Forum for Collaborative HIV Research

Recap of 2007 FCHR Expanded Access Meeting

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2009 Update on Rethinking Expanded Access Programs Roundtable Discussion

November 18, 2009

Washington, DC

Meeting Format

- Meeting date: February 17, 2007
- Location: Washington, DC
- Stakeholders Represented at the Meeting
  - Government Agencies
  - Pharmaceutical and Diagnostic Industries
  - HIV/AIDS researchers and clinicians
  - Payers
  - HIV/AIDS Patient advocacy community
- Meeting Format
  - Brief presentations that outlined the advantages and disadvantages of EAPs from various perspectives
  - Presentations provided the baseline framework for afternoon discussions, which then set the stage for the development of basic recommendations

Key Issues/Topics Discussed

- Size of patient population
- Tension between clinical and research sites
- Administrative burden that limits the ability for some sites to participate
- Funding of EAPs
- EAPs need to be conceived of within the context of clinical strategies overall
- Geographic limitations impeding on access for patients in small cities and rural areas
- Difficulty in finding information about EAPs

Recommendations

- Standardization of EAP
  - data collection requirements and reporting
  - reduce some of the administrative burdens
    - Development of case report forms and adverse events reporting
  - Further collaboration between regulatory agencies and pharmaceutical companies in EAP design to include the simultaneous use of multiple investigational agents and to identify creative study designs that will limit the use of virtual monotherapy and address therapeutic need of patients

Recommendations continued

- Provide guidance to CRO on data collection requirements
- Take advantage of technological modernization on adverse event reporting
- Consideration of different approach to expanded access programs
  - Two tiered approach where one would be an actual research protocol and the other a simplified protocol similar to current EAP protocols

2007 Meeting Outcomes

- FCHR Report
  - "Rethinking the Approach to Expanded Access Program"
    - Available at http://www.hivforum.org/storage/hivforum/documents/EAP/eap%20final%20report3.pdf
- FCHR Comments and recommendations
  - FDA Docket No. 2006N-0062 and RIN 0910-AF14 - Proposes Rules to Expand Availability of Investigational Drugs

Planning Committee

- **Rob Camp** ACTG NCAB
- **Ben Cheng** FCHR
- **Sheldon Fields** ANAC
- **Joel Gallant** JHU
- **Roy Gulick** Cornell University
- **Michael Horberg**Kaiser Permanente
- **Robert Huff** TAG
- **Daniel Kuritzkes** Harvard Medical School
- **Randi Leavitt** Merck & Co., Inc.
- **Veronica Miller** FCHR
- **Kimberly Struble** FDA
- **Pablo Tebas** UPenn
- **Randall Tressler** Pfizer, Inc.

Meeting Participants

enhancing & facilitating HIV research

Valerianna Amorosa – UPenn

Debra Birnkrant - FDA

Ben Cheng, M.Sc. -FCHR

Roy Gulick, - Cornell University

Ernest Igwacho FCHR

Katherine Laessig - FDA

Meagan Lyon - FCHR

Karen Manson - Tibotec BVBA

Scott McCallister - Panacos Pharmaceuticals

Luis Mendao - EATG

Nathalie Morgensztejn - EMEA

Linda Onaga - FCHR

Kimberly Struble - FDA

Randall Tressler - Pfizer, Inc.

Douglas Ward - Dupont Circle Physicians Group

Christine Balt - Indiana University, ANAC

Rob Camp - ACTG NCAB

Joel Gallant - JHU

Michael Horberg - Kaiser Permanente

Daniel Kuritzkes, M.D. Harvard

Randi Leavitt, - Merck & Co., Inc.

Bill Mannion - Pfizer, Inc.

Kendall Marcus, - FD

Marita McDonough – Boehringer Ingelheim Pharmaceuticals, Inc.

Veronica Miller - FCHR

Jeff Murray - FDA

Frederick Schmid - Panacos Pharmaceuticals

Pablo Tebas - UPenn

Nelson Vergel - Salvagetherapies.org

Eric Zechman - Medical Writer

More Information

- Link to Meeting Presentations and Report
  - http://www.hivforum.org/index.php?option=com_content&task=view&id=200&Itemid=98