

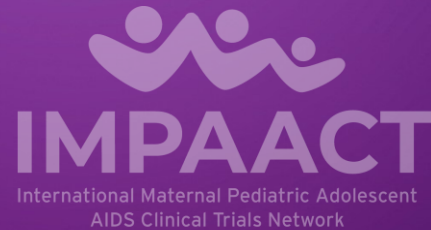
IMPAACT Network Overview

October 2025



Our Mission

To improve health outcomes for infancy, childhood, adolescence, pregnancy, and postpartum among those who are impacted by or living with HIV by evaluating novel treatments and interventions for HIV, tuberculosis, and other related complications



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 Women



Infants



Children



Adolescents

Novel and Durable Therapeutic/Preventive Interventions



Cure and Immunotherapy



Tuberculosis



Brain and Mental Health



IMPAACT

International Maternal Pediatric Adolescent
AIDS Clinical Trials Network

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** during pregnancy and in 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



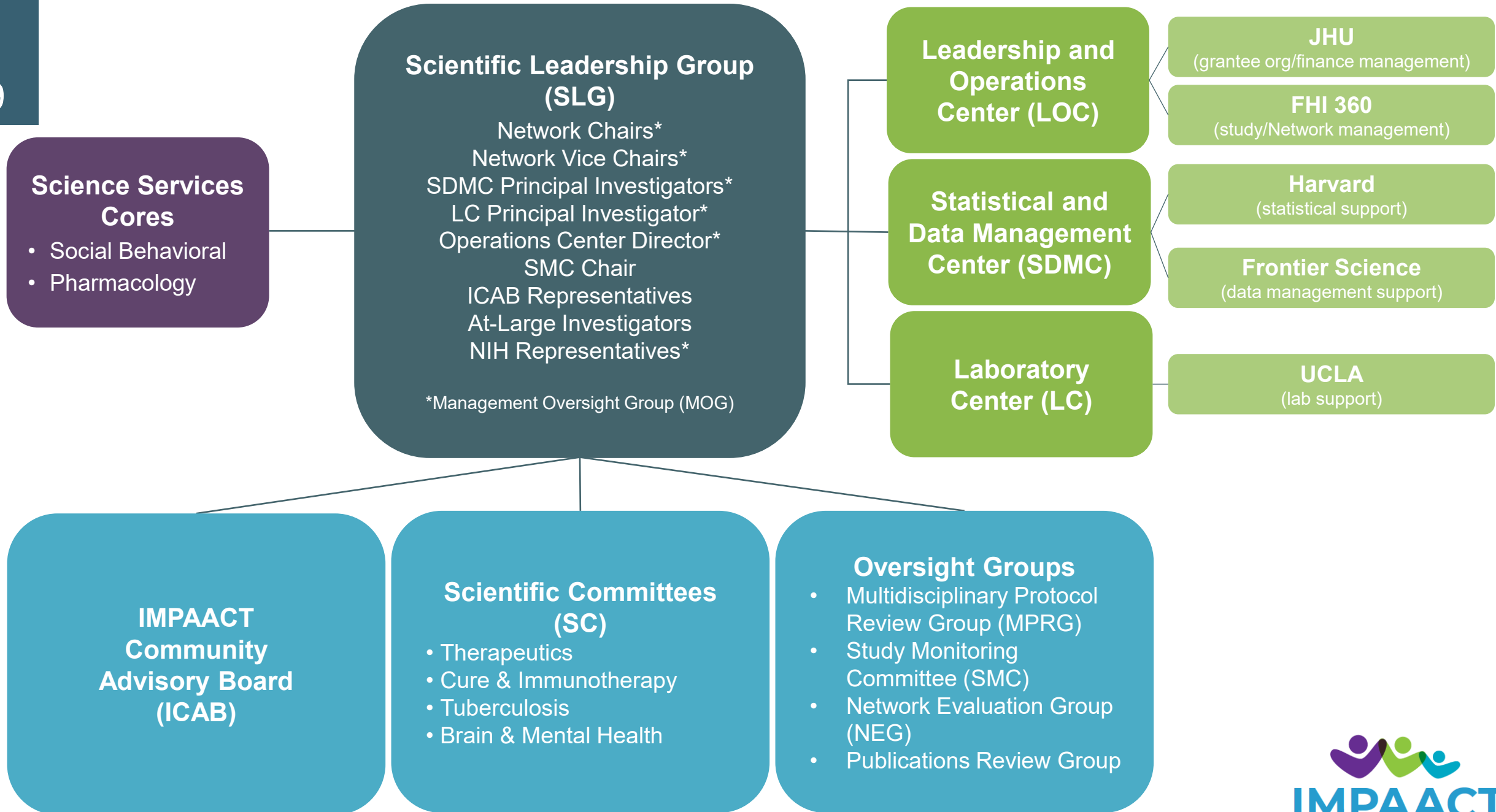
- Evaluate novel approaches for **tuberculosis prevention, diagnosis and treatment** in infants, children, and adolescents and in pregnant and postpartum women with and without HIV that will lead to optimal dosing and regimens, licensing and decreased morbidity and mortality
- Determine optimal and feasible biological and behavioral methods for the prevention and management of **neuropsychological and mental health complications of HIV and its treatment** in infancy, childhood, adolescence, pregnancy, and postpartum

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



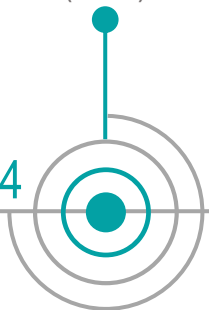


Significant IMPAACT Research Accomplishments *over the last decade*

CDC guidelines updated to
include influenza vaccine
recommendations in pregnancy

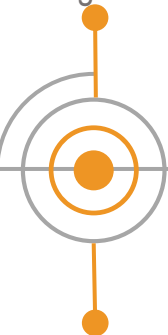
EMA update for HIV
treatment in adolescents
(DTG)

2014



Consensus statement to
include pregnant people in
TB drug studies

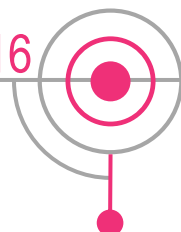
2015



DTG safe and effective in
adolescents

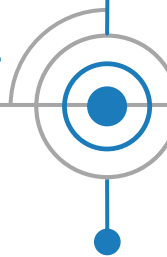
RAL safe and effective in
infants and toddlers

2016



Triple-drug therapy effective
in preventing HIV
transmission during
pregnancy

2017



FDA approval of first
integrase inhibitor in
neonates (RAL)

Continued ART postpartum
was safe and associated
with better health outcomes

2018

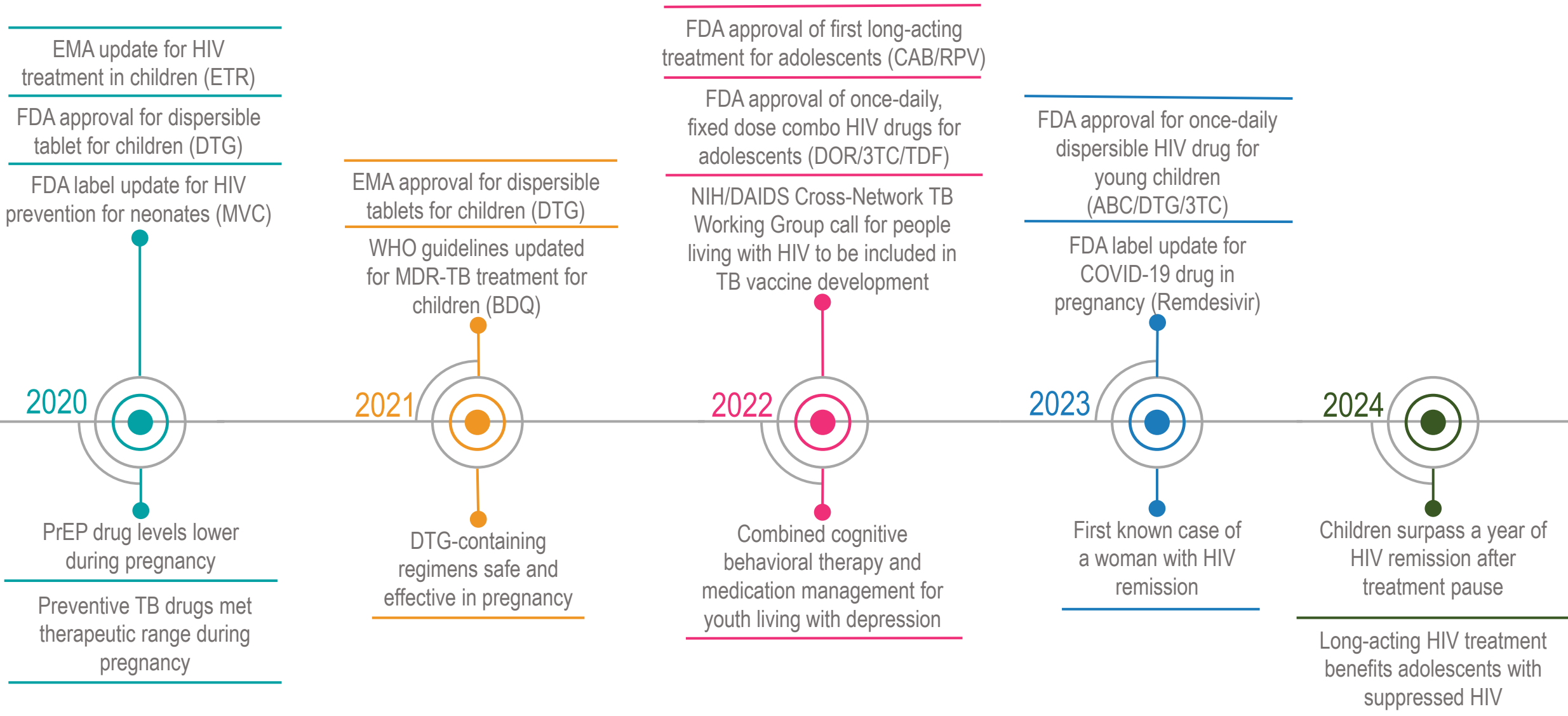


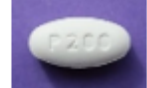
FDA label update for HIV
treatment in children (ETR)

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

Triple-drug therapy effective
in preventing HIV
transmission during
breastfeeding

Significant IMPAACT Research Accomplishments *over the last decade*



		Birth	1 mth	2 mths	6 mths	2 yrs	6 yrs	12 yrs	18 yrs	Pregnancy
Dolutegravir (DTG)		Dispersible tablet	Dispersible and film-coated tablets							
Abacavir (ABC)/DTG/lamivudine (3TC)*				Immediate-release and dispersible fixed-dose tablets						
Raltegravir (RAL)		Oral granules for suspension and chewable tablets								
Cabotegravir/rilpivirine (CAB/RPV)				Long-acting injectable			Long-acting injectable		Approved/Licensed Study in progress Study in development	
Doravirine (DOR)/3TC/TDF								Fixed-dose tablet		
Etravirine (ETR)				Tablet						
Maraviroc (MVC)*		Oral liquid								
Bedaquiline (BDQ)		Tablet				Tablet				
Pretomanid (Pa)*			Immediate-release and dispersible tablets							
Remdesivir										Injection
Glecaprevir/pibrentasvir (GLE/PIB)										Fixed-dose tablet

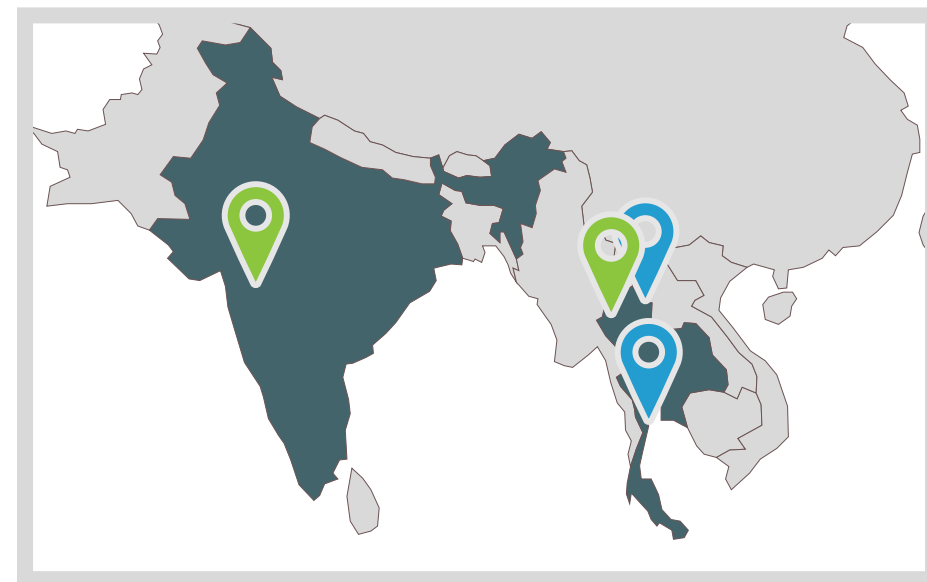
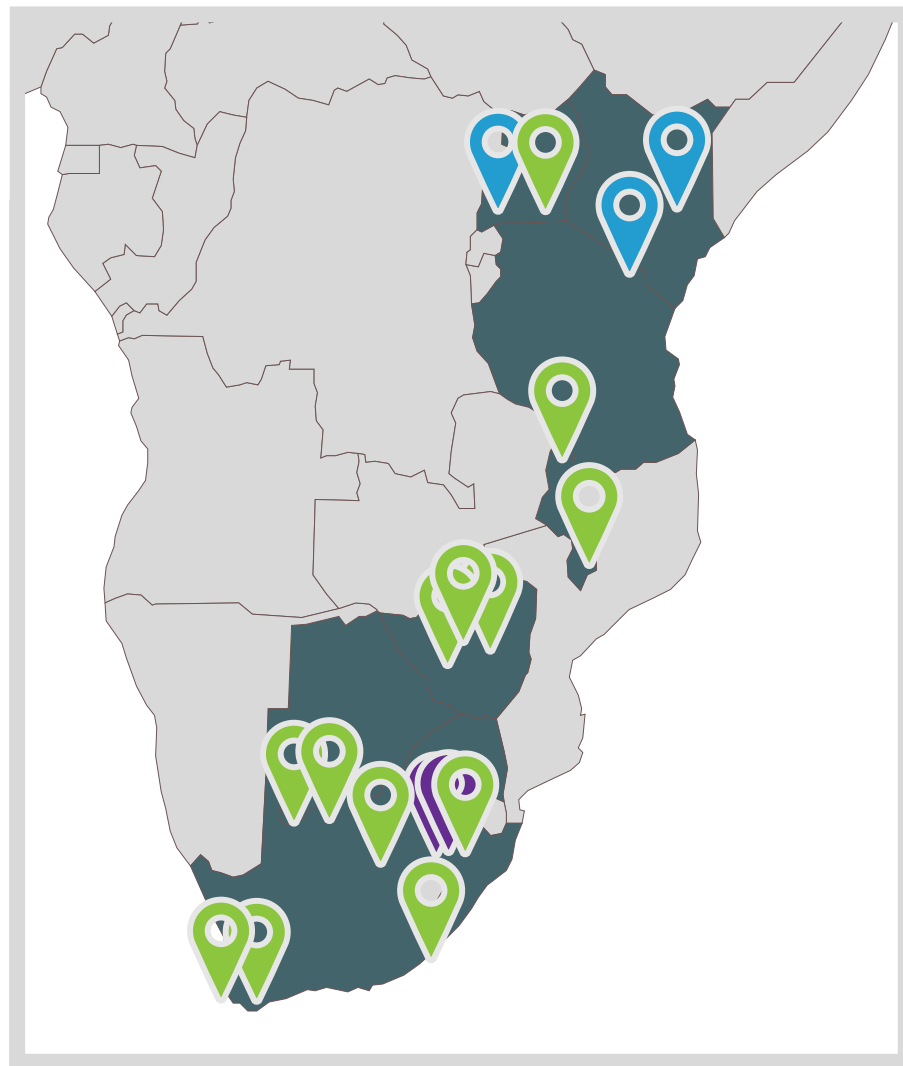
14 Sites in the United States

plus 2 protocol-specific sites



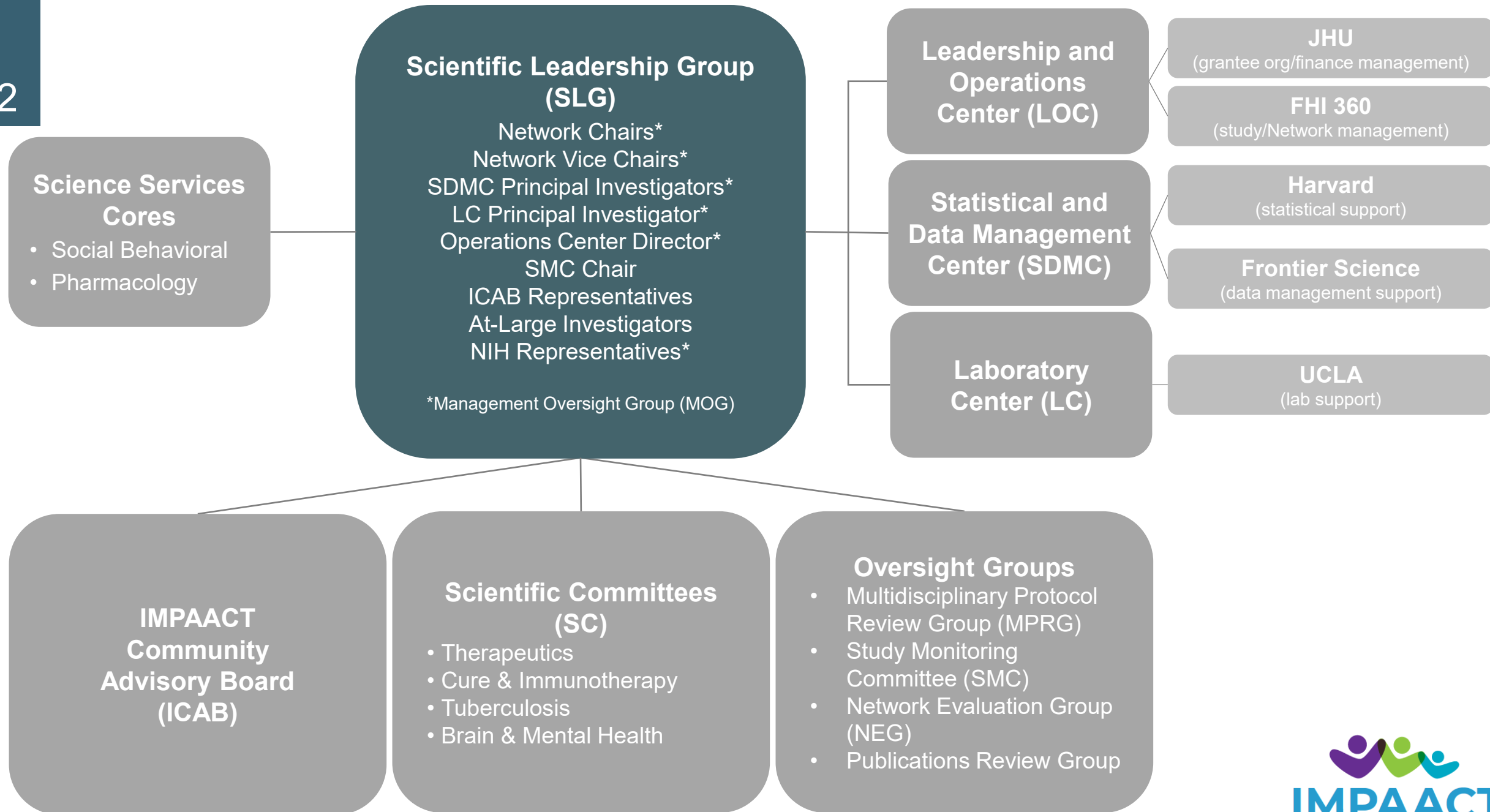
-  NIAID-supported sites
-  NICHD-supported sites
-  Protocol-specific sites

26 Sites in Africa, Asia and South America *plus 2 protocol-specific sites*



-  NIAID-supported sites
-  NICHD-supported sites
-  Protocol-specific sites

Scientific Leadership



23 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 Co-Chair
SUNY Health Science Center
at Stony Brook



Jennifer Jao, MD, MPH
Network Co-Chair
Northwestern University
Feinberg School of Medicine

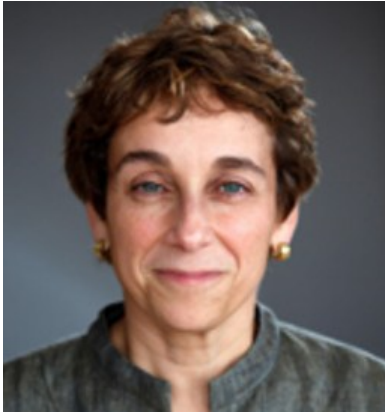


Philippa Musoke, MD
International Vice Chair
Makerere University-Johns Hopkins
University Research Collaboration



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

Scientific Leadership Group Members



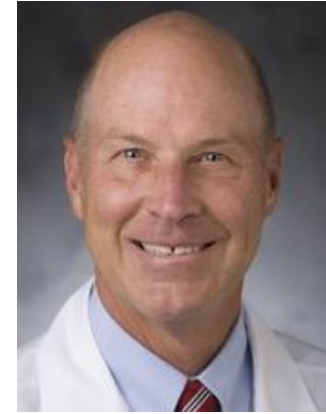
Elaine Abrams, MD
At-large member
Columbia University



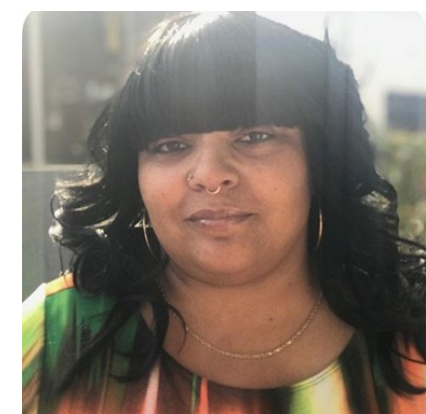
Grace John-Stewart, MD
At-large member
University of Washington



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



John Sleasman, MD
At-large member
Duke University



Jayda Arrington
ICAB Chair
UCLA



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

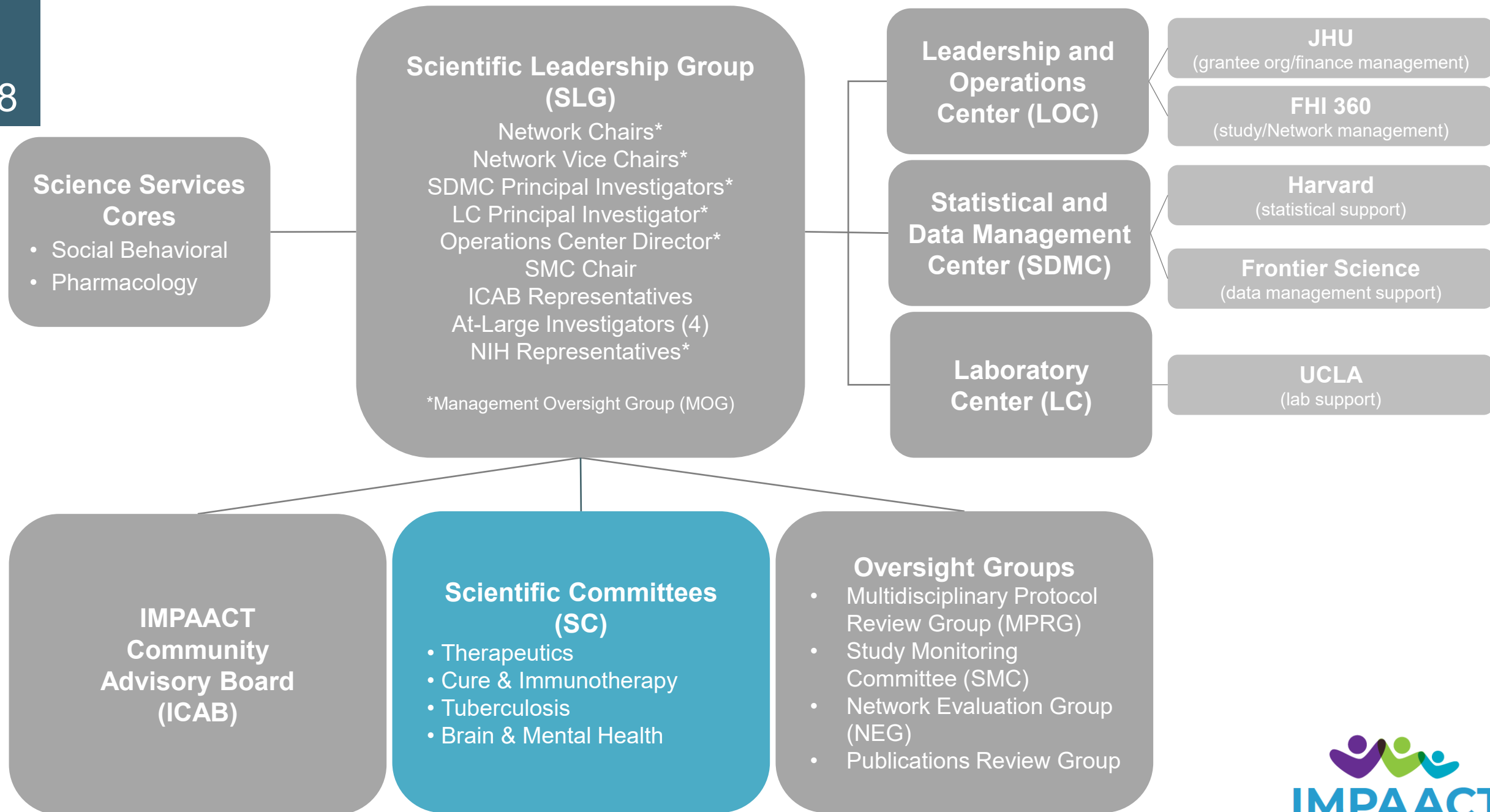
Scientific Leadership Group (SLG)

- 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

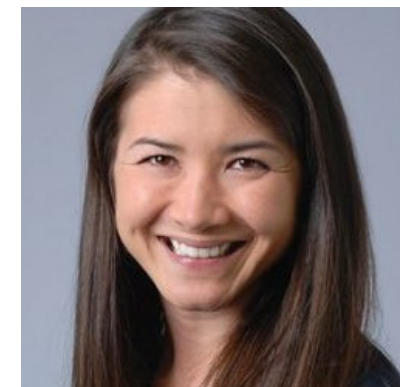


Moherndran Archary
University of
KwaZulu-Natal

Brain & Mental Health



Jackie Hoare
University of Cape Town

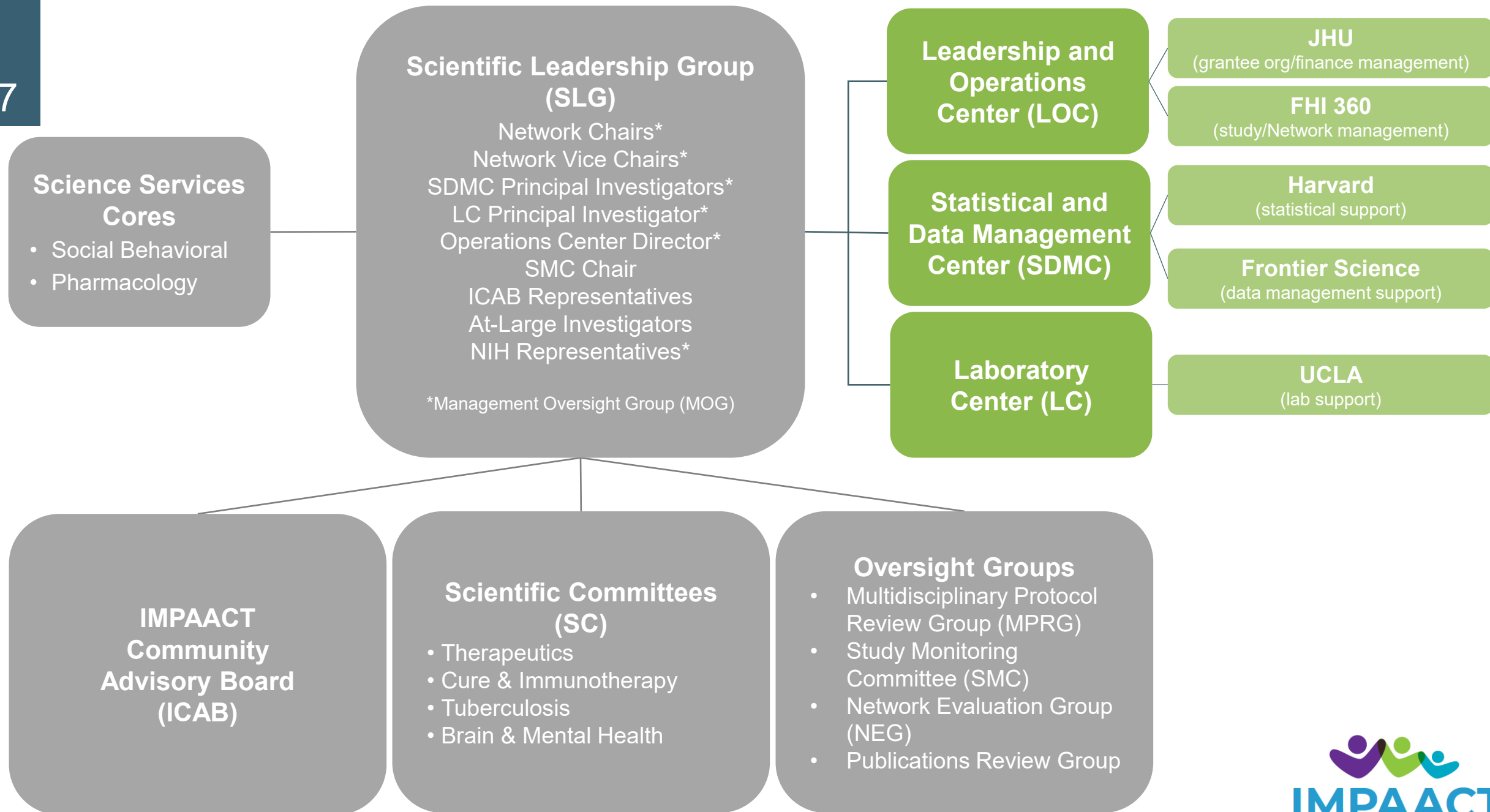


Megan McHenry
Indiana University

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



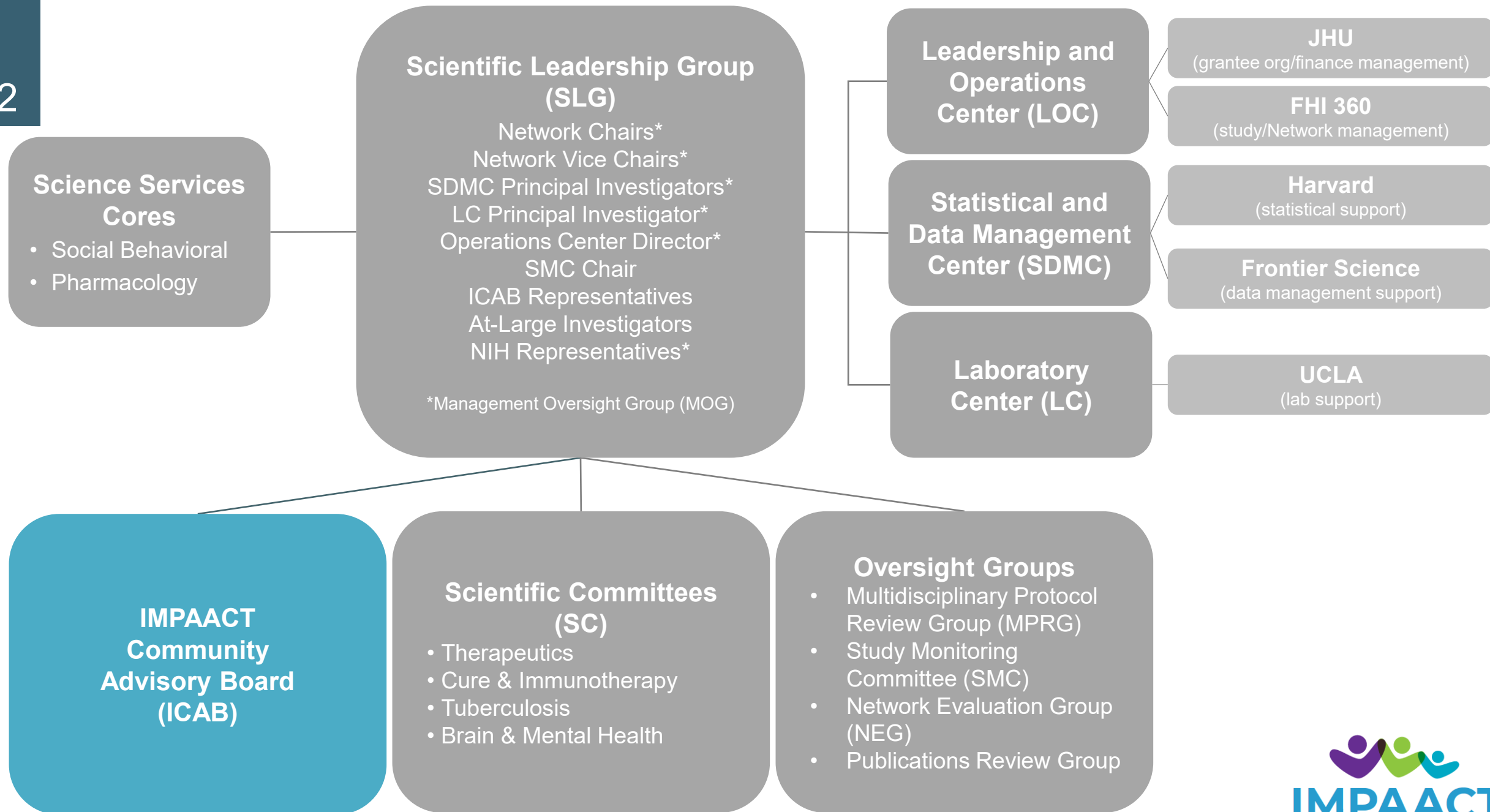
- Located at Johns Hopkins School of Medicine
- Administers the IMPAACT grant
- Administers Master Member Agreements (MMA), Protocol Specific Task Orders (PSTO), and Significant Financial Interest (SFI) with each IMPAACT NIAID site and any study-specific sites

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

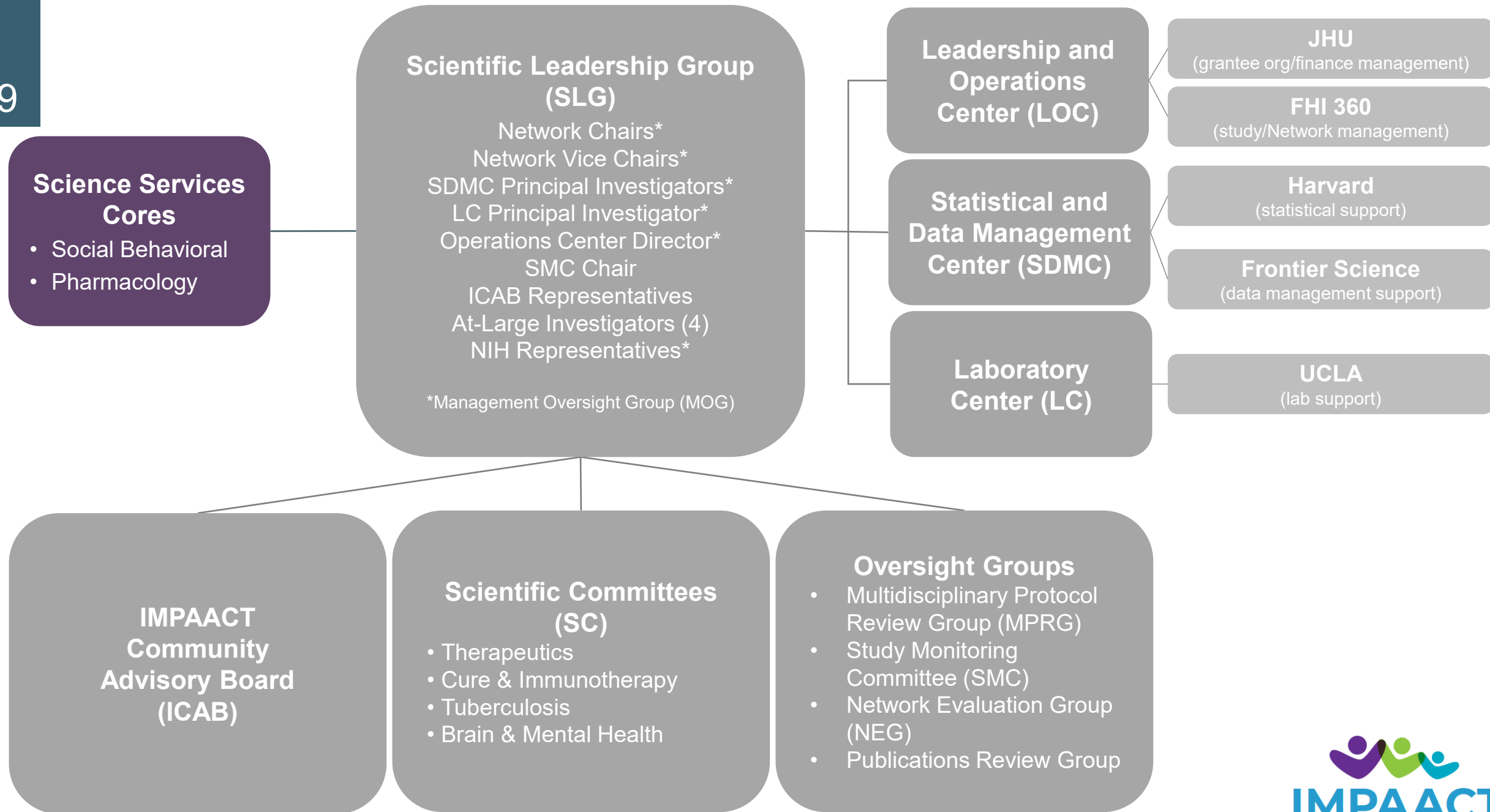
ICAB Representatives on Scientific Committees

- 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

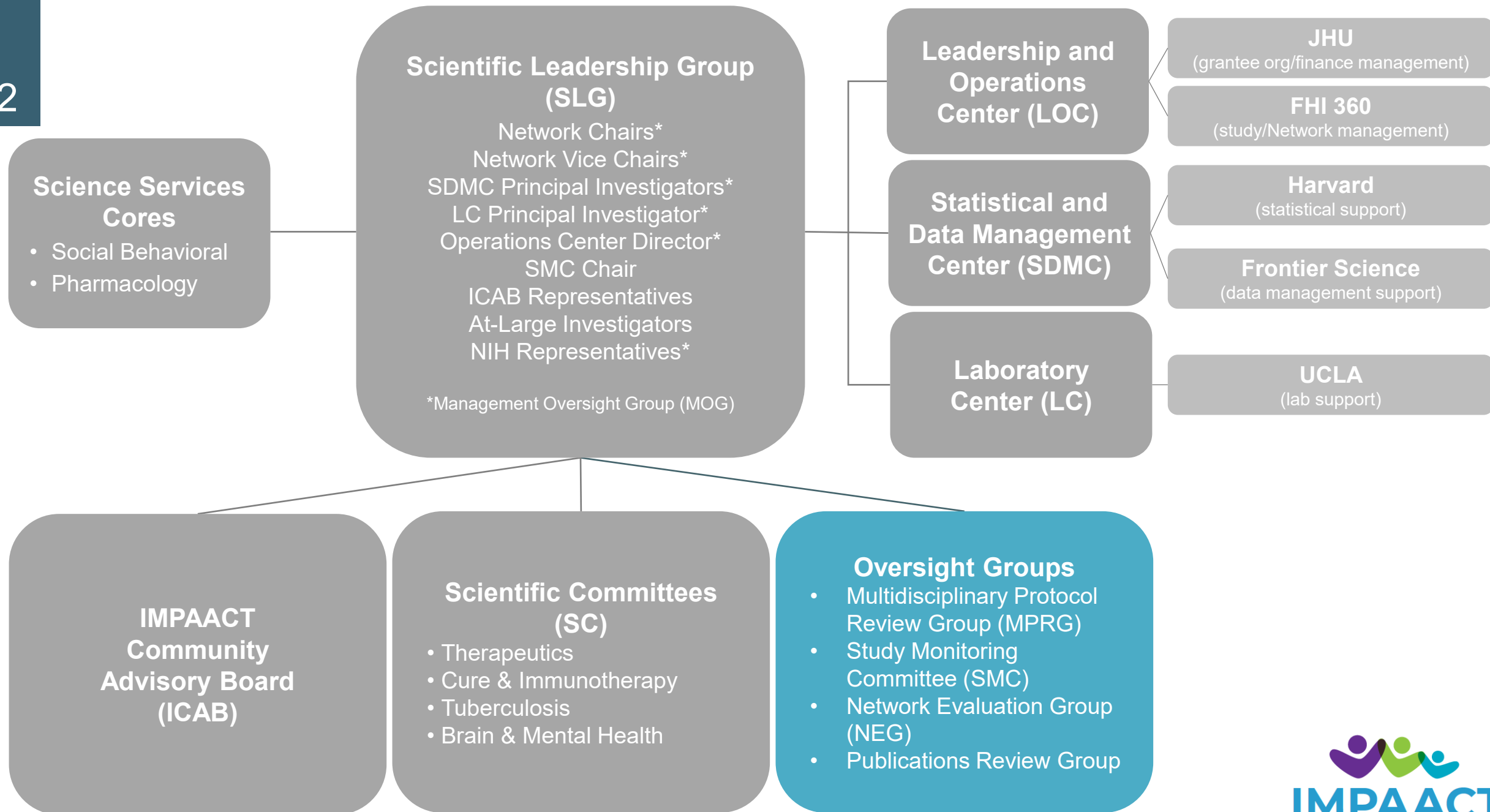
- Social Behavioral Core

- 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!