

NAMSAL/ANRS 12313

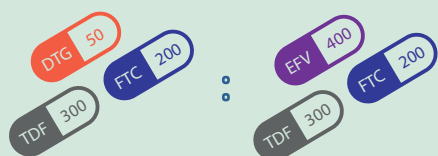
NAMSAL/ANRS 12313 is designed to provide evidence for recommending DTG instead of EFV 400 mg in combination with TDF/3TC or FTC regimens as preferred first line ART. This is in anticipation of predictions that EFV 400 mg will soon replace EFV 600 mg as the standard of care. DTG has demonstrated increased robustness, and safety, in addition to better patient tolerability and reduced costs. NAMSAL/ANRS 12313 aims to replicate these benefits within real-world resource constrained settings. Based on models, switching to DTG based regimens could enable LMICs to keep the pace of ART scale up needed to meet increasing treatment demands under “treat all” and to achieve the 90-90-90 targets.

DRUG ABBREVIATIONS

DTG	dolutegravir
EFV	efavirenz
TDF	tenofovir disoproxil fumarate
3TC	lamivudine
FTC	emtricitabine
RIF	rifampicin

Study Design & Methods

NAMSAL/ANRS 12313 is a phase 3 trial with 2 support studies that primarily intends to demonstrate the non-inferiority of DTG versus EFV 400 mg when both combined with TDF/FTC or 3TC in first-line HIV treatment for ART-naïve patients ≥18 years old. The trial will take place at 3 sites in Cameroon. Superiority will be assessed if non-inferiority is demonstrated.



Inclusion criteria: HIV-1 positive, ≥18 years of age, viral load > 1000 copies/mL.

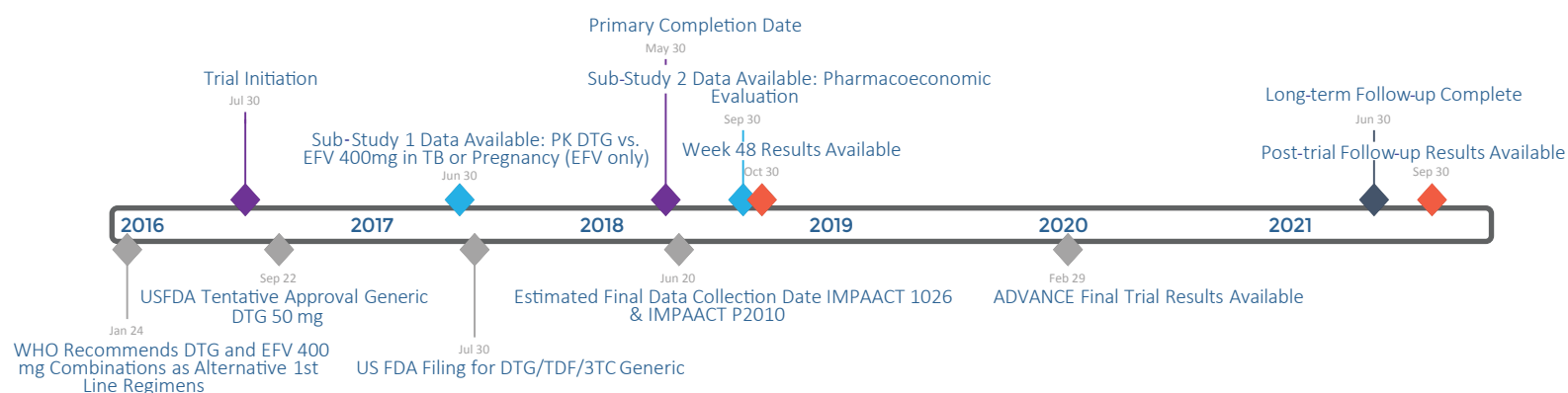
Exclusion criteria: Received >7 days of cumulative ART at any time, pregnant or breastfeeding, unstable tuberculosis (TB) infection, CrCl < 50 mL/min.

~606 male and female patients will be randomly assigned in a 1:1 ratio into the 2 treatment groups (303 per arm). The trial is open-label and participants will be followed for 48 weeks up and for an additional 3 years post-trial.

Primary Outcome Proportion of patients in regimen with undetectable plasma HIV-1 RNA levels (<50 copies/mL) at week 48

Secondary Outcomes Week 24 viral suppression, CD4 count changes, tolerability, overall safety, and efficacy of each regimen

Trial Timeline



Key Collaborations

NAMSAL/ANRS 12313 is sponsored by ANRS and co-funded by UNITAID and ANRS. It is being implemented by the French National Research Institute for Sustainable Development (IRD) (research Unit UMI 233) and the Institut Bouissou Bertrand. ViiV agreed to provide DTG for the trial at access price. NAMSAL/ANRS 12313 received ethics and regulatory approvals from the Cameroon National Ethics Committee and is overseen by the trial Scientific Advisory Board.

Key Considerations

The NAMSAL/ANRS 12313 trial also has 2 support studies: **1)** Pharmacokinetic (PK) analyses to assess drug-drug interaction between RIF and DTG or EFV 400 and to assess antiretroviral concentrations levels in pregnant women and in TB co-infected patients receiving RIF. In an effort to minimize bias within the larger study, the drug interaction sub-study will recruit an additional 30 adults. **2)** Economic study to confirm the cost-effectiveness of a DTG-based first-line strategy and the beneficial economic impact of its introduction in LIC.

REFERENCES

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