The Data Collection on Adverse events of Anti-HIV Drugs

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The Need for D:A:D

- February 1999, EMEA/Committee for Medicinal Products for Human Use (CHMP) – Industry

- Oversight Committee for the Evaluation of the Metabolic Complications of Highly Active Antiretroviral Therapy

- A collaborative committee with representation from academic institutions, EMEA, FDA, the patient community, and all pharmaceutical companies with licensed anti-HIV drugs in the U.S. market: Abbott, Agouron, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck, Pfizer, and Hoffmann–LaRoche
The Need for D:A:D

- Established to ensure corporate responsibility in researching the long-term effects of antiretroviral therapy
- Cohort collaboration with participating cohorts agreeing to a common research agenda where a need for collaboration is essential in order to have the questions answered
- Events are few; large sample size needed
DAD study

- A prospective multi-cohort study of HIV-infected persons under active follow up
- The purpose of the study is to assess the incidence of myocardial infarction among HIV/AIDS patients who are receiving anti-retroviral therapy
- 11 cohorts worldwide participate
- The data collection for DAD takes place at least every 8 months
- Each cohort gathers and computerises its data; subsequently it is merged in a database in Copenhagen.
- Core data is information on incident cases of cardiovascular disease, which are reported immediately to the local cohort coordinating office by fax, using the event reporting forms
- The data collection also includes information on risk factors for cardiovascular disease
Those Involved:

HAART Oversight Committee

Barcelona University Hospital
BASS HIV Cohort

Australian HIV Cohort

Data from >35,000 patients
>150,000 patient years of follow-up
The Need for D:A:D

- Initially identified events as: **MI, Stroke, Invasive Cardiovascular Procedure, Death, Diabetes**
- **17 publications** in peer-reviewed journals since 2003 including:

  Combination Antiretroviral Therapy and the Risk of Myocardial Infarction.


  Class of Antiretroviral Drugs and the Risk of Myocardial Infarction.


  Use of nucleoside reverse transcriptase inhibitors and risk of myocardial infarction in HIV-infected patients enrolled in the D:A:D study

  **Lancet. 2008; 371(9622): 1417-26.**
The Need for D:A:D

- Last year expanded due to success and increasing concern around the following: **Non-AIDS Defining Cancers, Chronic Liver Disease, End-stage Renal Disease**
D:A:D Organisation Structure

- Originally a Consortium of eight Pharmaceutical Companies (working through a Contract Research Organisation-PRISM Event Management)
- Prism contracts with the DAD Coordinating Centre to undertake a sponsored Study entitled: “Data Collection on Adverse Events of Anti-HIV Drugs”, “The D:A:D Study”
- The Site Principal Investigator for each cohort is affiliated with the Copenhagen HIV Programme (the “D:A:D Protocol Coordinating Centre”) and on the Steering Committee
D:A:D Ownership and Access to Data

D:A:D Steering Committee

- Scientific independence
- Rights to Primary trial data
- Agrees to engage best effort if the Oversight committee requests additional data analyses pursuant to an obligation under statute or to a statutory, regulatory or governmental body
- Oversight Committee representation on the D:A:D Steering Committee (participating in all teleconferences and annual face-to-face meeting)
Process around Publications from D:A:D

The D:A:D study Steering Committee may freely publish and disseminate the results of the research findings relating to their involvement in the Study. The “Institution” or Investigators will provide the “Oversight Committee” with a copy of any proposed abstract or manuscript prior to submission for publication.

Reasonable consideration will be given to comments from the “Oversight Committee” members to abstracts and manuscripts.

The “Institution” or Site Principal Investigator will allow the “Oversight Committee” at least 5 working days for review of abstracts and 15 working days for review of manuscripts.

From and after the date 24 months following completion of the Study, neither the “Institution” nor Site Principal Investigator will be required to provide a proposed publication to the “Oversight Committee” for its prior review, provided no confidential information owned by the “Oversight Committee” is disclosed.