Wednesday, March 12, 2025

197 - Response to HIV Treatment After Long-Acting Cabotegravir Preexposure Prophylaxis in HPTN 083

Raphael J. Landovitz

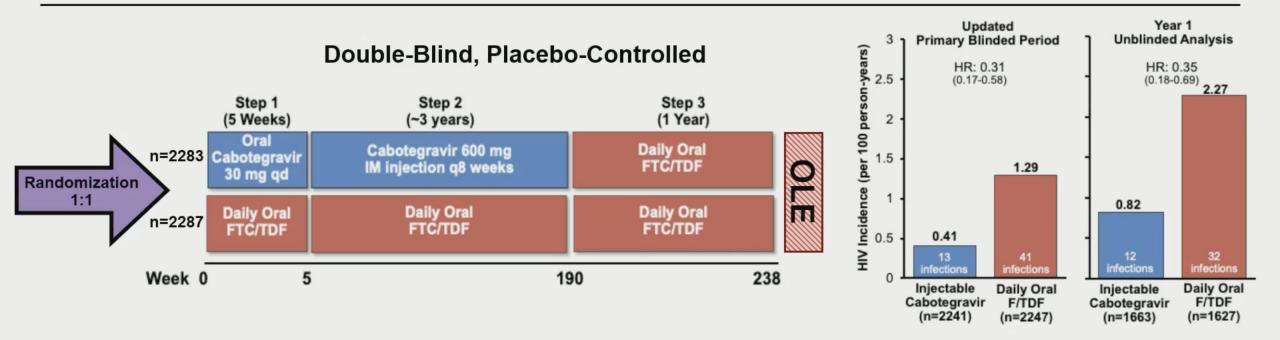
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Disclosure: Dr Landovitz has Self: Fees for participation in review activities, eg, data

monitoring boards, statistical analysis, or end point adjudication committees with Merck & Co, Inc and RedQueen Therapeutics and Self: Consulting or advisor fee with Gilead Sciences, Inc, Merck & Co, Inc, and ViiV Healthcare.

CROI 2025

BACKGROUND

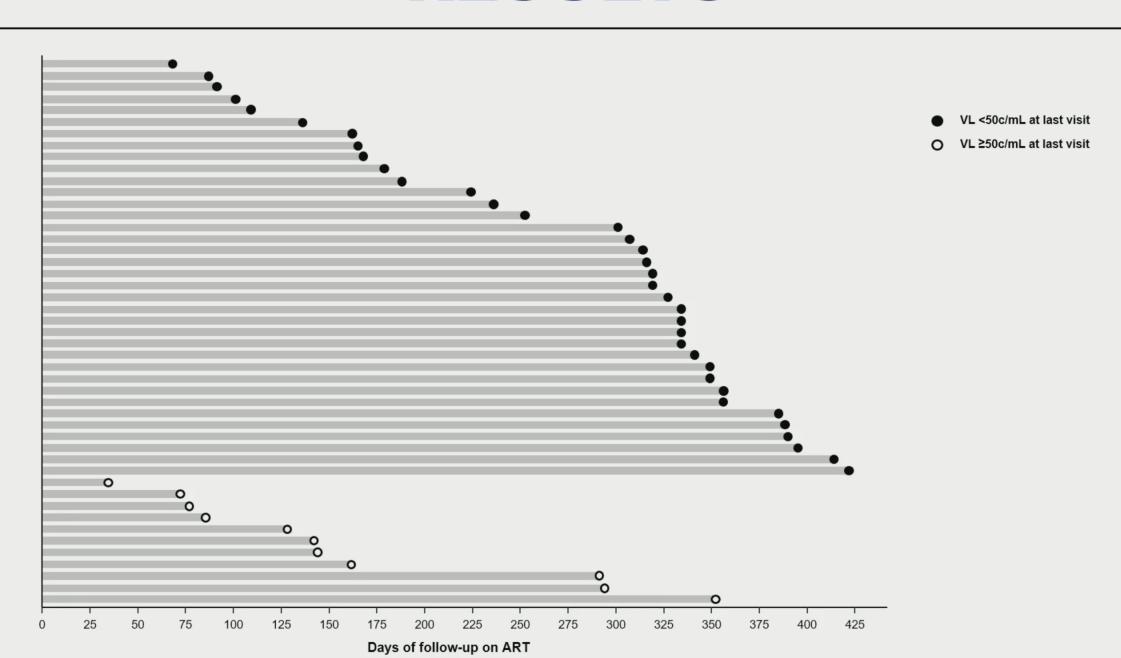


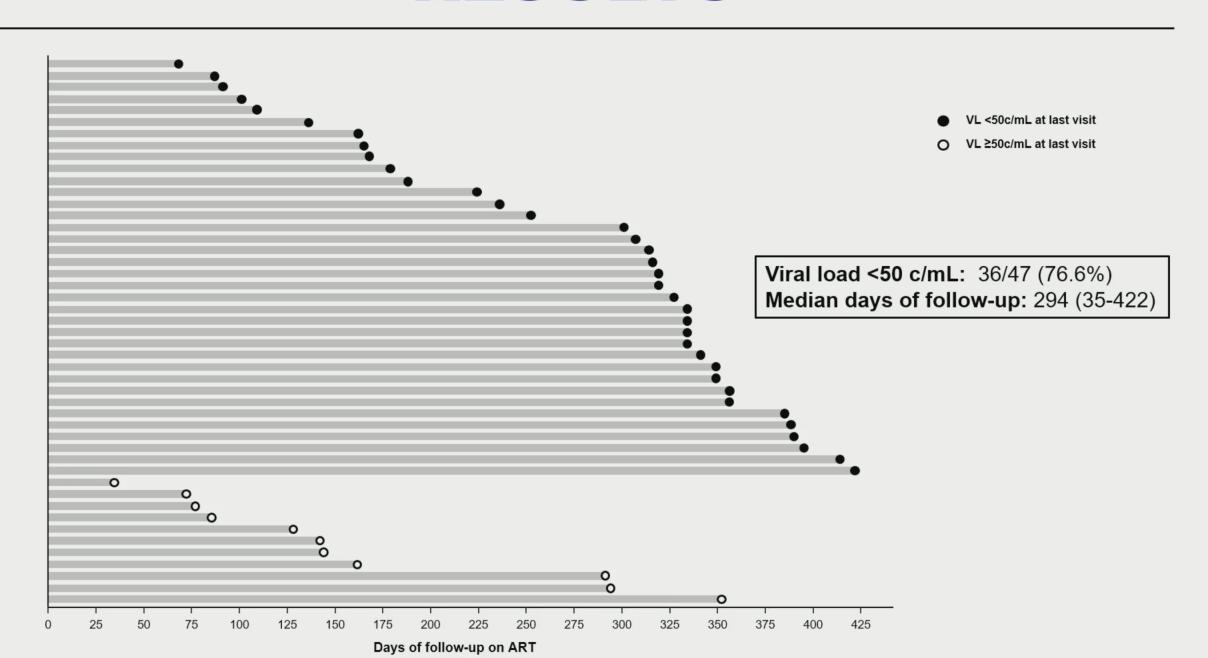
- Population: MSM/transgender women
- Enrollment Regions: US, Brazil, Peru, Argentina, South Africa, Vietnam, and Thailand

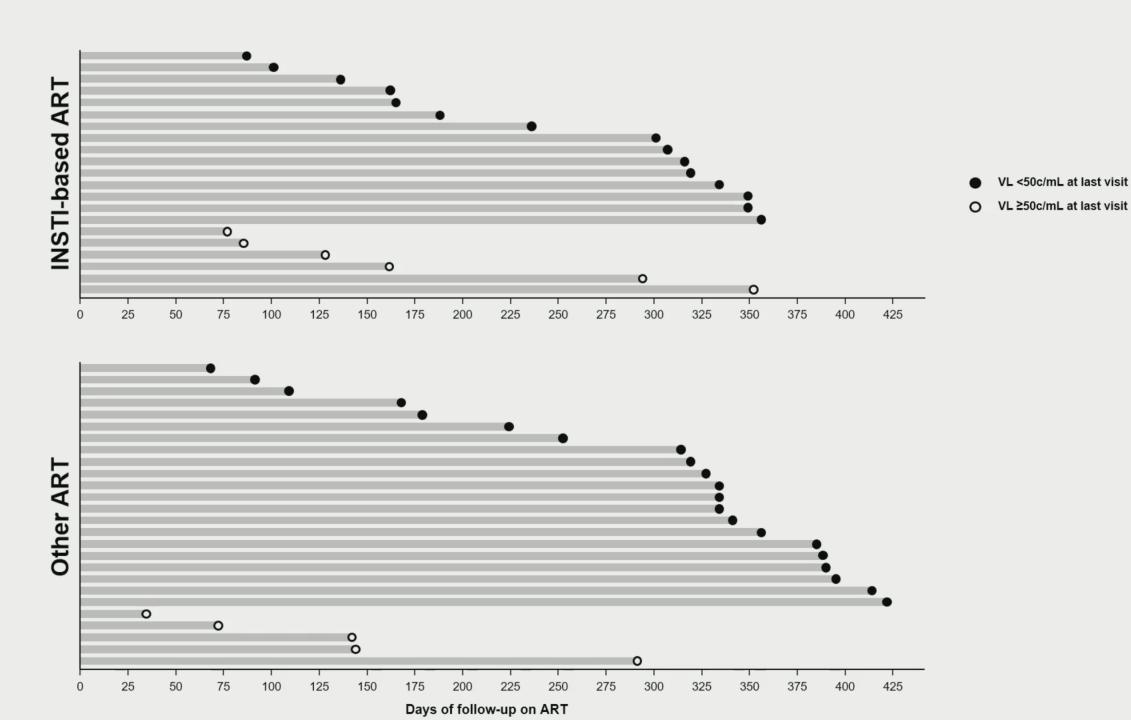
DSMB recommended early termination of blinded phase of this study, which continues as Open Label Extension (OLE)

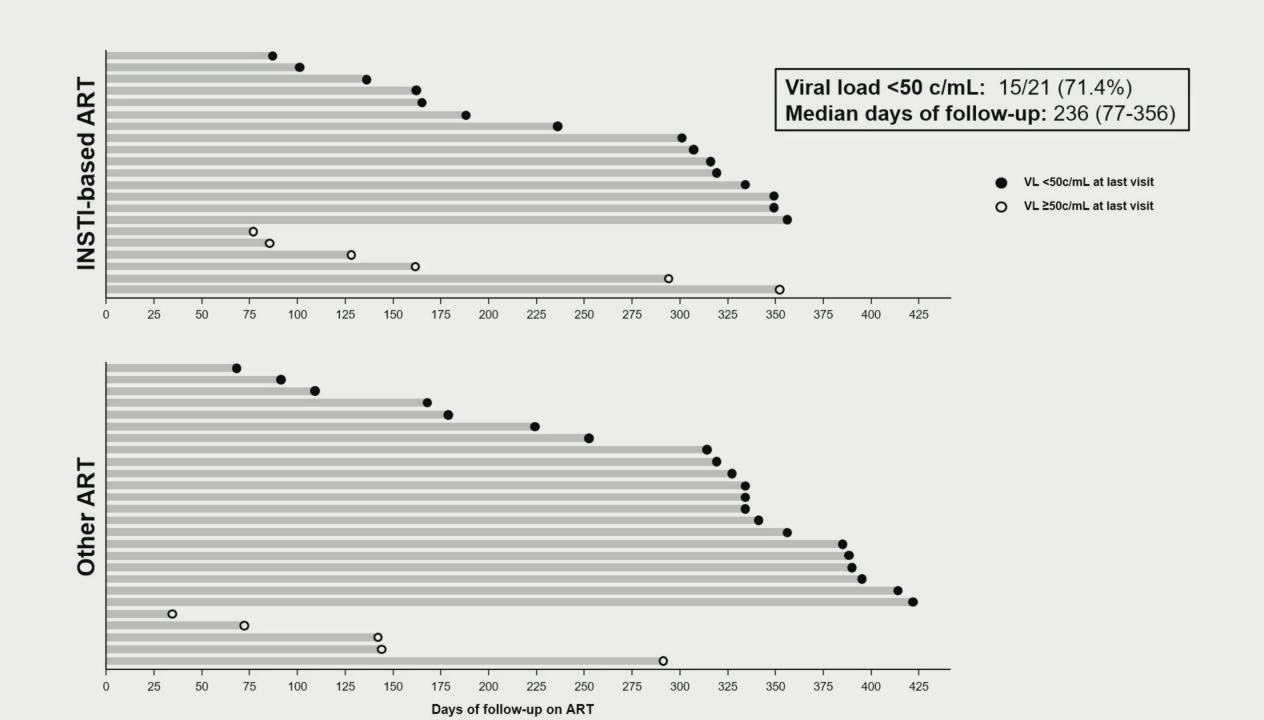
METHODS

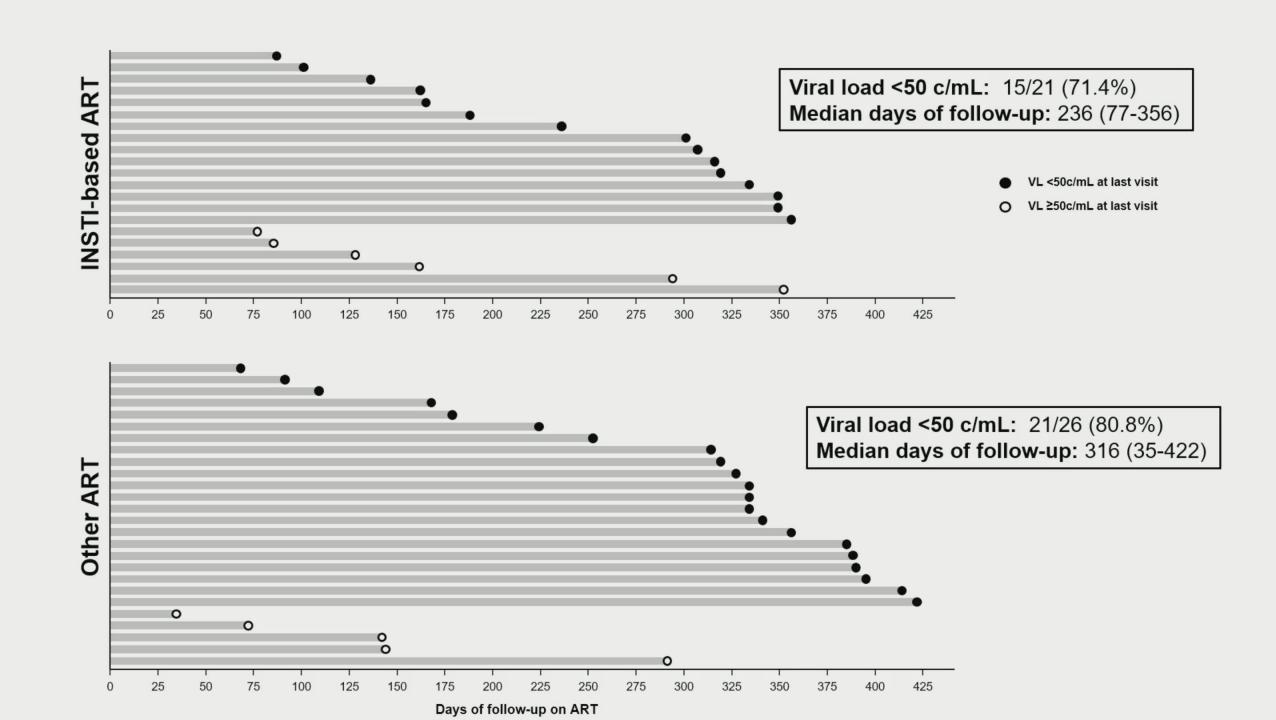
- Evaluated ART outcomes in MSM and TGW exposed to CAB-LA with HIV acquisition in HPTN 083
- ART regimens chosen locally; genotyping available for some
- Included those diagnosed post ≥1 CAB-LA injection, with >30 days ART follow-up (first HIV+ visit prior to 12/1/23)
- HIV viral load and genotyping based on retrospective centralized testing



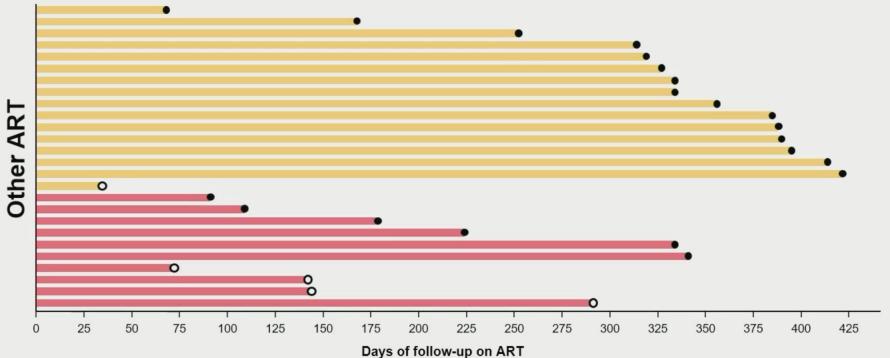










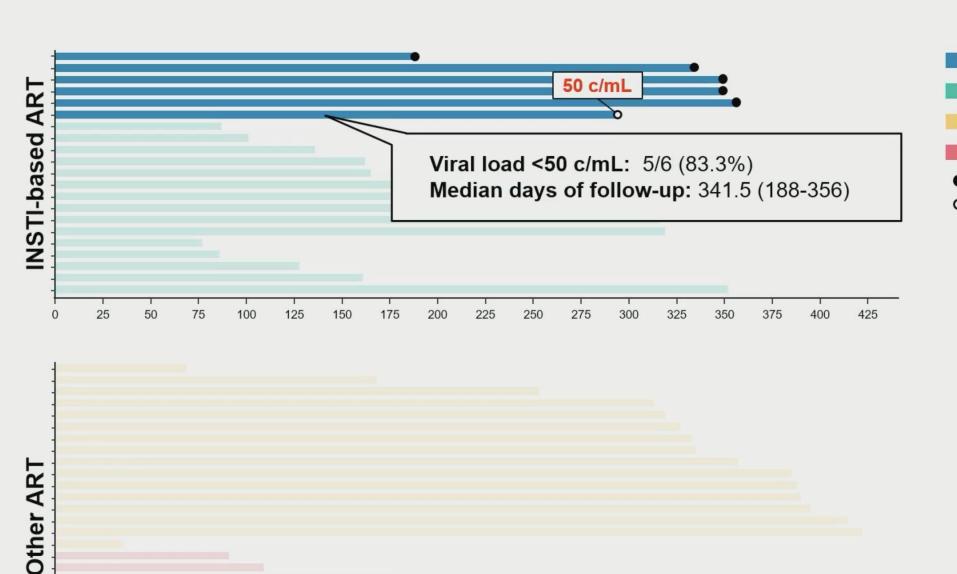


INSTI-based ART >6 months between last CAB and ART start

Other ART

<6 months between last CAB and ART start

- VL <50c/mL at last visit
- VL ≥50c/mL at last visit



Days of follow-up on ART

INSTI-based ART <6 months between last CAB and ART start

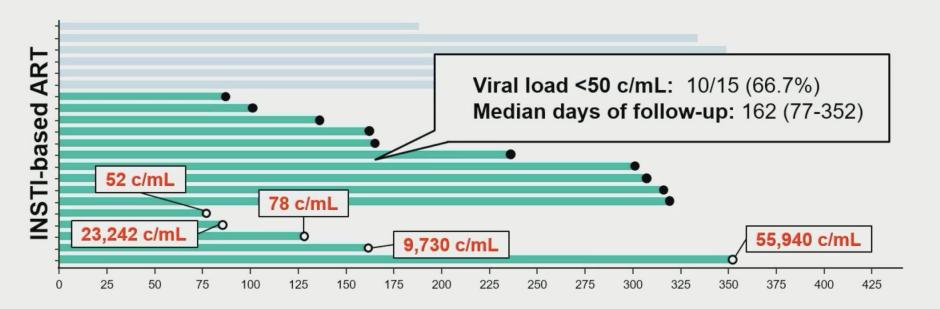
INSTI-based ART

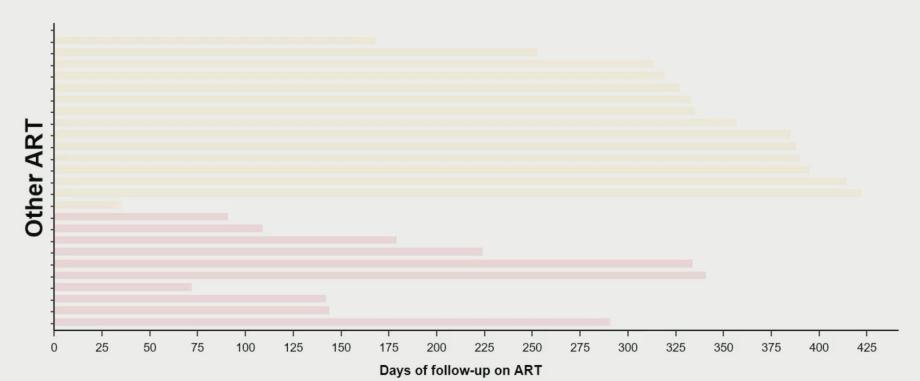
≥6 months between last CAB and ART start

Other ART

<6 months between last CAB and ART start

- VL <50c/mL at last visit
- VL ≥50c/mL at last visit





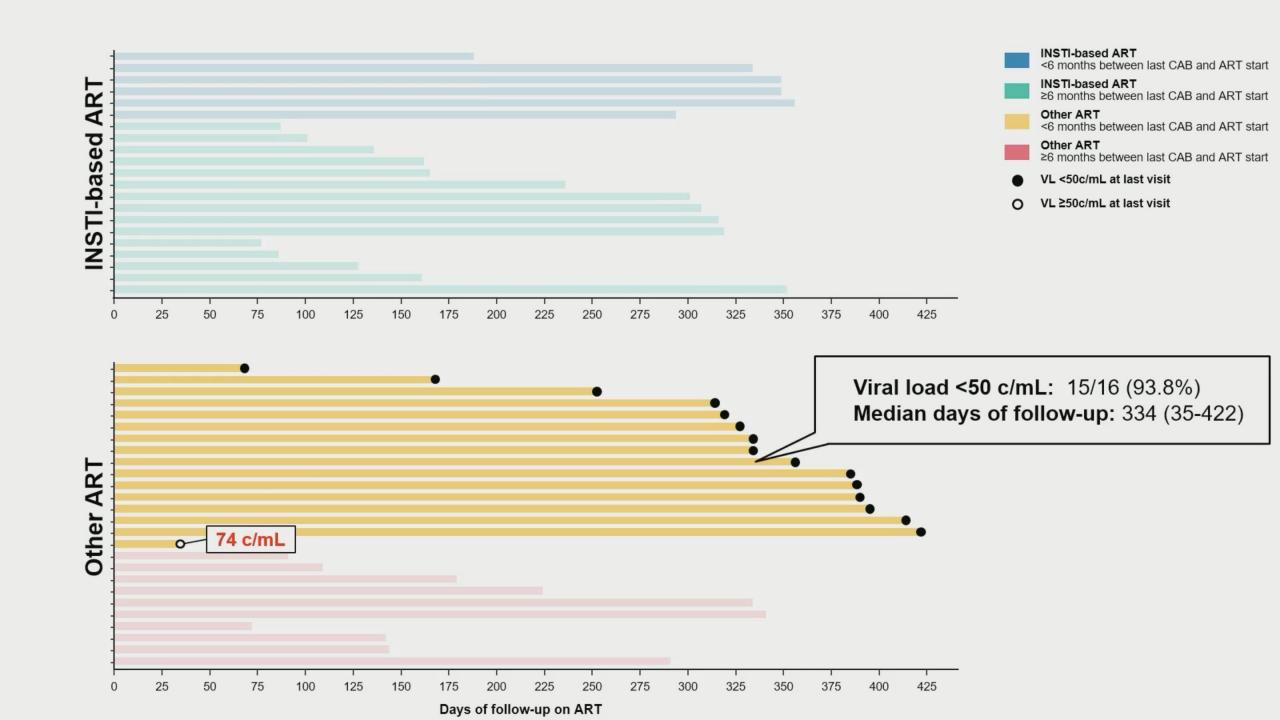
INSTI-based ART

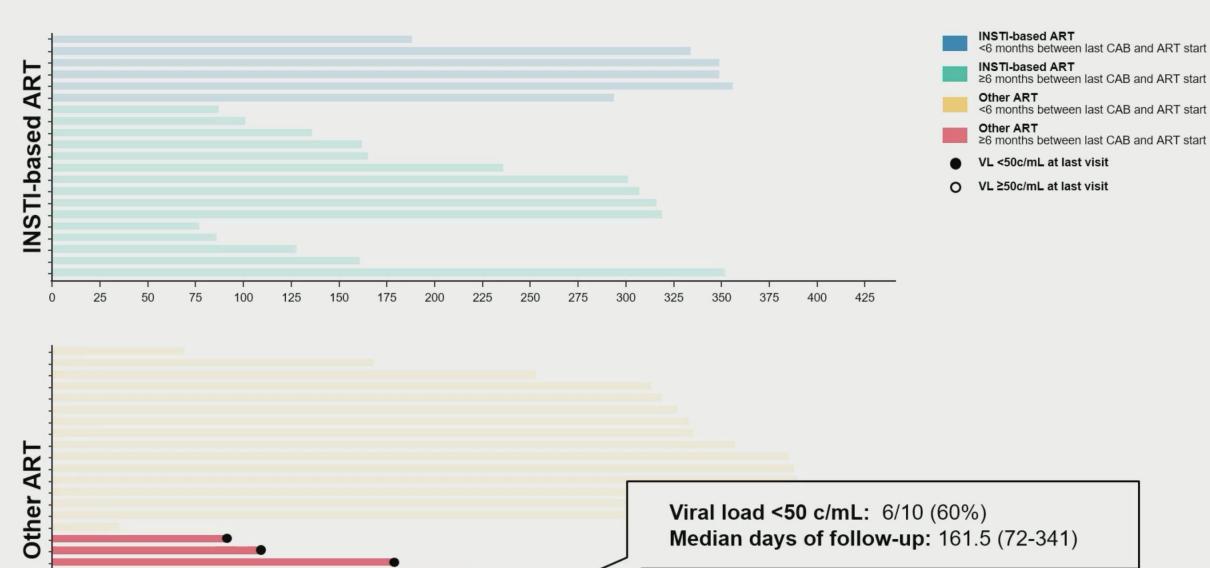
≥6 months between last CAB and ART start

Other ART

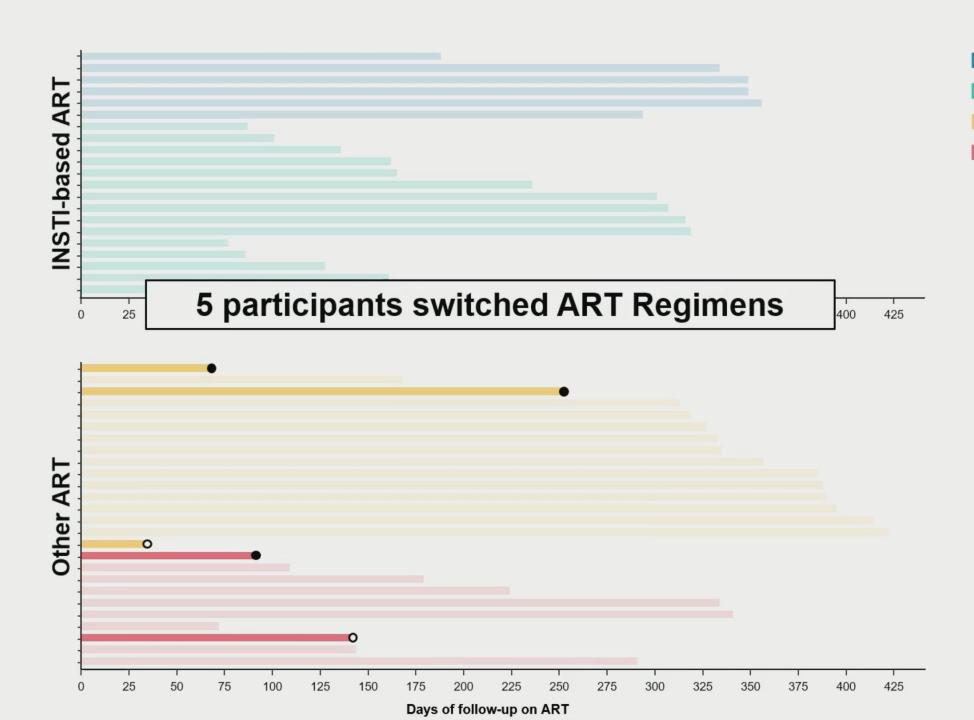
<6 months between last CAB and ART start

- VL <50c/mL at last visit
- VL ≥50c/mL at last visit





3,780 c/mL 2,330 c/mL 664,821 c/mL 10,476 c/mL Days of follow-up on ART



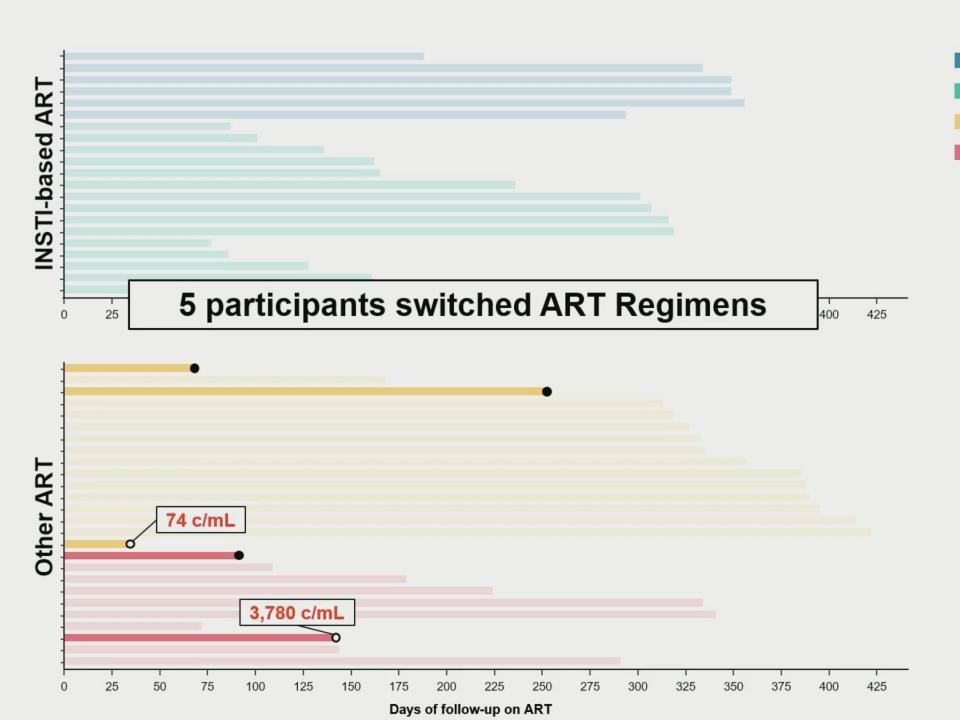
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INSTI-based ART

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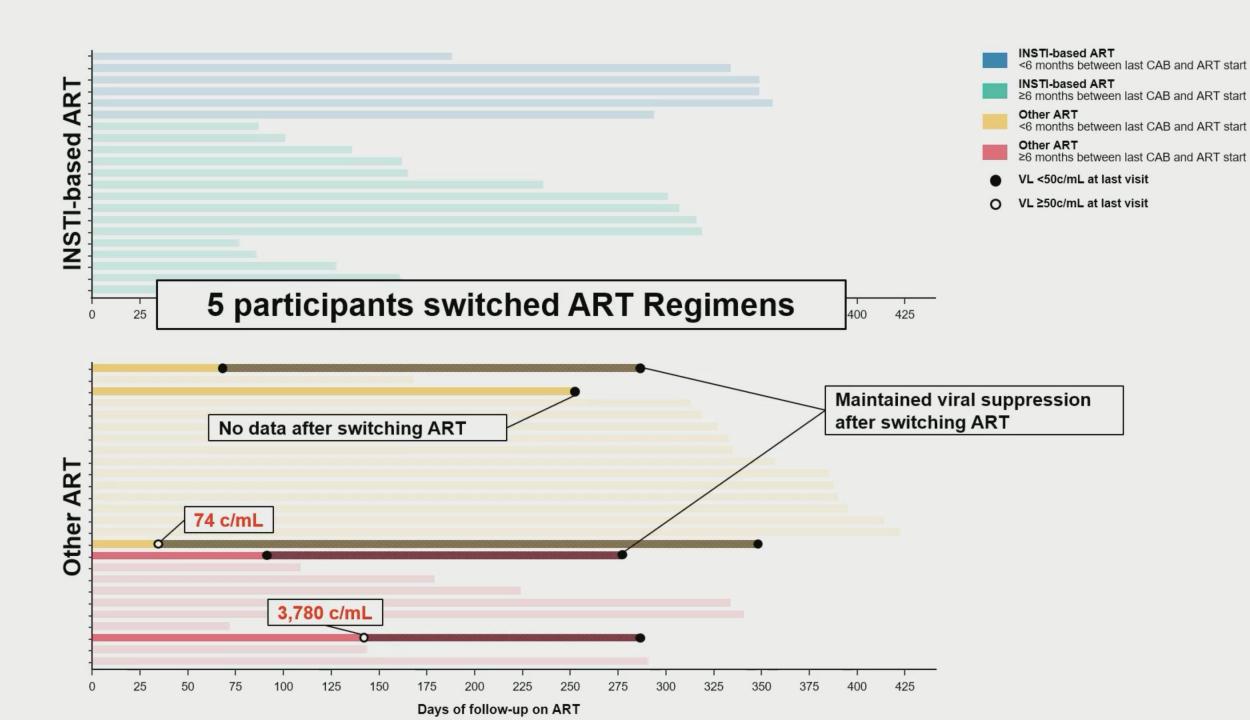
Other ART

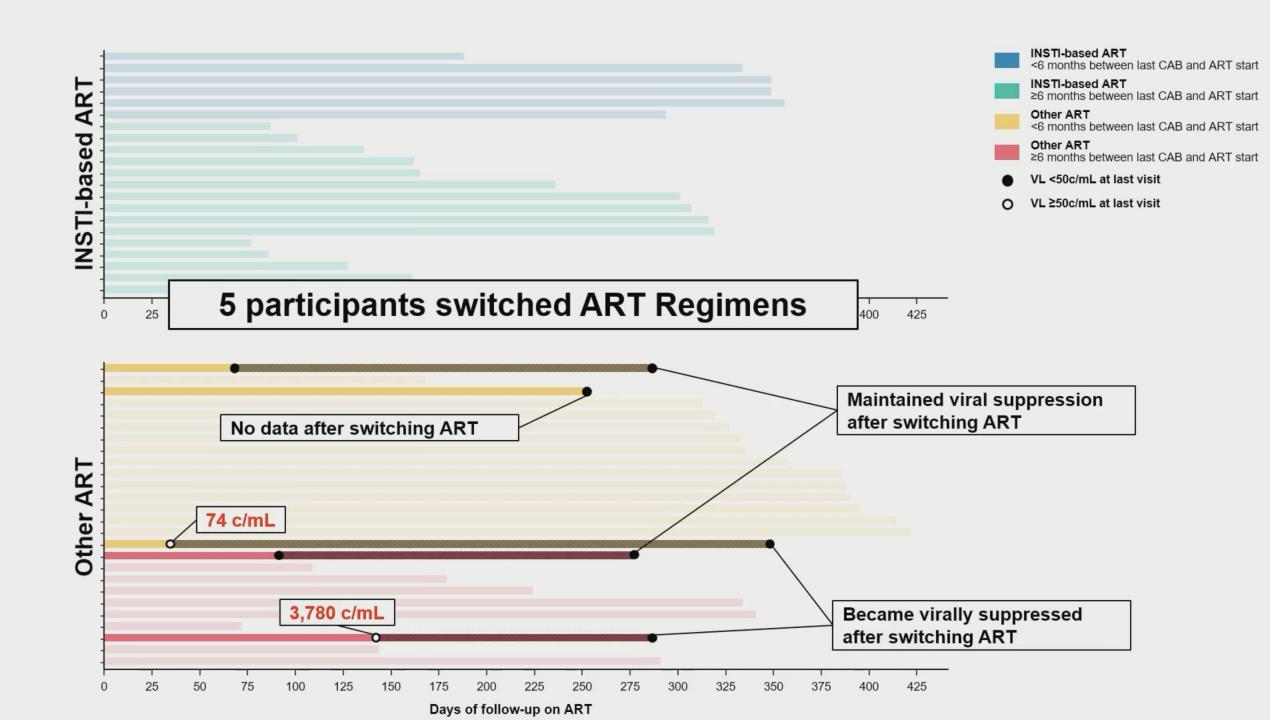
<6 months between last CAB and ART start

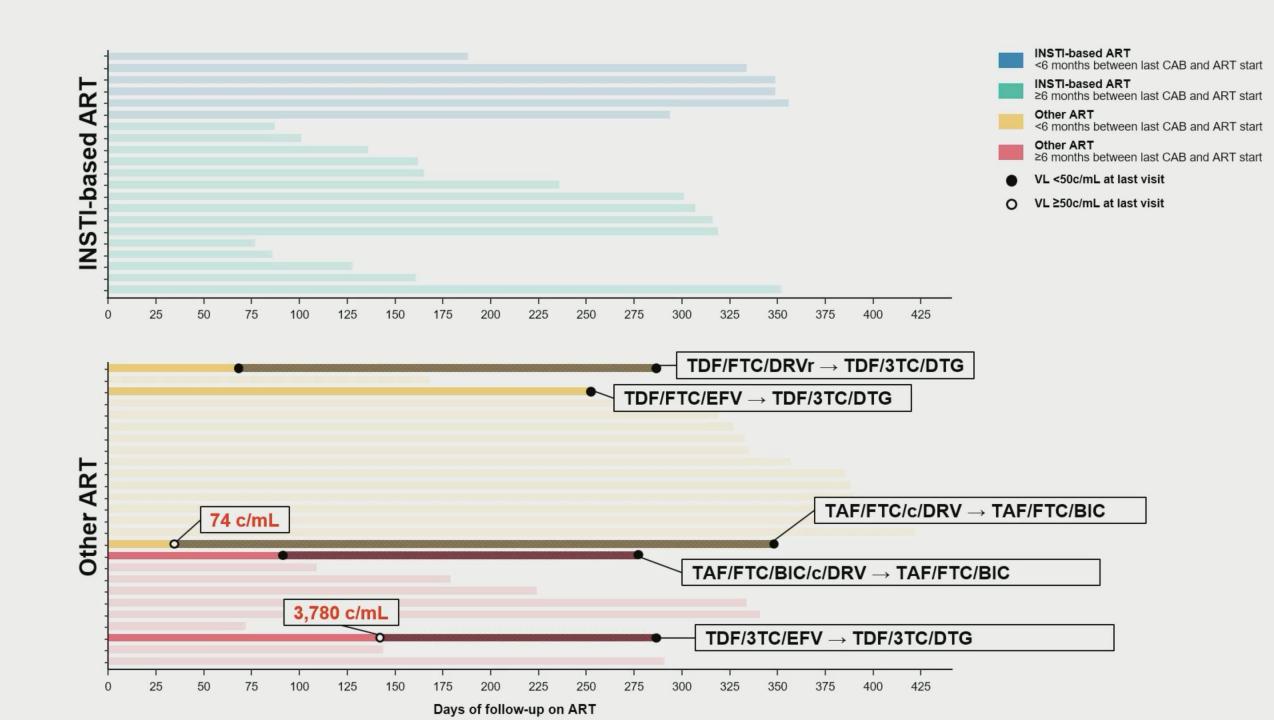
Other ART
≥6 months between last CAB and ART start

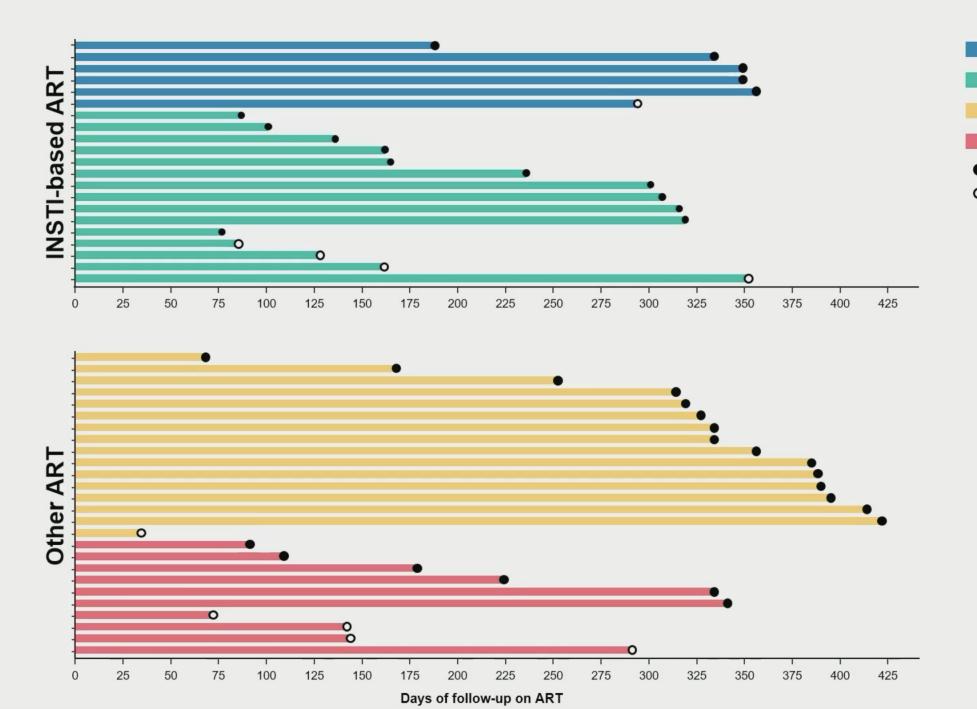
VL <50c/mL at last visit

VL ≥50c/mL at last visit







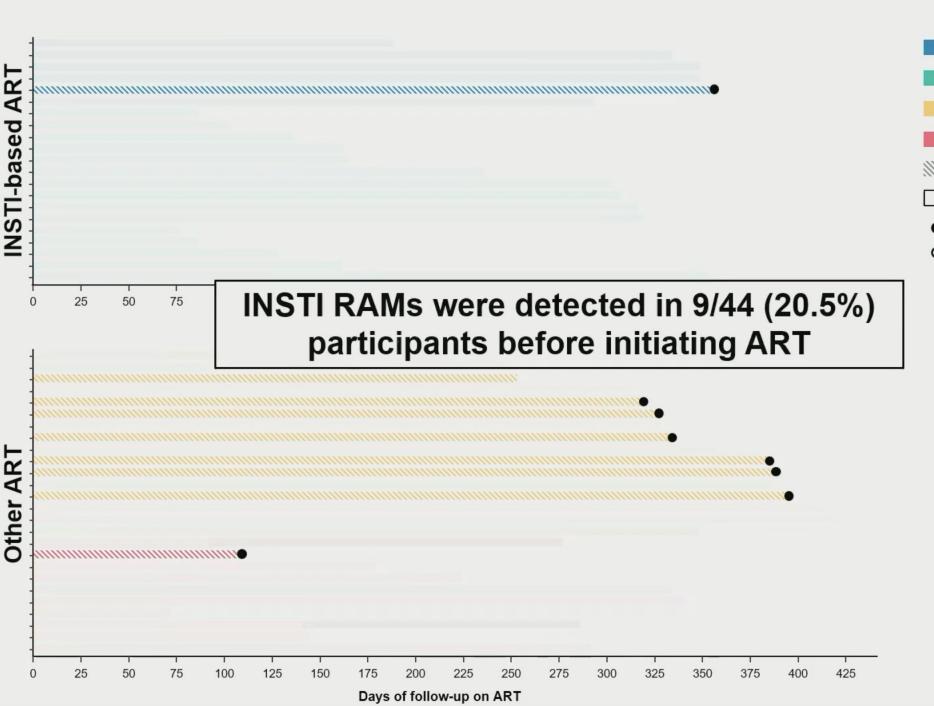


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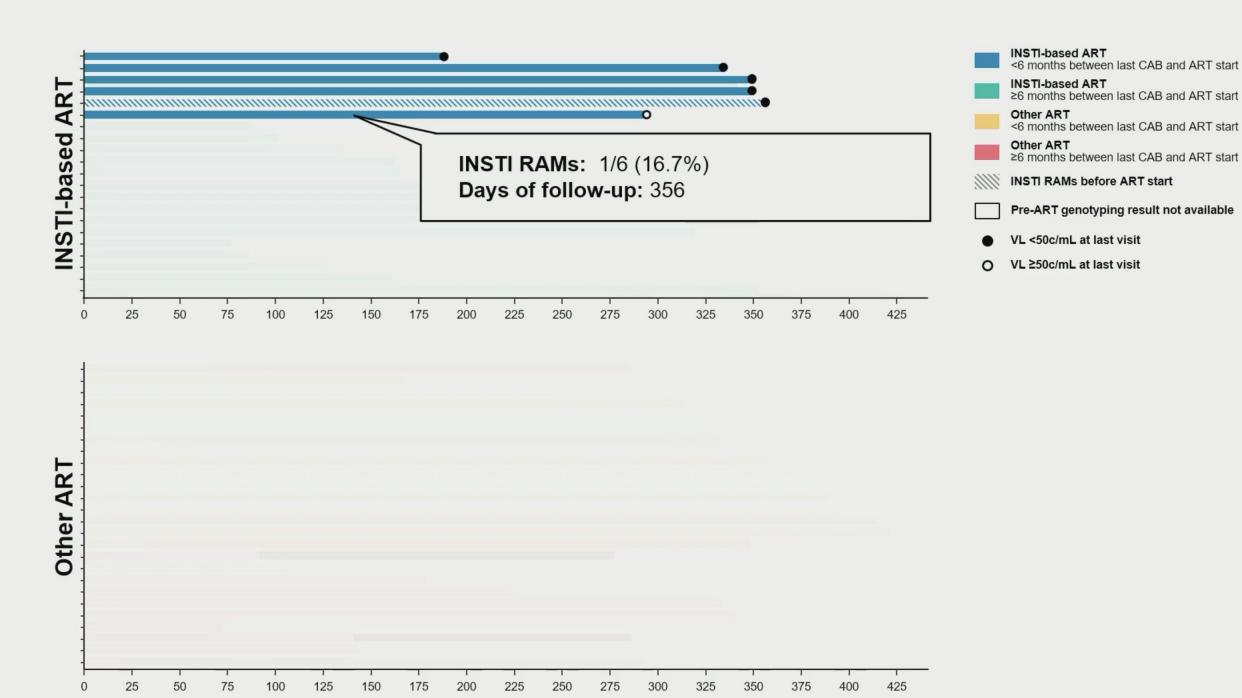
≥6 months between last CAB and ART start

INSTI RAMs before ART start

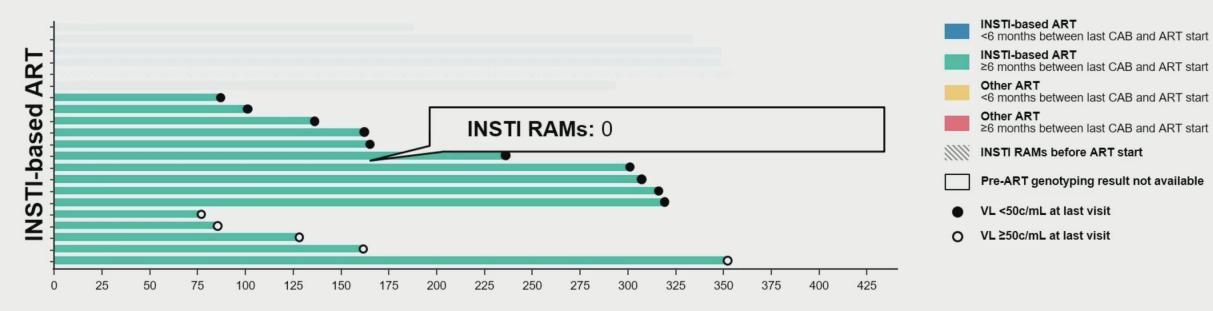
Pre-ART genotyping result not available

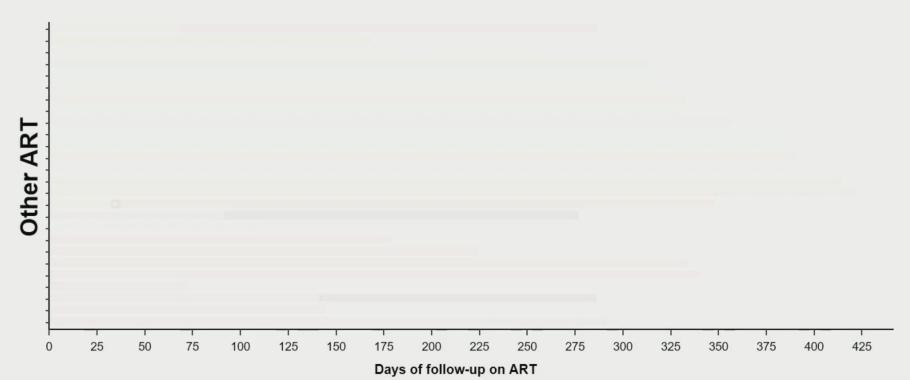
VL <50c/mL at last visit

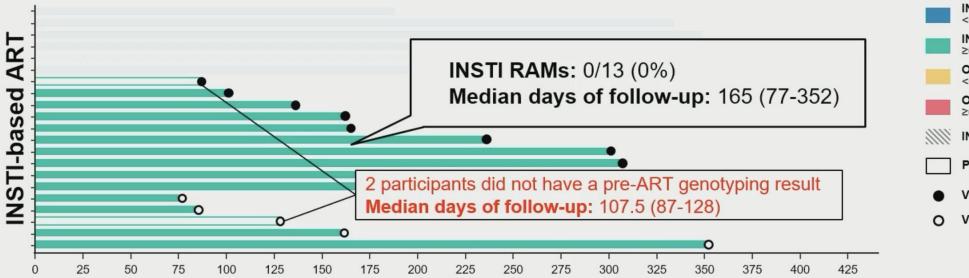
) VL ≥50c/mL at last visit

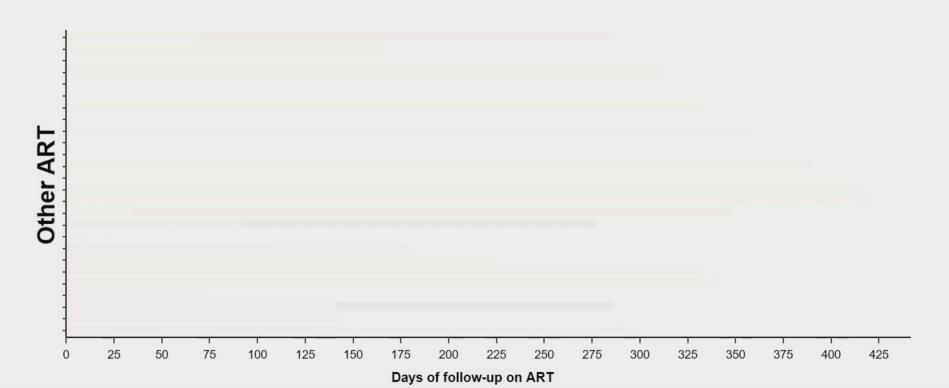


Days of follow-up on ART









INSTI-based ART

≥6 months between last CAB and ART start

Other ART

<6 months between last CAB and ART start

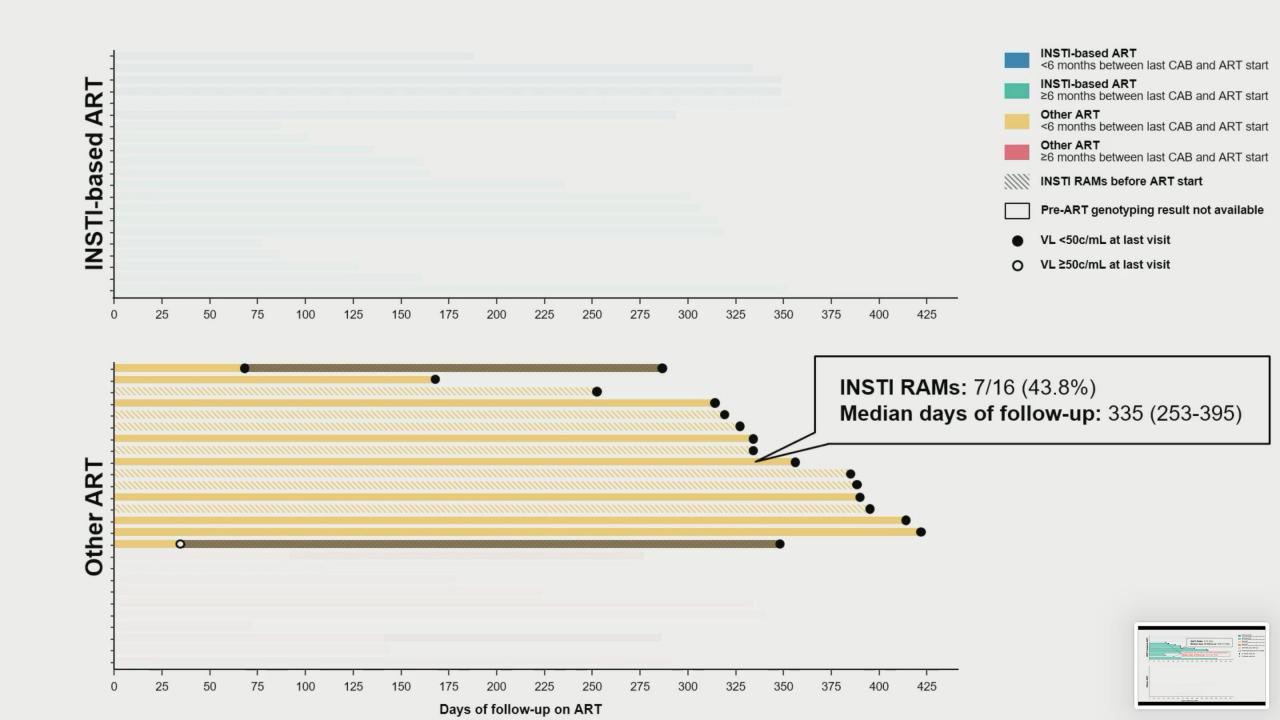
Other ART
≥6 months between last CAB and ART start

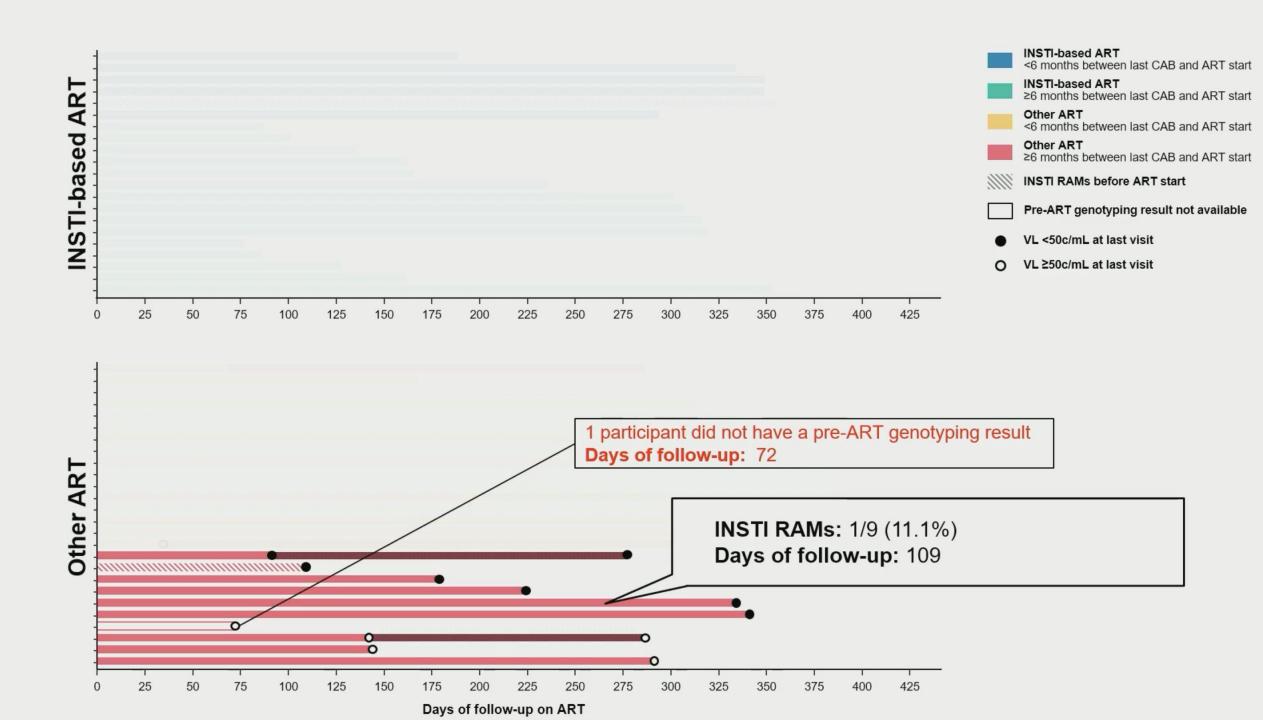
INSTI RAMs before ART start

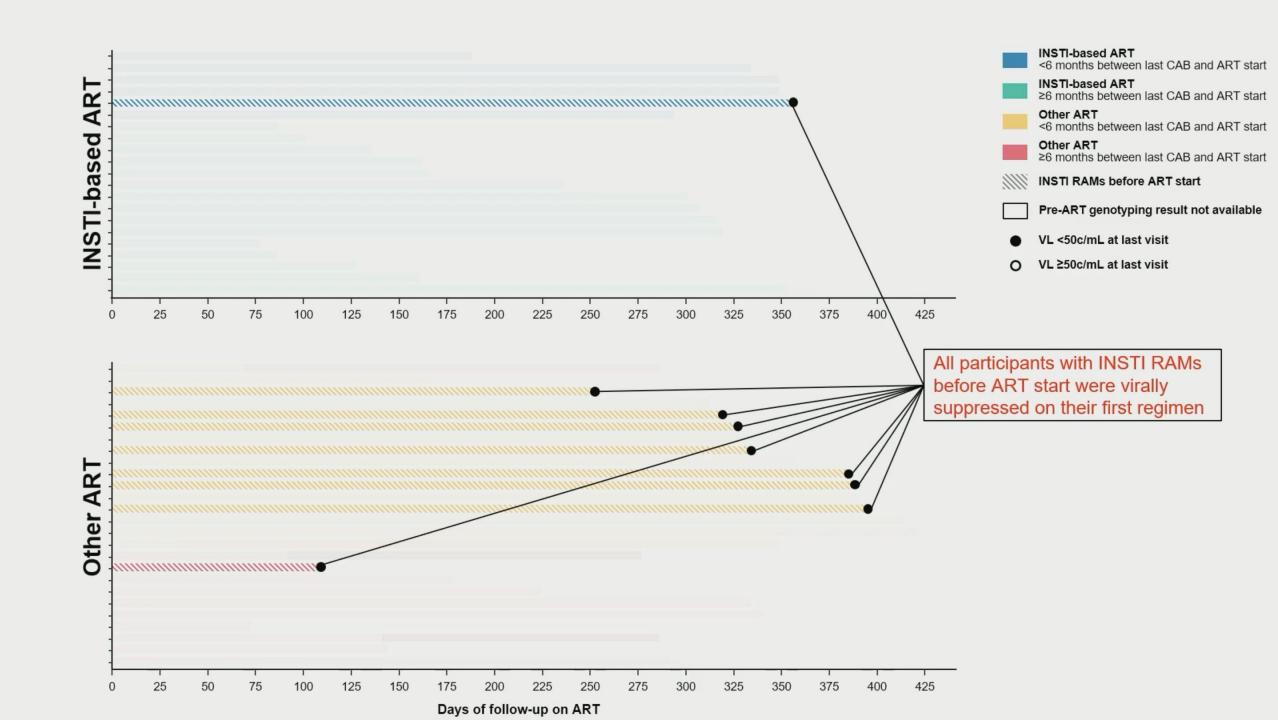
Pre-ART genotyping result not available

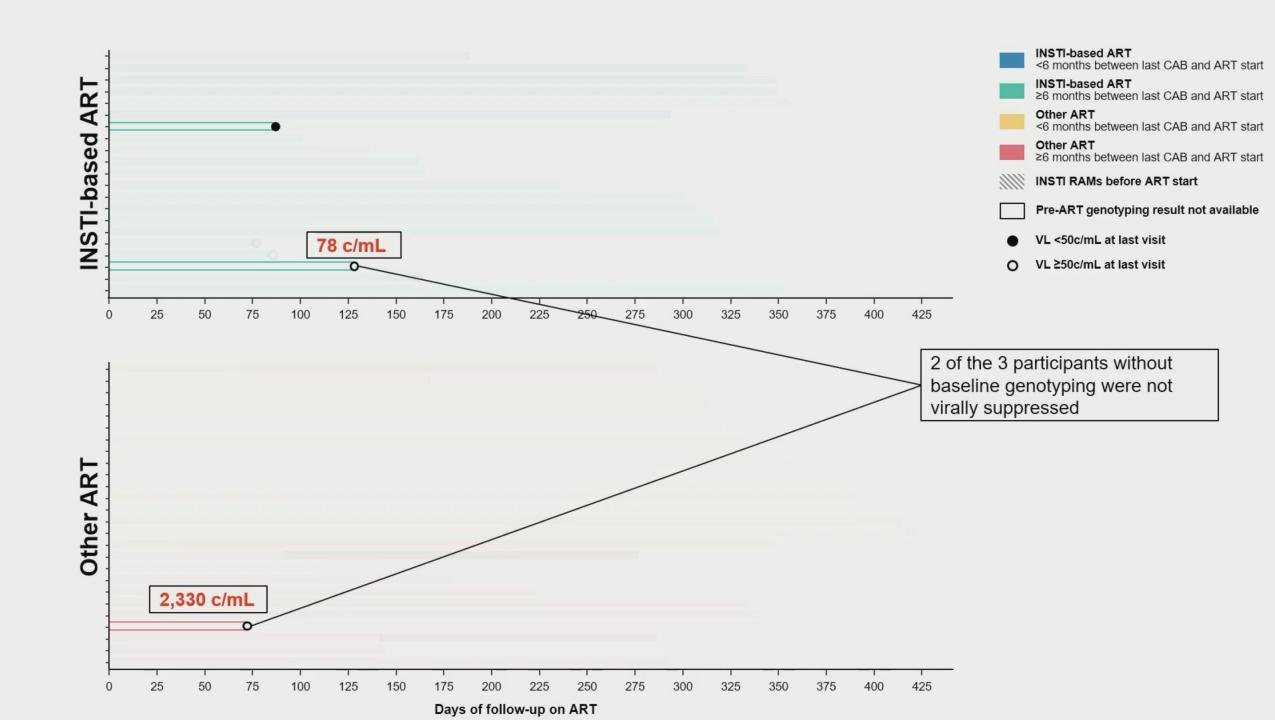
VL <50c/mL at last visit

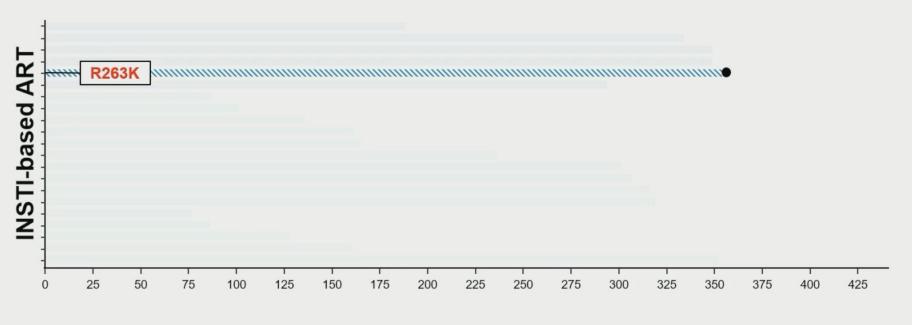
VL ≥50c/mL at last visit

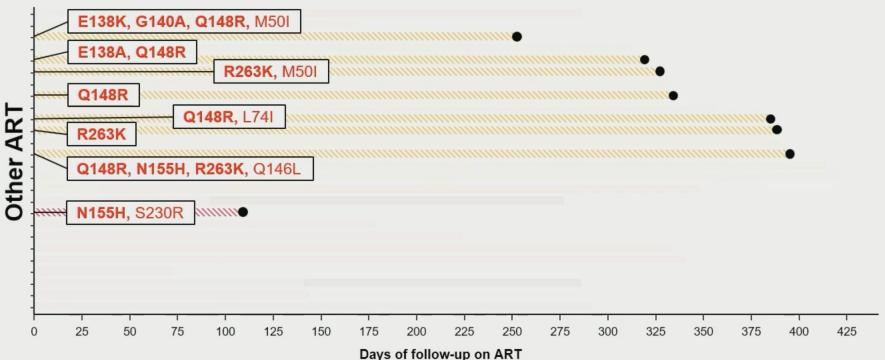












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≥6 months between last CAB and ART start

Other ART

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Other ART
≥6 months between last CAB and ART start

INSTI RAMs before ART start

Pre-ART genotyping result not available

VL <50c/mL at last visit

VL ≥50c/mL at last visit

	INS	STI-based A	RT	Other ART		
	Overall	<6 months*	≥6 months*	Overall	<6 months*	≥6 months*
VIRAL LOAD <50 C/mL, N (%)	15/21 (71.4)	5/6 (83.3)	10/15 (66.7)	21/26 (80.8)	15/16 (93.8)	6/10 (60)
DAYS OF FOLLOW-UP, MEDIAN (RANGE)	236 (77-356)	341.5 (188-356)	162 (77-352)	316 (35-422)	334 (35-422)	161.5 (72-341)
ART REGIMEN SWITCH, N (%)	0/21 (0)	0/6 (0)	0/15 (0)	5/26 (19.2)	3/16 (18.8)	2/10 (20)
MAINTAINED VIRAL SUPPRESSION	-	-	-	2/5 (40)	1/3 (33.3)	1/2 (50)
BECAME VIRALLY SUPPRESSED	-	-	-	2/5 (40)	1/3 (33.3)	1/2 (50)
NO FOLLOW-UP DATA	-	-	-	1/5 (20)	1/3 (33.3)	0/2 (0)
INSTI RAMS DETECTED, N(%)	1/19 (5.3) [†]	1/6 (16.7)	0/13 [†] (0)	8/25 (32.0)†	7/16 (43.8)	1/9 [†] (11.1)
VIRAL LOAD <50 c/mL, N (%)	1/1 (100)	1/1 (100)	-	8/8 (100)	7/7 (100)	1/1 (100)

^{*}Time between last CAB injection and start of ART.

[†]Pre-ART genotyping not available for 3 participants; two were not virally suppressed.

	INSTI-based ART Overall <6 months* ≥6 months*			Other ART Overall <6 months* ≥6 months*			
VIRAL LOAD <50 c/mL, N (%)	15/21 (71.4)	5/6 (83.3)	10/15 (66.7)	21/26 (80.8)	15/16 (93.8)	6/10 (60)	
DAYS OF FOLLOW-UP, MEDIAN (RANGE)	236 (77-356)	341.5 (188-356)	162 (77-352)	316 (35-422)	334 (35-422)	161.5 (72-341)	
ART REGIMEN SWITCH, N (%)	0/21 (0)		0/15 (0)	5/26 (19.2)	3/16 (18.8)		
MAINTAINED VIRAL SUPPRESSION				2/5 (40)	1/3 (33.3)		
BECAME VIRALLY SUPPRESSED				2/5 (40)	1/3 (33.3)		
NO FOLLOW-UP DATA					1/3 (33.3)		
INSTI RAMS DETECTED, N(%)	1/19 (5.3) [†]		0/13 [†] (0)	8/25 (32.0) [†]	7/16 (43.8)	1/9 [†] (11.1)	
VIRAL LOAD <50 c/mL, N (%)	1/1 (100)	1/1 (100)	-		7/7 (100)	1/1 (100)	

^{*}Time between last CAB injection and start of ART.

[†]Pre-ART genotyping not available for 3 participants; two were not virally suppressed.

CONCLUSIONS

- HIV Infections in the setting of CAB-LA PrEP are extremely rare
 - This is a case series of 47 infections over the life-cycle of HPTN 083
- Incomplete information guiding site-based ART choices confounds interpretation
- Similar short-term ART outcomes were observed for MSM/TGW acquiring HIV with CAB-LA PrEP between INSTI-based or other (PI-based) ART regimens
- The majority of cases identified within 6 months of CAB administration suppressed on INSTI-based ART
 - This includes one case with R263K
- More data are required to define optimal ART regimen selection for individuals acquiring HIV in the setting of CAB-LA PrEP

ACKNOWLEDGEMENTS

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HIV Prevention Trials Network (HPTN)

- Laboratory Center (Johns Hopkins University)
- Statistical Center for HIV/AIDS Research and Prevention (SCHARP), Fred Hutchinson Cancer Research Center
- Leadership and Operations Center, FHI 360
- HPTN Leadership

Pharmaceutical Support

- ViiV Healthcare
- · Gilead Sciences, Inc.

HPTN 083 Study Team

Ryan Kofron

Community Program Managers
Community Educators & Recruiters,
CAB Members

Our 43 Sites in 7 countries

And most of all, our Study Participants