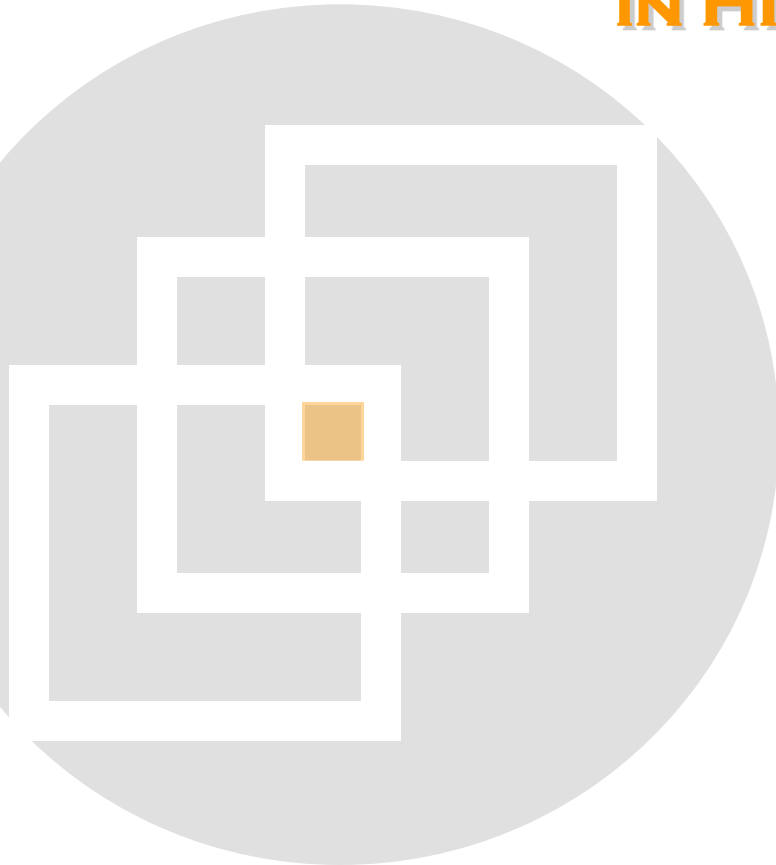




REVIEW OF CARDIOVASCULAR DISEASE RISK IN HIV TREATMENT



**Veronica Miller PhD
Forum for Collaborative HIV
Research**



enhancing & facilitating 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.



HISTORY OF FCHR WORK ON METABOLIC ABNORMALITIES AND CARDIOVASCULAR RISK

enhancing & facilitating HIV research

**Metabolic Abnormalities
& Consequences**

**Mitochondrial Tox,
Bone; Adipocytes**

**Cardiovascular Risk
Review***

**Regulatory Considerations
in Rx of Lipodystrophy**



http://www.hivforum.org/index.php?option=com_content&task=blogcategory&id=108&Itemid=102

*with support from HAART Oversight Committee



LATE 1990's: EMERGING FAT REDISTRIBUTION SYNDROME

enhancing & facilitating HIV research

- Lipodystrophy
- Series of roundtables*:
 - Metabolic abnormalities and consequences
- Discussions led to design and implementation of the FRAM Study (The Study of **F**at **R**edistribution and **M**etabolic Change in HIV Infection)

*http://www.hivforum.org/index.php?option=com_content&task=view&id=205&Itemid=102



2004: REGULATORY CONSIDERATIONS FOR TREATMENT OF LIPODYSTROPHY

- Goals:
 - recommend methods of objective and subjective measurement
 - recommend entry criteria for clinical trials based on the type of lipodystrophy
 - recommend the degree and duration of response that would merit regulatory approval of a treatment or intervention
 - assess any additional endpoints that might be required for the approval of a treatment intervention
- Recommendations applied in FDA review of tesamorelin for the treatment of excess abdominal fat in HIV patients with lipodystrophy



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

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 Ribaud (ACTG)
- Caroline Sabin
- Neil Shortman (HAART Oversight Committee)
- Jur Strobos (FCHR)
- Jeff Taylor
- Russ Tracy



enhancing & facilitating HIV research

SUPPORT ACKNOWLEDGMENT

- Abbott
- Gilead
- HAART Oversight Committee
- Pfizer
- Tibotec
- ViiV



enhancing & facilitating HIV research

TODAY'S AGENDA

- Introduction, Goals & Objectives and Perspectives
- Summary of roundtables
- Panels
 - Pathophysiology
 - Understanding Observational Database Analysis
 - Clinical Implications



INTRODUCTIONS: PANEL MODERATORS

- Jur Strobos MD JD (FCHR since Jan 2010)
 - Previously served as Director of Policy Research in the Office of the Commissioner FDA
 - More than 30 years of experience working in patient health care, clinical research, and international drug regulation.
 - ◉ drug law, clinical study design and good manufacturing practices



enhancing & facilitating HIV research

INTRODUCTIONS: PANEL MODERATORS

- Ralph D'Agostino Sr. (Boston University)
 - Chair Mathematics and Statistics Department
Director, Framingham Study: Statistics/Data
Management
Statistical Consultant, New England Journal of
Medicine
Editor, Statistics in Medicine
Editor, Encyclopedia of Clinical Trials



enhancing & facilitating HIV research

INTRODUCTIONS: PANEL MODERATORS

- Wendy Post MD MS (Johns Hopkins University)
 - Associate Professor of Medicine Div of Cardiology
 - Cardiologist JH Ciccarone Center for Prevention of Heart Disease and Echocardiography Laboratory
 - Principal Investigator MESA (Multi-Ethnic Study of Atherosclerosis)
 - PI Subclinical Vascular Disease and Metabolic Abnormalities in MACS



SOME RULES TO FOLLOW TODAY

- Sessions are being web-cast
 - Speak into microphones
 - Identify yourself when asking questions
 - Alternatively can submit question by handwriting and passing forward to panel
- Panel Sessions
 - Each panelist will start with brief comments
 - Audience participation expected in discussion



enhancing & facilitating HIV research

INTRODUCTIONS: SESSION 1

- Filip Josephson MD PhD
 - EMA
- Bob Munk PhD
 - AIDS InfoNet
- Neil Shortman
 - HAART Oversight Committee; ViiV
- Kendall Marcus
 - FDA