

High Effectiveness and Rare Virologic Failure in Treatment-Experienced Individuals on Long-Acting Cabotegravir + Rilpivirine Therapy Across Europe: Insights from the EuroSIDA Study



L. Peters¹, W. Bannister¹, G. Sridhar², M. Gardizi¹, M. van Frankenhuijsen³, M-A. De Scheerder⁴, I. S. Johansen⁵, J-P. Viard⁶, C. Duvivier^{7,8,9,10}, J. Bogner¹¹, O. Degen¹², A. Castagna¹³, T. Staub¹⁴, E. Martinez¹⁵, P. Domingo¹⁶, S. Moreno¹⁷, D. H. Reikvam¹⁸, M. Parczewski¹⁹, B. Knysz²⁰, Y. Shivkar²¹, K. Brown², J. van Wyk²¹, V. Vannappagari²

¹ Centre for Health and Infectious Disease Research, Department of Infectious Diseases, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark; ² ViV Healthcare, Durham, NC, USA; ³ Institute of Tropical Medicine, Antwerp, Belgium; ⁴ Ghent University Hospital, Ghent, Belgium; ⁵ Department of Infectious Diseases, Odense University Hospital, Odense, Denmark; ⁶ Diagnostic and Therapeutic Center, Hôtel-Dieu, AP-HP, Paris, France; ⁷ AP-HP, Necker-Enfants Malades Hospital, Department of Infectious and Tropical Diseases, Necker-Pasteur Infectious Diseases Center; ⁸ IHU Imagine; ⁹ Institut Cochin - CNRS 8104 - INSERM U1016, Université Paris Cité; ¹⁰ Institut Pasteur, Medical Center, Paris, France; ¹¹ Division of Infectious Diseases, Medizinische Klinik und Poliklinik IV, Ludwig Maximilian University of Munich, Munich, Germany; ¹² University Clinic Hamburg Eppendorf, Hamburg, Germany; ¹³ Infectious Diseases, San Raffaele Scientific Institute, Milano, Italy; ¹⁴ Centre Hospitalier de Luxembourg, Service des Maladies Infectieuses, Luxembourg; ¹⁵ Infectious Diseases Service, Hospital Clinic, Barcelona, Spain; ¹⁶ Hospital de la Santa Creu i Sant Pau, Barcelona, Spain; ¹⁷ Servicio Enfermedades Infecciosas, Hospital Universitario Ramón y Cajal, Madrid, Spain; ¹⁸ Dep. of Infectious diseases, Oslo University Hospital, Oslo, Norway; ¹⁹ Department of Infectious, Tropical Diseases and Immune Deficiency, Pomeranian Medical University, Szczecin, Poland; ²⁰ Wrocław Medical University, Wrocław, Poland; ²¹ ViV Healthcare, London, England, UK

PURPOSE

- Cabotegravir + rilpivirine long-acting therapy (CAB+RPV LA) is the first complete long-acting regimen approved for treatment-experienced, virologically suppressed (HIV-RNA<50 copies/mL) people with HIV.
- We evaluated clinical outcomes of CAB+RPV LA in real-world settings across Europe.

METHODS

- All adults with HIV initiating CAB+RPV LA (baseline) between January 2021 and December 2023 in the pan-European EuroSIDA cohort were included.
- We describe their characteristics, adherence, discontinuation, and virologic outcomes during follow-up.
- On-time injections were those received within +/-7 days of their next scheduled injection; delayed injections were injections occurring >7 days after target date; missed injections were those missed without receiving oral bridging therapy.
- Confirmed virologic failure (CVF) was defined as two consecutive viral loads (VLs) ≥200 copies/mL or one VL ≥200 copies/mL followed by CAB+RPV LA discontinuation within 1 month.

CONCLUSIONS

- In this real-world European cohort, CAB+RPV LA demonstrated high rates of virologic suppression and no CVF among individuals virologically suppressed at initiation, with no missed injections and only few delays.
- Most individuals who were viraemic at CAB+RPV LA initiation achieved virologic suppression, with CVF seen in 2/7 individuals.
- Virologic suppression was consistent across BMI categories.
- The adverse events leading to discontinuation are in line with the safety profile described in the summary of product characteristics.
- These real-world data support prior studies demonstrating durable effectiveness and tolerability of CAB+RPV/LA.

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CONTACT INFORMATION

Wendy Bannister
CHIP, Rigshospitalet University of Copenhagen
Email:
wendy.bannister@regionh.dk

RESULTS

Among 13,419 individuals under follow-up in the EuroSIDA cohort, 142 initiating CAB+RPV LA were included in the analysis; median age was 52 years (IQR: 43-60), 79% males and 86% white (**Table 1**).

Most individuals (94%) had on-time injections, 8 (6%) had one delayed injection (median delay 9 days (IQR: 8-11)) after the target window and no individual missed any injections. Most (93%) remained on CAB+RPV LA over a median follow-up of 323 days (IQR: 204-466) at the time of analysis. Ten individuals (7%) discontinued CAB+RPV LA without resistance tests performed (**Figure 1**).

In a subset of 115 individuals with baseline and follow-up VL assessments:

- 108 individuals had **VL <50 copies/mL** at initiation, of which 105 (97%) had most recent VL <50 copies/mL, 97 (90%) had all follow-up VLs <50 copies/mL, and no individuals experienced CVF. Virologic suppression was consistently high at 6, 12, and 24- months with rates above 95% (**Figure 2**).
- 7 individuals had **VL ≥50 copies/mL** at initiation, of which 6 (86%) had most recent VL <50 copies/mL and 3 (43%) had all follow-up VLs <50 copies/mL. Two individuals experienced CVF with no resistance testing, switched to boosted darunavir-based regimens, and resuppressed to VL<50 copies/mL (**Figure 3**).
- 84 had baseline BMI <30 kg/m² and 12 had baseline BMI ≥30 kg/m² (19 unknown BMI). Most recent VL was <50 copies/mL in 81 (96%) and 12 (100%) individuals, respectively. Virologic suppression was sustained in all follow-up assessments by 74 (88%) and 10 (83%) individuals, respectively.

Table 1 Baseline demographic and clinical characteristics of individuals initiating CAB+RPV LA between January 2021 and December 2023

		Total (N=142)
Age at initiation (years), n (%)	≥50	77 (54)
	Median (interquartile range, IQR)	52 (43-60)
Sex, n (%)	Male	112 (79)
	Female	29 (20)
	Transgender woman	1 (1)
White ethnicity, n (%)		122 (86)
Body mass index (BMI) (kg/m ²), n (%)	<18.5	3 (2)
	18.5-<25	62 (43)
	25-<30	33 (23)
	30+	12 (8)
Mode of HIV acquisition, n (%)	Men who have sex with men	89 (63)
	Heterosexual	27 (19)
	People who inject(ed) drugs	21 (15)
	Other/unknown	5 (4)
Region of Europe, n (%)	Central West	44 (31)
	Central East	43 (30)
	North	42 (30)
	South	13 (9)
	East	0 (0)
Viral load at initiation (copies/mL), n (%)	<50	127 (89)
	≥50	8 (6)
	Unknown	7 (5)
	Median (IQR)	19 (19-42)
No. of years since HIV diagnosis, median (IQR)		18 (10-27)
No. of years since antiretroviral therapy initiation, median (IQR)		15 (9-24)
History of previous virological failure*, n (%)		64 (45)
History of AIDS defining events, n (%)		25 (18)
People with both HIV and hepatitis C virus, n (%)		3 (2)
People with both HIV and hepatitis B virus**, n (%)		1 (1)

*Previous virological failures included 19 on NNRTI-based regimen and 2 on INSTI-based regimen.
**Hepatitis B surface antigen positive, no HBV-DNA results, started HBV therapy.

Figure 1 Reasons for discontinuation in 10 individuals who discontinued CAB+RPV LA

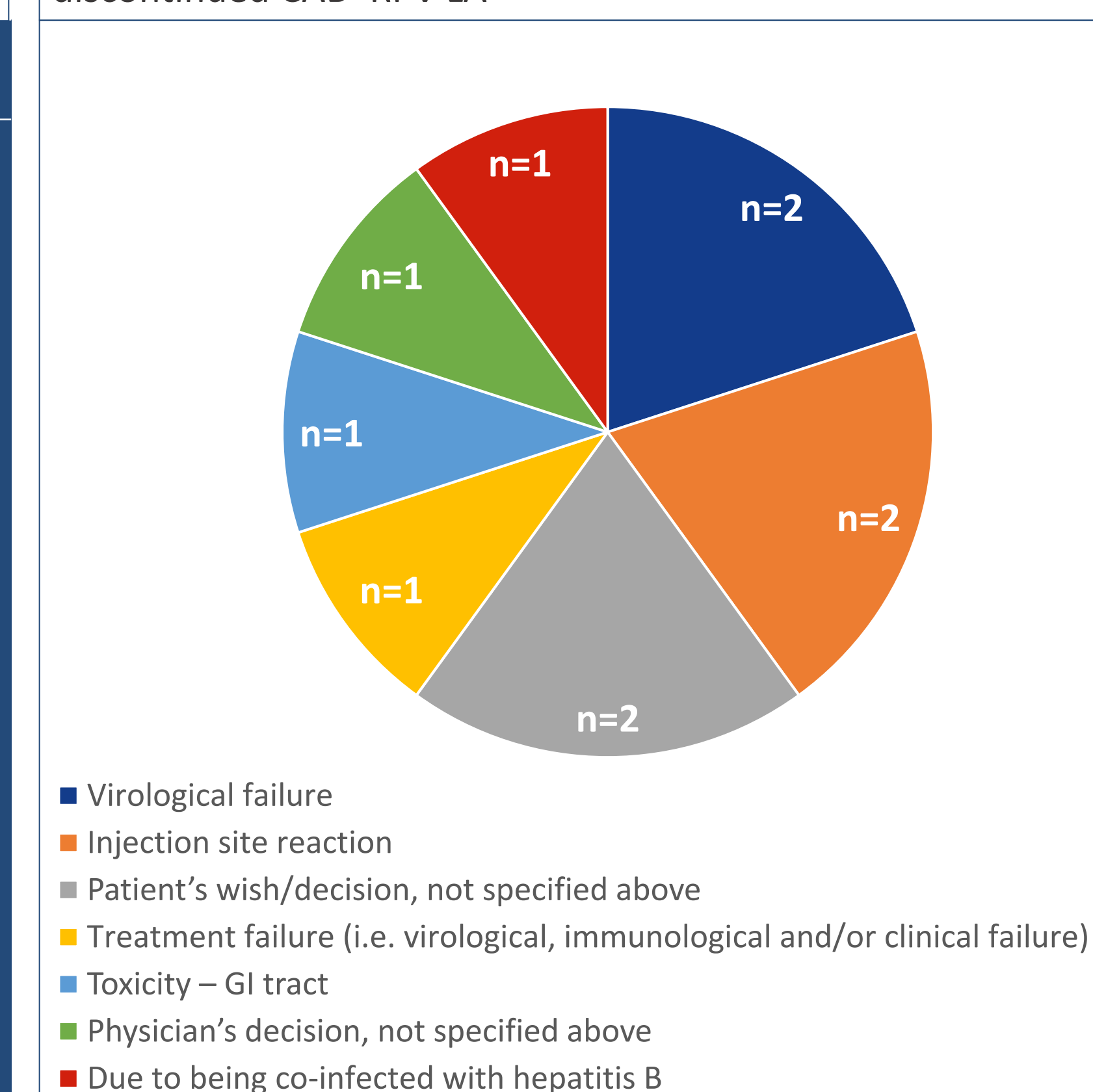


Figure 2 Percentage (and 95% CI) of VL <50 copies/mL at 6, 12, and 24 months after initiating CAB+RPV LA in 108 individuals with VL <50 copies/mL at initiation

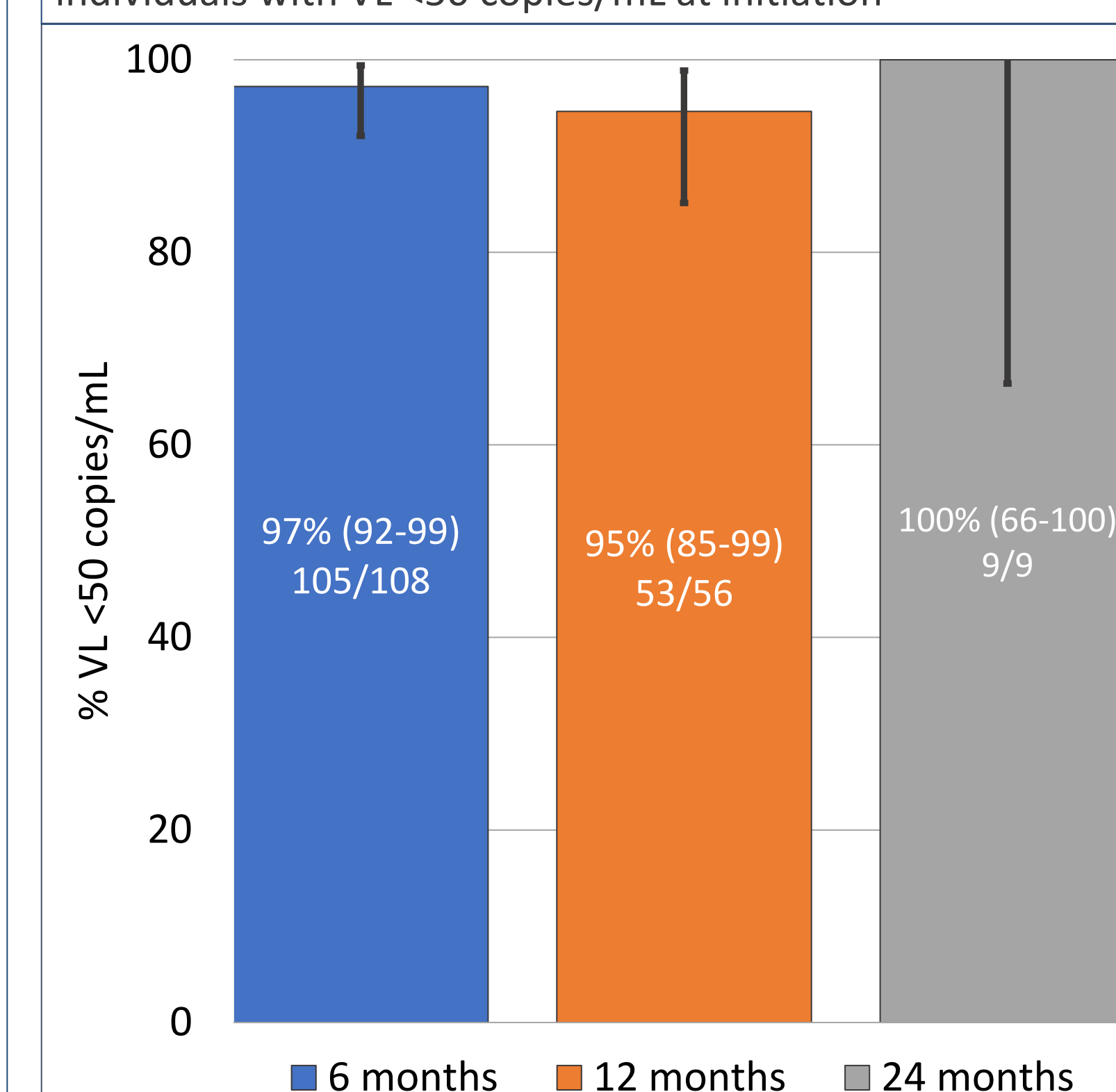


Figure 3 Timelines after initiating CAB+RPV LA in 2 individuals with confirmed virologic failure

