Forum for Collaborative HIV Research

Emerging Issues in HIV Clinical Trials for new ARVs: FCHR and FDA

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Forum Meetings: Recommendations

- 1999: Inclusion of heavily pretreated patients in trials
- 2004: Expanded access programs and collaboration between all stakeholders
- 2008: Minimize risk of functional monotherapy; patient classification based on number of available active drugs; virologic endpoint: <50 copies/ml

Roundtable Planning Committee

- **Robert Huff** AIDS Treatment Activists Coalition
- **Kim Struble** FDA
- **Sandra Palleja** Tobira Therapeutics
- **Nikos Dedes** European AIDS Treatment Group
- **Eoin Coakley** Monogram Biosciences
- **Roy Gulick** Weill-Cornell Medical Center
- **Nathalie Morgenztejn** EMA
- **Filip Josephson** EMA
- **Jur Strobos** FCHR
- **Veronica Miller** FCHR
- **Stefano Vella** Istituto Superiore di Sanita, Rome

2010 Meeting Goals

- How to evaluate the contribution of an investigational agent in the context of a fully suppressive OBR.
- Discuss new trial models and possible solutions for issues that impact trials and trial design

Newer Developments in Clinical Trials

- Non-inferiority trials: Discuss criteria for inferiority margin selection and regulatory perspective
- Adaptive design: Discuss FDA guidance and practical application

Treatment Experienced Patients

- Review recent clinical trial experiences
- Discuss new models for clinical trials
- Discuss issues that impact trials and possible solutions :
  - Treatment modifications for toxicities and study integrity maintenance
  - New or different trial endpoints
  - Viral load assays and management of “blips”
  - Patient enrollment at non-traditional sites for trials

Treatment Naïve Patients

- Discuss industry and regulatory experience
- Discuss role of CD4 levels in dose finding studies
- Discuss use of biomarkers for evaluation and correlation with long term safety

Meeting Format

- Formal presentations followed by discussion
- Panel III:
  - New clinical trial models
  - Brainstorming Session