

# IMPAACT Network Overview

May 2024



# IMPAACT's Mission

To improve health outcomes for infants, children, adolescents, and pregnant and postpartum people who are impacted by or living with HIV by evaluating novel treatments and interventions for HIV and its complications and for tuberculosis and other HIV-related conditions

# History and Funding

- Formed in 2006 (preceded by Pediatric AIDS Clinical Trial Group [PACTG])
- Successfully renewed in 2013 and in 2020
- Funded by US National Institutes of Health
  - Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID)
  - *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)
  - National Institute of Mental Health (NIMH)



**Pregnant & PP People**



**Infants**



**Children**



**Adolescents**

**Novel and Durable Therapeutic/Preventive Interventions**



**Cure and Immunotherapy**



**Tuberculosis**



**Brain and Mental Health**



# Research Agenda

- Advance **treatment during pregnancy and postpartum**, aiming to optimize maternal and child health outcomes, and accelerate the evaluation (PK, safety, antiviral efficacy), licensure and optimal use of **potent and durable ARVs and other therapeutics** for pregnant people and infants, children, and adolescents with HIV and related diseases and conditions
- Evaluate the potential for **ART-free remission** through therapeutic interventions aimed at prevention, clearance and post-treatment control of HIV reservoirs in infants, children, and adolescents with HIV and leverage expertise for evaluation of **vaccines** for HIV and related/co-occurring conditions in these populations



# Research Agenda



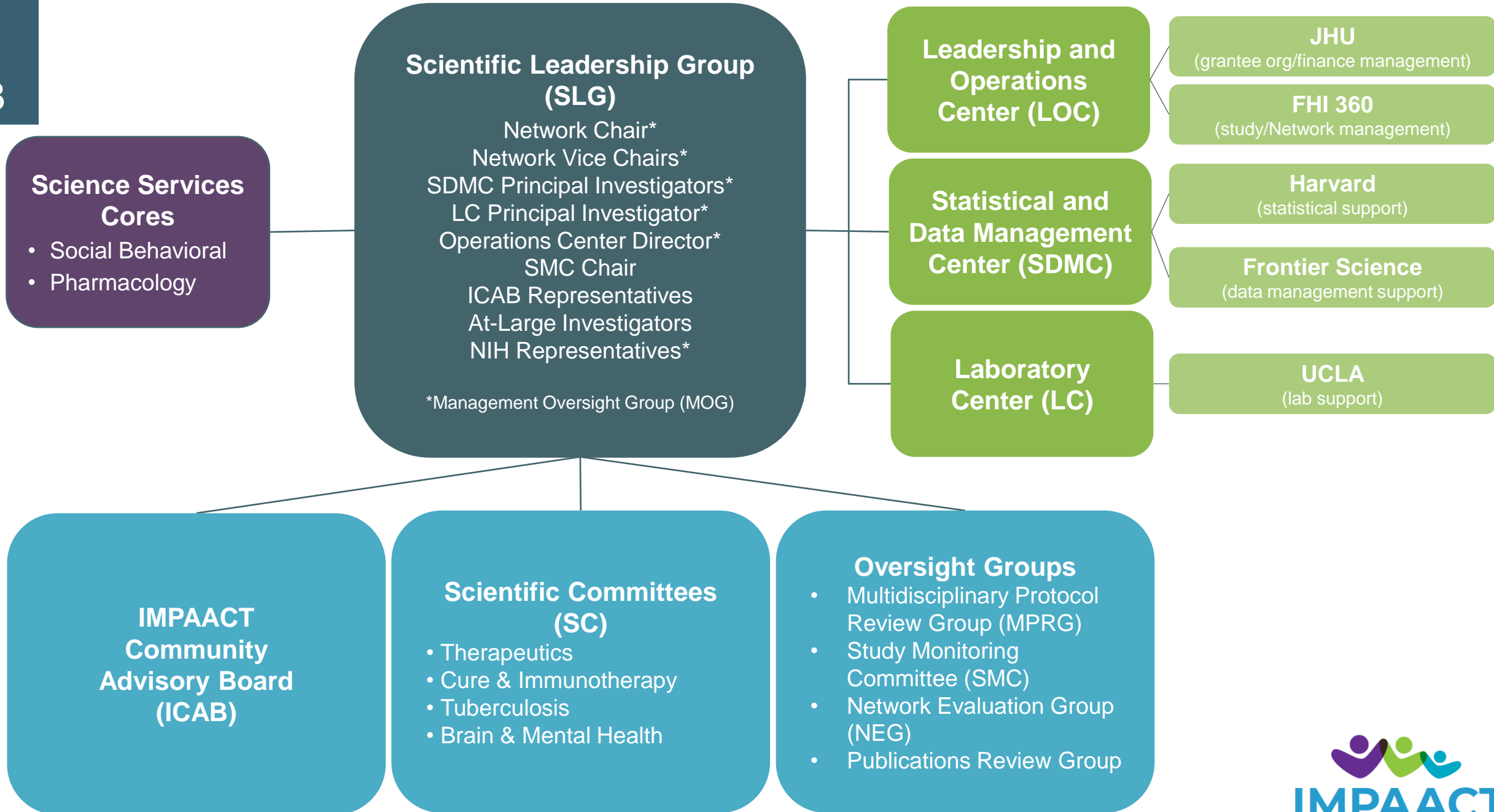
- Evaluate novel approaches for **tuberculosis prevention, diagnosis and treatment** in infants, children, and adolescents and in pregnant and postpartum people with and without HIV that will lead to optimal dosing and regimens, licensing and improved treatment outcomes
- Determine optimal and feasible biological and behavioral methods for the prevention and management of **neuropsychological and mental health complications of HIV and its treatment** infants, children, and adolescents and in pregnant and postpartum people

# Organization

IMPAACT is comprised of:

- Clinical research sites where studies are conducted
- Scientific and management leadership groups
- Central resources that support study operations, data collection and analysis, and laboratory testing for Network studies







# IMPAACT by the Numbers *over the last decade*

**37**  
studies enrolled  
1<sup>st</sup> participant

**56**  
studies  
completed  
follow-up

**11,872**  
participants  
enrolled

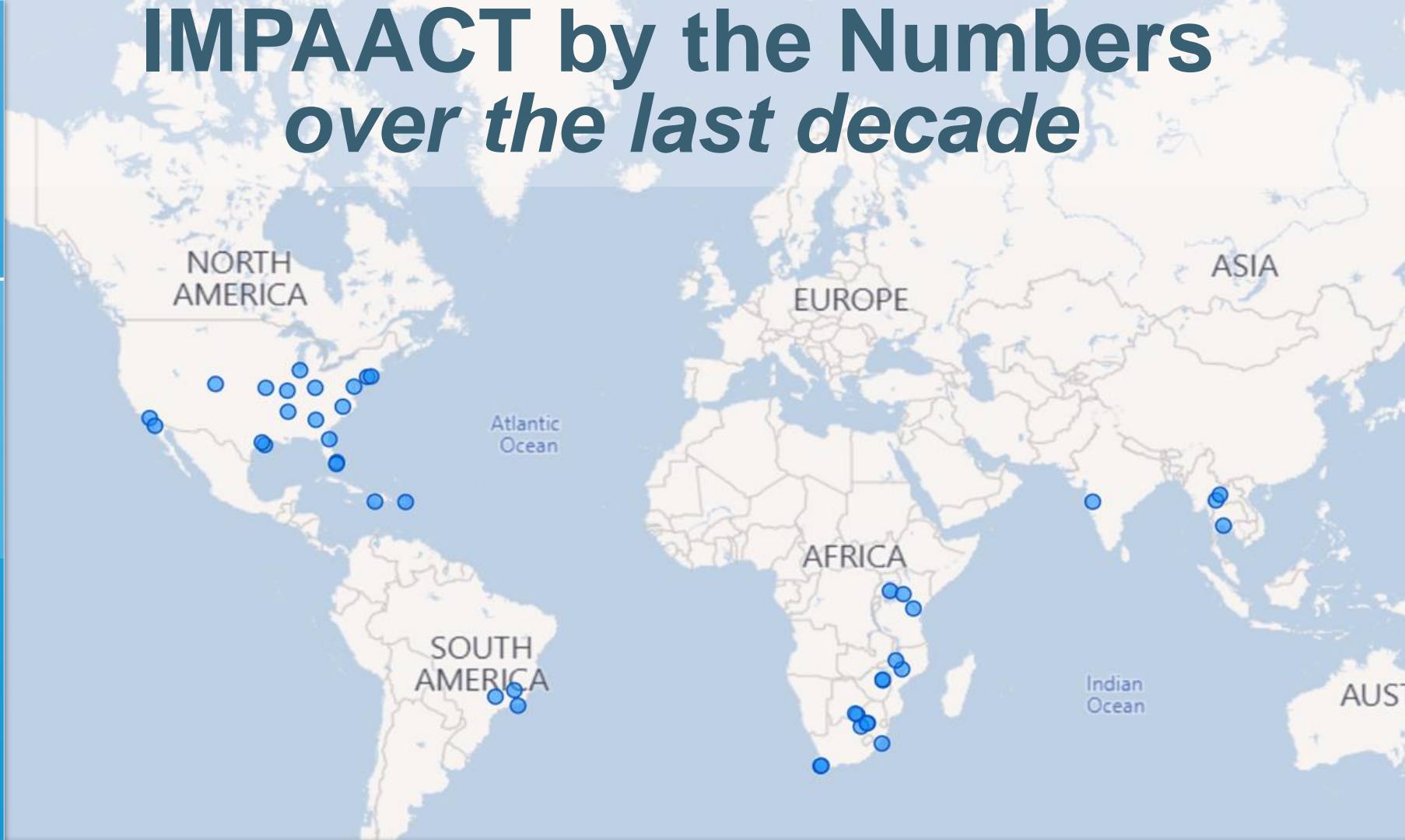
**14,433**  
participants  
followed

**82.7%**  
participants  
Black/African

**57%**  
participants are  
children

**94%**  
adults enrolled  
pregnancy/  
postpartum

**300+**  
publications



**52**  
IMPAACT Sites

**12**  
Countries

**4**  
Asian Sites

**18**  
African Sites

**25**  
North American Sites

**5**  
South American Sites



# Significant IMPAACT Research Accomplishments *over the last decade*

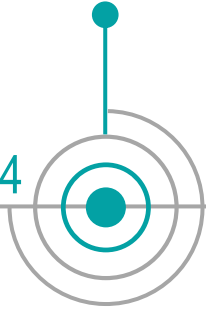
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CDC guidelines updated to include influenza vaccine recommendations in pregnancy

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EMA update for HIV treatment in adolescents (DTG)

2014



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Consensus statement to include pregnant people in TB drug studies

2015



DTG safe and effective in adolescents

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RAL safe and effective in infants and toddlers

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2016

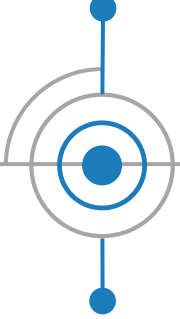


Triple-drug therapy effective in preventing HIV transmission during pregnancy

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FDA approval of first integrase inhibitor in neonates (RAL)

2017

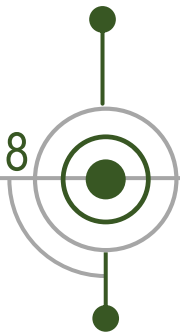


Continued ART postpartum was safe and associated with better health outcomes

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FDA label update for HIV treatment in children (ETR)

2018

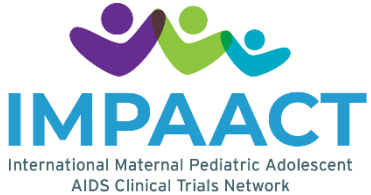


INH in pregnancy for TB prevention may have greater risks than compared to postpartum

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Triple-drug therapy effective in preventing HIV transmission during breastfeeding

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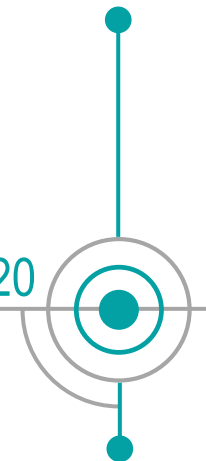
# Significant IMPAACT Research Accomplishments *over the last decade*

EMA update for HIV treatment in children (ETR)

FDA approval for dispersible tablet for children (DTG)

FDA label update for HIV prevention for neonates (MVC)

2020



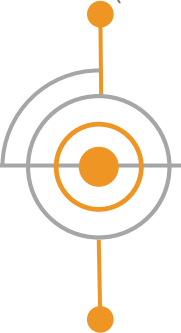
PrEP drug levels lower during pregnancy

Preventive TB drugs met therapeutic range during pregnancy

EMA approval for dispersible tablets for children (DTG)

WHO guidelines updated for MDR-TB treatment for children (BDQ)

2021



DTG-containing regimens safe and effective in pregnancy

FDA approval of first long-acting treatment for adolescents (CAB/RPV)

FDA approval of once-daily, fixed dose combo HIV drugs for adolescents (DOR/3TC/TDF)

NIH/DAIDS Cross-Network TB Working Group call for people living with HIV to be included in TB vaccine development

2022

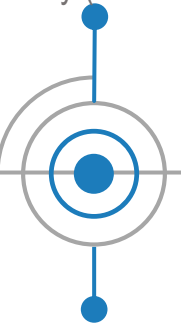


Combined cognitive behavioral therapy and medication management for youth living with depression

FDA approval for once-daily dispersible HIV drug for young children (ABC/DTG/3TC)

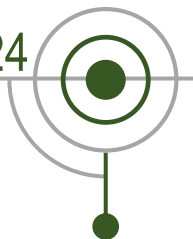
FDA label update for COVID-19 drug in pregnancy (Remdesivir)

2023



First known case of a woman with HIV remission

2024



Children surpass a year of HIV remission after treatment pause

Long-acting HIV treatment benefits adolescents with suppressed HIV

# Scientific Leadership

# Network Leadership

The Network is under the leadership of the Network Chair, Sharon Nachman, and the Network Vice Chairs, Patricia Flynn and Philippa Musoke.



**Sharon Nachman, MD**  
**Network Chair**  
SUNY Health Science Center  
at Stony Brook



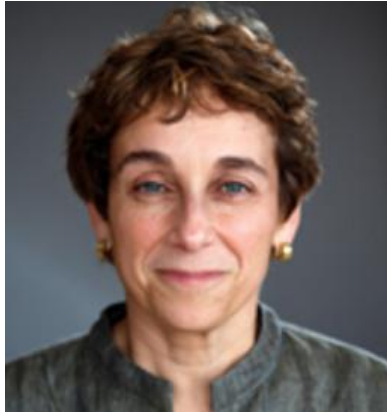
**Philippa Musoke, MD**  
**International Vice Chair**  
Makerere University-Johns Hopkins  
University Research Collaboration



**Patricia Flynn, MD**  
**Domestic Vice Chair**  
St Jude Children's  
Research Hospital

# Scientific Leadership Group Members

23



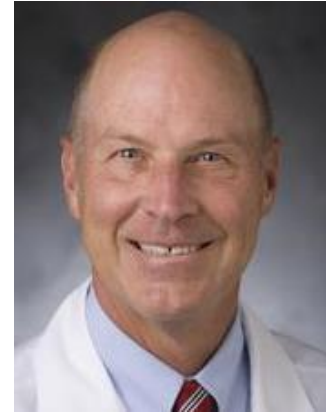
**Elaine Abrams, MD**  
*At-large member  
Columbia University*



**Grace John-Stewart, MD**  
*At-large member  
University of Washington*



**James McIntyre,  
MBChB, FRCOG**  
*Emeritus vice chair  
Anova Health Institute*



**John Sleasman, MD**  
*At-large member  
Duke University*



**Emanuelli Msuya**  
*ICAB Chair  
Moshi, Tanzania*



**David Shapiro, PhD**  
*SDMC Co-Principal  
Investigator  
Harvard University*



**Marlene Cooper, MS**  
*SDMC Co-Principal  
Investigator  
Frontier Science*



**Grace Aldrovandi, MD**  
*LC Principal Investigator  
University of California, Los  
Angeles*



**Melissa Allen, BA**  
*Operations Center Director  
FHI 360*

# Scientific Leadership Group (SLG)

- Sets the overall scientific agenda of the Network
- Prioritizes studies across the four research areas and the overall network portfolio
- Reviews proposals for new studies based on scientific merit, potential public health impact, and suitability for network implementation
- Fosters collaboration with other networks and partners

# Management Oversight Group (MOG)

- Subset of SLG members including the Network chairs and leaders of the Operations Center, Statistical and Data Management Center, and Laboratory Center
- Responsible for
  - Fiscal oversight
  - Regulatory compliance
  - Collaboration agreements
  - Policies and procedures
  - Performance monitoring and evaluation



# Scientific Committees

# Scientific Committee Leadership

## Cure & Immunology



**Deborah Persaud**  
Johns Hopkins



**Elizabeth McFarland**  
University of Colorado

## Tuberculosis



**Anneke Hesseling**  
Desmond Tutu TB Centre



**Amita Gupta**  
Johns Hopkins

## Therapeutics



**Theodore Ruel**  
University of California,  
San Francisco



**Moherndran Archary**  
University of  
KwaZulu-Natal

## Brain & Mental Health



**Jackie Hoare**  
University of Cape Town



**Megan McHenry**  
Indiana University

# Scientific Committee Responsibilities

- Review respective portfolio of studies in the context of evolving science and standards of care
- Identify gaps in the science and new interventions for priority populations
- Ensure that new high priority study proposals are developed for consideration by the SLG

# Central Resources

# Central Resource Components



## Leadership and Operations Center (LOC)

Johns Hopkins University  
(Grantee organization /  
Network financial management)

FHI 360  
(Study development and  
implementation / Network support)



## Statistical and Data Management Center (SDMC)

CBAR at Harvard School of Public  
Health (Statistical support)

Frontier Science Foundation  
(Data management support)



## Laboratory Center (LC)

University of California,  
Los Angeles (Laboratory support)

# Statistical and Data Management Center (SDMC)



- Located at Center for Biostatistics in AIDS Research (CBAR) at the Harvard School of Public Health in Boston, MA, and at Frontier Science Foundation (FSTRF) in Amherst, NY
- Provides statistical leadership and support through all phases of study design, implementation, and reporting of results
- Maintains databases for IMPAACT studies
- Provides training and technical assistance on data collection and data management for IMPAACT studies



# Laboratory Center (LC)



- Located at University of California, Los Angeles
- Identifies and implements state-of-the-art laboratory testing in support of IMPAACT's scientific agenda
- Assists in the development and quality assurance of local laboratory capacity at IMPAACT NIAID sites
- Provides technical assistance and support for laboratory aspects of IMPAACT studies

# Finance and Contracts



- Located at Johns Hopkins School of Medicine
- Administers the IMPAACT grant
- Administers Master Member Agreements (MMA), Protocol Specific Task Orders (PSTO), and Significant Financial Interest (SFI) with each IMPAACT NIAID site and any study-specific sites



# Operations Center



- Located at FHI 360, in Durham, North Carolina
- Supports the development, implementation and reporting of all IMPAACT scientific protocols
- Provides a central point of coordination, communications, and support to IMPAACT leadership and all Network committees and working groups, protocol teams, and clinical research sites
- Arranges and supports all Network meetings and leadership travel

# Community Engagement



# Site Community Programs

- Community Advisory Boards (CABs) build and foster partnerships between researchers and local study communities impacted by HIV/AIDS
- An active CAB with a committed membership is an integral part in the effort to combat AIDS
- CABs can help strengthen local capacity to respond to critical research needs in the future

# IMPAACT Community Advisory Board (ICAB)

- Representatives from IMPAACT site community programs participate in the ICAB
  - 1 community educator / community liaison
  - 1 CAB representative
- ICAB members provide input to protocol teams, by reviewing protocols in development and supporting development other study-related materials

# ICAB Representatives on Scientific Committees

- Including community members at all stages and levels of the research process helps build trust and mutual understanding
- Members of the ICAB Leadership Group also participate in IMPAACT scientific committees as voting members
- ICAB representatives on scientific committees review and provide feedback on all new concepts and protocols that are in development

# Operations Center Community Program

- Coordinates and supports the IMPAACT Network's community participation processes
- Responsible for outlining steps to develop, maintain, support, and encourage the full participation of community representatives in all phases of the research process
- Assists in the development of community education materials and presentations to explain research concepts that support informed consent and increase research literacy

# Science Service Cores



# Scientific Service Cores

- Social Behavioral Core

- Ensures that IMPAACT studies are designed and implemented with appropriate consideration of **social-behavioral factors** that may influence outcomes of interest or success of the study

- Pharmacokinetic Core

- Develops **pharmacokinetic (PK) and pharmacodynamic (PD) models**
- Applies statistical methods to optimize study design
- Performs PK/PD analyses of IMPAACT study data

# Oversight Groups

# Oversight Groups

## Multidisciplinary Protocol Review Group (MPRG)

- Ensures IMPAACT protocols are scientifically rigorous, accurate, consistent, complete, and standardized to the extent possible

## Study Monitoring Committee(s) (SMC)

- Monitors participant safety, progress, and quality and makes recommendations related to study continuation, cohort progression, and dose escalation/dose selection

# Oversight Groups

## Network Evaluation Group (NEG)

- Ensures that the performance of all components of the Network are evaluated
- On behalf of the MOG, oversees periodic evaluations of key Network components

## Publications Review Group (PRG)

- Reviews all abstracts and manuscripts reporting on Network studies and relevant investigations to ensure high quality products and scientific rigor

## [https://www.impaactnetwork.org/resources/ manual-procedures](https://www.impaactnetwork.org/resources/manual-procedures)

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### Manual of Procedures

This Manual of Procedures (MOP) describes the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network structure; operating policies; roles and responsibilities of entities and individuals within the IMPAACT Network; protocol development and approval processes; site selection; process; standardized study operations procedures; data and specimen collection and processing procedures; and quality management, monitoring and evaluation of trials conducted by IMPAACT. The IMPAACT MOP is to be used as a reference document for current IMPAACT policies and procedures. Clinical Trial Units are expected to maintain a hard copy of the current IMPAACT MOP at all clinical research sites.

The IMPAACT Network MOP does not replace the study-specific MOP that may be developed for specific IMPAACT studies. The study-specific MOP contains detailed guidance on study implementation. All study procedures within IMPAACT must be conducted in accordance with the study protocol, the study-specific MOP (if applicable), and this Network MOP. In the event that there are inconsistencies between these documents, the precedence that must be followed is:

- If this Network MOP is inconsistent with the study-specific MOP, the study-specific MOP must be followed.
- If the study-specific MOP is inconsistent with the study protocol, the protocol must be followed.

IMPAACT members are encouraged to contact the relevant individuals within the Network with procedural questions. For study-specific questions related to proper implementation, data collection, and laboratory concerns for a study protocol, contact the IMPAACT Operations Center Clinical Research Manager (CRM), the study-specific statistician and data manager, and the IMPAACT Laboratory Center (ILC) Quality Assurance/Quality Control Group.



**THANKS!**