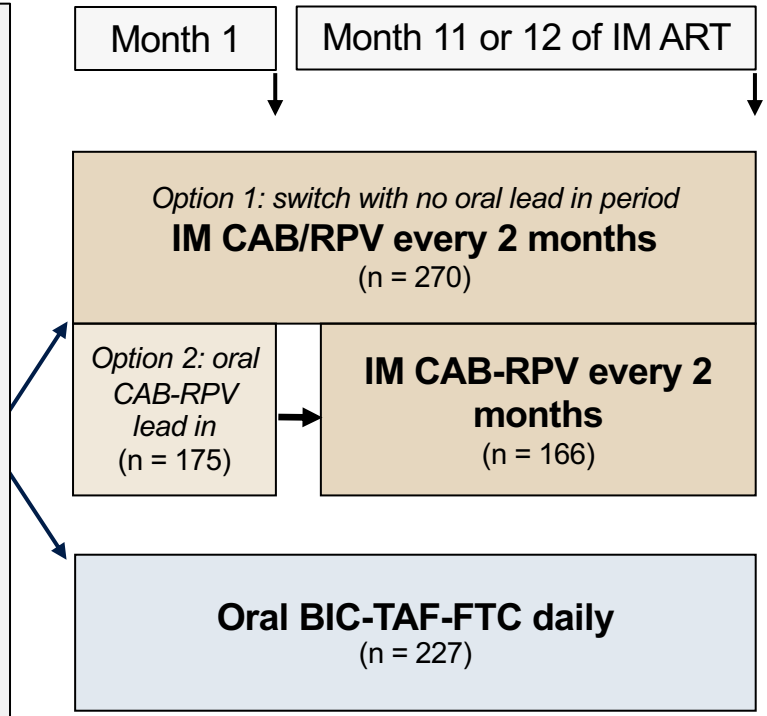
Switch to IM CAB and RPV Every 2 Months vs. Continued Oral BIC-TAF-FTC

SOLAR

Switch to IM CAB and RPV versus Continued BIC-TAF-FTC
SOLAR: Study Design

- **Background:** Randomized, multicenter, active-controlled, open-label, phase 3b, non-inferiority study designed to evaluate the efficacy and safety of switching to long-acting, intramuscular cabotegravir and rilpivirine versus continuing daily, oral, fixed-dose bictegravir-TAF-FTC
- **Inclusion Criteria**
  - Age >18 years
  - Taking bictegravir-TAF-FTC as a first or second regimen
  - No history of non-INSTI-based ART
  - No known or suspected resistance to study drugs
  - HIV RNA <50 copies/mL for at least 6 months
  - If pregnancy potential, agreed to contraception
- **Regimens (2:1 randomization)**
  - Bictegravir-TAF-FTC (50/25/200 mg) daily
  - CAB-RPV (600/900 mg) IM (oral lead-in period optional)



Source: Ramgopal MN, et al. Lancet HIV. 2023;10:e566-77.

Switch to IM CAB and RPV versus Continued BIC-TAF-FTC
SOLAR: Baseline Characteristics

SOLAR Study Baseline Characteristics		
Characteristic	**IM CAB-RPV** (n = 447)	**BIC-TAF-FTC** (n = 223)
Median age, years (range)	37 (18-74)	37 (18-66)
Age ≥50 years, n (%)	86 (19%)	42 (19%)
Cisgender female, n (%)	76 (17%)	41 (18%)
Cisgender male, n (%)	359 (80%)	178 (80%)
Transgender female, n (%)	9 (2%)	3 (1%)
Transgender male, n (%)	1 (<1%)	0
Gender non-binary, n (%)	1 (<1%)	0
Other gender, n (%)	1 (<1%)	1 (<1%)

Source: Ramgopal MN, et al. Lancet HIV. 2023;10:e566-77.

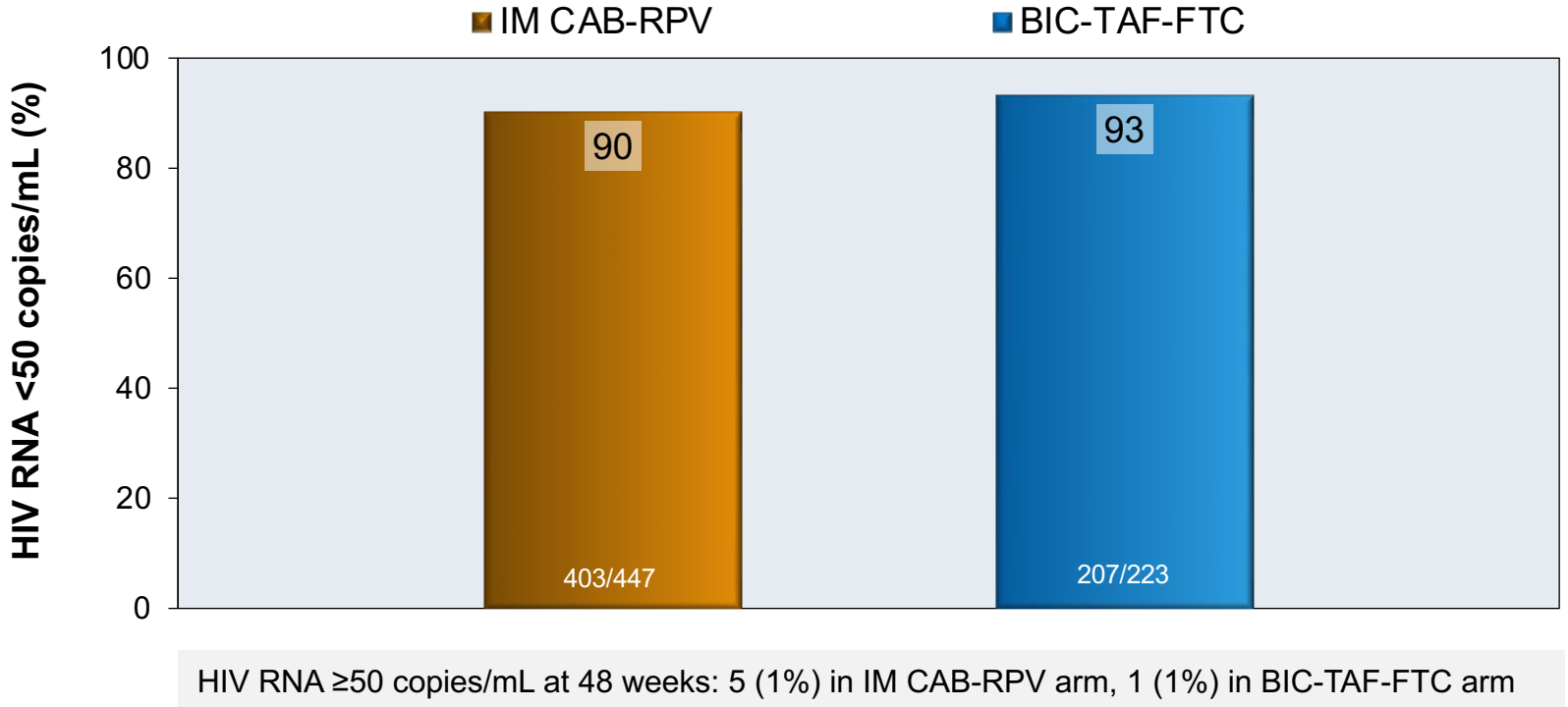
Switch to IM CAB and RPV versus Continued BIC-TAF-FTC
SOLAR: Baseline Characteristics

SOLAR Study Baseline Characteristics: Continued		
Characteristic	**IM CAB-RPV** (n = 447)	**BIC-TAF-FTC** (n = 223)
White race, n (%)	307 (69%)	156 (70%)
Black or African American race, n (%)	95 (21%)	49 (22%)
Asian race, n (%)	23 (5%)	11 (5%)
Other race, n (%)	22 (5%)	7 (3%)
Hispanic or Latinx ethnicity, n (%)	93 (21%)	38 (17%)
BMI, kg/m^2, median (IQR)	26.0 (23.2-29.4)	25.4 (23.4-29.6)
BMI ≥30, n (%)	93 (21%)	52 (23%)
Duration previous ART, years (median)	2.58	2.47
CD4 count, cells/mm^3, median (IQR)	649 (447-850)	640 (459-846)

Source: Ramgopal MN, et al. Lancet HIV. 2023;10:e566-77.

Switch to IM CAB and RPV versus Continued BIC-TAF-FTC SOLAR: Results

Virologic Response (Modified Intention-to-Treat Analysis) at Month 11-12



HIV RNA ≥50 copies/mL at 48 weeks: 5 (1%) in IM CAB-RPV arm, 1 (1%) in BIC-TAF-FTC arm

Source: Ramgopal MN, et al. Lancet HIV. 2023;10:e566-77.

Switch to IM CAB and RPV versus Continued BIC-TAF-FTC
SOLAR: Results

Treatment Emergent Adverse Events (AEs) Through Month 11-12		
	IM CAB-RPV (n = 447)	**BIC-TAF-FTC** (n = 223)
Any drug-related AE	327 (72%)	2 (1%)
Excluding ISR*	90 (20%)	NA
Any ≥grade 3 drug-related AE	22 (5%)	0
Excluding ISR*	7 (2%)	NA
Drug-related serious AE	4 (1%)	0
Drug-related AE in >2%		
Pyrexia	13 (3%)	0
Headache	11 (2%)	0
Fatigue	10 (2%)	0
Diarrhea	9 (2%)	0
Drug-related AE leading to withdrawal	19 (4%)	0

*Injection site reactions (ISRs) were reported by 70% of long-acting CAB-RPV participants; 98% were grade 1 or 2

Source: Ramgopal MN, et al. Lancet HIV. 2023;10:e566-77.

Switch to IM CAB and RPV versus Continued BIC-TAF-FTC
SOLAR: Conclusion

Interpretation: “These data support the use of long-acting cabotegravir plus rilpivirine dosed every 2 months as a complete antiretroviral regimen that has similar efficacy to a commonly used integrase strand transfer inhibitor-based first-line regimen, while addressing unmet psychosocial issues associated with daily oral treatment.”

Source: Ramgopal MN, et al. Lancet HIV. 2023;10:e566-77.

Acknowledgments

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National HIV Curriculum

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