



**Annual ACTG Network Meeting
June 23-27, 2014**

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PLENARY SESSION I

NETWORK LEADERSHIP, ACTG AWARDS, DIVISION OF AIDS, COMMUNITY, WOMEN'S HEALTH INTER-NETWORK SCIENTIFIC COMMITTEE, AND CO-INFECTIONS AND MALIGNANCIES SUBCOMMITTEE

Tuesday, June 24, 2014, 3:30 p.m. – 6:30 p.m.

Chair: Daniel Kuritzkes, MD
ACTG Network Chair

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

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

3:30	Welcome and State of the ACTG	Daniel Kuritzkes, MD
3:45	Recognition of ACTG Service	Daniel Kuritzkes, MD Judith Currier, MD, MSc Ian Sanne, MBBCH, FTP
3:55	Presentation of 2014 ACTG Awards	
	a. Minority HIV Investigator Mentoring Program	Daniel Kuritzkes, MD
	b. John Carey Young Investigator Award	Judith Currier, MD, MSc
	c. Constance B. Wofsy Women's Health Investigator Award	Susan Cohn, MD, MPH
	d. Donna Davis Community Award	Morenike Giwa Paul Klees Aaron Laxton Pamela Tshandu
4:15	Report from the Division of AIDS	Carl Dieffenbach, PhD
4:45	Community Updates <i>(Presentations 7 minutes each followed by 9 minutes Q&A)</i>	
	a. Women's Enrollment Initiative	Liz Barr
	b. New and Pluripotent Community Advisory Boards	Morenike Giwa Paul Klees

	c. Community and Researchers: Walking Shoulder to Shoulder	Pamela Tshandu Aaron Laxton
	d. Questions and Answers	All
5:15	Women's Health Inter-Network Scientific Committee <i>(15 minutes presentation and Q&A for each topic)</i>	Susan Cohn, MD, MPH
	a. A5283 (DMPA and LPV/RTV PK in HIV- Infected Women)	Amneris Luque, MD
	b. A5077 (Domestic Genital Secretions and Saliva Study)	Rami Kantor, MD
	c. NWCS 319: "Immune Activation Status and HIV Treatment Outcomes in Resource-limited Settings"	Jyoti Mathad, MD
6:00	Co-Infections and Malignancies Subcommittee <i>(15 minutes presentation and Q&A for each topic)</i>	Timothy Wilkin, MD, MPH
	a. Stage I Data for A5225 (Fluconazole for CM)	Lauren Komarow, MS
	b. Baseline Data for A5298 (qHPV Vaccine to Prevent Anal HPV)	Ross Cranston, MD FRCP

PLENARY SESSION II

HIV RESERVOIRS AND VIRAL ERADICATION TRANSFORMATIVE SCIENCE GROUP AND REPRIEVE (A5332: PITAVASTATIN TO PREVENT CVD)

Wednesday, June 25, 2014, 10:30 a.m. - 12:30 p.m.

Chair: John Mellors, MD
Pitt-Ohio State CTU

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

10:30	State of the Cure and Role of ACTG Studies	John Mellors, MD
10:50	Findings from A5276s [Residual Viremia Substudy of A5001 (ALLRT)]: Persistent Viremia Cohort	Sharon Riddler, MD
11:10	Reversal of Immune Exhaustion as a Curative Strategy	Joseph Eron, MD
11:30	The Potential of Broadly Neutralizing Monoclonal Antibodies for HIV-1 Prevention and Cure	John Mascola, MD
12:00	REPRIEVE Study: A5332 (Pitavastatin to Prevent CVD)	Steven Grinspoon, MD

PLENARY SESSION III

ANTIRETROVIRAL THERAPY STRATEGIES SUBCOMMITTEE, TUBERCULOSIS TRANSFORMATIVE SCIENCE GROUP, AND HEPATITIS TRANSFORMATIVE SCIENCE GROUP

Thursday, June 26, 2014 – 10:30 a.m. – 12:30 p.m.

Antiretroviral Therapy Strategies Subcommittee (ARTS SC)

Chair: Eric Daar, MD
University of California, Los Angeles

Vice Chair: Michael Para, MD
The Ohio State University

Tuberculosis Transformative Science Group (TB TSG)

Chair: Richard Chaisson, MD
Johns Hopkins Adult AIDS CRS

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

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

Hepatitis Transformative Science Group (HEP TSG)

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

Vice Chair: Raymond Chung, MD
Massachusetts General Hospital CRS

ARTS SC: A5257 (Treatment in Naïve Using Compact ARV Regimens) Findings (10:30-11:30)

10:30	Analysis of Primary Study Results with Additional Information Regarding Diversity, Race, and Gender Results	Raphael Landovitz, MD
10:42	Human Genetics and Antiretroviral Discontinuation	Saran Vardhanabhuti, PhD
10:50	Lipid Changes, Metabolic Changes, and Pharmacokinetics	Ighowwerha Ofotokun MD, MSc
10:55	Question and Answer Period	All Participants
11:03	Changes in Bone Mineral Density Presentation from Retrovirus	Todd Brown, MD, PhD

- 11:11 Cardiovascular Outcomes from A5260 (Substudy of A5257): Results from American College of Cardiology Meeting James Stein, MD
- 11:22 Question and Answer Period All Participants
- TB TSG (11:30-11:50)**
- 11:30 A5295 (Xpert MTB/RIF vs. Standard TB Diagnostics in TB Suspects) Annie Luetkemeyer, MD
- HEP TSG (11:50-12:30)**
- 11:50 All Oral DAA Failures in HCV: How Will We Manage Them? Mark Sulkowski, MD

SYMPOSIUM I

TUBERCULOSIS TRANSFORMATIVE SCIENCE GROUP

Wednesday, June 25, 2014, 1:30 p.m. – 3:30 p.m.

Chair: Richard Chaisson, MD
Johns Hopkins University CRS

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

Diane Havlir, MD
San Francisco Bay CTU

1:30	Welcome	Richard Chaisson, MD
1:35	OFLOTUB Trial – Implications for Phase 3 TB Trials	Piero Olliaro, MD, PhD WHO Geneva, Oxford University
1:50	RioMar Trial – Rifapentine and Moxifloxacin Phase 2 Trial	Susan Dorman, MD Johns Hopkins University
2:05	Capetown Rifapentine Trial – Adaptive, Dose-Escalation Study	Susan Dorman, MD
2:20	NC-002 (Pa824/Moxifloxacin/Pyrazinamide) and NC-003 (Multidrug EBA Trial)	Carl Mendel, MD TB Alliance
2:35	PanACEA Trials	Martin Boeree, MD, PhD Radboud University Michael Hoelscher, MD, FRCP International Medicine & Public Health
2:50	Individual Level Results from a Randomized Clinical Trial of INH Preventive Therapy in HIV+ Patients (THRio)	Jonathan Gollub, PhD Johns Hopkins University
3:15	Discussion	All Participants

SYMPOSIUM II

INTENSELY MONITORED ANTIRETROVIRAL PAUSE

Thursday, June 26, 2014, 8:00 a.m. – 10:00 a.m.

Chair: John Mellors, MD
Pitt-Ohio State CTU

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

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| 8:00 | How to Perform Antiretroviral Therapy Interruption Safely | Timothy Schacker, MD |
| 8:30 | Analyses of Analytical Treatment Interruption in Past ACTG Studies | Jonathan Li, MD |
| 9:00 | Community Perspective on Intensely Monitored Antiretroviral Pause (iMAP) | Michael Dorosh
Andrew Kaytes |
| 9:30 | Goals of ACTG iMAP Study | David Smith, MD, MAS |

SYMPOSIUM III

NATIONAL INSTITUTE OF DRUG ABUSE (NIDA)-FUNDED ACTG PROJECTS, ADHERENCE INTERVENTION CONCEPT PROPOSAL, AND NEUROLOGY COLLABORATIVE SCIENCE GROUP

Friday, June 27, 2014, 9:30 a.m. – 11:30 a.m.

NIDA-ACTG Projects and Adherence Intervention Concept Proposal

Co-Chairs: Eric Daar, MD
Harbor University of California Los Angeles Center CRS

Carlos del Rio, MD
The Ponce de Leon Center CRS

Neurology Collaborative Science Group (CSG)

Co-Chairs: Kevin Robertson, PhD
Chapel Hill CRS

Serena Spudich, MD
Yale University School of Medicine

NIDA-ACTG Projects and Adherence Intervention Concept Proposal (9:30-11:00)

9:30	Evaluation of High-Resolution Accurate Mass Spectroscopy as a Tool in the Management of Antiretroviral Therapy-Treated Drug Abusers	Gregory Lucas, MD
9:45	Evaluation of a Computer-Delivered Intervention for HIV-Infected Drug Users in Clinical Care	Geetanjali Chander, MD Heidi Hutton, MD
10:00	Impact of Methamphetamine Use on Immune Activation and HIV-1 Reservoir	David Smith, MD, MAS
10:15	Adherence Intervention Concept Proposal	Michelle Cespedes, MD

Neurology CSG (11:00-11:30)

11:00	Preview of A5324 (InMIND)	Kevin Robertson, PhD
11:05	CSF Escape	Scott Letendre, MD

**END-ORGAN DISEASE AND INFLAMMATION
TRANSFORMATIVE SCIENCE GROUP (ITSG)
EXERCISE FOCUS GROUP
BUSINESS SESSION**

Wednesday, June 25, 2014, 2:30 p.m. – 3:45 p.m.

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

Fred Sattler, MD
University of Southern California CRS

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|--|---|
| 1. Welcome and Introductions | Thomas Campbell, MD
Fred Sattler, MD |
| 2. Summary of Current Projects | Thomas Campbell, MD
Fred Sattler, MD |
| a. Position Statement | |
| b. Draft Proposals | |
| 3. Preparation for ITSG and Neurology Collaborative Science
Group Presentations | Thomas Campbell, MD
Fred Sattler, MD |

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

Thursday, June 26, 2014, 1:30 p.m. – 4:00 p.m.

Chair: Michael Lederman, MD
Case CTU

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

1:30	Exercise Focus Group Presentation and Discussion	Thomas Campbell, MD Fred Sattler, MD
2:30	Microbiome Focus Group Presentation and Discussion	Jeffrey Jacobson, MD
3:30	Inflammatory Interlude	Special Guests

**ANTIRETROVIRAL THERAPY STRATEGIES SUBCOMMITTEE
BUSINESS SESSION**

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

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

Vice Chair: Michael Para, MD
Ohio State University CRS

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| 1. Welcome and Introductions | Eric Daar, MD |
| 2. Overview of Enrollment Update for A5288 (3 rd Line ART in RLS) | Beatriz Grinsztejn, MD, PhD |
| 3. Vaccine Research Center Neutralizing Antibodies as an HIV Agent Protocol Development Plan | John Mascola, MD |
| 4. Current Development Plan for 744 as a Short and Long-Acting Agent | Kimberly Smith, MD, MPH |
| 5. Open Discussion of New Business | Eric Daar, MD
Michael Para, MD |

**CO-INFECTIONS AND MALIGNANCIES (COIMAL) SUBCOMMITTEE
BUSINESS SESSION**

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

Chair: Timothy Wilkin MD, MPH
Weill Cornell Chelsea CRS

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| 1. Welcome and Introductions | Timothy Wilkin, MD, MPH |
| 2. Brief Study Updates | |
| a. A5225 (Fluconazole for CM) | Lauren Komarow, MS |
| b. A5263 (Advanced KS Chemo) | Protocol Team Chairs |
| c. A5264 (Limited KS Study) | Protocol Team Chairs |
| d. A5282 (HPV Test-and-Treat) | Protocol Team Chairs |
| e. A5297 (Subclinical Parasitemia) | Protocol Team Chairs |
| 3. The Role of Viral Co-Infections on Immune Activation and Maintenance of the HIV Reservoir | David Smith, MD, MAS |
| 4. The Role of Inflammation and Immune Activation to the Development of Cancer Pathogenesis | Thomas Uldrick, MD, MS |
| 5. Roundtable Discussion: Future Direction of COIMAL | All Members |

HEPATITIS TRANSFORMATIVE SCIENCE GROUP THINK TANK

Thursday, June 26, 2014, 1:30 p.m. – 3:30 p.m.

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

Vice Chair: Raymond Chung, MD
Massachusetts General Hospital CRS

1. Welcome and Update
Marion Peters, MD
Raymond Chung, MD
2. Hepatocellular Carcinoma Outcomes in HIV Patients
Lewis R. Roberts, MB, ChB,
PhD
3. International Focus in HBV and HCV
a. Planning of an International DAA Trial for HCV
HEP TSG Members
b. Roundtable Discussion of Potential Interventional HBV Studies
4. Brief Study Updates
a. A5294 (BOC/PEG/RBV to Treat HCV Coinfection) Clinical
Trials Agreement
Adeel Butt, MD, MS
b. A5309s (PK and Drug Interaction of Boceprevir)
Adeel Butt, MD, MS
c. A5320 Long-Term HCV)
Robert Murphy, MD
d. A5327 (SWIFT-C)
Susanne Naggie, MD
e. A5329 (Interferon-free Tx for HCV Genotype 1)
Mark Sulkowski, MD
f. A5334s (A5329 PK Substudy)
Gene Morse, PharmD
g. A5335s (A5329 Liver Biopsy Substudy)
Mark Sulkowski, MD
h. A5339 (Triple DAAs for HIV/HCV Infection)
Debika Bhattacharya, MD
5. Open Discussion

HIV RESERVOIRS AND VIRAL ERADICATION TRANSFORMATIVE SCIENCE GROUP THINK TANK

Wednesday, June 25, 2014, 1:30 p.m. – 6:00 p.m.

Chair: John Mellors, MD
Pitt-Ohio State CTU

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

1:30 Introduction to Think Tank Goals John Mellors, MD

Year in Review: Protocols

- 1:40 Update on A5281 (HIV pDNA / IL12 by IM/EP or IM) Jeffrey Jacobson, MD
- 1:55 Update on A5308 (ART for HIV Controllers) Paul Sax, MD
- 2:10 Update on A5315 (Romidepsin to Awaken HIV) Deborah McMahon, MD
- 2:25 Update on A5321 (Reservoirs in Long-Term ART) and A5341s (Intensive Reservoir Sampling, A5321 Substudy) Rajesh Gandhi, MD
- 2:40 Update on A5326 (Anti-PD-L1 Antibody in HIV-1) Joseph Eron, MD
- 2:55 Update on A5337 (Sirolimus Study) Timothy Henrich, MD
- 3:10 Update on A5342 (Impact of VRC01 on HIV Persistence) Sharon Riddler, MD
- 3:25 **BREAK**

Year in Review: Concept Proposals

- 3:40 Update on PR 691, "Identification of Biomarkers to Predict Time to Plasma HIV RNA Rebound and Post-Treatment Viral Control During a Closely Monitored Antiretroviral Pause" Jonathan Li, MD
- 3:55 Update on "PR 693, "Effect of Antiretroviral Treatment Initiated During Acute HIV-1 Infection (AHI) on Measures of HIV-1 Persistence and on HIV-1-Specific Immune Responses" Eric Daar, MD

Year in Review: New Work Concept Sheets

- 4:10 Update on NWCS 360, "HIV Reservoir Measurements in HIV-infected Patients on Long-term (≥ 10 years) Suppressive Antiretroviral Therapy" John Mellors, MD
- 4:30 Update on NWCS 363, "HIV-1 Reservoirs in ccr5 Δ 32 Heterozygous Individuals" Timothy Henrich, MD

4:50 Update on NWCS 346, "Transcriptional Profiling of T Lymphocytes in HAART-Treated HIV-1 Patients After Treatment Intensification with Raltegravir" Mathias Lichterfeld, MD

New Horizons

5:10 Gene Therapy Working Group Update Pablo Tebas, MD

5:25 Therapeutic Vaccine Working Group Update Scott Hammer, MD
Richard Koup, MD

5:40 Open Discussion

TUBERCULOSIS TRANSFORMATIVE SCIENCE GROUP THINK TANK

Wednesday, June 25, 2014, 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 on TSG Agenda	Richard Chaisson, MD
4:15	XTEND Trial Results	Gavin Churchyard, MBBCh
4:30	Update on Molecular Testing for Drug Resistance, Including Sequencing of AFB Smears and an XDR Cartridge	David Alland, MD
4:50	Update on Studies in Development	
	a. A5289 (Phase II Study of Sutezolid vs Ethambutol in PTB)	Annie Luetkemeyer, MD
	b. A5319 (MARVEL: MDR-Additive Regimens Experimental Layouts)	C. Robert Horsburgh, MD Rosie Mngqibisa, MBBCh
	c. A5338 (DMPA in HIV/TB)	Kelly Dooley, MD, PhD
	d. A5343 (Bedaquiline Delamanid Study)	Gary Maartens, MBBCh, MMed
5:30	Mouse Data on Clofazimine	Deepak Almeida, PhD
5:45	New Concept Proposals	Richard Chaisson, MD

**NEUROLOGY COLLABORATIVE SCIENCE GROUP
BUSINESS SESSION**

Thursday, June 26, 2014, 3:30 p.m. – 5:30 p.m.

Chair: Kevin Robertson, PhD
Chapel Hill CRS

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

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|---|--|
| 1. Welcome and Introductions | Kevin Robertson, PhD
Serena Spudich, MD |
| 2. Report from Scientific Committee Representatives | Neurology Collaborative Science
Group Members |
| a. End-Organ Disease/Inflammation Transformative
Science Group (TSG) | |
| b. HIV Reservoirs and Viral Eradication TSG | |
| c. Co-infections and Malignancies Subcommittee | |
| d. Antiretroviral Therapy Strategies Subcommittee | |
| e. Hepatitis TSG | |
| 3. Working Groups Update | Working Group Chairs |
| a. Lumbar Puncture Working Group | |
| b. WHISC-Neuro Collaborations Working Group | |
| c. Inflammation TSG Neuro Exercise Focus Group | |
| 4. Active Protocols Update | Protocol Chairs |
| 5. Scientific Research Agenda Discussion | All Members |

**WOMEN'S HEALTH INTER-NETWORK SCIENTIFIC COMMITTEE INTERACTIVE
SESSION WITH HEPATITIS TRANSFORMATIVE SCIENCE GROUP AND
NEUROLOGY COLLABORATIVE SCIENCE GROUP**

Thursday, June 26, 2014, 4:30 p.m. – 6:30 p.m.

Women's Health Inter-Network Scientific Committee (WHISC)

Chair: Susan Cohn, MD
Northwestern University CRS

Vice Chair: Cynthia Firnhaber, MD
University of the Witwatersrand Helen Joseph CRS

Hepatitis Transformative Science Group (TSG)

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

Vice Chair: Raymond Chung, MD
Massachusetts General Hospital CRS

Neurology Collaborative Science Group (CSG)

Chair: Kevin Robertson, PhD
Chapel Hill CRS

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

4:30 Welcome

Susan Cohn, MD, MPH
Cindy Firnhaber, MD

Hepatitis TSG and WHISC Interactive Session (4:35-5:35)

4:35 Overview

Kristen Marks, MD

4:45 Hepatitis C in Pregnancy

Arthur Kim, MD

4:55 Hepatitis B

Debika Bhattacharya, MD

5:05 Hepatitis and Contraception

Kimberly Scarsi, PharmD

5:10 Discussion

All Participants

Neurology CSG and WHISC Interactive Session (5:35-6:30)

5:35	Overview	Serena Spudich, MD
5:45	Neurocognitive Dysfunction in Women: Lessons from a Longitudinal Cohort	Valerie Wojna, MD
5:55	HIV-Associated Neurocognitive Disorders: Age and Gender Issues	Scott Letendre, MD
6:05	Discussion	All Participants

DATA MANAGEMENT COMMITTEE BUSINESS SESSION

Wednesday, June 25, 2014, 5:30 p.m. – 6:30 p.m.

Co-Chairs: Robert Murphy, MD
Chicago CTU

Doug Kitch, MS
ACTG Statistical and Data Analysis Center

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

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| 1. Welcome and Introductions | Robert Murphy, MD |
| 2. Appendix 100 Update | All Members |
| 3. Any Other Business | All Members |

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

Wednesday, June 25, 2014, 9:30 a.m. – 10:30 a.m.

Chair: Lisa Kessels, RN, ACRN
Washington University Therapeutics CRS

Vice Chair: David Currin, RN, ACRN, CCRC
Chapel Hill CRS

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| 1. Welcome and Introductions | Lisa Kessels, RN, ACRN
David Currin, RN, ACRN, CCRC |
| 2. Functions and Interactions of SMCCC Subcommittees | Subcommittee Leadership |

**OUTREACH, RECRUITMENT, AND RETENTION (OR&R) SUBCOMMITTEE
BUSINESS SESSION**

Wednesday, June 25, 2014, 4:30 p.m. – 6:30 p.m.

Chair: Michael Louella
University of Washington AIDS Clinical Trials Unit CRS

Co-Vice Chairs: Christie Lyn Costanza, MPH
New Jersey Medical School Adult CRS

Savita Kanade, MSc
Byramjee Jeejeebhoy Government Medical College CRS

4:30	Welcome and Introductions	OR&R Chairs
4:35	OR&R Year in Review	Michael Louella Christie Lyn Costanza, MPH Savita Kanade, MSc
4:45	ACTG Day of Appreciation for Participants/ Volunteers – December 2, 2014	Michael Louella Study Coordinators
5:00	Recruitment and Retention of Women on ACTG Studies	Liz Barr, MS
5:15	Community Forum – Brainstorming and Sharing Adherence and Retention on ACTG Studies	Community Representatives All Members
5:45	Brochure Project – Update on Current Draft	Morag Maclachlan, MA
5:50	Social Media/Marketing Efforts	Morag Maclachlan, MA Larry Lawrence, BA Luis Lopez-Detres, BA
6:05	Flyer Production – Challenges	Savita Kanade, MS
6:20	Site Profiles	All Members

PHARMACY SUBCOMMITTEE BUSINESS SESSION

Tuesday, June 24, 2014, 8:00 a.m. – 9:00 a.m.

Chair: Amy Dill, PharmD
Cincinnati CRS

Vice Chair: Michael Royal, RPh
Washington University Therapeutics CRS

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| 1. Welcome | Amy Dill, PharmD
Michael Royal, RPh |
| 2. Roll Call/Introduction of Members | Amy Dill, PharmD
Michael Royal, RPh |
| 3. Overview of Subcommittee Activities | Amy Dill, PharmD |
| 4. Future Projects | Michael Royal, RPh |
| 5. Open Discussion | All Attendees |

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

Wednesday, June 25, 2014, 3:30 p.m. – 4:30 p.m.

Chair: Deborah Sutherland, RN, BSN, CCRP
Vanderbilt Therapeutics CRS

Vice Chair: Kathy Watson, RN
Ohio State University CRS

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|--------------------------------|---|
| 1. Welcome and Introductions | Deborah Sutherland, RN, BSN, CCRP
Kathy Watson, RN |
| 2. PDISC Overview and Projects | Deborah Sutherland, RN, BSN, CCRP
Kathy Watson, RN |

**SITE OPERATIONS SUBCOMMITTEE
BUSINESS SESSION**

Wednesday, June 25, 2014, 4:30 p.m. – 5:30 p.m.

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

Vice Chair: Suzanne Fiorillo, MSPH
University of Colorado Hospital CRS

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|---|---|
| 1. Welcome and Introductions | Ilene Wiggins, RN |
| 2. Record Destruction | Judith Brooks, RN, MS
Mary Anne Luzar, PhD |
| 3. Accomplishments for 2012-2014 | Jane Baum, RN
Ilene Wiggins, RN |
| 4. Ongoing Projects, Goals and Objectives for 2014-2015 | Ilene Wiggins, RN |
| 5. Open Discussion | All Members |

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

Thursday, June 26, 2014, 3:30 p.m. – 4:30 p.m.

Chair: Michelle Cespedes, MD, MS
Columbia Physicians & Surgeons CRS

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

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| 1. Welcome and Introductions | Michelle Cespedes, MD, MS |
| 2. Minority HIV Investigator Mentoring Program Report | Seble Kassaye, MD
Karen Vigil, MD |
| 3. UPC Short Range Objectives | Michelle Cespedes, MD, MS |
| 4. Adherence Intervention Study | Michelle Cespedes, MD, MS |

**COMMUNITY SCIENTIFIC SUBCOMMITTEE
BUSINESS SESSION I**

Wednesday, June 25, 2014, 6:00 p.m. – 7:00 p.m.

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

Aaron Laxton
Washington University Therapeutics CRS

Protocol Reporting Template

Aaron Laxton

**COMMUNITY SCIENTIFIC SUBCOMMITTEE
BUSINESS SESSION II**

Friday, June 27, 2014, 8:00 a.m. – 9:00 a.m.

Co-Chairs: Pamela Tshandu
Aaron Laxton

Recruiting Participants from Diverse Sites

GLOBAL COMMUNITY ADVISORY BOARD SESSION I

Monday, June 23, 2014, 9:00 a.m. – 12:00 p.m.

Co-Chairs: Morenike Giwa
Houston AIDS Research Team CRS

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

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|----|--|---|
| 1. | Welcome, Introductions and Announcements | Morenike Giwa
Paul Klees
Pamela Tshandu
Aaron Laxton |
| 2. | New CAB Presentations | Jacqueline Jacob
Nimit Tienudom
Donald Hughes |
| 3. | Tuberculosis Transformative Science Group Update | Larry Lyle |
| 4. | Hepatitis Transformative Science Group Update | Bernard Mpairwe |

GLOBAL COMMUNITY ADVISORY BOARD SESSION II

Monday, June 23, 2014, 1:00 p.m. – 6:00 p.m.

Co-Chairs: Morenike Giwa
Paul Klees

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| 1. | ACTG Update | Ian Sanne, FCP, FRCP |
| 2. | Genetic Markers in Cancer | Vikrant Sahasrabuddhe, MBBS,
MPH, DrPH |
| 3. | A Healthy Lifestyle | Amy Dill, PharmD |
| 4. | The Pharmacist's Role in Research | Michael Royal, RPh |
| 5. | Bridget Murtagh Awards | Morenike Giwa
Paul Klees |

GLOBAL COMMUNITY ADVISORY BOARD (GCAB) SESSION III

Tuesday, June 24, 2014, 8:00 a.m. – 12:00 p.m.

Co-Chairs: Morenike Giwa
Paul Klees

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| 1. | Community Partners Update | Nathaniel Johnson
Danielle Campbell
Sharon Maxwell
Modiko Moleofi |
| 2. | Women's Enrollment Initiative | Liz Barr |
| 3. | End Organ Disease/Inflammation Transformative Science Group Update | Peter Hunt, MD |
| 4. | CURE Transformative Science Group Update | Ann Collier, MD |
| 5. | Underepresented Populations Committee Discussion | Danielle Campbell
Martha Sichone-Cameron
Christopher Chauncey Watson
UPC and GCAB Panelists |

GLOBAL COMMUNITY ADVISORY BOARD SESSION IV

Friday, June 27, 2014, 12:00 p.m. – 3:00 p.m.

Co-Chairs: Sharon Maxwell
Paul Klees

1. Global Community Advisory Board's Got Talent ACTG Community Members
2. Neurology Transformative Science Group Update Serena Spudich, MD
3. Updates Community Representatives
 - a. Global Community Advisory Board
 - b. Community Scientific Subcommittee

**A5288 (3RD-LINE ART IN RLS) GENOTYPING LABORATORIES
BUSINESS SESSION**

Thursday, June 26, 2014, 1:30 p.m. – 2:30 p.m.

Chair: Carole Wallis, MSc MED, PhD
BARC Lancet Laboratories

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| 1. Welcome and Opening Remarks | Carole Wallis, PhD |
| 2. A5288 Genotyping Status Update | Carole Wallis, PhD |
| a. Protease/Reverse Transcriptase Resistance Testing | |
| b. Integrase Resistance Testing | |
| c. A5288 Site Registration Updates | |
| d. Genotyping Laboratory-specific Issues to Discuss
(Shipping, Alerts, Data Turn-Around, LDMS, World
Courier, etc.) | |
| 3. New Topics/Issues | All Participants |
| 4. Future ACTG A5288 Genotyping Laboratories Calls | ACTG NCC Laboratory Science
Group |
| a. Thursday, July 3, 2014 at 9:00 AM ET | |
| b. Thursday, August 7, 2014 at 9:00 AM ET | |

**LABORATORY WORKSHOP: ACTG WORKSHOP ON CLINICAL
PHARMACOLOGY BIOMATRICES FOR HIV, HCV AND TB –
ADHERENCE, PREVENTION, AND TREATMENT**

Monday, June 23, 2014, 2:30 p.m. – 5:30 p.m.

Chair: Gene Morse, PharmD
State University of New York at Buffalo Pharmacology Specialty Laboratory

PART I. Antiretroviral Drugs (ARVs)

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|---|-----------------------------------|
| 1. Welcome and Opening Remarks | Gene Morse, PharmD |
| 2. ARV Pharmacology Assays in Hair | Monica Gandhi, MD, MPH |
| 3. ARV Pharmacology Assays in Female and Male Genital Tract | Mark Marzinke, PhD |
| 4. ARV Pharmacology Assays in Gut Associated Lymphoid Tissue (GALT) | Peter Anton, MD |
| 5. ARV Pharmacology Assays in Red/White Blood Cells | Craig Sykes, MS |
| 6. ARV Pharmacology Assays in Cerebrospinal Fluid (CSF) | Robin DiFrancesco MT, (ASCP), MBA |

Question & Answer/Discussion for Part I

Topics for Discussion:

- a. What are the needs for tools to monitor adherence to ARV prevention of treatment agents?
- b. Process for developing pharmacologic assays (qualitative, semi-quantitative, quantitative)
- c. What are the pending research priorities that may utilize novel pharmacologic assays for protocols?

PART II. Direct Acting Antiviral (DAAs) in Liver

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| 7. HCV Direct Acting Antivirals in Living Tissue | Andrew Talal, MD, MPH |
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PART III. TB Drugs in Lung Tissue

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| 8. TB Drug Pharmacology Assays in Plasma vs. Lung Tissue | Kelly Dooley, MD, PhD |
| 9. TB Drug Measurements in Hair | Ruth Greenblatt, MD |

PART IV. Pharmacogenomics

10. Metabolism and Transporters In ACTG Protocols

David Haas, MD

Question & Answer/Discussion for Parts II-IV

Topics for Discussion:

- a. The scientific importance of liver vs. plasma PK
- b. The scientific importance of lung vs. plasma PK
- c. Can animal PK/PD studies guide clinical studies?
- d. Adherence and outcomes alternative biomatrix
- e. How can PK/PD of the alternative matrices be enhanced by genotyping and/or protein expression?

**LABORATORY TRAINING: ACTG/IMPAACT LABORATORY TECHNOLOGIST
COMMITTEE PROTOCOL SUPPORT TRAINING SESSION I**

Monday, June 23, 2014, 5:30 p.m. – 7:30 p.m.

Chair: Joan Dragavon, MLM, M(ASCP)
University of Washington AIDS Clinical Trials Unit CRS

Vice Chair: Cheryl Jennings
Rush University CRS

5:30	Welcome and Introductions	Joan Dragavon, MLM, M(ASCP) Cheryl Jennings
5:35	Overview of Laboratory Technologist Protocol Support Functions	Joan Dragavon, MLM, M(ASCP)
5:45	DARs: Understanding and Active Review	All Members
6:15	Blood Volumes: Intra and Inter Protocols	Carmen Irizarry, MT Kristine Coughlin
6:30	Shipping Preparation and Processing: Cost Accounting Challenges	Cheryl Jennings
6:40	Protocol Budgets: Understanding, Providing Active Review and Contributions	Lauren Robertson
7:10	Discussion	

**LABORATORY TRAINING: ACTG/IMPAACT LABORATORY TECHNOLOGIST
COMMITTEE PROTOCOL SUPPORT TRAINING SESSION II**

Tuesday, June 24, 2014, 8:00 a.m. – 10:00 a.m.

Chair: Joan Dragavon, MLM, M(ASCP)
University of Washington AIDS Clinical Trials Unit CRS

Vice Chair: Cheryl Jennings
Northwestern University CRS

8:00	Welcome and Introductions	Joan Dragavon, MLM, M(ASCP) Cheryl Jennings
8:05	Identification of and Handling Protocol Complexities	ACTG Network Coordinating Center Representatives
8:20	Training Tool Development for Novel or Complex PK Processing	Robin DiFrancesco, MT, MBA
8:35	Protocol Scoring and Determination of Processing Laboratory Effort by Visit	David Shugarts, MA Joan Dragavon, MLM, M(ASCP) Cheryl Jennings
9:20	Discussion	

LABORATORY TRAINING: FUTURE DIRECTIONS OF THE ACTG LABORATORY NETWORK

Monday, June 23, 2014, 9:00 a.m. – 11:00 a.m.

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

9:00	Welcome and Opening Remarks	Robert Coombs, MD, PhD
	a. Overview of the Laboratory Network in 2014	
	b. Accomplishment of the Laboratory Cores and Laboratory Technologist Committee	
9:10	Leukapheresis Processing Implementation and Quality Assurance in ACTG Protocols	Joan Dragavon, MLM, M(ASCP)
9:30	Pathology External Quality Assurance Update	Catherine Godfrey, MD
	a. ACTG A5282	
	b. A5263/64 PERCs	
9:50	Laboratory Division Data Management Updates and Innovations	Marlene Cooper, MS
	a. Flow Cytometry Electronic Data Transfer	
	b. PBMC Time to Process Tracking	
10:10	Virology Quality Assurance Update on Genotyping: Developing QA for Integrase Resistance Testing	James Bremer, PhD Cheryl Jennings, BS
10:30	Standardization in Diagnosis of Acute HIV Infection - Use of the LIAT system	Robert Coombs, MD, PhD
10:50.	TB Infection Control Checklist for ACTG Laboratories	Robert Coombs, MD, PhD
10:55	General Discussion	

**LABORATORY TRAINING: HARMONIZATION AND QUALITY ASSESSMENT
OF TUBERCULOSIS (TB) LABORATORY PROCEDURES
FOR ACTG CLINICAL STUDIES**

Monday, June 23, 2014, 1:00 p.m. – 3:00 p.m.

Chair: Anne-Marie Demers, MD
ACTG/IMPAACT/HVTN International TB Specialty Laboratory Centre for
Clinical Tuberculosis Research

Kathy Eisenach, PhD
University of Arkansas for Medical Sciences

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| 1:00 | Welcome and Opening Remarks | Kathy Eisenach, PhD
University of Arkansas for Medical Sciences |
| 1:05 | Setting Standards for TB Lab Tests and Harmonizing the Standards Across the TB Lab Network | Anne Marie Demers, MD
ACTG/IMPAACT/HVTN International TB Specialty Laboratory

Kathy Eisenach, PhD |
| 1:25 | TB External Quality Assurance and Key Indicators of Quality | Peggy Coulter, MDE, MT (HEW)
Patient Safety Monitoring in International Laboratories (pSMILE) |
| 1:45 | Molecular Testing External Quality Assurance Using Dried Culture Spots | Lesley Scott, PhD
University of the Witwatersrand |
| 2:00 | Open Forum: TB Lab Topics | Peggy Coulter, MDE, MT (HEW)

Anne Marie Demers, MD

Kathy Eisenach, PhD

Lesley Scott, PhD
University of the Witwatersrand

Marinus Barnard, PhD
ACTG/IMPAACT/HVTN International TB Specialty Laboratory

Moses Joloba, MD, PhD
ACTG/IMPAACT/HVTN Regional TB Diagnostic Laboratory Uganda-Case Western Reserve University Research Collaboration

All Participants |

IMMUNOLOGY SPECIALTY LABORATORIES DIRECTORS BUSINESS SESSION

Thursday, June 26, 2014, 4:15 p.m. – 6:00 p.m.

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

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| 4:15 | Welcome and Opening Remarks | Michael Lederman, MD |
| | Followup to April 24, 2014 Immunology Specialty Laboratories Directors Quarterly Call | |
| | New Business | |
| 4:20 | Comparison of R & D Systems, Inc. DuoSet vs Quantikine Platforms | Jill Plants
Rush-Presbyterian-St. Lukes Medical Center Immunology Specialty Laboratory |
| 4:45 | “Feeding Frenzy” - Plasma Cytokines | Michael Lederman, MD |
| 5:10 | International Tuberculosis Specialty Laboratories: Immunology Laboratory Updates | Nelita du Plessis PhD
ACTG/IMPAACT/HVTN International TB Specialty Laboratory |
| 5:35 | Fresh vs. Frozen Monocyte Staining Analysis | Jill Plants |

SPECIALTY LABORATORY DIRECTORS BUSINESS SESSION

Tuesday, June 24, 2014, 10:30 a.m. – 12:30 p.m.

Chair: Robert Coombs, MD, PhD
ACTG Network Laboratory Principal Investigator
University of Washington Virology Specialty Laboratory

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| 10:30 | Welcome and Opening Remarks | Robert Coombs, MD, PhD |
| | a. New ACTG Laboratories | |
| | b. Awards and Recognition: Lori Mong-Kryspin, MT (ASCP), SM (ASCP) | |
| 10:35 | Laboratory Technologist Committee Update | Joan Dragavon, MLM |
| 10:45 | International Pharmacology Specialty Laboratory Updates: Harare Developmental International Pharmacology Specialty Laboratory | Charles Maponga, PharmD |
| 11:00 | <i>5 minute session break - please move to breakout session rooms</i> | |

Breakout Sessions for Laboratory Cores

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| 11:05 | Mycobacteriology Laboratory Working Group and Tuberculosis Specialty Laboratories | Meeting Room 8 |
| 11:05 | Pharmacology Specialty Laboratories | Meeting Room 5 |
| 11:05 | Virology Specialty Laboratories, Genotyping Laboratories, Genomics Core, and Statistical and Data Analysis Center | Congressional A and B |

MYCOBACTERIOLOGY LABORATORY WORKING GROUP AND TUBERCULOSIS SPECIALTY LABORATORIES BREAKOUT SESSION

Tuesday, June 24, 2014, 11:00 a.m. – 12:30 p.m.

Mycobacteriology Laboratory Working Group

Co-Chairs: Constance Benson, MD
The University of California, San Diego CD4
Collaborative CTU

Susan Swindells, MBBS
University of Colorado Hospital CRS and
University of Nebraska

TB Specialty Laboratories

Co-Chairs: Anne-Marie Demers, MD
ACTG/IMPAACT/HVTN International TB Specialty
Laboratory Centre for Clinical Tuberculosis Research

Marinus Barnard, PhD
TASK Applied Science CRS

11:00	New Rapid Molecular Diagnostic Test for TB	Gavin Cloherty, PhD
11:20	Xpert Quality Assurance Program Data	Lesley Scott, PhD
11:35	Microbank Tube Validation	Peter Meewes, PhD
11:45	Mock Sputum Update	Anne-Marie Demers, MD
12:00	Standardization of TB Microbiology for Clinical Trials: Efforts of the TB Laboratory Core Team and Bridging the Gaps Between the Study Protocol, Laboratory Testing and Reporting Study Data	Kathleen Eisenach, PhD Anne-Marie Demers, MD All Participants

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

Tuesday, June 24, 2014, 11:00 a.m. – 12:30 p.m.

Chair: John Mellors, MD
University of Pittsburgh Virology Specialty Laboratory

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| 11: 00 | Welcome and Opening Remarks | John Mellors, MD |
| | Follow-up to May 15, 2014 Virology Specialty
Laboratories Directors Quarterly Call | |
| | New Business | |
| 11:15 | New Scientific Updates: SDAC | Ron Bosch, PhD |
| 11:25 | New Scientific Updates: Vanderbilt DNA Resources
Core | David Haas, MD |
| 11:35 | International Genotyping Laboratories Update | Carole Wallis, MSc MED,
PhD |
| 11:45 | New Scientific Updates: Harvard University ACTG
Virology Specialty Laboratory | Daniel Kuritzkes, MD
Jonathan Li, MD |
| 12:00 | New Scientific Updates: University of Washington
ACTG Virology Specialty Laboratory | Robert Coombs, MD, PhD |
| 12:15 | New Scientific Updates: University of Pittsburgh
ACTG Virology Specialty Laboratory | John Mellors, MD |

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

Tuesday, June 24, 2014, 11:00 a.m. – 12:30 p.m.

Chair: Judith Currier, MD, MSc
ACTG Vice Chair

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| 1. Introduction and ACTG Structure | Judith Currier, MD, MSc |
| 2. New Work Concept Sheets (NWCSs) and Data Analysis Concept Sheets (DACSSs) | Janet Andersen, ScD
ACTG Statistical and Data Analysis Center |
| 3. Concept Proposals | Eric Daar, MD
Harbor University of California Los Angeles Center CRS |
| 4. Protocol Team Involvement and Opportunities | Joseph Eron, MD
University of North Carolina Global HIV Prevention & Treatment CTU |
| 5. International New Investigator Perspective | Rosie Mngqibisa, MBChB
Durban International CRS |
| 6. Discussion and Wrap-up | Judith Currier, MD, MSc |

LEADERSHIP AND OPERATIONS CENTER PROTOCOL FUNDS TRAINING

Monday, June 23, 2014, 1:00 p.m. – 4:00 p.m.

Facilitator: Trisha Walton, BSN, RN
Case CRS

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| 1. Welcome and Introductions | Trisha Walton, BSN, RN |
| 2. Protocol Funds | Lauren Robertson, MHA, MSM
ACTG Leadership and Operations Center |
| a. Allocation Process | Angela Rhodes
ACTG Leadership and Operations Center |
| b. Contracts and Budgets | Lindsey Kreutzer, MPH
ACTG Leadership and Operations Center |
| c. Site Budgeting | Ina de Jongh
University of Witwatersrand HIV Research
Group CTU |
| 3. Question and Answer | All |

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

Monday, June 23, 2014, 8:00 a.m. – 9:00 a.m.

Facilitator: Valery Hughes, FNP
Weill Cornell Uptown CRS

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

**SITE STAFF TRAINING:
HOW TO “DO QUALITY ASSURANCE (QA)”**

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

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

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| 1. Welcome and Introductions | Valery Hughes, FNP |
| 2. Definition of QA | Ilene Wiggins, RN |
| 3. What Can QA Do For You? | Veronica Sims, PA-C |
| 4. Where to Find Popular Data Management QA Tools | Laura Smith, MPH |
| 5. QA Tools for Sites | Ilene Wiggins, RN |
| 6. Questions and Answers | All |

**SITE STAFF TRAINING:
MONITORING - HOW TO PREPARE AND WHAT TO EXPECT**

Monday, June 23, 2014, 10:00 a.m. – 11:00 a.m.

Facilitator: Valery Hughes, FNP
Weill Cornell Uptown CRS

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| 1. Welcome and Introductions | Valery Hughes, FNP |
| 2. Monitoring - How to Prepare and What to Expect | Veronica Sims, P.A.-C
Greg Lessing, BSc |
| 3. Questions and Answers | All |

**SITE STAFF TRAINING:
AN INTRODUCTION TO SOCIAL MEDIA
FOR OUTREACH**

Monday, June 23, 2014, 11:00 a.m. – 12:00 p.m.

Facilitator: Sara Mattiucci, BS, RN
University of Pittsburgh CRS

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| 1. Welcome and Introductions | Sara Mattiucci, BS, RN |
| 2. An Introduction to Social Media for Outreach | Morag MacLachlan, MA
Larry Lawrence
Michael Louella
Luis Lopez-Detres, BA |
| 3. Questions and Answers | All |

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

Monday, June 23, 2014, 4:00 p.m. – 5:30 p.m.

Facilitator: Leslie Degnan, MPH
Blantyre CRS

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| 1. Welcome and Introductions | Leslie Degnan, MPH |
| 2. Protocol Registration Office and Financial Disclosure | Melissa Kin, MS, MBA |
| 3. Informed Consent | Linda Ehler, RN, NM |
| 4. Essential Documents | Janet O'Brien |
| 5. Critical Events | Lyndi Lahl, RN, MS |
| 6. Protocol Documents | Lyndi Lahl, RN, MS |
| 7. CQMP | Karen Reese, MS |
| 8. Questions and Answers | All |

**SITE STAFF STRAINING:
INTERNATIONAL CLINICAL RESEARCH SITE ROUNDTABLE OPEN FORUM**

Tuesday, June 24, 2014, 7:00 a.m. – 9:00 a.m.

Facilitator: Christina Blanchard-Horan, PhD
ACTG Network Coordinating Center

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| 1. Welcome | Leslie Degnan, MPH |
| 2. International CRS Roundtable | Christina Blanchard-Horan, PhD |
| 3. Discussion | Site Staff |

**SITE STAFF TRAINING:
ACTG COMMITTEES**

Tuesday, June 24, 2014, 9:00 a.m. – 10:00 a.m.

Facilitator: Valery Hughes, FNP
Weill Cornell Uptown CRS

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| 1. Welcome and Introductions | Valery Hughes, FNP |
| 2. Overview of ACTG Committees | David Currin, RN, ACRN, CCRC |
| 3. Questions and Answers | All |

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

Tuesday, June 24, 2014, 10:00 a.m. – 11:00 a.m.

Facilitator: Madeline Torres, BSN
Columbia Physicians and Surgeons CRS

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| 1. Welcome and Introductions | Madeline Torres, BSN |
| 2. Improving Quality and Compliance through Effective SOP Development | Lisa Triantafillou, BA
Social & Scientific Systems, Inc. |
| 3. Questions and Answers | All |

**SITE STAFF TRAINING:
REGULATORY JUGGLING**

Tuesday, June 24, 2014, 11:00 a.m. – 12:00 p.m.

Facilitator: Fanny Rosas, RN
Barranco CRS

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| 1. Welcome and Introductions | Fanny Rosas, RN |
| 2. Regulatory Juggling | Leslie Degnan, MPH
Tania Hossain Caravella, MPH |
| 3. Questions and Answers | All |

**SITE STAFF-COMMUNITY INTERACTIVE:
WORKING AND LEARNING TOGETHER - COMMUNITY ENGAGEMENT
AND TRAINING RESOURCES**

Tuesday, June 24, 2014, 1:00 p.m. – 3:00 p.m.

Facilitator: Ramon Negrón
Columbia Physicians and Surgeons CRS

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| 1. Welcome and Introductions | Ramon Negrón |
| 2. Working and Learning Together - Community Engagement and Training Resources (Part I) | Rona Siskind, MHS
Marley Thrasher |
| 3. Questions and Answers | All |
| 4. Break | |
| 5. Working and Learning Together - Community Engagement and Training Resources (Part II) | Rona Siskind, MHS
Marley Thrasher |
| 6. Questions and Answers | All |

**A5322 (AGING, HIV INFECTION, & INFLAMMATION)
TEAM AND SITE TRAINING (AND RECERTIFICATION)**

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

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

Frank Palella, Jr., MD
Northwestern University CRS

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

Babafemi Taiwo, MBBS, MD
Northwestern University CRS

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| 1. | Welcome and Introductions | Kathy Tassiopoulos, DSc, MPH |
| 2. | A5322 (Aging, HIV Infection & Inflammation) Study Updates | Kathy Tassiopoulos, DSc, MPH
Frank Palella, MD |
| 3. | Study Update for A5323s (The Fit Substudy of A5322) | Kristine Erlandson, MD |
| 4. | Question & Answer | All Members |
| 5. | Frailty Assessment Training/Recertification | Kristine Erlandson, MD |

A5263 (ADVANCED KS CHEMO) SITE SESSION

Wednesday, June 25, 2014, 6:00 p.m. – 7:00 p.m.

Chair: Margaret Borok-Williams, MD
University of Zimbabwe CRS

Vice Chair: Susan Krown, MD
AIDS Malignancy Consortium

1. Management of Neutropenia
2. Survey on G-CSF Use
3. Site Updates

A5264 (LIMITED KS STUDY) TEAM AND SITE SESSION

Wednesday, June 25, 2014, 4:00 p.m. – 6:00 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

1. Accrual Update
2. Site Presentations on Community Engagement Efforts
3. Progress on Protocol Version 2.0

**QUESTION AND ANSWER SESSION WITH A5317 PROTOCOL TEAM
(TELMISARTAN FIBROSIS STUDY)**

Tuesday, June 24, 2014, 11:00 a.m. – 12:00 p.m.

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

Netanya Sandler Utay, MD
Houston AIDS Research Team CRS/University of Texas Medical Branch at
Galveston

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

Daniel C. Douek, MD, MRCP, PhD
Vaccine Research Center,
National Institute of Allergy and Infectious Diseases, NIH

1. Welcome and Introductions
2. Brief Protocol Update
3. Discussion of Frequently Encountered Issues
4. Question and Answer Period

**A5340 (PHASE I STUDY OF VRC01 DURING ATI)
TEAM AND SITE SESSION**

Wednesday, June 25, 2014, 4:00 p.m. – 5:30 p.m.

Co-Chairs: Pablo Tebas, MD
Penn Therapeutics CRS

Katharine Bar, MD
Penn Therapeutics CRS

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| 1. Welcome and Introductions | Pablo Tebas, MD
Katharine Bar, MD |
| 2. A5340 Study Overview and Updates | Pablo Tebas, MD |
| 3. Data Management Logistics | Bernadette Jarocki, BS |
| 4. Laboratory Logistics | Nancy Tustin, MLT (ASCP) (HEW) |
| 5. Question and Answer | All Members |