2nd Long-Acting Treatment and Prevention Conference

29 October 2024 | Johannesburg

From Trial to Implementation – can IMPALA help us jump across the Gap?

Prof Nigel Garrett
Head of HIV Vaccine & Pathogenesis Research
Centre for the AIDS Programme of Research in South Africa (CAPRISA)

Outline

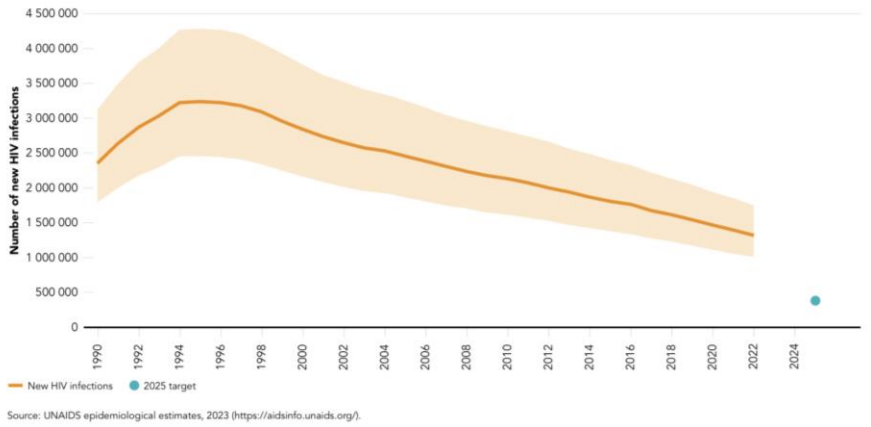
- Need for new approaches to HIV treatment
- Long-Acting Treatment
- Need for data from Africa
- Impala Trial Update
- Discussion

Global new HIV infections and AIDS-related deaths

New HIV infections are declining globally…

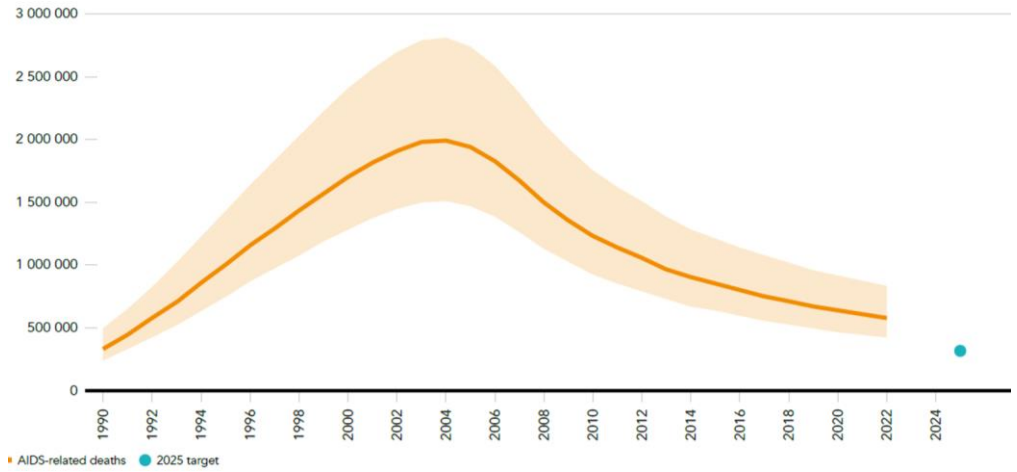
…but not fast enough to reach 2025 and 2030 targets

AIDS-related deaths declining - within reach of target



New HIV infections, global, 1990-2022 and 2025 target

2023: 1,300,000



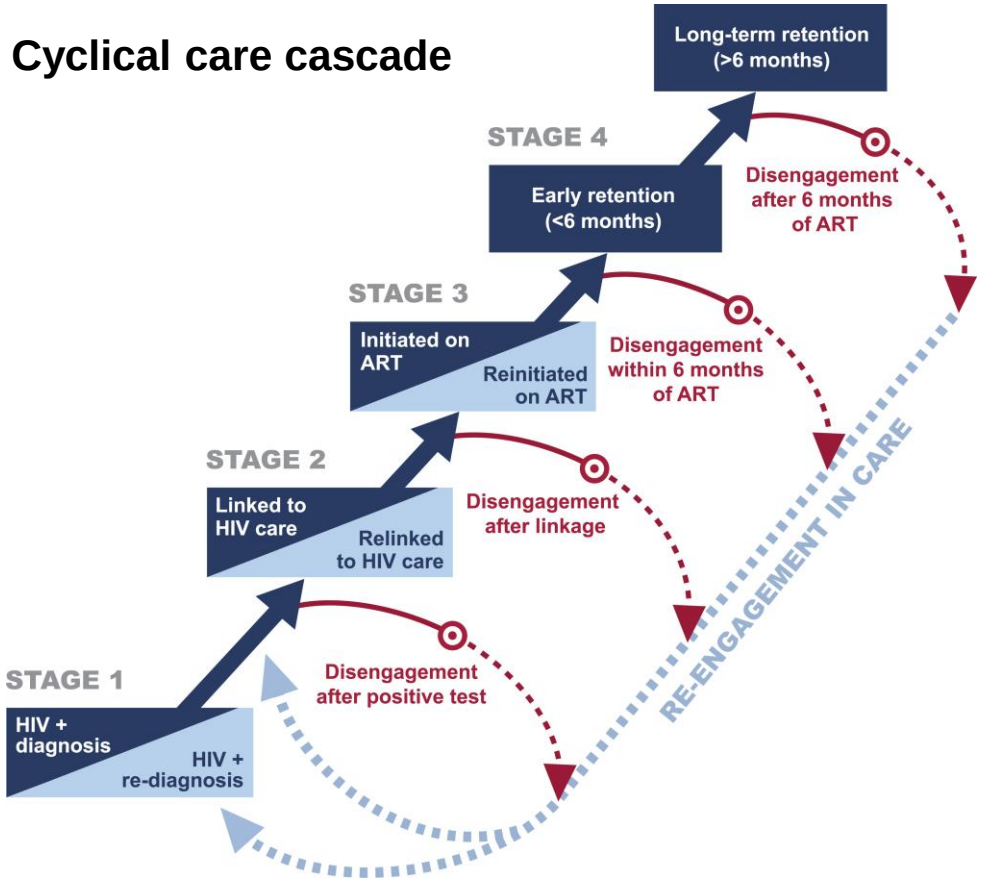
AIDS-related deaths, global, 1990-2022 and 2025 target

2023: 630,000

Source: UNAIDS 2023 epidemiological estimates.

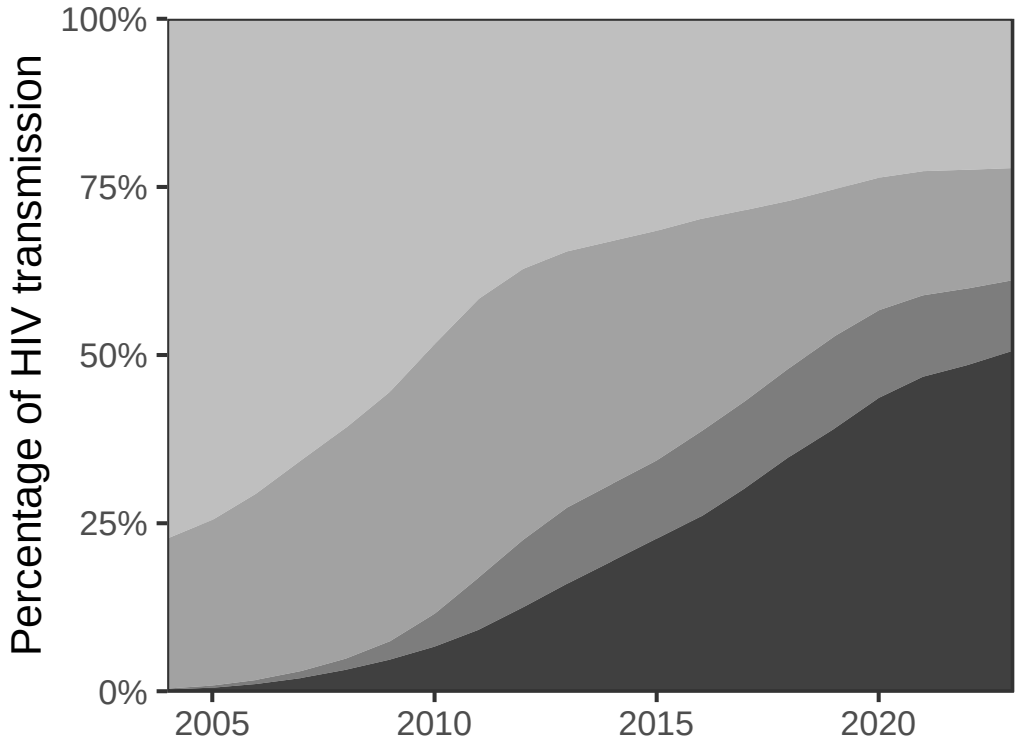
Large share of HIV transmission now among people who have interrupted treatment

Cyclical care cascade



Ehrenkranz *et al.* PLOS Med 2021

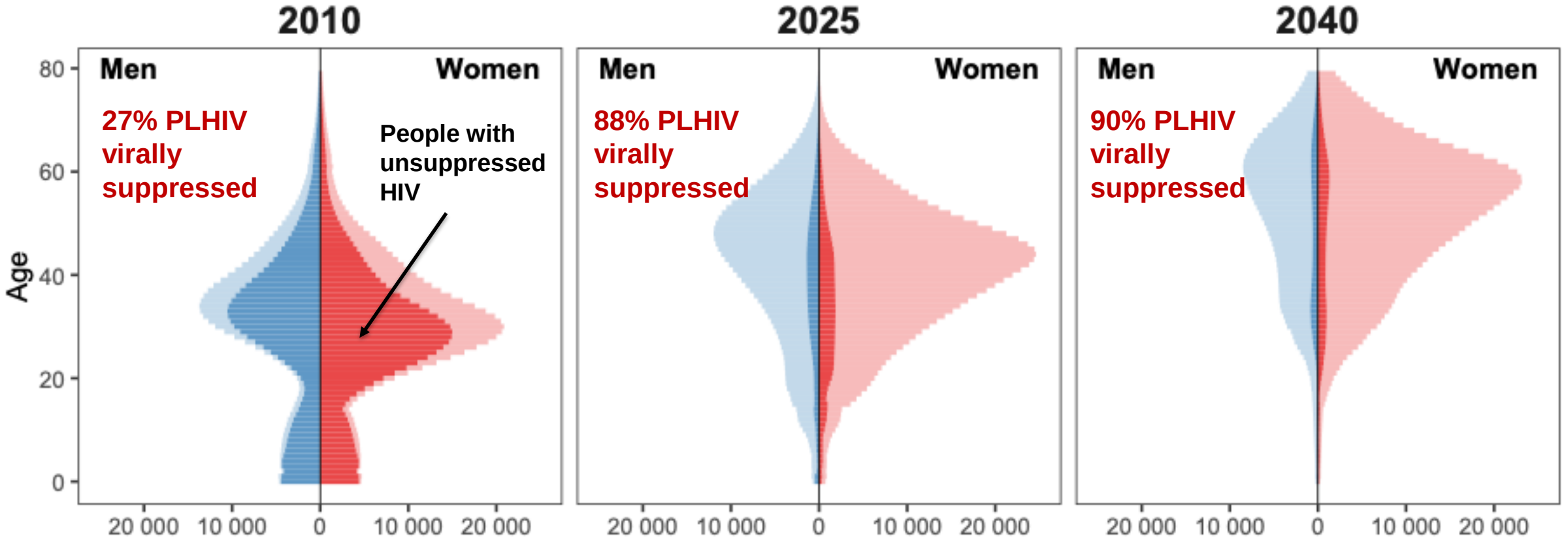
South Africa: **% of transmission** by care cascade stage (Thembisa 4.6)



Moolla, *personal communication*;
Johnson *et al.* JAIDS 2022

Large, rapidly ageing, HIV population

Follow the Virus: **Aging HIV population → aging population with viraemia → aging partners at risk and aging population needing HIV prevention & treatment**



Slide courtesy of Jeffrey Eaton

Pathway to Impact: Long-acting Treatment

As researcher, what is our role in this journey? How do we accelerate this process?

Recognise area of need

- Public health data
- Scientific rationale
- Community & stakeholder engagement

Ask the right questions

- Provide right evidence needed for policy change
- Datasets
- Publications

Impact Policy

- Working with policy makers
  - international
  - national
  - local

Advocate for change and funding

- Engagement
  - Ministries
  - Multilateral
- Activism

Implement

- Implementation studies
- Real world observational studies
- Learning and optimising

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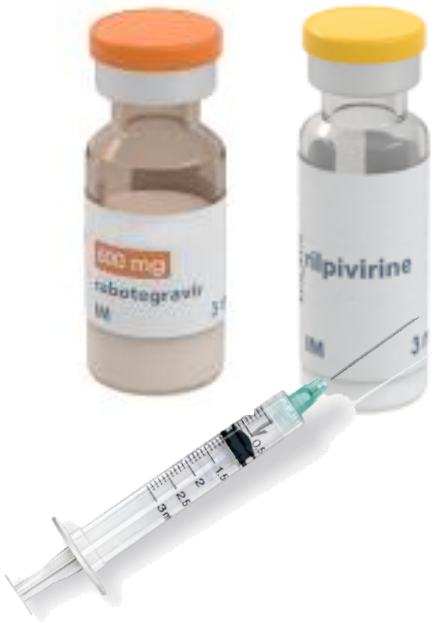
Europe/US

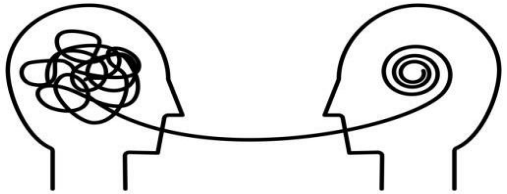
Africa / Asia

Rationale for LA treatment & prevention

BIOLOGICAL

- Dysphagia
- Malabsorption
- Cognitive impairment
- Mental health
- Addiction
- Improved ability to monitor adherence





PSYCHOSOCIAL

- Pill fatigue
- Reminder of HIV
- Fear of disclosure
- Privacy
- Convenience

LA CAB/RPV – efficacious for HIV treatment

Registrational trials

LATTE-2
- Phase 2
- **Dose finding**, safety, efficacy, tolerability
- CAB LA + RPV LA, IM every 4 or 8 weeks in **virally suppressed**
- Maintained HIV-1 RNA <50 copies/mL for >5 years

FLAIR
- Phase 3, open label, noninferiority, **treatment-naïve, virally suppressed**
- Monthly IM injections
- CAB LA + RPV LA noninferior to 3-drug oral ART in maintaining suppression
- Viral suppression maintained with 'direct to injection' and CAB + RPV 'oral lead-in'

ATLAS
- Phase 3, open-label, active-controlled, non-inferiority, **treatment experienced**
- Monthly IM injections vs oral ART in **virally suppressed** adults
- CAB/RPV LA noninferior to oral ART in maintaining virologic suppression
- 97% preferred LA to oral therapy

ATLAS-2M
- Phase 3, open-label, noninferiority design, **virally suppressed**
- **Q8W versus Q4W IM** CAB LA + RPV LA
- IM CAB/RPV LA Q8W noninferior to switch to Q4W at Week 152

- 2021 - US FDA approval (Q4W or Q8W) and EMA approval (Q8W)
- 2022 - UK National Institute of Clinical Excellence (Q8W)
- 2023 - Registered in Botswana and South Africa (but not available as not featured in policy yet)

2-monthly IM Cabotegravir + Rilpivirine

- **Efficacy:** Q1M LA CAB+RPV is non-inferior to oral ART, Q2M non-inferior to Q1M
- **Safety:** 2% withdrawal, Injection site reactions common but reduce over time
- **Virological failure rate:** 1-2%
- **Resistance:** usually NNRTI + INSTI, mostly in first year
- **OLI vs DTI:** equally safe but license mandates offering oral lead in
- **Satisfaction:** 9/10 prefer it to oral therapy

Implementation studies – Europe

Europe - CARISEL / CARLOS – IAS / Glasgow 2022

- **Highly acceptable** to >90% of patients
- 93% of injections occurred within 7 days of **target**
- Most (51%) spent **≤ 40 min in clinic** for injection visit
- **0.5% patients have experienced virological failure** to date

ILANA, UK - IAS 2023

- HCWs had **initial anxieties** about CAB+RPV LA, but these **subsided** after treatment began.
- While implementing CAB+RPV LA **increased demand on clinical resources and time**, HCWs found strategies to manage this, and feel **positive about the benefits** of CAB+RPV LA.
- HCWs more **hesitant about** delivery of CAB+RPV LA in **community settings**, and increased information and planning is required to facilitate community roll-out.

Pros and Cons of LA CAB/RIL treatment

Pros

1. **Increases choice**
2. **Invisible / discreet / less stigmatising**
3. **High levels of satisfaction** with LA CAB/RPV
4. Directly observed therapy
5. Less frequent dosing
6. Two drug regimens avoid NRTI toxicity
7. No requirement for dosing with meals
8. Fewer DDIs with parenteral formulations
9. Possibility of co-formulation or co-administration with other long-acting drugs e.g. contraception

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Cons

1. **Long PK tail risks emergence of viral resistance (2 class)**
2. **Lower genetic barrier to resistance than DTG, PIs**
3. Injectable drugs can't be rapidly withdrawn if toxic
4. Injections visits are time consuming to clinics
5. Injections are painful, ISRs are common
6. Skills required for insertion / removal of implants
7. Need to offer oral lead-in with CAB/RPV and oral bridging
8. Higher cost than oral treatment
9. **TDF & 3TC free LA regimens are not suitable for people co-infected with hepatitis B (what about prior infection?)**
10. **DDIs associated with drug metabolism - CAB/RPV can't be used with TB treatment**

Need for African data: Remaining gaps despite a decade of studies

Global Landscape	Phase III clinical trial landscape
Globally, >50% of all PLWH are female	• 25% female participants
In Africa, 61% of PLWH are of childbearing potential	• Pregnant women excluded • Arising pregnancies (n=26) switched to oral ART • No data in breastfeeding.
~2/3rd of PLWH are from sub-Saharan Africa	• <10% of participants were from Africa (all S. Africa) • 28% overall non-white
29 million receiving treatment in programmatic care settings	• PRIOR Hep B exposure (HepBcAb+) excluded. ~50% of Africa. • Baseline drug resistance tests, exclusion NNRTIs / INSTIs RAMs • HIV VL testing every 2 months

Clear need for more data from Africa to guide policy and implementation

- Efficacy, despite widespread NNRTI resistance, no baseline resistance testing
- Delivery in programme settings with annual HIV VL
- Hepatitis B: 7.5% HepBsAg+, 50% HepBcAb+, what testing strategy to use?
- Cold chain: Rilpivirine 2-8^{O}C
- Drug-drug interactions: TB drugs, antiepileptics, ?antimalarials
- Pregnancy & breastfeeding

Ongoing Clinical trials in Africa

Name and Trial Registration Number	Participant Characteristics	Regimens	Primary Endpoint(s)	Status	Countries with Recruitment Centres
CARES	Virologically suppressed, ART-experienced adults with HIV	Continuation of oral 2 NRTI plus INI (DTG) or NNRTI (EFV/NVP) containing regimen, or other FDC as per local country guidelines vs Switch to long-acting CAB 600mg intramuscularly plus long-acting RPV 900mg intramuscularly every 8 weeks following optional oral lead in	Month 12: proportion with plasma HIV-1 viral load <50 c/mL by FDA snapshot algorithm	Active, closed to recruitment	Uganda Kenya South Africa
IMPALA	Adults with HIV with a history of suboptimal adherence and/or engagement in care in the past 2 years, virologically suppressed (<200 c/mL for ≥3 months) at time of randomisation	Continuation of oral 2 NRTI+DTG containing regimen Vs Switch to long-acting CAB 600mg intramuscularly plus long-acting RPV 900mg intramuscularly every 8 weeks following optional oral lead in	Month 12: proportion with plasma HIV-1 viral load <50 c/mL by FDA snapshot algorithm	Active, recruiting	Uganda Kenya South Africa
LATA	Virologically supressed adolescents (aged 12-19) with HIV	Continuation of oral 2 NRTI+DTG containing regimen vs switch to long-acting CAB 600mg intramuscularly plus long-acting RPV 900mg intramuscularly every 8 weeks	96 weeks: proportion of participants with confirmed virological rebound, defined as 2 consecutive plasma HIV-RNA ≥50 copies/mL at any time up to the 96-week assessment	Not yet recruiting	Uganda Zimbabwe Kenya South Africa
AFINATY	Adolescents (12-24 years) living with HIV. Cohort 1: Currently taking first-line ART, virally suppressed for at least one year. Cohort 2: Currently taking ART, with evidence of recent poor adherence. Suppressed on oral standard of care before switch. Cohort 3: Never previously taken ART. Suppressed on oral standard of care ART before switch.	CAB 30mg and RPV 25mg daily oral lead in (optional); followed by long-acting CAB 600mg intramuscularly plus long-acting RPV 900mg intramuscularly every 8 weeks	Safety Tolerability Acceptability	Active, recruiting	South Africa
MOCHA	Virologically supressed adolescents (aged 12-17) with HIV	Cohort 1C: Oral CAB 30mg daily in addition to pre-study cART, followed by 2 separate injections of LA CAB Cohort 1R: Oral RPV 25mg daily in addition to pre-study cART, followed by 2 separate injections of LA RPV Cohort 2: CAB 30mg and RPV 25mg daily oral lead in; followed by long-acting CAB 600mg intramuscularly plus long-acting RPV 900mg intramuscularly every 8 weeks	Number of participants with Grade ≥3 AEs Number of participants with Grade ≥3 AEs assessed as related to study products Number of participants with SAEs assessed as related to study products Number of participants who discontinue study product due to AEs assessed as related to study products Number of participants who die due to AEs assessed	Active, recruiting	United States Botswana Puerto Rico South Africa Thailand Uganda
CRAYON	Virologically suppressed children (aged 2-less than 12) with HIV	Cohort 1: Oral CAB and RPV followed by long-acting CAB intramuscularly and RPV intramuscularly every 4 or 8 weeks Cohort 2A: oral CAB and RPV followed by long-acting CAB intramuscularly and RPV intramuscularly every 4 or 8 weeks Cohort 2B: long-acting CAB intramuscularly and RPV intramuscularly every 4 or 8 weeks	Safety Tolerability Acceptability PK	Not yet recruiting	United States Botswana Brazil South Africa Thailand Uganda
CREATE	Virologically suppressed pregnant people and their infants	Cohort 1: switch from pre-study oral cART to LA CAB intramuscularly and LA RPV intramuscularly every 4 weeks, or continuation of pre-study 4-weekly or 8-weekly LA CAB intramuscularly and LA RPV intramuscularly Cohort 2: switch from pre-study oral cART to LA CAB intramuscularly and LA RPV intramuscularly every 8 weeks	Safety PK Virologic outcomes	Not yet recruiting	South Africa United States

NRTI = nucleoside/nucleotide reverse transcriptase inhibitor, INI = integrase inhibitor, NNRTI = non-nucleoside reverse transcriptase inhibitor, FDC = fixed-dose combination, CAB = cabotegravir, RPV = rilpivirine, cART = combined oral ART, LA = long-acting, AE = adverse event, SAE = serious adverse event

Norcross, et al. Lancet HIV. 2023 Jul;10(7):e428-e429

Modelling the impact of LA CAB+RPV rollout

The potential role of long-acting injectable cabotegravir–rilpivirine in the treatment of HIV in sub-Saharan Africa: a modelling analysis

Andrew N Phillips, Loveleen Bansi-Matharu, Valentina Cambiano, Peter Ehrenkranz, Celicia Serenata, Francois Venter, Sarah Pett, Charles Flexner, Andreas Jahn, Paul Revill, Geoff P Garnett

- Comparator DTG-based ART

Introduction of LA CAB/RPV *vs* no introduction	All ART	VL >1000	VL <1000
Diff in VL of <1000 c/mL, %	+5.3%	+4.1%	+3.0%
Diff in AIDS-related mortality, per 100 person-yrs	-0.19	-0.17	-0.05
Diff in integrase inhibitor resistance, %	+0.8%	-0.4%	+1.0%
Diff in NNRTI resistance, %	+4.3%	+1.5%	+3.4%
Median cost per DALY averted (90% range)	$1638	$404	$2808

- VL >1000 group most effective group to target
- Deliver CAB/RPV for US$120 per year (cold chain not considered)
- Cost per DALY averted of $404 across all study settings
- Least contribution to resistance

Lancet Glob Health.2021 May;9(5):e620-e627

The IMPALA Trial: Improving HIV control in Africa with Long-Acting Antivirals

IMPALA
IMPROVING HIV OUTCOMES IN AFRICA WITH LONG ACTING ANTIRETROVIRALS

MRC/UVRI and LSHTM Uganda Research Unit

UKRI Medical Research Council

Uganda Virus Research Institute

London School of Hygiene & Tropical Medicine

University of Nairobi

CAPRISA
CENTRE FOR THE AIDS PROGRAMME OF RESEARCH IN SOUTH AFRICA

Desmond Tutu Health Foundation

Makerere University

IDI Infectious Diseases Institute

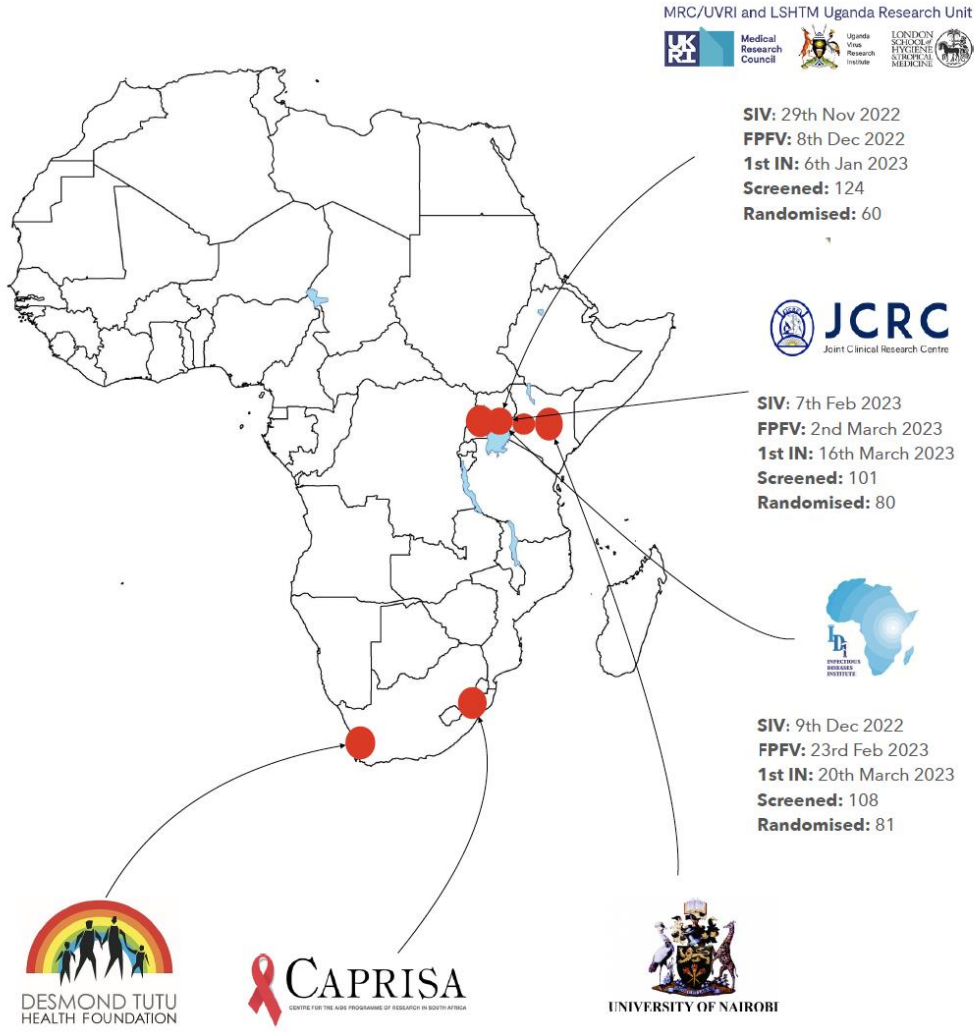
JCRC
Joint Clinical Research Centre

janssen

ViiV Healthcare

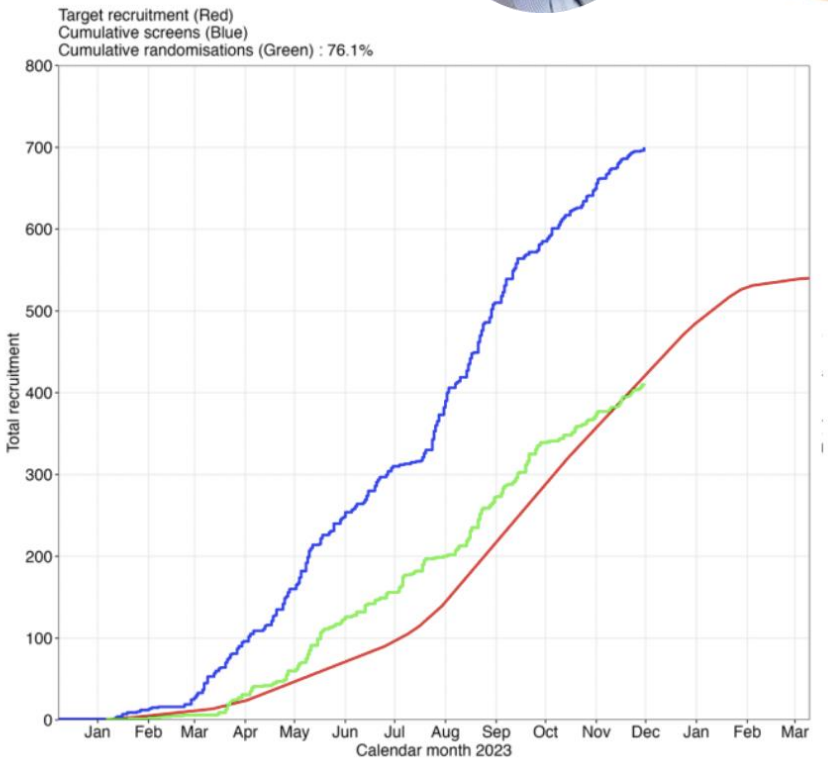
Impala Workshop in Entebbe, Uganda in 2023

Trial Sites and Recruitment



← **Trial Coordinating Centre**

PIs: Dr Eugene Ruzagira and Dr Fiona Cresswell



IMPALA: Study Design

SCREENING
PLHIV with history, or high risk of, suboptimal adherence/engagement

1. Documented **detectable HIV1 VL >1000 c/ml in the prior 2 years** despite being on oral ART for ≥ 3 months
2. History of LTFU (>4 weeks elapsed since a scheduled clinic appointment / refill in prior 2 years
3. Unlinked to HIV care despite ≥3 months elapsing since HIV diagnosis
4. **Key population** (MSM, sex-worker, transgender, drug user, adolescent/young adult 18-25 y.o.)

SCREENING PHASE

Virologically suppressed for >3 months at the end of screening

2NRTI + DTG

Optional 1 month oral lead in

N=270

LA RPV / CAB IM
600 mg / 900mg
IM Q8W

OPTIONAL REAL WORLD EXTENSION

Long-term durability LA ART CAB/RPV IM Q8W

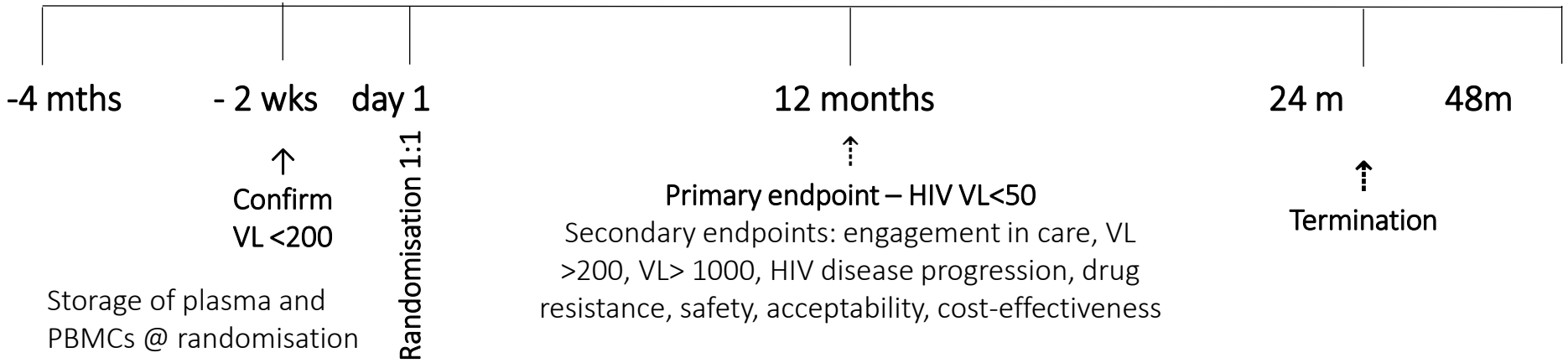
N=270

2NRTI + DTG

OPTIONAL REAL WORLD EXTENSION

Long-term durability LA ART CAB/RPV IM Q8W

- Anyone on EFV or NVP needs to switch to DTG prior to screening
- Must be on **DTG for >1 month prior to randomisation**
- **Confirmed duration of virological suppression >3 months** prior to randomisation



Objectives & endpoints

Primary objective:	Endpoint:
To demonstrate the non-inferior efficacy of switching to every 2 months (Q2M) intramuscular (IM) injection of cabotegravir (CAB) long acting (LA) plus rilpivirine (RPV) LA compared with continuation of daily oral ART over 12 months in PLHIV1	Proportion with plasma HIV-1 viral load (VL) <50 c/mL at 12 months (by Food and Drug Administration [FDA] snapshot algorithm)
Secondary objective	**Endpoints:**
To demonstrate the antiviral activity and the impact on retention in HIV care	• Proportion with confirmed virologic failure (CVF) [plasma HIV-1 VL ≥200 c/mL on 2 consecutive occasions] at 12 and 24m • Proportion with LTFU [>4 weeks elapsed since their last missed appointment] at 12 and 24 months • Proportion with plasma HIV-1 VL <200 c/mL at 12 months
To demonstrate the immunological activity	• Change in CD4+ T cell count from baseline (12 and 24 months) • Incidence of HIV disease progression (HIV/AIDS related hospitalizations, illness or deaths) (through 24 months)
To evaluate the safety and tolerability	• Incidence of adverse events (AEs) through 12 and 24 months • Incidence of AEs, Grade 3 and 4 (through 12 and 24 months) excluding ISRs • Frequency of injection site reactions of any grade

Impala Progress updates

- 845 participants screened
- 540 enrolled (Last participant enrolled on 6 May 2024)
- 16 pregnancies reported

	EBB	IDI	JCRC	KNH	JOOTRH	CAPRISA	DTHF
Enrolments	79	81	80	80	80	50	90
Active	79	79	79	78	80	50	89
Withdrawn	0	2	1	2	0	0	1

Demographics and follow up status (20 Oct 2024)

Characteristics	Category	CAPRISA n (%)	DTHF n (%)
Age	Median (IQR)	40.5 (34 - 48)	37.5 (32 - 42)
	Range	24 - 65	19 - 63
Sex at Birth	Male	28 (56)	16 (18)
	Female	22 (44)	74 (82)
Ethnicity	Black	49(98)	89(99)
	White	1(2)	0(0)
	Mixed-race	0(0)	1(1)
Highest level of education attained	No formal education	0(0)	1(1)
	Primary	2(4)	16(18)
	Secondary	45(90)	66(73)
	Tertiary	3(6)	7(8)
Marital status	Single	38(76)	42(47)
	Married	10(20)	4(4)
	In a relationship but not cohabiting	1(2)	29(32)
	Cohabiting	0(0)	11(12)
	Widowed	1(2)	2(2)
	Divorced/Separated	0(0)	2(2)

- Highest visit attended = M 22
- Earliest visit attended = M 3
- Overall visits attended = 3157/3306 (95%)
- Attended follow up visits (late/out of window) = 47 (1%)
- Confirmed missed visit = 4 (0%)

IMPALA
IMPROVING HIV OUTCOMES IN AFRICA WITH LONG ACTING ANTIRETROVIRALS

Qualitative Interviews at Month 6

- Participants relieved about not having to take daily pills
- No need to remember to take pills
- It is confidential - no evidence, less need for disclosure and less discrimination
- Freedom - no worries when travelling for extended periods
- Less chances of defaulting - ‘treatment is in the system’

“Getting injected is easier because I don't take it everyday like pills, I only take it at that time”

Participant 3, Male, 33 years-old

Ongoing sub-studies in IMPALA

Social Sciences

In-depth interviews with participants and stakeholders

- experience of LA
- impact on stigma
- barriers and facilitators at policy, programming and delivery level

Virology

Next generation sequencing of PBMCs and plasma

- Baseline resistance profiles in non-adherent PLWH on 1st line ART
- Emergent resistance
- Predictors of failure

Metabolic

Analysis of longitudinal metabolic data from people on LA ART vs oral ART

- Review existing knowledge
- Glycaemic control
- Weight, lipids
- Renal function

Health economics

Modelling analysis cost effectiveness

- Transmission
- HIV-related illness
- Hospitalisations
- Quality of life

…also, PK studies in pregnancy, among participants with TB co-infection

Long-acting Treatment – Pathway to Impact

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- Scientific rationale
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Implement

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2025 - 2028

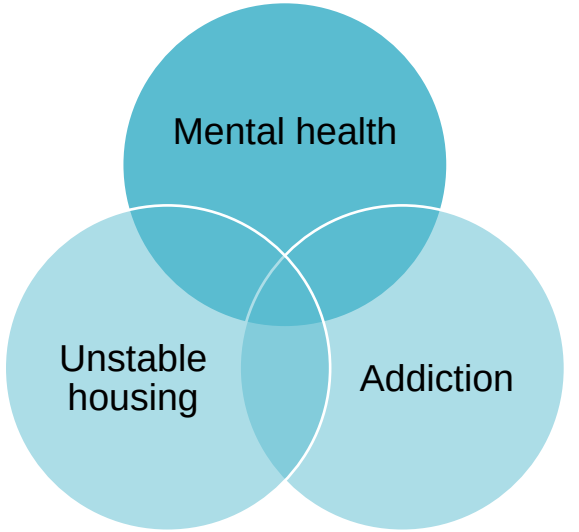
Europe/US

Africa / Asia

ACTG A5359: LATITUDE Trial

Study Design and Study Population

- A5359-**L**ong-**A**cting **T**herapy to **I**mprove **T**reatment success in **D**aily lif**E**
- Phase III prospective, randomized, open-label trial
- Monthly IM CAB/RPV-LA vs. oral Standard of Care (SOC) ART
- PWH who have barriers to adherence:
  a) Poor viral response despite oral ART for ≥6 months.
  b) Loss to clinical follow-up with ART non-adherence ≥6 months.
- No Hepatitis B
- No INSTI or RPV RAM historically or by screening.
- No exclusion based on CD4⁺ T-cell, HIV VL, active substance/alcohol use or unstable housing.



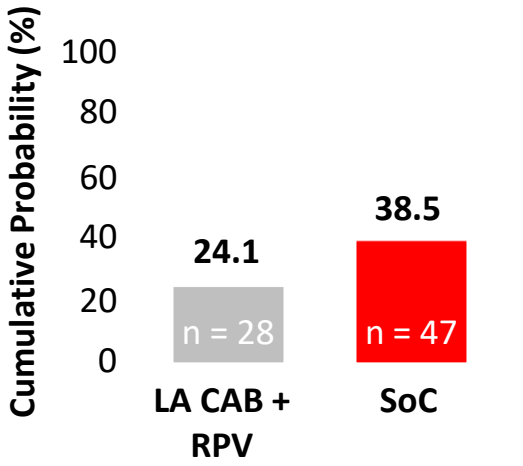
LATITUDE: Efficacy Outcomes

Primary Outcome

Regimen Failure

Difference -14.5%

Nominal 98.75% CI (-29.8% to 0.8%)

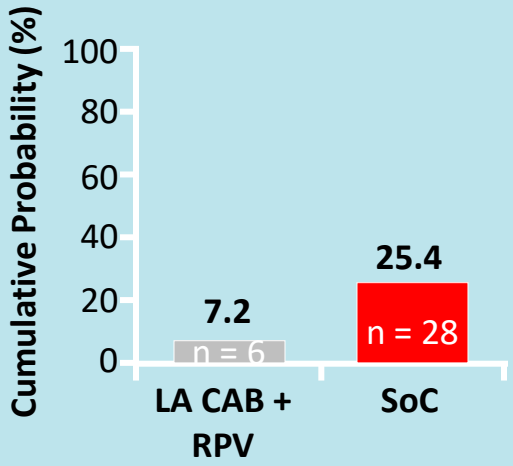


Secondary Outcomes

Virologic Failure

Difference -18.2%

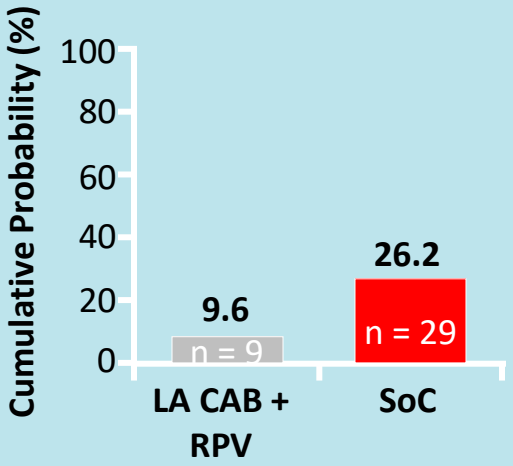
Nominal 98.75% CI (-31.1% to -5.4%)



Treatment-Related Failure

Difference -16.6%

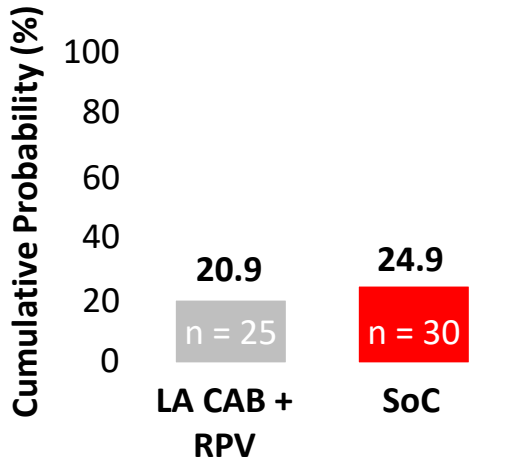
Nominal 98.75% CI (-29.9% to -3.3%)



Permanent Treatment Discontinuation

Difference -4.1%

Nominal 98.75% CI (-18.0% to 9.8%)



1 additional virologic failure after Wk 24 included in secondary endpoints, but not primary

Rana. CROI 2024. Abstract 212

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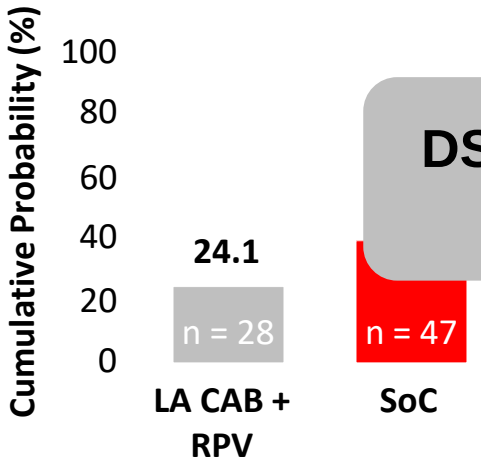

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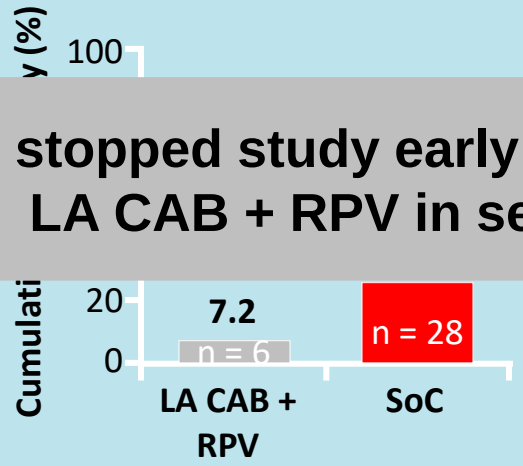
Difference -18.2%

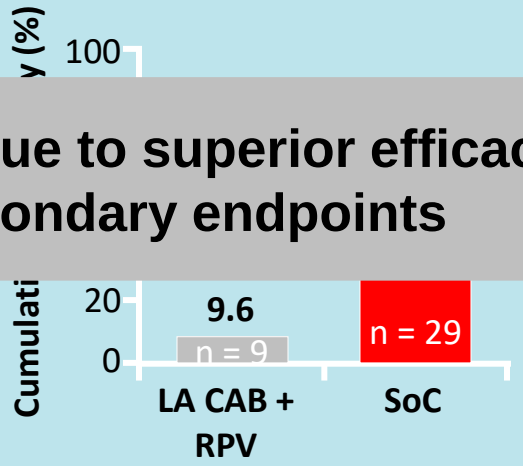
Nominal 98.75% CI (-31.1% to -5.4%)



Treatment-Related Failure

Difference -16.6%

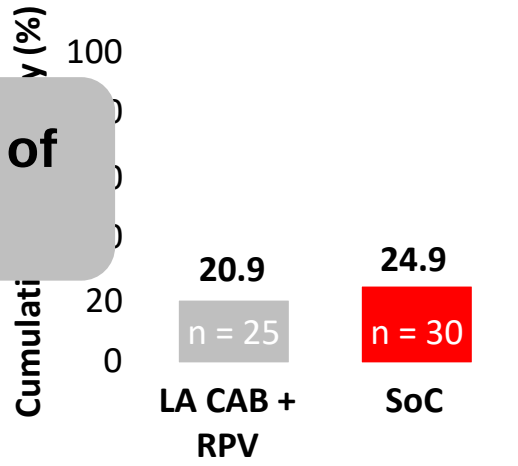
Nominal 98.75% CI (-29.9% to -3.3%)



Permanent Treatment Discontinuation

Difference -4.1%

Nominal 98.75% CI (-18.0% to 9.8%)



DSMB stopped study early due to superior efficacy of LA CAB + RPV in secondary endpoints

1 additional virologic failure after Wk 24 included in secondary endpoints, but not primary

Rana. CROI 2024. Abstract 212

Updated IAS-USA Recommendations for LA CAB + RPV (March 2024)

- When supported by **intensive follow-up** and **case management services**, injectable LA CAB + RPV may be **considered for people with viremia** who meet the criteria below when **no other treatment options are effective** due to a patient's persistent inability to take oral ART:
  - **Unable to take oral ART** consistently despite extensive efforts and clinical support
  - **High risk of HIV disease progression** (CD4 count <200/μL or history of AIDS-defining complications)
  - **Virus susceptible to both CAB and RPV**
- If applicable, patients should also be referred for treatment of substance use disorder and/or mental illness.

Sax, et al. JAMA. 2024;331(12):1060-1061

Differences between LATITUDE and IMPALA

	LATITUDE	IMPALA
Population	• 80% not achieved viral suppression despite ≥6 months ART • 32% suppressed (<200 c/ml) at study entry	• Engaged in HIV care • >90% VL<50 c/ml at screening 1
Drug resistance at entry	NNRTI or INSTI RAMs on prior or screening DRT excluded	No baseline DRT
Regimen	Q4W	Q8W
Design	• 6-month induction • Primary endpoint – time to regimen discontinuation or virological failure at 72 weeks	• HIV VL >1000 c/ml in prior 2 years • No induction period • Viral suppression for >3 months at randomisation • Primary endpoint VL < 50 c/ml at 12 months

Conclusions

- Understand the **changing Epidemic**
- Ensure Researchers drive the **Pathway to Impact** together with the community
- **Long-acting ART is coming**, because it is the clients' choice. We need to make it possibly through trials and advocacy in Africa.
- **IMPALA** will tell us about efficacy of CAB/RPV among clients with previous viraemia or LTFU, **LATITUDE** has shown value among viraemic clients.

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IMPALA
IMPROVING HIV OUTCOMES IN AFRICA WITH LONG ACTING ANTIRETROVIRALS

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janssen

ViiV Healthcare

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