

#### Study Design: SWIFT

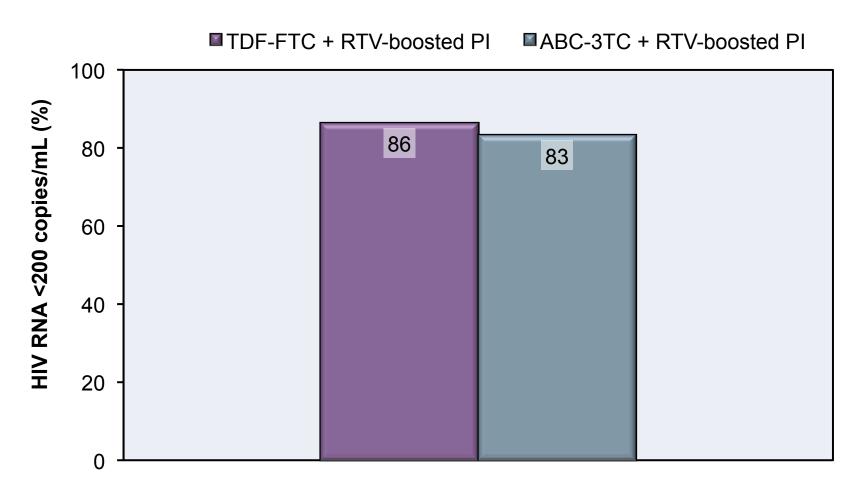
- Background: Prospective, randomized, open-label study to evaluate the efficacy and safety of a switch from ABC-3TC to TDF-FTC in virologically suppressed patients taking a RTV-boosted PI
- Inclusion Criteria:
  - Adults with HIV infection
  - Men and nonpregnant women
  - Receiving ABC-3TC + RTV-boosted PI (and no additional ARV agents)
  - No resistance to any study drug
  - HIV RNA <200 copies/mL ≥3 months
  - eGFR >50 mL/min
  - AST/ALT ≤5x upper limit of normal,
  - If on a lipid-lowering agent then stable dose x >3 months

Switch to TDF-FTC + PI/r (n = 155)

**Continue ABC-3TC + PI/r** (n = 156)

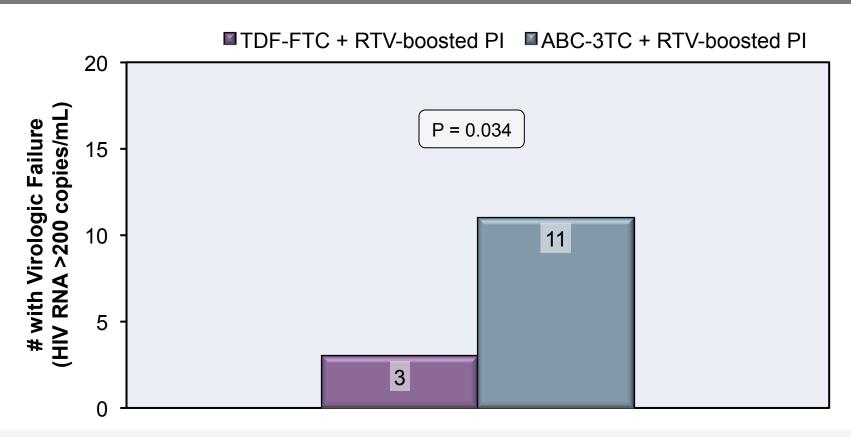


Week 48 Virologic Response (by TLOVR, Intention-to-Treat Analysis)





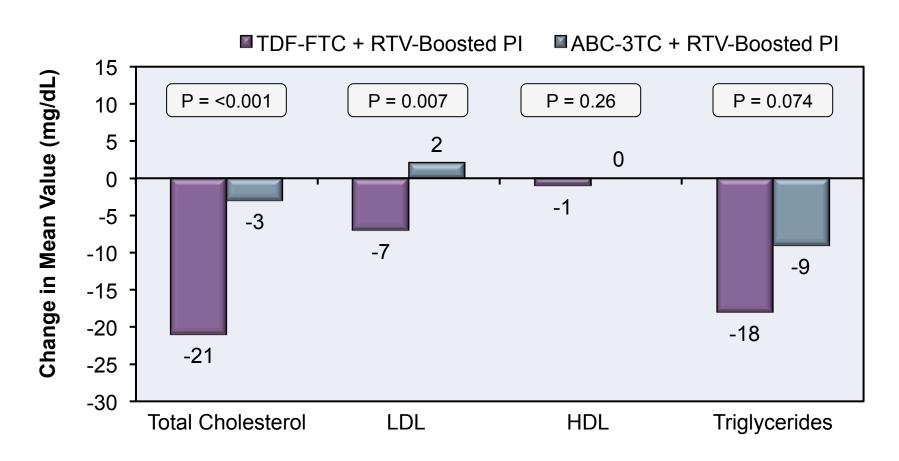
Week 48 Virologic Failure (Intention-to-Treat Analysis)



All 3 subjects with virologic failure in the TDF-FTC arm had low-level viremia (209-452 copies/mL) No genotypic resistance was observed with virologic failure in either arm



Week 48: Change in Plasma Lipids from Baseline





SWIFT Trial Results: Adverse Events (AE's)		
	<b>TDF-FTC + RTV + PI</b> (n = 155)	<b>ABC-3TC + RTV + PI</b> (n = 156)
Any AE	112 (72.3%)	120 (76.9%)
Grade 3 or 4 AE	13 (8.4%)	16 (10.3%)
AE related to study drug	16 (10.3%)	6 (3.8%)
Grade 3-4 AE related to study drug	1 (0.6%)	0 (0%)
AE leading to study drug discontinuation	7 (4.5%)	3 (1.9%)
Renal AE	7 (4.5%)	8 (5.1%)
Change in eGFR (baseline to 48 weeks, Cockroft-Gault)	-8.3 mL/min	-4.5 mL/min



**Conclusion**: "Switching to FTC/TDF from 3TC/ABC maintained virologic suppression, had fewer VFs, improved lipid parameters and Framingham scores but decreased eGFR."



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The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.



