Long-Acting ART: Transforming the HIV Treatment Landscape

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June 10, 2025

Continuum 2025 • June 10-12, 2025 • San Juan

Objectives of talk

- Clinical trials of long-acting injectables for HIV treatment
- Why long-acting ART in those with adherence challenges to improve virologic suppression?
- Real-world studies of long-acting injectables for HIV treatment

Only combination treatment for LA ART -Cabotegravir (CAB)/ Rilpivirine (RPV) - Trials done in those with virologic suppression

(Real world/Single arm: IMPAACT 2017 MOCHA – single arm; JABS; CARISEL, CARLOS, DAT;AIDS, BEYOND, ATHENA, UK Share)

	Confirmed Virologic failure rate & resistance
FLAIR: CAB/RPV LA in treatment naïve; First put on DTG/ABC/3TC for 20 weeks then LA ART (n=283)	**1.8% at 124 weeks;** 4 out of 5 with emergent INSTI/NNRTI resistance
ATLAS: CAB/RPV LA in treatment experienced participants every 4 weeks, on suppressive regimen for 6 months prior to switch (n=308)	**0.9% at 96 weeks;** 3 out of 3 with emergent INSTI/NNRTI resistance
ATLAS 2M: CAB/RPV LA in treatment experienced participants every 8 weeks after VS x ≥ 6 months (n=522)	**2.3% at 152 weeks;** 11 out of 12 with emergent INSTI/NNRTI resistance
SOLAR: CAB/RPV LA every 8 weeks in treatment experienced participants (47% expressed internal or external stigma) switched BIC/TAF/FTC when VS (n=447)	**0.7% at 48 weeks;** 3 out of 3 with emergent INSTI/NNRTI resistance
CARES: CAB/RPV LA every 8 weeks in treatment experienced participants who switched from oral ART in Uganda, Kenya, South Africa (n=512)	**1.6% at 96 weeks;** 3 out of 4 with emergent INSTI/NNRTI resistance

Orkin C. Lancet HIV 2021; Swindells S. AIDS 2022; Overton E. CID 2023; Ramgopal M. Lancet HIV 2023; Kityo C Lancet ID 2024 & CROI 2025

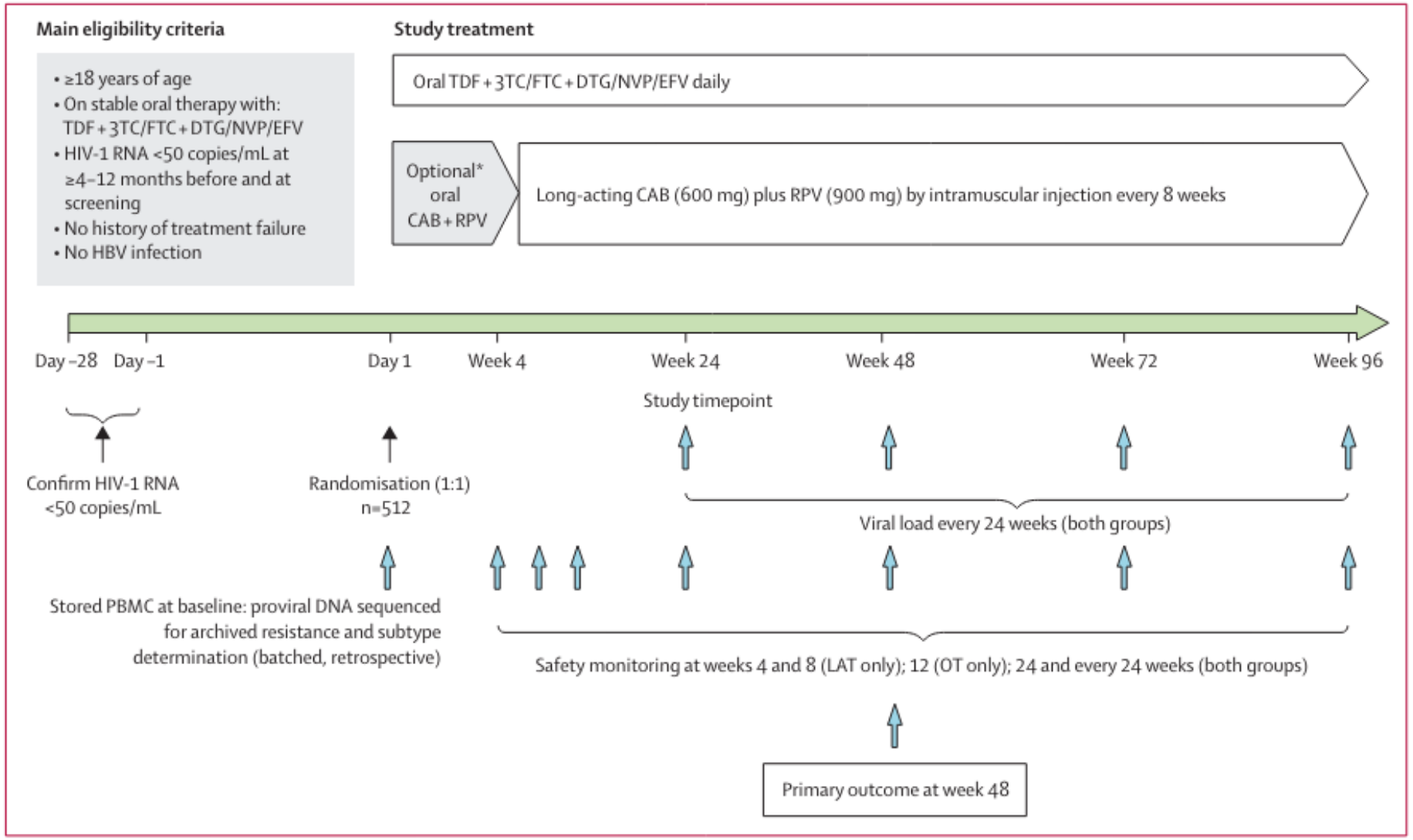
Switch to LA CAB + RPV in Adolescents With HIV

- IMPAACT 2017/MOCHA was Multicenter, open-label, single-arm study among adolescents in the US, Uganda, Botswana, South Africa, Thailand
- Wk 48 virologic success per FDA snapshot: 97.2%; All 140 had HIV-1 RNA <50 cp/mL at Week 48
- **No cases of CVF** (2 consecutive HIV-1 RNA ≥200 c/mL)
- Median predose CAB and RPV concentrations approximates those of adults
- All 140 participants preferred LA ART over oral ART
- (CROI 2025 abstract showing similar PK levels of LEN to adults

Gaur. AIDS 2024. Abstr OAB2606LB; Gill. CROI 2025. Abstr 120.

CARES Trial- CAB/RPV in LMICs

The Lancet Infectious Diseases
Available online 28 May 2024



48 week data in Lancet ID in May; 96 week data coming up

CARES Study Sites

Uganda (N=244, 47.7%)

Kenya (N=162, 31.6%)

South Africa (N=106,20.7%)

CARES: Baseline Characteristics

Characteristic	All Patients (N = 512)
Median age, yr (IQR)	42 (35-51)
Female, n (%)	295 (58)
BMI ≥30 kg/m^2, n (%)	108 (21)
Black race, n (%)	510 (>99)
Median time on first-line ART, yr (IQR)	8 (4-13)
Prior exposure to NNRTI, n (%)	380 (74)
INSTI regimen at screening, n (%)	471 (92)
NNRTI regimen at screening, n (%)	41 (8)
Archived proviral DNA analysis, n/n (%)	
▪ Subtype A1	236/433 (55)
▪ RPV resistance mutations	30/401 (7)
▪ RPV intermediate/high-level resistance	**12/401 (3)**
▪ CAB resistance mutations	20/202 (10)
▪ CAB intermediate/high-level resistance	**5/202 (2)**

- Baseline characteristics important in that 58% women, 21% with BMI >30, **prior exposure to NNRTIs 74%**, 92% on INSTIs
- Archived proviral DNA analysis performed 48 weeks
- APOBEC related mutations excluded by 96 weeks so cDNA resistance quite low

Wk 48

10%

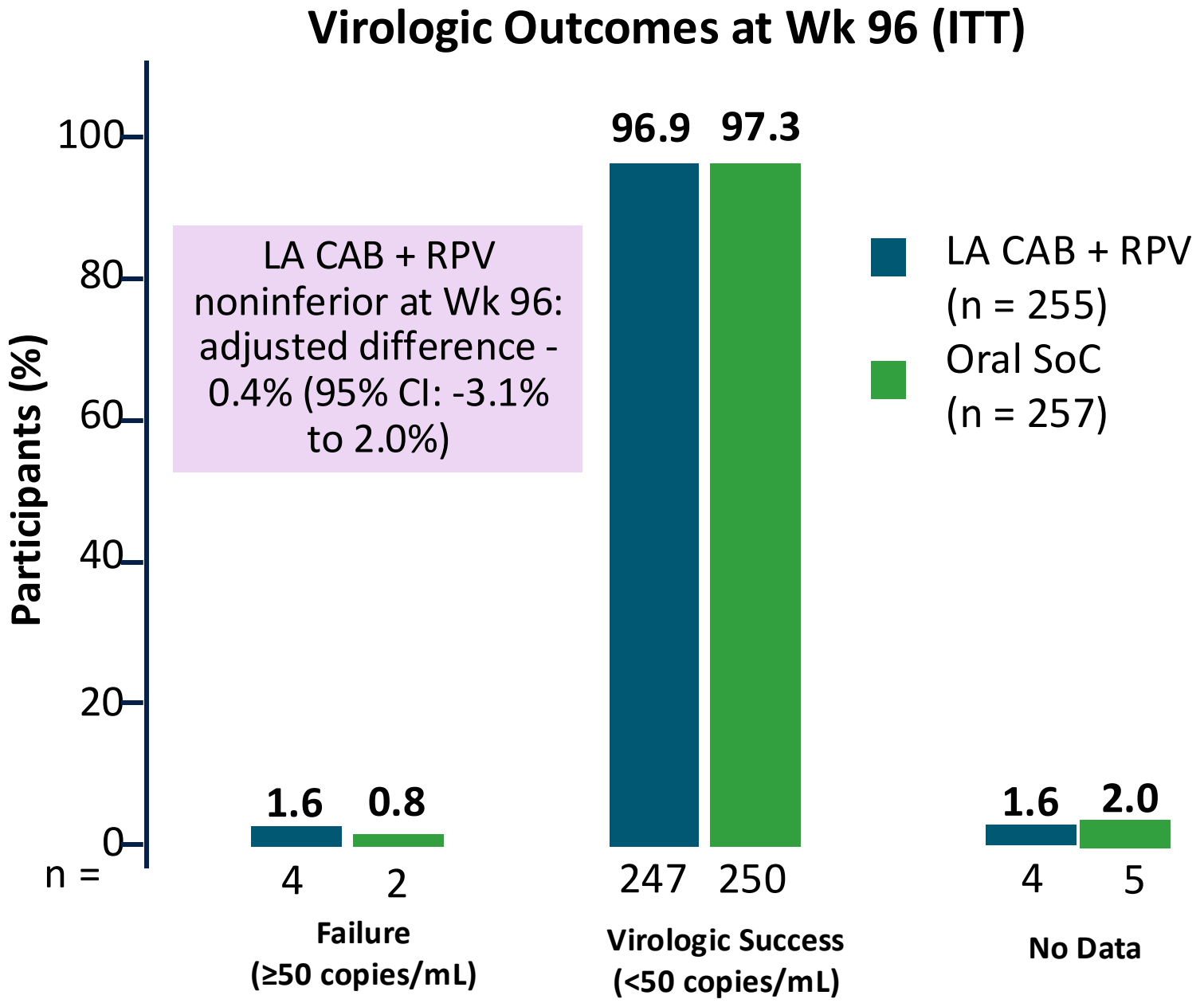
8%

APOBEC-related mutations excluded in current analysis

Kityo. CROI 2025. Abstr 202. Kityo. CROI 2024. Abstr 122.

CARES: VS, On-time Injections, Tolerability

- 81% got all injections; 97% on time!
- SAEs: 5% vs. 4% (oral); 2% SAEs related to drug in both
- Only 1 Grade 3 ISR led to discontinuation
- Treatment satisfaction was higher in LA and 99% preferred LA



Kityo. CROI 2025. Abstr 00202;
Slide Courtesy of Matt Spinelli

CARES: Virologic Failure at Wk 96 (4 in LA [1.6%] vs. 0); (difference 1.6%; 95% CI: 0.4% to 4.2%)

Outcome	Participant 1	Participant 2	Participant 3	Participant 4
At confirmed VF				
▪ Wk of failure	48	48	72	72
▪ HIV-1 RNA, copies/mL	8608 and 1612	44,984; no repeat	798 and 563	259 and 16,161
▪ RPV mutations (level)	V108I, E138K (intermediate)	K103N/S, V106V/A, E138A, M230M/L (high)	Test failed	E138A (low)
▪ CAB mutations (level)†	E92E/V, N155H, L74M (CAB: intermediate, DTG: potential low)	G118R (CAB: high, DTG: high)	Test failed	Q148R (M50I) (CAB: high, DTG: low)
At baseline‡				
▪ RPV mutations CAB mutations Viral subtype	None L74M A1	K103N/S, E138A None D	E138K Test failed A1	None None C
▪ BMI, kg/m^2	25.9	22.0	22.2	19.9

†Participants 1, 3, and 4 resuppressed on SoC.

‡ Retrospective, batched sequencing on archived viral DNA obtained from PBMCs collected/stored at baseline.

Kityo. CROI 2025. Abstr 202.; slide courtesy of Matt Spinelli

Long-acting medications help with adherence challenges in multiple fields

Treatment of psychiatric disorders

Adherence Challenges and Long-Acting Injectable Antipsychotic Treatment in Patients with Schizophrenia

Contraception

Long-Acting Reversible Contraception for Adolescents: A Review of Practices to Support Better Communication, Counseling, and Adherence

Substance use disorder treatment

What is long-acting (XR) buprenorphine injection?

Long-acting buprenorphine injection (XR-buprenorphine, currently available brand name: Sublocade) is an injectable formulation of buprenorphine that is given once a month to assist people in obtaining and sustaining long-term recovery from opioid use disorder (OUD). There may be additional XR-

Long-acting injectable naltrexone for the treatment of alcohol dependence

Is HIV epidemic control by 2030 realistic?

Chris Beyrer, Georgia D Tomaras, Huub C Gelderblom, Glenda E Gray, Holly E Janes, Linda-Gail Bekker, Gregorio Millett, Giuseppe Pan
Susan Buchbinder, Lawrence Corey

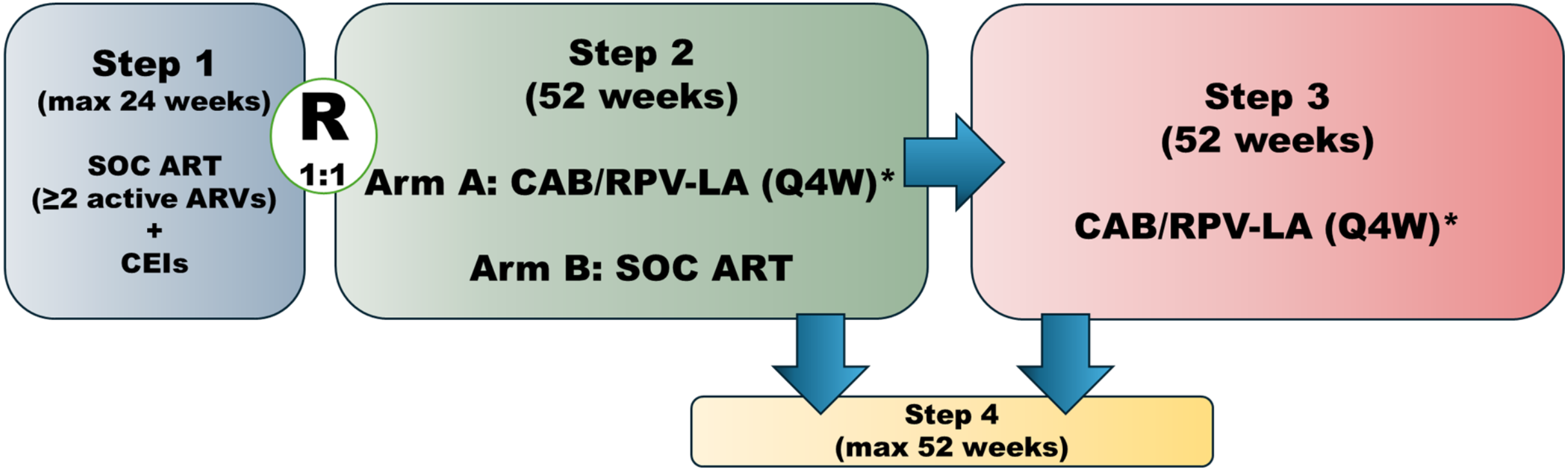
THE LANCET HIV

And this was before US funding cuts

UNAIDS update 2024 (AIDS at a Crossroads):

- 39.9 million people with HIV (highest) not counting Russia so probably >40 million
- 1.3 million new infections last year unchanged from 2022 update
- 630K deaths last year unchanged from 2022 update
- 43.3 million deaths total from beginning of epidemic and 88.4 million infections
- Only 77% on ART (72% suppressed)
- Stigma, rise of anti-LGBTQ sentiment, 8% loss of funding from 2020-23 playing roles

A5359 Study design



CEIs= conditional economic incentives
*Optional Oral lead-in

Primary Outcome: Regimen failure defined as the earliest occurrence of confirmed virologic failure or treatment discontinuation in Step 2

LATITUDE

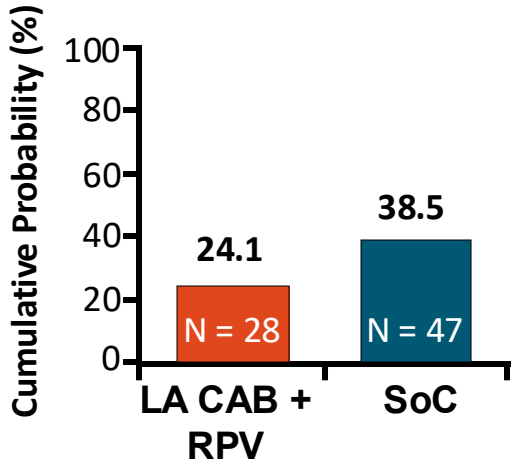
ACTG

ACTG A5359 LATITUDE: Efficacy Outcomes

Primary Outcome

Regimen Failure

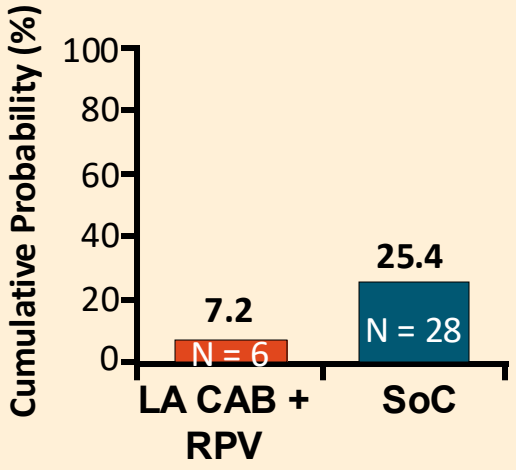
Difference -14.5%
Nominal 98.75% CI (-29.8% to 0.8%)



Secondary Outcomes

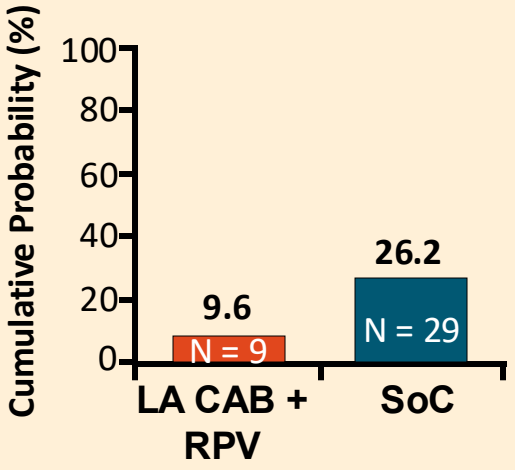
Virologic Failure

Difference -18.2%
Nominal 98.75% CI (-31.1% to -5.4%)



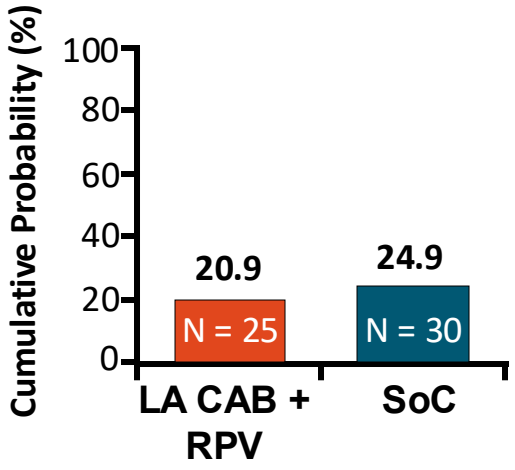
Treatment-Related Failure

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. Abstr 212.

Courtesy of CCO

Demonstration project at Ward 86 HIV Clinic

Inclusion criteria of trials:

- Virologically suppressed x at least 16 weeks on oral regimen first
- No history of virologic failure
- Only K103N in NNRTI; no INSTI mutations
- Oral CAB/RPV x 28 days but direct-to-inject approved FDA March ‘22

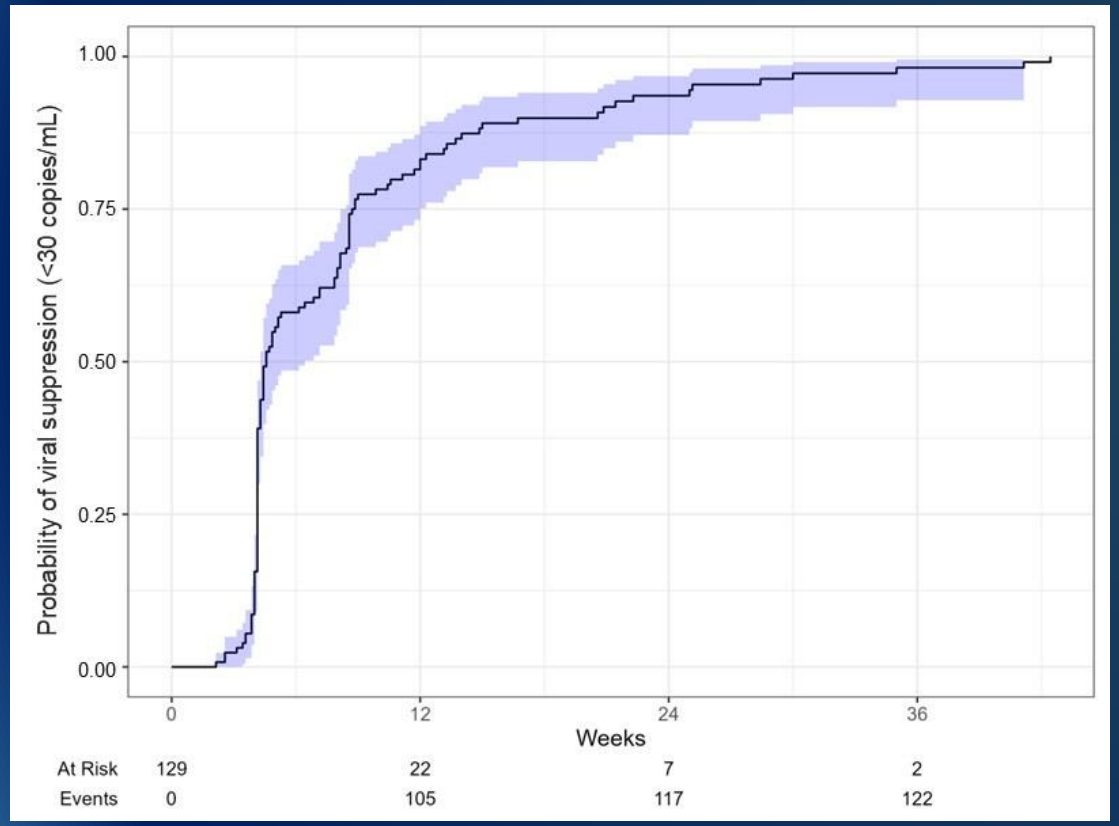
Inclusion criteria of Ward 86

- Need not be virologically suppressed or take oral ART before injectables
- No RPV or INSTI mutations (strengthened criteria later)
- **Express willingness to come to clinic q4 weeks, contact information, outreach from staff**
- Rigorous protocol, Biweekly review of patients

Descriptive statistics summarized patient characteristics, median/range number of injections received, viral suppression outcomes, stratified by viral load ≥30 copies/mL at LA-ART initiation; Kaplan Meier plot for viremic

Gandhi et al. Annals of Internal Medicine July 2023

Ward 86 PWH on LA-ART had rates of 48-week VS that did not differ among those starting with or without viremia



- 370 PWH on LA ART at Ward 86 as of October 2024 (129 started with viremia >50 copies/ml)
  - 40% had housing instability, 46% substance use.
- Substance use (OR 1.22), unstable housing (OR=1.11), and CD4 < 200 (1.21) higher in those with viremia than VS
- Median time to achieve VS (<=30 copies/ml) in PWH with viremia 32d
- At 48 weeks, **99.4% of those who started with VS remained suppressed and 97.9% of those with initial viremia achieved VS (not significantly different p 0.61)**

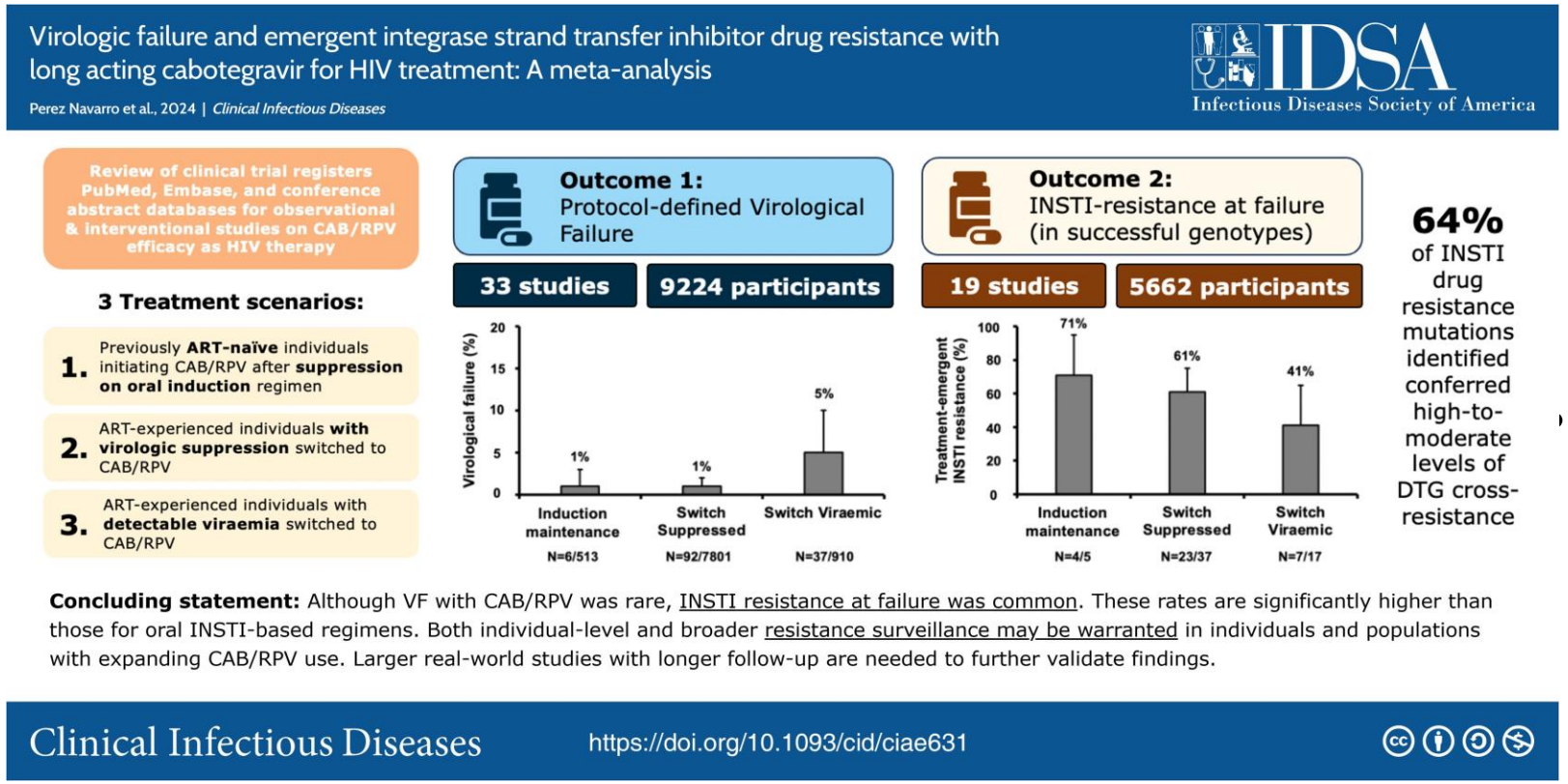
Gistand N et al. JAMA 2025

Clinical Infectious Diseases
MAJOR ARTICLE

Dec 2024

Virologic Failure and Emergent Integrase Strand Transfer Inhibitor Drug Resistance With Long-Acting Cabotegravir for HIV Treatment: A Meta-analysis

Andrea Perez Navarro,[1] Cameron T. Nutt,[2,3] Mark J. Siedner,[2,3,4] Suzanne M. McCluskey,[2,3] and Andrew Hill[5]



- Reviewed 33 studies (N=9224) which reported virologic failure prevalence, 19 reported resistance
- VF prevalence was 1% in induction-maintenance studies, 1% in switch-suppressed studies, 5% in studies where switch happened with viremia (n=910)
- INSTI resistance rate in those with VF was 64% overall (41% in those starting with viremia, 71% induction-maintenance; 61% switch suppressed)

Both IAS-USA guidelines (March 1, 2024) and DHHS guidelines (September 1, 2024) updated to include the use of LA-ART in those with adherence challenges/viremia

March 1, 2024

Updated Treatment Recommendation on Use of Cabotegravir and Rilpivirine for People With HIV From the IAS-USA Guidelines Panel

Paul E. Sax, MD[1]; Melanie A. Thompson, MD[2]; Michael S. Saag, MD[3]; et al

When supported by intensive follow-up and case management services, injectable cabotegravir and rilpivirine (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 (rating AIIa under the conditions described).

- Unable to take oral ART consistently despite extensive efforts and clinical support
- High risk of HIV disease progression (CD4 cell 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.

JAMA®

Updated: September 12, 2024
Reviewed: September 12, 2024

Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV

Virologic Failure

Updates made to the Virologic Failure section include the following:

- For people who experience virologic failure while on their first ARV regimen of a non-nucleoside reverse transcriptase inhibitor (NNRTI) plus two nucleoside reverse transcriptase inhibitors (NRTIs), a salvage regimen of DTG plus boosted darunavir can be used **(AI)**. This recommendation is based on data from the D^2EFT trial, a large randomized controlled trial comparing this regimen to a regimen of DTG plus two NRTIs.
- Some people with HIV cannot reach or maintain viral suppression on oral ART despite intensive adherence support. A complete regimen of long-acting injectable cabotegravir and rilpivirine (LA CAB/RPV) has been used in this population with some success, although long-term efficacy data are limited. Based on very limited data, the Panel recommends the use of LA CAB/RPV on a case-by-case basis in select individuals with persistent virologic failure despite intensive adherence support on oral ART, who have no evidence of resistance to CAB or RPV, and with shared decision-making between providers and people with HIV **(CIII).** The Panel notes that people with HIV and their providers must be aware of the significant risk of developing resistance to NNRTIs, and particularly integrase strand transfer inhibitors (INSTIs) if virologic failure occurs on LA CAB/RPV. Such resistance may limit future treatment options and may also lead to HIV transmission.

Sax. JAMA. 2024; DHHS guidelines September 12, 2024

Exploring predictors of HIV-1 virologic failure to long-acting cabotegravir and rilpivirine: a multivariable analysis

AIDS: July 15, 2021 - Volume 35 - Issue 9 - p 1333-1342

Conclusion: CVF is an infrequent multifactorial event, with a rate of approximately 1% in the long-acting CAB+RPV arms across Phase 3 studies (FLAIR, ATLAS and ATLAS-2M) through Week 48. Presence of at least two of proviral RPV RAMs, HIV-1 subtype A6/A1 and/or BMI at least 30 kg/m^2 was associated with increased CVF risk. These findings support the use of long-acting CAB+RPV in routine clinical practice.

BMI, low rilpivirine troughs, **presence of two proviral RPV RAMS**, HIV-1 subtype A1/A6 associated with increased risk of failure (updated CID 2023)

Clinical Infectious Diseases

MAJOR ARTICLE

Expanded Multivariable Models to Assist Patient Selection for Long-Acting Cabotegravir + Rilpivirine Treatment: Clinical Utility of a Combination of Patient, Drug Concentration, and Viral Factors Associated With Virologic Failure

Chloe Orkin,[1] Jonathan M. Schapiro,[2] Carlo F. Perno,[3] Daniel R. Kuritzkes,[4] Parul Patel,[5] Rebecca DeMoor,[6] David Dorey,[7] Yongwei Wang,[5] Kelong Han,[6]

What are clinically significant mutations?

- Mutations that are defined in vitro via serial passage as reducing susceptibility to ARVs vs resistance mutations identified during a breakthrough infection (on PrEP) or virologic failure (on treatment)
- CARES study made us think- don't think archived means much

*Archived DNA analysis * †*			
Viral subtype A1, n/n (%)	119/213 (55.9)	115/201 (57.2)	234/414 (56.5)
RPV resistance mutations, n/n (%)	25/200 (12.5)	26/177 (14.7)	51/377 (13.5)
RPV intermediate/high-level resistance, n/n (%)	17/200 (8.5)	21/177 (11.9)	38/377 (10.1)
CAB resistance mutations, n/n (%)	15/95 (15.8)	14/85 (16.5)	29/180 (16.1)
CAB intermediate/high-level resistance, n/n (%)	10/95 (10.5)	5/85 (5.9)	15/180 (8.3)

Archived DNA run later

Ward 86 restricts to mutations identified in breakthroughs or virologic failures- we don't do HIV DNA genotyping

HPTN083 breakthroughs

Summary of resistance mutations across HPTN083 (Phase 3 plus 1-year open label extension phase)

The table shows all INSTI resistance associated mutations (RAMs) detected in cases in the cabotegravir arm of HPTN 083. The mutations shown were detected at one or more study visits. Major INSTI RAMs are bolded.

ID Code	HIV Subtype	INSTI RAMs detected
A2	C	M50I, **E138K, Q148K**
A3	B	T97A
B3	AE	V151I
B6	B	M50I
B8	B	L74I
B9	B	L74I
B11	B	L74I
B15	B	M50M/I
C1	B	L74I, Q146Q/R, **E138E/K**, **G140G/S**, **Q148R**, E157Q
C3	B	**E138A**, **Q148R**
D1	Likely B	Q146L, **Q148R**, **N155H, R263K**
D2	Likely B	**N155H**, S230R
D3	BF	**R263K**
D4	C	M50I, **E138K**, **G140A**, **Q148R**
D5	F	M50I, **R263K**
D6	AE	L74I, **Q148R**
DX2	BF	V151I
BR1	BC	**Q148R**

Markzinke M et al: HPTN 083. AAC April 2023

Echo/Thrive failures

Antiviral Therapy 2013; 18:967–977 (doi: 10.3851/IMP2636)

Original article

96-Week resistance analyses of rilpivirine in treatment-naive, HIV-1-infected adults from the ECHO and THRIVE Phase III trials

Laurence Rimsky[1], Veerle Van Eygen[1], Annemie Hoogstoel[1], Marita Stevens[1], Katia Boven[2], Gaston Picchio[2], Johan Vingerhoets[1]*

[1]Janssen Infectious Diseases BVBA, Beerse, Belgium

- V90I
- L100I
- K101E
- E138K/Q
- V179I
- Y181C
- V189I
- H221Y
- F227C

ATLAS/ATLAS2M/FLAIR failures

18 out of 34 CAB failures developed 1 or more INSTI mutations (n=2244 in combined study)

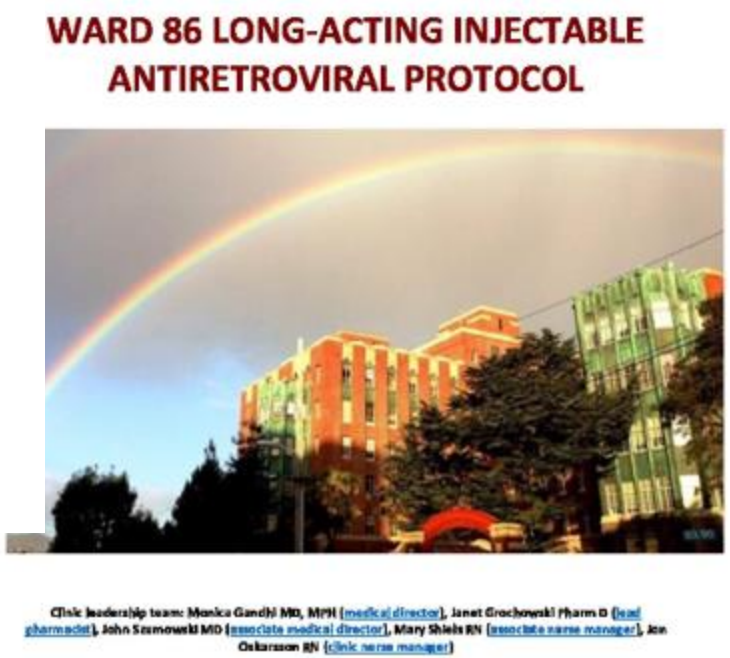
Treatment emergent resistance mutations in the confirmed virologic failures from ATLAS, ATLAS 2M, FLAIR, SOLAR, CARES, real world studies:

NNRTI: V106A V108I, E138A/G/K/T, K101E, K103N, Y181C, Y188L, P225H, M230L

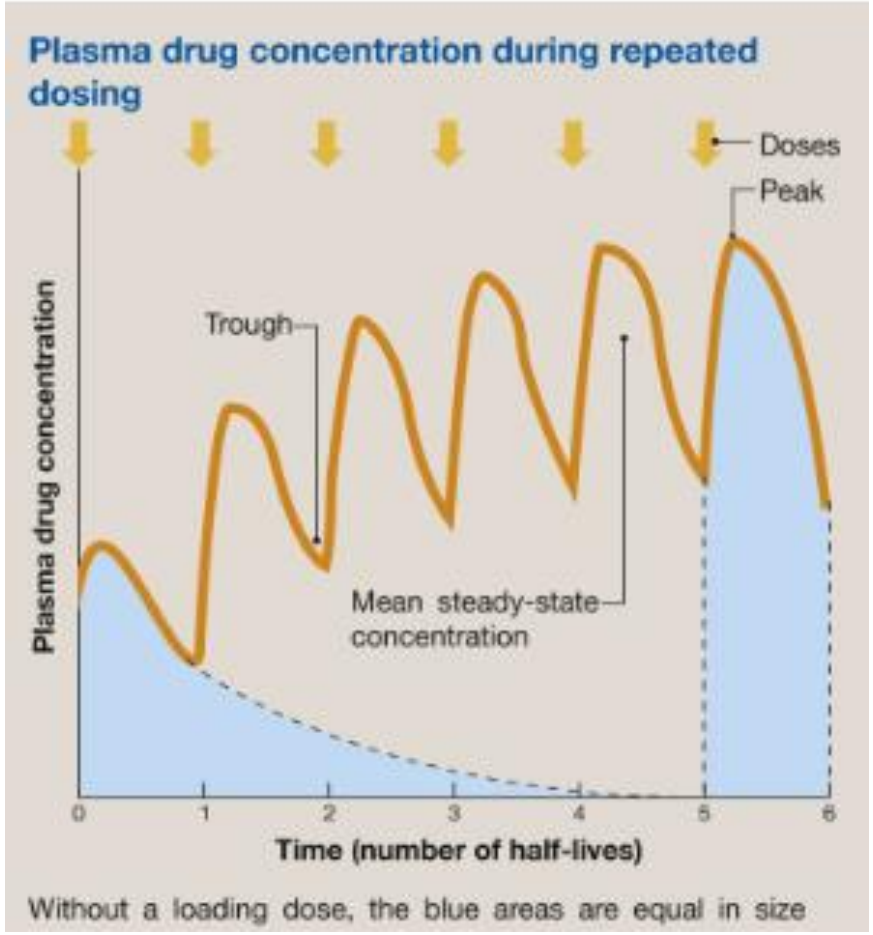
INSTI: T97A, G118R, E138K, G140R,Q148R, N155H, R263K

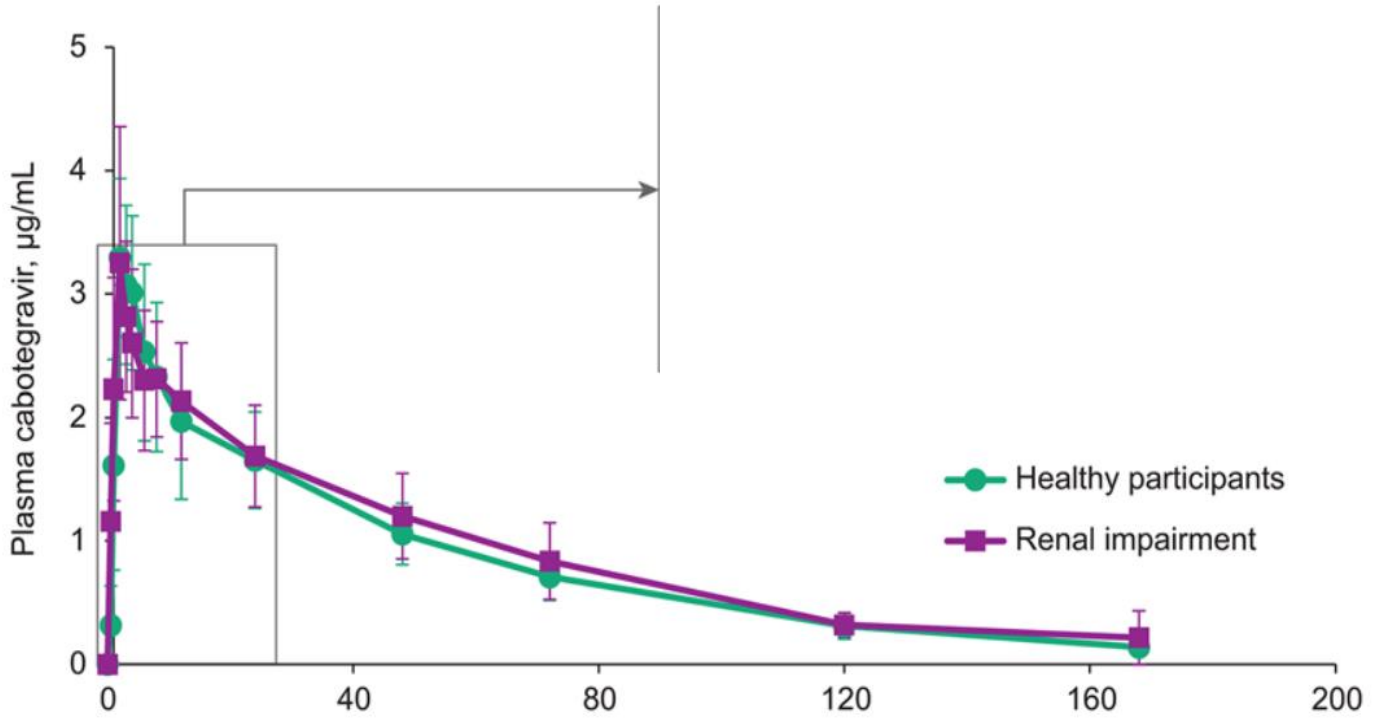
Ward 86 shares clinical considerations and recommendations for starting patients on CAB/RPV LA therapy [Updated May 2024]

- Patients with virus with any NNRTI mutations or INSTI mutations that could compromise either RPV or CAB in past genotypes should not be started on the long-acting regimen. We have decided on the mutations which we will exclude based on which rilpivirine or cabotegravir resistance associated mutations were associated with breakthrough infections in FLAIR, ATLAS, ATLAS 2M (the registrational trials for CAB/RPV); HPTN 083 (study examining every 8 weeks intramuscular CAB for HIV prevention) and the Echo/Thrive trials (studying rilpivirine versus efavirenz for first-line therapy in treatment naïve patients).
    - *Rilpivirine*: V90I, L100I, K101E, V106A, V108I, E138A/G/K/T, V179I, Y181C, Y188L, V189I, H221Y, P225H, F227C, M230L
    - *Cabotegravir*: T97A; G118R; Q148H/K/R; E138K; G140R; N155H; R263K



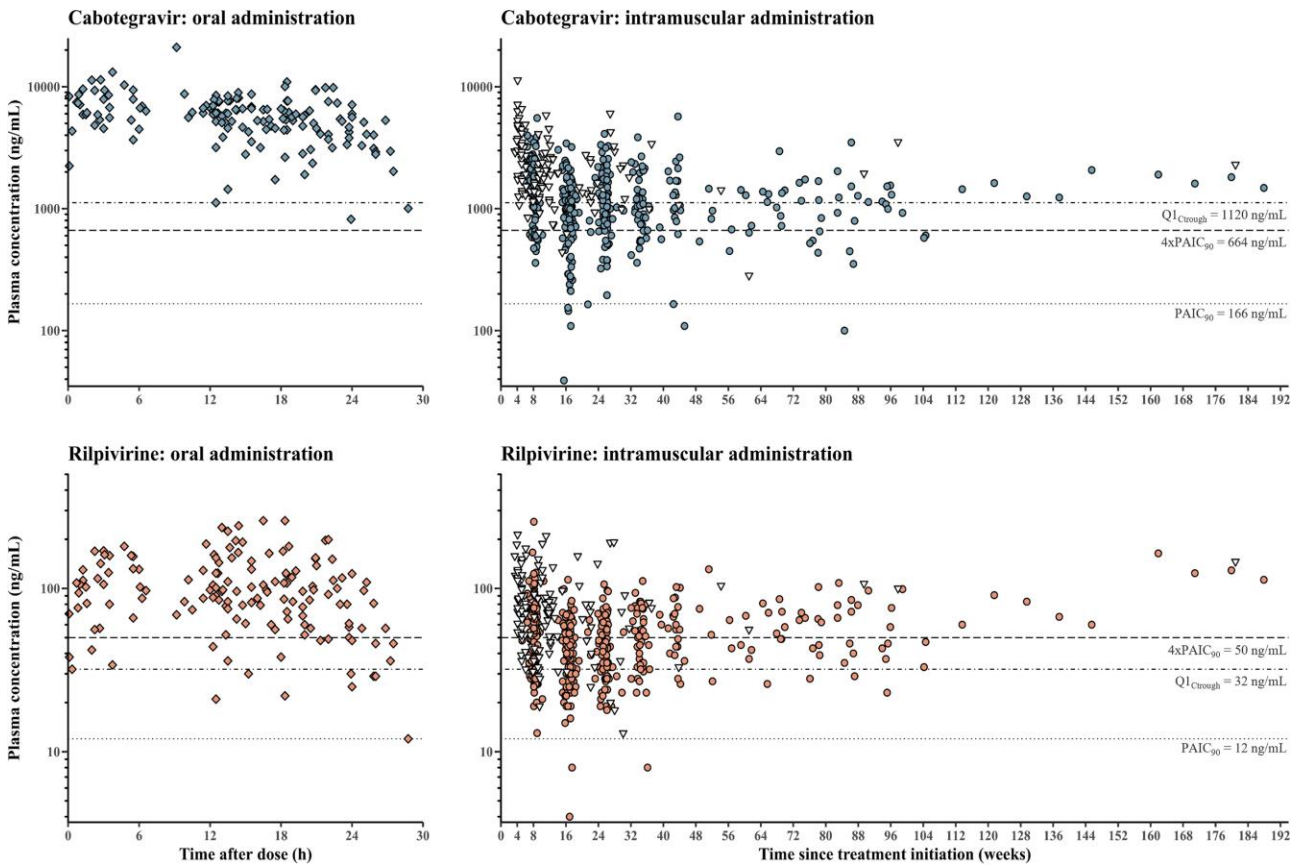
Pharmacokinetics of long-acting very different than oral drugs





Pharmacokinetics with long-acting CAB/RPV

- Surprisingly little known about the PK of long-acting ART
- Injection technique, where drug goes, BMI of patient impact LA levels
- Swiss HIV Cohort Study- 725 samples from 186 PWH March 2022-March 2023
  - High inter-individual variability CAB/RPV (some with repeatedly low)
  - Lower CAB troughs in men vs women (seen in other studied)
  - 172 (92%) remained suppressed; 3 with VF (2 with low levels)
  - No association between low trough levels and detectable viral load.



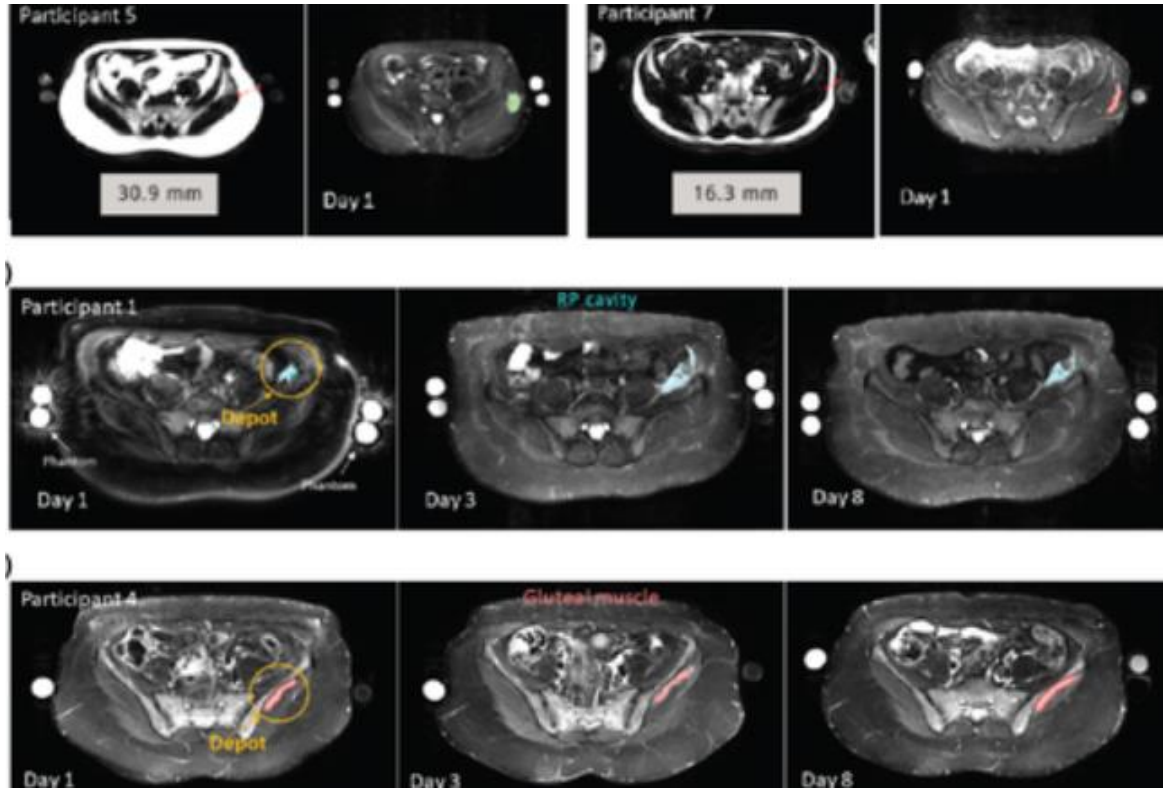
Real-world trough concentrations and effectiveness of long-acting cabotegravir and rilpivirine: a multicenter prospective observational study in Switzerland

THE LANCET *Regional Health* Europe

Higher BMI? We use longer needles

- In this EACS study, use of longer 2-inch needles resulted in higher median CAB trough concentrations in all BMI
- Pharmacology study showed deeper injections with more adipose tissue lead to more spread
- We use 2-inch needles in patients with BMI ≥30 kg/m^2
- Data from CARES intriguing though – 20% with that BMI

Jucker B. Br J of Pharm 2021



Age, median (IQR), years	43 (36-51)	42 (35-49)	42 (35-51)
BMI≥30 kg/m^2, n (%)	57 (22.4)	51 (19.8)	108 (21.1)
Black race, n (%)	254 (99.6)	256 (99.6)	510 (99.6)

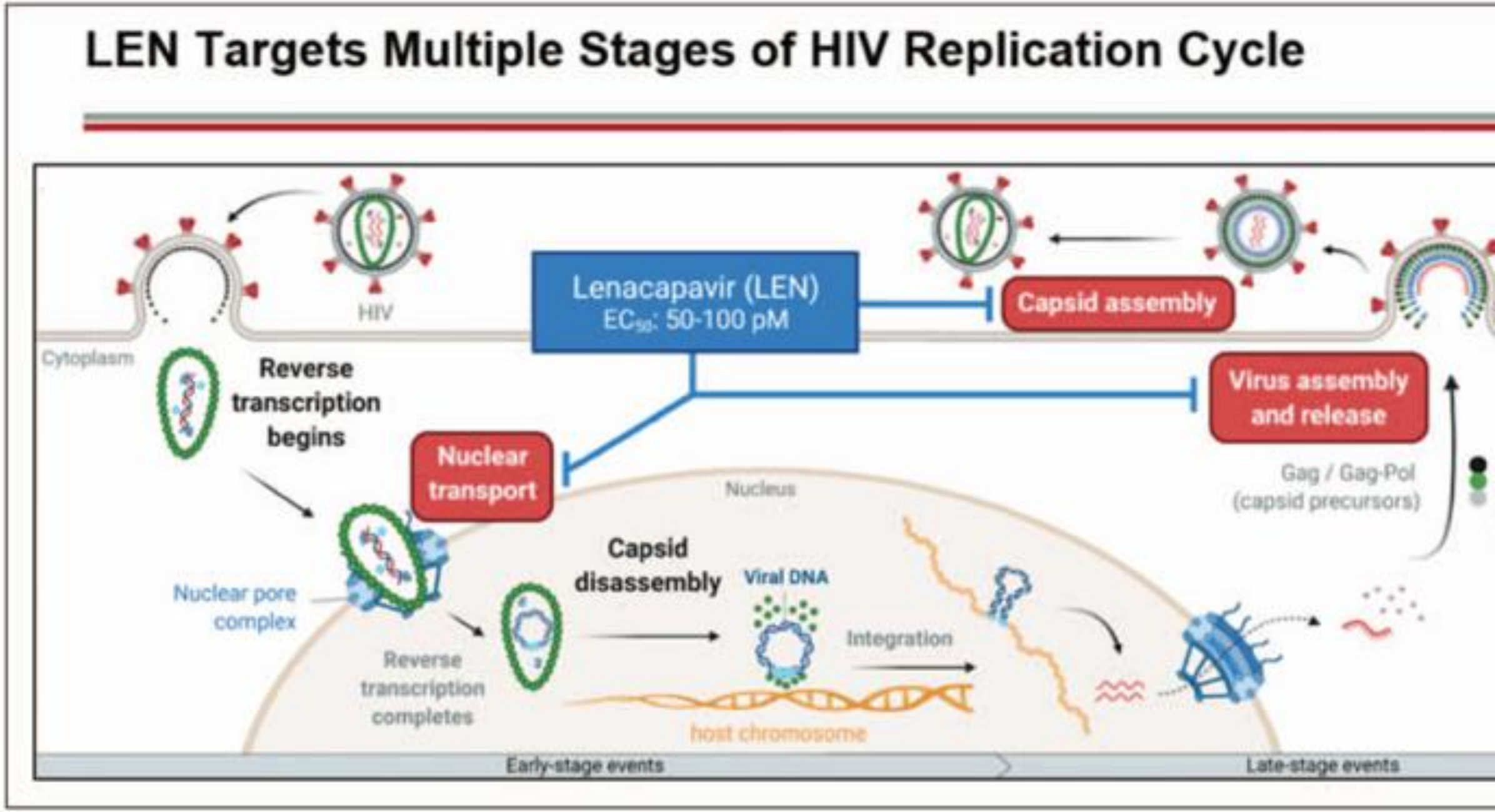
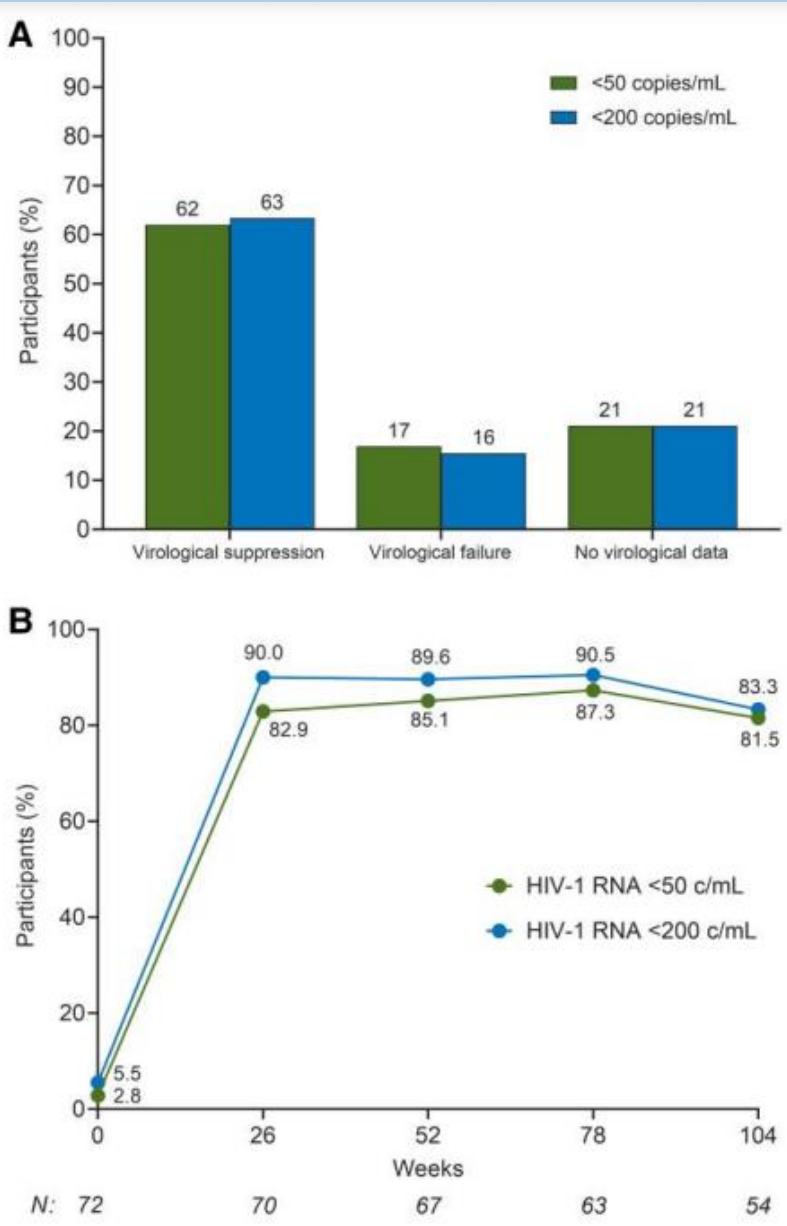


FIGURE 1. Lenacapavir targets multiple stages of the HIV replication cycle. Adapted from [4▪▪,5].

CAPELLA studied LEN + optimized background in HTE



Clinical Infectious Diseases

MAJOR ARTICLE

Efficacy and Safety of Long-Acting Subcutaneous Lenacapavir in Heavily Treatment-Experienced People with Multidrug-Resistant HIV-1: Week 104 Results of a Phase 2/3 Trial

- 83.3% virologic success at 104 weeks, 84.6% 156 weeks
- High CD4 count recovery
- Resuppression even with “LEN mutations”
- Mutations: M66I, K70S, T107A, N74D, A105T, K70S, Q67H

Ogbuagu et al. CID 2024; Ogbuagua ID week 2024

Open Forum Infectious Diseases

MAJOR ARTICLE

Gandhi OFID 2024

Case Series of People With HIV on the Long-Acting Combination of Lenacapavir and Cabotegravir: Call for a Trial

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Background. Injectable cabotegravir (CAB)/rilpivirine (RPV) is the only combination long-acting (LA) antiretroviral regimen approved for HIV. RPV may not be effective among individuals with non-nucleoside reverse transcriptase inhibitor (NNRTI) resistance, which has >10% prevalence in many countries. Lenacapavir (LEN) is an LA capsid inhibitor given every 6 months, but has not been studied in combination with other LA agents.

In this case series compiled from four US academic medical centers, 34 patients with adherence challenges were prescribed LA LEN subcutaneously off-label every 26 weeks with LA CAB (+/- LA RPV) every 4-8 weeks.24 After starting LA LEN therapy, 32/34 (94%) achieved virologic suppression at a median of 8 (4-16) weeks, with all 21 patients with documented or suspected NNRTI mutations (10 without VS at baseline) maintaining or achieving VS.

A5341: Trial of LEN/CAB approved

- These pharmaceutical companies have not historically worked together before
- After much advocacy, small trial (n=38) finally approved from the pharmaceutical companies of LEN/CAB in the ACTG
- Inclusion criteria:
  - NNRTI resistance
  - Viremic
  - Experiencing adherence challenges with oral ART
- Opening door to larger trial in LMICs
  - In those failing TLD due to adherence difficulties without suspicious for resistance (superiority study)- being planned in ACTG

Islatravir + Lenacapavir once weekly at 48 weeks

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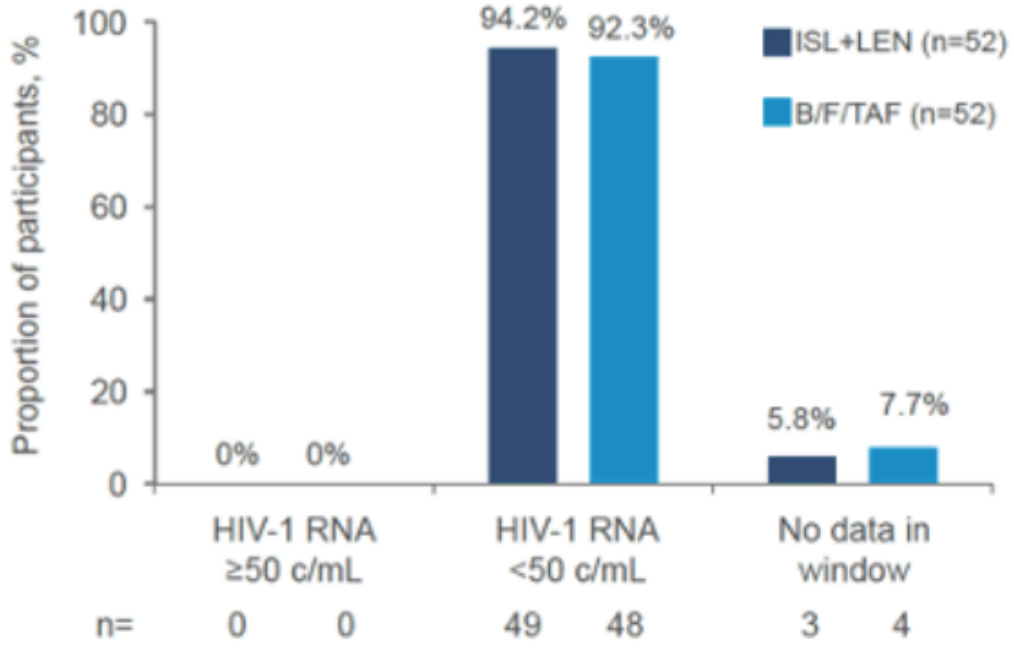
Virologic Outcomes at Week 48 by FDA Snapshot Algorithm



Participants with no data in window:

ISL+LEN

- Two participants discontinued due to AEs not related to study drug
- One participant discontinued due to other reasons not related to study drug
- All participants had HIV-1 RNA <50 c/mL at study discontinuation

B/F/TAF

- Three participants discontinued due to other reasons not related to study drug and had HIV-1 RNA <50 c/mL at study discontinuation
- One participant had missing data during window, but remained on study drug

Participants in both treatment groups maintained high rates of virologic suppression

Phase II study of LEN (capsid inhibitor) 300mg orally + Islatravir (NRTTI) 2mg orally once a week in participants with virologic suppression on oral ART – 94.2% maintained VS at 48 weeks– no significant toxicities- will move forward in phase 3

Conclusion

- Long-acting ART exciting development in HIV therapy
- Original clinical trials studied LA ART in those with virologic suppression on oral ART
- Need strategies to increase virologic suppression in those with adherence challenges
- Providers, clinics all trying LA ART in those with adherence challenges, with success, leading to change in US guidelines
- Will need LA ART options beyond long-acting CAB/RPV- under study