

Submission of OPTIMA Study for short oral presentation at STI II

1. **Title of presentation:** Tri-National Trial 1: Options in Management with Anti-Retrovirals (TNT-1: OPTIMA)
2. **Authors:** William Cameron, Mike Youle, Brian Gazzard, Sheldon Brown, Mark Holodniy and the OPTIMA Study Team¹.
3. **Patient Population:** 1300 patients from Canada, UK, and US Department of Veterans Affairs with advanced HIV disease who demonstrate virologic and immunologic failure on at least 2 ARV regimens.
4. **Study design:** randomized, controlled, multi-centre trial. 2 x 2 factorial design with first randomization to an antiretroviral drug free period of 3 months or no drug free period. 2nd randomization to standard (3 or fewer drugs) anti-retroviral therapy or mega (5 or more drugs) anti-retroviral therapy.
5. **Assays:** baseline genotyping, genotyping with failure of regimens. Plasma and PBMC banking at each visit.
6. **Numbers currently enrolled/anticipated enrollment:** 0 enrolled/1300 anticipated.
7. **Endpoints:** Primary: time to first or recurrent AIDS-defining event; time to development of a new non-HIV-related serious adverse event. Secondary: Quality of life; incidence of grade 3 or 4 clinical or laboratory adverse events; changes in CD4 counts, viral loads, and resistance.
8. **Results:** none to date; study anticipated to being in spring 2001
9. **Willingness to consider multicenter collaboration:** this is a multicenter trial
10. **Obstacles perceived to be hampering pace of work:** none to date
11. **Anticipated completion date:** spring 2004
12. **Estimated time required for presentation:** 15 minutes

¹Optima Study Team

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