

**BASELINE CHARACTERISTICS, ANTIRETROVIRAL RESISTANCE
PROFILE AND CLINICAL EVENTS IN THE OPTIMA TRIAL:
A PRELIMINARY REPORT**

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Background: The OPTIMA trial is a collaboration between the U.S. Department of Veterans Affairs, U.K. MRC and Canadian CIHR. OPTIMA is an ongoing HIV-1 strategy trial for patients with virologic failure and multi-drug resistant (MDR) virus.

Methods: Patients on antiretroviral (ARV) therapy (target N=504) with HIV RNA >2,500 copies/mL, CD4 < 300/mm³ are randomized in a 2 X 2 factorial to a 3 month antiretroviral drug-free period (ARDFP) vs. no ARDFP and then to treatment with a new regimen of standard ART (\leq 4 ARVs) vs. MegaART (\geq 5 ARVs). AIDS events/death and serious adverse events (SAE) are recorded for primary and secondary endpoints, respectively.

Results: 176 patients (98% male, mean age 48) have been enrolled thus far. Baseline mean HIV RNA = 4.79 log₁₀/ml and CD4 = 105 cells/mm³. ARV history included >2 PI (70%), NNRTI (90%) and NRTI (99%). Broad virtual phenotypic resistance to all ARV classes was seen. To date, there has been no loss to follow-up and crossover rates between arms is < 2%. There have been 19 new or recurrent AIDS events, 4 deaths (2 AIDS related), 70 Grade 3/4 AEs in 26 patients, 17 of which led to a change in ARV regimen. Ongoing analyses by the DSMB have determined that there are no safety concerns.

Conclusions: Although still blinded to treatment strategy, an ARDFP has not resulted in safety concerns. The clinical response to standard or MegaART, whether preceded by an ARDFP or not, will continue to be examined in this trial.