Forum for Collaborative HIV Research

Review of statistical and epidemiological approaches to assessing Cardiovascular Disease risk using observational cohort data, randomized clinical trials and meta-analyses

Veronica Miller PhD

Forum for Collaborative HIV Research

Forum Mission

- The Forum for Collaborative HIV Research is a public/private partnership including government agencies, industry, HIV researchers and clinicians, payors, foundations and the HIV patient advocacy community.

  Our mission is to facilitate and enhance HIV research.

enhancing & facilitating HIV research

Cardiovascular Risk in HIV Infection & Treatment 2010

- A series of Forum roundtables addressing:
  - Statistical issues
  - Biologic mechanisms
  - Clinical impact
- Public workshop
- Satellite symposium @ International AIDS Conference in Vienna

enhancing & facilitating HIV research

Objectives for RT #1

- Review statistical analyses that have been performed,
- Discuss potential gaps that exist
- Discuss whether (and how) these gaps could be addressed with additional data analyses based on observational cohorts and randomized clinical trials

Project Steering Committee

- Kendall Markus (FDA) (Co-chair RT#1)
- Judy Aberg (FCHR EC)
- Dominique Costagliola
- Courtney Fletcher
- Filip Josephson (EMA)
- Amy Keller (FCHR)
- Veronica Miller (FCHR)
- Neil Poulter
- Peter Reiss
- Heather Ribaudo (ACTG)
- Caroline Sabin
- Neil Shortman (HAART Oversight Committee)
- Jur Strobos (FCHR)
- Jeff Taylor
- Russ Tracy

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- Tibotec
- ViiV

Seven Questions

- Is it possible to define a level of certainty from observational studies that more closely approaches results from randomized clinical trials and which could more readily support regulatory actions, such as a label change, population restriction or removal of a product from the market?
- Are there certain methodologies that should be required in the evaluation of observational data?
- Should findings be robust to evaluation using different methodologies?
- How should inconsistencies between different studies impact interpretation of study findings?
- Can a magnitude of effect be defined such that we could be reasonably certain that findings are real?
- Is there a threshold of missing data above which study findings should be considered exploratory only?
- Should we require that analyses be independently verified?