| **Harm category** | **Study Author, year****Study design** | **Number of centers, Country** | **Study duration Mean followup** | **Intervention** | **Inclusion criteria** | **Patient characteristics** | **N** | **Funding source** | **Quality rating** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Multiple | Arribas 2017115 2 RCTs (GS-US-292-0104 and GS-US-292-0111) | GS-US-292-0104: 134 sites North America, Europe, Australia, Japan, and Thailand GS-US-292-0111: 128 sitesNorth America, Europe, and Latin America | 2 years | A. TAF + EVG/ COBI/FTC (n=866)B. TDF + EVG/ COBI/FTC (n=867) | Age ≥18 years, HIV-1 and no previous antiretroviral treatment, had HIV-1 RNA concentration ≥1,000 copies/mL, and eGFR ≥50 mL/min. Eligible patients had a screening HIV-1 genotype showing sensitivity to EVG, FTC, and tenofovir. | A vs. BMedian age: 33 vs. 35 years% Male: 85% vs. 85%Black/African heritage: 26% vs. 25%; Asian: 11% vs. 10%; Hispanic/Latino: 19% vs. 19%Median CD4 count: 404 vs. 406 cells/mm3HIV-1 RNA >100,000 copies/mL: 23% vs. 22%Median eGFR (Cockcroft-Gault): 117 vs. 114 mL/min | 1,733 | Gilead Sciences, Inc. | Good |
| Multiple | Rockstroh 2013116STARTMRK StudyRCT | 67 centersAustralia, Brazil, Canada, Columbia, Germany, India, Italy, Mexico, Peru, Spain, Thailand, U.S. | 4.6 years | A. RAL + TDF-FTC (n=281)B. EFV + TDF-FTC (n=282) | Treatment-naive HIV-infected patients age ≥18 years were eligible if their viral load was >5,000 RNA copies/mL without genotypic resistance to tenofovir, FTC, or EFV. Patients with stable chronic hepatitis could be enrolled if their serum aminotransferase levels were >5 xULN, patients with acute or decompensated chronic hepatitis excluded. | A vs. BMean age: 38 vs. 37 years% Male: 81% vs. 82%41% vs. 44% white; 12% vs. 8% black; 13% vs. 11% Asian; 21% vs. 24% Hispanic; 0.4% vs. 0.4% Native American; 13% vs. 13% multiracial | 563 | Merck | Good |
| Mortality | Kowalska, 2012121EuroSIDA StudyProspective cohort, single arm | 103 centers Europe, Israel, Argentina | Followed from time of starting ART or study entry until death or 6 months after last followup visitMedian followup: 5.4years (70,613 person- years) | cART | All patients recruited to EuroSIDA cohort after January 1996 who were on ART at some point while under followup, and had at least 1 CD4 count measurement available at or prior to baseline | Age: 38.2 years% Male: 74.6%Ethnicity: 88% whiteMode of HIV acquisition: MSM 40.6%, PWID 22.2%, heterosexual 29.3%HBV status: positive 5.5%, negative 73.1%, unknown 21.4%HCV status: positive 21.6%, negative 53.0%, unknown 25.4%Smoking: current 41.0%, previous 17.0%, never 20.3%, unknown 21.7%Hypertension: yes 10.2%, no 31.8%, unknown 58.0%Diabetes: yes 2.3%, no 84.0%, unknown 13.7% CD4 count: 288 cells/mm3HIV RNA viral load: 2.84 log10 copies/mL Median time of exposure to cART: 4.4 years | 12,069 | European Commission BIOMED 1,BIOMED 2, the 5th Framework, 6th Framework, and 7th Framework programs; grants by Gilead, Pfizer, Bristol-Myers Squibb, and Merck; the Swiss National Science Foundation | Fair |
| Myocardial Infarction | Sabin 2016102 D:A:D StudyProspective cohort | 11 cohorts Europe, Australia, U.S. | Followed from study entry until MI, death, February 2013, or 6months after last visit | ABC vs. not on ABC | HIV-1 positive patients followed prospectively during visits to outpatient clinics scheduled as part of regular medical care.Patients were enrolled into D:A:D consecutively as they were seen in the clinic from the time the D:A:D study was implemented in each of the participating cohorts. At enrollment and at least every 8 months thereafter standardized data collection forms are completed. Enrollment took place in 3 phases: cohort I (1999–2000), cohort II (added in 2004), cohort III (added in 2009) | Those under followup in 2012 (N=31,112): Male: 73.6%Median age: 50 years Previous AIDS: 27.8%10-year CVD risk: low 71.7%, moderate 71.7%, high 6.0%, unknown 11.1%Known smoking status: current smoker 39.8%, ex-smoker 30.6%, never smoked 29.6%Family history of CVD: 7.8% Diabetes: 6.3%Median TC: 5.0 mmol/L Median high-density lipoprotein cholesterol: 1.2 mmol/L Median trigylcerides: 1.5 mmol/L Median CD4: 566 cells/mm3Median viral load: 1.7 log10 copies/mL | 49,717 | See table note | Good |
| Myocardial Infarction | Monforte, 2013104 D:A:D StudyProspective cohort | Same as Sabin 2016 | Followed from study entry until MI, stroke, death, February 2011, or 6months after last visit | ATV, boosted or unboosted by RTV | Same as Sabin 2016 | ATV vs. other regimen vs. no ART Total person-years: 27,115 vs. 187,027 vs. 87,765Male: 73.5% vs. 75.7% vs. 69.4%Mode of HIV acquisition: MSM 45.3% vs. 46.0% vs. 41.9%PWID 16.1% vs. 14.5% vs. 17.6%Heterosexual 31.6% vs. 31.8% vs. 34.1%Other/unknown 6.9% vs. 7.8% vs. 6.5% Ethnicity:White 52.0% vs. 50.9% vs. 51.0%Black 7.2% vs. 8.1% vs. 9.0%Other 2.4% vs. 2.7% vs. 2.3%Unknown 38.4% vs. 38.2% vs. 37.7% Age:30–39 years: 21.0% vs. 29.8% vs. 16.4%40–49 years 44.2% vs. 39.3% vs. 11.8%50–59 years 21.2% vs. 17.6% vs. 3.8%Family history of MI: 9.3% vs. 8.1% vs. 7.0% Smoking history:Current smoker 41.3% vs. 37.8% vs. 41.4%Ex-smoker 24.3% vs. 22.1% vs. 17.5%Previous CVD event: 3.0% vs. 2.3% vs. 1.4%Diabetes: 6.8% vs. 4.9% vs. 3.5% | 49,734 | See table note | Same as Sabin 2016 |
| Myocardial Infarction | Monforte, 2013104 D:A:D StudyProspective cohort | See above | See above | See above | See above | Framingham score:Low (<10%) 60.3% vs. 50.3% vs. 49.1%Moderate (10%–20%) 19.8% vs. 14.0% vs. 8.9%High (>20%) 8.6% vs. 6.7% vs. 3.7%Unknown 11.3% vs. 29.0% vs. 38.3% | See above | See above | See above |
| Myocardial Infarction | Desai 2015103 Retrospective cohort | Database analysisU.S. | Enrolled from 1996–2009Mean followup varied according to study drug | Current ART exposure vs. no exposure | Patients with evidence of a positive HIV lab test on or after January 1, 1996, who also received subsequent medical care in the VA | Mean age: 46.5 years (SD, 10.1)% Male: 97.6%33.8% white; 42.4% black; 1.2% other; 22.6% missing race data; 5.5% Hispanic; 22.5% missing ethnicity data47.1% ever smokers11.6% diabetes8.7% chronic kidney disease0.36% history of stroke0.42% history of MI0.13% history of percutaneous coronary intervention0.09% history of coronary artery bypass surgery0.87% history of any cardiovascular event | 24,510 | NationalInstitutes of Health; Patient-Centered Outcomes Research Institute  | Fair |
| Cancer/Liver Disease | Bruyand, 2015109 D:A:D StudyProspective cohort | Same as Sabin 2016 | Followed from study entry or January 2004 until cancer diagnosis, February 2012, or 6months after last visit241,556Person-years (6.5 years per person) | Any cART vs.PIs vs. NNRTIs | Same as Sabin 2016 | Male: 73.6%Median age: 39 yearsMode of HIV acquisition: MSM 43.8%, PWID 14.5%, heterosexual 35.2%, other/unknown 6.5% Ethnicity: white 49.9%, black African 7.0%, other 2.0%, unknown 41.1%Smoking status: current smoker 39.8%, ex-smoker 17.7%, never smoker 24.8%, unknown 17.7% Median CD4 count: 433 cells/mm3Median plasma HIV RNA: 2.3 log10 copies/mL HCV: positive 10.5%, negative 63.0%, unknown 26.5%HBV: positive 4.2%, negative 66.0%, unknown 29.8%Previous cancer: 5.6%Any exposure to cART: 89.7% Median years of exposure: 7.1 years Any exposure to PIs: 68.7%Median years of exposure: 4.9 years Any exposure to NNRTIs: 68.7% Median years of exposure: 3.8 years | 41,762 | See table note | Same as Sabin 2016 |
| Cancer/Liver Disease | Ryom, 2016110 D:A:D StudyProspective cohort | Same as Sabin 2016 | Followed from study entry or February 2004 until the first of end-stage liver disease, orHepato-cellular carcinoma, death, February 2014, or 6 months after last visitMedian followup: 8.4 years | cART | Same as Sabin 2016 | White ethnicity: 49.6%% Male: 73.5% Median age: 40 yearsMode of HIV acquisition: MSM 44.5%, PWID 14.0%, heterosexual 33.6%, other/unknown 7.8% Ethnicity: white 49.6%, black African 9.4%, other 2.8%, unknown 38.2%CD4 cell count: 434 cells/mm3 HIV RNA: 2.3 log10 copies/mLHCV status: positive 18.1%, negative 63.7%, unknown 18.2%HBV status: positive 4.6%, negative 80.6%, unknown 14.8%Smoking status: current 38.7%, ex-smoker 17.0%, never 26.4%, unknown 17.9%Previous AIDS: 23.8% | 45,544 | See table note | Same as Sabin 2016 |
| Cancer/Liver Disease | Kovari, 2013117 D:A:D StudyProspective cohort | Same as Sabin 2016 | Followed from date of study entry until death or February 2010, or 6 months after last visitFollowup: 114,478 person- years; median 4.9 years | cART | Same as Sabin 2016All participants with negative HCV and HBV status | % Male: 73.1% Median age: 38 yearsEthnicity: white 47.3%, black 7.7%, other 2.2%, unknown 42.9%Mode of HIV acquisition: MSM 49.9%, PWID 1.8%, heterosexual 41.3%, other/unknown 7.0%CD4 cell count: 410 cells/mm3 Previous clinical AIDS: 22.6% Diabetes: 2.6%Smoking status: current 30.6%, former 20.6%, never 29.6%, unknown 19.2%Median cumulative exposure to treatment: ART 0.9 years, NRTI 0.8 years, PI 0.0 years, NNRTI 0.0 years Treatment status: naive 38.1%, interruption 4.7%, on ART 57.2% | 22,910 | See table note | Same as Sabin 2016 |
| Kidney Disease | Ryom, 2013123 D:A:D StudyProspective cohort | Same as Sabin 2016 | Followed from January 2004 until they had a confirmed eGFR of ≤70 mL/min or ≤60 mL/min or until last eGFR during followupMedian followup of4.5 years | cART | Same as Sabin 2016All participants with normal baseline renal function eGFR of≥90 mL/min | % Male: 73%Ethnicity: white 47%, African ancestry 8%, unknown 43%Mean age: 39 yearsMode of HIV acquisition: MSM 44%, PWID 14%, heterosexual 36%Prior AIDS-defining illness: 20% Mean CD4 count: 440 cells/mm3Mean HIV RNA load: 2.1 log10 copies/mL Mean duration of HIV positivity: 5.2 years HBV positive: 12%HCV positive: 12%Hypertension: 8%Diabetes: 3%Prior cardiovascular event: 2% Smoking: 42%cART exposure: 63% ART use:Tenofovir: 5,366 patients, 2,015 person-years followup, median 0 yearsLPV/r:-4,963 patients, 3,358 person years followup, median 0.1 yearsABC: 4,937 patients, 5,613 person-years followup, median 0.3 yearsATV/r: 1,055 patients, 296 person-years followup, median 0 yearsATV: 352 patients, 192 person- years followup, median 0.1 yearsOther RTV-boosted PI: 2,216 patients, 3,669 person-years followup, median 1.1 yearsIDV: 4,567 patients, 9,135 patient-years followup, median 1.5 years | 22,603 | See table note | Same as Sabin 2016 |
| Kidney Disease | Mocroft, 2016111D:A:D StudyProspective cohort | Same as Sabin 2016 | Followed from January 2004 until they had a confirmed eGFR of ≤60 mL/min per 1.73 m2 or until last eGFR during followup or February 2014Median followup duration of7.2 years | cART (TDF, ATV/r, LPV/r, other RTV-boosted PIs, ABC) | Same as Sabin 2016All participants with normal baseline renal function eGFR of ≥90 mL/min per 1.73 m2 | Median age: 39 years% Male: 73%Ethnicity: white 46%, black 8%, other 2%, unknown 44%Risk factor: MSM 45%, PWID 13%, heterosexual 36%, other 6%HBV status: negative 88%, positive 5%, unknown 7% HCV status: negative 72%, positive 18%, unknown 10%Mean baseline eGFR: 110 mL/min (IQR, 100–125) Median CD4 cell count: 441 cells/mm3Median viral load <400 copies/mL: 56% Antiretrovirals: never used ART 27%, ever started ART 72%Smoking status: current 42%, previous 18%, never 28%, unknown 12%Family history of CVD: no 64%, yes 7%, unknown 29%Hypertension: 8%Previous CVD: 1% Diabetes: 3%AIDS: 22% | 23,905 | See table note | Same as Sabin 2016 |
| Kidney Disease | Laprise 2013118Retrospective cohort | Single centerCanada | Enrollment 2002–2012Median followup 7.9 years | A. TDF exposure B. NonexposureOther ART comparisons:NRTI, NNRTI, PI exposure vs. nonexposure | Enrolled after January 2002 with eGFR measures | A vs. BMedian age: 39.3 years (total cohort)% Male: 95.9% vs. 96.7%95.9% vs. 96.7% white; 2.3% vs. 3.9% black; 5.4% vs. 5.2% otherDuration of HIV infection: 6.54 vs. 6.47 yearsMedian eGFR: 104.9 vs. 103.5 mL/min/1.73 m2  | 1,043 | None reported | Fair |
| Kidney Disease | Nkhoma 2016b120(see also **Fracture**)Retrospective cohort | Database analysisU.S. | Enrollment 2008–2014Mean followup 2.5 years | A. EVF + TDF-FTCB. RPV + TDF-FTC C. EVG + COBI + TDF-FTC  | Age ≥18 years with at least 1 medical record with a diagnosis of HIV-1 and treatment with EFV/TDF-FTC, RPV/TDF-FTC, or EVG/COBI/TDF-FTC; ≥6 months continuous enrollment prior to initiation of the index regimen  | A vs. B vs. C Renal outcomes (defined as ≥2 medical insurance claims that were associated with ICD-9-CM diagnosis codes for renal disease with the exclusion of codes associated with calculus of the kidney and ureter)Mean age 43.5 (10.5) vs. 42.3 (10.9) vs. 43.5 years (10.8)% Male: 87% vs. 84% vs. 89%Race/ethnicity NR | 9,876 | Bristol-Myers Squibb, authors are employees of and own stock in Bristol-Myers Squibb | Fair |
| Kidney Disease | Scherzer 2012119Retrospective cohort | National databaseU.S. | Enrollment from 1997–2007Median followup 3.9–5.5 years (varied according to outcome) | A. Tenofovir exposure (n=4,303)B. Nonexposure (n=6,538) | Treatment-naiveHIV-infected veterans at the time they entered clinicalcare in the VA system, who subsequently received monotherapy or cART with regular care and laboratory monitoring | A vs. BMean age 45 vs. 47 years% Male: 97% vs. 98%46% vs. 39% white; 47% vs. 51% black; 7% vs. 11% other race/ethnicityMedian eGFR: 97 (IQR, 82–113) vs. 96 (IQR, 82–114) mL/min per 1.73 m2Proportion with eGFR <60 mL/min per 1.73 m2: 4.7% vs. 7.3%Proteinuria: 19% vs. 21%  | 10,841 | National Institutes ofHealth, the NationalCenter for Research Resources, the American Heart Association Established InvestigatorAward, and the Veterans Affairs Public HealthStrategic Healthcare Group | Fair |
| Suicidality | Chang 2018108Prospective cohort | Single centerUganda | Enrollment 2005–20152 years mean followup | A. EFV, any use (n=305)B. NVP only (n=389) | Age ≥18 years, ART-naive, and living within 60 km (about 37.3 miles) of the clinic | A vs. BMedian age: 32 vs. 34 years66% vs. 73% femaleRace NR 7% vs. 7% suicidal ideation at enrollment33% vs. 33% probably depression at enrollment  | 694 | National Institutes of Health, Harvard and San Francisco Centers for AIDS Research, and DorisDuke Charitable Foundation | Fair |
| Suicidality | Smith, 2014107 D:A:D Study (abstract only)Prospective cohort | Same as Sabin 2016 | Followed from study entry until death, February 2013, or last study visit | cART, including efavirenz- containing regimens vs. other | Same as Sabin 2016 | NR, but see above for patient characteristics from other D:A:D publications | 49,717 | See table note | Same as Sabin 2016 |
| Suicidality | Nkhoma, 2016106Retrospective cohort | Unclear U.S. | Followed from study entry until death, end of exposure to anchor agent, disenrollment of insurance, or 2013 (end of study period) | cART, including:1. EFV- containing regimens (n=11,187 commercial database)
2. EFV- containing regimens (n=2,224 Medicaid database)
3. EFV-free regimens (n=8,796 commercial database)
4. EFV-free regimens (n=2,930 Medicaid database)
 | U.S. administrative claims data for commercially-insured (Truven Health MarketScan Commerical Claims and Encounters database) and Medicaid-insured (Multi State Medicaid database of 15 states) individuals; ART-naive patients age ≥12 years initiating an EFV- containing or EFV-free antiretroviral regimen with 6 months of continuous insurance enrollment prior to ART initiation period, 2007 to 2013 | A vs. B vs. C vs. DMean age: 40.1 vs. 41.7 vs. 40.8 vs. 39.7 years% Male: 86.0% vs. 56.7% vs. 79.1% vs. 50.2%Ethnicity (Medicaid data only available): 16 to 17% white, 69 to 70% black, 1.2 to 1.3% Hispanic, 12 to 13% unknown, 06% otherDepression: 16.7% vs. 29.0% vs. 20.0% vs. 34.8%Drug dependence: 0.6% vs. 5.3% vs. 0.9% vs. 8.1%Anxiety: 2.3% vs. 3.8% vs. 3.1% vs. 5.5%Attention deficit hyperactivity disorder: 0.4% vs. 0.4% vs. 0.6% vs. 0.5%Bipolar disorder: 0.6% vs. 3.5% vs. 1.3% vs. 5.8%Personality disorder: 0.1% vs. 0.7% vs. 0.2% vs. 1.2%Schizophrenia: 0.04% vs. 3.7% vs. 0.1% vs. 7.0%Suicidality: 0.2% vs. 1.3% vs. 0.4% vs. 2.9%Suicide attempt: 0.01% vs. 0.1% vs. 0.03% vs. 0.3%Suicide attempt (expanded): 0.1% vs. 0.3% vs. 0.1% vs. 0.8% | 25,137 | Bristol-Myers Squibb Authors are employees of Bristol-Myers Squibb and Truven Health Analytics | Fair |
| Fracture | Borges 2017112EuroSIDA StudyProspective cohort | 11 cohorts Europe, Australia, U.S. | Enrollment from 2004; mean followup unclear (total 86,118 person-years) | TDF exposure vs. no TDF exposure | Age >16 years withbaseline data on CD4 counts and viral loads with prospectivefollowup | Total populationMean age: 49 years% Male: 75%86% white; 6% black; 2% Asian; 6% other2% prior fracture97% ART use (defined as ZDV, ddl, D4L, 3TC, FTC, TDF, ABC, NVP, EFV, SQV, RTV, LPV, IDV, NFV, ATV, LPV/r, and any other boosted PIs) | 11,820 | Bristol-Myers Squibb,European Union 7th Framework Programme; Gilead; Glaxo-Smith Kline; Janssen Research and Development; Merck; Pfizer; Swiss National Science Foundation; Danish National Research Foundation | Fair |
| Fracture | Nkhoma 2016b120(see also **Kidney Disease**)Retrospective cohort | Database analysisU.S. | Enrollment 2008–2014Mean followup 2.5 years | A. EVF + TDF-FTCB. RPV + TDF-FTC C. EVG + COBI + TDF-FTC | Age ≥18 years with at least 1 medical record with a diagnosis of HIV-1 and treatment with EFV/TDF-FTC, RPV/TDF-FTC, or EVG/COBI/TDF-FTC; ≥6 months continuous enrollment prior to initiation of the index regimens | A vs. B vs. C Fracture (defined as ICD-9-CM diagnosis codes for bone fracture)Mean age: 43 (10.6) vs. 42 (11.0) vs. 43 years (11.1)% Male: 87% vs. 84% vs. 89%Race/ethnicity NR | 10,383 | Bristol-Myers Squibb, authors are employees ofand own stock in Bristol-Myers Squibb | Fair |

**Abbreviations:** 3TC=lamivudine; ABC=abacavir; ART=antiretroviral therapy; ATV=atazanavir; ATV/r=ritonavir-boosted atazanavir; cART=combination antiretroviral therapy; CD4=cluster of differentiation 4; COBI=cobicistat; CVD=cardiovascular disease; D4L=stavudine; D:A:D Study=Data Collection on Adverse Events of Anti-HIV Drugs Study; ddl=didanosine; eGFR=estimated glomerular filtration rate; EFV=efavirenz; EVG=elvitegravir; FTC=emtricitabine; HBV=hepatitis B virus; HCV=hepatitis C virus; ICD-9-CM=International Classification of Diseases, 9th Revision, Clinical Modification; IDV=indinavir; IQR=interquartile range; LPV=lopinavir; LPV/r=ritonavir-boosted lopinavir; MI=myocardial infarction; MSM=men who have sex with men; NFV=nelfinavir; NNRTI=nonnucleoside reverse transcriptase inhibitors; NR=not reported; NRTI=nucleoside reverse transcriptase inhibitors; NVP=nevriapine; PI=protease inhibitor, PWID=persons who inject drugs; RAL=raltegravir; RCT=randomized, controlled trial; RNA=ribonucleic acid; RPV=rilpivirine; RTV=ritonavir; SD=standard deviation; SQV=saquinavir; STARTMRK=Phase III Noninferiority Trial of Raltegravir-Based Versus Efavirenz-Based Therapy in Treatment-Naïve Patients; TAF=tenofovir alafenamide; TDF=tenofovir disoproxil fumarate; ULN=upper limit of normal; U.S.=United States; VA=U.S. Department of Veterans Affairs; ZDV=zidovudine.

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