



**Annual ACTG Network Meeting  
June 20-24, 2018**

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## PLENARY SESSION I

**Thursday, June 21, 2018, 8:00 a.m. – 10:30 a.m.**

**Moderators:** Judith Currier, MD, MSc  
ACTG Network Chair

Joseph Eron, MD  
ACTG Network Vice Chair

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

8:00	Welcome and Introductions	Judith Currier, MD, MSc Joseph Eron, MD Ian Sanne, MBBCH, FTP
8:00	State of the Institute and Priorities in HIV/AIDS Research	Anthony Fauci, MD
8:40	State of the ACTG	Judith Currier, MD, MSc

### **Tuberculosis Transformative Science Group**

8:50	A5279 (BRIEF TB)	Richard Chaisson, MD
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### **Antiretroviral Therapy Strategies Transformative Science Group**

9:20	A5288 (3 <sup>rd</sup> -Line ART in RLS)	Beatriz Grinsztejn, MD
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### **Scientific Agenda Steering Scientific Committee**

9:50	A5263 (Advanced KS Chemo)	Susan Krown, MD
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### **Women's Health Inter-Network Scientific Committee**

10:10	A5282 (HPV Test-and-Treat)	Timothy Wilkin, MD, MPH
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## PLENARY SESSION II

**Friday, June 22, 2018, 8:00 a.m. – 10:00 a.m.**

**Moderators:** Judith Currier, MD, MSc  
ACTG Network Chair

Joseph Eron, MD  
ACTG Network Vice Chair

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

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|------|---|---|
| 8:00 | Minority HIV Investigator Mentoring Program (MHIMP)       | Jose Castillo-Mancilla, MD                            |
|      | a. MHIMP, 20 Years Later                                  |   |
|      | b. 2018-2019 Award Announcement                           |   |
| 8:15 | Presentation of 2018 Awards                               |   |
|      | a. John Carey Young Investigator Award                    | Judith Currier, MD, MSc                               |
|      | b. Constance B. Wofsy Women's Health Award                | Elizabeth Connick, MD                                 |
|      | c. Donna Davis Community Award                            | Morenike Onaiwu<br>Belinda Ameterra<br>Lionel Hillard |
| 8:30 | Community Update  |   |
|      | a. 2018 Community Scientific Agenda                       | Angel Hernandez                                       |
|      | b. The Legacy and Future of Global HIV Community Advocacy | Morenike Onaiwu<br>Belinda Ameterra<br>Lionel Hillard |

### **End-organ Disease and Inflammation Transformative Science Group**

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|------|------------------------------|--------------------|
| 9:00 | A5314 (MTX in HIV Positives) | Ahmed Tawakol, MD  |
| 9:15 | A5350 (Effect of Visbiome)   | Turner Overton, MD |

### **Hepatitis Transformative Science Group**

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|------|--|----------------------|
| 9:30 | A5327 [Sofosbuvir for Acute HCV (SWIFT-C)] | Georg Lauer, MD, PhD |
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### **Women's Health Inter-network Scientific Committee**

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|------|-------------------------------------|-----------------------------|
| 9:45 | A5316 (Vaginal Ring & ART PK Study) | Kimberly Scarsi, PharmD, MS |
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## PLENARY SESSION III

**Saturday, June 23, 2018, 8:00 a.m. – 10:00 a.m.**

**Moderators:** Judith Currier, MD, MSc  
ACTG Network Chair

Joseph Eron, MD  
ACTG Network Vice Chair

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

### **ACTG Service Awards**

8:00	Recognition of ACTG Service	Judith Currier, MD, MSc Joseph Eron, MD Ian Sanne, MBBCH, FTP (SA)
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### **HIV Reservoirs and Viral Eradication Transformative Science Group**

8:15	ART Reduces T cell Activation and Immune Exhaustion Markers in HIV Controllers	Paul Sax, MD
8:35	Effect of ATI on Reservoir Size and Diversity	Jonathan Li, MD
8:55	Cure TSG Agenda and Future Directions	Rajesh Gandhi, MD

### **HIV Reservoirs and Viral Eradication Transformative Science Group and Neurology Collaborative Science Group**

9:15	HIV Persistence in CSF and Neurocognitive Performance in People on Long-term ART: Results from A5321	Kevin Robertson, PhD
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### **Antiretroviral Therapy Strategies Transformative Science Group**

9:40	NWCS 413 (Monogram Assay and bNAb Sensitivity)	Katharine Bar, MD
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## SYMPOSIUM I:

### TUBERCULOSIS TRANSFORMATIVE SCIENCE GROUP

**Friday, June 22, 2018, 4:00 p.m. – 6:00 p.m.**

**Chair:** Gavin Churchyard, MBBCh, MMed, FCP, PhD  
The Aurum Institute for Health Research

**Vice Chair:** Kelly Dooley, MD, PhD  
Johns Hopkins University CRS

#### **Tuberculosis Transformative Science Group**

4:00	TB Preventive Therapy in Pregnancy	Amita Gupta, MD
4:30	TB Diagnostics Landscape	Susan Dorman, MD
5:00	Long-acting TB Formulations	Sue Swindells, MBBS
5:30	To Have and Have Not: Immune Restoration and Lung Injury in HIV/TB	Gregory Bisson, MD, MSCE

**SYMPOSIUM II:**

**HEPATITIS TRANSFORMATIVE SCIENCE GROUP (HEP TSG)**

**Friday, June 22, 2018, 4:00 p.m. – 5:00 p.m.**

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

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

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|---|--|
| 1. Welcome and Update                                     | Mark Sulkowski, MD<br>Susanna Naggie, MD |
| 2. Immunologic Approaches to Hepatitis B Virus (HBV) Cure | Shyam Kottlilil, MD, PhD                 |
| 3. Virologic Approaches to HBV Cure                       | Chloe Thio, MD                           |
| 4. Roundtable Discussion                                  | HEP TSG Members                          |

### SYMPOSIUM III:

## BROADLY NEUTRALIZING MONOCLONAL ANTIBODIES (BNABS) AND ANTIRETROVIRAL THERAPY STRATEGIES TRANSFORMATIVE SCIENCE GROUP (ARTS TSG) AND HIV RESERVOIRS AND VIRAL ERADICATION TRANSFORMATIVE SCIENCE GROUP (CURE TSG)

Saturday, June 23, 2018, 1:30 p.m. – 3:30 p.m.

#### ARTS TSG

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

**Vice Chair:** Charles Flexner, MD  
The Johns Hopkins Baltimore-Washington-India CTU

#### CURE TSG

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

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

1:30	Overview of the State of bNAbs for Therapy and Cure	Marina Caskey, MD
1:55	Community Perspective on bNAb Research for Therapeutics and Cure	Andy Kaytes
2:20	Ongoing bNAb-oriented Protocols and Update on Pre-screening for Sensitivity	Katharine Bar, MD
2:45	Vaccine Research Consortium (VRC) bNAb Pipeline, VRC-ACTG Partnership	Grace Chen, MD Lucio Gama, MS, PhD
3:10	The ACTG's Role of bNAbs in the Cure TSG Agenda	Pablo Tebas, MD

**SYMPOSIUM IV:**

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

**Sunday, June 24, 2018, 9:00 a.m. – 11:00 a.m.**

**Chair:** Turner Overton, MD  
Alabama CTU

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

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|----|--|--|
| 1. | HIV and Aging-related ACTG Studies     | Turner Overton, MD<br>Netanya Utay, MD |
| 2. | Perspectives from the Community        | Jeffrey Taylor                         |
| 3. | Mixed Lineage Kinase 3 Inhibition      | Harris Gelbard, MD, PhD                |
| 4. | Aging among Women in HIV               | Phyllis Tien, MD                       |
| 5. | HIV and the Aging Brain/Nervous System | Ronald Ellis, MD, PhD                  |
| 6. | Discussion                             | All                                    |



## INTRODUCTION TO THE ACTG: WORKSHOP FOR NEW INVESTIGATORS

Thursday, June 21, 2018, 2:30 p.m. – 5:30 p.m.

**Facilitator:** Joseph Eron, MD  
ACTG Network Vice Chair

1. Introduction to the ACTG and Secondary Analysis Opportunities
  - a. Introduction to ACTG and Scientific Committees Joseph Eron, MD
  - b. Introduction to Statistical and Data Analysis Center Lu (Summer) Zheng, PhD
  - c. Biorepository Heather Ribaldo, PhD
  - d. Protocol Team/Protocol Development Eric Daar, MD
  - e. A5321: Opportunities for Involvement Rajesh Gandhi, MD
  - f. International Studies: Opportunities for Involvement Amita Gupta, MD
2. Interactive Mentoring Session for New Investigators Monica Gandhi, MD, MPH
  - a. Overview: Definitions of Mentoring and Mentoring Styles
  - b. Time Management for Academicians 101
  - c. Tips for Grant Writing
3. Wrap-Up Joseph Eron, MD

**TUBERCULOSIS TRANSFORMATIVE SCIENCE GROUP (TB TSG)  
RESEARCH AGENDA WORKSHOP  
FOR INTERNATIONAL AND JUNIOR INVESTIGATORS**

**Wednesday, June 20, 2018, 2:00 p.m. – 3:30 p.m.**

**Moderator:** Susan Swindells, MBBS

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|----|---|---------------------------|
| 1. | Welcome and Introductions                     | Susan Swindells, MBBS     |
| 2. | Latent TB Infection                           | Vidya Mave, MD, MPH       |
| 3. | Diagnosis and Management of Drug Sensitive TB | Alberto Mendoza, MD       |
| 4. | Diagnosis and Management of Drug-Resistant TB | Francesca Conradie, MBBCh |
| 5. | Open Discussion                               | All Participants          |
| 6. | Wrap Up / Next Steps                          | Susan Swindells, MBBS     |

**ANTIRETROVIRAL THERAPY STRATEGIES  
TRANSFORMATIVE SCIENCE GROUP (ARTS TSG)  
THINK TANK**

**Saturday, June 23, 2018, 4:00 p.m. – 6:00 p.m.**

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

**Vice Chair:** Charles Flexner, MD  
The Johns Hopkins Baltimore-Washington-India CTU

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|--|-------------------------------------|
| 1. Welcome and Introductions   | ARTS TSG Chairs                     |
| 2. Progress on A5381(Observe TLD)  | James Hakim, MBChB, MMed,<br>MMedSc |
| 3. Introduction: ACTG Experience with Biomarkers of<br>ARV Adherence Using Dried Blood Spots (DBS) | Charles Venuto, PharmD              |
| <hr/>  |                                     |
| Use of DBS (Dried Blood Spot) Technology to<br>Measure Adherence                                   | Peter Anderson, PharmD              |

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

**Friday, June 22, 2018, 10:30 a.m. – 12:30 p.m.**

**Chair:** Turner Overton, MD  
Alabama CTU

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

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| 1. Update on Recent ITSG Presentations and Publications  | Turner Overton, MD<br>Netanya Utay, MD                     |
| 2. Update on ITSG Studies and Focus/Working Groups       | Turner Overton, MD<br>Netanya Utay, MD                     |
| 3. Obesity and Fat Metabolism in HIV Meeting Overview    | Catherine Godfrey, MD                                      |
| 4. A5322 [Aging, HIV Infection and Inflammation (HAILO)] |  |
| a. Study Update  | Katherine Tassiopoulos, ScD, MPH<br>Kristine Erlandson, MD |
| b. Frailty, Physical Function and Exercise               |  |
| 5. CMV as a Pathogen in HIV Disease                      | Peter Hunt, MD<br>Michael Freeman, MD                      |

**HEPATITIS TRANSFORMATIVE SCIENCE GROUP (HEP TSG)  
THINK TANK**

**Friday, June 22, 2018, 1:30 p.m. – 3:30 p.m.**

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

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

1. Welcome and Update on the HEP TSG Scientific Agenda Mark Sulkowski, MD  
Susanna Naggie, MD
  
2. **Hepatitis C Virus (HCV)**
  - a. EASL Update with focus on Role of TSG in HCV Elimination Sunil Solomon, MBBS, PhD, MPH
  
  - b. Protocol Updates/Discussion
    - i. A5327 (SWIFT-C) Jennifer Kiser, PharmD
    - ii. A5360 (MINMON Study) Sunil Solomon, MBBS, PhD, MPH
    - iii. A5380 (PURGE- C) Susanna Naggie, MD
  
  - c. Discussion All HEP TSG Members
  
3. **Hepatitis B Virus (HBV)**
  - a. EASL Update with focus on HBV Capsid Inhibitors Jordan Feld, MD, MPH
  
  - b. Protocol Updates/Discussion
    - i. A5368 (CHECK HBV) Debika Bhattacharya, MD
    - ii. A5379 (Bee-HIVe) Kristen Marks, MD
    - iii. A5382 (HPV Test-and-Treat) Shyam Kottilil, MD, PhD
  
  - c. Discussion All HEP TSG Members
  
4. **Nonalcoholic Steatohepatitis (NASH)**
  - a. EASL Update with Focus on Leading Therapeutic Agents Richard Sterling, MD, FACP, FACG
  
  - b. Protocol Update/Discussion
    - i. DACS for HAILO Kara Chew, MD, MS
  
  - c. Discussion All HEP TSG Members
  
5. Roundtable Discussion All HEP TSG Members

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

**Saturday, June 23, 2018, 10:30 a.m. – 12:30 p.m.**

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

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

10:30	Review of the External Cure Advisory Group Feedback	Rajesh Gandhi, MD Pablo Tebas, MD
11:00	IL-15 Superagonist (ALT-803)	Jeffrey Safrit, PhD
11:30	In Vivo Targeting of Nucleic Acid Therapeutics	Drew Weissman, MD, PhD
12:00	ABCs of Data: Confounding Issues in HIV Research	Ronald Bosch, PhD Carlee Moser, PhD

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

**Friday, June 22, 2018, 10:30 a.m. – 12:30 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: Think Tank**

10:30	Welcome and Introductions	Scott Letendre, MD
10:35	HIV and Alzheimer's Disease	Eliezer Masliah, MD
11:05	HIV and Behavioral Science	Robert Remien, PhD
11:25	Discussion: Incorporation of Aging and Behavioral Science into the CSG Agenda	All Members and Guests

**Part II: Business Session**

11:45	Guided Discussion Regarding Other Scientific Priorities	All Members and Guests
	a. ART Neurotoxicity	
	b. Long-Acting ART	
	c. Drug Abuse (NIDA): Cannabis and Others	
12:10	Future Directions	All Members
	a. New Proposals	
	b. Recompensation Planning	

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

**Friday, June 22, 2018, 1:00 p.m. – 3:30 p.m.**

**Chair:** Gavin Churchyard, MBBCh, MMed, FCP, PhD  
The Aurum Institute for Health Research

**Vice Chair:** Kelly Dooley, MD, PhD  
Johns Hopkins University CRS

1:00	Welcome and Update	Gavin Churchyard, MBBCh Kelly Dooley, MD, PhD
1:10	New Drugs and Regimens	Eric Nuermberger, MD
1:40	New Trials Design	Michael Hughes, PhD Sachiko Miyahara, PhD Ritesh Ramchandani, PhD
2:05	A5338 (DMPA in HIV/TB) Primary Results	Rosie Mngqibisa, MB ChB, MPH
2:20	CURE-TB Strategy Proposals	Payam Nahid, MD
2:55	TB Meningitis Proposal	Felicia Chow, MD Vidya Mave, MD, MPH



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

**Thursday, June 21, 2018, 1:30 p.m. – 3:30 p.m.**

**Chair:** Elizabeth Connick, MD  
University of Arizona CRS

**Vice Chair:** Rosie Mngqibisa MBChB, MPH  
Durban International CRS

1:30 Welcome and Introductions Elizabeth Connick, MD  
Rosie Mngqibisa, MBChB, MPH

**Clinical Pharmacology Advisory Group and WHISC Joint Session**

1:35 Hormonal Contraception and ART/TB Drugs Kimberly Scarsi, PharmD, MS

1:50 Discussion All

1:55 PK Differences between Men and Women and their Relationship to Antiviral PD Responses Jose Castillo-Mancilla, MD

2:10 Discussion All

**WHISC**

2:15 Women's Participation in HIV Cure-Related Studies: What is Needed to Mind the Gap Karine Dubé, DrPH, MPhil

2:40 Discussion All

2:45 Women HIV Research Collaborative (WHRC) Liz Barr, PhD, MS

2:55 Discussion All

**DATA MANAGEMENT COMMITTEE  
BUSINESS SESSION**

**Friday, June 22, 2018, 3:00 p.m. – 4:00 p.m.**

**Co-Chairs:** Chad Achenbach, MD  
Northwestern University CRS

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 | Chad Achenbach, MD                    |
| 2. Overview of RAVE/Medidata | Kristine Coughlin, BA<br>Amanda Grant |
| 3. Form Reviews              | Kristine Coughlin, BA<br>Amanda Grant |

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

**Thursday, June 21, 2018, 4:00 p.m. – 6:00 p.m.**

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

**Co-Vice Chairs:** Joan Coetzee, CPN, PN  
Family Clinical Research Unit CRS

Joan Gottesman BSN, RN, CCRP  
Vanderbilt Therapeutics CRS

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|---|--------------------------|
| 1. Welcome and PDISC Working Group Overview   | Kathy Watson, RN         |
| 2. Presentation: Perceptions of People Living with HIV on HIV Cure-Related Research | Karine Dubé, DrPH, MPhil |
| 3. PDISC Working Group Updates  |                          |
| a. Field Representatives  | Kathy Watson, RN         |
| b. Outreach, Recruitment, and Retention   | Robert Bucklew, JD       |
| c. Pharmacy   | Grady Douglas, RPh       |
| 4. Discussion   | All                      |

**SITE MANAGEMENT AND CLINICAL CARE COMMITTEE (SMCCC)  
RESOURCE COMMITTEE FAIR**

**Thursday, June 21, 2018, 11:00 a.m. - 12:30 p.m.**

**Chair:** Ilene Wiggins, RN  
The Johns Hopkins Baltimore-Washington India  
CTU

**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. | Subcommittee Questions & Answers | All Participants         |

## SITE OPERATIONS SUBCOMMITTEE (SOS) SESSION

**Friday, June 22, 2018, 1:30 p.m. - 3:30 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. | Overview of SOS   | Jane Baum, RN<br>Vuyo Jezile, BBS<br>Shirley Ventresca |
| 3. | Suggestions for Topics for SOS:                                 | All Participants                                       |
|    | a. Study Coordinators and Data & Quality Managers Working Group |  |
|    | b. Training & Education Working Group                           |  |
| 4. | Review of Brainstorming Session for Topics:                     | All Participants                                       |
|    | a. Study Coordinators and Data & Quality Managers Working Group |  |
|    | b. Training & Education Working Group                           |  |

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

**Friday, June 22, 2018, 12:30 p.m. – 2:00 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 Minority HIV Investigator Mentoring Program (MHIMP) Presentations                                 | Moises A. Huaman, MD, MSc<br>Gustavo E. Velásquez, MD, MPH<br>Daniel Mendoza, MD, MPH |
| 3. 2018-2019 ACTG MHIMP Awardees Introductions   | Jose Castillo-Mancilla, MD  |
| 4. UPC Recommendations to Improve MHIMP Based on Survey and Incorporating International Investigators to MHIMP | Jose Castillo-Mancilla, MD<br>Carlos del Rio, MD                                      |
| 5. Update on A5359 (LA for Non-adherent) Participants  | Jose Castillo-Mancilla, MD  |
| 6. Discussion/Closing  | All Members   |
| a. Future Directions of the UPC  |   |
| b. Women and Minority Recruitment  |   |

## COMMUNITY SCIENTIFIC SUBCOMMITTEE SESSION I

Friday, June 22, 2018, 12:30 p.m. – 2:30 p.m.

**CSS Co-Chairs:** Belinda Ameterra, South African Tuberculosis Vaccine Initiative CRS

Liz Barr, Johns Hopkins University CRS

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|---|--------------------------------------|
| 1. CSS Team Building                      | Belinda Ameterra<br>Ronald Ssenyonga |
| 2. Overview of Online Resources/Education | Angel Hernandez                      |
| 3. Upcoming Positions                     | Belinda Ameterra<br>Angel Hernandez  |

## COMMUNITY SCIENTIFIC SUBCOMMITTEE SESSION II

Saturday, June 23, 2018, 2:30 p.m. – 4:30 p.m.

**CSS Co-Chairs:** Belinda Ameterra, South African Tuberculosis Vaccine Initiative CRS

Liz Barr, Johns Hopkins University CRS

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|---------------------------------------|---|
| 1. Mentoring Needs                    | Belinda Ameterra<br>Stanford Chimutimunzeve |
| 2. Setting Goals and Keeping Momentum | Belinda Ameterra<br>Angel Hernandez         |



## GLOBAL COMMUNITY ADVISORY BOARD SESSION I

Wednesday, June 20, 2018, 8:00 a.m. – 11:30 a.m.

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

Lionel Hillard  
Trinity Health and Wellness Center CRS

**CSS Co-Chairs:** Belinda Ameterra  
South African Tuberculosis Vaccine Initiative CRS

Liz Barr  
Johns Hopkins University CRS

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|---|--|
| 1. Welcome and Introductions  | Morenike Giwa Onaiwu<br>Lionel Hillard   |
| 2. Report Writing Interactive Part 1                                | Morenike Giwa Onaiwu<br>Tejaswi Sevekari   |
| 3. CAB Presentations<br>Harare, Birmingham, Philippines and Houston | Estere Mutero<br>Rick Walton<br>Morenike Giwa Onaiwu<br>Melissa Murry<br>Christian Cosning |
| 4. Aging Research in the ACTG Scientific Agenda                     | Turner Overton, MD   |
| 5. Open Discussion  | Community  |

## GLOBAL COMMUNITY ADVISORY BOARD SESSION II

Wednesday, June 20, 2018, 12:30 p.m. – 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:** Belinda Ameterra  
South African Tuberculosis Vaccine Initiative CRS

Liz Barr  
Johns Hopkins University CRS

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|---|---|
| 1. HIV and Transgender Population Session – CAB/Staff Interactive | Brian Minalga MSW<br>Michele Andrasik PhD                   |
| 2. How Nutrition Affects the Effectiveness of HIV Drugs           | Grady Douglas, BS, RPh                                      |
| 3. Women’s HIV Research Collaboration                             | Brian Minalga MSW<br>Morenike Giwa Onaiwu<br>Allegra Cermak |
| 4. Immunology of Persistence                                      | Bernard Macatangay, MD<br>Alan Landay, PhD                  |
| 5. Virology of Persistence  | Jonathan Li, MD, MMS  |

## GLOBAL COMMUNITY ADVISORY BOARD SESSION III

Thursday, June 21, 2018, 12:00 p.m. – 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:** Belinda Ameterra  
South African Tuberculosis Vaccine Initiative CRS

Liz Barr  
Johns Hopkins University CRS

1. ACTG Strong: Persisting and Rebuilding our Work in the Wake of a Disaster Angel Hernandez
2. HIV Life Cycle Video
3. ACTG Update Ian Sanne, MBBCH, FTP (SA)
4. HOPE in Action: HIV to HIV Transplantation in the United States Diane Brown RN, MSN
5. CSS Selection Process Morenike Giwa Onaiwu  
Lionel Hillard
6. The Secret Garden, the Female Microbiome Catherine Godfrey MD, FRACP

## GLOBAL COMMUNITY ADVISORY BOARD SESSION IV

Sunday, June 24, 2018, 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:** Belinda Ameterra  
South African Tuberculosis Vaccine Initiative CRS

Liz Barr  
Johns Hopkins University CRS

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|----|-----------------------------------|--|
| 1. | Report Writing Interactive Part 2 | Morenike Giwa Onaiwu<br>Tejaswi Sevekari                 |
| 2. | Community Reports                 | Community Attendees                                      |
| 3. | Community Awards                  | Morenike Giwa Onaiwu<br>Lionel Hillard<br>Allegra Cermak |

**ACTG NETWORK LABORATORY CENTER, ACTG AND TRANSFORMATIVE  
SCIENCE GROUP (TSG) LEADERSHIP JOINT SESSION\***

**(\*LABORATORIANs AND TSGs ENCOURAGED TO ATTEND)**

**Thursday, June 21, 2018, 12:30 p.m. – 5:30 p.m.**

**Chairs:** Alan Landay, PhD  
ACTG Network Laboratory Center Scientific Director

Grace Aldrovandi, MD  
ACTG Network Laboratory Center Principal Investigator

12:30	Welcome	Grace Aldrovandi, MD Alan Landay, PhD
12:35	Laboratory Retreat Follow-Up	
1:30	Laboratory/TSG Interactions	
2:30	Laboratory Technologist Integration Discussion	
3:00	New Science for ACTG Laboratories	
3:00	a. Omics	Mark Cameron, PhD Dr. Cheryl Cameron, PhD
3:30	b. Proviral DNA	Frank Laird , PhD Albine Martin, PhD
4:00	c. Flow Cytometry/Cytof	TBD
4:30	Open Discussion and Wrap Up	

## FUTURE DIRECTIONS OF THE NETWORK LABORATORY CENTER

Wednesday, June 20, 2018, 8:00 a.m. - 10:00 a.m.

**Chairs:** Grace Aldrovandi, MD  
ACTG Network Laboratory Center Principal Investigator

Alan Landay, PhD  
ACTG Network Laboratory Center Scientific Director

8:00	Introduction to the New Laboratory Principal Investigator	Grace Aldrovandi, MD
8:20	Laboratory Accreditation Requirements (ISO, WHO, GCLP)	Anita Gillis, MPH
8:50	Required Use of LDMS Preloads	Heather Sprenger, MS
9:10	Leukapheresis Processing Best Practices	Sarah Keinonen, BS
9:40	New ACTG Processes: MTA Requirements for Laboratories, Changes in ACTG Shipping Practices	Anita Gillis, MPH
9:50	Panel Questions	

Note: Speakers will each provide a brief overview/introduction to their topics.

# INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA) SHIPPING TRAINING

**Saturday, June 23, 2018, 3:00 p.m. - 6:30 p.m.**

**Chair:** David Shugarts, MA  
University of Colorado Denver

Christopher Lane, AAS  
University of Rochester

Irma Matic  
Biomedical Research Institute (BRI)

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

**LABORATORY TECHNOLOGIST COMMITTEE/DATA MANAGEMENT CENTER  
INTERACTIVE**

**Thursday, June 21, 2018, 10:30 a.m. - 12:30 p.m.**

**Chair:** Heather Sprenger, MS  
ACTG Data Management Center  
Frontier Science & Technology  
Research Foundation, Inc.

10:30	Welcome and Introductions	Heather Sprenger, MS
10:40	Query System	Katelyn Hergott, MPH, MSW
11:10	Documenting Data Corrections in LDMS	Alex Bennis
11:30	Laboratory Evaluation Metrics (including site laboratory and specialty laboratory metrics)	Alex Bennis
12:00	Web LDMS Updates	Alex Bennis
12:15	Questions & Answers	All



## LABORATORY TECHNOLOGIST COMMITTEE OPEN TRAINING SESSION

Wednesday, June 20, 2018 12:00 p.m. - 1:00 p.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, PhD, MS, MPH  
Gaborone CRS

12:00	LTC Past, Present and Future	David Shugarts, MA
12:15	Leukopak Certification/Recertification Process	David Shugarts, MA Sarah Keinonen
12:30	Laboratory Approval Process	Jenny Nguyen
12:45	MTA Process	Allan-Michael Bills

## SMILE: INNOVATIVE APPROACHES TO EQA

Wednesday, June 20, 2018, 11:00 a.m. - 12:00 p.m.

**Chair:** Anne Leach, BS, MT(ASCP)  
pSMILE Coordinator

11:00	Introduction and Welcome	Anne Leach, BS, MT (ASCP)
11:05	QuantiFERON	Orlinda Maforo, BS
11:20	NHLS SmartSpot for GeneXpert	Peggy Coulter, MDE, MT (HEW) Afton Dorasamy, BSc hon (HPCSA)
11:35	HAIN LPA Dry Panel EQA	Afton Dorasamy, BSc hon (HPCSA)
11:50	2 <sup>nd</sup> Level DST	Peggy Coulter, MDE, MT (HEW)

## SPECIALTY LABORATORY BREAKOUT SESSIONS

Wednesday, June 20, 2018, 10:00 a.m. - 5:30 p.m.

**Chairs:** Grace Aldrovandi, MD  
Children's Hospital Los Angeles

Alan Landay, PhD  
Rush University CRS

- 10:00      Pharmacology Specialty Laboratory (PSL) Breakout      Gene Morse, PharmD
- a. Introduction and Welcome
  - b. Brief Updates
    - i. Alabama PSL
    - ii. UCSF PSL
    - iii. UCSF Hair Analytical Laboratory
    - iv. UNMC PSL
    - v. UB PSL
    - vi. UZ IPSL
    - vii. UCT IPSL
    - viii. CPQA
  - c. Questions & Closing
- 11:30      Genomics Breakout      David Haas, MD
- Human Genomics and the ACTG: Leveraging  
Genomic Technologies for Pharmacogenomics and  
Beyond
- 11:40      Break
- 1:00      Virology Specialty Laboratory (VSL) Breakout      John Mellors, MD
- a. Introduction and Welcome
  - b. Brief Updates:
    - i. Harvard VSL
    - ii. University of Washington VSL
    - iii. University of Pittsburgh VSL
    - iv. International Genotyping Labs
    - v. LTC
    - vi. VQA
    - vii. SDAC

- c. Science
  - i. What new technologies are needed? HIV  
HBV, other viruses?
  - ii. What technologies are in development at  
VSLs?
  - iii. What assays should be automated or  
outsourced?
- d. Logistics/Operations
  - i. Budgets
  - ii. Assignment of protocol virologists
  - iii. Virology Core calls
  - iv. Annual Report
  - v. Equipment replacement
  - vi. How to improve work efficiency?
- e. Discussion of Strategy for Recompensation

3:00

Tuberculosis Specialty Laboratories Breakout

Carole Wallis, MS., MED, PhD

- a. Introduction and Welcome
- b. A5349 (TBTC S31)
- c. A5300B/I2003B PHOENix (MDR TB Households)  
Laboratory Training
- d. Validations:
  - i. QuantiFERON Gold PLUS
  - ii. GeneXpert Ultra
- e. Training and Competency Panels:
  - i. HAIN LPA
  - ii. GeneXpert Ultra
- f. New Assays
  - i. Whole Genome Sequencing
  - ii. Experience with the Abbott TB Assay
  - iii. Experience with GeneXpert Ultra NHLS

Questions & Discussion

**SITE STAFF TRAINING**

**COMMUNITY STAFF INTERACTIVE: HIV AND TRANSGENDER  
POPULATION SESSION**

**Wednesday, June 20, 2018, 12:30 p.m. – 2:00 p.m.**

**Facilitator:** Renee Weinman, MPPM  
University of Pittsburgh CRS

- |                                   |   |
|-----------------------------------|---|
| 1. Welcome and Introductions      | Renee Weinman, MPPM                         |
| 2. HIV and transgender population | Brian Minalga, MSW<br>Michele Andrasik, PhD |
| 3. Questions and Answers          | All   |

## SITE STAFF TRAINING

### DATA MANAGER/CLINICIAN INTERACTIVE

Thursday, June 21, 2018, 3:00 p.m. – 4:00 p.m.

**Facilitator:** Kathleen Donahue, MA  
ACTG Data Management Center

- |                                       |                      |
|---------------------------------------|----------------------|
| 1. Welcome and Introductions          | Kathleen Donahue, MA |
| 2. Data Manager/Clinician Interactive | Kathleen Donahue, MA |
| 3. Questions and Answers              | All                  |

## SITE STAFF TRAINING

### MONITORING/CQMP

Wednesday, June 20, 2018, 2:00 p.m. – 4:00 p.m.

**Facilitator:** Jane Baum, BSN, RN  
Case CRS

- |                              |                     |
|------------------------------|---------------------|
| 1. Welcome and Introductions | Jane Baum, BSN, RN  |
| 2. Monitoring/CQMP           | Manizhe Payton, MPH |
| 3. Questions and Answers     | All                 |

## SITE STAFF TRAINING

### TRAUMA INFORMED CARE FOR TRANSGENDER RESEARCH PARTICIPANTS

Wednesday, June 20, 2018, 8:00 a.m. – 10:00 a.m.

**Facilitator:** Renee Weinman, MPPM  
University of Pittsburgh CRS

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|---|---|
| 1. Introduction   | Renee Weinman, MPPM                         |
| 2. Trauma Informed Care for Transgender Research Participants | Brian Minalga, MSW<br>Michele Andrasik, PhD |
| 3. Questions and Answers                                      | All   |



## PROTOCOL-SPECIFIC TRAINING

### VRC 607/A5378 (SAFETY & VIROLOGIC EFFECT OF HIV-1 SPECIFIC BROADLY NEUTRALIZING HUMAN MABS [VRC01LS & VRC07-523LS]) PROTOCOL START-UP TRAINING

Thursday, June 21, 2018, 10:30 a.m. – 12:00 p.m.

#### Chair and VRC

**Principal Investigator:** Grace Chen, MD, MPH  
Vaccine Research Center (VRC), NIH

#### Co-Chair and ACTG

**Principal Investigator:** Pablo Tebas, MD  
Hospital of the University of Pennsylvania, Philadelphia HIV Treatment  
and Therapeutics CTU

1	Welcome and Introductions	Pablo Tebas, MD
2	Brief Overview of Protocol	Pablo Tebas, MD Grace Chen, MD, MPH
3	Schedule of Evaluations	Eileen Donaghy, BSN, CRNP Tanisha Sullivan, BA
4	Emmes Database Introduction	Anjali Nair, MS Haley Cochran
5	Laboratory Issues	Amy James-Loftis, BS
6	Pharmacy Issues	Justine Beck, PharmD Oladapo Alli, PharmD
7	Requirements for Site Activation	Jhoanna Roa, MD
8	Site Questions	Team

## PROTOCOL-SPECIFIC TRAINING

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

Thursday, June 21, 2018, 4:00 p.m. – 6:00 p.m.

**Chair:** Kevin Robertson, PhD  
University of North Carolina, Chapel Hill CRS

**Co-Chair:** Serena Spudich, MD  
Yale University School of Medicine, Weill Cornell Chelsea CRS

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

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|----|----------------------------|--|
| 1. | Welcome                    | Kevin Robertson, PhD                       |
| 2. | Study Update               | Kevin Robertson, PhD<br>Baiba Berzins, MPH |
| 3. | Neuropsychological Battery | Kevin Robertson, PhD                       |
| 4. | Neurological Examination   | Kevin Robertson, PhD                       |
| 5. | Lumbar Puncture            | Kevin Robertson, PhD                       |
| 6. | Site Questions             | Team                                       |

## PROTOCOL-SPECIFIC TRAINING

### A5349/TBTC STUDY 31 (RIFAPENTINE-CONTAINING TUBERCULOSIS TREATMENT SHORTENING REGIMENS)

**TBTC Co-Chairs:** Susan Dorman, MD  
Medical University of South Carolina

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

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

**ACTG Vice Chair:** Wadzanai Samaneka, MBChb, MSc  
Parirenyatwa CRS

1. A5349/TBTC Study 31 Team and Sites Session  
*Saturday, June 23, 2018, 10:30 a.m. – 12:30 p.m.*  
Susan Dorman, MD  
Payam Nahid, MD  
Sue Swindells, MBBS  
Richard Chaisson, MD  
Ekaterina Kurbatova, MD  
Erin Sizemore, MPH  
Andrew Vernon, MD  
Anne Purfield, PhD  
Kia Bryant, MPH

## PROTOCOL-SPECIFIC TRAINING

### A5366 (TAMOXIFEN AND VORINOSTAT)

**Thursday, June 21, 2018, 12:30 p.m. – 1:30 p.m.**

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

Eileen Scully, MD, PhD  
Johns Hopkins University CRS

**Vice Chair:** Daniel Kuritzkes, MD  
Harvard/Boston/Providence CTU

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|---|---|
| 1. Welcome  | Rajesh Gandhi, MD<br>Eileen Scully, MD, PhD |
| 2. Social Science Questionnaires (with A5345 Sites) | Karine Dubé, DrPH, MPhil                    |
| 3. Screening Updates, Review Screening Plan         | Apsara Nair, MS                             |
| 4. Site Questions and Comments                      |   |

**TEAM AND SITES SESSION**  
**REPRIEVE (A5332): OUR PATH FORWARD**

**Friday June 22, 2018, 12:30 p.m. – 1:30 p.m.**

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

Pamela Douglas, MD  
Duke University

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  
University of Cincinnati CRS

Judith Aberg, MD  
Mt. Sinai CRS

Markella Zanni, MD  
Massachusetts General Hospital

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|---|--|
| 1. Welcome  | Turner Overton, MD                             |
| 2. REPRIEVE Has Come a Long Way! Progress to Date     | Steven Grinspoon, MD                           |
| 3. Updates from National Heart Lung Blood Institute   | Gail Pearson, MD                               |
| 4. From the Heart: Updates from the Team Cardiologist | Pam Douglas, MD                                |
| 5. Team Awards!!!                                     | Carl Fichtenbaum, MD and<br>Turner Overton, MD |
| 6. Questions and Answers                              | Team   |

## TEAM AND SITES INTERACTIVE SESSION

### A5354 (EARLY ART IN ACUTE HIV)

**Friday, June 22, 2018, 4:00 p.m. – 5:00 p.m.**

**Co-Chairs:** Jintanat Ananworanich, MD, PhD  
US Military HIV Research Program

Eric Daar, MD  
Harbor-UCLA Medical Center CRS

**Co-Vice Chairs:** Trevor Crowell, MD, PhD  
US Military HIV Research Program

Javier Lama, MD, MPH  
San Miguel CRS

- |   |   |
|---|---|
| 1. Welcome  | Chairs  |
| 2. Update on Enrollment                                       | Chairs  |
| 3. a. Clinical Evaluations/Procedures and Optional Procedures | Team Members  |
| b. Laboratory Assays and Testing                              | <ul style="list-style-type: none"><li>• Chairs</li><li>• Data Manager</li><li>• Laboratory Data Manager</li><li>• Laboratory Technologist</li></ul>       |
| 4. Fiebig Staging   | Team Members  |
|   | <ul style="list-style-type: none"><li>• Statisticians</li><li>• Data Manager</li><li>• Laboratory Data Manager</li><li>• Robert Coombs, MD, PhD</li></ul> |
| 5. Samples Shipment Considerations                            | Laboratory Technologist   |
| 6. Questions from Team and Sites                              | All Attendees   |
| 7. Open Discussion  | All Attendees   |

**TEAM AND SITES INTERACTIVE SESSION**  
**A5357 (CAB LA+VRC01LS FOR HIV SUPPRESSION)**

**Thursday, June 21, 2018, 4:00 p.m. – 6:00 p.m.**

**Co-Chairs:** Babafemi Taiwo, MBBS  
Chicago CTU

Pablo Tebas, MD  
Philadelphia HIV Prevention and Therapeutics CTU

**Vice Chair:** Leah Burke, MD  
Weill Cornell Chelsea CRS

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|----------------------------------|---|
| 1. Welcome and Introductions     | Babafemi Taiwo, MBBS<br>Pablo Tebas, MD<br>Leah Burke, MD |
| 2. Study Overview                | Babafemi Taiwo, MBBS<br>Pablo Tebas, MD<br>Leah Burke, MD |
| 3. Electronic Case Report Forms  | Bernadette Jarocki, BS                                    |
| 4. Laboratory Considerations     | Team Member Designee                                      |
| 5. Questions from Team and Sites | All Attendees   |
| 6. Open Discussion               | All Attendees   |

## TEAM AND SITES SESSION

### A5359: Long Acting ARVs in Non-Adherent Participants

Wednesday, June 20, 2018, 10:00 a.m. – 12:00 noon

**Co-Chairs:** Jose Castillo-Mancilla, MD  
University of Colorado Hospital CRS

Aadia Rana, MD  
Alabama CTU

**Co-Vice Chairs:** Raphael Landovitz, MD, MSc  
University of California, Los Angeles CARE Center CRS

Karen Tashima, M.D.  
The Miriam Hospital CRS

10:00	Welcome & Introductions	Jose Castillo-Mancilla, MD Aadia Rana, MD
10:02	Protocol Overview	Jose Castillo-Mancilla, MD Aadia Rana, MD
	a. Background	
	b. Inclusion/Exclusion	
	c. Overview of SOE for each step	
	d. Experience with LA (1 slide on AE, 1 slide on management of injection site reactions)	
	e. DTG safety update	
10:37	Questions & Answers	All A5359 Team Members
10:50	eCRFs for Questionnaires	Kaileigh Johnson, MS
11:00	Adherence & Retention Training (for Study Coordinators)	Steven Shoptaw, PhD Michael Stirratt, PhD
	a. Counseling protocol	
	b. Role play	



## TEAM AND SITES SESSION

### A5360 (MINMON Study)

**Friday, June 22, 2018, 5:00 p.m. – 6:00 p.m.**

**Chair:** Sunil Solomon, MBBS, PhD, MPH  
Johns Hopkins Adult AIDS CRS

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

Mark Sulkowski, MD  
Johns Hopkins Adult AIDS CRS

5:00	Welcome and Overview of A5360	Sunil Solomon, MBBS, PhD, MPH
5:10	Review of Questionnaires	Christine Scello, MA
5:25	Team-Sites Questions and Answers	All attendees
5:45	Open Discussion	All attendees

## A5375 (OPTIMIZE LNG EC) SITE TRAINING AND INFORMATION SESSION

**Saturday, June 23, 2018, 10:00 a.m. - 11:00 a.m.**

**Chair:** Kimberly Scarsi, PharmD, MS  
Northwestern University CRS  
University of Nebraska Medical Center

**Vice Chair:** Rosie Mngqibisa, MB ChB, MPH  
Durban International CRS

10:30	Introductions	Kim Scarsi, PharmD, MS Rosie Mngqibisa, MB ChB, MPH
10:35	Protocol Overview	
10:50	Site Challenges and Emergency Contraception Barriers – Discussion	

**A5381 (OBSERVE TLD) SITE TRAINING AND INQUIRY FOR  
PREPAREDNESS SESSION**

**Saturday, June 23, 2018, 11:00 a.m. - 12:30 p.m.**

**Chair:** James Hakim, MBChB, MMed, MMedSc  
Parirenyatwa CRS

**Co-Chair:** Cissy Kityo, MBChB, MSc, PhD  
Joint Clinical Research Center/Kampala CRS

**Vice Chairs:** Charles Flexner, MD  
The John Hopkins Baltimore-Washington-India  
(BWI) CTU

John Mellors, MD  
Pitt-Ohio State CTU

11:00	Introductions	James Hakim, MBChB, MMed, MMedSc
11:05	Overview of the Study and Site Participation Overview	James Hakim, MBChB, MMed, MMedSc
11:15	Site Preparedness Discussion	James Hakim, MBChB, MMed, MMedSc Cissy Kityo, MBChB, MSc, PhD Charles Flexner, MD John Mellors, MD