



**Annual ACTG Network Meeting
June 25-29, 2017**

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PLENARY SESSION I

Monday, June 26, 2017, 4:00 p.m. – 6:00 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

4:00	Welcome and Introductions	Daniel Kuritzkes, MD Judith Currier, MD, MSc Ian Sanne, MBBCH, FTP
4:00	NIAID: State of the Institute and Priorities in HIV/AIDS Research	Anthony Fauci, MD
4:40	State of the ACTG	Daniel Kuritzkes, MD Judith Currier, MD, MSc Ian Sanne, MBBCH, FTP
4:55	Recognition of ACTG Service	Daniel Kuritzkes, MD
	a. 2016-2017 Minority HIV Investigator Mentoring Program	Judith Currier, MD, MSc
	b. Leadership Committees	Ian Sanne, MBBCH, FTP
5:05	Presentation of 2017 ACTG Awards (<i>4 minutes each</i>)	
	a. Minority HIV Investigator Mentoring Program	Daniel Kuritzkes, MD Judith Currier, MD, MSc
	b. John Carey Young Investigator Award	Cynthia Firnhaber, MD, MS
	c. Constance B. Wofsy Women's Health Investigator Award	Morénike Giwa Onaiwu
	d. Donna Davis Community Award	Lionel Hillard

Antiretroviral Therapy Strategies Subcommittee Scientific Committee

5:20	A5353: Dolutegravir Plus Lamivudine Dual Therapy in Treatment Naïve HIV-1 Patients	Babafemi Taiwo, MD, MBBS
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HIV Reservoirs and Viral Eradication Transformative Science Group Scientific Committee

5:40	A5315: A Phase I/II Study of Romidepsin in HIV-Infected Adults with Suppressed Viremia on ART to Assess Safety, Tolerability, and Activation of HIV-1 Expression”	Deborah McMahon, MD
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PLENARY SESSION II

Tuesday, June 27, 2017, 8:00 a.m. – 10:00 a.m.

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

National Institutes of Health, Office of AIDS Research

8:00 Future Challenges in HIV Research: Role of the Office of AIDS Research
Maureen Goodenow, PhD

Hepatitis Transformative Science Group

8:20 A5327: Sofosbuvir-Containing Regimens Without Interferon for Treatment of Acute HCV in HIV-1 Infected Individuals (SWIFT-C)
Susanna Naggie, MD

8:35 A5335s: Coinfected Subjects Treated with HCV Direct Acting Antivirals Plus Ribavirin: Intrahepatic HCV Dynamics and Pharmacology: A Substudy of A5329 (HCV GT 1 AbbVie)
Ashwin Balagopal, MD

8:50 A5320: Viral Hepatitis C Infection Long-term Cohort Study (V-HICS)
David Wyles, MD

End-organ Disease and Inflammation Transformative Science Group

9:05 A5317: Effects of Telmisartan on Fibrotic and Inflammatory Contributors to End-Organ Disease in HIV-Infected Patients Well Controlled on Antiretroviral Therapy
Jordan Lake, MD

9:20 A5325/A5330s: A Prospective Randomized Controlled Study to Evaluate the Effect of Isotretinoin on Immune Activation Among HIV-1 Infected Subjects with Incomplete CD4+ T Cell Recovery on Suppressive ART/ Evaluation of CD4+ T Cell Restoration in the Gut Mucosa of Virologically Suppressed HIV-Infected Subjects After Isotretinoin Treatment: A Substudy of A5325
Nina Lin, MD

9:40 A5314: Effect of Reducing Inflammation with Low Dose Methotrexate on Inflammatory Markers and Endothelial Function in Treated and Suppressed HIV Infection
Priscilla Hsue, MD

PLENARY SESSION III

Wednesday, June 28, 2017, 8:00 a.m. – 10:00 a.m.

Moderator: Judith Currier, MD, MSc
ACTG Vice Chair

ACTG Service Awards

8:00	Recognition of ACTG Service	Daniel Kuritzkes, MD
	a. Science Committees	Judith Currier, MD, MSc
	b. Resource Committees	Ian Sanne, MBBCH, FTP

Tuberculosis Transformative Science Group

8:15	A5290: Rifampin-Based vs. Rifabutin-Based TB Treatment in HIV	Constance Benson, MD
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HIV Reservoirs and Viral Eradication Transformative Science Group

8:30	HIV Cure Studies in the ACTG: Where we are now, where we need to be	Rajesh Gandhi, MD
8:50	VRC01 for HIV Reservoir Reduction (A5342)	Sharon Riddler, MD
9:10	HIV Persistence in the Cerebrospinal Fluid (CSF)	Serena Spudich, MD

HIV Reservoirs and Viral Eradication Transformative Science Group and Women's Health Inter-Network Scientific Committee

9:25	Systemic Exposure to ARVs and Relationship to HIV Reservoir Measures	Monica Gandhi, MD, MPH
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Discussion

9:40	Discussion, Questions and Answers	All Participants
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**SYMPOSIUM I:
END-ORGAN DISEASE AND INFLAMMATION
TRANSFORMATIVE SCIENCE GROUP (ITSG)**

Tuesday, June 27, 2017, 4:00 p.m. – 6:00 p.m.

Chair: Turner Overton, MD
Alabama CRS

Vice Chair: Netanya Utay, MD
Houston AIDS Research Team CRS

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|---|--|
| Welcome and Introductions | Turner Overton, MD
Netanya Utay, MD |
| 1. Key Focus Areas of the Past (Where have we been?) | |
| a. Handling HAND | David Clifford, MD |
| b. Cardiovascular Disease and Lipids | Michael Dube, MD |
| c. Bone Health | Michael Yin, MD |
| d. Inflammatory Biomarkers 101 | Nicholas Funderburg, PhD |
| e. Body Composition and Physical Function | Kristine Erlandson, MD |
| f. Inflammation International | Amita Gupta, MD |
| 2. The Present Focus Areas of the ITSG Agenda (Where are we now?) | Netanya Utay, MD |
| 3. Peering Into the Future (Where are we going?) | Turner Overton, MD |

**SYMPOSIUM II:
TUBERCULOSIS TRANSFORMATIVE SCIENCE GROUP, NEUROLOGY
COLLABORATIVE SCIENCE GROUP AND COMMUNITY SCIENTIFIC
SUBCOMMITTEE**

Wednesday, June 28, 2017, 10:30 a.m. – 12:30 p.m.

Tuberculosis TSG

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

Neurology CSG

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

Vice Chair: Ronald Ellis, MD, PhD
University of California San Diego AntiViral Research
Center CRS

Community Scientific Subcommittee and Global Community Advisory Board

Co-Chairs: Danielle Campbell, MPH
University of California Los Angeles CARE Center CRS

Morénike Giwa Onaiwu, MAHouston AIDS Research
Team CRS

Tuberculosis Transformative Science Group

10:30	TB-HIV Drug-Drug Interactions (Rifapentine-Dolutegravir/TAF)	Charles Flexner, MD
10:50	Advances in MDR and XDR TB Treatment	Francesca Conradie, MBBCh
11:10	Landscape of TB Diagnostics	Susan Dorman, MD
11:25	TB Morbidity and Mortality in People with Advanced HIV	Kevin Cain, MD

Neurology Collaborative Science Group

11:40	Imaging of the Brain: Challenges and Opportunities	Beau Ances, MD, PhD, MSc Ann Ragin, PhD
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Global Community Advisory Board and Community Scientific Subcommittee

12:10	Community Update Roots and Wings: Drawing From Our Past and Crafting Our Future	Danielle Campbell Morénike Giwa Onaiwu, MA
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**SYMPOSIUM III:
HEPATITIS TRANSFORMATIVE SCIENCE GROUP (TSG) AND
HIV RESERVOIRS AND VIRAL ERADICATION TRANSFORMATIVE SCIENCE
GROUP (CURE TSG)**

Thursday, June 29, 2017, 8:45 a.m. – 11:15 a.m.

Hepatitis TSG

Chair: Mark Sulkowski, MD
Johns Hopkins University CRS

Vice Chair: Susanna Naggie, MD
Duke University Medical Center CRS

CURE TSG

Chair: Rajesh Gandhi, MD
Massachusetts General Hospital CRS

Vice Chair: Pablo Tebas, MD
Philadelphia Therapeutics and Prevention CTU

Hepatitis Transformative Science Group

8:45	The Role of the Kupffer Cell in HIV Infection	Ashwin Balagopal, MD
9:10	HIV, Metabolomics and the Liver	Susanna Naggie, MD

HIV Reservoirs and Viral Eradication Transformative Science Group

9:30	Update on Ad26/MVA Vaccine Studies and Potential Applications to HIV Cure Research	Merlin Robb, MD
10:05	A5369: HIV-1-Gag Conserved-Element DNA Vaccine (p24CE) as Therapeutic Vaccination for HIV Infection	Jeffrey Jacobson, MD Alan Landay, PhD
10:40	Targeting HIV Where It Hurts	Tomas Hanke, PhD

ANTIRETROVIRAL THERAPY STRATEGIES SUBCOMMITTEE (ARTS SC) THINK TANK

Tuesday, June 27, 2017, 1:30 p.m. – 3:30 p.m.

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

Vice Chair: Ighowerha Ofotokun, MD, MSc
The Ponce de Leon Center CRS

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| 1. Welcome and Introductions | ARTS SC Leadership |
| 2. The Current “State of the Art” ART – What are our Opportunities? An Interactive Discussion | Roy Gulick, MD, MPH |
| 3. Modelling Collaborations to Inform Trial Design and Impact | Kenneth Freedberg, MD, MSc |
| a. PR 731: Simplified Treatment with a Dolutegravir-Based Antiretroviral Regimen (STAR) | Thomas Campbell, MD, PhD |
| b. A5359: Long Acting ARVs in Non-Adherent Participants | Jose Castillo-Mancilla MD |
| 4. Working Group Updates | |
| a. Monoclonal Antibodies Working Group | Pablo Tebas, MD |
| b. Hard to Reach Populations Working Group | Raphael Landovitz, MD |

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

Wednesday, June 28, 2017, 1:30 p.m. – 3:30 p.m.

Chair: Turner Overton, MD
Alabama CRS

Vice Chair: Netanya Utay, MD
Houston AIDS Research Team CRS

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|---|--|
| Welcome and Introductions | Turner Overton, MD
Netanya Utay, MD |
| 1. The Microbiome and Health Implications | |
| a. The IDO Metabolic Pathway in the Setting of HIV Dysbiosis | Richard Dunham, PhD |
| b. Changes in the Microbiome in Acute HIV | Irini Sereti, MD |
| 2. NASH/NAFLD | |
| a. Cenicriviroc for NASH in the Setting of HIV | Eric Lefebvre, MD |
| b. Update on NASH/NAFLD Proposals | |
| • PR 730, Version 3: “Potential Treatment Strategies for NAFLD, A Metabolic Syndrome with Insulin Resistance, Increased Hepatic Lipids, and Increased Cardiovascular Disease Risk” | Jordan Lake, MD |
| • PR 736, Version 2: “Pharmacokinetic Study of Contemporary Antiretroviral Agents Before and During Combined Administration with Obeticholic Acid in HIV-1 infected Participants with Suspected NASH” | Mark Sulkowski, MD |
| 3. Statistical and Data Analysis Center Orientation | Carlee Moser, PhD |
| a. Introduction of the ITSG Statistical Section | |
| b. The Role of the Protocol Statistician | |

HEPATITIS TRANSFORMATIVE SCIENCE GROUP THINK TANK

Tuesday, June 27, 2017, 10:30 a.m. – 12:30 p.m.

Chair: Mark Sulkowski, MD
Johns Hopkins University CRS

Vice Chair: Susanna Naggie, MD
Duke University Medical Center CRS

1. EASL 2017: NASH and Hepatitis B Virus (HBV) Recap Mark Sulkowski, MD
2. Overview of A5368: Anti-PD-1 Antibody in HBV Infected on Suppressive Antiviral Therapy Debika Bhattacharya, MD, MSc
3. Translational Approaches to HBV Cure Michael Sofia, PhD
4. Perspectives on Immune Checkpoint Inhibition and Hepatocellular Carcinoma Tim Greten, MD

**HIV RESERVOIRS AND VIRAL ERADICATION
TRANSFORMATIVE SCIENCE GROUP (Cure TSG)
THINK TANK**

Tuesday, June 27, 2017, 10:30 a.m. – 12:30 p.m.

Chair: Rajesh Gandhi, MD
Massachusetts General Hospital CRS

Vice Chair: Pablo Tebas, MD
Philadelphia Therapeutics and Prevention CTU

10:30 Introduction to Think Tank Goals
Rajesh Gandhi, MD
Pablo Tebas, MD

Guest Speaker

10:35 Immune Checkpoint Inhibitors
Jarushka Naidoo, MBBCh

Implications of Ongoing Trials

11:15 Latency Reversing Agents: Update on Current
and Future Agents
Mathias Lichterfeld, MD, PhD

11:35 A5354 (Early ART in Acute HIV): Update on
Current Status and Open Discussion of Potential
Interventional Studies
Jintanat Ananworanich, MD, PhD
Eric Daar, MD
Trevor Crowell, MD, PhD
Javier Lama, MD, MPH

Future Directions

11:55 Concept Proposal, “A Randomized Trial of
Therapeutic Vaccination with Conserved HIV-1
Immunogens in Early-treated HIV-infected Adults”
Sharon Riddler, MD

12:05 Open Discussion
All

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

Wednesday, June 28, 2017, 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	Adherence Monitoring for TB Trials	Jessica Haberer, MD, MS
4:30	Risk-benefit Analysis for TB Clinical Trials	Sachiko Miyahara, PhD Ritesh Ramchandani, PhD
4:55	LTBI Model in Non-human Primate (NHP)	Deepak Kaushal, PhD
5:15	Knowledge, Attitudes and Practices about Multidrug-Resistant Tuberculosis (MDR TB) and Preventive Therapy among Household Contacts of MDR TB Index Cases (A5300/I2003)	Vidya Mave, MD, MPH
5:25	Update from the NIH Meeting on TB Meningitis	Kelly Dooley, MD, PhD
5:40	Further Review of PR 742, “A Phase III, Randomized Controlled Trial for the Treatment of Isoniazid Mono- and Poly-Resistant Tuberculosis (The IMPaRT Trial)”	Jennifer Furin, PhD Serena Koenig, MD

NEUROLOGY COLLABORATIVE SCIENCE GROUP (NEURO CSG) SESSION AND THINK TANK

Tuesday, June 27, 2017, 2:30 p.m. – 4:30 p.m.

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

Vice Chair: Ronald Ellis, MD, PhD
University of California, San Diego AntiViral Research Center CRS

Part I Business Session

2:30	Welcome and Introductions	Neuro CSG Chairs
2:45	Review of 2016-2017 Accomplishments	Scott Letendre, MD
3:10	Discussion: The ACTG Process for New Research	All Members

Part II Think Tank

3:20	Mitochondria and the Central Nervous System (CNS)	Robert Kalayjian, MD
3:40	The Frailty Phenotype and the CNS	Kristine Erlandson, MD
4:10	OAR Priorities for Neuropsychiatric Research	Gina Brown, MD Stacy Carrington-Lawrence, PhD

WOMEN'S HEALTH INTER-NETWORK SCIENTIFIC COMMITTEE (WHISC) THINK TANK

Wednesday, June 28, 2017, 4:00 p.m. – 6:00 p.m.

Chair: Cynthia Firnhaber, MD, MS, DTM&H
University of Colorado Medical Center

Vice Chair: Elizabeth Connick, MD
University of Arizona CRS

4:00 Welcome and Introductions Cynthia Firnhaber, MD
Elizabeth Connick, MD

End-Organ Disease/Inflammation Transformative Science Group and WHISC Joint Session

4:05 A5322: The HIV Infection, Aging, and Immune
Function Long-Term Observational Study (HAILO) Kristine Erlandson, MD
Frank Palella, MD
Katherine Tassiopoulos, ScD

4:30 Discussion All

4:40 NWCS 407: Sex Differences in Weight Gain Sara Bares, MD
Following the Initiation of ART

4:50 Discussion All

A5282: HPV Test-and-Treat Study

5:00 A5282 Arm C Rosie Mngqibisa, MBChB, MPH

Women's Outreach Workers (WOW) Project/REPRIEVE (A5332)

5:15 Overview Susan Cohn, MD, MPH

5:17 History of WOW Initiative Liz Barr, PhD

5:25 WOW from Emory Anna Benbrook, MS

5:30 WOW from Rutgers Baljinder Singh, MS

5:35 Recruitment of Women and Under-represented
Group Carlos del Rio, MD

5:50 Update: REPRIEVE (A5332) Women's Objectives Sara Dolan Looby, PhD

**DATA MANAGEMENT COMMITTEE
BUSINESS SESSION**

Wednesday, June 28, 2017, 3:00 p.m. – 4:00 p.m.

Co-Chairs: Robert Murphy, MD
Chicago CTU

Doug Kitch, MS
ACTG Statistical and Data Analysis Center

Minhee Kang, PhD
ACTG Statistical and Data Analysis Center

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| 1. Welcome and Introductions | Robert Murphy, MD |
| 2. Demonstration of E-Screens | Kristine Coughlin, BA |
| 3. Medidata Rave Update | Kristine Coughlin, BA |
| 4. Generic CRF's Update | Kristine Coughlin, BA |
| 5. Open Discussion | All Members |

FIELD REPRESENTATIVES WORKING GROUP SESSION

Monday, June 26, 2017, 3:00 p.m. – 4:00 p.m.

Leader: Kathy Watson, RN
Ohio State University CRS

Co-Leader: Susan Pedersen, RN, BSN
Chapel Hill CRS

1. Introductions
Kathy Watson, RN
Susan Pedersen, RN, BSN
2. Field Representatives Recognition
Kathy Watson, RN
Susan Pedersen, RN, BSN
3. The Clinical Trials Specialist and the Field Representative
Conversation and Collaboration
Kathy Watson, RN
Susan Pedersen, RN, BSN
Evelyn Hogg, BA
Lara Hosey, MA, CCRP
Jennifer Tiu, BS, MPH
Vicki Stocker, RN, MS

**OUTREACH, RECRUITMENT, AND RETENTION (ORR) WORKING GROUP
BUSINESS SESSION**

Tuesday, June 27, 2017, 12:30 p.m. – 1:30 p.m.

Chair: Robert Bucklew Jr, JD
Case Clinical Research Site

Vice Chair: Jan Fritsche MS, APRN, PMHNP, BC
Rush University CRS

12:30	Welcome, Introductions and Updates	Robert Bucklew, Jr, JD Jan Fritsche, MS, APRN, PMHNP, BC
12:35	ORR Website	Patricia Kittelson BS, MLS
12:40	ACTG Day of Appreciation for Participants/Volunteers – December 2, 2017	Robert Bucklew, Jr, JD Jan Fritsche, MS, APRN, PMHNP, BC
12:45	ORR CRS Survey Project	Robert Bucklew Jr, JD
1:00	Recruitment without Resources: Sharing Low-Cost (No- Cost) Methods of Community Education/Outreach and Participant Recruitment and Retention	ORR Working Group Members/ Friends

PHARMACY WORKING GROUP (PWG) BUSINESS SESSION

Tuesday, June 27, 2017, 3:00 p.m. – 4:00 p.m.

Leader: Grady Douglas, RPh
Houston AIDS Research Team CRS

Co-Leader: Marelize Smuts, MPharm
Family Clinical Research Unit CRS

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|---|-------------------------|
| 1. Introductions | Grady Douglas, RPh |
| 2. HPTN 083, “A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC), for Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women who have Sex with Men” Requirements and Updates | Thiago Torres, RPh, PhD |
| 3. Review of PWG Role in Protocol Development and Implementation Steering Committee and the Community | All Members |
| 4. Future Projects | All Attendees |
| 5. Open Discussion | All Attendees |

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

Wednesday, June 28, 2017, 10:30 a.m. – 11:30 a.m.

Chair: Ilene Wiggins, RN
Johns Hopkins University CRS

Co-Vice Chairs: Suzanne Fiorillo, MSPH
University of Colorado Hospital CRS

Smita Nimkar, MSc
Byramjee Jeejeebhoy Government Medical
College CRS

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| 1. | Welcome and Introductions | Ilene Wiggins, RN |
| 2. | Subcommittee Updates | Subcommittee Leaderships |
| 3. | Source Documents Special Committee Update | Ilene Wiggins, RN |
| 4. | Brainstorm New Ideas for the Upcoming Year | All Participants |

SITE OPERATIONS SUBCOMMITTEE SESSION

Tuesday, June 27, 2017, 3:30 p.m. – 4:30 p.m.

Chair: Jane Baum, RN
Case CTU

Co-Vice Chairs: Vuyo Jezile, BBS
University of the Witwatersrand Helen Joseph CRS

Shirley Ventresca
Ohio State University CRS

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| 1. | Welcome and Introductions | Jane Baum, RN |
| 2. | Ongoing Projects | |
| | a. Reviewing and Updating the Checklists for Orientation: Research Nurse, Site Study Coordinator, Data Manager | Jane Baum, RN |
| | b. HANC and Financial Disclosures | Vuyo Jezile, BBS |
| | c. CRF Destruction and Notification to Sites when New Studies are Added | Shirley Ventresca |
| | d. Update on Source Documents Project | All Participants |
| 3. | Mentoring Program | Vuyo Jezile, BBS
James Gavel, BS |
| 4. | Suggestions for Topics for Study Coordinators and Data and Quality Managers Calls | All Participants |

**UNDERREPRESENTED POPULATIONS COMMITTEE
BUSINESS SESSION**

Wednesday, June 28, 2017, 12:30 p.m. – 1:30 p.m.

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

Vice Chair: Carlos del Rio, MD
The Ponce de Leon Center CRS

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| 1. Welcome and Introductions | Jose Castillo-Mancilla, MD |
| 2. 2017-2018 ACTG Minority HIV Investigator Mentoring Program (MHIMP) Awardees Introductions | Jose Castillo-Mancilla, MD |
| 3. 2016-2017 MHIMP Presentations | Jose Gutierrez Contreras, MD, MPH
Hansel Arroyo, MD |
| 4. Post-Women's Outreach Worker (WOW) Presentation Strategies | Susan Cohn, MD, MPH
Carlos del Rio, MD
Shobha Swaminathan, MD |
| 5. Discussion/Closing | All Members |

COMMUNITY SCIENTIFIC SUBCOMMITTEE (CSS) SESSION I

Tuesday, June 27, 2017, 12:00 p.m.– 2:00 p.m.

CSS Co-Chairs: Danielle Campbell
University of California, Los Angeles CARE Center CRS

Royce Hardin
Chapel Hill CRS

1. Inflammatory Markers –What do they do, where do they come from, what do they mean? Michael M. Lederman M.D
2. CSS Members Training Danielle Campbell
Royce Hardin

COMMUNITY SCIENTIFIC SUBCOMMITTEE (CSS) II

Wednesday, June 28, 2017, 2:00 p.m. – 4:00 p.m.

Co-Chairs: Danielle Campbell
University of California, Los Angeles CARE Center CRS

Royce Hardin
Chapel Hill CRS

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| 1. CSS Business Session | Danielle Campbell
Royce Hardin |
| 2. A5345 (HIV Rebound & Control Biomarkers) | Jonathan Li, MD
Bernard Macatangay, MD |

GLOBAL COMMUNITY ADVISORY BOARD (GCAB) SESSION I

Sunday, June 25, 2017, 9:00 a.m. – 12:00 p.m.

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

Lionel Hillard
Trinity Health and Wellness Center CRS

CSS Co-Chairs: Danielle Campbell, MPH
University of California, Los Angeles CARE Center CRS

Royce Hardin
Chapel Hill CRS

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| 1. Welcome and Introductions | Morenike Giwa Onaiwu
Lionel Hillard |
| 2. ACTG Oral History: Where we've been and where we might go | Liz Barr, PhD |
| 3. CAB Presentations: Kampala, Kericho | Ronald Ssenyonga,
Moses Nsubuga
Flavia Miiro
Janat Kayondo
John Rotich
Nickson Chepkwony |
| 4. Treatment Shortening Tuberculosis Research | Kelly Dooley MD, PhD |

GLOBAL COMMUNITY ADVISORY BOARD (GCAB) SESSION II

Sunday, June 25, 2017, 1:00 .pm. – 6:00 p.m.

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

Lionel Hillard
Trinity Health and Wellness Center CRS

CSS Co-Chairs: Danielle Campbell, MPH
University of California, Los Angeles CARE Center CRS

Royce Hardin
Chapel Hill CRS

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| 1. Community Agenda Discussion | Larry N. Lyle DO, MS |
| 2. Community Interactive | Morenike Giwa Onaiwu,
Lionel Hillard |
| 3. Cross Network Transgender Working Group | Rona Siskind MHS |
| 4. CAB Presentation
Philadelphia CAB/SATVI CAB Activities | Jay Johnson
Belinda Ameterra |
| 5. Community-Staff Interactive: Intersectionality | Jonatan E. Gioia MD
Melissa Murry, BA |

GLOBAL COMMUNITY ADVISORY BOARD (GCAB) SESSION III

Monday, June 26, 2017, 8:00 a.m. – 12:00 p.m.

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

Lionel Hillard
Trinity Health and Wellness Center CRS

CSS Co-Chairs: Danielle Campbell, MPH
University of California, Los Angeles CARE Center CRS

Royce Hardin
Chapel Hill CRS

1. Understanding the Human Microbiome in HIV Disease Alan Landay PhD
2. Education, Technology, Social Media, & Connecting with Our Communities: An Interactive Panel ORR, GCAB and CSS Members
3. Possible Drug/Drug Interactions of HIV Medications with Other Classes of Drugs Grady Doubllass RPh
4. Turning the Corner on the AIDS Pandemic: Refining the Science-Driven HIV Research Enterprise Carl Dieffenbach PhD

GLOBAL COMMUNITY ADVISORY BOARD (GCAB) SESSION IV

Monday, June 26, 2017, 1:15 p.m. – 3:30 p.m.

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

Lionel Hillard
Trinity Health and Wellness Center CRS

CSS Co-Chairs: Danielle Campbell, MPH
University of California, Los Angeles CARE Center CRS

Royce Hardin
Chapel Hill CRS

1. Sex Differences in HIV Cure Research

Sara Gianella MD
Eileen Scully MD, PhD

2. NASH

Mark S. Sulkowski MD

GLOBAL COMMUNITY ADVISORY BOARD (GCAB) SESSION V

Thursday, June 29, 2017, 12:00 p.m. – 3:00 p.m.

GCAB Co-Chairs:

Morenike Giwa Onaiwu
Houston AIDS Research Team CRS

Lionel Hillard
Trinity Health and Wellness Center CRS

CSS Co-Chairs:

Danielle Campbell, MPH
University of California, Los Angeles CARE Center CRS

Royce Hardin
Chapel Hill CRS

1. Incidental Findings
Betto Ortiz, MS, PMP, CIPM
Linda A. Ehler RN, MN
2. Reports
CSS and GCAB Representatives
3. Awards, Closing Thoughts
Morenike Giwa Onaiwu
Lionel Hillard
Allegra Cermak

**A5349/TBTC STUDY 31
(RIFAPENTINE-CONTAINING TUBERCULOSIS
TREATMENT SHORTENING REGIMENS)
LABORATORY FOCUSED TRAINING**

Tuesday, June 27, 2017, 7:00 a.m. – 8:00 a.m.

Chair: Anne Purfield, PhD
U.S. Centers for Disease Control and Prevention

7:00	Introductions and Welcome	Morgan Gapara, MPH
7:02	A5349 Laboratory Testing Review: Basics and Highlights	Anne Purfield, PhD Nicole Brown, PhD
7:10	Completing the Microbiology (MB) Form	Anne Purfield, PhD Nicole Brown, PhD
7:30	Questions and Answers/Closing	

**ELECTRONIC LABORATORY TESTING PLANS (ePAL)
MIS OVERVIEW SESSION**

Monday, June 26, 2017 12:30 p.m. – 1:30 p.m.

Facilitator: Kim Banks, MS, MBA, MT (AMT)
ACTG Network Coordinating Center

12:30	Introductions and Welcome	Kim Banks, MS, MBA, MT (AMT) Jenny Nguyen, BS
12:35	Electronic Laboratory Testing Plans (ePAL) Presentation and Demonstration	Kim Banks, MS, MBA, MT (AMT) Jenny Nguyen, BS
1:15	Questions and Answers/Closing	

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

Sunday, June 25, 2017, 8:00 a.m. – 10:00 a.m.

Chair: Robert Coombs, MD, PhD
ACTG Network Laboratory Center Principal Investigator
University of Washington AIDS Clinical Trials Unit CRS

8:00	Introductions and Welcome	Robert Coombs, MD, PhD
8:05	Laboratory Center Leadership Update	Robert Coombs, MD, PhD
8:50	QuantiFERON Gold Plus Validation Update	Peter Meewes
9:20	Evaluation of Xpert HIV-1 VL Assay and Non-inferiority of the Xpert Ultra Compared to the Xpert MRB/RIF for Initial Diagnosis of Pulmonary Tuberculosis and MDR-TB	Lesley Scott, PhD
9:50	Introduction of New TB QA Program	Daniella Livnat, BS
9:55	Questions and Answers/Closing	

**IMMUNOLOGY SPECIALTY LABORATORY (ISL)
BREAKOUT SESSION**

Wednesday, June 28, 2017, 11:15 a.m. – 1:15 p.m.

Chair: Michael Lederman, MD
Case Western Reserve University School of Medicine
Immunology Specialty Laboratory

11:15	Introductions and Welcome	Michael Lederman, MD
11:20	Case ISL: A Tale of 2 CDs	Michael Lederman, MD
11:45	Rush ISL: Immunometabolism and HIV	Alan Landay, PhD
12:05	Pittsburgh ISL: Evaluating Levels of pro- and anti-Inflammatory Soluble Mediators in Throat Washings of Participants in A5254 “HIV-Related Oral Mucosal Disease & Use of Saliva in Measuring HIV Viral Load”	Bernard Macatangay, MD
12:30	SUN-IRG: Phenotype and non-Humoral Functions of B Cells during <i>M.tb</i> Infection and Disease	Andre Loxton, PhD
12:55	Luminex-EIA Biomarker Project Next Steps	All Members
1:10	Questions and Answers/Closing	

IMPROVING QUALITY ASSURANCE PRACTICES IN THE LABORATORY

Sunday, June 25, 2017 11:30 a.m. – 1:30 p.m.

Facilitator: Kim Banks, MS, MBA, MT (AMT)
ACTG Network Coordinating Center

11:30	Blood Specimens Processing Quality Management	Joan Dragavon, MLM Sarah Keinonen, BS
12:10	Molecular Virology and TB Testing Laboratory Contamination Panel Discussion	Peter Meewes Peggy Coulter, BS Jeanette Coffin Cheryl Jennings, BS Raquel Viana, PhD
1:10	Improvement of Quality Assurance Management: AMPATH Perspective Panel	Ibrahim Daud, PhD Millicent Orido, BS Michele Imbach, MS Anita Gillis, MPH

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA) SHIPPING TRAINING

Sunday, June 25, 2017 1:30 p.m. – 5:00 p.m.

Chair: David Shugarts, MA
University of Colorado Hospital CRS

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|-----|---|--------------------|
| 1. | ACTG and BRI Shipping Regulations and Shipping | David Shugarts, MA |
| 2.. | Introduction to IACO/IATA, U.S. Department of Transportation Dangerous Goods Shipping | David Shugarts, MA |
| 3. | Category A Infectious Substance Shipping | David Shugarts, MA |
| 4. | Category B Infectious Substances Shipping | David Shugarts, MA |
| 5. | Procedure for Filling Cryovials for REPRIEVE (A5332) Studies | David Shugarts, MA |
| 6. | Liquid Nitrogen Dry Shipper Demonstration | David Shugarts, MA |
| 7. | Repository Instructions for Pass Through Shipments | David Shugarts, MA |
| 8. | Certification Test | David Shugarts, MA |

**LABORATORY SCIENCE GROUP (LSG)
DROP-IN ROOM**

Sunday, June 25, 2017, 3:00 p.m. – 4:30 p.m.
and
Monday, June 26, 2017, 1:30 p.m. – 2:30 p.m.

Facilitators: Members of the ACTG LSG

1. Meet with the ACTG Network Coordinating Center LSG
2. Hands-on Demonstrations Accessing and Updating the ePAL in MIS
3. Review and Provide Guidance to ACTG Laboratories on Meeting DAIDS and ACTG Laboratory Requirements
4. Answer Laboratory Readiness Questions
5. ACTG Laboratory Approval Questions
6. Review Upcoming Protocol Testing Requirements

**LABORATORY TECHNOLOGIST COMMITTEE (LTC)
DROP-IN ROOM**

Wednesday, June 28, 2017, 7:00 a.m. – 8:00 a.m.

Co-Chairs: Christopher Lane, AAS
University of Rochester Adult HIV Therapeutic Strategies Network CRS

David Shugarts, MA
University of Colorado Hospital CRS

Co-Vice Chairs: Francoise Giguel
Harvard University Virology Specialty Laboratory

Sikhulile Moyo, MS, MPH, PhD
Gaborone CRS

1. Questions and Answers Regarding the LTC

LTC Members

**LABORATORY TECHNOLOGIST COMMITTEE
OPEN TRAINING SESSION**

Sunday, June 25, 2017 5:00 p.m. – 6:00 p.m.

Co-Chairs: David Shugarts, MA
University of Colorado Hospital CRS

Christopher Lane, AAS
University of Rochester Adult HIV Therapeutic Strategies Network CRS

Co-Vice Chairs: Francoise Giguel
Harvard University Virology Specialty Laboratory

Sikhulile Moyo, PhD, MS, MPH
Gaborone CRS

5:00	Introductions and Welcome	David Shugarts, MA Christopher Lane, AAS
5:02	Validation and Verification of Spreadsheets to Comply with FDA and CFR11	Joan Dragavon, MLM
5:20	Statistical Presentation- Analyzing Data That Has Below Assay Limit	Ronald Bosch, PhD
5:35	Cold Change and Laboratory Clinic Interaction	Francoise Giguel Sikhulile Moyo, PhD, MS, MPH
5:55	Questions and Answers/Closing	

LDMS DROP-IN ROOM

Monday, June 26, 2017, 9:00 a.m. – 5:00 p.m.

and

Tuesday, June 27, 2017, 9:00 a.m. – 5:00 p.m.

Chair: Andrew Lohrum, MLIS
ACTG Data Management Center
Frontier Science

1. Walk-In LDMS Questions
2. Individual Help Sessions
3. Demonstrate and Instruct on All Functions of the LDMS for Windows or Web (Accessioning, Storage, Shipping and Supported Assays, Windows)

LDMS/LABORATORY TECHNOLOGIST COMMITTEE INTERACTIVE

Monday, June 26, 2017 2:00 p.m. – 4:00 p.m.

Facilitator: Morgan Gapara, MPH
ACTG Network Coordinating Center

2:00	Introductions and Welcome	Morgan Gapara, MPH
2:02	Brief Discussion on Recent Updates to Windows LDMS Version 12.X	Howard Gutzman, BS
2:10	Everything to Know About Web LDMS!	Howard Gutzman, BS
2:45	Status of Migrating Labs to Web LDMS	Howard Gutzman, BS
3:00	Live Demo of Web LDMS and LDMS Website	Howard Gutzman, BS
3:30	Overview of DMC Tools on FSTRF Portal	Howard Gutzman, BS
3:45	Question and Answers/Closing	

**PATIENT SAFETY MONITORING IN INTERNATIONAL LABORATORIES (PSMILE)
DROP-IN ROOM**

Sunday, June 25, 2017, 11:00 a.m. – 3:00 p.m.

Chair: Anne Leach, MT (ASCP)
pSMILE

1. Answer Clinical and TB Laboratory QA/QC Questions Including QuantiFERON-TB Gold Plus (QFT-Plus) Validation Update
2. Troubleshooting (Action Plans, Investigation Reports, Validation...)
3. Assist with EQA Submission Questions and Challenges Including 3rd and 4th Generation HIV Tests
4. Demonstrate and Assist with Accessing the pSMILE Website
5. Demonstrate and Assist with Accessing the MTS Competency and Training Website
6. Demonstrate the pSMILE Website Resources Section

**PHARMACOLOGY SPECIALTY LABORATORY (PSL)/
CLINICAL PHARMACOLOGY ADVISORY GROUP (CPAG)
BREAKOUT SESSION**

Wednesday, June 28, 2017 - 10:00 a.m. – 12:00 p.m.

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

10:00	Introductions and Welcome	Gene D. Morse, PharmD
10:05	Protocol Updates	CPAG Members
10:40	University of Alabama, Birmingham PSL Update	Chantelle Bennetto Hood, PhD
10:50	University of California, San Francisco PSL Update Can we spell out the lab names?	Anastasia Makarova, PhD
11:00	UCSF Hair Analytical Laboratory	Monica Gandhi, MD, MPH
11:10	University of Nebraska, Medical Center PSL Update	Anthony Podany, PharmD Kim Scarsi, PharmD, MS, BCPS
11:20	SUNY at Buffalo PSL	Charles Venuto, PharmD Qing Ma, PhD
11:30	University of Zimbabwe International PSL Update	Charles Maponga, PharmD
11:40	University of Capetown International PSL Update	Jennifer Norman, MSc
11:50	CPQA Update	Robin DiFrancesco, MT, (ASCP), MBA

SPECIALTY LABORATORY DIRECTORS BUSINESS SESSION

Monday, June 26, 2017 10:00 a.m. – 12:00 p.m.

Chair: Robert Coombs, MD, PhD
ACTG Laboratory Center Principal Investigator
University of Washington AIDS Clinical Trials Unit CRS

10:00	Introductions and Welcome	Robert Coombs, MD, PhD
10:05	Award for Cheryl Jennings	Robert Coombs, MD, PhD
10:15	Pharmacology Biomarker Update	Robin DiFrancesco, MT (ASCP), MBA
10:35	Genomics 101	David Haas, MD
11:10	Potential Crossover Studies for HIV Reservoirs and Viral Eradication Transformative Science Group	John Mellors, MD
11:45	Questions and Answers/Closing	

**TUBERCULOSIS LABORATORY MGIT TESTING
ALGORITHM AND INTERACTIVE**

Tuesday, June 27, 2017 4:00 p.m. – 5:30 p.m.

Co-Chairs: Nicole Brown, PhD
U.S. Centers for Disease Control and Prevention

Anne Purfield, PhD
U.S. Centers for Disease Control and Prevention

4:00	Introductions and Welcome	Anne Purfield, PhD
4:05	MGIT Testing Algorithm	Anne Purfield, PhD Nicole Brown, PhD
5:20	Questions and Answers/Closing	

TUBERCULOSIS (TB) QUALITY ASSURANCE LABORATORY DISCUSSION

Sunday, June 25, 2017, 10:00 a.m. – 11:30 a.m.

Facilitator: Morgan Gapara, MPH
ACTG Network Coordinating Center

10:00	Introductions and Welcome	Morgan Gapara, MPH
10:02	MRIGlobal Overview	Jeanette Coffin
10:20	TB Manual Presentation (<i>Harmonization Guides</i>)	Anne-Marie Demers, MD Kathy Eisenach, PhD
10:45	Comparing Genotypic and Phenotypic Drug Susceptibility Testing (DST)	Carole Wallis, PhD
11:00	A5349 (TBTC S31), Changes in Quality Assurance and TB Contamination	Anne Purfield, PhD
11:20	Questions and Answers/Closing	

**VIROLOGY SPECIALTY LABORATORIES (VSL),
GENOTYPING AND STATISTICAL AND DATA ANALYSIS CENTER (SDAC)
BREAKOUT SESSION**

Wednesday, June 28, 2017, 10:00 a.m. – 12:00 p.m.

Chair: John Mellors, MD
University of Pittsburgh VSL

10:00	Introductions and Welcome	John Mellors, MD
10:02	New Scientific Updates: Vanderbilt DNA Resources Core	David Haas, MD
10:15	New Scientific Updates: SDAC	Ronald Bosch, PhD
10:30	International Genotyping Laboratories Update	Carole Wallis, MSc, MED, PhD
10:45	New Scientific Updates: University of Pittsburgh VSL	John Mellors, MD
11:05	New Scientific Updates: University of Washington VSL	Robert Coombs, MD, PhD
11:25	New Scientific Updates: Harvard University VSL	Daniel Kuritzkes, MD
11:45	VQA Update on Virology Specialty Assays EQA Efforts	Cheryl Jennings, BS
12:00	Questions and Answers/Closing	

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

Monday, June 26, 2017, 10:30 a.m. – 12:00 p.m.

Chair: Judith S. Currier, MD, MSc
ACTG Network Vice Chair

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|----|---|-------------------------|
| 1. | Introduction and ACTG Structure | Judith Currier, MD, MSc |
| 2. | Scientific Committee Directions:
Opportunities for New Investigators | |
| | a. Antiretroviral Therapy Strategies
Subcommittee | TBA |
| | b. HIV Reservoir and Viral Eradication
Transformative Science Group
(TSG) | TBA |
| | c. Hepatitis TSG | Rajesh Gandhi, MD |
| | d. End-Organ and Inflammation TSG | TBA |
| | e. Tuberculosis TSG | Susan Swindells, MBBS |
| 3. | Introduction to the Statistical and Data
Analysis Center | Summer Zheng, PhD |
| 4. | Protocol Team Involvement and
Opportunities | TBA |
| 5. | Wrap-up | Judith Currier, MD, MSc |

SITE STAFF TRAINING

SOURCE DOCUMENTATION COMMISSION

Sunday, June 25, 2017, 10:15 a.m. – 11:00 a.m.

Facilitator: Kathy Watson, RN
Ohio State University CRS

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|------------------------------------|-----------------------|
| 1. Introduction | Kathy Watson, RN |
| 2. Source Documentation Commission | Shirley Ventresca, RN |
| 3. Questions and Answers | All |

SITE STAFF TRAINING

ADVERSE EVENT REPORTING/DIVISION OF AIDS ADVERSE EVENT REPORTING SYSTEM (DAERS)

Sunday, June 25, 2017, 1:00 p.m. – 3:00 p.m.

Facilitator: Sara Onesi, RN, CCRP
University of Pittsburgh CRS

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|---|---|
| 1. Welcome and Introductions | Sara Onesi, RN CCRP |
| 2. Division of AIDS Adverse Event Reporting System Training | Shirley Chacon, MD
Imran Hasnuddin, MD |
| 3. Questions and Answers | All |

SITE STAFF TRAINING

FIELD REPRESENTATIVE OVERVIEW

Sunday, June 25, 2017, 3:00 p.m. – 4:00 p.m.

Facilitator: Renee Weinman, BS, CCRP
University of Pittsburgh CRS

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| 1. Welcome and Introductions | Renee Weinman |
| 2. Field Representative Overview | Kathy Watson, RN |
| 3. Questions and Answers | All |

SITE STAFF TRAINING

COMMUNITY/STAFF INTERACTIVE - INTERSECTIONALITY

Sunday, June 25, 2017, 4:00 p.m. – 6:00 p.m.

Facilitator: Renee Weinman, RN, CCRP
University of Pittsburgh CRS

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|---------------------------------|---|
| 1. Welcome and Introductions | Renee Weinman, RN, CCRP |
| 2. Intersectionality Discussion | Jonatan Gioia, MD
Community Members
CRS Staff |
| 3. Questions and Answers | All |

SITE STAFF TRAINING

STANDARD OPERATING PROCEDURE WORKSHOP

Monday, June 26, 2017, 8:30 a.m. – 10:30 a.m.

Facilitator: Suzanne Fiorillo, MSPH
University of Colorado Hospital CRS

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| 1. Welcome and Introductions | Suzanne Fiorillo, MSPH |
| 2. Standard Operating Procedure Development | Lysa Triantafillou |
| 3. Questions and Answers | All |

SITE STAFF TRAINING

PROTOCOL FUNDING AND COSTING

Monday, June 26, 2017, 10:30 a.m. – 12:00 p.m.

Facilitator: Carl Bruton, BBA
Ohio State University CRS

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| 1. Welcome and Introductions | Carl Bruton, BBA |
| 2. Protocol Funding and Costing | Aisha Zaidi, MS
Ellyn Sherman |
| 3. Questions and Answers | All |

SITE STAFF TRAINING

MONITORING: UNDERSTANDING CODES AND RELATED FINDINGS & ELECTRONIC SOURCE RECORD

Monday, June 26, 2017, 1:00 p.m. – 3:00 p.m.

Facilitator: Carl Bruton, BBA
Ohio State University CRS

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| 1. Welcome and Introductions | Carl Bruton, BBA |
| 2. Monitoring: Understanding Codes and Related findings & Electronic Source Record | Pharmaceutical Product Development |
| 3. Questions and Answers | All |

PROTOCOL-SPECIFIC TRAININGS

A5349/TBTC STUDY 31 (RIFAPENTINE-CONTAINING TUBERCULOSIS TREATMENT SHORTENING REGIMENS) PROTOCOL-SPECIFIC TRAINING SESSIONS

ACTG Co-Chairs: Sue Swindells, MBBS
University of Nebraska Medical Center/
University of Colorado Hospitals CRS

Wadzanai Samaneka, MBChb, MSc
Pariirenyatwa CRS

TBTC Co-Chairs: Susan Dorman, MD
John Hopkins University

Payam Nahid, MD, MPH
University of California, San Francisco

1. A5349/TBTC Study 31 Laboratory Focus Training
Tuesday, June 27, 2017, 7:00 a.m. – 8:00 a.m. Nicole Brown, PhD
Ann Purfield, PhD
2. A5349/TBTC Study 31 Team and Sites Session
Tuesday, June 27, 2017, 1:30 p.m. – 3:30 p.m. Susan Dorman, MD
Sue Swindells, MD
Payam Nahid, MD
Ekaterina Kurbatova, MD
3. A5349/TBTC Study 31 Drop-in Room
Tuesday, June 27, 2017, 3:30 p.m. – 4:30 p.m. Susan Dorman, MD
Payam Nahid, MD
Ekaterina Kurbatova, MD
Andrew Vernon, MD
4. A5349/TBTC Study 31 Tuberculosis Lab MGIT Testing
Algorithm Interactive
Tuesday, June 27, 2017, 4:00 p.m. – 5:30 p.m. Nicole Brown, PhD
Anne Purfield, PhD
5. A5349/TBTC Study 31 Data Management Session
Wednesday, June 28, 2017, 1:30 p.m. – 3:30 p.m. Erin Sizemore, MPH

PROTOCOL-SPECIFIC TRAINING

A5354/EARLIER (EARLY ART IN ACUTE HIV) TEAM AND SITES INTERACTIVE TRAINING SESSION

Tuesday, June 27, 2017, 5:30 p.m. – 6:30 p.m.

Co-Chairs: Jintanat Ananworanich, MD, PhD
Kenya Medical Research Institute/Walter Reed Project Clinical Research Center CRS

Eric Daar, MD
Harbor University of California Los Angeles Center CRS

Co-Vice Chairs: Trevor Crowell, MD, PhD
Kenya Medical Research Institute/Walter Reed Project Clinical Research Center CRS

Javier Lama, MD, MPH
IMPACTA Peru CTU

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| 1. Welcome and Introductions | Eric Daar, MD |
| 2. Review of Acute HIV-1 Infection Eligibility Scenarios | Trevor Crowell, MD, PhD
Eric Daar, MD
Javier Lama, MD, MPH |
| 3. Discussion of Fiebig Staging Evolution | Trevor Crowell, MD, PhD
Robert Coombs, MD |
| a. Estimated Fiebig Groups and Actual Fiebig Stage Results | Eric Daar, MD
Javier Lama, MD, MPH |
| b. Management of Participants with Fiebig Stage VI from Centralized Testing | |
| 4. Blood Volume Considerations | Eric Daar, MD
Trevor Crowell, MD, PhD
LuAnn Borowski, MSc |
| 5. Site Questions and Comments | All Sites |
| 6. Concluding Remarks | Trevor Crowell, MD, PhD
Eric Daar, MD
Javier Lama, MD, MPH |

PROTOCOL-SPECIFIC TRAINING

A5360 (MINMON STUDY) PROTOCOL TRAINING

Tuesday, June 27, 2017, 4:00 p.m. – 5:30 p.m.

Chair: Sunil Solomon, MBBS, PhD, MPH
Johns Hopkins University CRS

Co-Vice Chairs: Sandra Wagner Cardoso, MD, PhD
Instituto de Pesquisa Clinica Evandro Chagas CRS

Mark Sulkowski, MD
Johns Hopkins University CRS

4:00	Self-hair Sample Collection	Monica Gandhi, MD, MPH
4:30	Development of Site-specific Contraindicated Medication Lists	Sunil Solomon, MBBS, PhD, MPH Sandra Wagner Cardoso, MD, PhD Mark Sulkowski, MD Anchalee Avihingsanon, MD, PhD
5:00	Remote Contact eCRFS	Christine Scello, MA Laura Weichmann, MPH

PROTOCOL-SPECIFIC TRAINING

NEUROPSYCHOLOGICAL BATTERY, NEUROLOGICAL EXAMINATION, AND LUMBAR PUNCTURE TRAINING FOR A5324 (ART INTENSIFICATION FOR HAND)

Wednesday, June 28, 2017, 4:00 p.m. – 6:00 p.m.

Co-Chairs: Kevin Robertson, PhD
Chapel Hill CRS

Serena Spudich, MD
Weill Cornell Chelsea CRS

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

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| 1. Welcome and Overview | Kevin Robertson, PhD |
| 2. Neurological Examination | Serena Spudich, MD |
| 3. Lumbar Puncture | Serena Spudich, MD |
| 4. Neuropsychological Examination | Kevin Robertson, PhD |
| a. Video | |
| b. Hands-on activity | |

A5264 (LIMITED KS STUDY) TEAM AND SITES SESSION

Tuesday, June 27, 2017, 12:30 p.m. – 1:30 p.m.

Chairs: Thomas Campbell, MD
University of Colorado Hospital CRS

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

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| 1. Welcome and Introductions | Thomas Campbell, MD
Mina Hosseinipour, MD, MPH |
| 2. Primary Results Presentation | Mina Hosseinipour, MD, MPH |
| 3. Review of Secondary Manuscripts | Mina Hosseinipour, MD, MPH |
| 4. Site Questions and Comments | All Sites |
| 5. Manuscript Writing Team Assignments | Mina Hosseinipour, MD, MPH
Thomas Campbell, MD |

A5300B/I2003B/PHOENIX SITE TRAINING

Protecting Households On Exposure to Newly Diagnosed Index Multidrug-Resistant Tuberculosis Patients (PHOENIX MDR-TB)

Monday, June 26, 2017, 8:00 a.m. – 12:00 p.m.

Co-Chairs: Gavin Churchyard, MBBCh, MMed, FRCP, FCP(SA), PhD (ACTG)
The Aurum Institute

Amita Gupta, MD, MHS (IMPAACT)
Johns Hopkins Center for Clinical Global Health Education

Anneke Hesselning, MD, PhD (IMPAACT)
Stellenbosch University

Sue Swindells, MBBS (ACTG)
University of Nebraska Medical Center

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| 1. Welcome and Introductions | Sue Swindells |
| 2. Lessons Learned from the
A5300/I2003/PHOENIX Feasibility Study, Including the
One Year Follow-Up | Amita Gupta |
| 3. A5300B/I2003B/PHOENIX Overview | Gavin Churchyard |
| 4. Site Preparations for Lab Assays | Patty Anthony, CLS
Anita Gillis |
| 5. TB Microbiological Considerations | Anne-Marie Demers, MD |
| 6. Review of Delamanid Literature and Adverse Events
Relevant to PHOENIX, PK in Adults and Children | Jeff Hafkin, MD, MSCE |
| 7. Adherence Overview and Use of Electronic Drug
Monitoring Device | Jessica Haberer, MD, MS |
| 8. Pediatric TB Contact Evaluation and Diagnosis | Nicole Salazar-Austin, MD |

**A5345 (HIV REBOUND AND CONTROL BIOMARKERS)/A5347s (SAMPLING
SUBSTUDY OF A5345) TEAM AND SITES SESSION**

GCAB/CSS Members Welcome

Wednesday, June 28, 2017, 4:00 p.m. – 5:00 p.m.

Co-Chairs: Jonathan Li, MD
Brigham and Women's Hospital Therapeutics CRS

Davey Smith, MD
University of California, San Diego AntiViral Research Center CRS

Bernard Macatangay, MD
University of Pittsburgh CRS

Co-Vice Chairs: Steven Deeks, MD
University of California, San Francisco HIV/AIDS CRS

Rajesh Gandhi, MD
Massachusetts General Hospital (MGH) CRS

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| 1. Welcome | Jonathan Li, MD |
| 2. A5345 Overview | Jonathan Li, MD |
| 3. A5347s Overview | Bernard Macatangay, MD |
| 4. Recruitment Discussion | Protocol Team Members and Staff |
| 5. Questions and Answers | All |

**REPRIEVE (A5332) SESSION:
NATIONAL HEART, LUNG, AND BLOOD (NHLBI) INITIATIVES
AND REPRIEVE TRIAL UPDATES**

Wednesday, June 28, 2017, 12:30 p.m. – 1:30 p.m.

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

Pamela Douglas, MD
Duke Clinical Research Center

Udo Hoffmann, MD, MPH
Massachusetts General Hospital

Heather Ribaldo, PhD
ACTG Statistical and Data Analysis Center

Co- Investigators: Turner Overton, MD
Alabama CRS

Carl Fichtenbaum, MD
Cincinnati CRS

Judith Aberg, MD
Mt. Sinai Beth Israel CRS

Markella Zanni, MD
Massachusetts General Hospital CRS

12:40	Welcome	Turner Overton, MD
12:45	Progress to Date/ REPRIEVE Updates	Steven Grinspoon, MD
1:00	NHLBI Initiatives	David Goff, MD
1:15	A5361s: PREPARE Substudy of REPRIEVE (A5332)	Kristine Erlandson, MD
1:20	Question and Answer	Team