Neil Shortman

HAART Oversight Committee

HAART Oversight Committee

- 1999
  - European Medicines Agency asked HIV Drug Companies to develop and fund a proposal to evaluate the metabolic complications of HAART
- HAART Oversight Committee created
  - Companies, academics, patient representatives, EMA and FDA
  - CV risk focus
- Two key initiatives supported
  - VA Retrospective Cohort Study of the Risk of Cardiovascular Events in HIV Patients on HAART (completed 2005)
  - Data Collection on Adverse Events of Anti-HIV Drugs study (D:A:D)

HAART Oversight Committee

- D:A:D identified increased risk of MI with
  - Protease Inhibitor class (2007)
  - Abacavir (2008)
  - Specific Protease Inhibitor drugs (2009)
- HAART OC continues to support D:A:D
  - At request of EMA additional end points are now being studied (malignancy, renal, liver all cause mortality)
  - Original cohort replenished twice
  - D:A:D maintains scientific independence

HAART Oversight Committee

- HAART OC/D:A:D pharmacovigilance model viewed positively
  - model may be expanded into other therapy areas

FCHR CV initiative is independent of the HAART OC