

2. Protocol Synopsis

PROJECT TITLE	<i>ER Niacin/laropiprant impact on cardiovascular markers and atheroprogession in HIV-infected individuals on cART: the NILACH trial</i>
BACKGROUND	HIV-infected patients are at increased risk for cardiovascular disease. Large investigations support an inverse correlation between HDL-C levels and coronary heart disease. Therefore a treatment lowering HDL-C such as niacin could reduce the risk of atheroprogession not only through its benefit in terms of lipid profile, but also by reducing atherosclerotic inflammation.
AIM	We aim at showing that a therapy targeting HDL-C increase in HIV-infected patients on suppressive cART has the potential for reducing subclinical atherosclerotic inflammation associated with HIV itself in HIV-individuals on cART.
INCLUSION/EXCLUSION CRITERIA	<p>Inclusion criteria</p> <ul style="list-style-type: none"> - Adult patients > 40 years - Signing the study consent form - Stable cART since at least 3 months (ie no recent drug change) - HIV-RNA below 100 copies for at least 6 months - HDL-cholesterol < 50 mg/dL for men and < 55 mg/dL for women <p>Exclusion criteria</p> <ul style="list-style-type: none"> - Pregnancy or lactation - Women of childbearing potential must use one or two reliable contraceptive methods during the trial - Acute and Chronic Congestive Heart Failure - Acute or chronic coronary artery diseases - Concomitant cancer, diabetes, rheumatologic disease or inflammatory bowel diseases - Concomitant renal or hepatic disease - Prior intolerance to niacin therapy (reported in a medical report) - No cyclosporine, anti-inflammatory drugs (other than aspirin 100 mg), fibrates or cytokine therapy in concomitant intake - Normal thyroid function, No excessive consumption of alcohol - Any grade 3 or 4 laboratory abnormalities

3. Project Description (5 pages maximum with font size 12, for parts a. to d.) : (cf attached file)

a. Budget :

	TOTAL	Year 1 -2011	Year 2	Year 3
To be financed by the CRC or Fondation Artères				
Personnel CHF* (*Include charges of 25%)	Study nurse 40% 114'000 CHF	37'000	38'000	39'000
Equipment et consommables	Lipid and apolipoprotein determination (145 CHF/patient for 4 determinations) 13'020 CHF	2'170	6'510	4'340
Other costs	Drugs : 80'000 (active drug) and 15'000 placebo	13'000 10'000	39'000 2'500	28'000 2'500
TOTAL From CRC/Artères	222'020	62'170	86'010	73'840
To be financed from your own resources				
Provide details and total amounts	1. Graziano Pelli Technician 2: salary (UNIGE - 40%): 150'000 2. Fabrizio Montecucco CDC scientifique (100%) -	50'000 45'000	50'000 45'000	50'000 45'000