

Advancing the Hepatitis B Virus Cure Research Agenda

ACTG: AIDS Clinical Trials Group
NIH/NIAID



ACTG Overview

- Mission: To cure HIV infection and reduce the burden of disease due to HIV infection and its complications, including Tb and viral hepatitis.
- Funding: NIH/NIAID (AI-68636)
 - December 2013 - November 2020
- ACTG Leadership
 - ACTG Chair, Dr. Judith Currier (UCLA)
 - ACTG Vice-Chair, Dr. Joseph Eron (UNC)
 - Leadership and Operations Center (LOC) Executive Director, Aisha Zaidi (Brigham and Women's Hospital)
 - Statistical and Data Management Center (SDAC), Dr. Michael Hughes, Harvard School of Public Health

ACTG Leadership and Operations Center (LOC)

- PI/Chair
- Co-PI/Vice Chair
- International Vice Chair

Executive Committee

Leadership Steering Committee

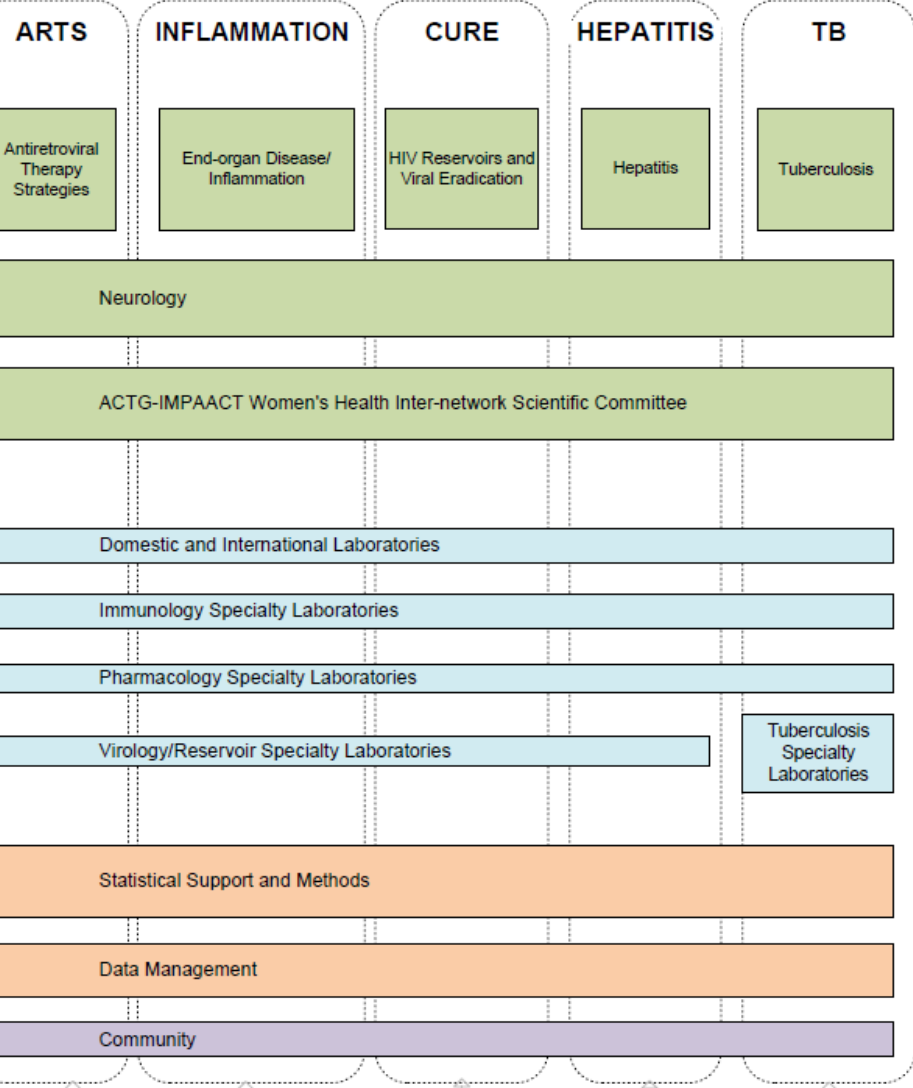
- LOC Administrative Core

COORDINATION & EVALUATION Committees

SCIENTIFIC Committees

RESOURCE Committees

FOCUS/MISSION



SASC
Scientific Agenda Steering Committee

- TRANSFORMATIVE Science Groups
- COLLABORATIVE Science Group
- LIAISON Group

Laboratory Center

Laboratory Steering Committee

Laboratory Technologist Committee

Statistical and Data Management Center

- Statistical and Data Analysis Center
- Data Management Center

Site Management & Clinical Care Committees

Subcommittees:

- Protocol Development and Implementation
- Site Operations

Underrepresented Populations Committee

Data Management Committee

Global Community Advisory Board

- Community Scientific Subcommittee

Network Coordinating Center

Performance Evaluation Committee

ACTG Clinical Sites

- United States including Puerto Rico: 32 sites
- International: Haiti, Brazil (2), Peru, South Africa (5), Botswana, Zimbabwe, Malawi (2), Uganda, Kenya (3), India (2), Thailand (2), Philippines



Hepatitis Transformative Science Group (TSG)

- Leadership
 - Mark Sulkowski, Chair
 - Ray Chung, Chair Ex-officio
 - Susanna Naggie, Vice-Chair
- Steering Committee
 - Marion Peters
 - Ken Sherman
 - Rob Murphy
 - Minhee Kang
 - Quinteka McNeil
- Hepatitis B cure working group
 - Marion Peters, Chair

Name	Role	Institution
Mark Sulkowski	Chair	Johns Hopkins University CRS
Raymond T. Chung	Chair Ex-officio	Massachusetts General Hospital (MGH) CRS
Susanna Naggie	Vice-Chair	Duke University Medical Center CRS
William Meyer	Consultant	Quest Diagnostics Incorporated
Nickson Chepkwony	CSS Representative	Kenya Medical Research Institute/Walter Reed Project Clinical Research Center (KEMRI/WRP) CRS
Julio Rolon-Mendez	CSS Representative	Puerto Rico AIDS Clinical Trials Unit CRS
Beverly Alston-Smith	DAIDS Representative	DAIDS/NIAID/NIH/CCRB
Christine Chiou	DAIDS Representative	Division of AIDS
Stephanie Caruso	DMC Representative	ACTG Data Management Center
Debika Bhattacharya	Investigator	University of California, Los Angeles CARE Center CRS
Timothy Block	Investigator	Baruch S. Blumberg Institute
Kara Chew	Investigator	University of California, Los Angeles CARE Center CRS
Kathleen Corey	Investigator	Massachusetts General Hospital
Jordan Feld	Investigator	University Health Network / Toronto Centre for Liver Disease
Daniel Fierer	Investigator	Weill Cornell Chelsea CRS
Adam Gehring	Investigator	University of Toronto
Quanhathai Kaewpoowat	Investigator	Chiang Mai University HIV Treatment (CMU HIV Treatment) CRS
Arthur Kim	Investigator	Massachusetts General Hospital (MGH) CRS
Jennifer Kiser	Investigator	University of Colorado Hospital CRS
Dimas Kliemann	Investigator	Hospital Nossa Senhora da Conceicao CRS
Shyam Kottlil	Investigator	University of Maryland School of Medicine
Annie Luetkemeyer	Investigator	University of California, San Francisco HIV/AIDS CRS
Charles Maponga	Investigator	Parirenyatwa CRS
Kristen Marks	Investigator	Weill Cornell Chelsea CRS
Robert Murphy	Investigator	Northwestern Univ. CRS
Hugo Perazzo	Investigator	Instituto de Pesquisa Clinica Evandro Chagas CRS
Marion Peters	Investigator	University of California, San Francisco HIV/AIDS CRS
Jennifer Price	Investigator	xxxx
Kenneth Sherman	Investigator	Cincinnati CRS
Sunil Solomon	Investigator	The Johns Hopkins Baltimore-Washington
Richard Sterling	Investigator	Virginia Commonwealth Univ. Medical Ctr. CRS
Chloe Thio	Investigator	Johns Hopkins University CRS
John Ward	Investigator	Centers for Disease Control and Prevention
David Wyles	Investigator	University of Colorado Hospital CRS
Cheryl Jennings	LTC Representative	Northwestern University CRS
Christopher Lane	LTC Representative	University of Rochester Adult HIV Therapeutic Strategies Network CRS
Quinteka McNeil	NCC Coordinator	ACTG Network Coordinating Center
Jennifer Tiu	NCC Representative	ACTG Network Coordinating Center
Scott Letendre	Neurologist	University of California, San Diego AntiViral Research Center CRS
Raquel Viana	Non-Voting Member	ACTG/IMPAACT/HVTN Regional TB Diagnostic Laboratory BARC SA and Lancet
Charles Venuto	Pharmacologist Elected	University of Rochester Adult HIV Therapeutic Strategies Network CRS
Minhee Kang	SDAC Representative	Statistical and Data Analysis Center
Gavin Cloherty	Virologist Appointed	Abbott Laboratories
Anna Kramvis	Virologist Elected	University of the Witwatersrand Helen Joseph (WITS HJH) CRS

Research Overview

- Protocol – developed in collaboration with industry partner
 - Concept Proposal
 - Scientific Review (HEP TSG and SASC)
 - Protocol Development with regulatory (IND) and scientific oversight
 - Version 1.0 to the sites (supported by ACTG)
- New Works Concept Sheet (NWCS)
 - Existing data and samples
- Data Analysis Concept Sheet (DACCS)
 - Existing data

Selected clinical trials ongoing or in development

- A5360: MINMON Study
 - Multi-national trial; HCV treatment with minimal monitoring
- A5380: PURGE-C Study
 - Acute HCV; short treatment (4 weeks)
- NWCS 455: Quantitative HBsAg and HBV RNA in HIV/HBV co-infected participants receiving anti-HBV active antiretroviral therapy

Selected clinical trials ongoing or in development

- A5368: Safety, pharmacokinetics and immunotherapeutic activity of an anti-PD-1 antibody in HBV-infected participants on suppressive antiviral therapy: A phase II ascending multiple dose study
- A5379: HBV vaccination in HIV-infected persons: RCT of HEPLISAV-B versus Engerix-B
- PR754: A Randomized study assessing the safety and efficacy of 24 weeks of REP 2139 monotherapy followed by 48 weeks of combined therapy with REP 2139 alone or in with peginterferon alfa-2a in participants with HBeAg negative chronic HBV infection suppressed on nucleos(t)ides (entecavir or tenofovir)

NIH/NIAID ACTG HEP TSG: Advancing the Hepatitis B virus cure research agenda

- Hepatitis TSG members are leaders in HBV virology, immunology and clinical interventions
 - HBV alone and HBV/HIV coinfection
 - Sites located in highly endemic areas with community representation and engagement
- Collaborative HBV cure research
 - Site and protocol cost support
 - Foster innovation such as the combination of 2 or more experimental agents
 - Data can support regulatory applications (if indicated)

HEP TSG Contacts

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