

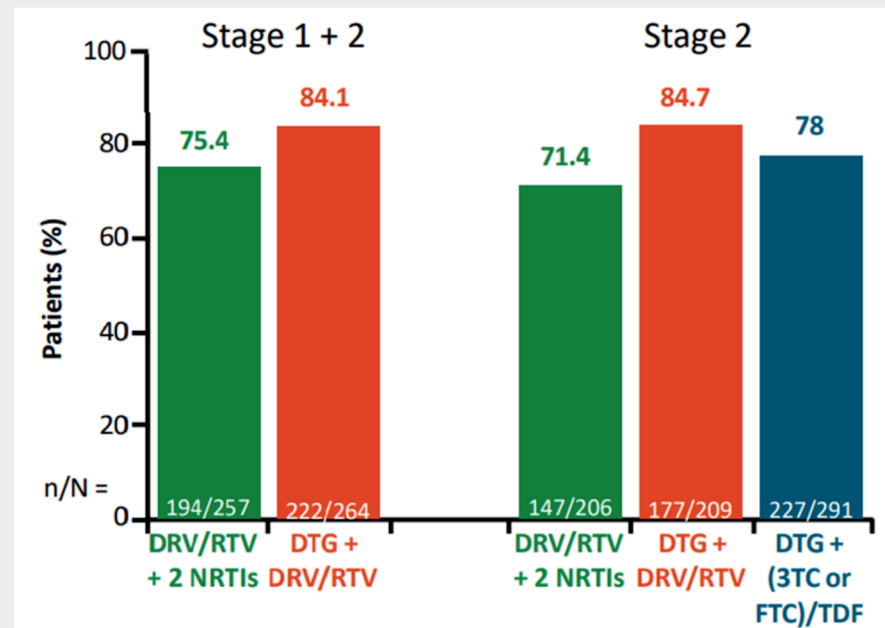
DOLUTEGRAVIR & DARUNAVIR EVALUATION IN ADULTS FAILING FIRST-LINE NNRTI THERAPY (D2EFT)

BACKGROUND: D2EFT is a randomized open-label trial comparing Arm 1 (SOC [DRV/r + 2 NRTIs]) vs Arm 2 (DRV/r + DTG) vs Arm 3 (DTG + TDF/XTC)

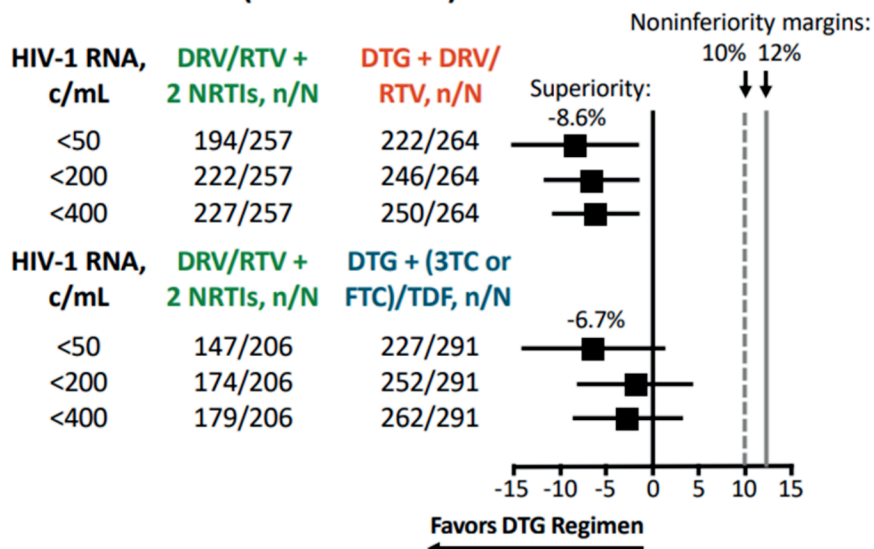
OBJECTIVE: To show non-inferiority against SOC in terms of HIV-RNA < 50c/mL at 48 weeks using a delta-12% (XTC= FTC or 3TC)

DESIGN OVERVIEW

- 831 participants over 14 countries across Asia/Africa/Latin America were randomized, with 109 recruited at Stage 1 (originally conceived as a two arms RCT looking at Arm 1 vs Arm 2 commencing 2017) and further 722 recruited at Stage 2 adding on Arm 3 in 2018
- Inclusion criteria: PLHIV aged > 18 with failed first-line NNRTI (82.7% EFV, 11.4% NVP) + 2 NRTIs (HIV-RNA > 500 c/mL).
- Exclusion criteria: prior PI/INSTI exposure, HBsAg positive, significant comorbidity/OI, pregnancy/breast feeding



Undetectable HIV-1 RNA at Wk 48 (Available Data)



RESULTS

- Median age was 55 years. 54% were female. Median CD4 was 206 c/mm³ and median HIV-RNA was 4.2 log₁₀c/mL
- Mean CD4 gain to week 48 was greater in both DTG+DRV/r (56.0 cells/mm³ [26.5, 85.5] p < 0.001) and DTG+TDF/XTC (39.9 cells/mm³ [9.6, 70.2] p=0.01) compared to SOC
- Compared to SOC, mean weight gain was greater in both DTG+DRV/r 2.7kg (1.5, 3.8kg, p < 0.001) and DTG+TDF/XTC 1.7kg (0.5, 2.9kg, p=0.006) arms

CONCLUSION

IDTG + DRV/r and DTG + TDF/XTC, as second-line cART after NNRTI-based ART failure, were non-inferior to DRV/r + 2 NRTIs. Both DTG-containing cART caused significant weight gain compared with SOC

REFERENCE: Matthews G, Borok M, Eriobou N, et al. D2EFT: dolutegravir and darunavir evaluation in adults failing first-line HIV therapy. Conference on Retroviruses and Opportunistic Infections (CROI); Feb 19-22, 2023 (abstract 198)