| **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 sites  North 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. B Median 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/mm3 HIV-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 2013116 STARTMRK Study  RCT | 67 centers Australia, 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. B Mean 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, 2012121  EuroSIDA Study  Prospective 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 visit  Median followup: 5.4  years (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% white  Mode 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/mm3  HIV 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 Study  Prospective cohort | 11 cohorts Europe, Australia, U.S. | Followed from study entry until MI, death, February 2013, or 6  months 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/mm3  Median viral load: 1.7 log10 copies/mL | 49,717 | See table note | Good |
| Myocardial Infarction | Monforte, 2013104  D:A:D Study  Prospective cohort | Same as Sabin 2016 | Followed from study entry until MI, stroke, death, February 2011, or 6  months 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. 87,765  Male: 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 Study  Prospective 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 analysis U.S. | Enrolled from 1996–2009 Mean 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 data 47.1% ever smokers 11.6% diabetes 8.7% chronic kidney disease 0.36% history of stroke 0.42% history of MI 0.13% history of percutaneous coronary intervention 0.09% history of coronary artery bypass surgery 0.87% history of any cardiovascular event | 24,510 | National Institutes of Health; Patient-Centered Outcomes Research Institute | Fair |
| Cancer/Liver Disease | Bruyand, 2015109 D:A:D Study  Prospective cohort | Same as Sabin 2016 | Followed from study entry or January 2004 until cancer diagnosis, February 2012, or 6  months after last visit  241,556  Person-years (6.5 years per person) | Any cART vs.  PIs vs. NNRTIs | Same as Sabin 2016 | Male: 73.6%  Median age: 39 years  Mode 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/mm3  Median 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 Study  Prospective cohort | Same as Sabin 2016 | Followed from study entry or February 2004 until the first of end-stage liver disease, or  Hepato-cellular carcinoma, death, February 2014, or 6 months after last visit  Median followup: 8.4 years | cART | Same as Sabin 2016 | White ethnicity: 49.6%  % Male: 73.5%  Median age: 40 years  Mode 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/mL  HCV 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 Study  Prospective cohort | Same as Sabin 2016 | Followed from date of study entry until death or February 2010, or 6 months after last visit  Followup: 114,478 person- years; median 4.9 years | cART | Same as Sabin 2016  All participants with negative HCV and HBV status | % Male: 73.1%  Median age: 38 years  Ethnicity: 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 Study  Prospective 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 followup  Median followup of  4.5 years | cART | Same as Sabin 2016  All participants with normal baseline renal function eGFR of  ≥90 mL/min | % Male: 73%  Ethnicity: white 47%, African ancestry 8%, unknown 43%  Mean age: 39 years  Mode of HIV acquisition: MSM 44%, PWID 14%, heterosexual 36%  Prior AIDS-defining illness: 20% Mean CD4 count: 440 cells/mm3  Mean 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 years  LPV/r:-4,963 patients, 3,358 person years followup, median 0.1 years  ABC: 4,937 patients, 5,613 person-years followup, median 0.3 years  ATV/r: 1,055 patients, 296 person-years followup, median 0 years  ATV: 352 patients, 192 person- years followup, median 0.1 years  Other RTV-boosted PI: 2,216 patients, 3,669 person-years followup, median 1.1 years  IDV: 4,567 patients, 9,135 patient-years followup, median 1.5 years | 22,603 | See table note | Same as Sabin 2016 |
| Kidney Disease | Mocroft, 2016111  D:A:D Study  Prospective 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 2014  Median followup duration of  7.2 years | cART (TDF, ATV/r, LPV/r, other RTV-boosted PIs, ABC) | Same as Sabin 2016  All 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/mm3  Median 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 2013118  Retrospective cohort | Single center Canada | Enrollment 2002–2012 Median followup 7.9 years | A. TDF exposure  B. Nonexposure  Other ART comparisons: NRTI, NNRTI,  PI exposure vs. nonexposure | Enrolled after January 2002 with eGFR measures | A vs. B Median 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% other Duration of HIV infection: 6.54 vs. 6.47 years Median 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 analysis U.S. | Enrollment 2008–2014 Mean followup 2.5 years | A. EVF + TDF-FTC B. 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 2012119  Retrospective cohort | National database U.S. | Enrollment from 1997–2007 Median followup 3.9–5.5 years (varied according to outcome) | A. Tenofovir exposure (n=4,303) B. Nonexposure (n=6,538) | Treatment-naive HIV-infected veterans at the time they entered clinical care in the VA system, who subsequently received monotherapy or cART with regular care and laboratory monitoring | A vs. B Mean age 45 vs. 47 years % Male: 97% vs. 98% 46% vs. 39% white; 47% vs. 51% black; 7% vs. 11% other race/ethnicity Median eGFR: 97 (IQR, 82–113) vs. 96 (IQR, 82–114) mL/min per 1.73 m2 Proportion with eGFR <60 mL/min per 1.73 m2: 4.7% vs. 7.3% Proteinuria: 19% vs. 21% | 10,841 | National Institutes of Health, the National Center for Research Resources, the American Heart Association Established Investigator Award, and the Veterans Affairs Public Health Strategic Healthcare Group | Fair |
| Suicidality | Chang 2018108  Prospective cohort | Single center Uganda | Enrollment 2005–2015 2 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. B Median age: 32 vs. 34 years 66% vs. 73% female Race NR  7% vs. 7% suicidal ideation at enrollment 33% vs. 33% probably depression at enrollment | 694 | National Institutes of Health, Harvard and San Francisco Centers for AIDS Research, and Doris Duke 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, 2016106  Retrospective 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. D  Mean 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% other  Depression: 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 2017112 EuroSIDA Study  Prospective 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 with baseline data on CD4 counts and viral loads with prospective followup | Total population Mean age: 49 years % Male: 75% 86% white; 6% black; 2% Asian; 6% other 2% prior fracture 97% 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 analysis U.S. | Enrollment 2008–2014 Mean followup 2.5 years | A. EVF + TDF-FTC B. 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 of and 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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