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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

Antiretroviral Therapy Strategies Transformative Science Group

9:20 A5288 (3rd-Line ART in RLS)
Beatriz Grinsztejn, MD

Scientific Agenda Steering Scientific Committee

9:50 A5263 (Advanced KS Chemo)
Susan Krown, MD

Women’s Health Inter-Network Scientific Committee

10:10 A5282 (HPV Test-and-Treat)
Timothy Wilkin, MD, MPH
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

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 Belinda Ameterra 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 Belinda Ameterra Lionel Hillard

End-organ Disease and Inflammation Transformative Science Group

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

Hepatitis Transformative Science Group

9:30 A5327 [Sofosbuvir for Acute HCV (SWIFT-C)] Georg Lauer, MD, PhD

Women’s Health Inter-network Scientific Committee

9:45 A5316 (Vaginal Ring & ART PK Study) Kimberly Scarsi, PharmD, MS
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)

**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

**Antiretroviral Therapy Strategies Transformative Science Group**

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

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

1. Welcome and Update
   Mark Sulkowski, MD
   Susanna Naggie, MD

2. Immunologic Approaches to Hepatitis B Virus (HBV) Cure
   Shyam Kottilil, 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

1. HIV and Aging-related ACTG Studies
   Turner Overton, MD
   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 Ribaudo, 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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<td>Welcome and Introductions</td>
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<td><strong>2.</strong></td>
<td>Latent TB Infection</td>
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<td><strong>3.</strong></td>
<td>Diagnosis and Management of Drug Sensitive TB</td>
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<td>Diagnosis and Management of Drug-Resistant TB</td>
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<td><strong>5.</strong></td>
<td>Open Discussion</td>
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<td><strong>6.</strong></td>
<td>Wrap Up / Next Steps</td>
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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

1. Welcome and Introductions
   ARTS TSG Chairs

2. Progress on A5381(Observe TLD)
   James Hakim, MBChB, MMed, MMedSc

3. Introduction: ACTG Experience with Biomarkers of ARV Adherence Using Dried Blood Spots (DBS)
   Charles Venuto, PharmD

________________________________________________________________________

Use of DBS (Dried Blood Spot) Technology to 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

1. Update on Recent ITSG Presentations and Publications
   Turner Overton, MD
   Netanya Utay, MD

2. Update on ITSG Studies and Focus/Working Groups
   Turner Overton, MD
   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
      Kristine Erlandson, MD
   b. Frailty, Physical Function and Exercise

5. CMV as a Pathogen in HIV Disease
   Peter Hunt, MD
   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)
      ii. A5360 (MINMON Study)
      iii. A5380 (PURGE-C)

   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)
      ii. A5379 (Bee-HIVE)
      iii. A5382 (HPV Test-and-Treat)

   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

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<td>Welcome and Introductions</td>
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<tr>
<td>10:35</td>
<td>HIV and Alzheimer's Disease</td>
<td>Eliezer Masliah, MD</td>
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<tr>
<td>11:05</td>
<td>HIV and Behavioral Science</td>
<td>Robert Remien, PhD</td>
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<tr>
<td>11:25</td>
<td>Discussion: Incorporation of Aging and Behavioral Science into the CSG Agenda</td>
<td>All Members and Guests</td>
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### Part II: Business Session

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<thead>
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<th>Time</th>
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<tr>
<td>11:45</td>
<td>Guided Discussion Regarding Other Scientific Priorities</td>
<td>All Members and Guests</td>
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<td></td>
<td>a. ART Neurotoxicity</td>
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<td>b. Long-Acting ART</td>
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<td></td>
<td>c. Drug Abuse (NIDA): Cannabis and Others</td>
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<td>12:10</td>
<td>Future Directions</td>
<td>All Members</td>
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<tr>
<td></td>
<td>a. New Proposals</td>
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<td>b. Recompetition Planning</td>
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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

1. Welcome and Introductions Chad Achenbach, MD
2. Overview of RAVE/Medidata Kristine Coughlin, BA
Amanda Grant
3. Form Reviews Kristine Coughlin, BA
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

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

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, BBSc
University of the Witwatersrand Helen Joseph CRS

Shirley Ventresca
Ohio State University CRS

1. Welcome and Introductions
   Jane Baum, RN

2. Overview of SOS
   Jane Baum, RN
   Vuyo Jezile, BBSc
   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

1. **Welcome and Introductions**  
   Jose Castillo-Mancilla, MD

2. **2017-2018 Minority HIV Investigator Mentoring Program (MHIMP) Presentations**  
   Moises A. Huaman, MD, MSc  
   Gustavo E. Velásquez, MD, MPH  
   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  
   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

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

1. Mentoring Needs
   Belinda Ameterra
   Stanford Chimutimunzeve

2. Setting Goals and Keeping Momentum
   Belinda Ameterra
   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

1. Welcome and Introductions
   Morenike Giwa Onaiwu
   Lionel Hillard

2. Report Writing Interactive Part 1
   Morenike Giwa Onaiwu
   Tejaswi Sevekari

3. CAB Presentations
   Harare, Birmingham, Philippines and Houston
   Estere Mutero
   Rick Walton
   Morenike Giwa Onaiwu
   Melissa Murry
   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

1. HIV and Transgender Population Session – CAB/Staff Interactive
   Brian Minalga MSW
   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
   Morenike Giwa Onaiwu
   Allegra Cermak

4. Immunology of Persistence
   Bernard Macatangay, MD
   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

1. Report Writing Interactive Part 2
   Morenike Giwa Onaiwu
   Tejaswi Sevekari

2. Community Reports
   Community Attendees

3. Community Awards
   Morenike Giwa Onaiwu
   Lionel Hillard
   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

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>12:30</td>
<td>Welcome</td>
<td>Grace Aldrovandi, MD</td>
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<td></td>
<td>Alan Landay, PhD</td>
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<tr>
<td>12:35</td>
<td>Laboratory Retreat Follow-Up</td>
<td>Mark Cameron, PhD</td>
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<td>Dr. Cheryl Cameron, PhD</td>
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<tr>
<td>1:30</td>
<td>Laboratory/TSG Interactions</td>
<td>Frank Laird, PhD</td>
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<td></td>
<td>Albine Martin, PhD</td>
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<tr>
<td>2:30</td>
<td>Laboratory Technologist Integration Discussion</td>
<td>TBD</td>
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<tr>
<td>3:00</td>
<td>New Science for ACTG Laboratories</td>
<td>Mark Cameron, PhD</td>
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<td>Dr. Cheryl Cameron, PhD</td>
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<tr>
<td>3:00</td>
<td>a. Omics</td>
<td>Frank Laird, PhD</td>
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<td>Albine Martin, PhD</td>
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<tr>
<td>3:30</td>
<td>b. Proviral DNA</td>
<td>TBD</td>
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<tr>
<td>4:00</td>
<td>c. Flow Cytometry/Cytof</td>
<td>TBD</td>
</tr>
<tr>
<td>4:30</td>
<td>Open Discussion and Wrap Up</td>
<td>TBD</td>
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### 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

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

-30-
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<tr>
<th>Time</th>
<th>Session Title</th>
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<tbody>
<tr>
<td>10:30</td>
<td>Welcome and Introductions</td>
<td>Heather Sprenger, MS</td>
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<tr>
<td>10:40</td>
<td>Query System</td>
<td>Katelyn Hergott, MPH, MSW</td>
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<tr>
<td>11:10</td>
<td>Documenting Data Corrections in LDMS</td>
<td>Alex Benns</td>
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<tr>
<td>11:30</td>
<td>Laboratory Evaluation Metrics (including site laboratory and specialty laboratory metrics)</td>
<td>Alex Benns</td>
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<tr>
<td>12:00</td>
<td>Web LDMS Updates</td>
<td>Alex Benns</td>
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<tr>
<td>12:15</td>
<td>Questions &amp; Answers</td>
<td>All</td>
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</table>
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
<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>11:00</td>
<td>Introduction and Welcome</td>
<td>Anne Leach, BS, MT (ASCP)</td>
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<tr>
<td>11:05</td>
<td>QuantiFERON</td>
<td>Orlinda Maforo, BS</td>
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<tr>
<td>11:20</td>
<td>NHLS SmartSpot for GeneXpert</td>
<td>Peggy Coulter, MDE, MT (HEW)</td>
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<td>Afton Dorasamy, BSc hon (HPCSA)</td>
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<td>11:35</td>
<td>HAIN LPA Dry Panel EQA</td>
<td>Afton Dorasamy, BSc hon (HPCSA)</td>
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<td>11:50</td>
<td>2nd Level DST</td>
<td>Peggy Coulter, MDE, MT (HEW)</td>
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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 Recompetition

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  
   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

1. Introduction
   Renee Weinman, MPPM

2. Trauma Informed Care for Transgender Research Participants
   Brian Minalga, MSW
   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

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

1. Welcome Kevin Robertson, PhD
2. Study Update Kevin Robertson, PhD
   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

1. Welcome
Rajesh Gandhi, MD
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
TEAMS 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 Ribaudo, 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

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 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

2. Update on Enrollment

3. a. Clinical Evaluations/Procedures and Optional Procedures
   b. Laboratory Assays and Testing

4. Fiebig Staging

5. Samples Shipment Considerations

6. Questions from Team and Sites

7. Open Discussion
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

1. Welcome and Introductions Babafemi Taiwo, MBBS
Pablo Tebas, MD
Leah Burke, MD

2. Study Overview Babafemi Taiwo, MBBS
Pablo Tebas, MD
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

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<th>Time</th>
<th>Event</th>
<th>Presenter/Attendees</th>
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<tr>
<td>5:00</td>
<td>Welcome and Overview of A5360</td>
<td>Sunil Solomon, MBBS, PhD, MPH</td>
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<tr>
<td>5:10</td>
<td>Review of Questionnaires</td>
<td>Christine Scello, MA</td>
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<tr>
<td>5:25</td>
<td>Team-Sites Questions and Answers</td>
<td>All attendees</td>
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<tr>
<td>5:45</td>
<td>Open Discussion</td>
<td>All attendees</td>
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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