
Influenza	2 (<1%)	4 (<1%)	0	0	6 (1%)
Paronychia	3 (<1%)	3 (<1%)	0	0	6 (1%)
Tonsillitis	5 (1%)	1 (<1%)	0	0	6 (1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Acute sinusitis	4 (<1%)	1 (<1%)	0	0	5 (1%)
Chlamydial infection	3 (<1%)	2 (<1%)	0	0	5 (1%)
Furuncle	4 (<1%)	1 (<1%)	0	0	5 (1%)
Oral herpes	4 (<1%)	1 (<1%)	0	0	5 (1%)
Giardiasis	1 (<1%)	3 (<1%)	0	0	4 (<1%)
Gonorrhoea	3 (<1%)	1 (<1%)	0	0	4 (<1%)
Molluscum contagiosum	3 (<1%)	1 (<1%)	0	0	4 (<1%)
Body tinea	3 (<1%)	0	0	0	3 (<1%)
Gastroenteritis viral	3 (<1%)	0	0	0	3 (<1%)
Herpes simplex	3 (<1%)	0	0	0	3 (<1%)
Laryngitis	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Pneumonia	0	1 (<1%)	1 (<1%)	1 (<1%)	3 (<1%)
Secondary syphilis	3 (<1%)	0	0	0	3 (<1%)
Staphylococcal abscess	1 (<1%)	2 (<1%)	0	0	3 (<1%)
Staphylococcal infection	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Urethritis	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Anal chlamydia infection	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Fungal skin infection	2 (<1%)	0	0	0	2 (<1%)
Genital herpes	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Lymphogranuloma venereum	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Oropharyngeal gonococcal infection	2 (<1%)	0	0	0	2 (<1%)
Proctitis chlamydial	2 (<1%)	0	0	0	2 (<1%)
Respiratory tract infection	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Subcutaneous abscess	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Tinea infection	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Tinea pedis	2 (<1%)	0	0	0	2 (<1%)
Tooth abscess	0	2 (<1%)	0	0	2 (<1%)
Tooth infection	0	2 (<1%)	0	0	2 (<1%)
Urethritis gonococcal	2 (<1%)	0	0	0	2 (<1%)
Vaginal infection	2 (<1%)	0	0	0	2 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Vaginitis bacterial	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Viral infection	2 (<1%)	0	0	0	2 (<1%)
Viral upper respiratory tract infection	2 (<1%)	0	0	0	2 (<1%)
Abscess limb	0	1 (<1%)	0	0	1 (<1%)
Acarodermatitis	1 (<1%)	0	0	0	1 (<1%)
Acute tonsillitis	1 (<1%)	0	0	0	1 (<1%)
Amoebiasis	1 (<1%)	0	0	0	1 (<1%)
Anisakiasis	0	1 (<1%)	0	0	1 (<1%)
Aspergillosis	0	0	0	1 (<1%)	1 (<1%)
Bacteraemia	0	1 (<1%)	0	0	1 (<1%)
Bacteriuria	1 (<1%)	0	0	0	1 (<1%)
Bronchopulmonary aspergillosis	0	0	1 (<1%)	0	1 (<1%)
Cellulitis of male external genital organ	1 (<1%)	0	0	0	1 (<1%)
Cellulitis staphylococcal	1 (<1%)	0	0	0	1 (<1%)
Cystitis	0	1 (<1%)	0	0	1 (<1%)
Diarrhoea infectious	1 (<1%)	0	0	0	1 (<1%)
Ear infection	1 (<1%)	0	0	0	1 (<1%)
Eczema infected	1 (<1%)	0	0	0	1 (<1%)
Enterobiasis	1 (<1%)	0	0	0	1 (<1%)
Epiglottitis	0	1 (<1%)	0	0	1 (<1%)
Escherichia urinary tract infection	0	1 (<1%)	0	0	1 (<1%)
Gastroenteritis shigella	1 (<1%)	0	0	0	1 (<1%)
Genital candidiasis	1 (<1%)	0	0	0	1 (<1%)
Genital infection fungal	1 (<1%)	0	0	0	1 (<1%)
Gingival infection	1 (<1%)	0	0	0	1 (<1%)
Groin abscess	0	1 (<1%)	0	0	1 (<1%)
Hepatitis C	0	0	1 (<1%)	0	1 (<1%)
Hordeolum	0	1 (<1%)	0	0	1 (<1%)
Impetigo	0	1 (<1%)	0	0	1 (<1%)
Kidney infection	0	1 (<1%)	0	0	1 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Latent syphilis	1 (<1%)	0	0	0	1 (<1%)
Latent tuberculosis	1 (<1%)	0	0	0	1 (<1%)
Lobar pneumonia	0	1 (<1%)	0	0	1 (<1%)
Localised infection	0	1 (<1%)	0	0	1 (<1%)
Lower respiratory tract infection	1 (<1%)	0	0	0	1 (<1%)
Meningitis cryptococcal	0	1 (<1%)	0	0	1 (<1%)
Neutropenic infection	1 (<1%)	0	0	0	1 (<1%)
Onychomycosis	0	1 (<1%)	0	0	1 (<1%)
Otitis externa	0	1 (<1%)	0	0	1 (<1%)
Otitis media	0	1 (<1%)	0	0	1 (<1%)
Papilloma viral infection	1 (<1%)	0	0	0	1 (<1%)
Periorbital cellulitis	0	1 (<1%)	0	0	1 (<1%)
Pharyngotonsillitis	0	1 (<1%)	0	0	1 (<1%)
Pneumococcal sepsis	0	0	1 (<1%)	0	1 (<1%)
Pneumonia bacterial	1 (<1%)	0	0	0	1 (<1%)
Proctitis bacterial	0	1 (<1%)	0	0	1 (<1%)
Proctitis gonococcal	1 (<1%)	0	0	0	1 (<1%)
Prostate infection	1 (<1%)	0	0	0	1 (<1%)
Pyelonephritis	0	1 (<1%)	0	0	1 (<1%)
Rectal abscess	0	1 (<1%)	0	0	1 (<1%)
Respiratory tract infection viral	0	1 (<1%)	0	0	1 (<1%)
Rhinitis	1 (<1%)	0	0	0	1 (<1%)
Scrotal abscess	0	0	1 (<1%)	0	1 (<1%)
Sepsis	0	0	0	1 (<1%)	1 (<1%)
Septic shock	0	0	0	1 (<1%)	1 (<1%)
Sexually transmitted disease	1 (<1%)	0	0	0	1 (<1%)
Skin infection	0	1 (<1%)	0	0	1 (<1%)
Staphylococcal skin infection	1 (<1%)	0	0	0	1 (<1%)
Systemic candida	0	0	0	1 (<1%)	1 (<1%)
Tinea barbae	1 (<1%)	0	0	0	1 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Tinea capitis	1 (<1%)	0	0	0	1 (<1%)
Trichomoniasis	1 (<1%)	0	0	0	1 (<1%)
Urethritis chlamydial	1 (<1%)	0	0	0	1 (<1%)
Vulvovaginal candidiasis	1 (<1%)	0	0	0	1 (<1%)
Gastrointestinal disorders					
Any Event	123 (29%)	54 (13%)	7 (2%)	0	184 (44%)
Diarrhoea	58 (14%)	15 (4%)	2 (<1%)	0	75 (18%)
Nausea	44 (11%)	13 (3%)	0	0	57 (14%)
Vomiting	13 (3%)	6 (1%)	0	0	19 (5%)
Abdominal pain upper	13 (3%)	1 (<1%)	0	0	14 (3%)
Abdominal pain	8 (2%)	4 (<1%)	1 (<1%)	0	13 (3%)
Constipation	8 (2%)	2 (<1%)	0	0	10 (2%)
Flatulence	7 (2%)	2 (<1%)	1 (<1%)	0	10 (2%)
Abdominal distension	7 (2%)	1 (<1%)	0	0	8 (2%)
Haemorrhoids	6 (1%)	2 (<1%)	0	0	8 (2%)
Toothache	5 (1%)	1 (<1%)	2 (<1%)	0	8 (2%)
Dyspepsia	5 (1%)	1 (<1%)	0	0	6 (1%)
Anal fissure	4 (<1%)	0	0	0	4 (<1%)
Anogenital dysplasia	1 (<1%)	2 (<1%)	1 (<1%)	0	4 (<1%)
Proctalgia	1 (<1%)	3 (<1%)	0	0	4 (<1%)
Abdominal pain lower	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Food poisoning	1 (<1%)	1 (<1%)	1 (<1%)	0	3 (<1%)
Oral pain	1 (<1%)	2 (<1%)	0	0	3 (<1%)
Proctitis	1 (<1%)	2 (<1%)	0	0	3 (<1%)
Abdominal discomfort	2 (<1%)	0	0	0	2 (<1%)
Anal fistula	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Anal pruritus	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Anal ulcer	2 (<1%)	0	0	0	2 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Aphthous stomatitis	2 (<1%)	0	0	0	2 (<1%)
Dental caries	0	1 (<1%)	1 (<1%)	0	2 (<1%)
Dry mouth	2 (<1%)	0	0	0	2 (<1%)
Gingivitis	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Glossitis	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Haematochezia	2 (<1%)	0	0	0	2 (<1%)
Rectal haemorrhage	2 (<1%)	0	0	0	2 (<1%)
Anal haemorrhage	1 (<1%)	0	0	0	1 (<1%)
Anal inflammation	1 (<1%)	0	0	0	1 (<1%)
Anal polyp	1 (<1%)	0	0	0	1 (<1%)
Anorectal discomfort	1 (<1%)	0	0	0	1 (<1%)
Breath odour	1 (<1%)	0	0	0	1 (<1%)
Cheilitis	1 (<1%)	0	0	0	1 (<1%)
Crohn's disease	1 (<1%)	0	0	0	1 (<1%)
Dysphagia	1 (<1%)	0	0	0	1 (<1%)
Enterocolitis	1 (<1%)	0	0	0	1 (<1%)
Eructation	1 (<1%)	0	0	0	1 (<1%)
Gastritis	1 (<1%)	0	0	0	1 (<1%)
Gastrointestinal pain	0	0	1 (<1%)	0	1 (<1%)
Gastrooesophageal reflux disease	1 (<1%)	0	0	0	1 (<1%)
Hiatus hernia	0	1 (<1%)	0	0	1 (<1%)
Lip swelling	0	1 (<1%)	0	0	1 (<1%)
Mouth cyst	1 (<1%)	0	0	0	1 (<1%)
Odynophagia	0	0	1 (<1%)	0	1 (<1%)
Proctocolitis	0	1 (<1%)	0	0	1 (<1%)
Rectal fissure	0	1 (<1%)	0	0	1 (<1%)
Salivary hypersecretion	1 (<1%)	0	0	0	1 (<1%)
Stomatitis	0	1 (<1%)	0	0	1 (<1%)
Tongue ulceration	1 (<1%)	0	0	0	1 (<1%)
Tooth disorder	0	1 (<1%)	0	0	1 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Nervous system disorders					
Any Event	168 (40%)	34 (8%)	9 (2%)	1 (<1%)	212 (51%)
Dizziness	127 (30%)	18 (4%)	3 (<1%)	0	148 (35%)
Headache	43 (10%)	11 (3%)	2 (<1%)	0	56 (13%)
Somnolence	19 (5%)	3 (<1%)	1 (<1%)	0	23 (5%)
Paraesthesia	8 (2%)	0	0	0	8 (2%)
Hypoaesthesia	6 (1%)	1 (<1%)	0	0	7 (2%)
Hypersomnia	3 (<1%)	1 (<1%)	1 (<1%)	0	5 (1%)
Disturbance in attention	3 (<1%)	1 (<1%)	0	0	4 (<1%)
Dysgeusia	4 (<1%)	0	0	0	4 (<1%)
Memory impairment	3 (<1%)	1 (<1%)	0	0	4 (<1%)
Poor quality sleep	3 (<1%)	1 (<1%)	0	0	4 (<1%)
Balance disorder	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Sciatica	2 (<1%)	0	1 (<1%)	0	3 (<1%)
Syncope	3 (<1%)	0	0	0	3 (<1%)
Amnesia	1 (<1%)	0	1 (<1%)	0	2 (<1%)
Aphonia	2 (<1%)	0	0	0	2 (<1%)
Migraine	2 (<1%)	0	0	0	2 (<1%)
Sinus headache	2 (<1%)	0	0	0	2 (<1%)
Tremor	2 (<1%)	0	0	0	2 (<1%)
Cerebrovascular accident	0	0	0	1 (<1%)	1 (<1%)
Cervicobrachial syndrome	1 (<1%)	0	0	0	1 (<1%)
Convulsion	1 (<1%)	0	0	0	1 (<1%)
Depressed level of consciousness	1 (<1%)	0	0	0	1 (<1%)
Dizziness postural	1 (<1%)	0	0	0	1 (<1%)
Dystonia	1 (<1%)	0	0	0	1 (<1%)
Hemiparesis	0	1 (<1%)	0	0	1 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Hydrocephalus	0	0	1 (<1%)	0	1 (<1%)
Intercostal neuralgia	0	1 (<1%)	0	0	1 (<1%)
Loss of consciousness	0	1 (<1%)	0	0	1 (<1%)
Mental impairment	0	1 (<1%)	0	0	1 (<1%)
Muscle contractions involuntary	1 (<1%)	0	0	0	1 (<1%)
Myelopathy	1 (<1%)	0	0	0	1 (<1%)
Neuralgia	1 (<1%)	0	0	0	1 (<1%)
Neuropathy peripheral	0	0	1 (<1%)	0	1 (<1%)
Neurotoxicity	0	0	1 (<1%)	0	1 (<1%)
Restless legs syndrome	1 (<1%)	0	0	0	1 (<1%)
Sensory loss	1 (<1%)	0	0	0	1 (<1%)
VIIth nerve paralysis	0	1 (<1%)	0	0	1 (<1%)
Psychiatric disorders					
Any Event	111 (26%)	42 (10%)	13 (3%)	2 (<1%)	168 (40%)
Abnormal dreams	63 (15%)	8 (2%)	1 (<1%)	0	72 (17%)
Insomnia	27 (6%)	16 (4%)	0	0	43 (10%)
Anxiety	15 (4%)	10 (2%)	2 (<1%)	0	27 (6%)
Depression	12 (3%)	9 (2%)	5 (1%)	0	26 (6%)
Nightmare	12 (3%)	4 (<1%)	1 (<1%)	0	17 (4%)
Sleep disorder	8 (2%)	3 (<1%)	0	0	11 (3%)
Depressed mood	7 (2%)	0	0	0	7 (2%)
Libido decreased	4 (<1%)	0	0	0	4 (<1%)
Suicidal ideation	1 (<1%)	1 (<1%)	1 (<1%)	1 (<1%)	4 (<1%)
Anger	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Nervousness	3 (<1%)	0	0	0	3 (<1%)
Affect lability	2 (<1%)	0	0	0	2 (<1%)
Alcohol abuse	0	0	1 (<1%)	1 (<1%)	2 (<1%)
Confusional state	2 (<1%)	0	0	0	2 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Depressive symptom	0	2 (<1%)	0	0	2 (<1%)
Disorientation	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Euphoric mood	0	2 (<1%)	0	0	2 (<1%)
Hallucination, visual	0	1 (<1%)	1 (<1%)	0	2 (<1%)
Homicidal ideation	0	1 (<1%)	1 (<1%)	0	2 (<1%)
Mood altered	2 (<1%)	0	0	0	2 (<1%)
Stress	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Acute stress disorder	1 (<1%)	0	0	0	1 (<1%)
Affective disorder	1 (<1%)	0	0	0	1 (<1%)
Agitation	1 (<1%)	0	0	0	1 (<1%)
Alcoholism	0	0	0	1 (<1%)	1 (<1%)
Bipolar I disorder	0	0	1 (<1%)	0	1 (<1%)
Bipolar II disorder	0	1 (<1%)	0	0	1 (<1%)
Claustrophobia	1 (<1%)	0	0	0	1 (<1%)
Drug abuse	1 (<1%)	0	0	0	1 (<1%)
Emotional disorder	0	1 (<1%)	0	0	1 (<1%)
Mania	0	0	1 (<1%)	0	1 (<1%)
Middle insomnia	1 (<1%)	0	0	0	1 (<1%)
Mood swings	1 (<1%)	0	0	0	1 (<1%)
Paranoia	0	0	0	1 (<1%)	1 (<1%)
Somnambulism	1 (<1%)	0	0	0	1 (<1%)
Substance abuse	0	1 (<1%)	0	0	1 (<1%)
Suicidal behaviour	0	0	0	1 (<1%)	1 (<1%)
Suicide attempt	0	0	1 (<1%)	0	1 (<1%)
Terminal insomnia	1 (<1%)	0	0	0	1 (<1%)
Thinking abnormal	1 (<1%)	0	0	0	1 (<1%)
Withdrawal syndrome	0	1 (<1%)	0	0	1 (<1%)
Skin and subcutaneous tissue disorders					
Any Event	84 (20%)	46 (11%)	3 (<1%)	0	133

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
					(32%)
Rash	39 (9%)	19 (5%)	0	0	58 (14%)
Pruritus	9 (2%)	4 (<1%)	0	0	13 (3%)
Night sweats	10 (2%)	2 (<1%)	0	0	12 (3%)
Alopecia	6 (1%)	2 (<1%)	0	0	8 (2%)
Rash generalised	6 (1%)	2 (<1%)	0	0	8 (2%)
Dermatitis	5 (1%)	2 (<1%)	0	0	7 (2%)
Dry skin	5 (1%)	2 (<1%)	0	0	7 (2%)
Acne	5 (1%)	0	0	0	5 (1%)
Eczema	3 (<1%)	1 (<1%)	1 (<1%)	0	5 (1%)
Rash maculo-papular	0	5 (1%)	0	0	5 (1%)
Hyperhidrosis	4 (<1%)	0	0	0	4 (<1%)
Drug eruption	0	2 (<1%)	1 (<1%)	0	3 (<1%)
Erythema	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Seborrhoeic dermatitis	2 (<1%)	0	1 (<1%)	0	3 (<1%)
Dermal cyst	2 (<1%)	0	0	0	2 (<1%)
Dermatitis allergic	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Dermatitis contact	2 (<1%)	0	0	0	2 (<1%)
Hyperkeratosis	2 (<1%)	0	0	0	2 (<1%)
Nail discolouration	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Prurigo	0	2 (<1%)	0	0	2 (<1%)
Skin lesion	2 (<1%)	0	0	0	2 (<1%)
Angioedema	1 (<1%)	0	0	0	1 (<1%)
Blister	1 (<1%)	0	0	0	1 (<1%)
Cold sweat	0	1 (<1%)	0	0	1 (<1%)
Dermatitis atopic	1 (<1%)	0	0	0	1 (<1%)
Dyshidrosis	1 (<1%)	0	0	0	1 (<1%)
Hair texture abnormal	1 (<1%)	0	0	0	1 (<1%)
Increased tendency to bruise	1 (<1%)	0	0	0	1 (<1%)
Ingrown hair	1 (<1%)	0	0	0	1 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Livedo reticularis	1 (<1%)	0	0	0	1 (<1%)
Neurodermatitis	1 (<1%)	0	0	0	1 (<1%)
Onychomalacia	1 (<1%)	0	0	0	1 (<1%)
Papule	1 (<1%)	0	0	0	1 (<1%)
Pruritus generalised	0	1 (<1%)	0	0	1 (<1%)
Rash macular	0	1 (<1%)	0	0	1 (<1%)
Rash pruritic	1 (<1%)	0	0	0	1 (<1%)
Rosacea	1 (<1%)	0	0	0	1 (<1%)
Sebaceous hyperplasia	1 (<1%)	0	0	0	1 (<1%)
Seborrhoea	0	1 (<1%)	0	0	1 (<1%)
Skin exfoliation	1 (<1%)	0	0	0	1 (<1%)
Skin ulcer	1 (<1%)	0	0	0	1 (<1%)
Urticaria	1 (<1%)	0	0	0	1 (<1%)
Urticaria thermal	1 (<1%)	0	0	0	1 (<1%)
Xeroderma	1 (<1%)	0	0	0	1 (<1%)
General disorders and administration site conditions					
Any Event	72 (17%)	27 (6%)	3 (<1%)	0	102 (24%)
Fatigue	41 (10%)	7 (2%)	2 (<1%)	0	50 (12%)
Pyrexia	16 (4%)	6 (1%)	0	0	22 (5%)
Asthenia	8 (2%)	5 (1%)	1 (<1%)	0	14 (3%)
Influenza like illness	3 (<1%)	2 (<1%)	0	0	5 (1%)
Pain	4 (<1%)	0	0	0	4 (<1%)
Chest pain	3 (<1%)	0	0	0	3 (<1%)
Feeling drunk	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Oedema peripheral	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Chills	2 (<1%)	0	0	0	2 (<1%)
Cyst	1 (<1%)	1 (<1%)	0	0	2 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Energy increased	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Feeling abnormal	2 (<1%)	0	0	0	2 (<1%)
Irritability	0	2 (<1%)	0	0	2 (<1%)
Malaise	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Thirst	0	2 (<1%)	0	0	2 (<1%)
Chronic fatigue syndrome	1 (<1%)	0	0	0	1 (<1%)
Discomfort	1 (<1%)	0	0	0	1 (<1%)
Feeling hot	1 (<1%)	0	0	0	1 (<1%)
Hernia	1 (<1%)	0	0	0	1 (<1%)
Local swelling	0	1 (<1%)	0	0	1 (<1%)
Mass	1 (<1%)	0	0	0	1 (<1%)
Non-cardiac chest pain	1 (<1%)	0	0	0	1 (<1%)
Musculoskeletal and connective tissue disorders					
Any Event	51 (12%)	29 (7%)	2 (<1%)	0	82 (20%)
Back pain	9 (2%)	7 (2%)	1 (<1%)	0	17 (4%)
Arthralgia	7 (2%)	8 (2%)	1 (<1%)	0	16 (4%)
Myalgia	15 (4%)	1 (<1%)	0	0	16 (4%)
Pain in extremity	6 (1%)	4 (<1%)	0	0	10 (2%)
Muscle twitching	3 (<1%)	0	0	0	3 (<1%)
Musculoskeletal pain	3 (<1%)	0	0	0	3 (<1%)
Tendonitis	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Coccydynia	2 (<1%)	0	0	0	2 (<1%)
Flank pain	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Groin pain	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Joint swelling	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Muscle spasms	2 (<1%)	0	0	0	2 (<1%)
Neck pain	2 (<1%)	0	0	0	2 (<1%)
Rotator cuff syndrome	1 (<1%)	1 (<1%)	0	0	2 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Costochondritis	1 (<1%)	0	0	0	1 (<1%)
Kyphoscoliosis	0	1 (<1%)	0	0	1 (<1%)
Muscle atrophy	0	1 (<1%)	0	0	1 (<1%)
Muscle tightness	1 (<1%)	0	0	0	1 (<1%)
Myositis	1 (<1%)	0	0	0	1 (<1%)
Osteochondrosis	1 (<1%)	0	0	0	1 (<1%)
Osteopenia	1 (<1%)	0	0	0	1 (<1%)
Osteoporosis	0	1 (<1%)	0	0	1 (<1%)
Patellofemoral pain syndrome	1 (<1%)	0	0	0	1 (<1%)
Spinal disorder	0	1 (<1%)	0	0	1 (<1%)
Synovitis	0	1 (<1%)	0	0	1 (<1%)
Respiratory, thoracic and mediastinal disorders					
Any Event	58 (14%)	13 (3%)	5 (1%)	1 (<1%)	77 (18%)
Cough	26 (6%)	3 (<1%)	0	0	29 (7%)
Oropharyngeal pain	10 (2%)	2 (<1%)	2 (<1%)	0	14 (3%)
Nasal congestion	9 (2%)	0	0	0	9 (2%)
Productive cough	5 (1%)	0	0	0	5 (1%)
Rhinitis allergic	3 (<1%)	2 (<1%)	0	0	5 (1%)
Rhinorrhoea	4 (<1%)	1 (<1%)	0	0	5 (1%)
Sinus congestion	4 (<1%)	1 (<1%)	0	0	5 (1%)
Dyspnoea	4 (<1%)	0	0	0	4 (<1%)
Sneezing	4 (<1%)	0	0	0	4 (<1%)
Asthma	1 (<1%)	1 (<1%)	1 (<1%)	0	3 (<1%)
Throat irritation	3 (<1%)	0	0	0	3 (<1%)
Nasal discomfort	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Respiratory distress	0	0	2 (<1%)	0	2 (<1%)
Allergic sinusitis	0	1 (<1%)	0	0	1 (<1%)
Chronic obstructive pulmonary disease	0	1 (<1%)	0	0	1 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Dyspnoea at rest	1 (<1%)	0	0	0	1 (<1%)
Dyspnoea exertional	1 (<1%)	0	0	0	1 (<1%)
Nasal ulcer	1 (<1%)	0	0	0	1 (<1%)
Pharyngeal oedema	0	1 (<1%)	0	0	1 (<1%)
Pharyngeal ulceration	1 (<1%)	0	0	0	1 (<1%)
Pneumonia aspiration	0	0	1 (<1%)	0	1 (<1%)
Pulmonary cavitation	0	1 (<1%)	0	0	1 (<1%)
Respiratory disorder	1 (<1%)	0	0	0	1 (<1%)
Respiratory failure	0	0	0	1 (<1%)	1 (<1%)
Respiratory tract congestion	1 (<1%)	0	0	0	1 (<1%)
Respiratory tract irritation	1 (<1%)	0	0	0	1 (<1%)
Sleep apnoea syndrome	0	1 (<1%)	0	0	1 (<1%)
Sputum discoloured	1 (<1%)	0	0	0	1 (<1%)
Sputum increased	1 (<1%)	0	0	0	1 (<1%)
Tonsillar hypertrophy	1 (<1%)	0	0	0	1 (<1%)
Injury, poisoning and procedural complications					
Any Event	26 (6%)	18 (4%)	3 (<1%)	2 (<1%)	49 (12%)
Contusion	4 (<1%)	2 (<1%)	0	0	6 (1%)
Ligament sprain	4 (<1%)	1 (<1%)	0	0	5 (1%)
Procedural pain	1 (<1%)	4 (<1%)	0	0	5 (1%)
Laceration	2 (<1%)	2 (<1%)	0	0	4 (<1%)
Hand fracture	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Muscle strain	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Animal bite	2 (<1%)	0	0	0	2 (<1%)
Arthropod bite	2 (<1%)	0	0	0	2 (<1%)
Epicondylitis	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Joint injury	0	2 (<1%)	0	0	2 (<1%)
Limb injury	2 (<1%)	0	0	0	2 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Muscle injury	0	1 (<1%)	0	1 (<1%)	2 (<1%)
Tooth fracture	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Arthropod sting	1 (<1%)	0	0	0	1 (<1%)
Excoriation	1 (<1%)	0	0	0	1 (<1%)
Exposure to communicable disease	1 (<1%)	0	0	0	1 (<1%)
Eye injury	1 (<1%)	0	0	0	1 (<1%)
Fall	1 (<1%)	0	0	0	1 (<1%)
Foot fracture	0	0	1 (<1%)	0	1 (<1%)
Limb crushing injury	0	1 (<1%)	0	0	1 (<1%)
Meniscus lesion	0	1 (<1%)	0	0	1 (<1%)
Muscle rupture	1 (<1%)	0	0	0	1 (<1%)
Overdose	0	0	1 (<1%)	0	1 (<1%)
Post procedural haemorrhage	1 (<1%)	0	0	0	1 (<1%)
Rib fracture	0	1 (<1%)	0	0	1 (<1%)
Road traffic accident	0	1 (<1%)	0	0	1 (<1%)
Sunburn	1 (<1%)	0	0	0	1 (<1%)
Upper limb fracture	0	0	1 (<1%)	0	1 (<1%)
Vascular pseudoaneurysm	0	0	0	1 (<1%)	1 (<1%)
Wound	0	1 (<1%)	0	0	1 (<1%)
Metabolism and nutrition disorders					
Any Event	23 (5%)	7 (2%)	6 (1%)	1 (<1%)	37 (9%)
Decreased appetite	13 (3%)	1 (<1%)	1 (<1%)	0	15 (4%)
Vitamin D deficiency	5 (1%)	0	0	0	5 (1%)
Hypercholesterolaemia	1 (<1%)	1 (<1%)	1 (<1%)	0	3 (<1%)
Alcohol intolerance	2 (<1%)	0	0	0	2 (<1%)
Gout	0	1 (<1%)	1 (<1%)	0	2 (<1%)
Hypertriglyceridaemia	0	1 (<1%)	0	1 (<1%)	2 (<1%)
Increased appetite	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Abnormal loss of weight	0	0	1 (<1%)	0	1 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Dehydration	1 (<1%)	0	0	0	1 (<1%)
Dyslipidaemia	1 (<1%)	0	0	0	1 (<1%)
Food intolerance	0	1 (<1%)	0	0	1 (<1%)
Hyperglycaemia	0	0	1 (<1%)	0	1 (<1%)
Hypophosphataemia	0	0	1 (<1%)	0	1 (<1%)
Type 2 diabetes mellitus	0	1 (<1%)	0	0	1 (<1%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Any Event	22 (5%)	4 (<1%)	1 (<1%)	0	27 (6%)
Anogenital warts	11 (3%)	2 (<1%)	0	0	13 (3%)
Skin papilloma	3 (<1%)	2 (<1%)	0	0	5 (1%)
Melanocytic naevus	2 (<1%)	0	0	0	2 (<1%)
Chondroma	1 (<1%)	0	0	0	1 (<1%)
Fibroma	1 (<1%)	0	0	0	1 (<1%)
Haemangioma of skin	1 (<1%)	0	0	0	1 (<1%)
Malignant melanoma	0	1 (<1%)	0	0	1 (<1%)
Morton's neuroma	1 (<1%)	0	0	0	1 (<1%)
Ovarian cancer	0	0	1 (<1%)	0	1 (<1%)
Seborrhoeic keratosis	1 (<1%)	0	0	0	1 (<1%)
Thyroid neoplasm	1 (<1%)	0	0	0	1 (<1%)
Reproductive system and breast disorders					
Any Event	18 (4%)	6 (1%)	0	0	24 (6%)
Erectile dysfunction	4 (<1%)	1 (<1%)	0	0	5 (1%)
Gynaecomastia	3 (<1%)	1 (<1%)	0	0	4 (<1%)
Prostatitis	2 (<1%)	0	0	0	2 (<1%)
Breast mass	1 (<1%)	0	0	0	1 (<1%)
Breast pain	0	1 (<1%)	0	0	1 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Cervical dysplasia	0	1 (<1%)	0	0	1 (<1%)
Menometrorrhagia	0	1 (<1%)	0	0	1 (<1%)
Menorrhagia	1 (<1%)	0	0	0	1 (<1%)
Menstrual disorder	1 (<1%)	0	0	0	1 (<1%)
Menstruation irregular	1 (<1%)	0	0	0	1 (<1%)
Orchitis noninfective	1 (<1%)	0	0	0	1 (<1%)
Penile pain	1 (<1%)	0	0	0	1 (<1%)
Scrotal pain	0	1 (<1%)	0	0	1 (<1%)
Testicular disorder	1 (<1%)	0	0	0	1 (<1%)
Testicular pain	1 (<1%)	0	0	0	1 (<1%)
Vaginal discharge	1 (<1%)	0	0	0	1 (<1%)
Vaginal odour	1 (<1%)	0	0	0	1 (<1%)
Vulvovaginal pruritus	1 (<1%)	0	0	0	1 (<1%)
Investigations					
Any Event	8 (2%)	11 (3%)	6 (1%)	2 (<1%)	27 (6%)
Blood creatine phosphokinase increased	0	2 (<1%)	2 (<1%)	2 (<1%)	6 (1%)
Weight decreased	3 (<1%)	1 (<1%)	1 (<1%)	0	5 (1%)
Alanine aminotransferase increased	0	3 (<1%)	0	0	3 (<1%)
Weight increased	2 (<1%)	1 (<1%)	0	0	3 (<1%)
Blood pressure increased	2 (<1%)	0	0	0	2 (<1%)
Aspartate aminotransferase increased	0	1 (<1%)	0	0	1 (<1%)
Blood bilirubin increased	0	0	1 (<1%)	0	1 (<1%)
Blood creatinine increased	0	1 (<1%)	0	0	1 (<1%)
Blood phosphorus decreased	0	0	1 (<1%)	0	1 (<1%)
Blood potassium increased	0	0	1 (<1%)	0	1 (<1%)
Human papilloma virus test positive	1 (<1%)	0	0	0	1 (<1%)
Liver function test abnormal	1 (<1%)	0	0	0	1 (<1%)
Platelet count decreased	0	1 (<1%)	0	0	1 (<1%)
Smear cervix abnormal	1 (<1%)	0	0	0	1 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Treponema test positive	0	1 (<1%)	0	0	1 (<1%)
Urine albumin/creatinine ratio increased	0	1 (<1%)	0	0	1 (<1%)
Eye disorders					
Any Event	17 (4%)	3 (<1%)	0	0	20 (5%)
Conjunctivitis	10 (2%)	2 (<1%)	0	0	12 (3%)
Eye swelling	2 (<1%)	0	0	0	2 (<1%)
Vision blurred	2 (<1%)	0	0	0	2 (<1%)
Blepharitis	1 (<1%)	0	0	0	1 (<1%)
Eye irritation	1 (<1%)	0	0	0	1 (<1%)
Lacrimation increased	1 (<1%)	0	0	0	1 (<1%)
Photophobia	1 (<1%)	0	0	0	1 (<1%)
Presbyopia	1 (<1%)	0	0	0	1 (<1%)
Visual acuity reduced	0	1 (<1%)	0	0	1 (<1%)
Ear and labyrinth disorders					
Any Event	15 (4%)	10 (2%)	1 (<1%)	0	26 (6%)
Vertigo	9 (2%)	6 (1%)	1 (<1%)	0	16 (4%)
Cerumen impaction	1 (<1%)	2 (<1%)	0	0	3 (<1%)
Ear pain	3 (<1%)	0	0	0	3 (<1%)
Deafness unilateral	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Tinnitus	2 (<1%)	0	0	0	2 (<1%)
Auricular swelling	0	1 (<1%)	0	0	1 (<1%)
Renal and urinary disorders					
Any Event	13 (3%)	6 (1%)	1 (<1%)	1 (<1%)	21 (5%)
Dysuria	3 (<1%)	1 (<1%)	0	0	4 (<1%)
Nephrolithiasis	1 (<1%)	2 (<1%)	0	0	3 (<1%)
Micturition urgency	1 (<1%)	1 (<1%)	0	0	2 (<1%)
Proteinuria	1 (<1%)	1 (<1%)	0	0	2 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Renal failure	1 (<1%)	0	0	1 (<1%)	2 (<1%)
Urethral discharge	2 (<1%)	0	0	0	2 (<1%)
Bladder fibrosis	0	1 (<1%)	0	0	1 (<1%)
Nocturia	1 (<1%)	0	0	0	1 (<1%)
Pyuria	0	1 (<1%)	0	0	1 (<1%)
Renal failure acute	0	1 (<1%)	0	0	1 (<1%)
Renal failure chronic	0	0	1 (<1%)	0	1 (<1%)
Urinary incontinence	1 (<1%)	0	0	0	1 (<1%)
Urinary tract pain	1 (<1%)	0	0	0	1 (<1%)
Urine odour abnormal	1 (<1%)	0	0	0	1 (<1%)
Immune system disorders					
Any Event	9 (2%)	2 (<1%)	4 (<1%)	0	15 (4%)
Seasonal allergy	6 (1%)	0	0	0	6 (1%)
Hypersensitivity	0	0	3 (<1%)	0	3 (<1%)
Drug hypersensitivity	1 (<1%)	0	1 (<1%)	0	2 (<1%)
Immune reconstitution syndrome	0	2 (<1%)	0	0	2 (<1%)
Multiple allergies	2 (<1%)	0	0	0	2 (<1%)
Vascular disorders					
Any Event	11 (3%)	5 (1%)	1 (<1%)	0	17 (4%)
Flushing	5 (1%)	1 (<1%)	0	0	6 (1%)
Hypertension	2 (<1%)	2 (<1%)	0	0	4 (<1%)
Hot flush	2 (<1%)	0	0	0	2 (<1%)
Angiopathy	0	1 (<1%)	0	0	1 (<1%)
Arterial disorder	1 (<1%)	0	0	0	1 (<1%)
Deep vein thrombosis	0	0	1 (<1%)	0	1 (<1%)
Hypotension	0	1 (<1%)	0	0	1 (<1%)
Varicose vein	1 (<1%)	0	0	0	1 (<1%)

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Blood and lymphatic system disorders					
Any Event	6 (1%)	1 (<1%)	3 (<1%)	1 (<1%)	11 (3%)
Anaemia	3 (<1%)	0	1 (<1%)	0	4 (<1%)
Lymphadenopathy	3 (<1%)	0	1 (<1%)	0	4 (<1%)
Neutropenia	0	1 (<1%)	0	1 (<1%)	2 (<1%)
Disseminated intravascular coagulation	0	0	1 (<1%)	0	1 (<1%)
Cardiac disorders					
Any Event	3 (<1%)	2 (<1%)	1 (<1%)	0	6 (1%)
Palpitations	2 (<1%)	0	0	0	2 (<1%)
Atrial fibrillation	0	0	1 (<1%)	0	1 (<1%)
Atrial flutter	0	0	1 (<1%)	0	1 (<1%)
Cardiac flutter	0	1 (<1%)	0	0	1 (<1%)
Coronary artery disease	0	1 (<1%)	0	0	1 (<1%)
Tachycardia	1 (<1%)	0	0	0	1 (<1%)
Hepatobiliary disorders					
Any Event	0	2 (<1%)	1 (<1%)	0	3 (<1%)
Autoimmune hepatitis	0	1 (<1%)	0	0	1 (<1%)
Cholecystitis	0	0	1 (<1%)	0	1 (<1%)
Cholelithiasis	0	1 (<1%)	0	0	1 (<1%)
Pregnancy, puerperium and perinatal conditions					
Any Event	0	1 (<1%)	1 (<1%)	0	2 (<1%)
Abortion spontaneous	0	1 (<1%)	0	0	1 (<1%)
Ectopic pregnancy	0	0	1 (<1%)	0	1 (<1%)
Congenital, familial and genetic disorders					

Treatment: Atripla QD (N=419)

System Organ Class Preferred Term	Maximum Toxicity Grade 1	Grade 2	Grade 3	Grade 4	Total
Any Event	1 (<1%)	0	0	0	1 (<1%)
Dermoid cyst	1 (<1%)	0	0	0	1 (<1%)
Social circumstances					
Any Event	0	1 (<1%)	0	0	1 (<1%)
Family stress	0	1 (<1%)	0	0	1 (<1%)

Table S6. Summary of Serious Adverse Events by System Organ Class

Protocol: ING114467
Population: Safety
Summary of Serious Adverse Events by System Organ Class

System Organ Class Preferred Term	DTG 50 mg +ABC/3TC QD (N=414)	Atripla QD (N=419)
ANY EVENT	37 (9%)	35 (8%)
Infections and infestations		
Any event	13 (3%)	12 (3%)
Pneumonia	2 (<1%)	2 (<1%)
Bronchitis	1 (<1%)	1 (<1%)
Syphilis	2 (<1%)	0
Appendicitis	1 (<1%)	0
Bacteraemia	0	1 (<1%)
Cellulitis	0	1 (<1%)
Gastroenteritis	0	1 (<1%)
Infected dermal cyst	1 (<1%)	0
Meningitis	1 (<1%)	0
Meningitis cryptococcal	0	1 (<1%)
Mycobacterium avium complex infection	1 (<1%)	0
Neurosyphilis	1 (<1%)	0
Pneumococcal sepsis	0	1 (<1%)
Post procedural infection	1 (<1%)	0
Postoperative wound infection	1 (<1%)	0
Scrotal abscess	0	1 (<1%)
Sepsis	0	1 (<1%)
Septic shock	0	1 (<1%)
Staphylococcal abscess	0	1 (<1%)
Subcutaneous abscess	0	1 (<1%)
Systemic candida	0	1 (<1%)
Toxoplasmosis	1 (<1%)	0
Tuberculosis	1 (<1%)	0

System Organ Class Preferred Term	DTG 50 mg +ABC/3TC QD (N=414)	Atripla QD (N=419)
Viral infection	1 (<1%)	0
Injury, poisoning and procedural complications		
Any event	8 (2%)	3 (<1%)
Foot fracture	1 (<1%)	1 (<1%)
Intentional overdose	2 (<1%)	0
Head injury	1 (<1%)	0
Humerus fracture	1 (<1%)	0
Jaw fracture	1 (<1%)	0
Overdose	0	1 (<1%)
Road traffic accident	1 (<1%)	0
Subdural haematoma	1 (<1%)	0
Vascular pseudoaneurysm	0	1 (<1%)
Psychiatric disorders		
Any event	3 (<1%)	8 (2%)
Suicidal ideation	1 (<1%)	2 (<1%)
Suicide attempt	2 (<1%)	1 (<1%)
Depression	0	2 (<1%)
Homicidal ideation	1 (<1%)	1 (<1%)
Alcohol abuse	0	1 (<1%)
Bipolar I disorder	0	1 (<1%)
Hallucination, visual	0	1 (<1%)
Mania	0	1 (<1%)
Paranoia	0	1 (<1%)
Suicidal behaviour	0	1 (<1%)
Nervous system disorders		
Any event	3 (<1%)	3 (<1%)
Cerebrovascular accident	1 (<1%)	1 (<1%)
Carpal tunnel syndrome	1 (<1%)	0
Convulsion	0	1 (<1%)

System Organ Class Preferred Term	DTG 50 mg +ABC/3TC QD (N=414)	Atripla QD (N=419)
Grand mal convulsion	1 (<1%)	0
Sciatica	0	1 (<1%)
Respiratory, thoracic and mediastinal disorders		
Any event	2 (<1%)	4 (<1%)
Respiratory distress	0	2 (<1%)
Asthma	0	1 (<1%)
Pleural effusion	1 (<1%)	0
Pneumonia aspiration	0	1 (<1%)
Respiratory failure	0	1 (<1%)
Tonsillar disorder	1 (<1%)	0
Blood and lymphatic system disorders		
Any event	1 (<1%)	3 (<1%)
Anaemia	0	1 (<1%)
Disseminated intravascular coagulation	0	1 (<1%)
Febrile neutropenia	1 (<1%)	0
Lymphadenopathy	0	1 (<1%)
Cardiac disorders		
Any event	1 (<1%)	2 (<1%)
Atrial fibrillation	0	1 (<1%)
Atrial flutter	0	1 (<1%)
Cardiac failure congestive	1 (<1%)	0
Coronary artery disease	0	1 (<1%)
Immune system disorders		
Any event	1 (<1%)	2 (<1%)
Hypersensitivity	0	2 (<1%)
Drug hypersensitivity	1 (<1%)	0
Musculoskeletal and connective tissue disorders		

System Organ Class Preferred Term	DTG 50 mg +ABC/3TC QD (N=414)	Atripla QD (N=419)
Any event	2 (<1%)	1 (<1%)
Myalgia	1 (<1%)	0
Osteoarthritis	1 (<1%)	0
Rotator cuff syndrome	0	1 (<1%)
Tendon disorder	1 (<1%)	0
Renal and urinary disorders		
Any event	1 (<1%)	2 (<1%)
Renal cyst	1 (<1%)	0
Renal failure	0	1 (<1%)
Renal failure chronic	0	1 (<1%)
General disorders and administration site conditions		
Any event	2 (<1%)	0
Non-cardiac chest pain	1 (<1%)	0
Pyrexia	1 (<1%)	0
Pregnancy, puerperium and perinatal conditions		
Any event	0	2 (<1%)
Abortion spontaneous	0	1 (<1%)
Ectopic pregnancy	0	1 (<1%)
Reproductive system and breast disorders		
Any event	2 (<1%)	0
Bartholin's cyst	1 (<1%)	0
Priapism	1 (<1%)	0
Gastrointestinal disorders		
Any event	1 (<1%)	0
Food poisoning	1 (<1%)	0
Hepatobiliary disorders		

System Organ Class Preferred Term	DTG 50 mg +ABC/3TC QD (N=414)	Atripla QD (N=419)
Any event	0	1 (<1%)
Cholelithiasis	0	1 (<1%)
Metabolism and nutrition disorders		
Any event	1 (<1%)	0
Type 2 diabetes mellitus	1 (<1%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Any event	0	1 (<1%)
Ovarian cancer	0	1 (<1%)
Skin and subcutaneous tissue disorders		
Any event	1 (<1%)	0
Angioedema	1 (<1%)	0
Vascular disorders		
Any event	0	1 (<1%)
Deep vein thrombosis	0	1 (<1%)

Table S7. Viral Genotyping and Phenotyping Data.

Subject	Mutation	Phenotype	Treatment arm
Integrase inhibitor resistance genotypic and phenotypic results at PDVF (n=7; each arm)			
None	None	None	None
NNRTI resistance genotypic and phenotypic results at PDVF (n=9)			
A	K101E	1.9 FC to EFV	EFV/TDF/FTC
B	K103K/N	14 FC to EFV	EFV/TDF/FTC
C	K103N, G190G/A	22 FC to EFV	EFV/TDF/FTC
D	G190G/A	20 FC to EFV	EFV/TDF/FTC
NRTI resistance genotypic and phenotypic results at PDVF (n=9)			
E	0	1.39 FC to DDI*	DTG+ABC/3TC
D	K65K/R†	No change	EFV/TDF/FTC

*DDI clinical cutoff = 1.30;

†The Monogram Biosciences Net Assessment predicted resistance to ABC, DDI, FTC, 3TC, and TDF.

ABC denotes abacavir, DDI didanosine, DTG dolutegravir, EFV efavirenz, FC fold change, FTC emtricitabine, NRTI nucleoside reverse transcriptase inhibitor, NNRTI non-nucleoside reverse transcriptase inhibitor, PDVF protocol-defined virologic failure, 3TC lamivudine, and TDF tenofovir disoproxil fumarate.

Figure S1. Graphical Representation of the Snapshot Algorithm.

***Week X VL:** last on-treatment (double-blind, if applicable) HIV-1 RNA VL in week X window.

†Last VL: last on-treatment (double-blind, if applicable) HIV-1 RNA VL prior to week X.

Subreasons: ‡discontinued due to AE or death; §discontinued for other reasons; ¶missing data but on-treatment. **Note:** In addition, changes in background antiretroviral therapy means virologic failure according to the Snapshot algorithm. However, no changes in antiretroviral therapy were permitted in this protocol and none were made. AE denotes adverse event, VL viral load.

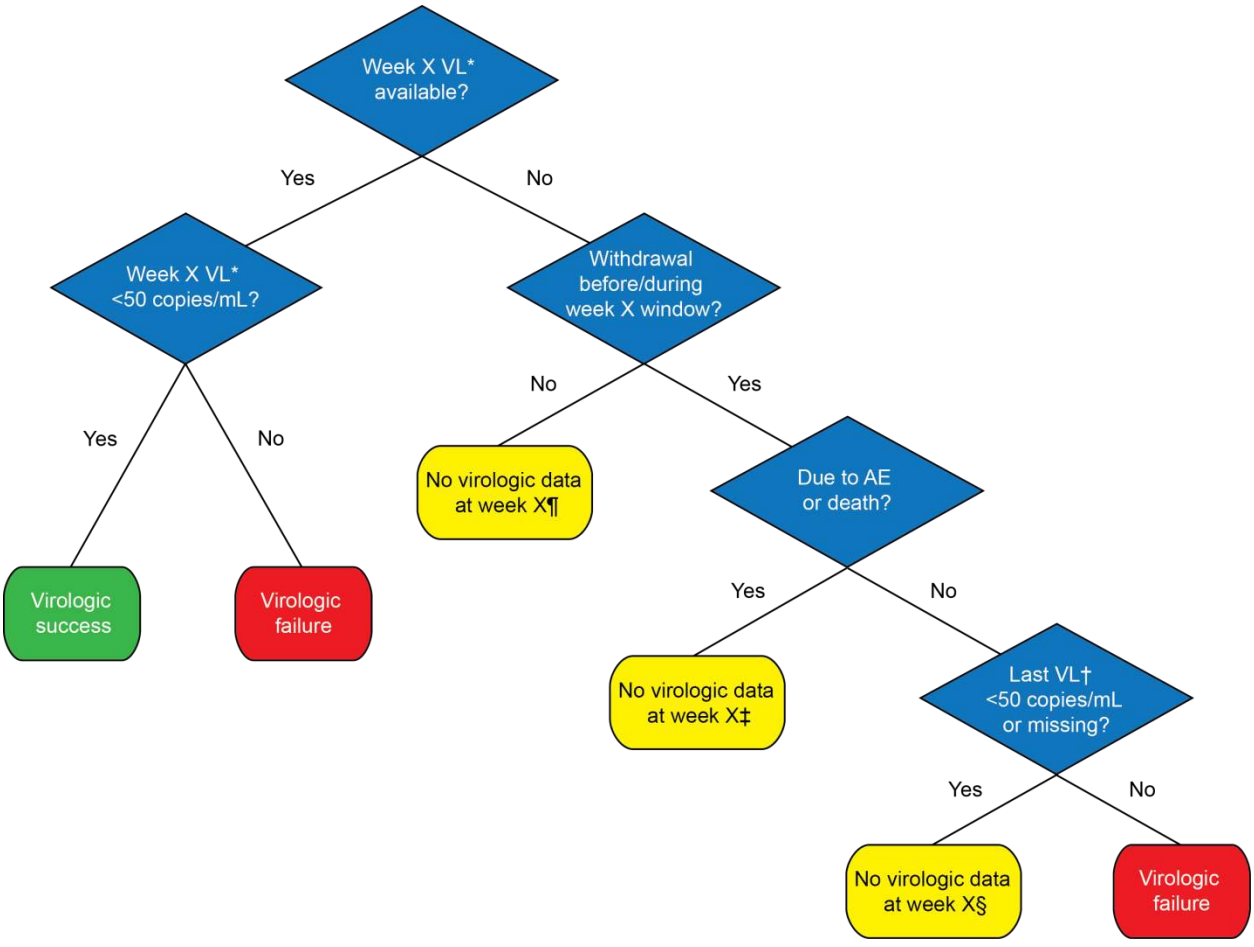

Figure S2. Kaplan-Meier Plot of Time to Viral Suppression (Viral Load <50 copies/mL).

The median time to viral suppression was 28 versus 84 days for DTG + ABC/3TC and EFV/TDF/FTC, respectively; the hazard ratio was estimated using Cox proportional hazard regression model. ABC denotes abacavir, DTG dolutegravir, EFV efavirenz, FTC emtricitabine, 3TC lamivudine, QD once daily, and TDF tenofovir disoproxil fumarate.