CSR synopsis for study GS-US-380-1490

Name of finished products: Biktarvy 50 mg/200 mg/25 mg film-coated tabletts (EU/1/18/1289/001-002)

Name of active substances: Bictegravir/Emtricitabin/ Tenofoviralafenamid

Date: June 2022

Name of company:
Gilead Sciences GmbH
Fraunhoferstraße 17
D-82152 Martinsried

FINAL CLINICAL STUDY REPORT

Study Title:	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9883/Emtricitabine/Tenofovir Alafenamide Versus Dolutegravir + Emtricitabine/Tenofovir Alafenamide in HIV-1 Infected, Antiretroviral Treatment-Naive Adults
Name of Test Drug:	Bictegravir (previously referred to as GS-9883)/Emtricitabine/Tenofovir Alafenamide (Biktarvy® [BVY])
Dose and Formulation:	Fixed-dose combination tablet containing 50 mg bictegravir (BIC, B), 200 mg emtricitabine (FTC, F), and 25 mg tenofovir alafenamide (TAF)
Indication:	Human immunodeficiency virus type 1 (HIV-1) infection
Sponsor:	Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA
Study No.:	GS-US-380-1490
Phase of Development:	Phase 3
IND No.: **EudraCT No.:**	125589 2015-003988-10
ClinicalTrials.gov Identifier:	NCT02607956
Study Start Date:	11 November 2015 (first participant screened)
Study End Date:	12 May 2017 (last participant last visit for the primary end point) 05 July 2021 (last participant last visit for this report)
Principal or Coordinating Investigator:	Name: Paul Sax, MD Affiliation: Brigham and Women's Hospital Infectious Disease Unit
Sponsor Responsible Medical Monitor:	Name: PPD MD, MPH Telephone: PPD
Report Date:	22 November 2021
Previous Report Date(s):	10 September 2019 (Week 144 Clinical Study Report) 08 October 2018 (Week 96 Clinical Study Report) 21 August 2017 (Week 48 Clinical Study Report, Amendment 1) 24 May 2017 (Week 48 Clinical Study Report)

This study was conducted in accordance with the guidelines of Good Clinical Practice, including archiving of essential documents.

STUDY SYNOPSIS

Study GS-US-380-1490
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404
USA

Title of Study: A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9883/Emtricitabine/Tenofovir Alafenamide Versus Dolutegravir + Emtricitabine/Tenofovir Alafenamide in HIV-1 Infected, Antiretroviral Treatment-Naive Adults

Investigators: This is a multicenter study.

Study Centers: Participants were enrolled and treated a total of 126 study centers: 6 in Australia, 2 in Belgium, 6 in Canada, 1 in the Dominican Republic, 4 in France, 8 in Germany, 3 in Italy, 8 in Spain, 11 in the United Kingdom (UK), and 77 in the United States (US).

Publications:

Sax PE, Pozniak A, Montes ML, Koenig E, DeJesus E, Stellbrink HJ, et al. Coformulated bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir with emtricitabine and tenofovir alafenamide, for initial treatment of HIV-1 infection (GS-US-380-1490): a randomised, double-blind, multicentre, phase 3, non-inferiority trial. Lancet. 2017 Nov 4;390(10107):2073-2082.

White K, Kulkarni R, Willkom M, Martin R, Chang S, Wei X, et al. Pooled week 48 efficacy and baseline resistance: B/F/TAF in treatment naive patients. [Poster 532]. Conference on Retroviruses and Opportunistic Infections; 2018 March 4-7; Boston, USA

Acosta R, White K, Garner W, Wei X, Andreatta K, Willkom M, et al. HIV-1 subtype (B or non B) had no impact on the efficacy of B/F/TAF or resistance development in five phase 3 treatment-naïve or switch studies. [Poster THPEB077]. 22nd International AIDS Conference; 2018 July 23-27; Amsterdam, Netherlands

Wohl D, Clarke A, Maggiolo F, Garner W, Laouri M, Martin H, et al. Patient reported symptoms over 48 weeks among participants in randomized, double blind, phase III non inferiority trials of adults with HIV on co formulated bictegravir, emtricitabine, and tenofovir alafenamide versus co formulated abacavir, dolutegravir, and lamivudine. Patient. 2018 Oct;11(5):561-573.

Acosta R, Willkom M, Martin R, Chang S, Wei X, Garner W, et al. Resistance analysis of bictegravir emtricitabine tenofovir alafenamide in HIV-1 treatment naive patients through 48 weeks. Antimicrob Agents Chemother 2019, May 63(5): e02533-18. https://doi.org/10.1128/AAC.02533-18.

Wohl DA, Yazdanpanah Y, Baumgarten A, Clarke A, Thompson M, Brinson C, et al. Bictegravir combined with emtricitabine and tenofovir alafenamide versus dolutegravir, abacavir, and lamivudine for initial treatment of HIV-1 infection: week 96 results from a randomised, double-blind, multicentre, phase 3, non-inferiority trial. The Lancet HIV 2019, Jun 6(6):e355 363. http://dx.doi.org/10.1016/S2352-3018(19)30077 3.

Stellbrink HJ, Arribas JR, Stephens JL, Albrecht H, Sax PE, Maggiolo F, et al. Co-formulated bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir with emtricitabine and tenofovir alafenamide for initial treatment of HIV-1 infection: week 96 results from a randomised, double-blind, multicentre, phase 3, non-inferiority trial. Lancet HIV. 2019 Jun;6(6):e364-e372

Gupta SK, Post FA, Arribas JR, Eron JJ Jr, Wohl DA, Clarke AE, et al. Renal safety of tenofovir alafenamide vs. tenofovir disoproxil fumarate: a pooled analysis of 26 clinical trials. AIDS. 2019 Jul 15;33(9):1455-1465.

Acosta R, Willkom M, Martin R, Chang S, Liu X, Hedskog C, et al. Low-frequency resistance variants in ART-naive participants do not affect bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) triple therapy outcome. [Poster MOPEB242]. 10th IAS Conference on HIV Science (IAS 2019); 2019 July 21-24; Mexico City, Mexico.

Acosta R, Andreatta K, D'Antoni M, Collins S, Martin H, White K. HIV Viral Blips in Adults Treated with INSTI-Based Regimens Through 144 Weeks. [Poster 540]. Conference on Retroviruses and Opportunistic Infections 2020 (CROI 2020); 2020 March 8-11; Boston, Massachusetts.

Mills A, Gupta SK, Brinson C, Workowski K, Clarke A, Antinori A, Stephens JL, et al. 144-Week Efficacy and Safety of B/F/TAF in Treatment-Naive Adults Age ≥50 Years. [Poster 477]. Conference on Retroviruses and Opportunistic Infections 2020 (CROI 2020); 2020 March 8-11; Boston, Massachusetts.

Orkin C, DeJesus E, Sax PE, Arribas JR, Gupta SK, Martorell C, et al. Fixed-dose combination bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir containing regimens for initial treatment of HIV-1 infection: week 144 results from two randomised, double-blind, multicentre, phase 3, non-inferiority trials. Lancet HIV 2020;7(6):e389-e3400.

Ramgopal M, Maggiolo F, Ward D, Leboucche B, Rizzardini G, Molina JM, et al. Pooled Analysis of 4 International Trials of Bictegravir/Emtrictabine/Tenofovir Alafenamide (B/F/TAF) in Adults Aged ≥ 65 Years Demonstrating Safety and Efficacy: Week 48 Results. [Oral OAB0403].AIDS 2020; 2020 July 6-10; Virtual.

Acosta R, Andreatta K, D'Antoni M, Collins S, Martin H, White K. Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) shows high efficacy in clinical study participants infected with HIV-1 subtype F. [Poster P124]. HIV Drug Therapy 2020 (HIV Glasgow 2020); 2020 October 5-8; Glasgow, United Kingdom.

Acosta R, Chen G, Chang S, Martin R, Wang X, Huang H, et al. HIV with Transmitted Drug Resistance Is Durably Suppressed by B/F/TAF at Week 144. [Poster 430]. Conference on Retroviruses and Opportunistic Infections 2021 (CROI 2021); 2021 June 3-November 3; Virtual.

Acosta R, Chen G, Chang S, Martin R, Wang X, Huang H, et al. Three-year study of pre-existing drug resistance substitutions and efficacy of bictegravir/emtricitabine/tenofovir alafenamide in HIV-1 treatment-naive participants. J Antimicrob Chemother 2021, Jul 15;76(8):2153-2157. doi: 10.1093/jac/dkab115.

Workowski K, Orkin C, Sax P, Hagins D, Koenig E, Stephens JL, et al. Four-Year Outcomes of B/F/TAF in Treatment-Naïve Adults [Poster 415]. Conference on Retroviruses and Opportunistic Infections 2021 (CROI 2021); 2021 June 3-November 3; Virtual.

Acosta R, Chen G, Qin L, Wang X, Huang H, Hindman J, et al. Achievement of Undetectable HIV-1 RNA in the B/F/TAF Treatment-Naive Clinical Trials. [Poster PEB150]. 11th IAS Conference on HIV Science (IAS 2021); 2021 July 18-21; Virtual.

Acosta R, Chen G, Huang H, Liu H, White K. Unreturned Pill Bottles in the 1489 and 1490 Clinical Trials: An Important Measure of Poor Adherence That Is Often Ignored in Pill Count Calculations. [Poster 902]. IDWeek 2021; 2021 September 29-October 3; Virtual.

Arribas J, Orkin C, Maggiolo F, Antinori A, Lazzarin A, Yasdanpanah, et al. Long-term Analysis of B/F/TAF in Treatment-Naïve Adults Living With HIV Through Four Years of Follow-up. [PEB151]. 11th IAS Conference on HIV Science (IAS 2021); 2021 July 18-21; Virtual.

Daar E, Orkin C, Sax P, Stephens J, Koenig E, Clarke A, et al. Incidence of Metabolic Complications Among Treatment-naïve Adults Living With HIV-1 Randomized to B/F/TAF, DTG/ABC/3TC or DTG+F/TAF After 3 Years. [Oral 69]. IDWeek 2021; 2021 September 29-October 3; Virtual.

Pozniak A, et al. Outcomes 48 Weeks After Switching From DTG/ABC/3TC or DTG+F/TAF to B/F/TAF. [PE2/68]. 18th European AIDS Conference (EAC 2021), 2021 October 27–30; London, United Kingdom.

Study Period:

11 November 2015 (first participant screened)
12 May 2017 (last participant last visit for the primary end point)
05 July 2021 (last participant last visit for this report)

Phase of Development: Phase 3

Study Objectives and End Points:

Primary Objective(s)	Primary End Point(s)
• To evaluate the efficacy of a fixed-dose combination (FDC) containing bictegravir (BIC, B; previously referred to as GS-9883)/emtricitabine (FTC, F)/tenofovir alafenamide (TAF) (B/F/TAF; Biktarvy® [BVY]) versus dolutegravir (DTG) + an FDC containing FTC/TAF (F/TAF) in HIV-1 infected, antiretroviral therapy (ART)-naive adult participants as determined by the achievement of HIV-1 RNA < 50 copies/mL at Week 48	• The proportion of participants who achieve HIV-1 RNA < 50 copies/mL at Week 48 as defined by the (US) Food and Drug Administration (FDA)-defined snapshot algorithm
Secondary Objective(s)	**Secondary End Point(s)**
• To evaluate the efficacy, safety, and tolerability of the 2 treatment groups through Weeks 48, 96, and 144 • To evaluate the long term efficacy and safety of FDC BVY through open-label (OL) Weeks 48 and 96	The secondary efficacy end points included: • The proportion of participants who achieve HIV-1 RNA < 50 copies/mL at Week 96 and 144 as defined by the US FDA-defined snapshot algorithm • The proportion of participants who achieve HIV-1 RNA < 20 copies/mL at Weeks 48, 96, and 144 as defined by the US FDA-defined snapshot algorithm • The change from baseline in $\log_{10}$ HIV-1 RNA and in CD4 cell count at Weeks 48, 96, and 144 • The proportion of participants who achieve HIV-1 RNA < 50 copies/mL at Weeks 48 OL and 96 OL as defined by Missing = Excluded and Missing = Failure algorithm • The change from baseline in CD4 cell count at Weeks 48 OL and 96 OL.
	Other Criteria for Evaluation:
	Pharmacokinetics: No pharmacokinetic (PK) analyses were performed for this report. Safety assessments included: • Monitoring of adverse events (AEs) and concomitant medications, clinical laboratory analyses including chemistry, hematology, metabolic parameters, urinalysis, hepatitis B and C virus (HBV and HCV) monitoring, pregnancy testing, vital signs measurements, electrocardiograms (ECGs), and complete and symptom directed physical examinations.

Methodology: This was a randomized, double-blind study to evaluate the safety and efficacy of BVY versus DTG+F/TAF in HIV-1 infected, ART-naive adults. Participants who provided written consent and met all eligibility criteria were randomized in a 1:1 ratio to 1 of the following 2 treatment groups:

Treatment Group 1: BVY (B/F/TAF; 50/200/25 mg) FDC tablet + placebo-to-match DTG and placebo-to-match F/TAF administered orally, once daily, without regard to food (n = 300)

Treatment Group 2: DTG 50 mg + F/TAF (200/25 mg) FDC tablet + placebo-to-match BVY administered orally, once daily, without regard to food (n = 300)

Randomization was stratified by HIV-1 RNA level (≤ 100,000 copies/mL, > 100,000 to ≤ 400,000 copies/mL, or > 400,000 copies/mL) at screening, CD4 cell count (< 50 cells/µL, 50 to 199 cells/µL, or ≥ 200 cells/µL) at screening, and region (US vs. Ex-US) at randomization.

After Week 144, all participants continued to take their blinded study drug and attended visits every 12 weeks until the End of Blinded Treatment Visit. Once the last participant completed the Week 144 visit and Gilead Sciences, Inc. (Gilead) completed the Week 144 analysis, all participants returned to the clinic (preferably within 30 days) for an End of Blinded Treatment Visit. At the End of Blinded Treatment Visit, participants were given BVY in an open-label (OL) extension phase for 96 weeks (Week 96 OL). After Week 96 OL, participants discontinued the study drug, transitioned onto commercially available treatment, and completed a 30-Day Follow-up Visit. In a country where BVY was not available, participants were given the option to continue OL BVY until the product became accessible to participants through an access program, or until Gilead elected to discontinue the study in that country, whichever occurred first.

Number of Participants (Planned and Analyzed):
Planned: 600 participants (300 participants in each treatment group)
Analyzed (All BVY Analysis Set):

	BVY	DTG+ F/TAF to BVY	Total
Participants in All BVY Analysis Set	320	265	585

Diagnosis and Main Criteria for Inclusion: Eligible participants were ART naive (≤ 10 days of prior therapy with any antiretroviral agent following a diagnosis of HIV-1 infection except the use for pre-exposure prophylaxis [PrEP] or postexposure prophylaxis [PEP], up to 1 month prior to screening), HIV-1 infected adults with plasma HIV-1 RNA levels ≥ 500 copies/mL and screening genotype showing sensitivity to FTC and tenofovir (TFV), and an estimated glomerular filtration rate (eGFR) ≥ 30 mL/min (≥ 0.5 mL/sec) according to the Cockcroft-Gault ($eGFR_{CG}$) formula for creatinine clearance. Participants with chronic hepatitis B or C infection were permitted to enter the study.

Duration of Treatment: 144 weeks of randomized, double-blind treatment, followed by optional OL extension in which all participants received BVY for 96 weeks.

Test Product, Dose, Mode of Administration, and Batch No.: BVY (B/F/TAF; 50/200/25 mg) FDC tablet, plus placebo-to-match DTG and placebo-to-match F/TAF administered orally, once daily, without regard to food.

Batch Numbers:

BVY: EN1503B2, EN1504B1, EN1601B2, EN1604B2, EN1606B2, EN1608B1, EN1609B1, EN1610B2, EN1614B2, 6485706P, EN1704B1, EN1705B1

Placebo-to-match DTG: EK1501B1, EK1502B1, EK1503B1, EK1701B1

Placebo-to match F/TAF: CR1311B1, CR1507B1, CR1507B2, CR1602B1, CR1608B1

Reference Therapy, Dose, Mode of Administration, and Batch No.: (blinded phase only): DTG 50 mg + F/TAF (200/25 mg) FDC tablet, plus placebo-to-match BVY administered orally, once daily, without regard to food.

Batch Numbers:

DTG: 5ZP0220, 5ZP0221, 5ZP0222, 6ZP6085, 6ZP6123, 6ZP5809, 6ZP8682, 7ZP0981, 7ZP5966, 7ZP7196, 8ZP1819

F/TAF: CR1412B1, CR1509B1, CR1604B1, CR1605B1

Placebo-to-match BVY: EN1502B1, EN1607B1, EN1607B2, EN1703B1

Statistical Methods:

Efficacy: The primary efficacy analysis used the Full Analysis Set (FAS), which included all participants who (1) were randomized and (2) received at least 1 dose of study drug.

The All BVY Analysis Set included all participants who (1) were randomized into the study and (2) received at least 1 dose of BVY in the blinded phase or at least 1 dose of BVY in the extension phase. This was the primary analysis set for the all BVY efficacy and safety analyses.

Primary Efficacy Analysis:

The primary efficacy analysis was the assessment of noninferiority of BVY compared with DTG+F/TAF with respect to the proportion of participants with HIV-1 RNA < 50 copies/mL at Week 48 as defined by the FDA snapshot algorithm. The statistical analysis methods for the primary efficacy end point were described in the Week 48 statistical analysis plan (SAP) and the analysis was performed as presented in the GS-US-380-1490 Interim Week 48 Clinical Study Report (CSR).

Other Efficacy Analyses

The proportion of participants with HIV-1 RNA < 50 copies/mL was analyzed using the following 2 methods for imputing missing HIV-1 RNA values: Missing = Failure (M = F) and Missing = Excluded (M = E) using the All BVY Analysis Set for the all BVY analysis.

The analysis of CD4 cell count was based on on-treatment data (ie, up to 1 day after the last dose date of study drug) using the All BVY Analysis Set for the all BVY analysis. The changes from baseline in CD4 cell count at each visit were summarized by treatment group using descriptive statistics. No statistical comparisons were made for the all BVY analysis. Similar analysis was conducted for CD4% using the All BVY Analysis Set for the all BVY analysis.

Pharmacokinetics: No PK analyses were performed for this report. Full details of the PK analyses are provided in the GS-US-380-1490 Interim Week 48 CSR.

Safety: Adverse event and clinical laboratory data were summarized by treatment group using descriptive statistics. Adverse events were coded using the Medical Dictionary for Regulatory Activities (MedDRA) Version 24.0. Selected safety end point were also analyzed for participants with HIV/HBV coinfection at baseline, incident HIV/HBV coinfection while on study drug (if any), HIV/hepatitis C virus (HCV) coinfection at baseline, and incident HIV/HCV coinfection while on study drug (if any).

Preferred terms for defining hepatic events (ie, noninfectious and noncongenital hepatobiliary disorders) and cardiovascular or cerebrovascular events were selected from relevant Standardized MedDRA Query (SMQ). The number and percentage of participants with treatment-emergent hepatic AEs/serious adverse events (SAEs) and cardiovascular or cerebrovascular AEs/SAEs by preferred term were summarized by treatment group based on the All BVY Analysis Set.

Laboratory data were summarized based on values reported in conventional units. For the lipid panel and glucose, only measurements under fasting status were summarized.

SUMMARY OF RESULTS:

Participant Disposition: Of the 742 participants screened, 657 were randomized to study drugs (BVY 327 participants; DTG+F/TAF 330 participants). Seven participants randomized to BVY and 5 participants randomized to DTG+F/TAF did not receive study drugs (4 due to withdrawn consent, 3 due to investigator's discretion, 3 due to lost to follow-up, and 2 due to protocol violation). A total of 645 participants (BVY 320 participants; DTG+F/TAF 325 participants) were randomized and received at least 1 dose of study drugs.

Of the 645 randomized and treated participants, 534 participants completed the study drug in the double-blinded phase (BVY 81.3%, 260 participants; DTG+F/TAF 84.3%, 274 participants). 519 (BVY 254 participants; DTG+F/TAF 265 participants) entered the open-label phase and were treated with BVY. For the BVY group, 226 participants completed OL study treatment and 236 participants who had been randomized to DTG+F/TAF in the double-blind phase completed OL study treatment. The most common reasons for discontinuation of study drugs were participant decision (BVY 11 participants, DTG+F/TAF to BVY 17 participants), lost to follow-up (BVY 13 participants, DTG+F/TAF to BVY 6 participants), and death (BVY 1 participant, DTG+F/TAF to BVY 3 participants).

Participant Demographics and Baseline Disease Characteristics: It should be noted that baseline values for participants that switched from DTG+F/TAF to BVY were defined as the last nonmissing value obtained on or prior to the first dose of OL BVY.

In both groups, most participants were male (BVY 87.5%; DTG+F/TAF to BVY 90.2%) and not Hispanic/Latino (BVY 74.1%; DTG+F/TAF to BVY 72.5%). Most participants were either white (BVY 57.2%; DTG+F/TAF to BVY 60.4%) or black (BVY 30.3%; DTG+F/TAF to BVY 30.2%). Median age on or prior to the first dose of BVY was 33 years (range: 18 to 71 years) for the BVY group and 38 years (range 21 to 80 years) for the DTG+F/TAF to BVY group. Median (Q1, Q3) body mass index (BMI) was 25.0 (22.2, 28.3) kg/m^2 for the BVY group and 26.3 (23.5, 30.8) kg/m^2 for the DTG+F/TAF to BVY group.

The most common HIV risk factor was homosexual sex (76.1% of participants; 74.1% in the BVY group and 78.5% in the DTG+F/TAF to BVY group); 24.3% of participants reported heterosexual sex as an HIV risk factor (25.3% in the BVY group and 23.0% in the DTG+F/TAF to BVY group). The majority of participants (88.9%) had asymptomatic HIV-1 infection (89.4% in the BVY group and 88.3% in the DTG+F/TAF to BVY group); 3.2% (3.1% in the BVY group and 3.4% in the DTG+F/TAF to BVY group) had symptomatic HIV-1 infection, and 7.9% were diagnosed with acquired immunodeficiency syndrome (AIDS; 7.5% in the BVY group and 8.3% in the DTG+F/TAF to BVY group). The median (Q1, Q3) $eGFR_{CG}$ at receiving BVY was 120.3 (100.8, 141.8) mL/min for the BVY group and 111.0 (95.1, 134.8) mL/min for the DTG+F/TAF to BVY group. For the BVY group, the median (Q1, Q3) baseline HIV-1 RNA value on or prior to receiving BVY was 4.43 (3.95, 4.9) log_{10} copies/mL. The majority of participants in the BVY group (79.4%) had HIV-1 RNA $\leq$ 100,000 copies/mL; 16.9% of participants had > 100,000 to $\leq$ 400,000 copies/mL, and 3.8% of participants had > 400,000 copies/mL. On or prior to the first dose of OL BVY, the majority of participants in the DTG+F/TAF to BVY group (99.2%) had HIV-1 RNA < 50 copies/mL, and 2 participants (0.8%) had HIV-1 RNA $\geq$ 50 copies/mL.

Coinfection with HBV and/or HCV was low; 2.1% of participants had HIV/HBV coinfection (2.5% in the BVY group and 1.5% in the DTG+F/TAF to BVY group), and 1.4% of participants had HIV/HCV coinfection (1.6% in the BVY group and 1.1% in the DTG+F/TAF to BVY group).

Efficacy Results: Results from the primary efficacy analysis of Study GS-US-380-1490 demonstrated that BVY was noninferior to DTG+F/TAF when administered for 48 weeks to HIV-1 infected, ART-naive adults, as assessed using the FDA-defined snapshot algorithm with HIV-1 RNA < 50 copies/mL (GS-US-380-1490 Interim Week 48 CSR).

High rates of virologic suppression were achieved and maintained through 240 weeks of BVY treatment (including 96 weeks of OL BVY). For the BVY group, the percentages of participants at Week 192 (OL Week 48) and Week 240 (OL Week 96) with HIV-1 RNA < 50 copies/mL analyzed using M = E for imputing missing HIV-1 RNA values were 99.2% and 99.5%, respectively. Using M=F for imputing missing HIV-1 RNA values, the percentages were 75.3% and 68.1%, respectively.

For the group that switched from DTG+F/TAF to BVY, percentages of participants with HIV-1 RNA < 50 copies/mL analyzed using M = E for imputing missing HIV-1 RNA values at OL Weeks 48 and 96 were 99.6% and 99.1%, respectively. Using M=F for imputing missing HIV-1 RNA values, the percentages of participants with HIV-1 RNA < 50 copies/mL at OL Weeks 48 and 96 were 84.5% and 87.5%, respectively.

For the BVY group, the CD4 cell count and CD4% increased through 240 weeks of BVY treatment. During the OL extension phase, CD4 cell counts and CD4% continued to be maintained in those participants who remained on BVY and those who switched from DTG+F/TAF to BVY. At Week 192 (OL Week 48) and Week 240 (OL Week 96) the mean (SD) changes from baseline in CD4 cell count for the BVY group were 304 (249.2)/µL and 336 (235.1)/µL, respectively. The mean (SD) change from baseline in CD4 cell percentage for the BVY group was 12.3% (6.97%) and 12.5% (7.00%) at Week 192 (OL Week 48) and Week 240 (OL Week 96), respectively. For the DTG+F/TAF to BVY group, the mean (SD) changes from baseline in CD4 cell count at OL Week 48 and OL Week 96 were 9 (198.0)/µL and -10 (181.1)/µL, respectively. The mean (SD) changes from baseline in CD4 cell percentage at OL Week 48 and OL Week 96 were 0.5% (4.22%) and 1.5% (4.01%), respectively.

Through end of study, no participant in the Final Resistance Analysis Population (RAP) developed treatment emergent resistance to study drugs.

Pharmacokinetics Results: No PK analyses were performed for this report. Pharmacokinetic results are presented in the GS-US-380-1490 Interim Week 48 CSR.

Safety Results: BVY was well tolerated through a median duration of exposure of 252.1 weeks (BVY group) and 96.0 weeks (DTG+F/TAF to BVY group), respectively.

Adverse Events

The percentages of participants with AEs were as follows: BVY 93.4%, 299 of 320 participants; DTG+F/TAF to BVY 81.1%, 215 of 265 participants The most commonly reported AEs for each treatment group were as follows:

- BVY group: diarrhea (23.8%, 76 of 320 participants), headache (20.9%, 67 participants), nasopharyngitis (18.8%, 60 participants), and upper respiratory tract infection (16.6%, 53 participants)
- DTG+F/TAF to BVY group: coronavirus disease 2019 (COVID-19; 12.1%, 32 of 265 participants), nasopharyngitis (8.3%, 22 participants), and headache (7.2%, 19 participants)

The majority of the AEs reported in the study were Grade 1 or 2 in severity. Grade 3 or 4 AEs reported for each treatment group were as follows: BVY 20.3%, 65 participants; DTG+F/TAF to BVY 10.6%, 28 participants. Adverse events considered related to study treatment were reported as follows: BVY 24.1%, 77 participants; DTG+F/TAF to BVY 3.0%, 8 participants.

Twelve deaths were reported during the study. Eight of these deaths (4 in the BVY group and 4 in the DTG+F/TAF group) occurred during the blinded phase of the study. In the BVY group, 1 participant died as a result of cardiac arrest, which occurred following appendicitis and septic shock; 1 participant died as a result of gastric adenocarcinoma; 1 participant died as

a result of hypertensive heart disease and congestive cardiac failure; 1 participant died from sudden cardiac arrest. None of the deaths were considered related to study drugs. In the DTG+F/TAF group, 2 participants died from unknown causes (no relevant AEs were reported for either participant), 1 participant died as a result of lymphoma, and 1 participant died from pulmonary embolism (the participant had an ongoing serious adverse event (SAE) of chronic obstructive pulmonary disease). With the exception of 1 participant in the DTG+F/TAF group who died from unknown causes, none of the deaths were considered related to study drugs.

The remaining 4 deaths occurred during OL treatment with BVY (1 in the BVY group and 3 in the DTG+F/TAF to BVY group). In the BVY group, 1 participant died as a result from unknown cause. In the DTG+F/TAF to BVY group, 2 participants died from unknown causes and 1 participant died of malignant neoplasm of urinary bladder (unspecified site). None of the deaths were considered related to study drugs.

Serious AEs were reported as follows: BVY 23.4%, 75 participants; DTG+F/TAF to BVY 12.1%, 32 participants. The incidence of SAEs considered related to study drugs was low (0.9%, 3 participants) in the BVY group and no SAEs related to study drugs were reported in DTG+F/TAF to BVY group.

The incidence of AEs that led to discontinuation of study drugs was low in the BVY group (1.9%, 6 participants), and no participant in the DTG+F/TAF to BVY group discontinued study drugs due to AEs. None of the AEs leading to discontinuation were reported for > 1 participant. The following AEs leading to discontinuation of study drugs were considered serious: cardiac arrest, chest pain, depression. The following AEs leading to discontinuation of study drugs were considered related to study drugs: chest pain, depression, abdominal distension (2 reports in the same participant), sleep disorder, dyspepsia, tension headache, depressed mood, and insomnia (all reported in the same participant).

Sixteen confirmed pregnancies were reported for 13 participants during the study (BVY 6 participants; DTG+F/TAF 5 participants; DTG+F/TAF to BVY 2 participants). No congenital defects were reported. The outcomes of the pregnancies were as follows: 6 deliveries of a healthy baby, 5 continuing pregnancies, 3 spontaneous abortions, 1 elective abortion, and 1 induced abortion.

Hepatic Safety

Hepatic AEs were reported for each treatment group as follows: BVY 9.1%, 29 participants; DTG+F/TAF to BVY 2.3%, 6 participants. The following hepatic AEs were reported for ≥ 2 participants in either treatment group: hepatic steatosis (BVY 9 participants, DTG+F/TAF to BVY 3 participants), aspartate aminotransferase (AST) increased (BVY 5 participants, DTG+F/TAF to BVY 0 participants), transaminases increased (BVY 4 participants, DTG+F/TAF to BVY 1 participant), hypoalbuminaemia (BVY 2 participants, DTG+F/TAF to BVY 1 participant), alanine aminotransferase (ALT) increased (BVY 2 participants, DTG+F/TAF to BVY 0 participants), cholelithiasis (BVY 2 participants, DTG+F/TAF to BVY 0 participants), hepatosplenomegaly (BVY 2 participants, DTG+F/TAF to BVY 0 participants), and liver function test increased (BVY 2 participants, DTG+F/TAF to BVY 0 participants). No hepatic AEs resulted in discontinuation of study drug.

All hepatic AEs were considered not related to study drug except for the following: a nonserious AE of liver function test increased (Grade 1; Day 23 to 57; 1 participant in the BVY group); nonserious AEs of ALT increased and AST increased (both Day 29 to 263; 1 participant DTG+F/TAF to BVY group); nonserious AEs of hepatic steatosis in 2 participants in the DTG+F/TAF to BVY group (Day 777 and Day 1031), which were ongoing.

There were SAEs of cholecystitis acute and transaminases increased in the BVY group, which both resolved and were considered unrelated to study drug. Both SAEs occurred during the double-blind phase.

There were no clinically relevant changes from baseline in median values for the liver related laboratory parameters ALT, AST, alkaline phosphatase (ALP), and total bilirubin in any treatment group. No participant met Hy's Law criteria.

BVY was safe and well tolerated in baseline HBV- or HCV-coinfected participants. Elevations in AST and ALT in participants with HIV/HCV were consistent with those routinely observed in patients with chronic HCV infection. One HIV/HBV baseline-coinfected participant (BVY) had a confirmed on-treatment (up to the last dose day) ALT flare reported as a Grade 2 AE of immune reconstitution inflammatory syndrome that was not considered related to study drugs. This participant had baseline Grade 2 ALT and Grade 1 AST, both increasing to Grade 4 at Week 12. At Week 144, ALT and AST were both Grade 0. Study drugs were not interrupted.

Cardiovascular and Cerebrovascular Events

Cardiovascular or cerebrovascular AEs were reported for the BVY group (3.4%, 11 participants) and the DTG+F/TAF to BVY group (0.8%, 2 participants). Cardiovascular or cerebrovascular SAEs were reported for 3 participants in the BVY group (0.9%) and 1 participant in the DTG+F/TAF to BVY group (0.4%). The 3 participants in the BVY group had events of angina pectoris, ischaemic stroke and myocardial infarction. The participant in the DTG+F/TAF to BVY group had an event of vertebral artery stenosis. One additional participant in the BVY group discontinued study drugs due to a fatal SAE of cardiac arrest, which occurred following appendicitis and septic shock. None of these SAEs were considered related to study drug.

Renal Safety

Renal and urinary disorders were reported for the BVY group (17.8%, 57 participants) and the DTG+F/TAF to BVY group (9.1%, 24 participants). None of the reported renal or urinary AEs led to study drug discontinuation. Four participants in the BVY group (1.3%) reported renal and urinary SAEs of acute kidney injury (0.9%, 3 participants) and chronic kidney disease (0.3%, 1 participant) that were considered not related to study drug. No participants in the DTG+F/TAF to BVY group reported renal or urinary SAEs.

Serum creatinine increased from baseline by Week 4 and remained stable in the BVY group over time throughout the double-blind and OL phases. At Week 240 (OL Week 96), the median (Q1, Q3) change from baseline was 0.11 (0.00, 0.19) mg/dL. Serum creatinine remained stable during the OL phase in the DTG+F/TAF to BVY group. At OL Week 96, the median (Q1, Q3) change from baseline was -0.02 (-0.09, 0.06) mg/dL.

Decreases in median $eGFR_{CG}$ were observed by Week 4 for the BVY group that remained stable through Week 240 (OL Week 96). The median (Q1, Q3) change from baseline at Week 240 was -8.5 (-18.4, 4.4) mL/min. For the DTG+F/TAF to BVY group, $eGFR_{CG}$ remained stable during the OL phase. The median (Q1, Q3) change from baseline at OL Week 96 was 1.3 (-7.3, 11.1) mL/min.

Laboratory Evaluations

There were no clinically relevant changes from baseline within either treatment group or differences between the treatment groups in median values for hematology or clinical chemistry parameters (including metabolic parameters), and median values were generally within reference ranges. The majority of participants in each treatment group had at least 1 laboratory abnormality (BVY 97.8%, 307 of 314 participants; DTG+F/TAF to BVY 90.2%, 238 of 264 participants).

Grade 3 or 4 laboratory abnormalities were reported for 31.5% of participants in the BVY group (99 participants) and 15.9% of participants (42 participants) in the DTG+F/TAF to BVY group. The most common Grade 3 or 4 laboratory abnormalities (≥ 3% in either group) were neutrophils decreased, ALT increased, amylase increased, AST increased, creatine kinase increased, hyperglycemia (nonfasting) and low-density lipoprotein (LDL) increased (fasting).

There were no clinically relevant changes from baseline within either treatment group in median values for systolic blood pressure, diastolic blood pressure, pulse, respiration rate, or body temperature. For the BVY group, the median (Q1, Q3) changes from baseline in body weight through Weeks 192 and 240 (OL Weekes 48 and 96) were 4.6 (1.8, 10.1) kg and 6.1 (2.3, 12.6) kg, respectively. The DTG+F/TAF group median (Q1, Q3) values for body weight gained at Week 144 were 5.0 [0.5, 9.7] kg. Over the time of OL BVY, the median (Q1, Q3) changes from baseline in body weight for the DTG+F/TAF to BVY group were 1.2 (-1.3, 3.9) kg and 1.3 (-1.9, 5.0) kg at OL Weeks 48 and 96, respectively.

Other Results: No other outcome measures were evaluated in this study.

CONCLUSIONS:

The conclusions from this final analysis of Study GS-US-380-1490 are as follows:

- Potent antiviral efficacy was maintained in HIV-1 infected, ART naive adults who received BVY once daily through 240 weeks and in participants previously treated with DTG+F/TAF once daily for 144 weeks who switched to OL BVY treatment through 96 weeks.
- No participant in the Final RAP developed treatment-emergent resistance during long-term treatment with BVY.
- Antiviral HIV response was also as robust in HIV/HBV coinfected participants as it was in HIV monoinfection.
- Immunologic benefits were demonstrated by improvements in CD4 cell counts and CD4 percentages.

- BVY was safe and well tolerated. Common AEs were generally consistent with those expected in the participant population and the known safety profiles of FTC- and TAF-containing regimens and DTG.
- No participant met Hy's Law criteria. No participant discontinued study drugs due to hepatic AEs. No clinically relevant changes from baseline in liver-related laboratory parameters were seen for either treatment group.
- No participant receiving BVY during the study had proximal tubulopathy (including Fanconi syndrome) or discontinued study drugs due to a renal and urinary disorder or associated investigation AE.
- BVY was safe and well tolerated in participants with HIV/HBV and HIV/HCV coinfection at baseline.

CCI [redacted]

7.7.1. Changes in the Conduct of the Study

The original protocol (21 October 2015) was amended 3 times (on 19 February 2016, 19 October 2016, and 06 May 2019); in addition, there were 7 country-specific amendments (4 in UK, 3 in France) and 1 country-specific addendum (France). Administrative letters were issued on 05 May 2017 and 03 January 2018. All participants were enrolled under either the original protocol or Amendment 1, 2, or 3 with associated country-specific amendments. Key changes to the study protocol are described below for each amendment. Complete summaries of the changes implemented in each global amendment are provided in Appendix 16.1.1.

Contingency measures implemented to manage study conduct during disruption of the study as a result of COVID-19 pandemic control measures that were not included in a protocol amendment or administrative letter are described in the study's Coronavirus Outbreak Crisis Management Plan (Appendix 16.1.1).

Protocol Amendment 0.1 – UK (18 December 2015)

- Clarified that study medication was to be withheld if a participant met discontinuation criteria as outlined in amended protocol

Protocol Amendment 0.1 – France (16 February 2016)

- Clarified criteria for discontinuation of study treatment and for management of laboratory toxicity
- Included guidance for management of potential hepatobiliary toxicity and management of potential posterior uveitis case

Protocol Amendment 1 (19 February 2016)

- Clarified criteria for discontinuation of study treatment and for management of laboratory toxicity
- Included guidance for management of potential hepatobiliary toxicity

Protocol Amendment 1.1 – UK (08 April 2016)

- All changes listed for global Protocol Amendment 1 were incorporated
- Modified study duration language to define the blinded treatment period
- Added prothrombin time/international normalized ratio (INR) under blood sample collection as it was previously missed in error
- Included guidance for management of potential hepatobiliary toxicity
- Added UK-specific tertiary objectives and end point
  - The tertiary objectives included the following:
    - To evaluate the efficacy, safety, and tolerability of continuing BVY in the OL extension phase for up to 48 weeks for participants on BVY during the blinded phase
    - To evaluate the efficacy, safety, and tolerability of switching to BVY in the OL extension phase for up to 48 weeks for participants on DTG+F/TAF during the blinded phase
  - The tertiary efficacy end point was the proportion of participants with HIV-1 RNA < 50 copies/mL in the OL extension phase for up to 48 weeks

Protocol Amendment 2 (19 October 2016)

- Extended duration of blinded phase from 96 weeks of treatment to 144 weeks of treatment
- Revised secondary objectives and end point to include Week 144
- Added OL rollover extension and treatment assessments for participants who receive OL BVY
- Revised language to the risk/benefit assessment for the study
- Revised prior and concomitant medications
- Added hepatitis B virus (HBV) and hepatitis C virus (HCV) serology testing at Week 48 and every 48 weeks after Week 48
- Revised Gilead reporting requirements to clarify that in addition to using the reference safety information in the investigator's brochure and relevant local label as applicable, Gilead may also use the European Union (EU) summary of product characteristics for the assessment of expectedness of serious adverse events (SAEs)
- Revised the definition of special situations
- Added peripheral blood mononuclear cell (PBMC) collection at Week 132 in the PBMC substudy

The changes listed above for Amendment 2 were also incorporated into the following country-specific amendments issued on 03 November 2016: Protocol Amendment 2.1 – UK and Protocol Amendment 2.1 – France. No changes other than the ones listed above were incorporated in these country-specific amendments.

Protocol Amendment 3 (06 May 2019)

- Extended the duration of the OL Extension phase of the study from 48 to 96 weeks to allow collection of longer term safety and efficacy data
- Revised the secondary objectives and end point
- Revised the duration of treatment
- Revised the procedures for breaking treatment codes
- Added prior and concomitant medications table for BVY OL Extension
- Revised End of Blinded Treatment Visit
- Revised treatment assessments (OL Rollover Extension)
- Revised participant with HIV-1 RNA $\geq$ 50 copies/mL instructions to include Week 96 OL
- Revised instructions for reporting special situation
- Added a section for All BVY Analysis Set and an efficacy analysis for all BVY analysis

- Revised safety analysis
- Revised Analysis Schedule
- Revised Appendix 3 to include OL visits through 96 Weeks

The changes listed above for Amendment 3 were also incorporated into the following country-specific amendments issued on 06 May 2019: Protocol Amendment 3.1 – UK and Protocol Amendment 3.1 – France. No changes other than the ones listed above were incorporated in these country-specific amendments.

Addendum #1.0 (France; 20 January 2016)

Administrative Letter #1 (08 April 2016)

An administrative letter was issued to clarify per protocol the requirement to collect Day 1 PT/INR as part of Section 6.2.2 and the study procedures table.

Administrative Letter #2 (05 May 2017)

- An administrative letter was issued to provide notification of change of medical monitor and their contact details.

Administrative Letter #3 (03 January 2018)

- An administrative letter was issued to provide notification of change of medical monitor and their contact details.

Administrative Letter #4 (12 September 2018)

- An administrative letter was issued to provide notification of change of medical monitor and their contact details.

Administrative Letter #5 (12 September 2019)

- An administrative letter was issued to provide notification of change of medical monitor and their contact details.

Administrative Letter #6 (12 February 2020)

- An administrative letter was issued to provide notification of change of medical monitor and their contact details.

Administrative Letter #7 (14 December 2020)

- An administrative letter was issued to provide notification of change of medical monitor and their contact details.

CCI [redacted]

[redacted]

FINAL CLINICAL STUDY REPORT AMENDMENT 1

Study Title:	A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9883/Emtricitabine/Tenofovir Alafenamide Versus Dolutegravir + Emtricitabine/Tenofovir Alafenamide in HIV-1 Infected, Antiretroviral Treatment-Naive Adults
Name of Test Drug:	Bictegravir (previously referred to as GS-9883)/Emtricitabine/Tenofovir Alafenamide (Biktarvy® [BVY])
Dose and Formulation:	Fixed-dose combination tablet containing 50 mg bictegravir (BIC, B), 200 mg emtricitabine (FTC, F), and 25 mg tenofovir alafenamide (TAF)
Sponsor:	Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA
Study No.:	GS-US-380-1490
Report Date:	22 November 2021
Amendment Date(s):	Amendment 1: 10 February 2022

Rationale: Herein is a summary of amendments made to the final clinical study report (CSR) dated 22 November 2021.

1) The CSR has been amended to correct the number of United States (US) and total study centers.

2) The List of Investigators for Study GS-US-380-1490 has been updated to correct the number of enrolled participants for one study center each in Italy and the United Kingdom (UK). A link to the revised list of investigators is provided in this CSR amendment.

These errors did not impact the analyses or conclusions made in the CSR.

Summary of Specific Changes

Specific changes of key new and updated text are shown below. Added text is indicated by ***bold italicized*** font and deleted text is indicated by ~~strikethrough~~ font.

CSR Section No. and Title:	Synopsis 6. Investigators and Study Administrative Structure
Original Text:	Participants were enrolled and treated a total of 126 study centers: 6 in Australia, 2 in Belgium, 6 in Canada, 1 in the Dominican Republic, 4 in France, 8 in Germany, 3 in Italy, 8 in Spain, 11 in the United Kingdom (UK), and 77 in the United States (US).
Revised Text:	Participants were enrolled and treated ***at*** a total of ~~126~~***127*** study centers: 6 in Australia, 2 in Belgium, 6 in Canada, 1 in the Dominican Republic, 4 in France, 8 in Germany, 3 in Italy, 8 in Spain, 11 in the United Kingdom (UK), and ~~77~~***78*** in the United States (US).
Rationale:	To correct the number of US and total study centers.

CSR Section No. and Title:	8.1. Disposition of Study Participants
Original Text:	Participants were enrolled and treated at a total of 126 centers in 10 countries as reported in the GS-US-380-1490 Interim Week 48 and Week 144 CSRs.

Revised Text:	Participants were enrolled and treated at a total of ~~126~~*127* centers in 10 countries ~~as reported in the GS-US-380-1490 Interim Week 48 and Week 144 CSRs~~.
Rationale:	To correct the number of total study centers.

CSR Section No. and Title:	16.1.4. List and Description of Investigators
Original Text:	A list of principal investigators participating in the study (ie, that screened participants) and a summary of the number of participants enrolled in each country are provided below. • List of Investigators for Study GS-US-380-1490
Revised Text:	A list of principal investigators participating in the study (ie, that screened participants) and a summary of the number of participants enrolled in each country are provided below. • List of Investigators for Study GS-US-380-1490
Rationale:	The List of Investigators for Study GS-US-380-1490 has been updated to correct the number of enrolled participants for one study center each in Italy and the UK. A link to the revised list of investigators is provided in this CSR amendment. The following study center entries were updated to reflect the revised enrollment numbers: • Site 02247: the enrollment number was changed from 11 to 10 • Site 07837: the enrollment number was changed from 2 to 3.

GILEAD SCIENCES, INC.

SIGN-OFF FOR FINAL CLINICAL STUDY REPORT AMENDMENT 1

Study Title: A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9883/Emtricitabine/Tenofovir Alafenamide Versus Dolutegravir + Emtricitabine/Tenofovir Alafenamide in HIV-1 Infected, Antiretroviral Treatment-Naive Adults

I have read this final clinical study report amendment and, to the best of my knowledge, it accurately reflects the results and conduct of Gilead Sciences, Inc., Study GS-US-380-1490.

Gilead Sciences, Inc., Responsible Medical Monitor:

PPD MD, MPH
Executive Director, Clinical Development

PPD 10 Feb 2022

Signature Date

GS-US-380-1490: List of Principal Investigators

Geographic Region/ Country Principal Investigator	Investigator No.	Study Site	No. of Subjects Enrolled	No. of Additional Subjects Transferred From Another Study Site[a]
APAC/Australia Bloch, Mark, MD	00959	Raileigh Pty Ltd trading as Holdsworth House Medical Practice 26 College stSydney, New South Wales 2010 Australia	3	
McMahon, James, MD	08366	Alfred Health Alfred Hospital 85 Commercial Road, Infectious Diseases Unit, Level 2, Burnet Institute Melbourne, Victoria 3004 Australia	2	
Moore, Richard, MD	03685	Northside Clinic 370 St. Georges Road Fitzroy North, Victoria 3068 Australia	1	
Roth, Norman, MD	03686	Prahran Market Clinic, Cnr. Commercial Rd &Chapel Prahran, Victoria 3181 Australia	3	
Schmidt, Martina, MD	05215	Melbourne Sexual Health Centre, 580 Swanston Street Carlton, Victoria 3053 Australia	3	
Woolley, Ian, MD	05009	Monash Medical Centre, 246 Clayton Road, Clayton Campus Clayton, Victoria 3168 Australia	2	
EMEA/Belgium Florence, Eric, MD	03960	Institute of Tropical Medicine Antwerp Nationalestraat 155 Antwerpen, 2000 Belgium	3	
Vandekerckhove, Linos, MD	04152	UZ Gent De Pintelaan 185 Gent, 9000 Belgium	5	
EMEA/France Ghosn, Jade, MD **Former PI:** Yazdanpanah, Yazdan, MD (02434)	11830	CHU Bichat, 46, rue Henri Huchard Paris, 75877 France	5	1 subject transferred from Antinori, Andrea [01202]

Geographic Region/ Country Principal Investigator	Investigator No.	Study Site	No. of Subjects Enrolled	No. of Additional Subjects Transferred From Another Study Site[a]
Meybeck, Agnes, MD	09742	CH de Tourcoing 135 rue du President Coty Tourcoing, 59208 France	2	
Pugliese, Pascal, MD	11288	CHU Nice - Hôpital Archet 1, 151, route St Antoine de Ginestière Nice, 06200 France	1	
Reynes, Jacques, MD	01551	CHU de Montpellier Hopital Gui de Chauliac, 80, avenue Augustin Fliche Montpellier Cedex 05, 34295 France	4	
EMEA/Germany Arastéh, Keikawus, MD	00731	EPIMED GmbH Budapester Strasse 15-19 Berlin, 10787 Germany	10	
Esser, Stefan, MD	01160	Universitatsklinikum Essen, Klinik fur Dermatologie, HIV/HPSTD-Ambulanz Hufelandstrasse 55 Essen, North-Rhine Westphalia 45122 Germany	8	
Jonsson-Oldenbüttel, phil. Celia, MD **Former PI:** Jäger, Hans, MD (01017)	19469	MUC Research GmbH Waltherstraße 32 Munich, Bavaria 80337 Germany	4	
Lehmann, Clara, MD	11806	Universitulsklinikum Koln Kerpener str, 62, Koeln North-Rhine Westphalia 50924 Germany	5	
Lutz, Thomas, MD	03976	Infektiologikum Frankfurt Stresemannallee 3 Frankfurt, Hessen 60596 Germany	7	
Mauss, Stefan, MD	01154	Zentrum fur HIV und Hepatogastroenterologie Grafenberger Allee 128a Dusseldorf, North-Rhine Westphalia 40237, Germany	1	
Rockstroh, Jurgen, MD	00684	Universitätsklinikum Bonn Sigmund -Freud-straBe25 North-Rhine Westphalia Bonn, 53105 Germany	0	

Geographic Region/ Country Principal Investigator	Investigator No.	Study Site	No. of Subjects Enrolled	No. of Additional Subjects Transferred From Another Study Site[a]
Stellbrink, Hans-Jürgen, MD	00554	Infektionsmedizinisches Centrum Hamburg (ICH), Study Center Grindelallee 35, Hamburg, 20146 Germany	13	
Stephan, Christoph, MD	03975	Universitätsklinikum Frankfurt Theodor-Stern-Kai 7, Medizinische Klinik II, Schwepunkt Infektiologie, Haus 68 Frankfurt am Main, Hessen, 60590 Germany	1	
EMEA/Italy Antinori, Andrea, MD	01202	Istituto Nazionale per le Mallattie Infettive "Lazzaro Spallanzani",IRCCS Via Portuense, 292, Day Service Unificato, Roma, 00149 Italy	11	2 (1 subject transferred from Berenguer, Juan [02852] and 1 subject transferred from Lazzarin, Adriano [01021])
Castagna, Antonella, MD **Former PI:** Lazzarin, Adriano, MD (01021)	02247	UO Malattie Infettive IRCCS Ospedale San Raffaele, Via Stamira D'Ancona 20 Milano, Milano 20127 Italy	10	
Maggiolo, Franco, MD	02322	ASST Papa Giovanni XXII Piazza OMS 1 Bergamo, BG 24127 Italy	13	
EMEA/Spain Arribas Lopez, Jose Ramon, MD	01553	Hospital Universitario La Paz Paseo de la Castellana 261 Madrid, 28046 Spain	5	1 subject transferred from Hsu, Ricky [04170]
Berenguer, Juan, MD	02852	Hospital General Universitario Gregorio Maranon C/Dr. Esquerdo, n 46 Madrid, 28007 Spain	6	1 subject transferred from Antinori, Andrea [01202]
Clotet Sala, Bonaventura, MD	00688	Hospital Universitari Germans Trias i Pujol Carretera del Canyet s/n Badalona, Barcelona, 08916 Spain	0	
Dronda, Fernando, MD	12256	Hospital Universitario Ramon y Cajal Carretera de Colmenar, Km 9,1, Madrid, 28034 Spain	2	

Geographic Region/ Country Principal Investigator	Investigator No.	Study Site	No. of Subjects Enrolled	No. of Additional Subjects Transferred From Another Study Site[a]
Miralles Alvarez, Celia, MD	02794	Hospital Clinic de Barcelona Estrada Clara Campoamor, 341 Vigo, Pontevedra 36312 Spain	2	
Palacios, Rosario, MD **Former PI:** Marquez Solero, Manuel, MD (01556)	03569	Hospital Universitario Virgen de la Victoria Campus Teatinos, s/n Malaga, 29010 Spain	4	
Portilla Sogorb, Joaquin, MD	03718	Hospital General Universitario de Alicante Pintor Baeza, s/n, Alicante, 03010 Spain	2	
Pulido, Federico, MD	01029	Hospital Universitario 12 de Octubre Avda. Cordoba, s/n Madrid, Madrid 28041 Spain	4	
Saumoy Linares, Maria, MD **Former PI**: Podzamczer, Daniel, MD (02511)	08610	Hospital Universitari de Bellvitge C/ Feixa Llarga, s/n, Hospitalet de Llobregat Barcelona, 08907 Spain	9	2 (1 subject transferred from Yazdanpanah, Yazdan, MD [02434] and 1 subject transferred from Fox, Julie [05126])
EMEA/United Kingdom Fox, Julie, MD	05126	Guy's and St. Thomas' NHS Foundation Trust Harrison wing, St Thomas' Hospital, London, SE1 7EH United Kingdom	7	
Hamzah, Lisa, MD **Former PIs:** Dragovic, Bojana, MD (15641), Bird, Elspeth, MD (15466), Hay, Phillip, MD (00691) and Pakianathan, Mark, MD (11935)	17084	St George's Healthcare NHS Trust The Courtyard Clinic London, SW17 0QT United Kingdom	5	
Johnson, Margaret Anne, MD	00062	Royal Free London NHS Foundation Trust Pond Street London, NW3 2QG United Kingdom	3	
Orkin, Chloe Meave, MD	02817	Barts Health NHS Trust Ambrose King Centre, Royal London Hospital, Whitechapel Road London, E1 1BB United Kingdom	5	1 subject transferred from Schembri, Gabriel [07480]

Geographic Region/ Country Principal Investigator	Investigator No.	Study Site	No. of Subjects Enrolled	No. of Additional Subjects Transferred From Another Study Site[a]
Post, Frank Alexander, MD	06259	King's College Hospital NHS Foundation Trust Cutcombe Road London, SE5 9RJ United Kingdom	6	
Pozniak, Anton Louis, MD	00694	Chelsea & Westminster NHS Trust St Stephens Centre, 369 Fulham Road Kobler Pharmacy, Ground Floor, London, SW10 9TH United Kingdom	5	
Ross, Jonathan, MD	03814	Whittall Street Clinic Queen Elizabeth Medical Centre, Edgbaston Birmingham, B15 2TH United Kingdom	2	
Schembri, Gabriel, MD	07480	Central Manchester University Hospitals NHS Foundation Trust 280 Upper Brook Street Manchester, M13 0FH United Kingdom	6	
Taylor, Stephen, MD	03952	Heart of England NHS Foundation Trust Bordesley Green East Birmingham, B9 5SS United Kingdom	5	
Ustianowski, Andrew Peter, MD	05294	Pennine Acute Hospitals NHS Trust Royal Manchester General Hospital, Delaunays Road Manchester, M8 5RB United Kingdom	1	
Waters, Laura Jane, MD	07837	Central and North West London NHS Foundation Trust Off Capper Street London, WC1E 6JB United Kingdom	3	
Latin America/Dominican Republic Koenig, Ellen, MD	00986	Instituto Dominicano de Estudios Virologicos (IDEV) Dr. Pineyro 211, Zona Universitaria Santo Domingo Republica Dominicana	45	

Geographic Region/ Country Principal Investigator	Investigator No.	Study Site	No. of Subjects Enrolled	No. of Additional Subjects Transferred From Another Study Site[a]
North America/Canada Andany, Nisha, MD **Former PI:** Rachlis, Anita (00573)	14832	Sunnybrook Health Sciences Centre 2075 Bayview Avenue Toronto, Ontario M4N 3M5 Canada	4	
Angel, Jonathan, MD	03670	The Ottawa Hospital - General Campus 501 Smyth Road Ottawa, Ontario K1H 8L6 Canada	1	
Brunetta, Jason, MD	05171	Maple Leaf Research/ Maple Leaf Medical Clinic 14 College Street Toronto, Ontario M5G 1K2 Canada	5	
Cox, John Joseph, MD	12196	McGill University Health Centre (MUHC) - Chronic Viral Illness Service 1001 Decarie Boulevard, Room D02.4017 Montreal, Quebec H4A 3J1 Canada	4	
Kasper, Ken, MD	03972	Winnipeg Regional Health Authority - Health Sciences Centre Winnipeg 820 Sherbrook Street Winnipeg, Manitoba R3A 1R9 Canada	2	
Walmsley, Sharon, MD	02856	Toronto General Hospital - University Health Network 585 University Avenue, 13 North Toronto, Ontario M5G 2N2 Canada	6	
North America/United States of America Akil, Bisher, MD	00765	Chelsea Village Medical 155 West 19th Street, 4th Floor New York, New York 10011 United States of America	1	
Albrecht, Helmut, MD	02838	Palmetto Health Richland Nine Medical Park, Suite 370 Columbia, South Carolina 29203 United States of America	1	
Bartczak, Jennifer, MD	03379	Rowan Tree Medical, P.A. 3197 NE 18th Terrace Oakland Park, Florida 33306 United States of America	3	

Geographic Region/ Country Principal Investigator	Investigator No.	Study Site	No. of Subjects Enrolled	No. of Additional Subjects Transferred From Another Study Site[a]
Bellos, Nicholaos C, MD	00302	Southwest Infectious Disease Clinical Research, Inc. 2603 Oak Lawn Avenue, Suite 210 Dallas, Texas 75219 United States of America	4	
Benson, Paul, DO	01236	Be Well Medical Center 1964 11 Mile Road Berkley, Michigan 48072 United States of America	10	1 subject transferred from DeJesus, Edwin [00698]
Berger, Daniel S, MD	00433	Northstar Healthcare 2835 North Sheffield Avenue, Suite 500 Chicago, Illinois 60657 United States of America	5	4 (1 subject transferred from Prelutsky, David J [01966], 1 subject transferred from Cruickshank, Frederick A [02825], 1 subject transferred from Dietz, Craig [00580] and 1 subject transferred from Shalit, Peter [00364])
Berhe, Mezgebe, MD	11678	North Texas Infectious Diseases Consultants, PA 3409 Worth Street, Suite 710, 725, 740 Dallas, Texas 75246 United States of America	14	3 (1 subject transferred from Sinclair, Gary [15110], 1 subject from Brinson, Cynthia [01624],and 1 subject transferred from DeJesus, Edwin [00698])
Brar, Indira, MD	01534	Henry Ford Hospital 2799 West Grand Boulevard Detroit, Michigan 48202 United States of America	3	1 subject transferred from Sinclair, Gary [15110]
Brinson, Cynthia, MD	01624	Central Texas Clinical Research 900 East 30th Street, Suite 302 Austin, Texas 78705 United States of America	13	
Colson, Amy, MD	01548	Community Research Initiative of New England 38 Chauncy Street, Suite 500 Boston, Massachusetts 02111 United States of America	2	1 subject transferred from Wohlfeiler, Michael B [02480]

Geographic Region/ Country Principal Investigator	Investigator No.	Study Site	No. of Subjects Enrolled	No. of Additional Subjects Transferred From Another Study Site[a]
Cook, Paul Peniston, MD	01808	East Carolina University, The Brody School of Medicine, Division of Infectious Diseases Brody School of Medicine at ECU 2390 Hemby Lane Greenville, NC 27858 United States of America	6	
Coulston, Daniel R, MD	00524	Multicare Rockwood HIV Critical Care Clinic 910 W 5th Ave Spokane, Washington 99204 United States of America	3	
Creticos, Catherine, MD	01645	Howard Brown Health Center 4025 North Sheridan Road Chicago, Illinois 60613 United States of America	3	1 subject transferred from DeJesus, Edwin [00698]
Crofoot Jr, Gordon E, MD	02475	Gordon E. Crofoot MD PA 3701 Kirby Drive, Suite 1230 Houston, Texas 77098 United States of America	11	(1 subject transferred from Brinson, Cynthia [01624]) 1 subject transferred from Johnson, Marc [05490]
Cruickshank, Frederick A, MD	02825	Rosedale Infectious Diseases 103 Commerce Centre Drive, Suite 103 Huntersville, North Carolina 28078 United States of America	9	
Cunningham, Douglas L, DO	02035	Pueblo Family Physicians 4350 North 19th Avenue, Suites 6 Phoenix, AZ, 85015 United States of America	2	
DeJesus, Edwin, MD	00698	Orlando Immunology Center 1707 North Mills Avenue Orlando, Florida 32803 United States of America	31	2 (1 subject transferred from Benson, Paul [01236] and 1 subject transferred from Brinson, Cynthia [01624])
Dietz, Craig, DO	05580	Kansas City CARE Clinic 3515 Broadway Kansas City, Missouri 64111 United States of America	2	1 subject transferred from Jain, Mamta [01691]

Geographic Region/ Country Principal Investigator	Investigator No.	Study Site	No. of Subjects Enrolled	No. of Additional Subjects Transferred From Another Study Site[a]
Eron, Joseph J, Jr, (MD) **Former PI:** Wohl, David, MD (00994)	00025	NC TraCS Institute- CTRC University of North Carolina at Chapel Hill 160 Dental Circle, Burnett-Womack, 1st Floor, Room 1036, CB #7064 Chapel Hill, North Carolina 27599 United States of America	1	1 subject transferred from Mogyoros, Miguel [04081]
Fichtenbaum, Carl, MD	02000	University of Cincinnati College of Medicine 200 Albert Sabin Way, Clinical Trials Unit, Division of Infectious Diseases Cincinnati, Ohio 45267-0405 United States of America	1	
Flamm, Jason, MD	01537	Kaiser Hospital 2025 Morse Avenue Sacramento, California 95825 United States of America	6	
Gathe Jr, Joseph C, MD	00031	Therapeutic Concepts, PA 4900 Fannin Street Houston, Texas 77004 United States of America	10	
Gupta, Samir K, MD	02146	Indiana University Infectious Diseases Research 720 Eskenazi Avenue, Fifth Third Faculty Office Building, B1062 Indianapolis, Indiana 46202 United States of America	1	1 subject transferred from Palmieri, Philip [02124]
Hagins, Debbie P, MD	04838	Chatham County Health Department 107B Fahm Street Savannah, Georgia 31401 United States of America	4	
Hassler, Shawn K, MD	10067	Optimus Medical Group 870 Market Street, Suite 600 San Francisco, California 94102 United States of America	2	
Henry, William Keith, MD	00659	Hennepin County Medical Center Positive Care Clinic 701 Park Avenue Minneapolis, Minnesota 55415 United States of America	0	
Hsiao, Chiu-Bin, MD	11572	Positive Health Clinic - Federal North Building 1307 Federal Street, Suite #B110 Pittsburgh, Pennsylvania 15212 United States of America	5	

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Hsu, Ricky, MD	04170	Dr. Ricky Hsu MD PC 352 Seventh Avenue, Suite 1205 New York, New York 10001 United States of America	3	3 (1 subject transferred from Arribas Lopez, Jose Ramon [1553], 1 subject transferred from Sax, Paul E [01912] and 1 subject transferred from Akil, Bisher [00765])
Jain, Mamta, MD	01691	UT Southwestern Medical Center, Amelia Court HIV Research Clinic 1936 Amelia Court, 2nd Floor Dallas, Texas 75235 United States of America	6	1 subject transferred from Slim, Jihad [00310]
Jayaweera, Dushyantha T, MD **Former PI:** Campo, Rafael, MD (00652)	01692	University of Miami, Miller School of Medicine 1800 Northwest 10th Avenue, 1st Floor Miami, Florida 33136 United States of America	4	1 subject transferred from Oguchi, Godson [08888]
Johnson, Marc, MD	05490	Atrium Health Infectious Disease Kenilworth 1225 Harding Place Suite 2100 Charlotte, North Carolina 28204 United States of America	9	4 (1 subject transferred from Berhe, Mezgebe [11678], 1 subject transferred from Crofoot Jr, Gordon E [02475], 1 subject transferred from Wohlfeiler, Michael B [02480] and 1 subject transferred from Ward, Douglas [0121])
Jordan, Wilbert C, MD	00804	OASIS Clinic 1807 East 120th Street Los Angeles, California 90059 United States of America	1	
Kinder, Clifford A, MD	02675	AHF-Kinder Medical Group 3661 South Miami Avenue, Suite 806 Miami, Florida 33133 United States of America	6	1 subject transferred from Wohlfeiler, Michael B [02480]
Martorell, Claudia T, MD	02191	Claudia T Martorell, MD., LLC d/b/a The Research Institute 57 Mulberry Street Springfield, Massachusetts 01105 United States of America	5	

Geographic Region/ Country Principal Investigator	Investigator No.	Study Site	No. of Subjects Enrolled	No. of Additional Subjects Transferred From Another Study Site[a]
Mayer, Cynthia Anne, DO	02843	St. Joseph's Hospital Comprehensive Research Institute 4600 North Habana Avenue, Suite 23 Tampa, Florida 33614 United States of America	4	1 subject transferred from Johnson, Marc [05490]
McDonald, Cheryl, MD	01609	Tarrant County Infectious Disease Associates 1025 College Avenue Fort Worth, Texas 76104 United States of America	8	
McGowan, Joseph, MD	00660	North Shore University Hospital / Division of Infectious Diseases 400 Community Drive Manhasset, New York 11030 United States of America	3	1 subject transfer from Scarsella, Anthony [4134]
Mills, Anthony, MD	02728	Mills Clinical Research 9201 Sunset Boulevard, Suite 812 Los Angeles, California 90069 United States of America	4	1 subject transferred from Ward, Douglas [0121]
Mogyoros, Miguel, MD	04081	Kaiser Permanente Colorado Skyline Medical Center 1375 East 20th Avenue, Infectious Disease Department Denver, Colorado 80205 United States of America	2	
Morales-Ramirez, Javier O, MD	00661	Clinical Research Puerto Rico 359 De Diego Avenue, Suite 501 San Juan, Puerto Rico 00909-1711 United States of America	9	1 subject transferred from DeJesus, Edwin [00698]
Mounzer, Karam, MD	01961	Philadelphia FIGHT 1233 Locust Street, Fifth Floor Philadelphia, Pennsylvania 19107 United States of America	1	
Nahass, Ronald G, MD	02493	ID Care 105 Raider Boulevard, Suite 101 Hillsborough, New Jersey 08844 United States of America	3	

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Oguchi, Godson, MD	08888	Midland Florida Clinical Research Center, LLC 665 Peachwood Drive Deland, Florida 32720 United States of America	5	
Osiyemi, Olayemi, MD	02106	Triple O Research Institute, P.A. 2580 Metro Centre Blvd, Suite 4 West Palm Beach, Florida 33407 United States of America	14	1 subject transferred from DeJesus, Edwin [00698]
Palmieri, Philip J, MD	02124	Upstate Infectious Diseases Associates, LLP 404 New Scotland Avenue Albany, New York 12208 United States of America	3	2 subjects transferred from Crofoot Junior, Gordon [02475]
Park, Connie, MD **Former PIs:** Shor, Asaf, MD (15625) and Klein, Daniel, MD (05083)	15994	Kaiser Permanente, Department of Infectious Diseases 2500 Merced Street, 2nd Floor San Leandro, California 94577 United States of America	2	
Parks, David, MD	01965	Southampton Clinical Research Group, Inc. 3960 Lindell Boulevard Saint Louis, Missouri 63108 United States of America	1	
Peyrani, Paula, MD	07934	University of Louisville Hospital 550 South Jackson Street, AC, 2nd Floor Louisville, Kentucky 40202 United States of America	0	
Prelutsky, David J, MD	01966	Southampton Healthcare, Inc. 2340 Hampton Avenue Saint Louis, Missouri 63139 United States of America	8	2 (1 subject transfer from DeJesus, Edwin [00698] and 1 subject from Vanig, Thanes J [00754])
Ramgopal, Moti, MD	01950	Midway Immunology and Research Center 360 East Midway Road Fort Pierce, Florida 34982 United States of America	8	
Rashbaum, Bruce, MD	00315	Capital Medical Associates. PC 1640 Rhode Island Avenue Northwest, Suite 800 Washington, DC 20036 United States of America	2	

Geographic Region/ Country Principal Investigator	Investigator No.	Study Site	No. of Subjects Enrolled	No. of Additional Subjects Transferred From Another Study Site[a]
Richmond, Gary J, MD	01598	Gary J. Richmond, M.D., P.A. 315 Southeast 14th Street Fort Lauderdale, Florida 33316 United States of America	2	
Roberts, Afsoon, MD	00589	Medical Faculty Associates 2150 Pennsylvania Avenue Northwest Washington, DC 20037 United States of America	1	
Ruane, Peter J, MD	00407	Ruane Clinical Research Group Inc. 5901 West Olympic Boulevard, Suite 420 Los Angeles, California 90036 United States of America	3	1 subject transfer from Crofoot, Gordon [02475]
Santiago Colon, Lizette, MD	01549	HOPE Clinical Research 1503 Asia Street, Asia Building, 6th Floor San Juan, Puerto Rico 00909 United States of America	4	
Sax, Paul E, MD	01912	Brigham and Women's Hospital 75 Francis Street Boston, Massachusetts 02115 United States of America	1	1 subject transferred from Colson, Amy [01548]
Scarsella, Anthony John, MD	04134	Pacific Oaks Medical Group 150 North Robertson Boulevard, Suite 300 Beverly Hills, California 90211 United States of America	2	
Scribner, Anita, MD	02058	DCOL Center for Clinical Research 707 Hollybrook Drive, Suite 501 Longview, Texas 75605 United States of America	4	
Shah, Namrata, MD **Former PIs:** Goldstein, Deborah, MD (01198), Hardy, William David, MD (00033) and Henn, Sarah, MD (01805)	19755	Whitman-Walker Health 1525 14th Street Northwest Washington, DC 20005 United States of America	4	
Shalit, Peter, MD	00364	Peter Shalit, M.D. 901 Boren Avenue, Suite 850 Seattle, Washington 98104 United States of America	4	2 (1 subject transferred from Gathe Junior, Joseph [00031] and 1 subject transferred from Berger, Daniel S [00433])

Geographic Region/ Country Principal Investigator	Investigator No.	Study Site	No. of Subjects Enrolled	No. of Additional Subjects Transferred From Another Study Site[a]
Sims III, James, MD	01208	St. Hope Foundation 6800 West Loop South, Suites 500, 560, 580 Bellaire, Texas 77401 United States of America	2	
Sinclair, Gary, MD **Former PIs:** Voskuhl, Gene W, MD (6046)	15110	Aids Arms, Inc. Trinity Health & Wellness Center 219 Sunset Avenue, Suite 116 A Dallas, Texas 75208 United States of America	6	2 subjects transferred from Bellos, Nicholaos C [00302]
Slim, Jihad, MD	00310	Saint Michael's Medical Center 111 Central Avenue Newark, New Jersey 07102 United States of America	8	1 subject transferred from Jain, Mamta [01691]
Sokol-Anderson, Marcia L MD	02731	Saint Louis University - New Hope Clinic 3691 Rutger Street, Suite 100 Saint Louis, Missouri 63110 United States of America	1	
Stein, David K, MD	02873	Jacobi Medical Center 1400 Pelham Parkway South Bronx, New York 10461 United States of America	1	
Stephens, Jeffrey, MD	00991	Mercer University, Department of Internal Medicine 433 Cherry Street Macon, Georgia 31201 United States of America	9	
Tebas-Medrano, Pablo, MD	00729	Perelman Center for Advanced Medicine at the Hospital of the University of Pennsylvania 3400 Civic Center Boulevard Philadelphia, Pennsylvania 19104 United States of America	2	
Thompson, Melanie A, MD	00255	AIDS Research Consortium of Atlanta 440 Ralph McGill Boulevard Atlanta, Georgia 30312 United States of America	2	

Geographic Region/ Country Principal Investigator	Investigator No.	Study Site	No. of Subjects Enrolled	No. of Additional Subjects Transferred From Another Study Site[a]
Towner, William James, MD	01543	Kaiser Permanente Los Angeles Medical Center 1505 North Edgemont Street, 2nd Floor, Infectious Disease Department Los Angeles, California 90027 United States of America	2	
Van Dam, Cornelius, MD	12135	Cone Health/Regional Center for Infectious Disease Wendover Medical Center, 301 East Wendover Avenue, Suite 111 Greensboro, North Carolina 27401 United States of America	1	1 subject transferred from Johnson, Marc [05490]
Vanig, Thanes J, MD	00754	Spectrum Medical Group 52 East Monterey Way Phoenix, Arizona 85012 United States of America	7	
Waldman, Sarah, MD **Former PI:** Asmuth, David M, MD (00843)	17354	CARES Community Health 1500 21st Street, Research 2nd Floor Sacramento, California 95811 United States of America	6	
Ward, Douglas J, MD	00121	Dupont Circle Physician's Group 1737 Twentieth Street Northwest Washington, DC 20009 United States of America	6	1 subject transferred from Johnson, Marc [05490]
Wheeler, David A, MD	00550	Clinical Alliance for Research and Education - Infectious Diseases, LLC (CARE-ID) 3289 Woodburn Road, Suite 250 Annandale, Virginia 22003 United States of America	4	
Whitehead, Mitchell, MD **Former PI:** Wade, Barbara H, MD (01942)	15947	Aids Healthcare Foundation - Pensacola 4300 Bayou Boulevard, Suite 17D Pensacola, Florida 32503-2671 United States of America	7	1 subject transferred from DeJesus, Edwin [00698]
Wiberg, Kjell, MD	12175	Sinai Hospital of Baltimore 2401 West Belvedere Avenue Baltimore, Maryland 21215 United States of America	1	
Wilkin, Aimee Maree, MD	05221	Wake Forest Baptist Health 100 Medical Center Boulevard Winston-Salem, North Carolina 27157 United States of America	1	

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Wohlfeiler, Michael B, MD	02480	AIDS Healthcare Foundation - South Beach 4308 Alton Road, Suite 950-960 Miami Beach, Florida 33140 United States of America	15	
Workowski, Kimberly, MD	02140	Emory Hospital Midtown Infectious Disease Clinic 550 Peachtree Street, Northeast, 7th Floor MOT Atlanta, Georgia 30308 United States of America	9	6 (1 subject transferred from Sokol-Anderson, Marcia L [02731], 1 subject transferred from Scarsella, Anthony John [04134] and 1 subject transfer from Cook, Paul Peniston [01808], 1 subject transferred from DeJesus, Edwin [0698], 1 subject transferred from Sims III, James [01208] and 1 subject transferred from Stephens, Jeffrey [00991])
Wurapa, Anson Kwame, MD	02316	Infectious Disease Specialists of Atlanta 2665 North Decatur Road #330 Decatur, Georgia 30033 United States of America	12	

a Blank cells in this column indicate no subjects transferred from another study site