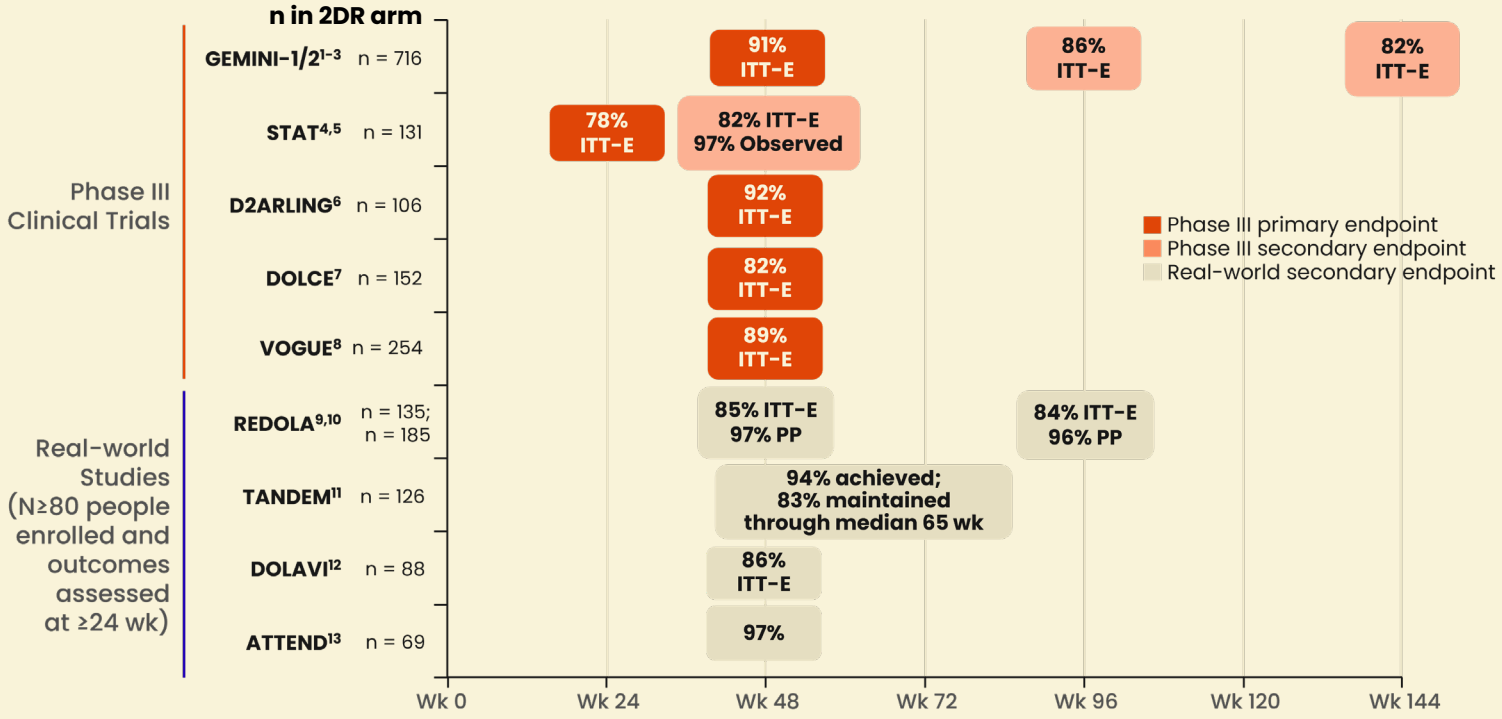
KEY DATA

Initial Oral ART With 2DR vs 3DR

DECERA CLINICAL Education

Oral 2DR as Initial ART Across Phase III Clinical Trials and Real-world Studies

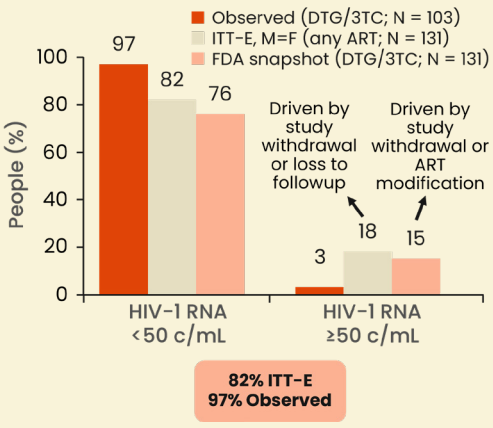
Efficacy and effectiveness (variable across studies) rates at each timepoint



Oral 2DR as Initial ART Using Rapid Start/Test-and-Treat Approach

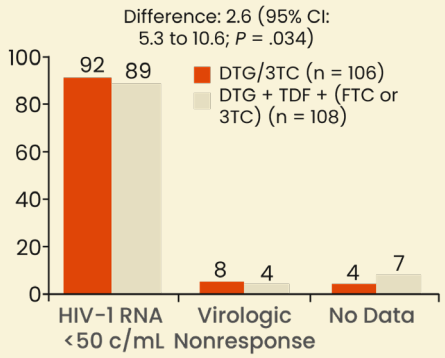
STAT: Single-arm pilot study of DTG/3TC[4,5]

Virologic Outcomes at Wk 48



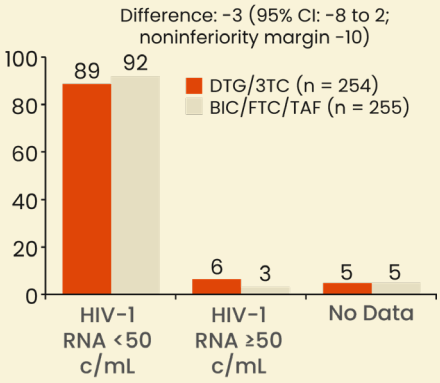
D2ARLING: Open-label, randomized trial of DTG/3TC vs DTG-based 3DR[6]

Virologic Outcomes at Wk 48 (ITT-E/FDA Snapshot)



VOGUE: Open-label, randomized trial of DTG/3TC vs BIC/FTC/TAF[8]

Virologic Outcomes at Wk 48 (FDA Snapshot)

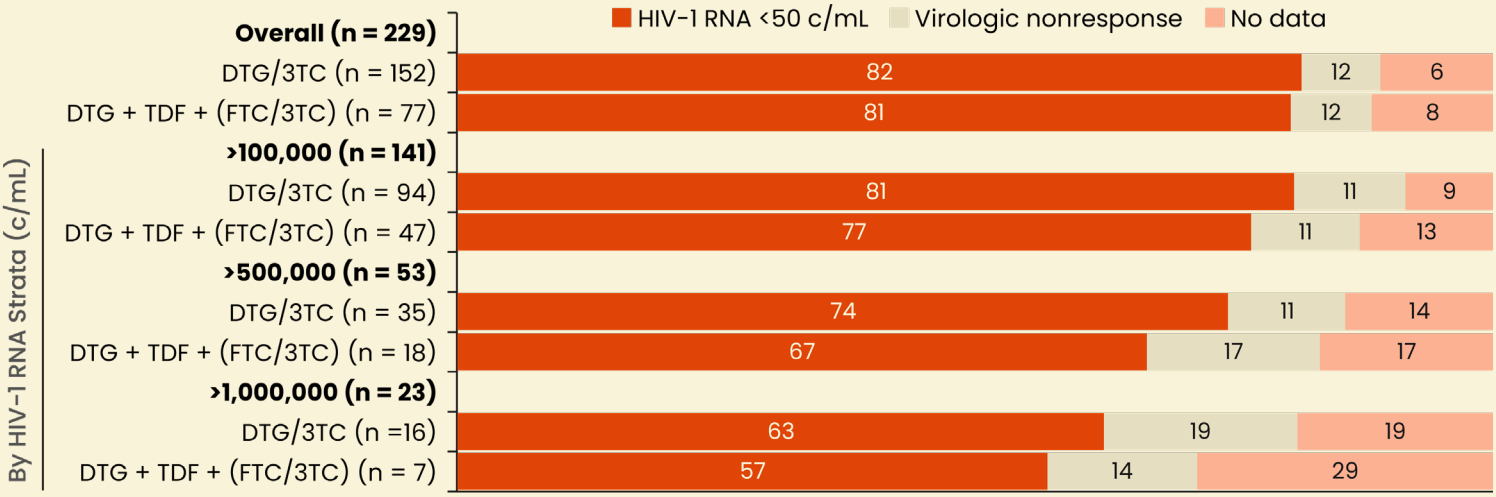


Oral 2DR as Initial ART in Advanced HIV

DOLCE[7,14]: Randomized, open-label trial of initial ART with DTG/3TC vs DTG + TDF + (FTC/3TC) in people with baseline CD4+ cell counts ≤200 cells/mm^3

- Time to viral suppression and CD4+ cell count recovery similar between treatment arms

Virologic Outcomes at Wk 48 (ITT-E)



Oral 2DR as Initial ART in Pregnancy

- **PREGNANCY[15]:** single-arm, proof-of-concept phase III trial of DTG/3TC as initial ART during pregnancy in Brazil (N = 20)
  - All women achieved viral suppression (mean time to HIV-1 RNA <50 c/mL: 40.4 days)
  - No perinatal transmission
  - No ART discontinuations or modifications
  - No ART-related AEs and no congenital anomalies by surface examination
- **PREDUAL[16]:** randomized trial in Argentina and Brazil of initial DTG/3TC vs DTG + 2 NRTIs in treatment-naive pregnant women (estimated primary completion mid-2028)

Oral 2DR as Bridging Regimen Before Switch to LA ART

VOLITION: nonrandomized, open-label trial of initial ART with DTG/3TC for 4-16 wk followed by optional switch to LA CAB + RPV maintenance after achieving HIV-1 RNA <50 copies/mL

Suppression phase (DTG/3TC)[17]

- Viral suppression at Wk 16: 98% (167/171)
  - Median time to suppression: 4.1 wk (95% CI: 4.1-4.3)
- No treatment-emergent resistance

Maintenance phase in switch cohort[18]

Virologic Outcomes at 11 Mo, n (%)	Modified Snapshot (n = 129)	Observed (n = 119)
HIV-1 RNA <50 c/mL	113 (88)	113 (95)
HIV-1 RNA ≥50 c/mL	6 (5)	6 (5)
No data in window	10 (8)	—

- 1 participant met CVF criteria with emergent INSTI/NNRTI RAMs
- 3 other participants withdrew after CVF; none met CVF criteria per retrospective retest, and none had treatment-emergent RAMs

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Abbreviations

2DR, 2-drug regimen
3DR, 3-drug regimen
3TC, lamivudine
AE, adverse event
ART, antiretroviral therapy
BIC, bictegravir
CVF, confirmed virologic failure
DTG, dolutegravir
FTC, emtricitabine
INSTI, integrase strand transfer inhibitor
ITT-E, intent to treat-exposed
LA CAB, long-acting cabotegravir
M=F, missing equals failure
NNRTI, nonnucleoside reverse transcriptase inhibitor
NRTI, nucleoside reverse transcriptase inhibitor
PP, per protocol
RAM, resistance associated mutation
RPV, rilpivirine
TAF, tenofovir alafenamide
TDF, tenofovir disoproxil fumarate