Additional File 2:

Table S1 Characteristics of Adverse drug events studies carried out on general patient Cohorts

Author, Year	Country	Data Sources & Duration	Study Design	Setting	ADE Definition	Population's Characteristics	Method of Detection	ADE Assessment		
								Causality	Seriousness or severity	Preventability
Adult Population										
Adedapo, 2020 [18]	Nigeria	Single-Center (May 2012 to April 2013)	Prospective Cohort Study	Medical Wards	ADR (WHO)	N= 1280 Adult 41.8% Female	Examination of medical, and nursing records, reviewing prescription charts, and patient interviews.	WHO-UMC	Assessed but NR	Assessed but NR
Aderemi-Williams Ri, 2015 [19]	Nigeria	Single-Center (January 2009, to December 2009)	Retrospective Chart Review	Medical Wards	ADR (WHO)	N=624 Adult 42.6% female	Medical record review	NR	NR	NR
Angamo, 2018 [20]	Ethiopia	Single-Center (May 2015 to August 2016)	Cross-Sectional Observational Study	Medical Wards	ADR (WHO)	N= 1001 Adult 45.5% Female	Review of medical records, laboratory tests, and patient interviews.	Naranjo	Hartwig	Schumock
Angamo, 2017 [21]	Ethiopia	Single-Center (May 2015 to August 2016).	Prospective Cross-sectional Study	Medical Wards	ADR (WHO)	N= 1001 Adult 45.5% Female	Review of medical records, laboratory tests, patient interviews, and physical observation.	Naranjo	NR	Schumock
Asio, 2023 [22]	Uganda	Single-Center (November 2013 to April 2014)	Cross-sectional Study	Medical and Gynaecological Wards	ADR(WHO)	N=762 Adult 70% Female	Clinical charts	Naranjo	DAIDS AE Grading Table	Schumock
Ersulo, 2022 [27]	Ethiopia	Single-Center (February 2021 to July 2021)	Prospective observational study	Medical Ward	ADE (Jha)	N=240 Adult 52.5% Female	Medical charts, patient interview, Laboratory data	Naranjo	Hartwig	Schumock
Jennane, 2011 [28]	Morocco	Single-Center (during six weeks	Prospective Cohort Study	ICU	ADE (National Coordinating	N=63	Clinical round, voluntary, and verbal report, chart Review, assessing prescriptions and transcriptions voluntary,	NR	WHO	NR

		of September 2009)			Council for Medication Error Reporting and Prevention)	Adult 41% female	and verbally report by medical and paramedical staff, chart review and studying prescriptions and transcriptions			
Kiguba, 2017 [29]	Uganda	Single-Center (December 2013 to April 2014)	Prospective Cohort Study	Medical and Gynaecological Wards	ADR (WHO)	N=762 Adult 70% Female	Clinical Examination, Medical Record Review, Patient/Caregiver/Ward Staff Interviews	Naranjo	DAIDS AE Grading Table	Schumock
Matsaseng, 2005 [32]	South Africa	Single-Center (9-month period)	Retrospective Chart Review	Gynaecology Ward	AE (Brennan)	N=793 All Female	Medical record review	Leappe	Brennan	Leappe
Mehta, 2008 [33]	South Africa	Single-Center (September to November 2005)	Prospective Observational Study	Medical Wards	ADR (WHO)	N=665 Adult 51% Female	Medical record review	WHO	Temple	Schumock
Mouton, 2016 [34]	South Africa	Multicenter (30-day periods during 2013)	Cross-Sectional Survey	Medical Wards	ADR (Aronson and Ferner)	N=1904 Adult 56% Female	Medical record review, medication history, and Review of laboratory data	WHO-UMC	Temple	Schumock
Mouton, 2015 [36]	South Africa	Multicenter (April to September 2013)	Cross-Sectional	Medical Wards	ADR (Aronson and Ferner)	N=1904 Adult 56% female	Medical record review, medication history, review of prescriptions, and laboratory data	WHO-UMC	NR	Schumock
Mouton, 2021 [37]	South Africa	Multicenter (December 2014 to November 2015)	Retrospective Study	Non-trauma Emergency Unit	ADR (Aronson and Ferner)	N = 1010 Adult 57% Female	Folder reviews	WHO-UMC	Temple	Schumock
Sahilu, 2020 [40]	Ethiopia	Single-Center (3-month)	Prospective Observational Study	Medical Ward	ADE (National action plan for adverse drug event prevention)	N=319 Adult 50.5% Female	Medical charts, patient interviews, and direct observation.	Naranjo	Hartwig	Schumock
Sendekie, 2023 [41]	Ethiopia	Single-Center (May to October 2022)	Prospective Matched Nested Case–Control Study	Medical Ward	NR	N=206 Adult 35.4% Female	Patient interviews, patient medical record review, laboratory results and direct observation	Naranjo	Hartwig	NR

Tumwikirize, 2011 [43]	Uganda	Multicenter (July to December 2005.)	Longitudinal Observational Study	Medical Wards	ADR(WHO)	N=728 Adult 56% Female	History and physical examination, medical Record review	Naranjo	Dorman	Schumock
All age groups										
Benkirane, 2009 [23]	Morocco	Multicenter (April to July 2007)	Prospective Cohort Study	ICU	ADE (Bates)	N=696 Adult, and Pediatric 45.4% Female	Daily physician rounds, monitoring for medication ordering, and transcribing, solicited reports from health professionals	Begaud	WHO	Consensus agreement
Benkirane, 2009 [24]	Morocco	Single-Center (13 to 17 December 2004)	Retrospective Cross-sectional	Medical, Surgical, ICUs, and EDs	ADE (Bates)	N=1390 Adult and Pediatric 40% Female	Solicited information from clinicians	Begaud	WHO	Schumock
Letaief, 2010 [30]	Tunisia	Single-Center (during 2005)	Retrospective Cohort Study	Clinical Departments	AE (Letaief)	N=620 General Population 53.4% Female	Medical record review	Wilson	Wilson	Wilson
Pediatric Population										
Dedefo, 2016 [25]	Ethiopia	Single-Center (February to March 2014).	Prospective Observational Study	Pediatric Ward	ADE (American Society of Health-System)	N=233 Pediatric 36.1% Female	Chart review, ward round, patient/caregiver interview, voluntary report	Naranjo	NCCMERP	Consensus agreement
Eshetie, 2015 [26]	Ethiopia	Single-Center (February to May 2011)	Prospective Observational Study	Pediatric Ward	ADE (Bates)	N=600 Pediatric 38.2% Female	Chart review, ward round, patient/caregiver interview, voluntary staff report	WHO-UMC	NCCMERP	Schumock
Makiwane, 2019 [31]	South Africa	Single-Center (December 2015 to February 2016)	Prospective Observational Study	Pediatric Wards	ADR (WHO)	N= 282 Pediatric NR	Chart Reviews	Naranjo	Hartwig	Assessed but NR
Mouton, 2020 [35]	South Africa	Single-Center (April to May 2015)	Observational Study	Medical wards, ICU	ADR (Aronson and Ferner)	N=1050 Pediatric 44% Female	Clinical notes, medication prescription charts, and laboratory results	WHO	Temple	Schumock

Oshikoya, 2011 [38]	Nigeria	Single-Center (July 2006 to December 2007)	Prospective Observational Study	Pediatric Ward	ADR (Edwards and Aronson)	N=2004 Pediatric 39% Female	Medical and nursing records review, review of prescription charts, attending clinical rounds, reports from healthcare professionals	Jones	Schirm	Schumock
Oshikoya, 2007 [39]	Nigeria	Single-Center (July 2006 to December 2007)	Retrospective Prospective Study	Pediatric Ward	ADR(WHO)	N=3821 Pediatric 42% Female	Medical and nursing record review, prescription chart review	Jones	Martınez-Mir	Assessed but NR
Elderly Population										
Tipping, 2006 [42]	South Africa	Single-Center (February to May 2005).	Prospective Cross-Sectional Study	Emergency Unit	ADE (*South African Medicines Formulary* (6th Edition))	N=517 Elderly 59% Female	Primary physician and/or principal investigator assessment	Nebeker	NR	NR
Yadesa, 2022 [44]	Uganda	Single-Center (November 2020 to May 2021)	Prospective Cohort	Medical, Oncology, and Surgery wards	ADR (Edwards and Aronson)	N=523 Elderly 48.6 % Female	Medical record review, physical assessments and laboratory data	Naranjo	NR	NR

ADE Adverse drug event, *ADR* Adverse drug reaction, *AE* Adverse event, *ICU* Intensive care unit, *ED* Emergency department, *NR* Not recorded, *NS* Not stated, *DAIDS* Division of AIDS, *NCCMER* National Coordinating Council for Medication Error Reporting and Prevention, *WHO* World Health Organization, *WHO-UMC* World Health Organization-Uppsala Monitoring Centre.

Note: Angamo [20] and Angamo [21] used the same groups of patients but different outcome of interest in both studies; Mouton [34] and Mouton [36], used the same groups of patients but different outcome of interest in both studies.

Table S2 Characteristics of Adverse drug events studies carried out on specific patient Cohorts

Author, Year	Country	Data Sources & Duration	Study Design	Setting	ADE Definition	Population's Characteristics	Method of Detection	ADE Assessment		
								Causality	Seriousness or severity	Preventability
Adult Population										
Abah, 2021 [45]	Nigeria	Single-center (January 2004 to December 2015)	Retrospective Cohort Study	Outpatient Clinic	ADR (WHO)	N=13,983 HIV-infected Adult 66% Female	Standard clinical evaluation	NR	WHO	NR
Abah, 2018 [46]	Nigeria	Single-center (June 2004 to February 2012)	Retrospective Cohort Study	Healthcare Facility	ADR (WHO)	N=12115 HIV-positive Adult 67.3% female	Electronic medical record system	NR	Assessed but NR	NR
Abah,2015 [47]	Nigeria	Single-center (January 2004 to December 2011)	Retrospective Cohort Study	HIV Clinic	ADR (WHO)	N=2920 HIV-1 infected Adult 22% Female	Standard clinical procedures, spontaneous reports by patients	NR	WHO and Pharmacovigilance definitions	NR
Abdissa, 2012 [48]	Ethiopia	Single-center (October 2008 to December 2009)	Prospective Observational Study	HIV Outpatient Clinics	NR	N=228 HIV positive Adult 64% Female	Structured questionnaire	NR	Assessed but NR	NR
Babirye, 2023 [52]	Uganda	Single-Center (November 2021 to January 2022)	cross-sectional	Hypertension Clinic	ADR (WHO)	N=228 Adult hypertensive patients 75.9% Female	Medical records	Naranjo	NR	NR
Bahta, 2020 [54]	Eritrea	Single-center (August to October 2018)	Cross-sectional Descriptive, and Analytical Study	Outpatient Departments	ADR (WHO)	N=251 Adult with schizophrenia 43% Female	Patients self-administered questionnaires	NR	NR	NR
Berhe, 2017 [55]	Ethiopia	Multicenter NS	Cross-sectional Study	Outpatient Clinics	NR	N=925 Hypertensive Adult	Interview, medical records	NR	NR	NR

						63% Female.				
Beyene, 2022 [56]	Ethiopia	Single-Center (September 2020 to May 2021)	Prospective observational	Ambulatory care clinic	ADR (Beyene)	N=320 Adult epileptic patients 45% Female	interviewing and medical records review	NR	NR	NR
Bezabhe, 2015 [57]	Ethiopia	Multicenter (December 2012 to May 2014)	Prospective Cohort Study	ART Clinics	ADR (WHO)	N=211 HIV/AIDS Adult 60.2% Female	Patients, caregivers' interviews, and review of patients' medical records	Naranjo	AIDS AE (DAIDS AE) grading table	Schumock
Chikowe, 2019 [58]	Malawi	Single-center (4 weeks)	Cross-sectional Observational Study	Outpatient Department	NR	N= 40 Adult with psychotic disorders 32.5% Female	Structured self-reporting questionnaire	NR	GASS	NR
Elangwe, 2020 [59]	Cameroon	Single-center (June 2018 to June 2019)	Cross-sectional Study	Diabetes Clinic	NR	N=350 T2DM Adult 58.8% Female	Self-reported by the patients	Naranjo	Modified Hartwig and Siegel's	NR
Elhamdouni, 2020 [60]	Morocco	Multicenter (January 2014 to January 2016)	Multi-centric Observational Prospective Cohort Study	Multi-centers	NR	N=2532 TB 15 years or above 28% Female	Clinical charts, medical charts	WHO	WHO	NR
Gebremeskel, 2021 [62]	Ethiopia	Single-center (January 2017 to February 2020)	Retrospective Cohort Study	ART Clinics	ADR (WHO)	N=452 HIV-positive Adult 51.5% female	ART registry logbook and electronic medical record (EMR) system	NR	Assessed but NR	NR
Gudina, 2017 [63]	Ethiopia	Multicenter (September 2009 to December 2013)	Prospective and Retrospective Cohort Study	ART Clinics	ADR (WHO)	N=3921 HIV positive Adult 61.9% Female	Clinical and/or laboratory data	NR	WHO	NR
Hagos, 2019 [64]	Eritrea.	Single center (September 2005 to December 2016)	Retrospective Study	ART Clinic	ADR (WHO)	N=309 HIV Adult 64.1% Female	Patients' clinical cards	Naranjo	ICH E2A guideline	NR

Kiguba, 2017 [65]	Uganda	Single-center (December 2013 to April 2014)	Prospective Cohort Study	Medical and Gynaecological Wards	aa-ADR (WHO)	N=762 Adult 70% Female	Clinical examination	Naranjo	Division of AIDS Table	Schumock
Kindie, 2017 [67]	Ethiopia	Single-center (July 2011 to June 2016)	Retrospective Study	Felege Hiwot Referral Hospital	ADR (WHO)	N=602 HIV positive Adult 59.5% Female	Patient card	NR	NR	NR
Luma, 2012 [70]	Cameroon	Single-center (between 2003 to 2009)	Cross-sectional Clinical Chart Review	HIV Outpatient Clinics	ADR (Edwards)	N=339 Adult HIV patients 60.2% Female	Clinical chart.	NR	NR	NR
Michael, 2016 [72]	Nigeria	Single-center (January 2006 to June 2007)	Prospective observational Study	Chest Clinic	NR	N=103 HIV and TB co-infected Adult 38.8% female	Clinical examination and Patient interview	NR	Assessed but NR	NR
Mitkie, 2021 [73]	Ethiopia	Multicenter (July 2006 to August 2017)	Retrospective Cohort	Multi-Hospitals	ADR (Gudina)	N= 592 HIV positive Adult 65.5% female	Follow-up forms	NR	NR	NR
Namulindwa, 2022 [74]	Uganda	Single-Center	Mixed Design Study	Immune Suppression Syndrome Clinic	NR	N=375 Adult HIV patients 40.5% Female	Medical files and Patients interview	NR	DAIDS grading of ADEs	NR
Nemaura, 2013 [76]	Zimbabwe	Multicenter (NS)	Cross-sectional, Case-control Study	Outpatient Department	NR	N=430 HIV/AIDS and/or TB-infected Adult 65% female	Questionnaire	NR	WHO	NR
Onoya, 2018 [79]	South Africa	Multicenter (April 2004 to January 2016)	Prospective Cohort Study	ART Clinics	NS	N = 7708 HIV-1-infected Adult 65.0% female	Clinical notes, laboratory data	NR	NR	NR

Otubanjo, 2008 [81]	Nigeria	Communities (1996-2000)	Retrospective Study	Communities	NS	N=2398 Adult 50.1% Female	Interview	NR	NR	NR
Oumar, 2019 [82]	Mali	Single-center (June 2011 to May 2012)	Prospective Cohort Study	HIV/AIDS care and Counselling Centre (CESAC)	NS	N=843 HIV-infected Adult 71.9% Female	Patient interviews, medical charts	Naranjo	NR	NR
Sherfa, 2012 [89]	Ethiopia	Multicenter (January 2013 to December 2018)	Retrospective Cohort Study	Public Health Facilities	ADR (WHO)	N=456 HIV Adult 61.18% Female	ART registers and medical record review	NR	NR	NR
Tamirat, 2020 [90]	South Ethiopia	Single-center (2005 to 2014)	Cross-sectional Study	ART Clinic	ADR (WHO)	N= 231 HIV/AIDS Adult 64.5% Female	Medical records review	NR	Assessed but NR	NR
Van Der Walt, 2013 [92]	South Africa	Multicenter (2000 to 2004)	Prospective Cohort	Multi-center	ADR (Van der walt)	N=1390 MDR-TB Adult 38.9% Female	Patient self-reporting or through observation by the clinician/nurse	NR	Assessed but NR	NR
Wangai, 2011 [93]	Kenya	Single-center (mid-2003 to the end of 2007)	Retrospective Cohort Study Design	HIV Comprehensive Care Clinic	NS	N=413 HIV infected Adult 65.9% Female	Medical record	NR	NR	NR
Weldegebreal, 2016 [94]	Ethiopia	Single-center (March 2006 to March 2014)	Retrospective study	ART Unit	ADR (Teklay)	N=358 HIV/AIDS Adult 68.4% Female	Clinical records	NR	WHO	NR
All age groups										
Amalba, 2021 [50]	Ghana	Single center (October 2017 to April 2018)	Cross-sectional Study	Chest Clinic	ADR (Edwards)	N= 66 All patients on first-line anti-tubercular therapy 50% Female	Questionnaire	NR	NR	NR

Ategyeka, 2023 [51]	Uganda	Multi-Center (Jan, 2016 to Dec, 2020)	Retrospective cohort	TB wards	NR	N=856 All MDR-TB patients 36.6% female	Medical records review	NR	NR	NR
Eluwa, 2012 [61]	Nigeria	Multicenter (May 2006 to May 2009)	Retrospective Cohort Analysis	Multi-Hospitals	ADR (WHO)	N=2650 All patients on ART 64% Female	ADR screening form	NR	WHO	NR
Kim, 2007 [66]	Kenya,	Single center (February 2003 to February 2005)	Retrospective Cohort Study	Outpatient Clinic	NR	N=283 All HIV patients 70% female	History, clinical examination, and Laboratory test	NR	Assessed but NR	NR
Lartey, 2014 [68]	Ghana	Single-center (December 2003 to June 2007)	Cross-sectional Retrospective study	Fevers Unit	ADR (WHO)	N=167 All HIV/AIDS patients 62.3% Female	Review of patient data	NR	NR	NR
Isa, 2018 [69]	Nigeria	Single-center (February to July 2017)	Prospective Observational Study	ART Clinic	ADR (WHO)	N=167 HIV/AIDS patients > 13 years 60% Female	Patient interviews, medical records, and follow-up	WHO	Hartwig	NR
Merid, 2019 [71]	Ethiopia	Multicenter (September 2010 to December 2017)	Retrospective Cohort Study	Multi-center	NR	N=570 All DR-TB patients 43.2% Female	Patient charts, medical notes, follow up green cards and registries	NR	NR	NR
Ndagije, 2018 [75]	Uganda	Community (April to July 2017)	Observational, Active, Follow-up Study	Health Facilities and Drug Outlets	ADR (Basu)	N=782 All Patients treated for uncomplicated malaria 58.6% Female	Reported by patients, or recorded by healthcare workers	Naranjo	NR	P-method
Njau, 2013 [77]	Tanzania	Rural districts (2003 to 2005).	Cross-sectional Study	Health Facilities and Households	ADR (Phillips-Howard)	N=67 All patients treated with Sulphadoxine-pyrimethamine and artemsinin	Passive and active surveillance	NR	NR	NR

						60% Female				
Nkenfou-Tchinda, 2020 [78]	Cameroon	Single-center (January 2013 to December 2013)	Retrospective Study	Outpatient ART Center	ADR(Ejigu)	N = 1254 All HIV-positive patients female 67.4% Female	Patient complaints and/or observations made and reported in the patient's record	NR	NR	NR
Reginald, 2012 [84]	Nigeria	Single-center (NS)	Prospective Cohort Study	ART Center	ADR (Edwards)	N=3641 All HIV- infected patients 67.5% female	Reported by patients, or were detected by nurses and clinicians	Naranjo	Assessed but NR	NR
Sagwa, 2014 [85]	Namibia	Single-center (January 2008 to February 2010)	Retrospective Observational Cohort Study	DR-TB Treatment Ward	NS	N=57 All Patients with DR-TB NS	Observed by clinician or reported by patient	NR	DR-TB patient treatment booklet	NR
Sagwa, 2012 [86]	Namibia	Single-center (January 2008 to February 2010)	Cross-sectional Descriptive Study	DR-TB Ward	NS	N= 59 All Patients with DR-TB 34% Female	Patient records	NR	Assessed but NR	NR
Shean, 2013 [87]	South Africa	Multicenter (August 2002 to February 2008)	Retrospective Observational Study	XDR-TB Treatment Centers	NS	N=115 All XDR-TB patients NS	Case records	NR	Modified American National Institute of Health common terminology criteria for AE	NR
Shegena, 2022 [88]	Uganda	Single-Center (November 2021 to January 2022)	Prospective Observational Study	Medical and Pediatric Ward	ADR (Edwards and Aronson)	N=118 All heart Failure patients 61% Female	Medical file and Physical examination	Naranjo	Hartwig	Schumock

Pediatric Population

Abdela, 2019 [49]	Ethiopia	Multicenter (March 2007 to April 2015)	Retrospective Cross-sectional Study	ART Clinics	ADR (WHO)	N=153 Pediatric on ART 53.6% female	Medical record	NR	Assessed but NR	NR
Bahina, 2018 [53]	Cameroon	Community (January 2013 to November 2013)	Prospective Observational Cohort Study	Community - Home Setting	NR	N=479 Pediatrics with malaria 43.2% female	An elaborated Pharmacovigilant form Clinical records	NR	NR	NR
Opanga, 2019 [80]	Kenya	Single-center (December 2016 to May 2017)	Observational Study	Pediatric Oncology Ward	NS	N= 85 Pediatrics with non-Hodgkin's Lymphomas 21% Female	Review of patients' records, retrospective review of patients' records	NR	NR	NR
Oumar, 2012 [83]	Mali	Single-center (June to November 2010)	Prospective Study	Pediatric Department	NS	N= 92 HIV-positive pediatric patients 44.6% Female	Interview with the patient and/ or the patient's attendants, as well as a review of outpatient case records, laboratory reports, clinicians' notes, and prescriptions at each follow-up visit.	WHO	Modified Hartwig	Modified Shumock
Tola, 2023 [91]	Ethiopia	Single-Center (October and December 2020	Prospective Observational Study	Pediatric Oncology Unit	ADE(Common terminology criteria for adverse events (CTCAE) version 4.0.	N=73 Pediatric cancer Patients 37% Female	Clinical rounds, Interview children and/or parents/ caregiver and Pediatrics oncology staff voluntary reports.	WHO-UMC	NCI CTCAE	NR
Workalemahu 2020 [95]	Ethiopia	Multicenter (July 2017 to August 2019)	Cross-sectional study	Medical Wards	ADR (WHO)	N= 287 Pediatric with cancer 38.7% Female	Patient charts	WHO-UMC	Hartwig and Siegel	NR

ADE Adverse drug event, *ADR* Adverse drug reaction, *AE* Adverse event, *TB* Tuberculosis, *ART* Antiretroviral therapy, *DR-TB* Drug resistant tuberculosis, *HIV* Human immune virus, *AIDS* Acquire immune deficiency syndrome, *XDR* Extensively drug resistant, *MDR* Multidrug resistant, *NR* Not recorded, *NS* Not stated, *DAIDS* Division of AIDS, *WHO* World Health Organization, *WHO-UMC* World Health Organization-Uppsala Monitoring Centre, *GASS* Glasgow antipsychotic side effects. NCI CTCAE, national cancer institute common terminology criteria for adverse events version.