

Appendix 3

Mapping future clinical research in the field of ARVs for treatment and prevention of HIV A resource

- The table and list below are meant to map the most important clinical trials and observational studies related to ARVs in the various settings and their expected year of results publication.
- This map cannot and should not cover everything, but seeks to identify the most relevant sources of future clinical evidence, specifically evidence which might have significant impact on future WHO guidance.
- All mentioned trials are hyperlinked to a reference, mostly to ClinicalTrials.gov of the USA NIH.
 - Clinical trial names and titles are mostly from this source and represent the status of the information in November 2011
 - The clinical trials are listed in that year, where it is expected that the findings from the finalized trials become public. This of course may change e.g. due to trials being finalized earlier than expected, or taking longer than planned.

Clinical Science Map and expected timing of final trial results made public

Topics	Recent Supporting Evidence	Current set of ARV related Guidance	2011	2012	2013	2014	2015	2016	
	Ongoing global PV surveillance and resistance surveillance / observational cohort studies								
ART adults and adolescents	CIPRA HT001 SMART	ART Adult Guidelines 2010 revision	RADAR PROGRESS	DREAM	TEMPRANO NEAT 001/ANRS 143 ACTG5257 MODERN MARCH SECOND-LINE GARDEL	PROTEA PIVOT EARNEST SALT	START		
ART infants and children	CHER HPPMCS	ART Children Guidelines 2010 revision	P1060 PREDICT	KONCERT ARROW CHER CHAPAS2 EPPICC P1103	NEVEREST 3 PROMOTE PED 3Cs4kids P1092 P1095	ARROW MONOD/ANRS 12206	MONOD/ANRS 12206 PENTA 16	REALITY P1060 START	
HIV/TB	Meta-Analysis: Effect of TB on Mortality in HIV SAPIT CAMELIA	Guidelines for intensified case-finding and INH treatment	STRIDE HPTN 052		TEMPRANO		START		
PMTCT	Various RCTs and cohort studies Cochrane Review	PMTCT Guidelines 2010 version	Zambia cohort triple ARV with LPV prophylaxis	Country programme impact evaluation Zambia Pilot	ANRS 12174 PHPT-5	PROMISE * Antepartum and maternal health TIP PROMOTE	PROMISE * Postpartum and infant health START	PROMISE 1077HS	
ART for prevention		CHTC Recommendat. for Prevention and treatment for MSM	Cochrane Review on TasP in serod. couples		TasP ANRS 12249	PARTNER	HPTN 052 Longterm f/u cohort START	PopART	
PrEP	iPREX	Rapid Advice for the implementation of PrEP demonstration projects (in development)	Partners PrEP TDF2 FEMPrEP IAVI E001-2	HPTN 066 Bangkok TDF study	VOICE iPrEx OLE	HPTN 067/ADAPT	IPERGAY		
Micro-bicides	CAPRISA				VOICE	FACTS 01	MTN 020 CAPRISA 008?		

. * PROMISE 1st interim analysis 2012

Clinical trials on simplification of ART regimens

Mono-therapy	PI/r	ATZ/r	LPV/r	DRV/r	MVC	RAL	3TC
PI/r	PIVOT				MARCH		
ATV/r						SPARTAN	SALT
LPV/r			DREAM EARNEST			PROGRESS SECOND-LINE EARNEST CCTG589	GARDEL
DRV/r				PROTEA MONET MONOI EARNEST PIVOT	MODERN	RADAR NEAT 01 ACTG A5262	
MVC						Several small pilot studies	
RAL							

- [3Cs4kids](#)
 - Markers for predicting mortality in untreated HIV-infected children in resource-limited settings: a meta-analysis
- [ACTG 5257](#)
 - Comparative Study of Three NNRTI-Sparing HAART Regimens
- [ACTG A5262](#)
 - Safety and Effectiveness of Raltegravir Plus Darunavir/Ritonavir in Treatment-Naive HIV-Infected Adults
- [ANRS 12174](#)
 - Comparison of Efficacy and Safety of Infant Peri-exposure Prophylaxis With LPV/r Versus 3TC to Prevent HIV-1 Transmission by Breastfeeding (PROMISE-PEP)
- [ARROW](#)
 - Trial Evaluating Two Strategic Approaches for Management of Antiretroviral Therapy in Children
- [BANGKOK TDF Study](#)
 - Bangkok Tenofovir Study in IDU(CDC 4370)
- [CAMELIA](#)
 - Early vs. Late Introduction of ART in HIV-infected Patients With Tuberculosis (ANRS 1295)
- [CAPRISA](#)
 - Safety and Effectiveness Study of a Candidate Vaginal Microbicide for Prevention of HIV
- [CCTG 589](#)
 - Raltegravir + Lopinavir/Ritonavir Versus Efavirenz + Tenofovir + Emtricitabine in Treatment Naive Patients
- [CHAPAS2](#)
 - A Randomised Trial to Determine the Pharmacokinetics and Acceptability of Ritonavir-boosted Lopinavir in Sprinkle and Tablet Formulation for Treatment of HIV Infected Children in Africa
- [CHER](#)
 - Anti-HIV Drugs for Treating Infants Who Acquired HIV Infection at Birth
- [CIPRA HT001](#)
 - Early Versus Standard Start of Anti-HIV Therapy for Treatment-Naive Adults in Haiti
- [DREAM](#)
 - Evaluation of a Lopinavir/Ritonavir Monotherapy vs a Triple Therapy as Maintenance Regimens in HIV-1 Infected Patients
- [EARNEST](#)

- [EPPICC](#)
 - Europe-Africa Research Network for Evaluation of Second-line Therapy
 - Use and safety of fosamprenavir in HIV-infected children in the European Union: an ongoing post-marketing surveillance study
- [FACTS 01](#)
 - Safety and Effectiveness of Tenofovir Gel in the Prevention of Human Immunodeficiency Virus (HIV-1) Infection in Young Women and the Effects of Tenofovir Gel on the Incidence of Herpes Simplex Virus (HSV-2) Infection
- [FEMPrEP](#)
 - Study to Assess the Role of TDF/FTC in Preventing HIV Acquisition in Women
- [GARDEL](#)
 - Study of Lopinavir/ Ritonavir and Lamivudine Versus Standard Therapy in Naïve HIV-1 Infected Subjects
- [HPPMCS](#)
 - HIV Pediatric Prognostic Markers Collaborative Study
- [HPTN 052](#)
 - Preventing Sexual Transmission of HIV With Anti-HIV Drugs
- [HPTN 066](#)
 - Dose-Proportionality and Intra-Individual Variability of Intracellular TFV-DP and FTC-TP in Healthy Volunteers
- [HPTN 067 / ADAPT](#)
 - Intermittent use of FTC and TDF for Pre-Exposure Prophylaxis
- [IAVI E001-2](#)
 - A Pilot Study of PrEP to Evaluate Safety, Acceptability, and Adherence in At-risk Populations in Uganda and Kenya, Africa
- [IPERGAY](#)
 - Traitement antirétroviral « à la demande » en prophylaxie pré exposition de l'infection par le VIH chez les hommes ayant des rapports sexuels avec des homes en France et au Canada.
- [iPrEX](#)
 - Emtricitabine/Tenofovir Disoproxil Fumarate for HIV Prevention in Men
- [iPrEx OLE](#)
 - iPrEx Open Label Extension
- [KONCERT](#)
 - A Kaletra ONCE Daily Randomised Trial of the Pharmacokinetics, Safety and Efficacy of Twice-daily Versus Once-daily LPV/r Tablets Dosed by Weight as Part of Combination Antiretroviral Therapy in HIV-1 Infected Children
- [MARCH](#)
 - Maraviroc Switch Collaborative Study

- [MODERN/A4001095](#)
 - Comparative Trial Of MRV Versus FTC/TDF Both With DRV/r In Antiretroviral-Naïve Patients Infected With Ccr5 Tropic HIV 1
- [MONET](#)
 - Treatment Simplification by Darunavir/Ritonavir 800/100 mg Once a Day Versus a Triple Combination Therapy With Darunavir/Ritonavir
- [MONOI](#)
 - Study Comparing Efficacy and Safety of DRV/r to HART With 2 NRTI and DRV/r in HIV-1 Infected Patients (ANRS136)
- [MONOD/ANRS 12206](#)
 - Evaluation of Simplified Antiretroviral Treatment Strategies in HIV Infected Children Treated by ARV Before One Year of Age
- [MTN 020/ASPIRE](#)
 - Phase III study that seeks to determine whether a woman's use of a vaginal ring containing the antiretroviral ARV drug dapivirine is a safe and effective method for protecting against HIV infection
- [NEAT001/ANRS 143](#)
 - Study of Darunavir/r + Tenofovir/Emtricitabine vs. Darunavir/r + Raltegravir in HIV-infected Antiretroviral naïve Subjects
- [NEVEREST 3](#)
 - Treatment Options for Protease Inhibitor-exposed Children
- [P1060](#)
 - NVP- vs. LPV/r-based ART among HIV+ Infants in Resource-limited Settings
- [P1092](#)
 - Evaluation of steady state PK of syrup formulations of ZDV, 3TC, NVP, and lopinavir/rtonavir in severely malnourished children imitating HAART
- [P1095](#)
 - PK study of tenofovir, 3TC, and lopinavir/ritonavir as once daily regimens in HIV+ 8-18 year olds
- [P1103](#)
 - Pilot Nevirapine PK Study

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_28584

