

# ABBREVIATIONS

<b>AE</b> Adverse event	<b>FDA</b> Food and drug administration	<b>PD</b> Pharmacodynamics
<b>AGYW</b> Adolescent girls and young women	<b>FDC Act</b> Federal food, drug, and cosmetics Act	<b>PEPFAR</b>
<b>AI</b> Active ingredient	<b>FDF</b> Final dosage form	<b>PGLA</b> Polyglycolic acid
<b>ANDA</b> Abbreviated new drug application	<b>FSW</b> Female sex worker	<b>PI</b> Protease inhibitors
<b>API</b> Active pharmaceutical ingredient	<b>FTC</b> Emtricitabine	<b>PK</b> Pharmacokinetics
<b>ART</b> Antiretroviral therapy	<b>HCP</b> Healthcare provider	<b>PLWH</b> People living with HIV
<b>ARV</b> Antiretroviral	<b>HCV</b> Hepatitis C virus	<b>PP</b> Paliperidone palmitate
<b>AUC</b> Area under the curve	<b>HCW</b> Healthcare worker	<b>PPPY</b> Per person per year
<b>AVAC</b> AIDS vaccine advocacy coalition	<b>HIV</b> Human immunodeficiency virus	<b>PrEP</b> Pre-exposure prophylaxis
<b>AZT</b> Azidothymidine	<b>HME</b> Hot melt extrusion	<b>PSG</b> Product-specific guidance
<b>BA</b> Bioavailability	<b>HTE</b> Highly treatment experienced	<b>RA</b> Regulatory authority
<b>BCS</b> Biopharmaceutical classification system	<b>HV</b> Healthy volunteer	<b>RAL</b> Raltegravir
<b>BE</b> Bioequivalence	<b>IM</b> Intramuscular	<b>R&amp;D</b> Research and development
<b>CAB</b> Cabotegravir	<b>IP</b> Intellectual property	<b>RCT</b> Randomized controlled trial
<b>CELT</b> Centre of excellence for long-acting therapeutics	<b>IPT</b> Isoniazid prevention treatment	<b>RLD</b> Reference listed drug
<b>CHAI</b> Clinton health access initiative	<b>IR</b> Immediate release	<b>RLS</b> Resource-limited setting
<b>CHW</b> Community health worker	<b>ISL</b> Islatravir	<b>RPV</b> Rilpivirine
<b>CI</b> Confidence interval	<b>IV</b> Intravenous	<b>SA</b> South Africa
<b>CMC</b> Chemistry, manufacturing, and controls	<b>JHU</b> Johns Hopkins university	<b>SC</b> Subcutaneous
<b>CNS</b> Central nervous system	<b>Ka</b> Absorption constant	<b>SD</b> Single dose
<b>COGs</b> Cost of goods	<b>Kel</b> Elimination constant	<b>SG&amp;A</b> Selling, general, & administrative
<b>CQI</b> Continuous quality improvement	<b>LA</b> Long-acting	<b>SQVr</b> Saquinavir boosted with ritonavir
<b>CSA</b> Coordinated Scientific Advice	<b>LAI</b> Long-acting injectable	<b>SR</b> Sustained release
<b>DAA</b> Direct-acting antiviral	<b>LAPaL</b> Long-acting therapeutics, patents, and licenses	<b>SRA</b> Supervisory authority
<b>DAIDS</b> Division of AIDS	<b>LEAP</b> Long-acting extended release antiretroviral research program	<b>SS</b> Steady state
<b>DAP</b> Drug absorption profile	<b>LEN</b> Lenacapavir	<b>SSA</b> sub-Saharan Africa
<b>DCE</b> Discrete choice experiment	<b>LMIC</b> Low-middle income country	<b>TB</b> Tuberculosis
<b>DcNP</b> Drug combination nanoparticles	<b>LMNC</b> Lymphomononuclear cell	<b>TDF</b> Tenofovir
<b>DDI</b> Drug-drug interaction	<b>mAbs</b> Monoclonal antibodies	<b>TE</b> Therapeutic equivalence
<b>DE</b> Data exclusivity	<b>MD</b> Multiple dose	<b>TLC-ART</b> Targeted long-acting and combination antiretroviral therapy
<b>DMPA</b> Depo-Provera	<b>MIE</b> Model-integrated evidence	<b>TLD</b> Tenofovir, lamivudine, and dolutegravir
<b>DPV</b> Dapivirine	<b>MMF</b> Model master file	<b>TLE</b> Tenofovir, lamivudine, efavirenz
<b>DSD</b> Differentiated service delivery	<b>MPP</b> Medicines patent pool	<b>TPP</b> Target product profile
<b>DTG</b> Dolutegravir	<b>M&amp;S</b> Modeling and simulation	<b>WHO</b> World Health Organization
<b>EFV</b> Efavirenz	<b>MSM</b> Men who have sex with men	<b>WHO CRP</b> WHO collaborative registration procedure
<b>EMA or EMEA</b> European medicines agency	<b>NDA</b> New drug application	<b>WHO PQ</b> WHO prequalification
<b>EOI</b> Expression of interest	<b>NGO</b> Non-governmental organization	<b>YW</b> Young women
<b>ER</b> Extended release	<b>NHP</b> Non-human primate	<b>3TC</b> Lamivudine
<b>EU</b> European Union	<b>NIH</b> National institutes of health	
<b>FAST-TB</b> Facilitating accelerated science and translation for TB regimen development	<b>NTP</b> National treatment program	
	<b>NVP</b> Nevirapine	
	<b>OLI</b> Oral lead-in	
	<b>pAUC</b> Partial area under the curve	
	<b>PBMC</b> Peripheral blood mononuclear cell	
	<b>PBPK</b> Physiologically based pharmacokinetic	