



**Annual ACTG Network Meeting  
June 22-26, 2015**

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## PLENARY SESSION I

**Tuesday, June 23, 2015, 3:30 p.m. – 6:30 p.m.**

**Chair:** Daniel Kuritzkes, MD  
ACTG Network Chair

**Vice Chairs:** Judith Currier, MD, MSc  
ACTG Network Vice Chair

Ian Sanne, MBBCH, FTP (SA)  
ACTG Network International Vice Chair

3:30	Welcome	Daniel Kuritzkes, MD
	NIAID: State of the Institute and Priorities in HIV Therapeutics Research	Anthony Fauci, MD
4:30	State of the ACTG	Daniel Kuritzkes, MD
4:45	Recognition of ACTG Service	Daniel Kuritzkes, MD Judith Currier, MD, MSc Ian Sanne, MBBCH, FTP
5:00	Presentation of 2015 ACTG Awards (5 minutes each)	
	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	Cynthia Firnhaber, MD, MS
	d. Donna Davis Community Award	Morenike Giwa Paul Klees Aaron Laxton Pamela Tshandu
5:20	Community Updates	
	a. Community Scientific Agenda (10 minutes)	Liz Barr
	b. Women's Enrollment Initiative (5 minutes)	Liz Barr
	c. Women's Outreach Worker Proposal (15 minutes)	Liz Barr Danielle Campbell
5:50	A5274 [REMEMBER (Empiric TB Tx )]	Mina Hosseinipour, MD

## PLENARY SESSION II

**Wednesday, June 24, 2015, 10:30 a.m.-12:30 p.m.**

**Co-Chairs:** Daniel Kuritzkes, MD  
ACTG Network Chair

Judith Currier, MD, MSc  
ACTG Network Vice Chair

### **New Clinical Trials Data Management System**

10:30 The New Data Management System and New Data Standards Marlene Cooper, MS

### **HIV Reservoirs and Viral Eradication TSG**

11:00 Update on A5321 (ACTG HIV Reservoirs Cohort) and A5341s (A5321 Sampling Substudy) Rajesh Gandhi, MD

11:15 Update on A5276s (Residual Viremia Substudy of A5001 [ALLRT]) Sharon Riddler, MD

11:30 Predictors of HIV Rebound after Treatment Interruption Jonathan Li, MD

### **Antiretroviral Therapy Strategies SC**

11:45 A5273 (2nd line ART in RLS) Primary Results Alberto La Rosa, MD

12:00 Cost-Effectiveness of Preventing AIDS Complications (CEPAC) Team: The Cost-Effectiveness and Budgetary Impact of a Two-Drug Dolutegravir-Lamivudine Regimen in the United States Paul Sax, MD

### **Tuberculosis TSG**

12:15 A5295/TBTC Study 34 (Xpert for MTB/RIF): Use of XPert MTB/RIF in Low TB Prevalence Settings Annie Luetkemeyer, MD

## PLENARY SESSION III

Thursday, June 25, 2015, 10:30 a.m. – 12:30 p.m.

**Co-Chairs:** Daniel Kuritzkes, MD  
ACTG Network Chair

Judith Currier, MD, MSc  
ACTG Network Vice Chair

### **End-organ Disease and Inflammation TSG**

10:30	A5303 (Bone, Immunologic, and Virologic Effects of an ARV Regimen)	Babafemi Taiwo MBBS, MD Todd T. Brown, MD, PhD
	A5260s (Substudy of A5257)	Grace McComsey, MD
	A5275 (Atorvastatin Biomarker Study) Preliminary Results	Daniel E. Nixon, MD, PhDDO

### **Hepatitis TSG**

11:10	A5327 (Sofosbuvir for Acute HCV)	Susanna Naggie, MD
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### **Neurology Collaborative Science Group**

11:22	A5271 (Neurocognitive Data)	Kevin Robertson, MD
	A5199 (International Neurological Study)	Kevin Robertson, MD

### **Co-infections and Malignancies Working Group and Women's Health Inter-network Scientific Committee**

11:48	A5282 (HPV Test-and-Treat) Baseline Data	Thandie Lungu, MBBS
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### **Oral HIV/AIDS Research Alliance**

12:00	A5265 (GV vs. Nystatin for OC )	Robert Salata, MD
	A5254 (Oral Assessment Validation Study)	Caroline H. Shiboski, DDS, MPH, PhD
	A5272 (Oral HPV Warts After ART)	Caroline H. Shiboski, DDS, MPH, PhD

## SYMPOSIUM I: TUBERCULOSIS (TB) BIOMARKERS

Wednesday, June 24, 2015, 1:30 p.m. – 3:30 p.m.

**Chair:** Richard Chaisson, MD  
Johns Hopkins University CRS

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

Diane Havlir, MD  
San Francisco Bay CTU

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|------|--|---------------------------------|
| 1:30 | Host Biomarkers of Protective Immunity, Diagnosis of Active Disease and Monitoring of Treatment Response | Gerhard Walzl, MBChB, MMed, PhD |
| 2:00 | Prospective Correlates of Risk of TB – Opportunities for Intervention                                    | Mark Hatherill, MD, MBChB       |
| 2:30 | Transcriptomics of <i>M. tuberculosis</i> During Treatment   | Gary Schoolnik, MD              |
| 3:00 | Persisters during TB treatment   | Andreas Diacon, MD, PhD         |

## SYMPOSIUM II

### END-ORGAN DISEASE AND INFLAMMATION TRANSFORMATIVE SCIENCE GROUP AND HIV RESERVOIRS AND VIRAL ERADICATION TRANSFORMATIVE SCIENCE GROUP

Thursday, June 25, 2015, 8:00 a.m. – 10:00 a.m.

**Session Co-Chairs:** Joseph J. Eron, Jr, MD  
University of North Carolina Global HIV Prevention and Treatment CTU

Rajesh Gandhi, MD  
Massachusetts General Hospital CRS

Catherine Godfrey, MD  
Division of AIDS, NIAID, NIH

Peter W. Hunt, MD  
University of California, San Francisco HIV/AIDS CRS

Turner Overton, MD  
Alabama CRS

8:00	Innate Immunity and its Potential Role in HIV Eradication	Galit Alter, PhD
8:25	Discussion	All Participants
8:40	The Role of IFN-induced Host Restriction Factors and the HIV Reservoir	Satish Pillai, PhD
9:05	Discussion	All Participants
9:20	TLR7 Agonists and Broadly Neutralizing Antibody Therapy for HIV	Romas Gelezuinas, PhD
9:45	Discussion	All Participants

**ANTIRETROVIRAL THERAPY STRATEGIES SUBCOMMITTEE (ARTS SC)  
BUSINESS SESSION**

**Wednesday, June 24, 2015, 8:00 a.m. – 10:00 a.m.**

**Chair:** Babafemi Taiwo, MBBS, MD  
Northwestern University CRS

**Vice Chair:** Raphael Landovitz, MD  
University of California, Los Angeles CARE Center CRS

1. Welcome and Introductions ARTS SC Leadership
  
2. ARTS SC Studies Under Development Babafemi Taiwo, MBBS, MD
  - a. A5353 (Dolutegravir Plus Lamivudine in Treatment Naïve HIV-1 Participants) Karen Tashima, MD
  
  - b. Long Acting Antiretroviral Therapy Treatment Regimens in Challenging Populations Carole Wallis, MD
  
  - c. Mechanism of PI Resistance in A5273 (2nd Line ART in ALS) Samples
  
3. Potential Studies Frank Palella, MD
  - a. Utilizing the Database for A5322 (Aging, HIV Infection & Inflammation)
  
  - b. Monoclonal Antibodies Workshop Summary Sudhir Penugonda, MD  
Max Lataillade, MD
  
  - c. Bristol-Myers Squibb AI and MI

**END-ORGAN DISEASE AND INFLAMMATION  
TRANSFORMATIVE SCIENCE GROUP  
THINK TANK**

**Wednesday, June 24, 2015, 4:00 p.m. – 6:00 p.m.**

**Chair:** Peter W. Hunt, MD  
University of California, San Francisco HIV/AIDS CRS

**Vice Chair:** Turner Overton, MD  
Alabama CRS

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|------|--|---|
| 4:00 | Long-term Impact of Highly Active Antiretroviral Therapy and Inflammatory Diseases in Resource-limited Settings      | Nagalingeswaran Kumarasamy, MBBS, PhD                                 |
| 4:15 | A5322 (Aging, HIV Infection and Inflammation) Clinical Event Rates through the First Year of Follow-up               | Katherine Tassiopoulos, ScD, MPH                                      |
| 4:30 | HIV Microbiome Meeting Summary   | Brett Williams, MD  |
| 4:45 | The Sordid Affair between CMV and HIV  | Sara Gianella-Wiebel, MD  |
| 5:00 | CMV Antibody Titer as a Predictor of HIV-related Non-AIDS defining Outcomes in Virologically Suppressed HIV+ Persons | Aimee Hodowanec, MD   |
| 5:15 | Pro-inflammatory Lipids in HIV   | Nicholas Funderburg, PhD<br>Guest NHLBI Moderator: Nehal N. Mehta, MD |
| 5:35 | HIV, Inflammation, and Chronic Pulmonary Diseases: Research Opportunities within the ACTG                            | Kristina Crothers, MD   |



**HEPATITIS TRANSFORMATIVE SCIENCE GROUP  
THINK TANK**

**Thursday, June 25, 2015, 4:00 p.m. – 6:00 p.m.**

**Chair:** Raymond Chung, MD  
Massachusetts General Hospital CRS

**Vice Chair:** Mark Sulkowski, MD  
Johns Hopkins University CRS

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|--|---|
| 1. Welcome and Update  | Raymond Chung, MD<br>Mark Sulkowski, MD |
| 2. Hepatitis B Virus (HBV) Cure Discussion                   | Tim Block, PhD                          |
| 3. HBV Core as a Target and NVR 3-778 as a First Development | Klaus Klumpp, PhD                       |
| 4. NS5A Resistance and its Implications                      | David Wyles, MD                         |
| 5. Roundtable Discussion                                     | HEP TSG Members                         |

**HIV RESERVOIRS AND VIRAL ERADICATION  
TRANSFORMATIVE SCIENCE GROUP THINK TANK**

**Thursday, June 25, 2015, 3:00 p.m. – 6:00 p.m.**

**Chair:** Joseph Eron, MD  
University of North Carolina Global HIV Prevention and Treatment CTU

**Vice Chair:** Rajesh Gandhi, MD  
Massachusetts General Hospital CRS

- 3:00 Introduction to Think Tank Goals Joseph Eron, MD
- Year in Review: Protocols (5 minutes presentation; 2 minutes discussion) (3:10-4:15)**
- 3:10 Update on A5308 (ART for HIV Controllers) Jonathan Li, MD
- 3:17 Update on A5315 (Romidepsin to Awaken HIV) Deborah McMahon, MD
- 3:24 Update on A5321 (Reservoirs in Long-Term ART) and A5341s (Intensive Reservoir Sampling, A5321 Substudy) Rajesh Gandhi, MD
- 3:31 Update on A5326 (Anti-PD-L1 Antibody in HIV-1) Joseph Eron, MD
- 3:38 Update on A5337 (Sirolimus Study) Catherine Godfrey, MD
- 3:45 Update on A5342 (Impact of VRC01 on HIV Persistence) Christine Durand, MD
- 3:52 Update on A5345 (HIV Rebound & Control Biomarkers) Jonathan Li, MD
- 3:59 Update on A5354 (Effect of ART Initiated During Acute AHI on Measures of HIV-1 Persistence and Immune Responses) Jintanat Ananworanich, MD
- 4:06 Reservoir Assay Working Group Update John Mellors, MD
- 4:15 BREAK
- Combination Cure Strategies (4:25-5:00)**
- 4:25 Outline of Study Design Questions for Combination Cure Strategies and Overview of Current Combination Therapy Studies Joseph Eron, MD  
Rajesh Gandhi, MD
- 4:45 Impact of HDAC Inhibitors on the Immune System R. Brad Jones, PhD
- 5:00 Discussion
- New Horizons (15 minutes presentation; discussion to follow) (5:15-5:30)**
- 5:15 Combination Interventions of HIV Reservoir Reduction; Clinical Study Design Jintanat Ananworanich, MD  
Trevor Crowell, MD
- 5:30 Discussion

**TUBERCULOSIS (TB) TRANSFORMATIVE SCIENCE GROUP  
THINK TANK**

**Wednesday, June 24, 2015, 4:00 p.m. – 6:00 p.m.**

**Chair:** Richard Chaisson, MD  
Johns Hopkins University CRS

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

Diane Havlir, MD  
San Francisco Bay CTU

4:00	Welcome and Update	Richard Chaisson, MD
4:05	TB Infection Control	Susan Swindells, MBBS
4:10	A5274 [REMEMBER (Empiric TB Tx)]: An Initial Look at Select Secondary Outcomes	Mina Hosseinipour, MD
4:30	Designing the Next Generation of TB Trials – Lessons from the Field	Susan Dorman, MD
5:00	TB Household Cohort Studies – Partners In Health Peru	Mercedes Becerra, ScD
5:30	Latent TB Infection Treatment: Next Steps in Addressing Research Gaps	Diane Havlir, MD Constance Benson, MD

**NEUROLOGY COLLABORATIVE SCIENCE GROUP (NEURO CSG)  
THINK TANK**

**Wednesday, June 24, 2015, 8:00 a.m. – 10:30 a.m.**

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

**Vice Chair:** Scott Letendre, MD  
University of California, San Diego AntiViral Research Center CRS

**Part I: Business Session**

8:00	Welcome, Introduction and Goals	Neuro CSG Chairs
8:05	Lumbar Puncture Video Working Group Update	Ronald Ellis, MD Andrew Kaytes
8:15	Neurology Master Protocol Update	Scott Letendre, MD

**Part II: Think Tank**

8:30	HIV Neurotherapeutics in Development: Dimethyl Fumarate	Dennis Kolson, MD
8:55	HIV Neurotherapeutics in Development: Intranasal Insulin	Norman Haughey, MD
9:30	Future Priorities and Plans for Domestic and International ACTG Neuro Studies	Scientific Committee Leadership Panel and Group Discussion

**WOMEN'S HEALTH INTER-NETWORK SCIENTIFIC COMMITTEE (WHISC)  
SESSION**

**Thursday, June 25, 2015, 1:30 p.m. – 3:30 p.m.**

**Chair:** Cynthia Firnhaber, MD, MS, DTM & H  
University of Witwatersrand Helen Joseph CRS

**Vice Chair:** Elizabeth Connick, MD  
University of Colorado Hospital CRS

1. Welcome Cynthia Firnhaber, MD, MS, DTM & H
2. Tuberculosis (TB) and Women's Health
  - a. Screening Pregnant Women for TB Richard Chaisson, MD
  - b. Improving Screening for Women with TB All Participants
  - c. Pregnancy in Women on MDR-TB Drugs Francesca Conradie, MBChB
  - d. Contraception Needs in Women with TB All Participants
3. Recruiting Women into Studies Liz Barr, MS  
Michelle Cespedes, MD
4. Recruiting Pregnant Women into Studies - "Just Say No to No" Karin Klingman, MD
5. REPRIEVE (A5332) Study: Gender/Sex Issues in CVD Risk and Risk Reduction Markella Zanni, MD

## CO-INFECTIONS AND MALIGNANCIES WORKING GROUP BUSINESS SESSION

Thursday, June 25, 2014, 8:00 a.m. – 10:00 a.m.

**Chair:** Timothy Wilkin, MD, MPH  
Weill Cornell Chelsea CRS

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|---|------------------------------------|
| 1. Where Are We Now? Brief Summary of Ongoing Projects                  | Timothy Wilkin, MD, MPH            |
| 2. A5297 (Subclinical Parasitemia)                                      | A5297 Leadership                   |
| 3. A5263 (Advanced KS Chemo) and A5264 (Limited KS Study)               | A5263 and A5263 Leadership         |
| 4. Gene Xpert High Risk Human Papillomavirus Test in HIV-Infected Women | Cynthia Firnhaber, MD, MS, DTM & H |
| 5. Open Discussion  | All Members                        |

## DATA AND QUALITY MANAGERS BUSINESS SESSION

Wednesday, June 24, 2015, 7:00 a.m. – 8:00 a.m.

**Co-Leaders:** James Gavel, BS  
University of Pittsburgh CRS

Vuyokazi Jezile, BBS  
University of the Witwatersrand Helen Joseph (WITS HJH) CRS

Julia Wagner, MPH  
Weill Cornell Chelsea CRS

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|---|----------------------|
| 1. Welcome and Introductions                | All Members          |
| 2. Overview of Data Managers Mentor Program | Vuyokazi Jezile, BBS |
| 3. Documentation Tool Sharing               | All Members          |
| 4. Solicitation of Future Call Agenda Items | All Members          |
| 5. Open Discussion                          | All Members          |

**DATA MANAGEMENT COMMITTEE  
BUSINESS SESSION**

**Thursday, June 25, 2015, 1:00 p.m. – 2:00 p.m.**

**Co-Chairs:** Robert Murphy, MD  
Chicago CTU

Doug Kitch, MS  
ACTG Statistical and Data Analysis Center

Lu (Summer) Zhang, PhD  
ACTG Statistical and Data Analysis Center

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|---|-------------------|
| 1. Welcome and Introductions              | Robert Murphy, MD |
| 2. Clinical Trials Data Management System | Robert Murphy, MD |
| 3. Open Discussion                        | All Members       |



## PHARMACY SUBCOMMITTEE BUSINESS SESSION

Tuesday, June 23, 2015, 1:00 p.m. – 3:00 p.m.

**Chair:** Michael Royal, RPh  
Washington University Therapeutics CRS

**Vice Chair:** Grady Douglas, RPh  
Houston AIDS Research Team (HART) CRS

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| 1. Welcome and Introductions           | Michael Royal, PPh                       |
| 2. Overview of Subcommittee Activities | Michael Royal RPh                        |
| 3. Future Projects                     | Michael Royal, RPh<br>Grady Douglas, RPh |
| 4. Open Discussion                     | All Attendees                            |

**PROTOCOL DEVELOPMENT AND IMPLEMENTATION  
SUBCOMMITTEE (PDISC)  
BUSINESS SESSION**

**Wednesday, June 24, 2015, 1:30 p.m. – 2:30 p.m.**

**Chair:** Kathy Watson, RN  
Ohio State University CRS

**Vice Chair:** Asuman Ssentamu, BSN, MBA  
Joint Clinical Research Center (JCRC)/Kampala CRS

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|--|---|
| 1. Welcome and Introductions   | Kathy Watson, RN<br>Asuman Ssentamu, BSN, MBA |
| 2. Review of the Protocol Development Process                                    | Evelyn Hogg, BA<br>Barbara Bastow, BSN        |
| 3. Update on PDISC Tools   | Kathy Watson, RN                              |
| 4. Group Discussion  | All   |
| a. Expanding Educational Support for Current Field<br>Representatives Discussion |   |
| b. Challenges for International Field<br>Representatives                         |   |
| c. Teleconference/Web Meeting Plans  |   |

**SITE MANAGEMENT AND CLINICAL CARE COMMITTEE (SMCCC)  
BUSINESS SESSION**

**Wednesday, June 24, 2015, 9:00 a.m. – 10:00 a.m.**

**Chair:** David Currin, RN, ACRN, CCRC  
University of North Carolina Chapel Hill CRS

**Vice Chair:** Ilene Wiggins, RN  
Johns Hopkins University CRS

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|----|---|---|
| 1. | Welcome and Introductions                     | David Currin, RN, ACRN, CCRC<br>Ilene Wiggins, RN |
| 2. | Overview and Mission of the Subcommittees     | Subcommittee Leaderships                          |
| 3. | Subcommittees' Goals for the Next 6-12 Months | Subcommittee Leaderships                          |
| 4. | Subcommittees' Restructuring Proposal         | All Participants                                  |
| 5. | SMCCC and Subcommittees' Goals and Plans      | All Participants                                  |

**SITE OPERATIONS SUBCOMMITTEE (SOS)  
BUSINESS SESSION**

**Wednesday, June 24, 2015, 2:30 p.m. – 3:30 p.m.**

**Chairs:** Suzanne Fiorillo, MSPH  
University of Colorado Hospital CRS

**Vice Chair:** Jane Baum, RN  
Case CTU

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|---|---|
| 1. Welcome and Introductions                            | Suzanne Fiorillo, MSPH                  |
| 2. Accomplishments for 2014-2015                        | Suzanne Fiorillo, MSPH<br>Jane Baum, RN |
| 3. Ongoing Projects, Goals and Objectives for 2015-2016 | Suzanne Fiorillo, MSPH<br>All Members   |
| 4. Open Discussion                                      | All Members                             |

**UNDERREPRESENTED POPULATIONS COMMITTEE (UPC)  
BUSINESS SESSION**

**Thursday, June 25, 2015, 3:30 p.m. – 4:30 p.m.**

**Chair:** Michelle Cespedes, MD, MS  
Columbia Physicians & Surgeons (P&S) CRS and  
Mount Sinai St. Luke's Roosevelt - Spencer Cox Center for Health: Samuels  
Clinic CRS

**Vice Chair:** Jose Castillo-Mancilla, MD  
University of Colorado Hospital CRS

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|---|--------------------------------------|
| 1. Welcome and Introductions  | Michelle Cespedes, MD, MS            |
| 2. Minority HIV Investigator Mentoring Program  |                                      |
| a. Introduction of the 2015 – 2016 awardees   | Michelle Cespedes, MD, MS            |
| b. Presentation by Current Award Recipients   | Bisrat Abraham, MD<br>Jose Bazan, MD |
| c. Proposed Changes to Eligibility Criteria   | Michelle Cespedes, MD, MS            |
| 3. Overview of the Community Scientific Subcommittee/<br>Women's Health Inter-network Scientific Committee/<br>UPC Women's Outreach Worker Proposal | Michelle Cespedes, MD, MS            |
| 4. State of the UPC   | Michelle Cespedes, MD, MS            |
| a. Review of Data over the  |                                      |
| b. Past Year Priorities   |                                      |
| c. Future Directions  |                                      |
| 5. Open Discussion  | All Members                          |

## COMMUNITY SCIENTIFIC SUBCOMMITTEE (CSS) BUSINESS SESSION

Friday, June 26, 2015, 8:00 a.m. – 10:00 a.m.

**CSS Co-Chairs:** Pamela Tshandu  
University of Witwatersrand Helen Joseph CRS

Aaron Laxton  
Washington University Therapeutics CRS

CSS Participation Discussion and New Member  
Solicitations

Pamela Tshandu  
Aaron Laxton

# GLOBAL COMMUNITY ADVISORY BOARD (GCAB) SESSION I

Monday, June 22, 2015, 9:00 a.m. – 12:00 p.m.

**GCAB Co-Chairs:** Morenike Giwa  
Houston AIDS Research Team CRS

Paul Klees  
University of California, San Francisco HIV/AIDS CRS

**CSS Co-Chairs:** Pamela Tshandu  
University of the Witwatersrand Helen Joseph CRS

Aaron Laxton  
Washington University Therapeutics CRS

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|---|--|
| 1. Welcome and Introductions                        | Morenike Giwa<br>Paul Klees                        |
| 2. CAB Presentations                                | Zanele Gwamanda<br>Lamont Holley<br>Modiko Moleofi |
| 3. Early Antiretroviral Therapy - CUREiculum Module | Karine Dube  |

## GLOBAL COMMUNITY ADVISORY BOARD (GCAB) SESSION II

Monday, June 22, 2015, 1:00 p.m. – 6:00 p.m.

**GCAB Co-Chairs:** Morenike Giwa  
Houston AIDS Research Team CRS

Paul Klees  
University of California, San Francisco HIV/AIDS CRS

**CSS Co-Chairs:** Pamela Tshandu  
University of the Witwatersrand Helen Joseph CRS

Aaron Laxton  
Washington University Therapeutics CRS

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|---|--|
| 1. Monoclonal Antibodies Workshop Report            | Angel Hernandez  |
| 2. Community Interactive                            | Morenike Giwa<br>Paul Klees                            |
| 3. Preventing Patient Burnout                       | Michael C. Royal R.Ph.<br>Grady G. Douglas B.S., R.Ph. |
| 4. How to Read a Protocol                           | Jeffrey T. Schouten M.D., J.D.                         |
| 5. Community Scientific Agenda Community Discussion | Liz Barr   |
| 6. Micro-minority Issues in Community               | Danielle Campbell                                      |
| 7. GCAB Subcommittees                               | Lionel Hillard   |
| 8. GCAB Elected Positions Overview                  | Morenike Giwa<br>Paul Klees                            |



## GLOBAL COMMUNITY ADVISORY BOARD (GCAB) SESSION III

Tuesday, June 23, 2015, 9:00 a.m. – 12:00 p.m.

**GCAB Co-Chairs:** Morenike Giwa  
Houston AIDS Research Team CRS

Paul Klees  
University of California, San Francisco HIV/AIDS CRS

**CSS Co-Chairs:** Pamela Tshandu  
University of the Witwatersrand Helen Joseph CRS

Aaron Laxton  
Washington University Therapeutics CRS

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|--|---|
| 1. Tuberculosis Priorities and Studies for ACTG and IMPAACT Networks | Amita Gupta M.D.                              |
| 2. Neurology Update  | Scott L. Letendre M.D.                        |
| 3. Staff/Community Interactive – Contraception Guidelines            | Karin Klingman M.D.<br>Catherine Godfrey M.D. |

## GLOBAL COMMUNITY ADVISORY BOARD (GCAB) SESSION IV

Tuesday, June 23, 2015, 1:00 p.m. – 3:00 p.m.

**GCAB Co-Chairs:** Morenike Giwa  
Houston AIDS Research Team CRS

Paul Klees  
University of California, San Francisco HIV/AIDS CRS

**CSS Co-Chairs:** Pamela Tshandu  
University of the Witwatersrand Helen Joseph CRS

Aaron Laxton  
Washington University Therapeutics CRS

1. Randomized Trial to Prevent Vascular Events in HIV – REPRIEVE (A5332) Steven K. Grinspoon M.D.  
Carl J. Fichtenbaum M.D.
2. Bone Complications of HIV and Its Therapy Philip Grant, M.D.

## GLOBAL COMMUNITY ADVISORY BOARD (GCAB) SESSION V

Friday, June 26, 2015, 12:00 p.m. – 3:00 p.m.

**GCAB Co-Chairs:** Morenike Giwa  
Houston AIDS Research Team CRS

Paul Klees  
University of California, San Francisco HIV/AIDS CRS

**CSS Co-Chairs:** Pamela Tshandu  
University of the Witwatersrand Helen Joseph CRS

Aaron Laxton  
Washington University Therapeutics CRS

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| 1. Community Awards                              | Morenike Giwa<br>Paul Klees                            |
| 2. ACTG Update                                   | Ian Sanne, MBBCH, FTP (SA)                             |
| 3. CSS and GCAB Committee Representative Reports | TSG, Science and Resource<br>Committee Representatives |
| 4. Election Announcements and CSS solicitations  | GCAB and CSS Co-Chairs                                 |

**LABORATORY TRAINING:  
FUTURE DIRECTIONS AND PROGRESS OF THE  
ACTG NETWORK LABORATORY CENTER**

**Monday, June 22, 2015, 9:00 a.m. – 11:00 a.m.**

**Chair:** Robert Coombs, MD, PhD  
University of Washington AIDS Clinical Trials Unit CRS

9:00	Introduction and Welcome	Robert Coombs, MD, PhD
9:05	Update on Centralizing HIV Viral Load Testing for Domestic Trials	Robert Coombs, MD, PhD
9:10	Plans for Acute Infection Studies/Changes in HIV Diagnosis Algorithm	Robert Coombs, MD, PhD
9:20	Laboratory in a Tube (LIAT) Field Evaluation Pilot Program	Wendy Stevens, MD
9:35	Update on the Xpert MTB/RIF Quality Program and the Expansion of GeneXpert's Testing Profile to HIV and HPV	Lesley Scott, PhD
10:05	Pathology External Quality Assurance Update	Catherine Godfrey, MD
10:20	Update on the New Virology Quality Assurance Efforts in Development of EQA Programs	Cheryl Jennings, BS James Bremer, PhD
	a. Brief Overview of Hepatitis	
	b. Change in Roche HIV-1 Baseline	
	c. Trends in 200/mL Copy Control	
10:50	Questions and Answers/Closing	

**LABORATORY TRAINING:  
TUBERCULOSIS HARMONIZATION – A SESSION WITH THE TUBERCULOSIS  
TRANSFORMATIVE SCIENCE GROUP’S  
MYCOBACTERIOLOGY LABORATORY WORKING GROUP**

**Monday, June 22, 2015, 11:00 a.m. – 1:00 p.m.**

**Chair:** Robert Coombs, MD, PhD  
University of Washington AIDS Clinical Trials Unit CRS

11:00	Introduction and Welcome	Robert Coombs, MD, PhD
11:05	Microbiology 101 for Clinical Trial Coordinators	Kathleen Eisenach, PhD
11:30	Standard Operating Procedure Harmonization Guides and Update on the Harmonization Process	Anne-Marie Demers, MD
11:55	Laboratory and Site Requirements for A5349/TBTC Study 31 (Rifapentine-containing Tuberculosis Treatment Shortening Regimens)	Anne Purfield, PhD
12:20	Questions & Answers	
12:45	Closing	

**LABORATORY TRAINING:  
INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA)  
SHIPPING TRAINING - WITH SPECIAL TOPICS**

**Monday, June 22, 2015, 1:30 p.m. – 5:00 p.m.**

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|------|--|--|
| 1:30 | Introduction to IACO/IATA, US DOT Dangerous Goods Shipping                                   | David Shugarts, MA<br>Christopher Lane |
|      | a. Category B Infectious Substances Shipping   |  |
|      | b. ACTG Protocol Shipping -Biomedical Repository (BRI) Shipping and Problem Shipping Scoring |  |
|      | c. Category A Infectious Substance Shipping  |  |
|      | d. Liquid Nitrogen Dry Shipper Demonstration   |  |
|      | e. Certification Test  |  |
| 4:40 | Questions and Answers  | John Ward                              |
| 4:55 | Closing  |  |

# INTERNATIONAL TUBERCULOSIS SPECIALTY LABORATORIES (ITBSL) CORE BREAKOUT SESSION

**Monday, June 22, 2015, 3:00 p.m. – 5:00 p.m.**

**Chair:** Andreas Diacon, MD, PhD  
TASK Applied Science CRS  
CCTR UCT and SU Consortium ITBSL

- 3:00 Introduction and Welcome Andreas Diacon, MD, PhD
- 3:05 Update from ACTG/IMPAACT/HVTN IBTSL Centre for Clinical Tuberculosis Research, University of Cape Town, and Stellenbosch University Consortium
- 3:20 Connecting the ITBSLs/ Future Projects Brainstorming
- a. Setup of Future Projects - Development of Techniques Useful in Clinical Trials Independent of Drug Type and Participant Demographics.
  - b. Plans for Future Communications
- 4:50 Wrap-Up Discussion

**LABORATORY TRAINING:  
LABORATORY TECHNOLOGISTS COMMITTEE TRAINING SESSION**

**Monday, June 22, 2015, 5:30 p.m. – 6:30 p.m.**

**Chair:** Cheryl Jennings, BS  
Rush University CRS

**Co-Vice Chairs:** Christopher Lane  
University of Rochester Adult HIV  
Therapeutic Strategies Network CRS

David Shugarts, MA  
University of Colorado Hospital CRS

**Ex-Officio Chair:** Joan Dragavon, MLM  
University of Washington AIDS Clinical Trials Unit CRS

5:30	Introduction and Welcome	Cheryl Jennings, BS David Shugarts, MA
5:40	The Laboratory Processing Chart : A Refresher and a Quest for Improvements	Christopher Lane Joan Dragavon, MLM
5:50	Laboratory Data Management System Pre-Loads for Clinical Trial Processing	
6:00	Ways to Communicate New Features, Novel Processes and Other Critical Protocol Information to the Sites/Laboratories, Including Mechanisms for Feedback	
6:10	Managing Blood Volumes for Clinical Trial Protocols	
6:20	Questions and Answers/Closing	



**LABORATORY TRAINING:  
LDMS-LABORATORY TECHNOLOGISTS COMMITTEE INTERACTIVE**

**Tuesday, June 23, 2015, 8:00 a.m. – 10:00 a.m.**

**Moderator:** Howard Gutzman, BS  
ACTG Data Management Center

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|------|---|--------------------|
| 8:00 | Introduction and Welcome                            | Howard Gutzman, BS |
| 8:05 | Laboratory Data Management System (LDMS) Version 10 |                    |
| 8:30 | Preloads and Condition Codes                        |                    |
| 8:55 | LDMS for the Web                                    |                    |
| 9:20 | LDMS Website  |                    |
| 9:45 | Questions and Answers/Closing                       |                    |

## SPECIALTY LABORATORY DIRECTORS' BUSINESS SESSION

Tuesday, June 23, 2015, 10:30 a.m. – 11:30 a.m.

**Chair:** Robert Coombs, MD, PhD  
University of Washington AIDS Clinical Trials Unit CRS

10:30	Introduction and Welcome	Robert Coombs, MD, PhD
10:35	Preparation for the 2015 Progress Report	Robert Coombs, MD, PhD
10:45	Performance Evaluation Committee Monitoring/Utility for Assay Development	Robert Coombs, MD, PhD
10:55	Laboratory Technologists Committee Update	LTC Leadership
11:05	Clinical Pharmacology Quality Assurance Update	Gene Morse, PharmD
11:15	Update from the Cape Town International Pharmacology Specialty Laboratory	Lubbe Wiesner, PhD
11:25	Questions and Answers/Closing	

**LABORATORY TRAINING:  
HEPATITIS, GENOTYPING, RNA/DNA, DETECTION/QUANTITATION AND  
EXTERNAL QUALITY ASSURANCE**

**Tuesday, June 23, 2015, 11:30 a.m. – 1:00 p.m.**

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|-------|---|--|
| 11:30 | Introduction and Welcome  |  |
| 11:35 | Hepatitis Assays for Genotyping and RNA/DNA<br>Detection/Quantitation | William Meyer, PhD<br>Meghan Starolis, PhD |
| 12:05 | External Quality Assurance Support for Hepatitis Assay<br>Training    | Cheryl Jennings, BS<br>James Bremer, PhD   |
| 12:35 | Questions and Answers   |  |
| 12:55 | Closing   |  |

**IMMUNOLOGY SPECIALTY LABORATORIES (ISL) CORE  
BREAKOUT SESSION**

**Tuesday, June 23, 2015, 11:30 a.m. – 1:30 a.m.**

**Chair:** Michael Lederman, MD  
Case Western Reserve University ISL  
Case CTU

11:30	Introduction and Welcome	Michael Lederman, MD
11:35	Luminex Update	Greg Sempowski, PhD
11:50	Case ISL: Cellular Mechanisms of CV Risk in HIV Infection	Michael Lederman, MD
12:15	Rush ISL: Innate Lymphoid Cells in Tonsil and Gut Tissue	Alan Landay, PhD
12:40	Pittsburgh ISL: Multiple Inhibitory Receptor Expression in ART-Suppressed HIV-1(+) Individuals	Bernard Macatangay, MD Charles Renaldo, PhD
1:05	SUN-IRG: TB Biomarker Research at SUN Immunology Research Group	Andre Loxton, PhD
1:30	Questions and Answers/Closing	

**PHARMACOLOGY SPECIALTY LABORATORIES (PSL) CORE  
BREAKOUT SESSION**

**Tuesday, June 23, 2015, 11:45 a.m. – 1:45 p.m.**

**Chair:** Gene Morse, PharmD  
State University of New York at Buffalo PSL  
University of Rochester Adult Therapeutic Strategies Network CRS

11:45	Introduction and Welcome	Gene D. Morse, PharmD
11:50	Update on New Transformative Science Group Protocols with PSL Assignments	Gene D. Morse, PharmD
12:10	Developmental PSL Activity and Online Performance Evaluation Committee Report	Gene D. Morse, PharmD
12:30	Clinical Pharmacology Quality Assurance Proficiency Testing	Robin DiFrancesco, MT, (ASCP), MBA.
12:50	International PSL Updates	Lubbe Wiesner, PhD, Charles Maponga, PharmD
1:10	Questions and Answers	
1:40	Closing	

**LABORATORY TRAINING:  
BEST PRACTICES FOR PROCESSING SPECIMENS FOR FUNCTIONAL ASSAYS**

**Tuesday, June 23, 2015, 2:00 p.m. – 3:00 p.m.**

**Chair:** Robert Coombs, MD, PhD  
University of Washington AIDS Clinical Trials Unit CRS

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|------|--|------------------------------------|
| 2:00 | Introduction and Welcome   |                                    |
| 2:05 | External Quality Assurance Improves Both Domestic and International Laboratory Performance for PBMC Cryopreservation | Robert Coombs, MD, PhD             |
| 2:20 | Leukapheresis Processing and Laboratory Improvements Due to the External Quality Assurance Program                   | Joan Dragavon, MLM                 |
| 2:35 | Peripheral Blood Mononuclear Cells Processing Review   | Sarah Keinonen<br>Raul Louzao, MPA |
| 2:50 | Q&A/Closing  |                                    |

**FUTURE TUBERCULOSIS (TB) TECHNOLOGY AND  
EXTERNAL QUALITY ASSURANCE (EQA)  
BUSINESS SESSION**

**Wednesday, June 24, 2015, 8:00 a.m. – 10:00 a.m.**

**Facilitators:** Marco Schito, PhD  
Critical Path Institute

Marinus Barnard, PhD  
Task Applied Science CRS

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|------|---|--------------------------|
| 8:00 | Introduction and Welcome  |                          |
| 8:05 | ReSeqTB: A Collaborative Effort to Provide a Centralized Global TB Database | Marco Schito, PhD        |
| 8:25 | Ghost Cells - Gram Neutral Acid Fast Bacilli                                | Andreas Diacon, MD, PhD  |
| 8:45 | Isothermal Microcalorimetry for TB  | Olivier Braissant, PhD   |
| 9:05 | EQA for New Anti-TB Drugs   | Daniela Cirillo, MD, PhD |
| 9:25 | Mycobacterium Microbank Validation Update                                   | Peter Meewes             |
| 9:35 | Questions and Answers   |                          |
| 9:50 | Closing   |                          |

**CLINICAL PHARMACOLOGY ADVISORY GROUP  
BUSINESS SESSION**

**Wednesday, June 24, 2015, 12:30 p.m. – 1:30 p.m.**

**Chair:** Gene Morse, PharmD  
State University of New York at Buffalo Pharmacology Specialty Laboratory  
University of Rochester Adult Therapeutic Strategies Network CRS

12:30	Introduction and Welcome	Gene D. Morse, PharmD
12:35	Review of Current ACTG Protocols with Clinical Pharmacologists	Gene D. Morse, PharmD
12:45	Integration of Physiological-base PK into ACTG Protocols	Gene D. Morse, PharmD
12:55	Clinical Pharmacology Quality Assurance Program Update	Robin DiFrancesco, MT, (ASCP), MBA
1:05	Clinical Pharmacology Tutorial Update	Kelly M. Tooley, BS, MEd
1:15	Questions and Answers	
1:25	Closing	



**VIROLOGY SPECIALTY LABORATORIES (VSL),  
GENOTYPING LABORATORIES, AND GENOMICS CORE  
BREAKOUT SESSION**

**Thursday, June 25, 2015, 12:30 p.m. – 2:30 p.m.**

**Chair:** John Mellors, MD  
University of Pittsburgh VSL  
Pitt-Ohio State CTU

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|-------|--|------------------------|
| 12:30 | Introduction and Welcome   | John Mellors, MD       |
| 12:35 | New Scientific Updates: Statistical and Data Analysis Center - IUPM Calculations and NWCS 367 (Decay Rate of Archived K103N from Individuals with a History of K103N Viremia)  | Ron Bosch, PhD         |
| 12:50 | New Scientific Updates: Vanderbilt DNA Resources Core - Update on Phenome-Wide Association Studies (PheWAS) in Clinical Trials   | David Haas, PhD        |
| 1:05  | International Genotyping Laboratories Update: Feedback on the Integrase Validation Across the Laboratories, Plans to Move Forward into <i>env</i> Sequencing for PI Resistance | Carole Wallis, PhD     |
| 1:20  | New Scientific Updates: Harvard University ACTG VSL  | Jonathan Li, MD        |
| 1:35  | New Scientific Updates: University of Washington ACTG VSL  | Robert Coombs, MD, PhD |
| 1:50  | New Scientific Updates: University of Pittsburgh ACTG VSL  | John Mellors, MD       |
| 2:05  | Questions and Answers/Closing  |                        |

**ABBOTT M2000 MONITORING WEB APPLICATION DEMO ROOM**

**Thursday, June 25, 2015, 3:00 p.m. – 4:00 p.m.**

**Chair:** Robert Coombs, MD, PhD  
University of Washington AIDS Clinical Trials Unit CRS

3:00 Introduction and Welcome

3:05 Demonstration of Abbott mView Program

Laura Comilla, MA  
Anke Coblentz-Korte, MD

3:15 Hands-on Demo of Abbott mView Program

3:40 Questions and Answers with Abbott Representatives

**INTRODUCTION TO THE ACTG:  
A WORKSHOP FOR NEW INVESTIGATORS**

**Tuesday, June 23, 2015, 11:00 a.m. – 12:00 p.m.**

**Chair:** Judith Currier, MD, MSc  
ACTG Vice Chair

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|--|---|
| 1. Introduction and ACTG Structure   | Judith Currier, MD, MSc   |
| 2. New Work Concept Sheets (NWCSs) and Data Analysis Concept Sheets (DACSSs) | Janet Andersen, ScD<br>ACTG Statistical and Data Analysis Center                      |
| 3. Concept Proposals   | Eric Daar, MD<br>Harbor University of California Los Angeles Center CRS               |
| 4. Protocol Team Involvement and Opportunities                               | Joseph Eron, MD<br>University of North Carolina Global HIV Prevention & Treatment CTU |
| 5. New Sample Repository   | Robert Coombs, MD, PhD<br>Network Laboratory Principal Investigator                   |
| 6. Wrap-up   | Judith Currier, MD, MSc   |

**SITE STAFF TRAINING:  
OVERVIEW OF THE MEETING**

**Monday, June 22, 2015, 8:00 a.m. – 9:00 a.m.**

**Facilitator:** Valery Hughes, FNP  
Weill Cornell Uptown CRS

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|------------------------------|--------------------|
| 1. Welcome and Introductions | Valery Hughes, FNP |
| 2. Overview of the Meeting   | Valery Hughes, FNP |
| 3. Questions and Answers     | All                |

**SITE STAFF TRAINING:  
CONSENTING**

**Monday, June 22, 2015, 9:00 a.m. – 10:30 a.m.**

**Facilitator:** Sara Mattiucci, RN, CCRP  
University of Pittsburgh CRS

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|------------------------------|--------------------|
| 1. Welcome and Introductions | Valery Hughes, FNP |
| 2. Consenting Process        | Kathy Watson, RN   |
| 3. Questions and Answers     | All                |

**SITE STAFF TRAINING:  
CLINICAL RESEARCH SITE-CLINICAL TRIALS UNIT  
COORDINATOR SESSION**

**Monday, June 22, 2015, 10:30 a.m. – 12:00 p.m.**

**Moderators:** Suzanne Fiorillo, MSPH  
University of Colorado Hospital CRS  
Chair, Site Operations Subcommittee

Jane Baum, RN, BSN  
Case CTU  
Vice Chair, Site Operations Subcommittee

**Panel Members:** Graham Ray, RN, MSN  
University of Colorado Hospital CRS

Lisa Kessels, RN, ACRN  
Washington University Therapeutics CRS

Susan Pederson, RN, BSN  
Chapel Hill CRS

Baiba Berzins, MPH  
Northwestern University CRS

**Site Management: Sharing Experiences**

- |   |                    |
|---|--------------------|
| 1. Welcome and Introductions  | Jane Baum, RN, BSN |
| 2. Creative Staffing: Doing More with Less Including Uses of Non-clinical Staff | Panel Members      |
| 3. Recruitment: Identifying Subjects for REPRIEVE and Other ACTG Trials         | Panel Members      |
| 4. Implementation: Incorporating REPRIEVE into Existing ACTG Workflow           | Panel Members      |

**SITE STAFF TRAINING:  
DIVISION OF AIDS (DAIDS) UPDATE TO THE  
GRADING TABLE FOR ADVERSE EVENTS**

**Monday, June 22, 2015, 1:00 p.m. – 2:00 p.m.**

**Facilitator:** Trisha Walton, RN  
Case CRS

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|---|-----------------------|
| 1. Welcome and Introductions                      | Trisha Walton, RN     |
| 2. Update to the Grading Table for Adverse Events | DAIDS Representatives |
| 3. Questions and Answers                          | All                   |

**SITE STAFF TRAINING:  
DATA MANAGER-CLINICIAN INTERACTIVE**

**Monday, June 22, 2015, 2:00 p.m. – 3:00 p.m.**

**Facilitator:** Sara Mattiucci, RN, CCRP  
University of Pittsburgh CRS

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|--|--------------------------|
| 1. Welcome and Introductions                     | Sara Mattiucci, RN, CCRP |
| 2. Data Manager-Clinician Interactive Discussion | Sharon Kohrs, RN         |
| 3. Questions and Answers                         | All                      |



**SITE STAFF TRAINING:  
IMPROVING QUALITY AND COMPLIANCE THROUGH  
EFFECTIVE STANDARD OPERATING PROCEDURE (SOP) DEVELOPMENT**

**Monday, June 22, 2015, 3:00 p.m. – 4:30 p.m.**

**Facilitator:** Valery Hughes, FNP  
Weill Cornell Uptown CRS

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|---|--------------------|
| 1. Welcome and Introductions  | Valery Hughes, FNP |
| 2. Improving Quality and Compliance Through Effective SOP Development | Lysa Triantafillou |
| 3. Questions and Answers  | All                |
| 4. CPQA Update  | Gene Morse, PharmD |

**SITE STAFF TRAINING:  
INTERNATIONAL ROUNDTABLE SESSION**

**Tuesday, June 23, 2014, 9:00 a.m. – 10:00 a.m.**

**Chair:** Akbar Shahkolahi, PhD  
ACTG Network Coordinating Center

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|--|-----------------------|
| 1. Welcome and Introductions                                 | Valery Hughes, FNP    |
| 2. International Roundtable Open Question and Answer Session | Nefertari Johnson, MS |
| 3. Other Items for Discussion                                | All                   |

**SITE STAFF TRAINING:  
QUALITY ASSURANCE**

**Tuesday, June 23, 2015, 10:00 a.m. – 11:00 a.m.**

**Facilitator:** Fanny Rosas, RN  
Barranco CRS

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|---------------------------------|---------------------|
| 1. Welcome and Introductions    | Fanny Rosas, RN     |
| 2. Quality Assurance Discussion | Felluna Chauwa, MPH |
| 3. Questions and Answers        | All                 |

**SITE STAFF TRAINING:  
COMMUNITY-STAFF INTERACTIVE**

**Tuesday, June 24, 2015, 11:00 a.m. – 12:00 p.m.**

**Facilitator:** Lisa Kessels, RN, ACRN  
Washington University Therapeutics CRS

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|------------------------------|---|
| 1. Welcome and Introductions | Lisa Kessels, RN, ACRN                      |
| 2. Contraception Guidelines  | Karin Klingman, MD<br>Catherine Godfrey, MD |
| 3. Questions and Answers     | All   |

**SITE STAFF TRAINING:  
POLICY UPDATES FROM THE DIVISION OF AIDS (DAIDS)  
OFFICE OF POLICY IN CLINICAL RESEARCH OPERATIONS**

**Tuesday, June 23, 2015, 1:00 p.m. – 2:00 p.m.**

**Facilitator:** Ramon Negrón  
Columbia Physicians & Surgeons CRS

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|------------------------------|-----------------------|
| 1. Welcome and Introductions | Ramon Negrón          |
| 2. Policy Updates from DAIDS | DAIDS Representatives |
| 3. Questions and Answers     | All                   |

**SITE STAFF TRAINING:  
HEPATITIS C VIRUS MEDICATIONS**

**Tuesday, June 23, 2015, 3:00 p.m. – 4:00 p.m.**

**Facilitator:** Nikhil Gupte, PhD  
Byramjee Jeejeebhoy Government Medical College CRS

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|---|----------------------|
| 1. Welcome                              | Nikhil Gupte, PhD    |
| 2. Hepatitis C Virus Medications Update | Ashwin Balagopal, MD |
| 3. Discussion                           | All                  |

**A5322 (AGING, HIV INFECTION & INFLAMMATION) PROTOCOL  
TRAINING/RECERTIFICATION SESSION**

**Thursday, June 25, 2015, 9:00 a.m. – 10:30 a.m.**

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

Frank Palella, Jr., MD  
Northwestern University CRS

**Co-Vice Chairs:** Susan Koletar, MD  
Pitt-Ohio State CTU

Babafemi Taiwo, MBBS, MD  
Northwestern University CRS

Frailty Assessment Training/Recertification

Kristine Erlandson, MD

**A5349/TBTC Study 31**  
**[Rifapentine-containing Tuberculosis (TB) Treatment Shortening Regimens]**  
**Protocol-Specific Training Sessions**

**ACTG Chair:** Sue Swindells, MBBS  
University of Nebraska Medical Center  
University of Colorado Hospital CRS

**TBTC Chairs:** Payam Nahid, MD, MPH  
University of California, San Francisco

Susan Dorman, MD  
John Hopkins University

**Monday, June 22, 2015, 11:00 a.m. – 1:00 p.m.**

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|-------|--|-------------------------|
| 11:00 | a. TB Harmonization from the TB Core TeamMicrobiology 101 for Clinical Trials Coordinators | Kathy Eisenach, PhD     |
|       | b. SOP Harmonization Guides and Update of the Harmonization Process                        | Anne-Marie Demeres, PhD |
|       | c. Laboratory and Site Requirements for Study 31/A5349                                     | Anne Purpified, PhD     |

**Wednesday, June 24, 2015, 12:30 p.m. – 2:30 p.m.**

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|-------|---|--------------------|
| 12:30 | Introduction to the TBTC Web Application and Data Entry | Erin Sizemore, MPH |
|-------|---|--------------------|

**Thursday, June 25, 2015, 4:00 p.m. – 6:00 p.m.**

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|------|--------------------------------|---|
| 4:00 | CRF Utilization and Completion | Stefan Godlberg, MD<br>Erin Sizemore, MPH |
|------|--------------------------------|---|

**Friday, June 26, 2015, 7:30 a.m. – 2:00 p.m.**

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|-------|---|---|
| 7:30  | Study Overview and Management                                 | Stefan Goldberg, MD<br>Pei-Jean Feng, MPH<br>Erin Sizemore, MPH   |
| 10:30 | Protocol Start-Up Team/Site Meeting                           | Sue Swindells, MBBS<br>Anthony Podany, PharmD<br>Stefan Goldberg, MD<br>Pei-Jean Feing, MPH<br>Erin Sizemore, MPH |
| 12:00 | Management of Drug Supply and Directly Observed Therapy (DOT) | Stefan Goldberg, MD<br>Pei-Jean Feing, MPH<br>Erin Sizemore, MPH  |



**A5263 (ADVANCED KS CHEMO) AND  
A5264 (LIMITED KS STUDY)  
TEAM AND SITE SESSION**

**Thursday, June 25, 2015, 1:30 p.m. – 3:30 p.m.**

**A5263** Margaret Borok-Williams, MD  
**Co-Chairs:** Parirenyatwa CRS

Susan Krown, MD  
AIDS Malignancy Consortium

**A5264** Thomas Campbell, MD  
**Co-Chairs:** University of Colorado Hospital CRS

Mina Hosseinipour, MD, MPH  
University of North Carolina Global HIV Prevention and Treatment CTU

1. Welcome and Introductions
2. A5263/A5264 EQA Updates
3. A5263 Site Training: MOPS Changes
4. A5263: Updates in Recent Letters of Amendments and Clarification Memoranda
5. A5264: Updates in Forthcoming Amendment
6. A5264 Site Training: Reviewing Chest X-Rays
7. A5263/64 Data Management: FAQs and Avoiding Queries
8. Site Reports
  - a. A5263/64 Accrual
  - b. A5263/64 Community Outreach Efforts
  - c. Status of A5263 LOA/CM Registrations

## A5274 [EMPIRIC TB TX (REMEMBER)] TEAM AND SITE SESSION

Wednesday, June 24, 2015, 8:00 a.m. – 9:00 a.m.

**Co-Chairs:** Mina Hosseinipour, MD, MPH  
University of North Carolina Global HIV Prevention and Treatment CTU

Johnstone Kumwenda, MD, MBBS, MMed  
Blantyre CRS

**Co-Vice Chairs:** Amita Gupta, MD, MHS  
The Johns Hopkins Baltimore-Washington-India (BWI) CTU

Gregory Bisson, MD, MSCE  
Penn Therapeutics CRS

Andrew Zolopa, MD  
Stanford University

1. Welcome & introductions
2. Update on study status
3. Brief overview of primary findings
4. Plans for additional analyses

## A5288 [3RD-LINE ART IN RLS (MULTI-OCTAVE)] TEAM AND SITES SESSION

Thursday, June 25, 2015, 2:30 p.m. – 3:30 p.m.

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

Peter Mugenyi, MD  
Joint Clinical Research Center (JCRC)/Kampala CRS

**Co-Vice Chairs:** Ann Collier, MD  
University of Washington AIDS Clinical Trials Unit CRS

Robert Salata, MD  
Case CRS

1. Welcome and Introduction
2. Update on Study Status
3. Important Reminders
4. Cohort Selection Challenges
5. Preview of Upcoming Changes

**A5300/IMPAACT 2003/PHOENIX MDR TB MAIN STUDY AND PREP STUDY  
TEAM AND SITES SESSION**

**Thursday, June 25, 2015, 2:30 p.m. - 3:30 p.m.**

**Co-Chairs:** Gavin Churchyard, MBBCh, MMed, FCP, PhD  
The Aurum Institute – Johannesburg, South Africa

Amita Gupta, MD, MHS  
The Johns Hopkins Baltimore-Washington-India CTU

Anneke Hesselning, MD, PhD  
Stellenbosch University – Stellenbosch, South Africa

Susan Swindells, MBBS  
University of Nebraska – Omaha, Nebraska  
University of Colorado Hospital CRS

1. Overview of Prep Study and Main Study
2. Site Selection Process
3. Mechanics of Data Collection and Funding Support for Prep Study
4. Timeline for Version 1.0 of Prep Study and Main Study to Sites
5. Timeline for Institutional Review Board Approvals, Accrual, and Completion of Prep Study
6. Site Questions

**A5321 (ACTG HIV RESERVOIRS COHORT) AND  
A5341S (INTENSIVE RESERVOIR SAMPLING)  
TEAM AND SITES SESSION**

**Thursday, June 25, 2015, 1:30 p.m. – 2:30 p.m.**

**Co-Chairs:** Rajesh Gandhi, MD  
Massachusetts General Hospital (MGH ) CRS

**Co-Vice Chairs:** Deborah McMahon, MD  
University of Pittsburgh CRS

Joseph Eron, MD  
University of North Carolina Global HIV Prevention and Treatment CTU

John Mellors, MD  
Pitt-Ohio State CTU

1. Welcome and Introductions
2. A5321
  - a. Study Status
  - b. Analyses to Date
  - c. Planned Analyses
  - d. Lumbar Punctures and CNS Investigations
3. A5341s
  - a. Overview and Rationale
  - b. Sampling Procedures
  - c. Study Status
  - d. Enrollment Plan

# REPRIEVE (A5332) SESSION: MOVING A LANDMARK TRIAL

Wednesday, June 24, 2015, 8:00 a.m. – 9:00 a.m.

**Principal Investigators:** Steven Grinspoon, MD  
Harvard Medical School/Massachusetts General Hospital

Pamela Douglas, MD  
Duke Clinical Research Institute

Udo Hoffmann, MD, MPH  
Massachusetts General Hospital

Heather Ribaldo, PhD  
ACTG Statistical and Data Analysis Center

**ACTG Investigators:** Turner Overton, MD  
Alabama CRS

Carl Fichtenbaum, MD  
Washington University Therapeutics CRS

Judith Aberg, MD  
Mt. Sinai CRS

Markella Zanni, MD  
Massachusetts General Hospital CRS

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|-------------------------------------|---|
| 1. Welcome                          | Steven Grinspoon, MD  |
| 2. Introductions from NIH           | Sarah Read, MD<br>Monica Shah, MD                             |
| 3. ACTG Network Perspective         | Judith Currier, MD  |
| 4. Progress to Date                 | Steven Grinspoon, MD  |
| 5. Timelines and Study Requirements | Carl Fichtenbaum, MD  |
| 6. Screening Experience             | Heather Ribaldo, PhD  |
| 7. Strategies for Success           | Steven Grinspoon, MD<br>Monica Shah, MD<br>Turner Overton, MD |
| 8. Question and Answer              | Team  |