

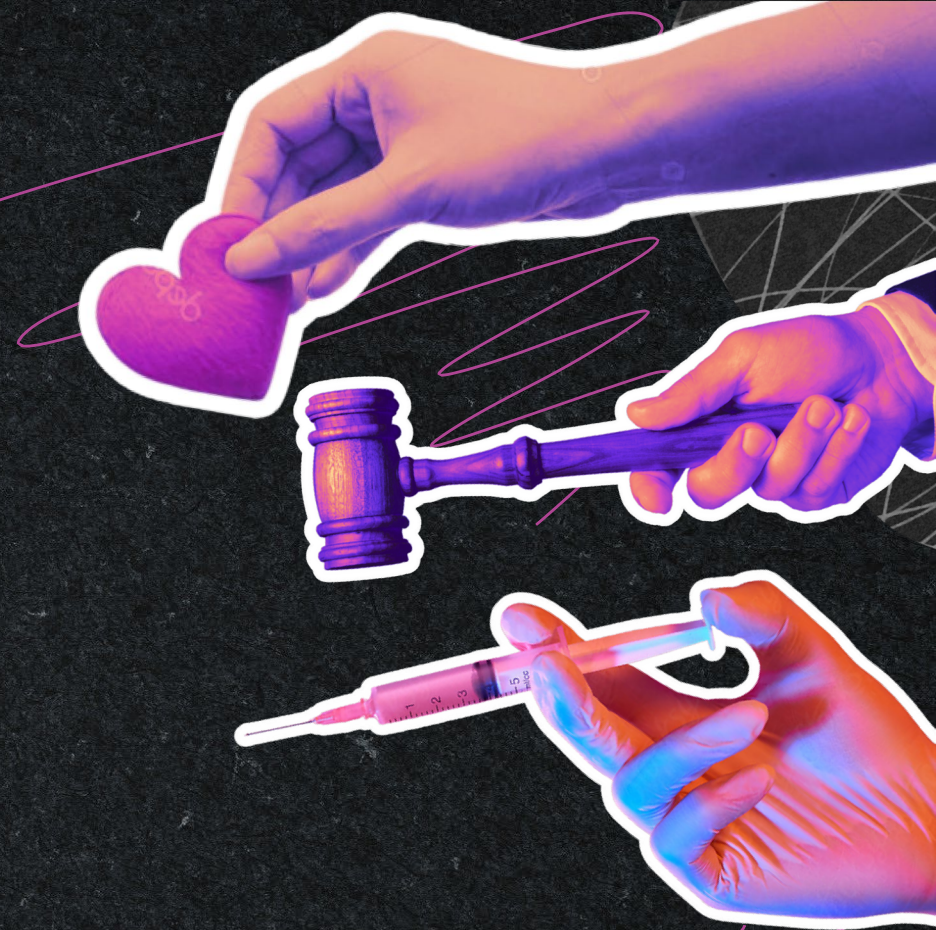
The Adolescent Medicine Trials Network (ATN)

& the CHOICE Agenda present

Research addressing HIV health  
inequities among US adolescents  
and young adults

February 15, 2024

Thank you for joining us today!



Adolescent Medicine  
Trials Network  
for HIV Interventions

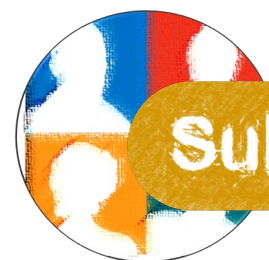
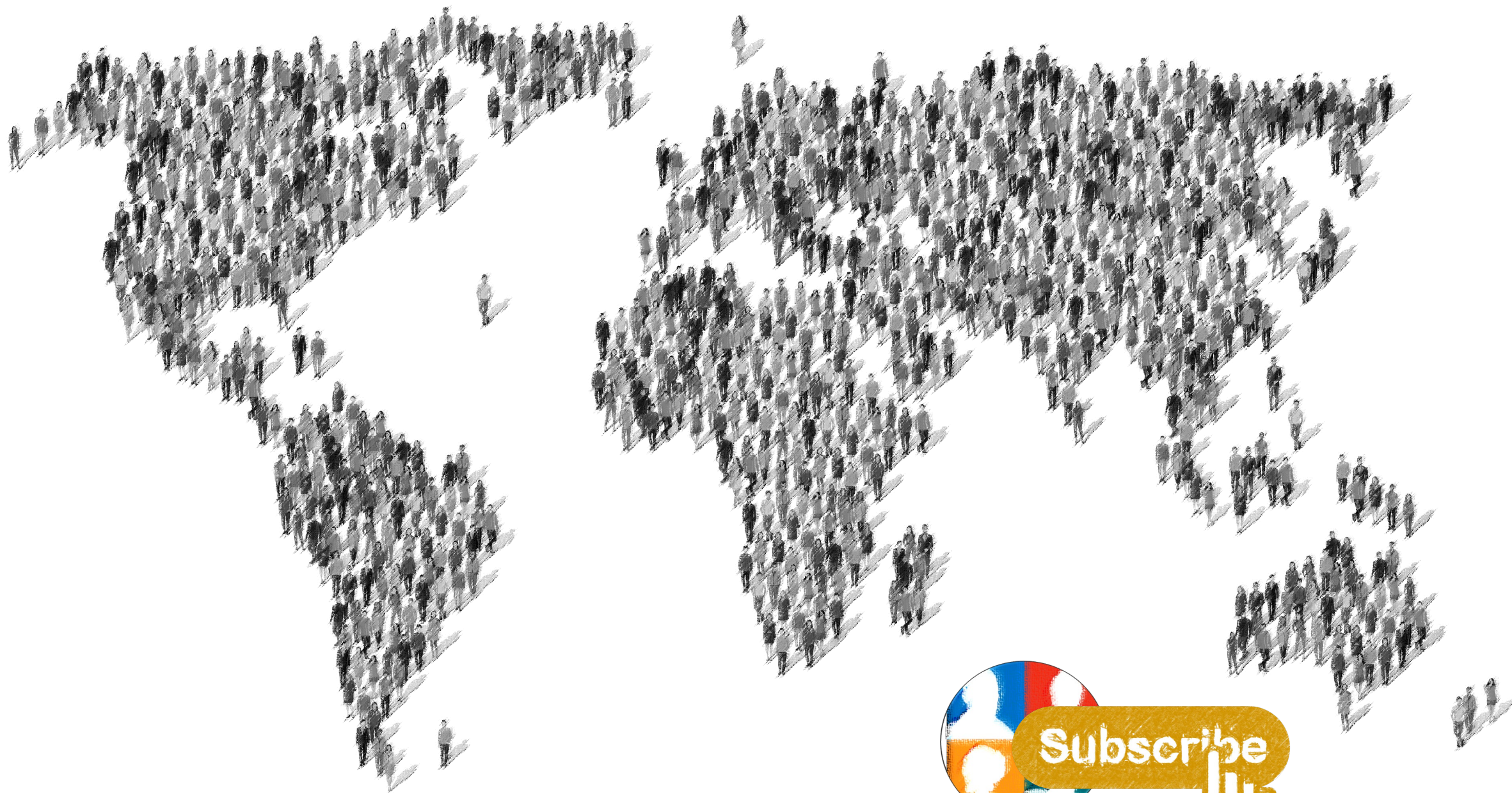






HIV prevention research - a new forum  
for advocacy on the latest

[avac.org/project/choice-agenda](http://avac.org/project/choice-agenda)



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## Today's playlist

Lemon Kenshi Yonezu

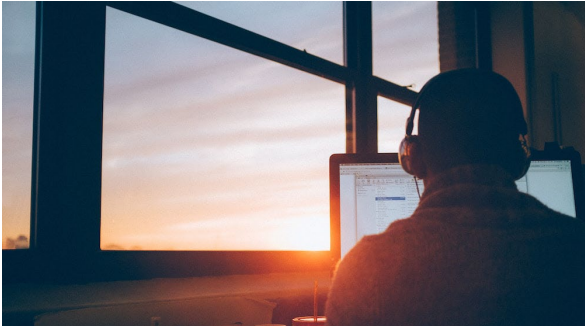
Whipped Cream Ari Lennox

Hungry Like the Wolf Duran Duran

Break My Soul Beyoncé

Rock With U Janet Jackson





Next up!  
Feb 29



**THE  
CHOICE  
AGENDA**



Webinar  
29 February 2024  
9:00 AM – 10:30 AM ET

The New Public  
Health Order:  
How is Africa  
preparing for  
pandemics?

Register and speaker info:  
[tinyurl.com/africaprepares](https://tinyurl.com/africaprepares)

**WACI**  
HEALTH





# Speakers

**Dr. Lisa Hightow-Weidman, ATN PI**

**Dr. Sybil Hosek, ATN PI**

**Dr. Kate Muessig, Linking Youth to PrEP Services**

**Dr. Audrey Pettifor, Linking Youth to PrEP Services**

**Dr. Sari Reisner, Legal, Economic, and Affirming Peer Support**

**Dr. Kristi Gamarel, Legal, Economic, and Affirming Peer Support**

**Zoe Njemanze, Subject Matter Research Consultant**

**Kendrick Forte, Subject Matter Research Consultant**

**Rodrigo Cabrera, National Community Advisory Board**



Adolescent Medicine  
Trials Network  
for HIV Interventions







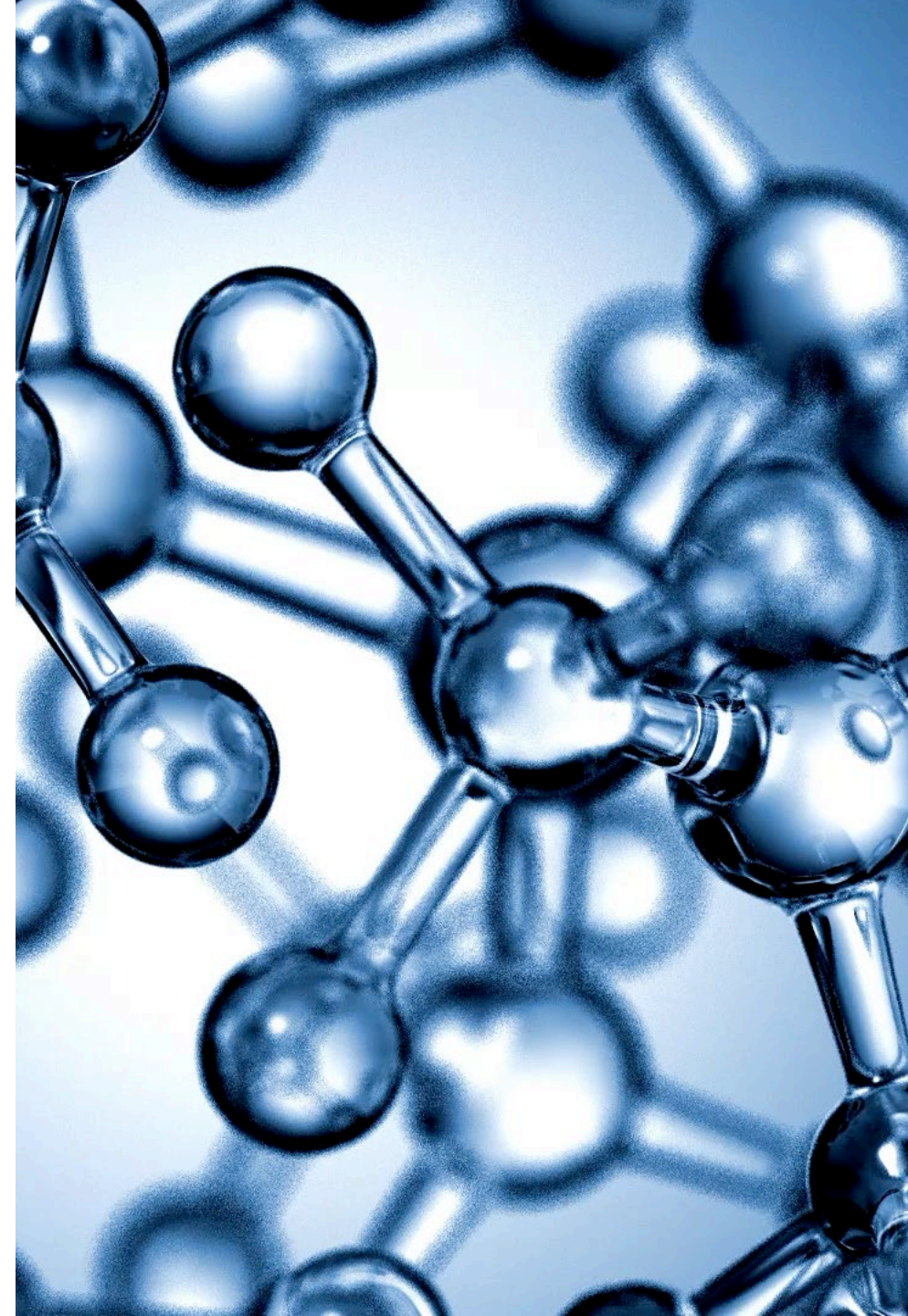
**Adolescent Medicine  
Trials Network**   
for HIV Interventions





## ATN 4, past work

- **Since 2001, the ATN has completed four funding cycles and is currently beginning its fifth cycle**
- **ATN IV ran from 2016 through 2022 and included three research programs:**
  - CARES
  - iTech (Center for Innovative Technology)
  - Scale It Up
- **Each research program included multiple research studies, and the ATN also included a few studies that spanned the entire network.**





# STRUCTURE OF THE “NEW” ATN



# Scientific Leadership Center (SLC) Leads



## Complementary Expertise and Shared Vision

- Both have worked in the field of adolescent HIV prevention & treatment for the entirety of their careers
- Involved in ATN since 2004 (Hosek) & 2006 (Hightow-Weidman)
- Working collaboratively together for past 17 years

**Lisa Hightow-Weidman, MD, MPH**  
(she/her)

Distinguished & Endowed  
McKenzie Professor of  
Nursing

Training: Medicine and  
Infectious Diseases

**Sybil Hosek, PhD**  
(she/her)

Research Professor

Training: Clinical  
Psychology

# Guiding Leadership Principles

## Responsiveness

Maintain a **flexible and responsive** approach to emerging challenges to ensure that the **highest priorities** are addressed expeditiously.

## Efficiency

Improve network and leadership efficiency through the **shared use** of key support services, common elements and **harmonized systems, shared/standardized training for common needs**, and streamlined implementation processes.

## Collaboration

**Highlight and leverage SLC expertise** and resources to foster equitable partnerships and collaborations to **maximize opportunities, avoid duplication, and be responsive to the priorities of youth.**

## Transparency

Ensure **overall SLC goals and roadmap** to achieve outputs are **effectively communicated, with feedback solicited** and critically examined, and **accountability enforced** at all levels.

## Youth-Focused

Acknowledge the **unique challenges of AYA** and the need for expertise to conduct HIV research in the context of their **cognitive, social, and emotional development.**



# Focus on Health Equity and Inclusion

## Box 1: Health Equity Research Impact Assessment for the ATN

### Community Engagement and Research Partnerships

- How will the [ATN/study] engage with diverse, and marginalized communities, especially addressing histories of mistrust?
- How will community partners be engaged?

### Representation and Generalizability

- Who are included in the [ATN/study]? Who are excluded?
- Are there processes in place to ensure the ATN/study sample is representative of the local community/communities most at risk for HIV?

### Intervention Design

- To what extent will/has the population of focus been engaged in the development and tailoring of the intervention?
- Will the intervention act at multiple social-ecological levels?

### Interpretation and Conceptualization

- Will the [ATN/study] employ adequate methods to facilitate accurate interpretation of research findings, particularly from the perspective of racial and ethnic minority and other marginalized communities?
- How might the study's results affect the population of focus, including potential for unintended, negative consequences?

### Dissemination

- What are the ATN/investigator's plans to translate research findings to recommendations for specific policy reforms?
- What are the ATN/investigator's plans to disseminate study results to communities, either directly or through translational research partnerships?

### Impact and Community Benefit

- If successful, how and to what extent will this research address health, healthcare and/or social inequities and outcomes for vulnerable youth?

**Health equity and inclusion cuts across all scientific areas and is the lens through which we view all research activities and outcomes.**

# Statistical and data management center (SDMC)



**Aim 1:** Collaborate across the network to support the overall management, integration, and coordination of all ATN activities.



**Aim 2:** Provide leadership and services for biostatistical analysis, study design and interpretation of study results, including the use of innovative statistical and simulation modeling methods.



**Aim 3:** Provide services and systems for clinical and laboratory data collection and management required to support the research projects and the overall ATN research agenda.

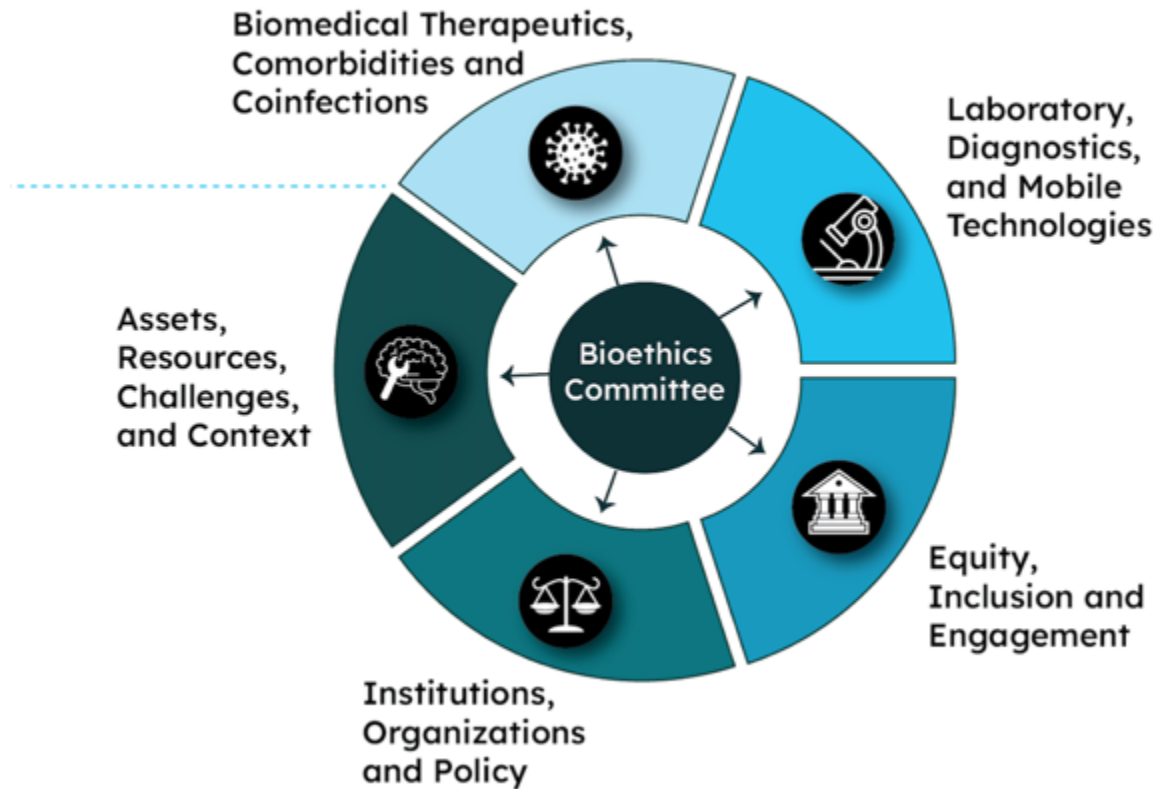


**Aim 4:** Promote equitable use, accessibility, and dissemination of data and catalyze mentorship and involvement of early-stage investigators and under-represented minorities.



# Scientific Leadership Group (SLG)

## Scientific Leadership Teams

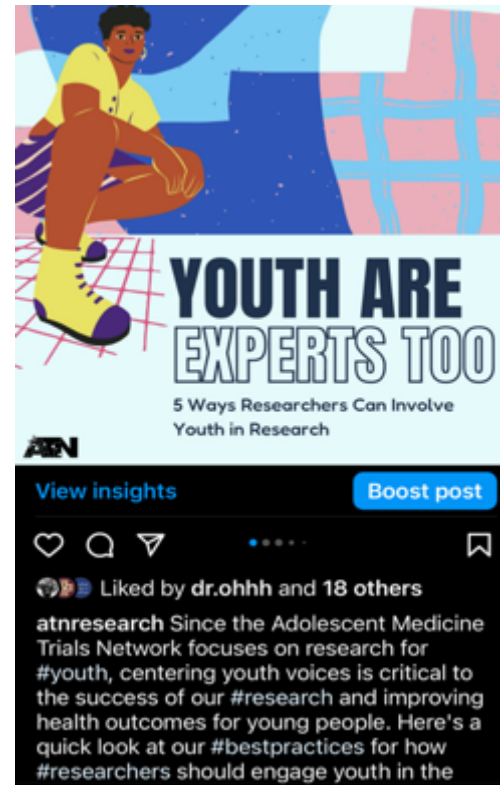


The primary mission of the SLG is to ensure that the ATN conducts innovative, significant, and feasible research.

To achieve this goal, the SLG is configured to address the diverse scientific agenda of the ATN through **six Leadership Teams** organized around specific areas of focus

# Communication and Dissemination Hub (C-D Hub)

Promote dissemination and implementation of research discoveries for maximum public health impact including translation into clinical and community practice guidelines and policy recommendations.





# Youth Leadership

## **SUBJECT MATTER RESEARCH CONSULTANTS (SMRC)**

- Young professionals that reflect the target demographic of various project studies, enhancing the projects
- Participating on protocol teams and SLGs

## **NATIONAL COMMUNITY ADVISORY BOARD (NCAB)**

- Youth recommended by SC to provide bidirectional information from local community YCABs
- Build community nationally at their local SCs

**Both groups review protocols, measures, recruitment methodologies, scientific priorities**

# Operations and Collaborations Center (OCC) Leads



## Complementary Qualifications & Experience



Barbara  
Driver, M.S.  
(she/her)

Co-Principal  
Investigator



Dan Reirden,  
M.D.  
(he/him)

Co-Principal  
Investigator

- Involved in ATN since 2000
- HIV clinical care of ATN target populations
- Medical Director of the Children's Colorado's Adolescent & Young Adult HIV Program
- Community-based research for HIV prevention solutions
- Specialists in HIV clinical research operations support
- Collaborations with HIV research networks, NIH, CDC, and pharma companies

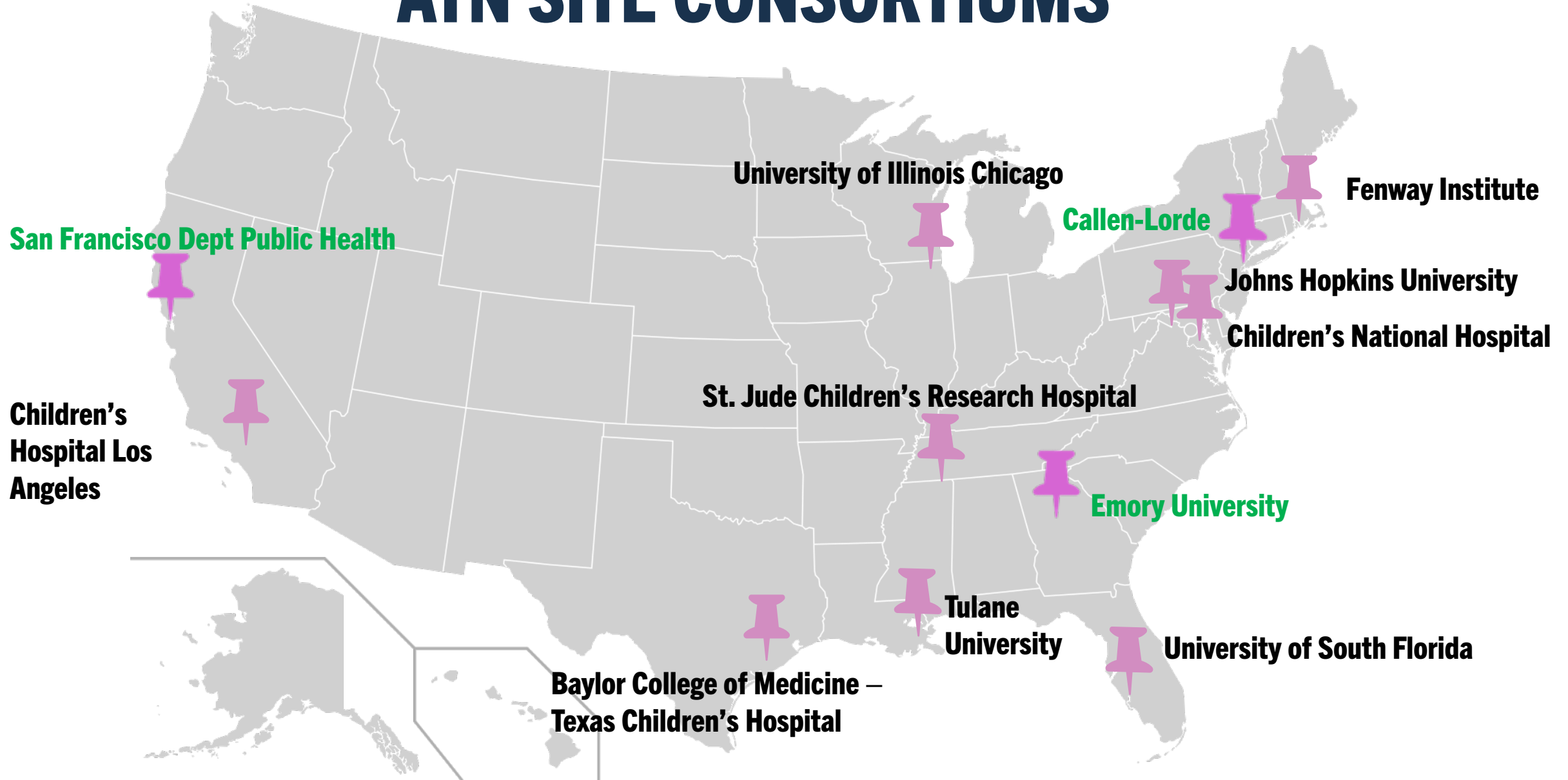


Dina Monte,  
RN  
(she/her)

Project  
Manager



# ATN SITE CONSORTIUMS





# Active Protocols

**ATN 164: Screen to Prevent (S2P)**

**ATN 165: Linking Youth to PrEP Services (LYPS)**

**ATN 166: Combating HIV Or Other STIs Early (CHOOSE)**

**ATN 167: Legal, Economic, and Affirming Peer Support for Trans Youth (LEAP)**

**ATN 168: HIV and Pregnancy Prevention for Youth (HAPPY)- Part I**

**ATN 170: Impact**

**ATN 172: HIV and Pregnancy Prevention for Youth (HAPPY)- Part II**



## Protocols in Development

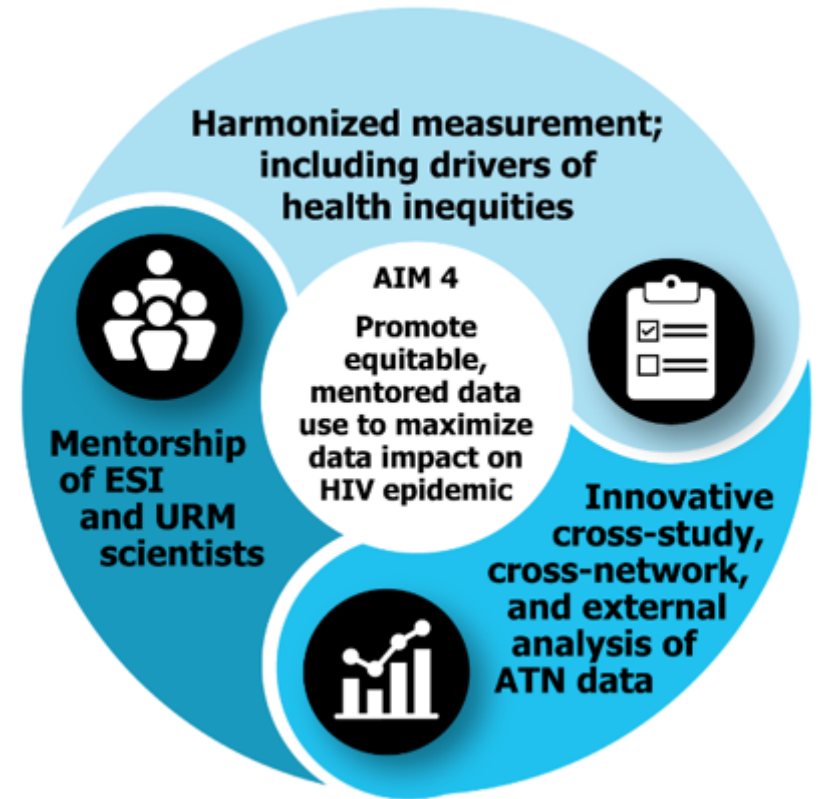
**ATN 171: SASSY**

**ATN 173: Doxy-PEP**



# ATN Mentorship

- **Develop, mentor and train early-stage investigators**
  - prioritizing involvement of underrepresented minorities and investigators from resource-limited settings
  - to foster the next generation of multidisciplinary HIV researchers who will sustain the future of innovative adolescent HIV research.
- Will develop partnerships and collaborations with established mentoring programs to maximize resources and learning opportunities





**LINKING YOUTH TO PrEP SERVICES**



# ATN 165: Linking youth to PREP Services (LYPS)

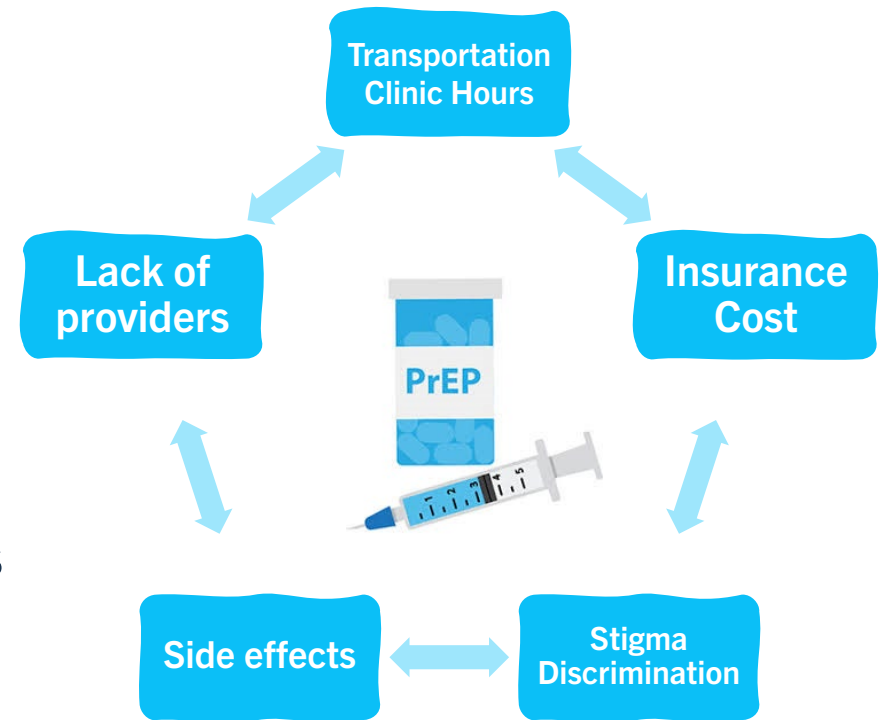
## BACKGROUND



Sexual and gender minority (SGM) adolescents experience health inequities driven by multi-level barriers to care

These factors pose challenges for adolescents to engage in regular PrEP visits

Optimal PrEP use for adolescents **can benefit from day-to-day self-management and support** to address emergent barriers to PrEP adherence and care



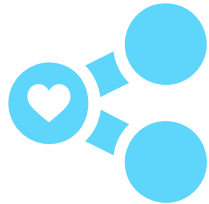
# ATN 165: Linking Youth to PREP Services (LYPS)

## BACKGROUND



Differentiated models of service delivery that extend outside of the clinic are effective in global settings and for other health areas like HIV care.

Priorities include:



**Offering more choices** for service and support strategies, in addition to additional PrEP modalities (e.g. daily oral, 2-1-1, injectable)



**Identifying delivery approaches** for injectable PrEP (CAB-LA) to adolescents in new settings



**Leveraging customizable mobile health tools** to support PrEP adherence and persistence



# Differentiated Care for Adolescents: offering choice

## Getting CAB-LA out of clinics may pose more challenges than oral PrEP

- Who can provide injections?
- Where can it be delivered?
- What else needs to be provided with CAB-LA?





# ATN 165: LYPS Research Aims



## Aim 1

Test whether an intervention that combines Community Health Providers and ongoing mobile Health support to deliver services outside the clinic (e.g., home, mobile van, community center) **improves PrEP adherence and persistence** at 6 and 9 months.

## Aim 2

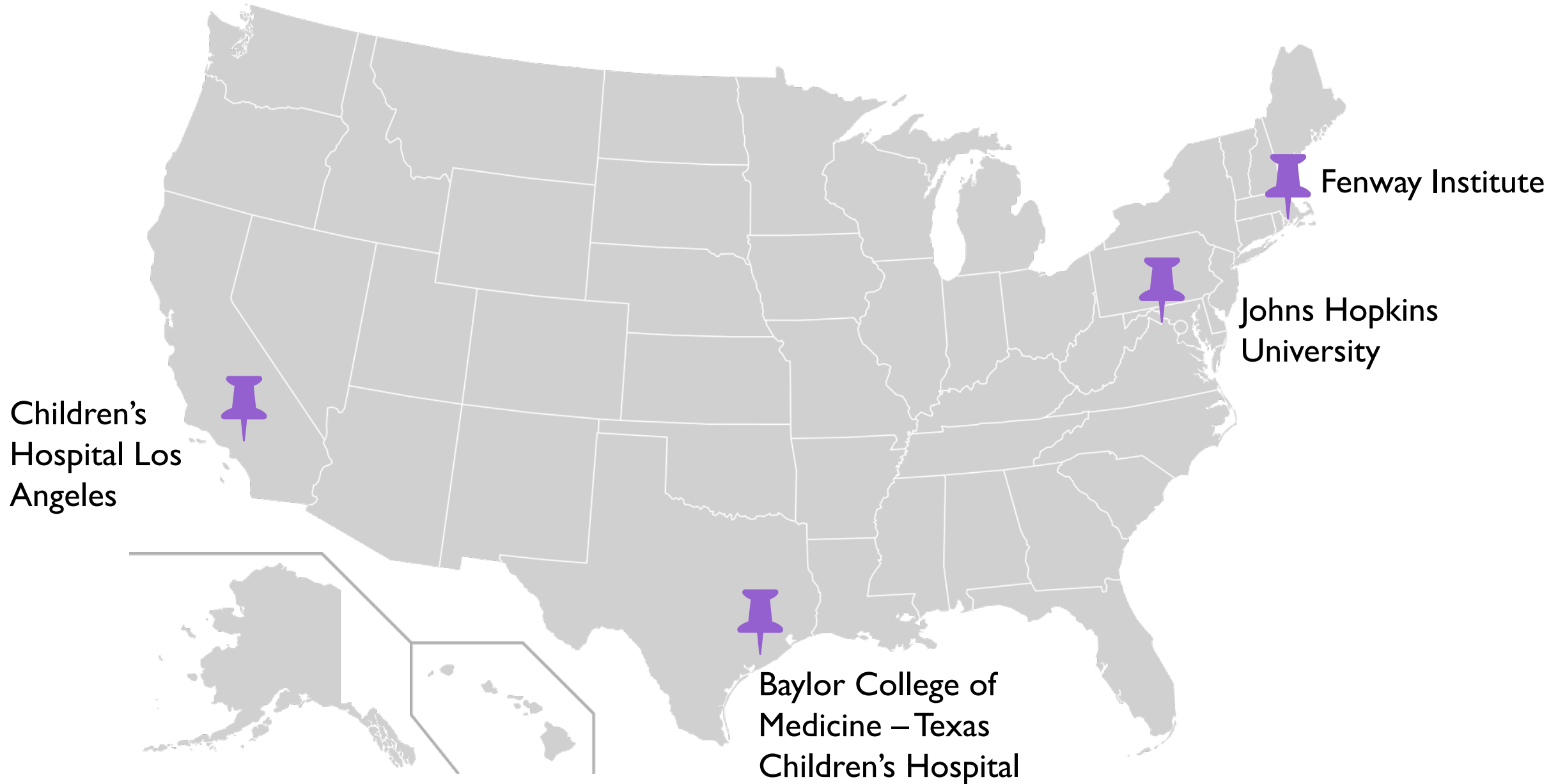
Evaluate **the resource use costs and cost-effectiveness of LYPS** to inform the interpretation and implementation of study results.

## Study population:

272 transgender women and gay, bisexual, and other sexual minority men, age 13 – 24.

Protocol Co-Chairs: Keith J. Horvath, Kate Muessig & Audrey Pettifor

## ATN 165 : LYPS STUDY IMPLEMENTATION SITES



# ATN 165: LYPS Intervention Components



	PrEP Care	LYPS App
All Participants	<ul style="list-style-type: none"><li>• Oral (daily or 2-1-1) or injectable</li><li>• Regular re-assessment of PrEP options</li><li>• Referral to other services</li></ul>	<ul style="list-style-type: none"><li>• Appointment reminders</li><li>• Interactive informational resources</li></ul>
Intervention Arm only	<ul style="list-style-type: none"><li>• Out-of-clinic services (testing, specimen collection, medication)</li></ul>	<ul style="list-style-type: none"><li>• Adherence tracking &amp; self-monitoring</li><li>• Monthly PrEP check-ins</li><li>• Ongoing social support</li></ul>



# Developing PrEP delivery outside of the clinic



## Proposed Delivery Models

### **Community Venues**

recreational centers, libraries, CBO partners



### **Mobile Clinics**



### **Home Visits**

Healthcare provider comes to home to deliver care



- **Overarching goal:** to reduce barriers to PrEP access and meet youth where they are with PrEP care
- **Engaged intervention development process**
  - Subject Matter Research Consultants, National CAB, Site Consortia
- Continuous contact via mobile app to address issues and make changes
- Some sites may offer choice of location

# Developing PrEP delivery outside of the clinic

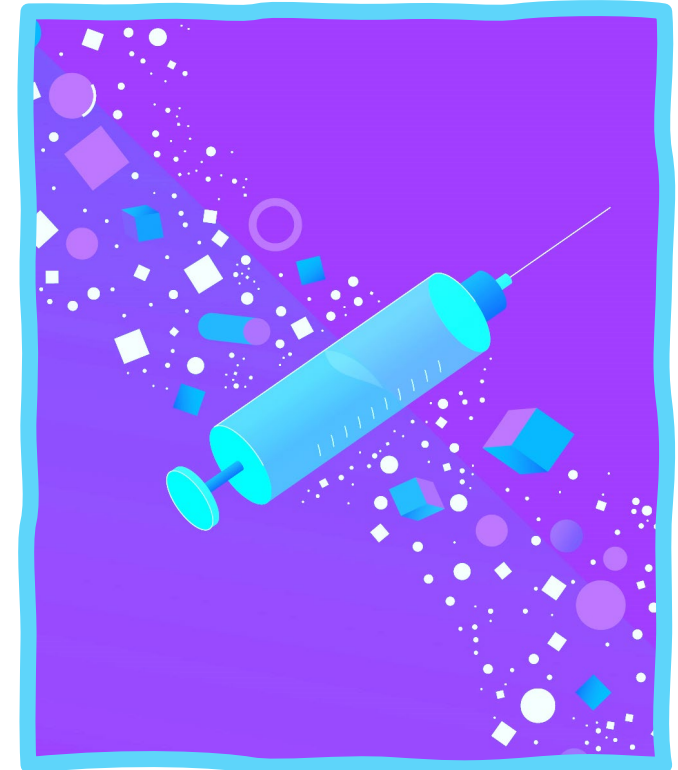


## Challenges and Considerations

- Maintaining safety for participants and staff
- Obtaining study drugs
- Laws vary by state for CAB-LA
- Cold storage for CAB-LA and biological samples

## Timeline:

- Anticipated launch: mid-2024
- Results: 2026



# Implications and Next Steps



**Differentiated models of PrEP delivery for adolescents are urgently needed.**

**But we still need more evidence on how to implement these models in different settings.**



**Sustainability and Scale Up**, if found to be acceptable, feasible and effective in supporting PrEP adherence for youth need



**Cost-effectiveness** of different ways to deliver care outside of clinics may also help with adaptation and tailoring



**Other service packaging** beyond PrEP to meet the needs of different populations (e.g. combined with reproductive health services for cisgender women)



# ATN 165 Protocol Team



- **Keith J. Horvath**, Protocol Co-Chair SDSU
- **Kate Muessig**, Protocol Co-Chair, FSU
- **Audrey Pettifor**, Protocol Co-Chair, UNC
- **Lisa Hightow-Weidman**, Co-Investigator/ATN-PI, FSU
- **Joshua Espada**, FSU Subject Matter Research Consultant
- **Rahim Miller**, FSU Subject Matter Research Consultant
- **Sybil Hosek**, ATN-PI, UIC
- **Jordan Lundeen**, Emmes
- **Gretchen Buckler**, NICHD
- **Jonathan Warus**, CHLA
- **Litty Koshy**, Baylor
- **Jessica Coleman Lewis**, Johns Hopkins
- **Nancy Liu**, Westat

# References



- 1) PrEP continuum for US BIPOC SGM Bonett, 2022; <https://pubmed.ncbi.nlm.nih.gov/34546472/>
- 2) PrEP drop-off, US SGM: Serota, 2020; <https://pubmed.ncbi.nlm.nih.gov/31499518/>
- 3) PrEP drop-off, young Brazilian SGM: Dourado, 2023; <https://pubmed.ncbi.nlm.nih.gov/37953006/>
- 4) Telehealth for PrEP: Touger, 2019; <https://pubmed.ncbi.nlm.nih.gov/30701404/>
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- 6) eHealth HIV prevention & care: Maloney, 2020; <https://pubmed.ncbi.nlm.nih.gov/31909896/>
- 7) CHW care delivery in Africa: Khumalo, 2021; <https://fmch.bmj.com/content/9/4/e000958.abstract>
- 8) Mobile PrEP AGYW in South Africa: Rousseau, 2021; <https://pubmed.ncbi.nlm.nih.gov/34454505/>

# THANK YOU!!!



**Questions**



**Ideas**



**Discussion**





# **ATN 167: Legal, Economic, and Affirming Peer Support for Trans Youth (LEAP)**

**Kristi Gamarel, PhD, EdM (she/her) and Sari L. Reisner, ScD, MA (he/him)**  
*Protocol Co-Chairs*



# ATN 167: LEAP TEAM



**Robin Davison**



**Dionté Gill**



**Laura Jadwin-Cakmak**



**Larissa Jennings Mayo-Wilson**



**Omar Martinez**



**Arjee Restar**



**Erin Ricketts**



**Ini-Abasi Ubong**



**Genesis Valera**

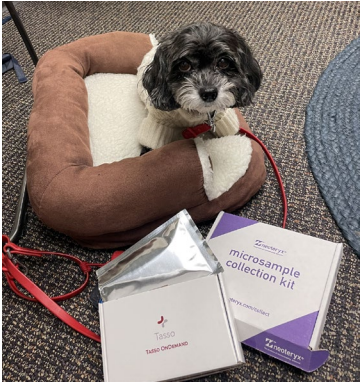


**Cassie Vuong**

**ATN SLC, OCC, SDMC/Emmes, SLGs, SCs, SMRCs & NCAB!**



# ATN 167: LEAP TEAM



Lucy



Marcel



Mochi



Ollie



Ollie Bean



Roman & Ahsoka



Squints



Bea & Benny



Perla



Moo Moo



Juno & Harley



Yolko Ono





## ATN 167: LEAP

### Study Background

Transgender and gender diverse (trans) youth are **burdened by HIV with stark racial/ethnic disparities** across the HIV prevention and care continua.

**Intersectional oppression fuels social determinants of HIV**, including health-harming legal issues, economic vulnerability, and unmet gender affirmation needs (e.g., legal, social, medical affirmation).

Several Black trans-led organizations have developed **programs to address these social determinants of HIV**.

There is a **need to systematically evaluate integrated community-driven strategies** for impact on HIV prevention and care continua.



Photo credit: Monica Alexander





**Carter Brown**  
*Executive Director*

National Black Trans Advocacy Coalition is the only social justice organization led by black trans people to address systemic racism and inequities in the black transgender experience, advocating for structural changes for health, employment, housing, and education.



**Marissa Miller**  
*Executive Director*

Trans Solutions Research and Resource Center advocates for safety and universal access, and offers social and health services, in addition to mentorship and job programs, for transgender and nonbinary communities in the US.



**Liliana Reyes**  
*Executive Director*

The mission of TSOCP is to uplift and impact the lives of trans women of color through trans-centric programming, providing no-strings attached emergency assistance to their community since 2017. In 2020 Julisa Abad founded the Trans Name Change Project to provides free peer and legal support to trans individuals.



**Bethany Hamilton**  
*Co-Director*

Founded in 2006, the National Center for Medical-Legal Partnership leads education, research, and technical assistance efforts to help every health organization in the US leverage legal services as a standard part of the way they respond to social need.



## Legal, Economic, and Affirming Peer Support for Trans Youth (LEAP)

Combines community-led strategies designed to address social determinants of HIV to:

### Aim 1

Test the effectiveness of LEAP on **increasing HIV prevention and treatment outcomes** compared to those in a delayed intervention control condition.

### Aim 2

Assess the **heterogeneity of treatment effects** (e.g., HIV status, gender, site) and the **effects of LEAP on theory-based mediators** (e.g., gender affirmation, legal, and economic needs).

### Aim 3

Conduct a **prospective implementation process evaluation** using the Health Equity Implementation Framework (HEIF) and Consolidated Framework for Implementation (CFIR), which includes resource uses, costs, and cost-effectiveness analyses.

# LEAP Sites

## Eastern U.S.

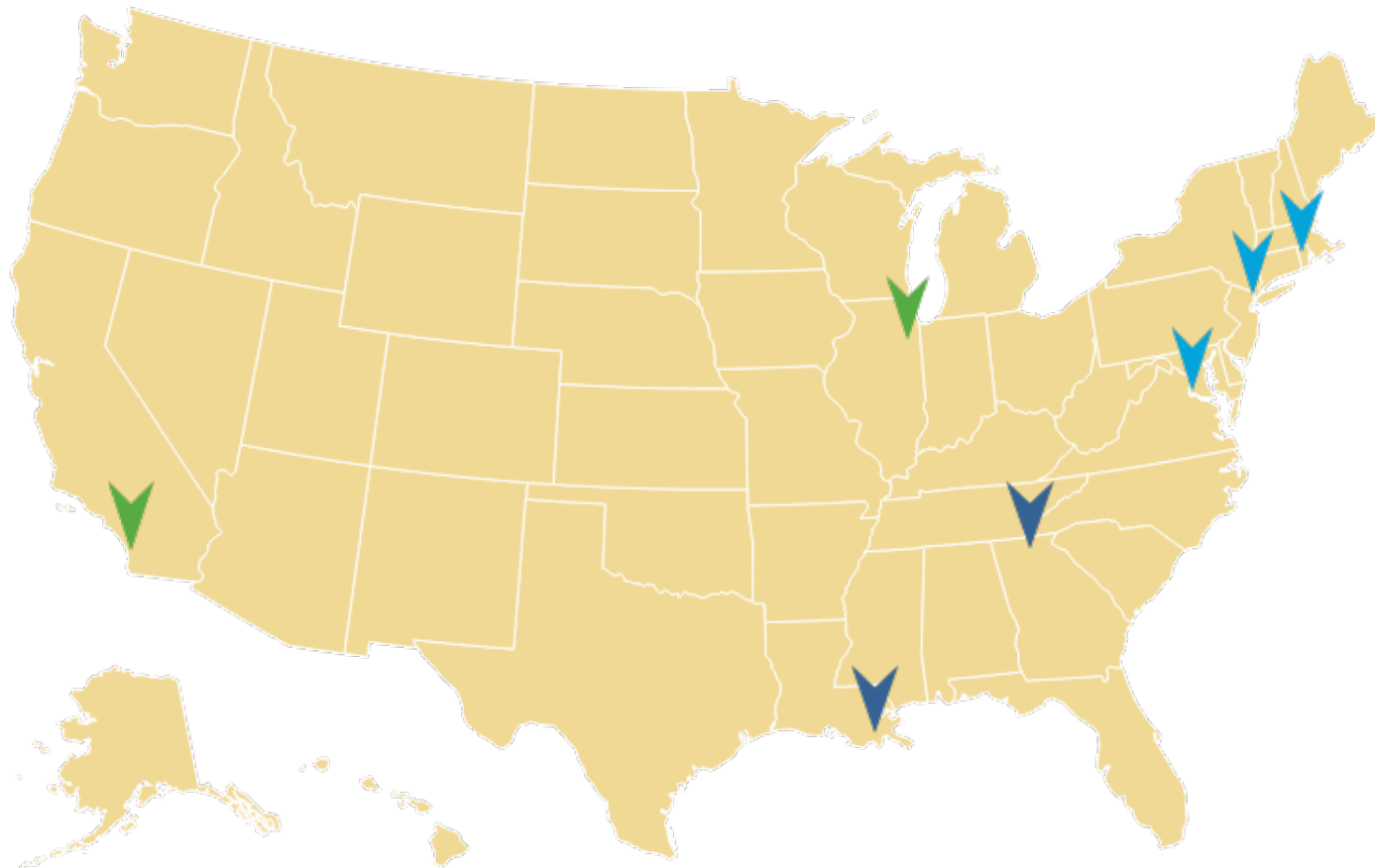
- Callen-Lorde (New York, NY)
- Fenway Institute (Boston, MA)
- Children's National Hospital (Washington, DC)

## Southern U.S.

- Tulane University Adolescent Medicine (New Orleans, LA)
- St. Jude Children's Research Hospital (Memphis, TN)

## Western & Midwestern U.S.

- Children's Hospital, Los Angeles (Los Angeles, CA)
- The CORE Center (Chicago, IL)



# LEAP Design

- **Eligibility criteria**

- Ages 15 to 24 years
- Self-identify as a gender identity that does not correspond with the sex assigned on their original birth certificate
- Self-identify as a person of color
- Any condomless sex in past 6 months
- English-or Spanish-speaking
- Willing and able to provide informed consent

- **Waitlist control design**

- Receive the LEAP intervention immediately or 6 months later

- **Participants followed quarterly for 12 months**

- **Participants enrolled in-person with remote options for intervention activities and follow ups**

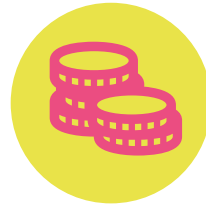


# LEAP Intervention Components



## Legal

- Health-harming legal needs screener
- 1 education session
- Linkage to lawyers



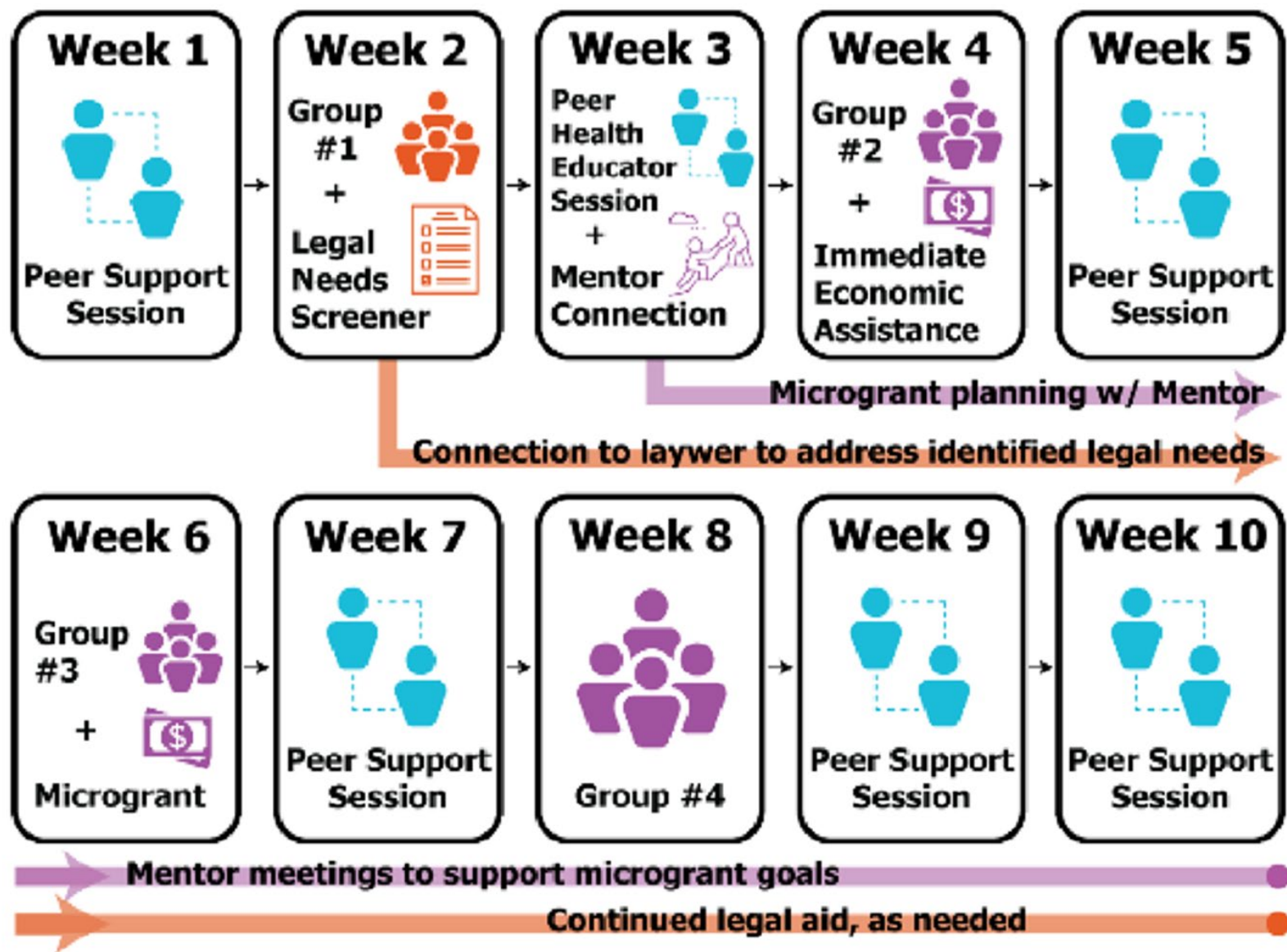
## Microeconomic

- 3 education group sessions
- Immediate assistance (\$200)
- Unconditional grant (\$800)
- Mentoring for education and/or employment goals



## Peer Support

- 6 individual peer support sessions focused on gender affirmation and HIV based on the Healthy Divas curriculum



# Group Session Content

Session #	Session Name	Session Objectives
<b>1</b>	<b>Legal Empowerment</b>	<ul style="list-style-type: none"><li>• Understand how legal empowerment relates to trans liberation</li><li>• Define and identify health-harming legal needs</li><li>• Understand different types of laws and the role of lawyers</li></ul>
<b>2</b>	<b>Financial Planning</b>	<ul style="list-style-type: none"><li>• Understand funds received through LEAP</li><li>• Beginning planning to use emergency assistance</li><li>• Understand the benefits of budgeting</li></ul>
<b>3</b>	<b>Strengths and Passions</b>	<ul style="list-style-type: none"><li>• Identify strengths and passions</li><li>• Develop plan for spending the \$800 micro-grant</li></ul>
<b>4</b>	<b>Building Credit and Using It Wisely</b>	<ul style="list-style-type: none"><li>• Understand credit and how to build/ repair it</li><li>• Discuss plans and experiences relating to the \$800 micro-grant</li></ul>

# Individual Session Content

Session #	Session Name	Session Objectives
1	All of You – Taking Care of Your Whole Self	<ul style="list-style-type: none"> <li>• Understand the structure and goals of LEAP</li> <li>• Learn about a holistic approach to well-being and health</li> <li>• Set a personal health vision</li> </ul>
2	You Got This – Strengths and Resilience	<ul style="list-style-type: none"> <li>• Discuss sexual health</li> <li>• Identify personal strengths</li> <li>• Understand how strengths play in achieving health goals</li> </ul>
3	Talk to Me – Communication and Boundaries	<ul style="list-style-type: none"> <li>• Learn and practice communication skills</li> <li>• Apply communication skills to increase health care engagement</li> <li>• Revise personal health vision</li> </ul>
4	Keeping It Together – Support and Your Health	<ul style="list-style-type: none"> <li>• Learn about types of social support</li> <li>• Consider the impact of stigma, transphobia, trauma, and substance abuse on social support</li> <li>• Identify sources of social support</li> </ul>
5	Work It – Recognizing Your Successes and Overcoming Challenges	<ul style="list-style-type: none"> <li>• Discuss progress towards goals</li> <li>• Identify recent successes</li> <li>• Identify challenges to reaching health and HIV goals</li> </ul>
6	LEAP Forward – Your Future Self and Health	<ul style="list-style-type: none"> <li>• Discuss progress towards goals</li> <li>• Identify continued health care challenges and barriers to care</li> <li>• List future goals and visualize future success</li> </ul>



**Thank you**