### Plenary Sessions

1-5

### Symposia

6-9

### Scientific Committee Sessions

10-16

- Transformative Science Groups and Subcommittees
- Collaborative Science Groups

17-18

- Resource Committee Sessions

19

- Data Management Committee
- Underrepresented Populations Committee

20

### Community Sessions

21-26

### Laboratory Sessions

27-28

### Site Management Sessions

29

- Site Management and Clinical Care Committee
- Outreach, Recruitment, and Retention Subcommittee
- Protocol Development and Implementation Subcommittee

30

### Interactive Sessions

31

- Laboratory Training: Clinician-Laboratory Interactive
- International Study Coordinator Roundtable
- Global CTU/CRS Study Coordinators Roundtable

32

34

35
Pharmacy-Clinician Interactive: Hepatitis C 36
Site Staff and Community Interactive: The Consenting Process 37

**Trainings**

Future Directions of the ACTG Laboratory Network 38
Oral Examination and Specimen Collection 39
Site Staff and Investigators 40-45
Protocol-Specific 46-55
PLENARY SESSION I

ACTG AWARDS, NETWORK LEADERSHIP, COMMUNITY, CO-INFECTIONS AND MALIGNANCIES SUBCOMMITTEE, AND HIV RESERVOIRS AND VIRAL ERADICATION TRANSFORMATIVE SCIENCE GROUP

Tuesday, July 30, 2013, 3:30 p.m. – 6:30 p.m.

Chair: Daniel Kuritzkes, MD
Partners/Harvard/Boston Medical Center CTU

Co-Vice Chairs: Judith Currier, MD, MSc
University of California, Los Angeles CARE Center CRS
Ian Sanne, MBBCH, FTP
Wits HIV Research Group CTU

3:30-3:40 Welcome and State of the ACTG
Daniel Kuritzkes, MD

3:40-3:50 A5001 Recognition
Constance Benson, MD

3:50-3:55 Recognition of ACTG Service
Daniel Kuritzkes, MD
Judith Currier, MD, MSc
Ian Sanne, MBBCH, FTP

3:55-4:10 Presentation of 2013 ACTG Awards

a. Minority HIV Investigator Mentoring Program
   Daniel Kuritzkes, MD

b. John Carey Young Investigator Award
   Judith Currier, MD, MSc

c. Constance B. Wofsy Women’s Health Investigator Award
   Susan Cohn, MD, MPH

d. Donna Davis Community Award
   Sharon Maxwell
   Paul Klees
   Eric Lawrence
   Stanford Chimutimunzeve

4:10-4:30 Global Community Advisory Board: Community Scientific Agenda Survey Results
Paul Klees
Sharon Maxwell
David Palm
4:30-5:15 Co-infections and Malignancies Subcommittee

a. Welcome and Introductions

   Charles van der Horst, MD

b. A5247: Impact of Zostavax Vaccination on VZV-specific Cellular Immune Responses - Final Results

   Jeffrey Lennox, MD

c. A5240: Immunogenicity and Safety of the Quadrivalent Human Papillomavirus Vaccine in HIV-1-Infected Females

   Erna Kojic, MD

d. A5246/AMC 052: Testing the Safety of the HPV Vaccine in HIV-Infected Men

   Jennifer Webster-Cyriaque, DDS, PhD

5:15-5:30 Break

5:30-6:30 HIV Reservoirs and Viral Eradication Transformative Science Group

   (presentations 20 minutes each)

   John Mellors, MD

   Joseph Eron, MD

   a. A5281: “A Phase I Randomized, Partially Double-Blind, Placebo-Controlled, Dose-Escalation Study to Evaluate the Safety and Immunogenicity of a Cytokine Enhanced HIV-1 Multi-Antigen (HIV MAG) pDNA Vaccine Delivered Intramuscularly Followed by in Vivo Electroporation (IM/EP) or Intramuscularly in HIV-1 Infected Adults Receiving ART”

   Jeffrey Jacobson, MD


   Rajesh Gandhi, MD

   c. “Apheresis 101”

   Marisa Marques, MD
PLENARY SESSION II

HEPATITIS AND TUBERCULOSIS TRANSFORMATIVE SCIENCE GROUPS (TSGs)

Wednesday, July 31, 2013, 10:30 a.m. – 12:30 p.m.

HEPATITIS TSG

Chair: Marion Peters, MD
University of California, San Francisco AIDS CRS

Vice Chair: Raymond Chung, MD
Massachusetts General Hospital ACTG CRS

TUBERCULOSIS TSG

Chair: Richard Chaisson, MD
Johns Hopkins Adult AIDS CRS

Co-Vice Chairs: Gavin Churchyard, MBBCh, MMed, FCP, PhD
The Aurum Institute for Health Research

Diane Havlir, MD
University of California, San Francisco Adult AIDS CTU

Hepatitis TSG

10:30-11:00 Hepatitis C Virus (HCV) Resistance Testing in the Era of DAAs (VHICS)  
David Smith MD, MAS

11:00-11:30 Noninvasive Markers of Hepatic Fibrosis and Liver Biopsies  
Kenneth Sherman MD, PhD

Tuberculosis TSG

Kelly Dooley, MD, PhD

11:50-12:10 A5311: “Phase I Clinical Trial of the Pharmacokinetics of High-dose Daily Rifapentine, Given as a Single Dose or in Divided Doses to Healthy Volunteers”  
Kelly Dooley, MD, PhD

12:10-12:30 Preliminary Pharmacokinetics Data from A5279: “Phase III Clinical Trial of Short-Course Rifapentine/Isoniazid for the Prevention of Active Tuberculosis in HIV-Infected Adults with Latent Tuberculosis Infection”  
Courtney Fletcher, PharmD
PLENARY SESSION III

END-ORGAN DISEASE/INFLAMMATION
TRANSFORMATIVE SCIENCE GROUP (ITSG) AND
ANTIRETROVIRAL THERAPY STRATEGIES SUBCOMMITTEE

Thursday, August 1, 2013, 10:30 a.m. – 12:30 p.m.

END-ORGAN DISEASE AND INFLAMMATION TSG

Chair: Michael Lederman, MD
Case AIDS CTU

Vice Chair: Peter Hunt, MD
University of California, San Francisco AIDS CRS

ANTIRETROVIRAL THERAPY STRATEGIES SUBCOMMITTEE

Chair: Eric Daar, MD
Harbor-University of California Los Angeles Medical Center CRS

Vice Chair: Michael F Para, MD
The Ohio State University AIDS CRS

End-Organ Disease/Inflammation TSG
1. Welcome and Introductions ITSG Chairs
2. A5286 Data: “A Pilot Study of Rifaximin as a Modulator of Gut Microbial Translocation and Systemic Immune Activation in HIV-Infected Individuals with Incomplete CD4+ T-cell Recovery on Antiretroviral Therapy” Allan Tenorio, MD
3. A5296 Data: “Sevelamer Carbonate for Reducing Endotoxemia and Immune Activation: A Proof of Concept Study” Netanya Sandler Utay, MD
4. Surrogate Markers of Immune Activation and Inflammation in Clinical Trials Peter Hunt, MD

Antiretroviral Therapy Strategies Subcommittee
1. Welcome and Introductions ARTS SC Chairs
2. A5241 CROI Abstract: “Omitting NRTIs from ARV Regimens Is Not Inferior to Adding NRTIs in Treatment Experienced HIV+ Subjects Failing a PI Regimen: The ACTG OPTIONS Study” Karen Tashima, MD
3. Primary Analysis for A5234: “mDOT vs. Self-Administered Therapy for First Virologic Failure on NNRTI”
   Robert Gross, MD, MSCE

4. Primary Analysis for DACS 292: “Efavirenz and Association of Baseline Factors on Suicidality in Treatment Naïve Subjects”
   Katie Mollan, MS

5. Analysis from the ACTG 5208 Trial: “Renal Insufficiency Among Women Treated With Tenofovir/Emtricitabine/Lopinavir/Ritonavir (TDF/FTC/LPV/R) or TDF/FTC/Nevirapine (NVP)”
   Mina Hosseinipour, MD

   Nagalingeswaran Kumarasamy, MBBS, PhD
SYMPOSIUM I
STATISTICS

Wednesday, July 31, 2013, 4:00 p.m. – 5:00 p.m.

Moderator: Janet Andersen, ScD
ACTG Statistical and Data Analysis Center

Speaker: Linda Harrison, MS
ACTG Statistical and Data Analysis Center

1. Welcome and Overview
Janet Andersen, ScD

2. Secondary work with protocol data and samples: Study
design and Interpretation; see abstract below
Linda Harrison, MS
(and panel members)

3. Question and Answer Period
Panel and Audience

Abstract: The ACTG’s main focus is prospective clinical trials capturing valuable information on
key interventions for people living with HIV and other infectious diseases. This talk focuses on
designs of studies that address secondary objectives within a clinical trial, or that are
subsequently developed to explore research questions (DACS or NWCS). For example, A5202
had a secondary objective to study conditions as the immune system recovered when patients
start anti-HIV drugs. Study designs to evaluate the occurrence or incidence of these and other
conditions, and the factors that may be associated with them, will be introduced and compared
and contrasted. We will provide a flavor of how to conduct the analysis. This is intended to be
an introductory talk on the design and interpretation of non-randomized studies with little
mathematical content.
SYMPOSIUM II

HIV RESERVOIRS AND VIRAL ERADICATION
TRANSFORMATIVE SCIENCE GROUP

Thursday, August 1, 2013, 8:00 a.m. – 10:00 a.m.

Chair: John Mellors, MD
University of Pittsburgh CTU

Vice Chair: Joseph Eron, MD
University of North Carolina AIDS CTU

8:00-8:30 Quantifying HIV Reservoirs in ACTG Trials John Mellors, MD

8:30-9:00 What’s your Favorite Histone Deacetylase Inhibitor? Joseph Eron, MD

9:00-9:30 Anti-PD-1 in Hepatitis C – Experience from a Phase I Trial David Gardiner, PhD

9:30-10:00 Screening Trials of Curative Strategies: How Small Can N Be? Ronald Bosch, PhD
SYMPOSIUM III

WOMEN’S HEALTH INTERNETWORK COMMITTEE AND TUBERCULOSIS TRANSFORMATIVE SCIENCE GROUP

Friday, August 2, 2013, 8:00 a.m. – 11:15 a.m.

ACTG WOMEN’S HEALTH INTERNETWORK COMMITTEE (WHISC)

Chair: Susan E. Cohn, MD, MPH
Northwestern University CRS

Vice Chair: Cynthia S. Firnhaber, MD
Wits HIV CRS

TUBERCULOSIS TRANSFORMATIVE SCIENCE GROUP (TB TSG)

Chair: Richard Chaisson, MD
Johns Hopkins Adult AIDS CRS

Co-Vice Chairs: Gavin Churchyard, MBBCh, MMed, FCP, PhD
The Aurum Institute for Health Research
Diane Havlir, MD
University of California, San Francisco Adult AIDS CTU

<table>
<thead>
<tr>
<th>WHISC</th>
<th>Schedule</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00-8:05</td>
<td>Welcome and Introductions</td>
<td>Susan Cohn, MD, MPH</td>
</tr>
<tr>
<td>8:05-8:15</td>
<td>Global Community Advisory Board Perspective on Women’s Enrollment</td>
<td>Liz Barr, MS</td>
</tr>
<tr>
<td>8:15-8:25</td>
<td>Enrollment of Women in the ACTG Over Time</td>
<td>Karin Klingman, MD</td>
</tr>
<tr>
<td>8:25-8:40</td>
<td>Statistical and Data Analysis Center Perspective on Women’s Enrollment</td>
<td>Laura Smeaton, MS</td>
</tr>
<tr>
<td>8:40-8:50</td>
<td>A5185s: Sex Differences in HIV Shedding</td>
<td>Thomas Campbell, MD</td>
</tr>
<tr>
<td>8:50-9:00</td>
<td>A5202: Sex Differences by Sex and Race</td>
<td>Kimberly Smith, MD, MPH</td>
</tr>
<tr>
<td>9:00-9:15</td>
<td>Recruitment and Retention of Women in Studies - Lessons Learned from ACTG and non-ACTG Trials</td>
<td>Sally Hodder, MD</td>
</tr>
</tbody>
</table>
TB TSG
9:15-10:30 Recent Clinical Trials – Implications for Treatment Shortening and Multidrug-Resistant (MDR) TB
   a. High-RIF Study
   b. Rifaquin and Rifatex Studies
   c. TBTC Study 29 and 29X
   d. STREAM Study

   Richard Chaisson, MD, Moderator
   Martin Boeree, MD
   Amina Jindani, MD, FRCP
   Susan Dorman, MD
   Andrew Nunn, MSc

10:30-11:15 TB Diagnostics Research
   a. Rapid Diagnosis of Pyrazinamide (PZA) Resistance
   b. Integrating PZA Resistance Testing into a Cross-platform Drug Sensitivity Testing
   c. Xpert® MTB/RIF for Enrollment in Trials

   Richard Chaisson, MD, Moderator
   Paul van Helden, PhD
   David Alland, MD
   Annelies Van Rie, MD, PhD
END-ORGAN DISEASE/INFLAMMATION
TRANSFORMATIVE SCIENCE GROUP THINK TANK

Wednesday, July 31, 2013, 1:30 p.m. – 3:30 p.m.

Chair: Michael Lederman, MD
Case AIDS CTU

Vice Chair: Peter Hunt, MD
University of California, San Francisco AIDS CRS

Welcome and Introductions
Michael Lederman, MD
Peter Hunt, MD

1:30–2:05 Overview of the Hypothesized Contribution of Monocytes/Macrophages to End-organ Disease in HIV Infection
Irini Sereti, MD

2:05–2:40 Monocyte Function, Coagulation and Cardiovascular Risk
Nicholas Funderberg, PhD

2:40–2:50 The Effects of Freezing on Monocyte Phenotypes
Alan Landay, PhD

2:50–3:00 Statin Endpoint Trial Overview
Turner Overton, MD

3:00–3:30 Musical Recital: An Inflammatory Interlude
Daniel Kuritzkes, MD
Peter Hunt, MD
Vincent Parrillo
Moses “Supercharger” Nsubuga
HEPATITIS TRANSFORMATIVE SCIENCE GROUP
THINK TANK

Wednesday, July 31, 2013, 1:30 p.m. – 3:30 p.m.

Chair: Marion Peters, MD
University of California, San Francisco AIDS CRS

Vice Chair: Raymond Chung, MD
Massachusetts General Hospital, AIDS CRS

1. Welcome and Update
   Marion Peters, MD
   Raymond Chung, MD

2. Review of the European Association for the Study of the Liver (EASL) Data
   Ira Jacobson, MD

3. Possible Mechanisms of Hepatitis C Virus (HCV) Genotype 3 Failure
   Raymond Chung, MD

4. Genotype 4 HCV: Focus on East Africa
   Francis Ssali, ChB, MMED, MSc

5. Brief Study Updates
   a. A5294: “Boceprevir, Interferon, Ribavirin to Treat Hepatitis C HCV/HIV Coinfected Subjects (BIRTH)”
      Kenneth Sherman, MD
   b. A5309s: “Pharmacokinetics and Drug Interaction Potential of Boceprevir”
      Jennifer Kiser, PharmD
   c. A5320: “Viral Hepatitis C Infection Long-term Cohort Study (V-HICS)”
      David Wyles, MD
   d. A5327: “Sofosbuvir plus Ribavirin without Interferon for Treatment of Acute HCV in HIV-1 Infected Individuals (SWIFT-C)”
      Raymond Chung, MD
   e. A5329: “Interferon-Free Therapy for Chronic Hepatitis C Virus Genotype 1 Infection in Patients with HIV-1 Coinfection on Raltegravir or Rilpivirine based Antiretroviral Therapy”
      David Wyles, MD

6. Open Discussion
HIV RESERVOIRS AND VIRAL ERADICATION TRANSFORMATIVE SCIENCE GROUP THINK TANK

Thursday, August 1, 2013, 4:00 p.m. – 7:00 p.m.

Chair: John Mellors, MD
University of Pittsburgh CTU

Vice-Chair: Joseph Eron, MD
University of North Carolina AIDS CTU

4:00-4:10 Introduction to Think Tank Goals John Mellors, MD

Year in Review: Protocols
4:10-4:20 Update on A5276s: “Residual Viremia Substudy of A5001 (ALLRT)” Sharon Riddler, MD

4:20-4:30 Update on A5301: “Administration of an Anti-PD-1 Antibody (MK3475) for Reducing the Latent Reservoir: A Phase I Pilot Study” Steven Deeks, MD

4:30-4:40 Update on A5308: “A Prospective, Single-arm, Open-Label Study to Evaluate the Effect of Fixed-Dose Emtricitabine/Rilpivirine/Tenofovir Disoproxil Fumarate on T-cell Activation, Absolute CD4+ T-cell Count, inflammatory Biomarkers and Viral Reservoir in Treatment-naïve HIV-1 Controllers” Paul Sax, MD

4:40-4:50 Update on A5315: “A Phase I/II Study of Single Single Dose Romidepsin in HIV-infected Adults with Suppressed Viremia on Antiretroviral Therapy to Assess Safety, Tolerability, and Activation of HIV-1 Expression” Deborah McMahon, MD

4:50-5:00 Update on A5326: “Safety and Immunotherapeutic Activity of an Anti-PD-L1 Antibody (BMS-936559) in HIV-1 Infected Subjects on Suppressive cART: a Pilot Phase II, 24 week, Double-Blind, Placebo-Controlled, Ascending Single Dose Study” Joseph Eron, MD

Year in Review: Concept Proposals
5:00-5:10 Update on PR 678, “Safety and Efficacy of Sirolimus for HIV Reservoir Reduction in Individuals on Suppressive ART” Timothy Henrich, MD
Year in Review: New Work Concept Sheets
5:10-5:25 Update on NWCS 363: "HIV-1 Reservoirs in ccr5Δ32 Heterozygous Individuals"  
Timothy Henrich, MD

5:25-5:35 BREAK

Summary of International AIDS Society (IAS) Cure Workshop
5:35-6:00 Summary of IAS Cure Workshop  
Steven Deeks, MD

New Horizons
6:00-6:15 Allogeneic Stem Cell Transplantation and HIV Persistence  
Timothy Henrich, MD

6:15-6:30 Safety of Treatment Interruptions  
Randall Tressler, MD

6:30-6:45 Report from the Gene Therapy Working Group  
Ronald Mitsuyasu, MD Pablo Tebas, MD

6:45-7:00 Open Discussion
TUBERCULOSIS TRANSFORMATIVE SCIENCE GROUP (TB TSG) THINK TANK

Thursday, August 1, 2013, 4:00 p.m. – 7:00 p.m.

Chair: Richard Chaisson, MD
Johns Hopkins Adult AIDS CRS

Co-Vice Chairs: Gavin Churchyard, MBBCh, MMed, FCP, PhD
The Aurum Institute for Health Research
Diane Havlir, MD
University of California, San Francisco Adult AIDS CTU

4:00-4:15 Welcome and Update on TSG Scientific Agenda
Richard Chaisson, MD

4:15-4:30 Status Updates on Enrolling and Pending Studies
Protocol Leaderships

4:30-5:15 International TB Specialty Laboratory and Standardization of Methodologies
Andreas Diacon, MD, PhD

5:15-5:45 New Data from Animal Models – Prophylactic and Treatment Regimens
Eric Nuermberger, MD

5:45-6:10 Update on A5289: “Evaluating Novel Regimens for Treatment of Drug-sensitive TB”
Annie Luetkemeyer, MD
Diane Havlir, MD

6:10-6:35 Update on A5319: “MDR-Additive Regimens Experimental Layouts (MARVEL)”
C. Robert Horsburgh, MD

6:35-7:00 Taking the Defensive in the War against Mycobacterium TB
Richard Hafner, MD
ANTIRETROVIRAL THERAPY STRATEGIES (ARTS)
SUBCOMMITTEE BUSINESS SESSION

Thursday, August 1, 2013, 1:30 p.m. – 3:30 p.m.

Chair:  Eric Daar, MD
Harbor-University of California Los Angeles Medical Center CRS

Vice Chair:  Michael Para, MD
The Ohio State University AIDS CRS

1. Welcome and Introductions  Eric Daar, MD
2. Simplification of ART Working Group Presentation  Babafemi Taiwo, MD
3. Special Populations ART Concepts Working Group Presentation  Sharon Riddler, MD
4. Closing Discussion  All Members
CO-INFECTIONS AND MALIGNANCIES SUBCOMMITTEE
BUSINESS SESSION

*Wednesday, July 31, 2013, 3:00 p.m. – 4:00 p.m.*

**Chair:** Charles van der Horst, MD
University of North Carolina CRS

**Vice Chair:** Timothy Wilkin, MD, MPH
Cornell CRS

1. **Welcome and Introductions**
   Charles van der Horst, MD

2. Feasibility of a study evaluating the timing of ARV following initiation of fluconazole for asymptomatic cryptococcal antigenemia”.
   Dr. Peter Pappas, University of Alabama at Birmingham

3. **A5225: “A Phase I/II Dose-Finding Study of High-Dose Fluconazole Treatment in AIDS-Associated Cryptococcal Meningitis”**
   Umesh Laloo, MD, FRCP

4. **A5263: “A Randomized Comparison of Three Regimens of Chemotherapy with Compatible Antiretroviral Therapy for Treatment of Advanced AIDS-KS in Resource-Limited Settings”**
   Margaret Borok-Williams, MD, CHB, FRCP

5. **A5264: “A Randomized Evaluation of Antiretroviral Therapy Alone or with Delayed Chemotherapy versus Antiretroviral Therapy with Immediate Adjunctive Chemotherapy for Treatment of Limited Stage AIDS-KS in Resource-Limited Settings (REACT-KS AMC 067)”**
   Mina Hosseinipour, MD

6. **A5282: “A Randomized Trial To Compare An HPV Test-And-Treat Strategy To Cytology-Based Strategy for Prevention Of CIN 2+ In HIV-Infected Women”**
   Timothy Wilkin, MD, MPH

7. **A5297: “An Open-Label, Proof of Concept, Randomized Trial Comparing a LPV/r-Based to an nNRTI-Based Antiretroviral Therapy Regimen for Clearance of Plasmodium falciparum Subclinical Parasitemia in HIV-infected Adults with CD4+ Counts >200 and <350 cells/mm3”**
   Johnstone Kumwenda, FRCP

8. **A5298: “A Randomized, Double-Blinded, Placebo-Controlled, Phase III Trial of the Quadrivalent HPV Vaccine to Prevent Anal Human Papillomavirus Infection in HIV-Infected Men and Women”**
   Timothy Wilkin, MD, MPH

9. **Other Business**
   Charles van der Horst, MD
NEUROLOGY COLLABORATIVE SCIENCE GROUP  
BUSINESS SESSION  

Wednesday, July 31, 2013, 8:00 a.m. – 10:00 a.m.

Chair: Kevin Robertson, PhD  
University of North Carolina AIDS CRS

Vice Chair: Serena Spudich, MD  
Yale University School of Medicine

1. Welcome and Introductions  
   Kevin Robertson, PhD  
   Serena Spudich, MD

2. Metabolic Syndrome and Neurocognitive Impairment in HIV and Potential Treatment Strategies  
   Ronald Ellis, MD, PhD

3. DACS 301: “Relationship between Medication Adherence, ART Regimen and Verbal Memory among Participants in the ALLRT Cohort”  
   Ronald Ellis, MD, PhD

4. Report from Scientific Committee Representatives
   a. End-Organ Disease/Inflammation Transformative Science Group (TSG)  
      Christina Marra, MD
   b. HIV Reservoirs and Viral Eradication TSG  
      Serena Spudich, MD
   c. Co-infections and Malignancies Subcommittee  
      Thomas Campbell, MD
   d. Antiretroviral Therapy Strategies Subcommittee  
      Adriana Andrade, MD  
      Giovanni Schifitto, MD
   e. Hepatitis TSG  
      Scott Letendre, MD

5. New Concept Proposal Development  
   All Members

6. Master Neurology Protocol  
   All Members
ORAL HIV/AIDS RESEARCH ALLIANCE (OHARA)  
COLLABORATIVE SCIENCE GROUP BUSINESS SESSION

*Wednesday, July 31, 2013, 8:00 a.m. – 10:00 a.m.*

**Chair:** Mahmoud Ghannoum, PhD, MSc, EMBA  
Case CRS

**Vice Chair:** Caroline Shiboski, DDS, MPH, PhD  
University of California, San Francisco AIDS CRS

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Description</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00-8:05</td>
<td>Introductions</td>
<td>All Members</td>
</tr>
<tr>
<td>8:05-8:15</td>
<td>2012 External Scientific Expert Group (ESEG) Report</td>
<td>Mahmoud Ghannoum, PhD, MSc, EMBA</td>
</tr>
<tr>
<td>8:15-8:35</td>
<td>Scientific Research Agenda: Protocol Updates</td>
<td>Mahmoud Ghannoum, PhD, MSc, EMBA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Caroline Shiboski, DDS, MPH, PhD</td>
</tr>
<tr>
<td>8:35-8:50</td>
<td>Urban Legends about Oral Manifestations of HIV</td>
<td>Lauren Patton, DDS</td>
</tr>
<tr>
<td>8:50-9:35</td>
<td>Oral Antimicrobial Concept Proposal</td>
<td>Malcolm John, MD, MPH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Jennifer Webster-Cyriaque, DDS, PhD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mahmoud Ghannoum, PhD, MSc, EMBA</td>
</tr>
<tr>
<td>9:35-9:50</td>
<td>OHARA: Future Directions</td>
<td>Mahmoud Ghannoum, PhD, MSc, EMBA</td>
</tr>
<tr>
<td>9:50-10:00</td>
<td>Other Business</td>
<td>All Members</td>
</tr>
</tbody>
</table>
DATA MANAGEMENT COMMITTEE (DMC)  
BUSINESS SESSION  

*Thursday, August 1, 2013, 1:00 p.m. – 3:00 p.m.*

**Co-Chairs:**  Robert Murphy, MD  
Northwestern University CTU  

Lauren Komarow, MS  
Statistical and Data Management Center  

Lu (Summer) Zhang, PhD  
Statistical and Data Management Center  

1. Welcome and Introductions  
2. Event Reports (Resolution & Procedure)  
3. Future DMC Projects  
4. Any Other Business
UNDERREPRESENTED POPULATIONS COMMITTEE
SESSION

Thursday, August 1, 2013, 4:00 p.m. – 6:00 p.m.

Chair: Kimberly Smith, MD, MPH
       Rush University Medical Center ACTG CRS

Vice-Chair: Michelle Cespedes, MD
           New York University HIV/AIDS CRS

1. Minority HIV Investigator Mentoring Program Final Reports

2. Updates:
   a. ACTG Patient Survey
   b. Adherence Intervention Study
   c. Recruitment and Retention of Underrepresented Populations
COMMUNITY SCIENTIFIC SUBCOMMITTEE
BUSINESS SESSION

Wednesday, July 31, 2013, 3:00 p.m. – 5:00 p.m.

Co-Chairs: Stanford Chimutimunzeve
           Eric Lawrence

1. Welcome and Introductions
   Stanford Chimutimunzeve
   Eric Lawrence

2. Discussion Departing Members and Open Positions
   All

3. Transformative Science Group Training and
   Confidentiality Issues
   David Palm
COMMUNITY SESSION I

Monday, July 29, 2013, 9:00 a.m. – 12:00 noon

Co-Chairs: Sharon Maxwell
            Paul Klees

1. Welcome and Introductions
   Sharon Maxwell
   Paul Klees
   Stanford Chimutimunzeve
   Eric Lawrence

2. Leadership Update
   Ian Sanne, MBBCH, FCP (SA), DTM&H

3. Culture and HIV Prevention
   Nathaniel Johnson

4. Community Advisory Board (CAB) Presentations
   UCLA, CPCRA, Lilongwe CABs
COMMUNITY SESSION II

Monday, July 29, 2013, 3:00 p.m. – 6:00 p.m.

Co-Chairs: Sharon Maxwell
            Paul Klees

1. Informed Consent Panel – *Held in Independence A*
   Marcia Ellis
   Ilene Wiggins, RN
   Jayinthie Govender, RN

2. Bridget Murtagh Awards
   Allegra Cermak

3. Human Genes and HIV: Where Are We and Where Are We Going?*
   David Haas, MD

4. Women’s Enrollment in Clinical Trials
   Liz Barr
COMMUNITY SESSION III

*Tuesday, July 30, 2013, 8:00 a.m. – 12:30 p.m.*

**Co-Chairs:** Sharon Maxwell  
Paul Klees

1. Community Partners Report  
   Nathaniel Johnson  
   Liz Barr  
   Jeff Mazo  
   Bridget Mwewa

2. Update on Tuberculosis (TB) Biomarker Research and Other TB Topics  
   Constance Benson, MD

3. The Transgender Community's Barriers to Health Care Access  
   Andy Bowen  
   (Social Policy Organizer at DC Trans Coalition)

4. Demystifying Statistics in ACTG Research  
   Laura Smeaton, MS
COMMUNITY SESSION IV

Tuesday, July 30, 2013, 1:30 p.m. – 3:00 p.m.

Co-Chairs:  Sharon Maxwell
            Paul Klees

Panel:  Rajesh Gandhi, MD
        Jordan Lake, MD
        Morag MacLachlan, MA
        Deborah D. McMahon, MD
        Netanya Sandler, MD

1. Overview of A5321, The AHRC Study

2. What Lymph Node and Adipose Tissue can Tell Us
COMMUNITY SESSION V

Friday, August 2, 2013, 12:30 p.m. – 5:00 p.m.

Co-Chairs: Sharon Maxwell
Paul Klees

1. Update on NeuroAIDS
   David Clifford, MD

2. Global Community Advisory Board (GCAB) Co-chair
   Nomination/Introductions
   Paul Klees

3. GCAB/Community Scientific Subcommittee
   Committee Updates
   Community Representatives

4. GCAB Committees Discussion
   Paul Klees

5. Goodbye to Retiring Members
LABORATORY TECHNOLOGISTS COMMITTEE
BUSINESS SESSION

Thursday, August 1, 2013 1:00pm – 4:00pm

Co-Chairs: Joan Dragavon, MLM, M(ASCP)
University of Washington AIDS CRS
Lori Mong-Kryspin, MT (ASCP), SM (ASCP)
The Ohio State University AIDS CRS

Co-Vice-Chairs: Cheryl Jennings, BS
Rush University Medical Center ACTG CRS
Carmen Irizarry, MT (ASCP)
Puerto Rico AIDS CRS

1:00-1:10 Welcome and Opening Remarks
Joan Dragavon, MLM, M(ASCP)
Lori Mong-Kryspin, MT, SM (ASCP)

1:10-1:40 Office of HIV/AIDS Network Coordination (HANC) Laboratory Resource Updates and Portal Redesign
Melissa Austin, BS

1:40-1:55 ACTG Protocols: Laboratory Implementation Issues
a. Lessons Learned from A5315, A5321, A5325
b. Laboratory Survey and Implementation Plan, L-SIP
c. Laboratory Technologist Assistance with Blood Volume Calculation Tool
Joan Dragavon, MLM, M(ASCP)

1:55-2:10 Data Analysis Reports/Preload Update
Marlene Cooper, MS

2:10-2:25 Overview of Pending LTC Document Updates:
Joan Dragavon, MLM, M (ASCP)
a. Laboratory Processing Chart Templates
Lori Mong-Kryspin, MT, SM (ASCP)
b. Standard Wording Documents
c. Protocol and LPC Review Procedure and Checklist

2:25-4:00 Breakout Working Groups for Document Updates
LTC Voting Members
SPECIALTY LABORATORY DIRECTORS SESSION

Wednesday, July 31, 2013, 4:00 p.m. – 7:00 p.m.

Chair: Robert Coombs, MD, PhD
University of Washington AIDS CRS

4:00-4:15 Welcome and Opening Remarks: Review of the Proposed Network Lab Structure Awards and Recognition
a. Susan Fiscus
b. Paige Etter
c. William Kabat
d. Richard Pollard
e. Vicki Johnson
f. David Katzenstein

4:15-4:25 Laboratory Technologist Committee Update
Joan Dragavon, MLM
Lori Mong-Kryspin, MT, SM (ASCP)

4:25-4:40 Virology Quality Assurance (VQA) Program Updates
James Bremer, PhD
a. HPV Testing
   • Updates on lab performance
   • Linear Array Assay Validation
   • HPV genotypes
b. HIV RNA Stability Study - NWCS324

4:40-4:55 Immunology Quality Assurance (IQA) Program Updates
John Wong
Ana Sanchez, PhD
a. IQA CD38 External Quality Assurance (EQA) Program Development
b. EQA Program Oversight Laboratory

4:55-5:10 Statistical and Data Analysis Center Update
Ronald Bosch, PhD

5:10-5:15 5-minute session break - please move to breakout session rooms

Breakout Sessions for Laboratory Cores

5:15-6:15 Oral HIV/AIDS Research Alliance Specialty Laboratories
Latrobe

5:15-7:00 Tuberculosis Specialty/ Regional Laboratories
Farragut Square

5:15-7:00 Immunology Specialty Laboratories
Lafayette Park

5:15-7:00 Pharmacology Specialty Laboratories
Franklin Square

5:15–7:00 Virology Specialty Laboratories and Genomics
Constitution A
SITE MANAGEMENT AND CLINICAL CARE COMMITTEE SESSION

Tuesday, July 30, 2013, 1:00 p.m. – 2:00 p.m.

Chair: Lisa Kessels, RN, ACRN
Washington University CRS

Vice-Chair: Todd Lusch, BA
The Ohio State University AIDS CRS

1. Welcome
   Lisa Kessels, RN, ACRN
   Todd Lusch, BA

2. Comedy Relief
   Janice Fritsche, MS, APN, PMHNP-BC

3. Aromatherapy
   Amy Dill, PharmD, BCPS

4. Meditation and Breathing Techniques
   Linda Naini, MPH, CCRP
OUTREACH, RECRUITMENT AND RETENTION (OR&R)
SUBCOMMITTEE SESSION

Wednesday, July 31, 2013, 3:00 p.m. – 5:00 p.m.

Chair: Michael Louella
University of Washington AIDS CRS

Co-Vice Chairs: Christie Lyn Costanza, MPH
New Jersey Medical School Adult CRS
Savita Kanade, MSc
BJ Medical College CRS

1. Welcome and Introductions
   OR&R Chairs

2. OR&R Year in Review
   Michael Louella

3. OR&R Membership Duties and Mission, Term Extensions
   OR&R Chairs

4. OR&R Working Group Projects
   All Members

5. International Needs
   All Members

6. Outreach and Recruitment Materials Development
   Michael Louella
   Savita Kanade, MSc

7. Centralized Advertising for Recruitment of ACTG Studies
   Michael Louella

8. December 2, 2013 - ACTG Day of Appreciation for Participants/Volunteers
   Michael Louella

9. Social Media/Social Marketing Efforts
   Morag MacLachlan, BA, MA
   Michael Louella

10. Community Forum
    All
PROTOCOL DEVELOPMENT AND IMPLEMENTATION SUBCOMMITTEE (PDISC) BUSINESS SESSION

Thursday, August 1, 2013, 10:00 a.m. – 10:30 a.m.

Chair: David N. Currin, RN, ACRN, CCRC
University of North Carolina AIDS CRS

Vice Chair: Deborah D. Sutherland, RN, BSN, CCRP
Vanderbilt Therapeutics CRS

1. Welcome and Introductions
   David N. Currin, RN, ACRN, CCRC
   Deborah D. Sutherland, RN, BSN, CCRP

2. PDISC Function, Goals, and Objectives
   David N. Currin, RN, ACRN, CCRC

3. PDISC Projects
   David N. Currin, RN, ACRN, CCRC

4. Comments and Suggestions
   All
LABORATORY TRAINING: CLINICIAN-LABORATORY INTERACTIVE

Tuesday, July 30, 2013, 2:00 p.m. – 3:30 p.m.

Laboratory Technologist Committee

Co-Chairs: Joan Dragavon, MLM, M(ASCP)
University of Washington AIDS CRS

Lori Mong-Kryspin, MT, SM ASCP
The Ohio State University AIDS CRS

Co-Vice-Chairs: Cheryl Jennings, BS
Rush University Medical Center ACTG CRS

Carmen Irizarry, MT
Puerto Rico AIDS CRS

Training and Education Subcommittee of the Site Management and Clinical Care Committee

Chair: Valery Hughes, FNP
Cornell CRS

1. Welcome and Opening Remarks
   Valery Hughes, FNP
   Lori Mong-Kryspin, MT (ASCP), SM (ASCP)

2. Session Icebreaker
   Kathy Watson, RN, BSN, ACRN
   Lori Mong-Kryspin, MT (ASCP), SM (ASCP)

3. Implementation of Protocols Involving Leukapheresis, Implications for the Clinic and Laboratory
   Chris Lane, AAS
   Joan Dragavon, MLM, M(ASCP)
   Debbie Slamowitz, RN, BSN, ACRN
   a. Lab Processing
   b. Complex Specimen Collection

4. Complex Pharmacology Samples
   Robin DiFrancesco, MBA, MT (ASCP)
   Jill Hochreiter, MT (ASCP)
   a. FAQs
   b. A5294 and A5309 case studies
5. Scheduling, Time Constraints, Collection, and Processing Complexities
   Carmen Irizarry, MT (ASCP)
   Chris Lane, AAS
   Cheryl Jennings, BS
   Baiba Berzins, MPH

6. Case Report Form and Laboratory Data Management System Reconciliation for Data Analysis Reports and Site Evaluations
   Marlene Cooper, MS
   Sikhulile Moyo, MSc, MPH

7. Blood Volume Awareness
   Julie Ziegler, MA
   Joan Dragavon, MLM, M(ASCP)
INTERNATIONAL STUDY COORDINATOR ROUNDTABLE

Tuesday, July 30, 2013, 7:00 a.m. – 9:00 a.m.

Chair: Jane Govender, R.N
Durban Adult HIV CRS

Vice-Chair: Leslie H. Degnan MPH
Johns Hopkins University College of Medicine CRS

1. Introduction Christina Blanchard-Horan, PhD, MA, CCRP
2. Expert Support Advisors – Challenges Tonia Caravella, MPH,
   Larry Allan
   Lynda Lahl, RN, MS
3. Breakouts – Solving Challenges Christina Blanchard-Horan, PhD, MA, CCRP
4. Workgroup presentations and discussion All
5. Complete session evaluations (5 minutes) All

Special thanks to the Training and Education Subcommittee Members for their assistance with this session.
GLOBAL CTU/CRS STUDY COORDINATORS ROUNDTABLE

(This session is for study coordinators and/or site leaders only)

Tuesday, July 30, 2013, 9:00 a.m. – 10:00 a.m.

Co-Chairs: Ilene Wiggins, RN
Johns Hopkins University ACTG CRS

Jane Baum, BSN, RN
Case Western Reserve CRS

9:00 Introductions

9:05 Harmonization Across Networks: What Has Already Been Done; What is the Process?
Jeffrey Schouten, MD

Open Discussion by the Coordinator Group

9:20 What are the Perceived Priorities for Harmonization?
What Should be Harmonized Across Networks First?

9:35 What Would be Reasonable to Attempt to Harmonize across Statistical and Data Management Centers in the Short and Long Terms?

9:50 Future Ideas for Harmonization: Goals to Work Toward
# PHARMACY-CLINICIAN INTERACTIVE:
## HEPATITIS C

**Monday, July 29, 2013, 3:30 p.m. – 5:30 p.m.**

**Moderators:** Amy Dill, PharmD  
University of Cincinnati CRS  
Stephen D. Bartlett, RPh, MSPH  
University of Colorado Hospital CRS

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Welcome</td>
</tr>
<tr>
<td>2.</td>
<td>Staging for Treatment</td>
</tr>
<tr>
<td>3.</td>
<td>Pharmacology – HCV Protease Inhibitors</td>
</tr>
<tr>
<td>4.</td>
<td>Drug Interactions</td>
</tr>
<tr>
<td>5.</td>
<td>Management of Dose Modifications</td>
</tr>
<tr>
<td>6.</td>
<td>Patient Counseling</td>
</tr>
<tr>
<td>7.</td>
<td>Open Discussion</td>
</tr>
</tbody>
</table>
### SITE STAFF AND COMMUNITY INTERACTIVE: THE CONSENTING PROCESS

**Monday, July 29, 2013, 1:00 p.m. – 3:00 p.m.**

**Moderators:**
- Marcia Ellis, BA, MA  
  Georgetown University CRS
- Jayinthie Govender, RN  
  Durban Adult HIV CRS
- Ilene Wiggins, RN  
  Johns Hopkins University AIDS CRS

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:00-1:05</td>
<td>Introductions</td>
<td>Suzanne Fiorillo, MSPH</td>
</tr>
<tr>
<td>1:05-1:25</td>
<td>Elements of the Consenting Process: Clinician and Participant Perspective</td>
<td>Jayinthie Govender, RN</td>
</tr>
<tr>
<td>1:25-1:45</td>
<td>Essential Elements of the New Sample Informed Consent Template</td>
<td>Betto Ortiz, MS, PMP, CIPM</td>
</tr>
<tr>
<td>1:45-2:05</td>
<td>The New Genetics Consent for Future Testing and Storage of Samples</td>
<td>Linda A. Ehler, RN, MN</td>
</tr>
<tr>
<td>2:05-2:30</td>
<td>Letters of Amendment that Change the Consent</td>
<td>Ilene Wiggins, RN</td>
</tr>
</tbody>
</table>
| 2:30-3:00  | Language: in Consents, in Participant Summaries; That Identifies the Community | Ilene Wiggins, RN  
  Michael Louella  
  Marcia Ellis, BA, MA |
LABORATORY TRAINING:
FUTURE DIRECTIONS OF THE
ACTG LABORATORY NETWORK

Monday, July 29, 2013, 9:00 a.m. – 11:00 a.m.

9:00 Welcome and Opening Remarks
   a. Overview of the Laboratory Network in 2013
   b. New Laboratory Cores (Hepatitis, Tuberculosis)
   c. Accomplishment of the Cores and Laboratory Technologist Committee

Robert Coombs, MD, PhD

9:10 Leukapheresis Quality Assurance Development
     Kyle Liebl

9:25 Clinical Pharmacology Quality Assurance Program
     Gene Morse, PharmD

9:40 Tuberculosis External Quality Assurance (EQA) Development
     Anne Marie Demers, MD

9:55 Human Papilloma Virus EQA
     a. Telepathology
     b. Pathology EQA
     Catherine Godfrey, MD

10:10 Genexpert EQA Program Update
     Lesley Scott, PhD

10:25 Lab in a Tube Validation
     Shuqi Chen, PhD

10:40 Malaria Laboratory Network Update
     Ann Stewart, MD
ORAL EXAMINATION AND SPECIMEN COLLECTION TRAINING

Tuesday, July 30, 2013, 1:30 p.m. – 3:30 p.m.

Chair: Mahmoud Ghannoum, PhD, MSc, EMBA
Case CRS

Vice-Chair: Caroline Shiboski, DDS, MPH, PhD
University of California, San Francisco AIDS CRS

A5263/AMC066:
“Three Chemo Regimens as an Adjunct to ART for Treatment of AIDS-KS”

A5264/AMC067:
“ART Versus ART with Adjunctive Chemo for Limited Stage AIDS-KS”

A5265:
“Gentian Violet Versus Nystatin Oral Suspension for Treatment of Oropharyngeal Candidiasis”

A5298:
“Quadrivalent HPV Vaccine to Prevent Anal HPV Infection in HIV-Infected Men”

1. Oral Examination: All Protocols
   Caroline Shiboski, DDS, MPH, PhD

2. Specimen Collection and Processing
   Jennifer Webster-Cyriaque, DDS, PhD
   
   a. A5263-A5264: Throat Wash and Whole Saliva
   
   b. A5265: Swab Collection, Throat Wash, Whole Saliva
   
   c. A5298: Throat Wash and Whole Saliva

3. A5265: Training on Karnofsky Assessment
   Caroline Shiboski, DDS, MPH, PhD
   Robert Salata, MD

4. Interactive Training
   Volunteers
ORIENTATION TO THE ACTG MEETING AND WHERE TO FIND IMPORTANT INFORMATION

Monday, July 29, 2013, 8:00 a.m. – 9:00 a.m.

1. Orientation: Review of Sessions Planned for the Meeting
   Todd Lusch, BS

2. Review of Data Management Sessions
   Kristine Coughlin, BA
   Laura Smith, MPH
SITE STAFF TRAINING: SCIENTIFIC AGENDA

Monday, July 29, 2013, 9:00 a.m. – 10:30 a.m.

1. Overview of the ACTG Site Management and Clinical Care Committee
   Deborah Sutherland, BSN

2. Scientific Agenda Overview of Transformational Science Groups (TSGs), Scientific Subcommittees, and Collaborative Science Groups (CSGs) with assigned SMCCC representatives

   **TSGs**
   - a. End-organ Disease/Inflammation TSG
     Mario Guerrero, MD
   - b. HIV Reservoirs and Viral Eradication TSG
     Mary Adams, RN, MPH
   - c. Hepatitis TSG
     Valery Hughes, FNP
   - d. Tuberculosis TSG
     Kogieleum Naidoo, MBChB

   **Scientific Subcommittees**
   - a. Co-Infections and Malignancies Subcommittee
     Mulinda Nyrienda, MMED, MBBS
   - b. Antiretroviral Therapy Strategies Subcommittee
     Jenifer Baer, RN, BSN

   **CSGs**
   - a. Oral HIV AIDS Research Alliance
     Baiba Berzins, MPH
   - b. Neurology Collaborative Science Group
     Kim Whitely RN, CCRC
SITE STAFF TRAINING:  
THE PHYSIOLOGY OF INFLAMMATORY MARKERS AND CYTOKINES

*Tuesday, July 30, 2013, 11:00 a.m. – 12:30 p.m.*

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Describe Processes Leading to Excessive Immune Activation in HIV Infected Individuals</td>
<td>Daniel Nixon, DO, PhD</td>
</tr>
<tr>
<td>2</td>
<td>Discuss Relationship Between Immune Activation and AIDS/Non AIDS Morbidity in HIV Infected Individuals</td>
<td>Daniel Nixon, DO, PhD</td>
</tr>
<tr>
<td>3</td>
<td>Identify Biomarkers that can Help Monitor Immune Activation and Inflammation in HIV Infected Individuals</td>
<td>Daniel Nixon, DO, PhD</td>
</tr>
<tr>
<td>4</td>
<td>Describe Processes Leading to Excessive Immune Activation in HIV Infected Individuals</td>
<td>Daniel Nixon, DO, PhD</td>
</tr>
<tr>
<td>5</td>
<td>Discuss Relationship between Immune Activation and AIDS/Non AIDS Morbidity in HIV Infected Individuals</td>
<td>Daniel Nixon, DO, PhD</td>
</tr>
<tr>
<td>6</td>
<td>Identify Biomarkers that can Help Monitor Immune Activation and Inflammation in HIV Infected Individuals</td>
<td>Daniel Nixon, DO, PhD</td>
</tr>
<tr>
<td>7</td>
<td>Open Discussion, Q&amp;A</td>
<td>Daniel Nixon, DO, PhD</td>
</tr>
</tbody>
</table>
SITE STAFF TRAINING:
TUBERCULOSIS (TB) DRUGS, DIAGNOSTICS,
AND CLINICAL CARE GUIDELINES

Tuesday, July 30, 2013, 10:00 a.m. – 11:00 a.m.

1. Describe Procedures Used to Diagnose HIV-Related TB.  
   Richard Chaisson, MD

2. Identify Standard of Care TB Therapy for HIV-Infected Patients and Monitoring for Efficacy and Toxicity.  
   Richard Chaisson, MD

3. Discuss Optimal Timing of Antiretroviral Therapy for Patients with TB and HIV.  
   Richard Chaisson, MD

4. Open Discussion, Q&A  
   Richard Chaisson, MD
INTRODUCTION TO THE ACTG: A WORKSHOP FOR NEW INVESTIGATORS

Tuesday, July 30, 2013, 12:00 noon – 1:30 p.m.

Chair: Judith Currier, MD, MSc  
University of California, Los Angeles CARE Center CRS

1. Introduction  Judith Currier, MD, MSc
2. ACTG Structure  Daniel Kuritzkes, MD
3. New Work Concept Sheets (NWCSs) and Data Analysis Concept Sheets (DACSs)  Janet Andersen, ScD
4. Concept Proposals  Eric Daar, MD
5. Protocol Team Involvement and Opportunities  Joseph Eron, MD
6. Panel Discussion  Judith Currier, MD, MSc, Facilitator
7. Wrap-up  Judith Currier, MD, MSc
# STUDY MONITORING:
THE ELEPHANT IN THE ROOM

*Monday, July 29, 2013, 5:30 p.m. – 7:00 p.m.*

<table>
<thead>
<tr>
<th></th>
<th>Topic</th>
<th>Facilitators</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>State The Definition and Purpose of Monitoring</td>
<td>Thomas Lauffenburger, RN, CCRA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gregory Lessing, Bsc</td>
</tr>
<tr>
<td>2.</td>
<td>List The Different Assessments That a Monitor May Be Required to</td>
<td>Thomas Lauffenburger, RN, CCRA</td>
</tr>
<tr>
<td></td>
<td>Complete and Strategies to Expedite Them</td>
<td>Gregory Lessing, Bsc</td>
</tr>
<tr>
<td>3.</td>
<td>Identify The Characteristics of Good Source Documentation</td>
<td>Thomas Lauffenburger, RN, CCRA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gregory Lessing, Bsc</td>
</tr>
<tr>
<td>4.</td>
<td>List Common Clinical Research Issues Most Often Identified During</td>
<td>Thomas Lauffenburger, RN, CCRA</td>
</tr>
<tr>
<td></td>
<td>Monitoring Visits and Strategies to Reduce Occurrences</td>
<td>Gregory Lessing, Bsc</td>
</tr>
<tr>
<td>5.</td>
<td>Describe The Process for Releasing a Report and the Options Available if the Report Appears Inaccurate</td>
<td>Thomas Lauffenburger, RN, CCRA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gregory Lessing, Bsc</td>
</tr>
<tr>
<td>6.</td>
<td>List The Criteria Used By NIAID Auditing Services Program for</td>
<td>Thomas Lauffenburger, RN, CCRA</td>
</tr>
<tr>
<td></td>
<td>Selecting Sites for Audits</td>
<td>Gregory Lessing, Bsc</td>
</tr>
<tr>
<td>7.</td>
<td>Open Discussion, Q&amp;A</td>
<td>Thomas Lauffenburger, RN, CCRA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gregory Lessing, Bsc</td>
</tr>
</tbody>
</table>
A5263 VERSION 2.0 START-UP SESSION

Tuesday, July 30, 2013, 8:00 a.m. – 10:00 a.m.

Co-Chairs: Margaret Borok-Williams, MD
University of Zimbabwe Parirenyatwa CRS

Susan Krown, MD
Cornell CRS

1. Protocol Version 2.0 Overview
2. Identification of Eligible Participants
3. Chemo Preparation
4. Vesicant Administration
5. Evaluating Kaposi’s Sarcoma Progression
6. Site Updates
7. Site Training Visits and Review of Activation Process

Note: An Oral Exam and Specimen Collection Training will be held on July 30th, 1:30-3:30 p.m. The training will include focus on A5263.
A5264 TEAM AND SITE SESSION

Tuesday, July 30, 2013, 10:00 a.m. – 11:00 a.m.

Chairs: Thomas Campbell, MD
University of Colorado Hospital CRS

Mina Hosseinipour, MD, MPH
University of North Carolina Lilongwe CRS

1. Screening/Enrollment Update
2. Site Supplement for Community Outreach and Recruitment
3. Data Management Issues
4. Independent Endpoint Review Committee (IERC) Overview and Feedback
5. Site Questions

Note: An Oral Exam and Specimen Collection Training will be held on July 30th, 1:30-3:30 p.m. The training will include focus on A5264.
A5288 START-UP TRAINING

Thursday, August 1, 2013, 2:00 p.m. – 3:30 p.m.

Co-Chairs: Beatriz Grinsztejn, MD, PhD
Fiocruz Therapeutic & Prevention HIV/AIDS CTU

Peter Ndimbirwe Mugyenyi, MD
Joint Clinical Research Center CRS

Co-Vice Chairs: Ann Collier, MD
University of Washington Clinical HIV Research Program CTU

Robert Salata, MD
Case CRS

1. Welcome and Introductions
   Beatriz Grinsztejn, MD, PhD
   Peter Ndimbirwe Mugyenyi, MD

2. Major changes from Letter of Amendment (LOA) #2
   a. Cohort Allocations
   b. Hair Sampling
   Beatriz Grinsztejn, MD, PhD
   Peter Ndimbirwe Mugyenyi, MD

3. Interactive Case Reviews
   Site Staff
   John Mellors, MD
   Carole Wallis, PhD

4. Overview of Hair Sampling
   Ann Collier, MD

5. CRF Revisions and Updates
   Linda Wieclaw, BS

6. Interactive Discussion: Cell Phone Based Adherence Intervention (CPI) Issues
   Site Staff
   Team

7. Questions and Answers
   Site Staff
   Team
A5314 TEAM-SITES START-UP TRAINING

Thursday, August 1, 2013, 8:00 a.m. – 10:00 a.m.

Co-Chairs:  Priscilla Hsue, MD  
University of California, San Francisco AIDS CRS

Judith Currier, MD, MSc  
University of California, Los Angeles CARE Center CRS

Co-Vice Chairs:  James H. Stein, MD  
Northwestern University CRS

Steven G. Deeks, MD  
University of California, San Francisco AIDS CRS

1. Welcome and Introduction  
Judith Currier, MD, MSc

2. Overview of Protocol  
Priscilla Hsue, MD

3. Brachial Artery Reactivity Testing Procedures  
James H. Stein, MD

4. Schedule of Evaluations  
Marti Farrough, BSN

5. Review of Study Specific Forms  
Dave Rusin, MT, ASCP

6. Pharmacy Issues  
Michelle Wildman, PharmD

7. Laboratory Issues  
LuAnn Borowski, MSc  
Brian Clagett

8. Site Questions/Comments  
All
A5315 START-UP SESSION

Wednesday, July 31, 2013, 8:00 a.m. – 9:00 a.m.

Co-Chairs: Deborah McMahon, MD
Pitts CRS

John Mellors, MD
University of Pittsburgh CTU

Co-Vice Chairs: Rajesh Gandhi, MD
Massachusetts General Hospital ACTG CRS

Michael Para, MD
The Ohio State University AIDS CRS

1. Welcome, Introduction, and Overview of Protocol Deborah McMahon, MD
2. Schedule of Evaluations Deborah Sutherland, RN, BSN, CCRP
3. Study Specific Forms Amy Mirand, PhD
4. Laboratory Issues Carmen Irizarry, MT, (ASCP)
5. Pharmacy Issues Katherine Shin, PharmD
6. Site Questions/Comments All
A5316 PROTOCOL TRAINING

Wednesday, July 31, 2013, 5:30 p.m. – 6:30 p.m.

Co-Chairs: Susan Cohn, MD, MPH
Northwestern University CRS

Kimberly Scarsi, PharmD, MS, BCPS
Northwestern University CRS

Co-Vice Chairs: Kristine Patterson, MD
University of North Carolina AIDS CRS

Carmen Zorrilla, MD
University of Puerto Rico CTU

1. Introduction
   Susan Cohn

2. Protocol Summary with Focus on GYN Procedures and Samples
   Kimberly Scarsi

3. Demonstration and GYN Training for A5316
   Carmen Zorrilla

4. Questions
   Susan Cohn
   Kimberly Scarsi
   Carmen Zorrilla
A5317 SITE START-UP TRAINING

Thursday, August 1, 2013, 1:30 p.m. – 3:00 p.m.

Co-Chairs:  Jordan E. Lake, MD
University of California, Los Angeles CARE Center CRS

Netanya G. Sandler, MD
University of Texas Medical Branch at Galveston

Co-Vice Chairs:  Judith Currier, MD, MSc
University of California, Los Angeles AIDS Prevention and Treatment CTU

Daniel C. Douek, MD, PhD
National Institutes of Health, Vaccine Research Center

1. Welcome
2. Brief Study Overview
3. Site Preparation
4. Reagent Startup Kits
5. Specimen Handling and Shipping
6. Biopsy Procedure Video
7. Questions & Answers
A5321 START-UP SESSION

Wednesday, July 31, 2013, 9:00 a.m. – 10:00 a.m.

Co-Chairs: Rajesh Gandhi, MD
Massachusetts General Hospital ACTG CRS
Deborah McMahon, MD
University of Pittsburgh CRS

1. Welcome and Introductions
Team and Sites

2. Update on Recruitment and Enrollment
   a. Selection of Subjects/Sites
      Raj Gandhi, MD
   b. Timeline for Enrollment
      Deb McMahon, MD

3. Brief Laboratory Processing Chart and Case Report
   Form (CRF) Review
   a. Study-specific Issues in LPC
      Joan Dragavon, MLM
   b. Data Sharing Between Studies (CRFs)
      Amy Mirand, PhD

4. Step 2 Discussion
   Team and Sites
   a. Site Participation
   b. Subject Selection and Consent
   c. Monitoring Plan
   d. Timeline

5. Open Forum for Questions
   Team and Sites
A5322 TEAM AND SITE TRAINING

Wednesday, July 31, 2013, 3:30 p.m. – 5:30 p.m.

Co-Chairs: Katherine Tassiopoulos, DSc, MPH
Statistical and Data Analysis Center

Frank Palella, Jr., MD
Northwestern University CRS

Co-Vice Chairs: Susan Koletar, MD
Ohio State University AIDS CTU

Babafemi Taiwo, MBBS, MD
Northwestern University CRS

1. Welcome and Introductions Kathy Tassiopoulos, DSc, MPH
2. Follow-up from Start-up Call Kathy Tassiopoulos, DSc, MPH
   Frank Palella, MD
3. Frailty Assessment Training Kristine Erlandson, MD
4. A5322 Laboratory Logistics Joan Dragavon, MLM
5. Question & Answer All Members
A5325 IPLEDGE PROGRAM AND A5330S SPECIMEN PROCESSING TRAINING SESSION

Monday, July 29, 2013, 11:00 a.m. – 12:00 p.m.

Co-Chairs: Douglas Kwon, MD, PhD
Massachusetts General Hospital ACTG CRS

Nina Lin, MD
Massachusetts General Hospital ACTG CRS

1. iPLEDGE Program
   a. What is It?
   b. Information for Prescribers, Pharmacists, and Patients
   c. Isotretinoin Treatment: Review of Common Side
   d. Effects and Monitoring
   e. Questions

2. Colonoscopy and Biopsies
   a. Overview of the Procedure
   b. Subject Procedure Preparation
   c. Procedure Risks and Potential Complications
   d. Specimen Collection, Processing and Shipping
   e. Questions