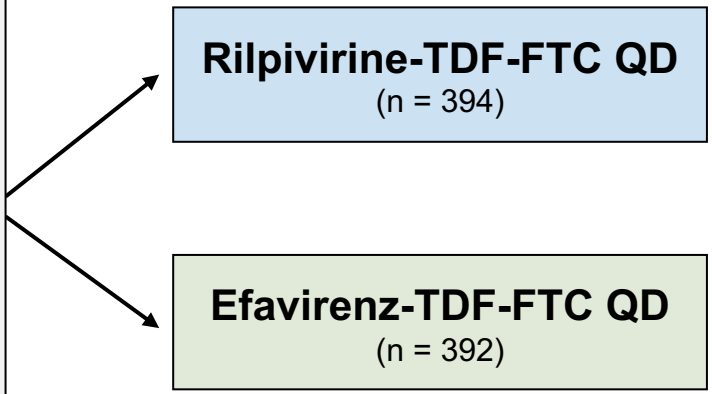
Rilpivirine-TDF-FTC versus Efavirenz-TDF-FTC

STaR Trial

Rilpivirine-TDF-FTC versus Efavirenz-TDF-FTC STaR Study: Design

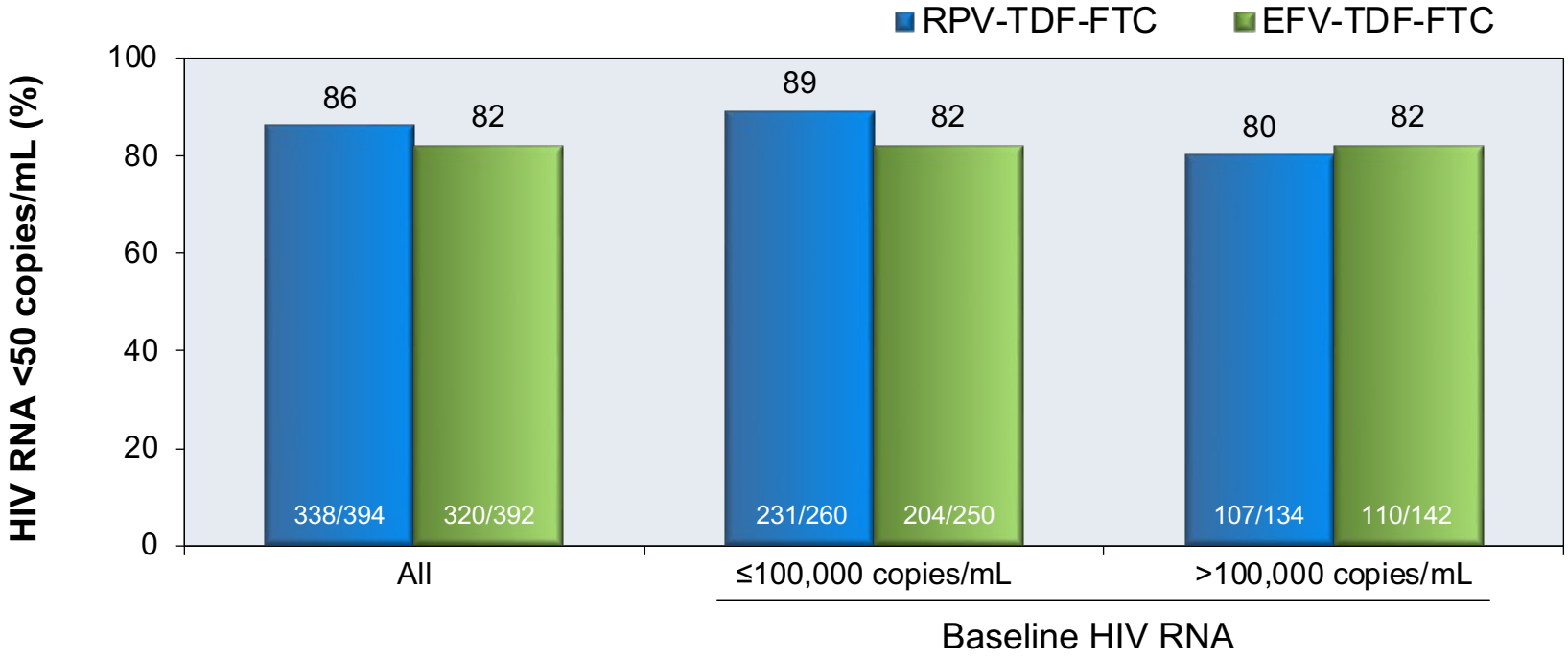
- **Background**: Randomized, open-label, phase 3b trial comparing safety and efficacy of two single-tablet regimens, RPV-TDF-FTC and EFV-TDF-FTC, in treatment-naïve adults with HIV
- **Inclusion Criteria (n = 786)**
  - Antiretroviral-naïve adults
  - Age ≥18 years
  - HIV RNA ≥2,500 copies/mL
  - No resistance to EFV, RPV, TDF, or FTC
- **Treatment Arms**
  - Rilpivirine-tenofovir DF-emtricitabine
  - Efavirenz-tenofovir DF-emtricitabine



Source: Cohen CJ, et al. AIDS. 2014;28:989-97.

Rilpivirine-TDF-FTC versus Efavirenz-TDF-FTC STaR: Result

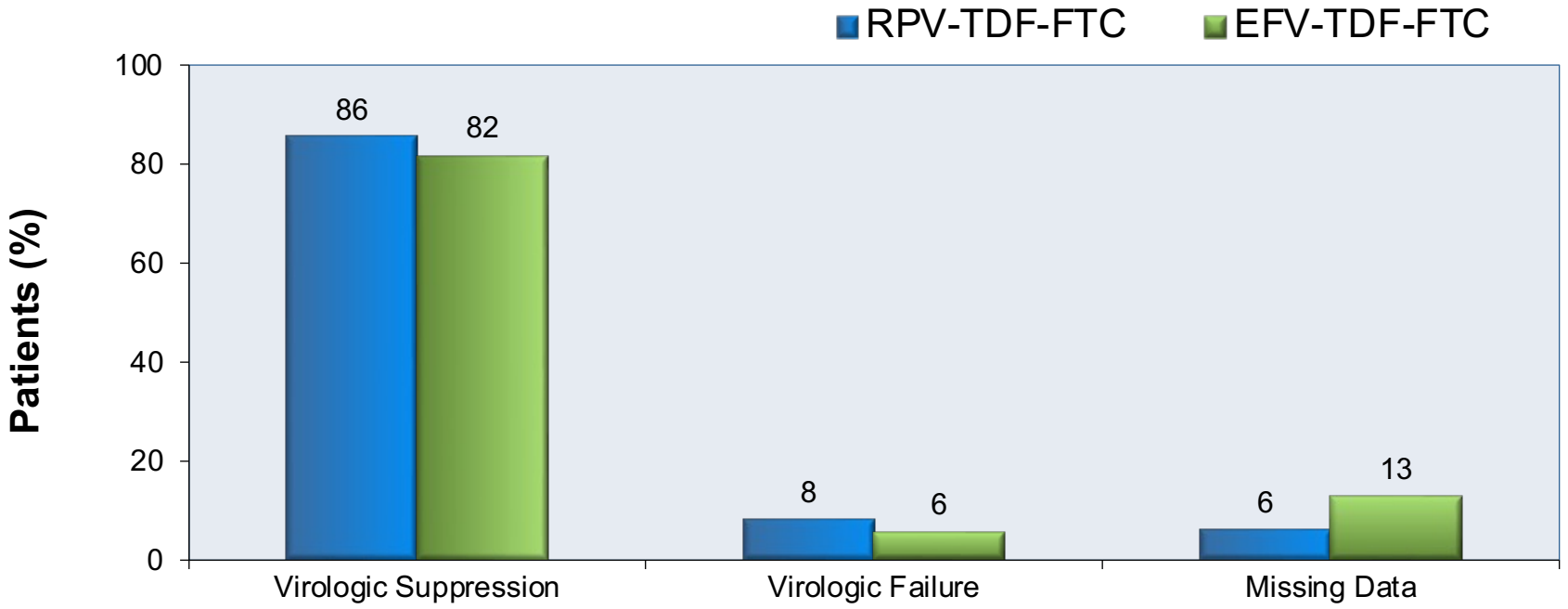
Week 48 Virologic Response (Intent-to-Treat Analysis)



Source: Cohen CJ, et al. AIDS. 2014;28:989-97.

Rilpivirine-TDF-FTC versus Efavirenz-TDF-FTC
STaR: Results

48 Week Virologic Outcomes



Source: Cohen CJ, et al. AIDS. 2014;28:989-97.

Rilpivirine-TDF-FTC versus Efavirenz-TDF-FTC
STaR: Common Adverse Events

Treatment Emergent Adverse Events in > 5% of Subjects in Either Arm		
	RPV-TDF-FTC (n = 392)	**EFV-TDF-FTC** (n = 394)
Dizziness	6.6%	22.2%
Insomnia	9.6%	14.0%
Somnolence	2.5%	6.9%
Headache	12.4%	13.5%
Abnormal Dreams	5.8%	24.5%
Depression	6.6%	8.9%
Anxiety	5.1%	8.4%
Folliculitis	5.3%	1.0%
Rash	6.1%	12.0%

Source: Cohen CJ, et al. AIDS. 2014;28:989-97.

Rilpivirine-TDF-FTC versus Efavirenz-TDF-FTC STaR: Conclusions from Primary Analysis

Conclusion: “In treatment-naïve participants, RPV/FTC/TDF demonstrated noninferior efficacy and improved tolerability compared with EFV/FTC/TDF, as well as a statistically significant difference in efficacy for participants with baseline HIV-1 RNA 100,000 copies/mL or less at week 48.”

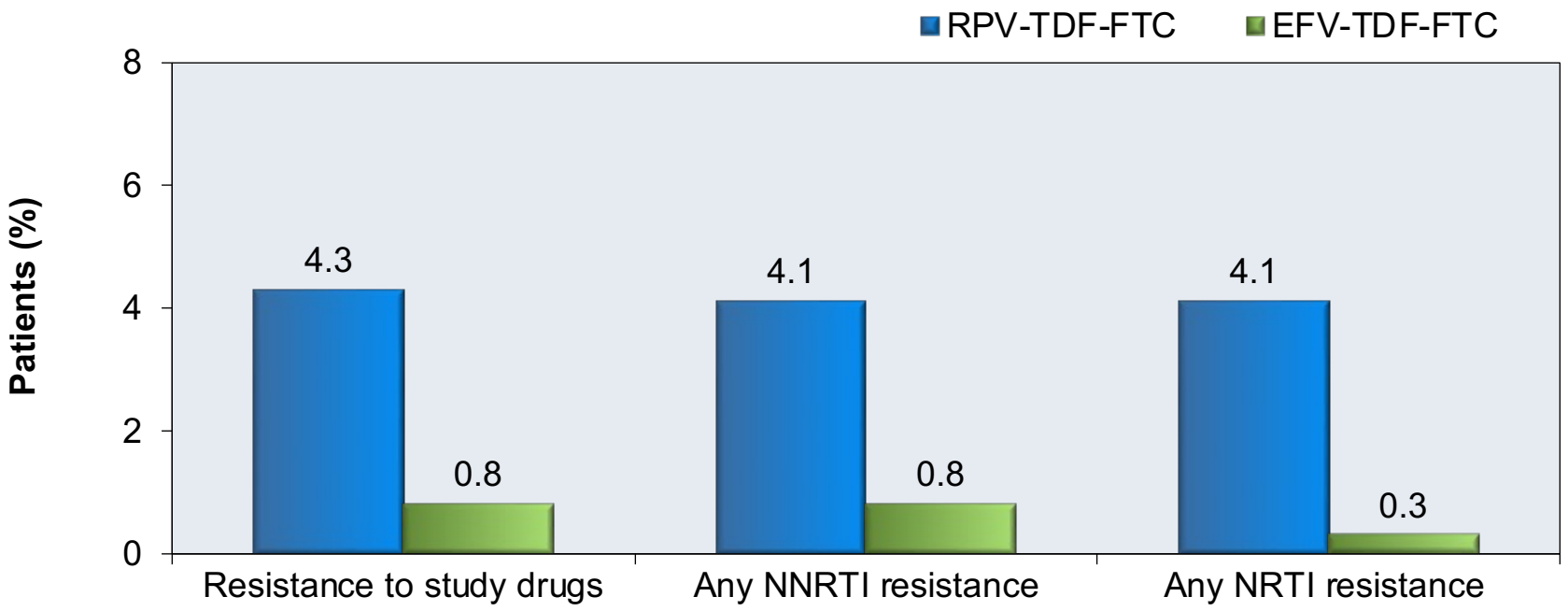
Source: Cohen CJ, et al. AIDS. 2014;28:989-97.

Rilpivirine-TDF-FTC versus Efavirenz-TDF-FTC

STaR Trial: Week 96 Resistance Data

Rilpivirine-TDF-FTC versus Efavirenz-TDF-FTC STaR Resistance Analysis: Result

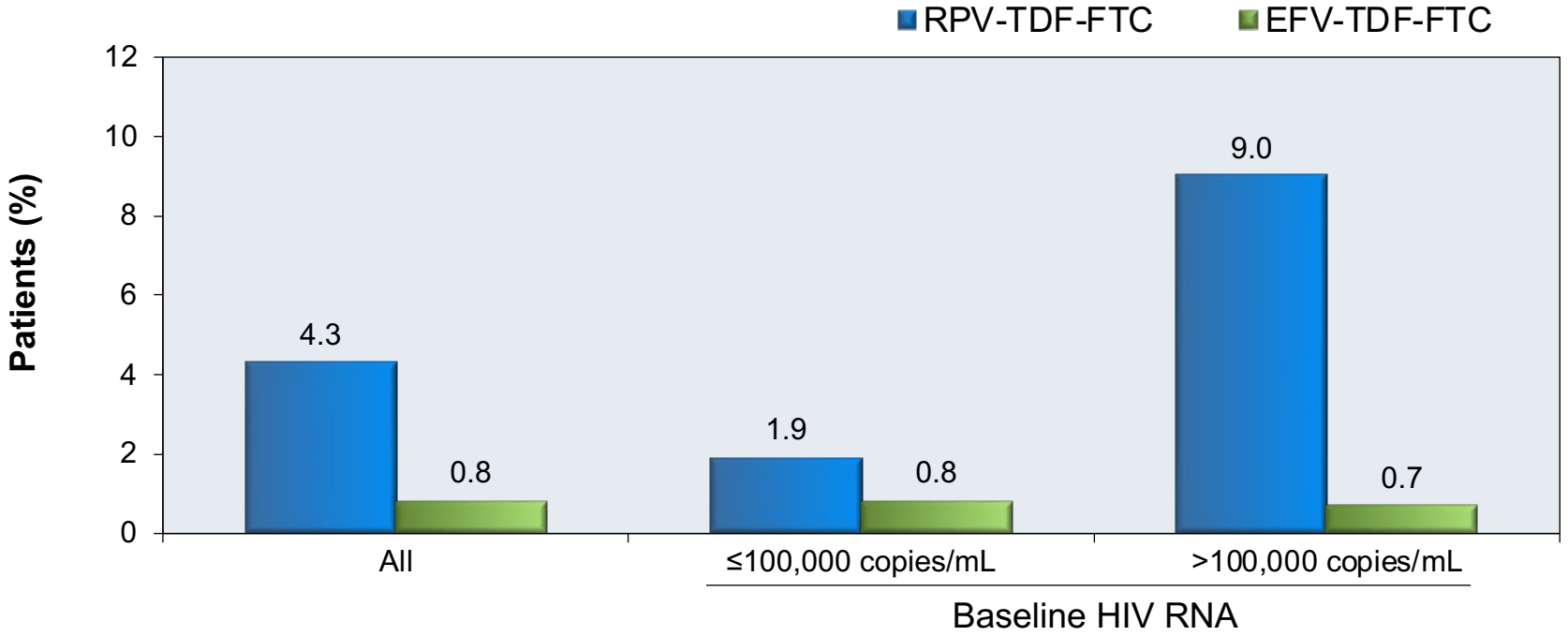
Development of Genotypic Resistance at Week 48



Source: Porter D, et al. J Acquir Immune Defic Syndr. 2014;65:318-26.

Rilpivirine-TDF-FTC versus Efavirenz-TDF-FTC STaR Resistance Analysis: Result

Development of Resistance to Study Drugs at 48 weeks, by Viral Load



Source: Porter D, et al. J Acquir Immune Defic Syndr. 2014;65:318-26.

RPV-FTC-TDF versus EFV-FTC-TDF
STaR Resistance Analysis: Conclusions

Conclusions: “Among subjects in the primary resistance associated populations (RAP), resistance development to RPV/FTC/TDF consisted of NNRTI and NRTI mutations and was more frequent than resistance development to EFV/FTC/TDF. In subjects with baseline viral load ≤ 100,000 copies/mL, resistance development was low (<2%) for both RPV/FTC/TDF and EFV/FTC/TDF arms and less frequent compared with subjects with baseline viral load >100,000 copies/mL, for RPV/FTC/TDF.”

Source: Porter D, et al. J Acquir Immune Defic Syndr. 2014;65:318-26.

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AETC AIDS Education & Training Center Program

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