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EMA

Goals and Objectives for June 23, 2010

- Review of previous Forum roundtables on the statistical, biological and clinical implications of CVD risk in patients with HIV infection
- Review and discuss current knowledge of the pathophysiology of CVD in patients with HIV
- Understand how to best use observational cohorts in assessing CVD risk
- Understand the clinical implications as regards practice, guidelines and regulatory issues

Roundtable 1 (statistical issues)

- Are the standard (parametric) statistical approaches in observational studies on CVD risk due to HIV and its treatment appropriate ?
- What are the possibilities of (or obstacles to) sharing cohort datasets between investigators, or otherwise cooperating to allow for alternative statistical approaches?
- Is standardised data collection and endpoint adjudication between cohorts feasible, to facilitate validation of outcomes?

Roundtable 2 (mechanisms)

- By what mechanisms might HIV infection cause atherogenesis and thrombosis?
- How is this best studied in preclinical models?
- What can we learn from other inflammatory diseases (e.g., RA, SLE)?
- How should biomarkers of CVD risk best be studied and evaluated in patients, and how can we infer causation from multiple associations?

Roundtable 3 (clinical implications)

- Can CVD risk in patients with HIV be adequately estimated by traditional risk factor assessment ?
- Should HIV infection per se prompt more intensive CVD diagnostic workup and preventive intervention?
- Does antiretroviral treatment decrease or increase CVD risk?
- Should high CVD risk prompt earlier ARV therapy than would otherwise have been considered?
- What are appropriate and feasible designs for further studies?