

HPTN Scientific Agenda

Key Updates for 2021 and Beyond

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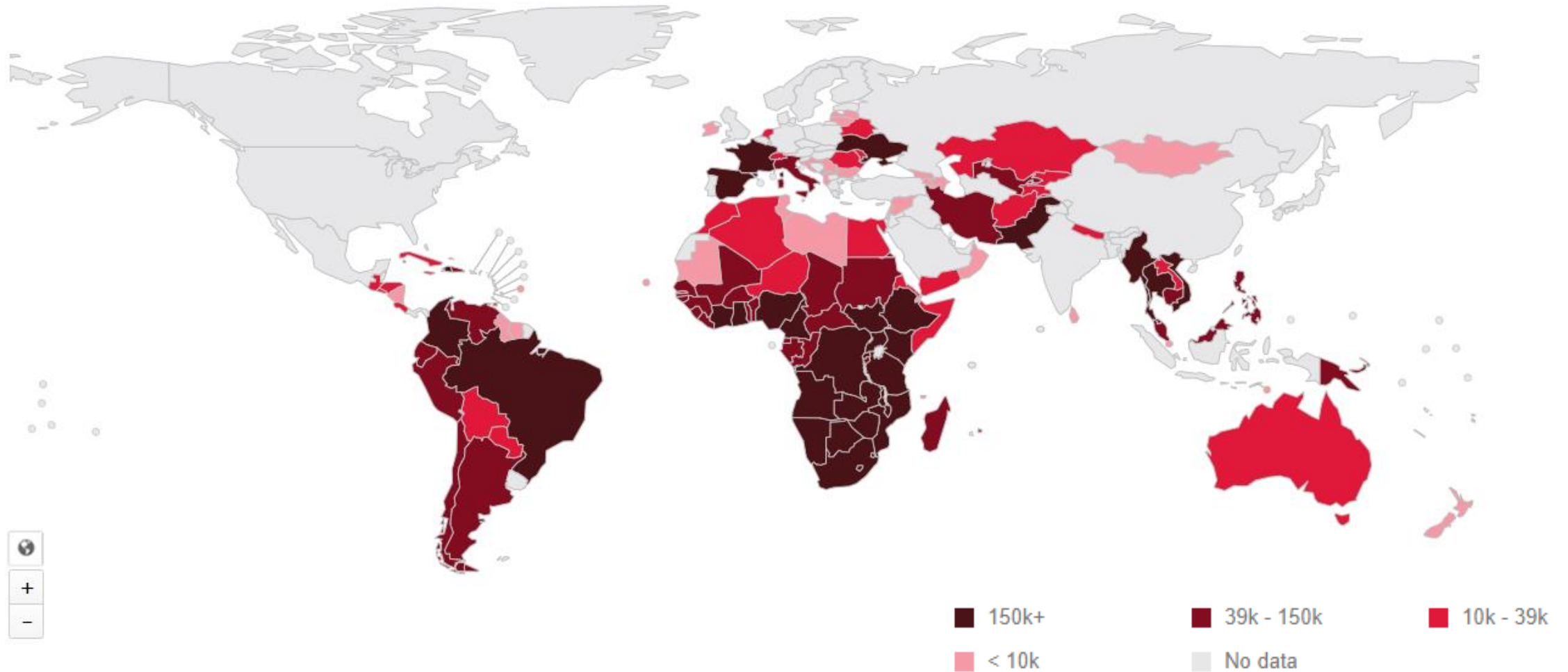
**::: HPTN ANNUAL :::
::: MEETING 2021 :::::**



Overview of Presentation

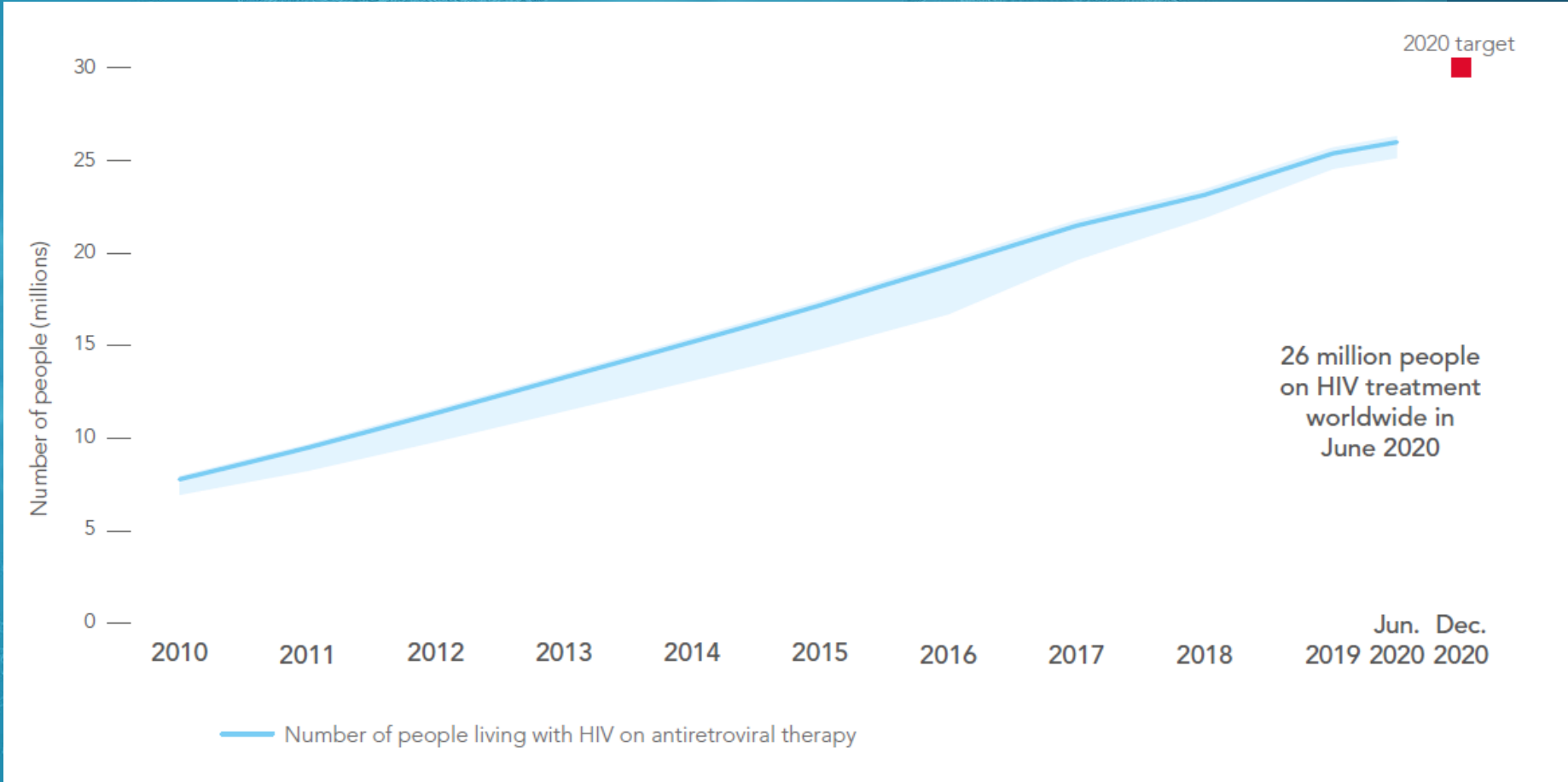
- State of the HIV Epidemic
- HPTN vision and conceptual framework
- Ongoing HPTN studies
- Recent and planned HPTN studies
- Looking ahead
- Conclusions

Adults and children living with HIV | 2019

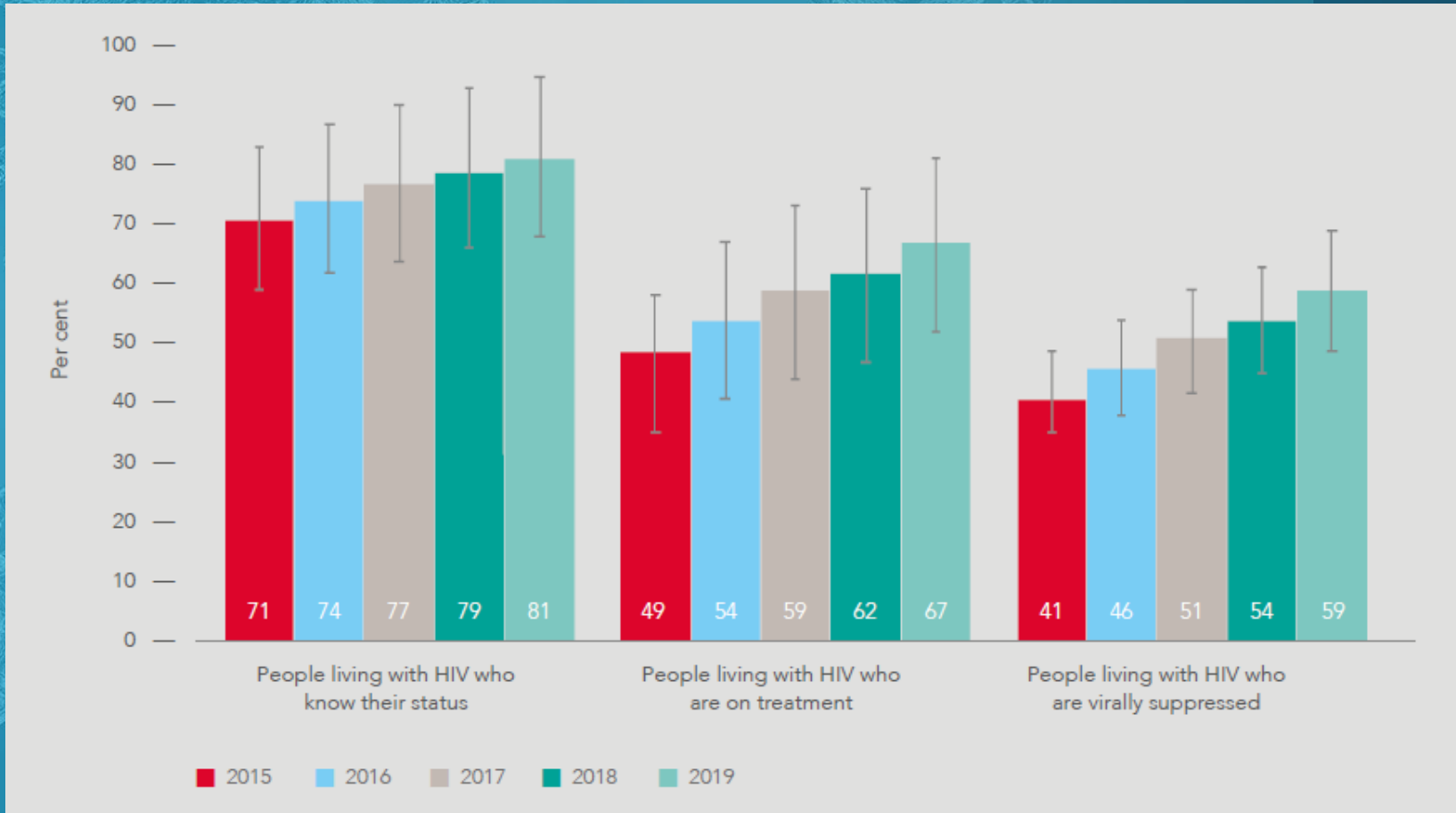


Total: 38.0 million [31.6 million–44.5 million]

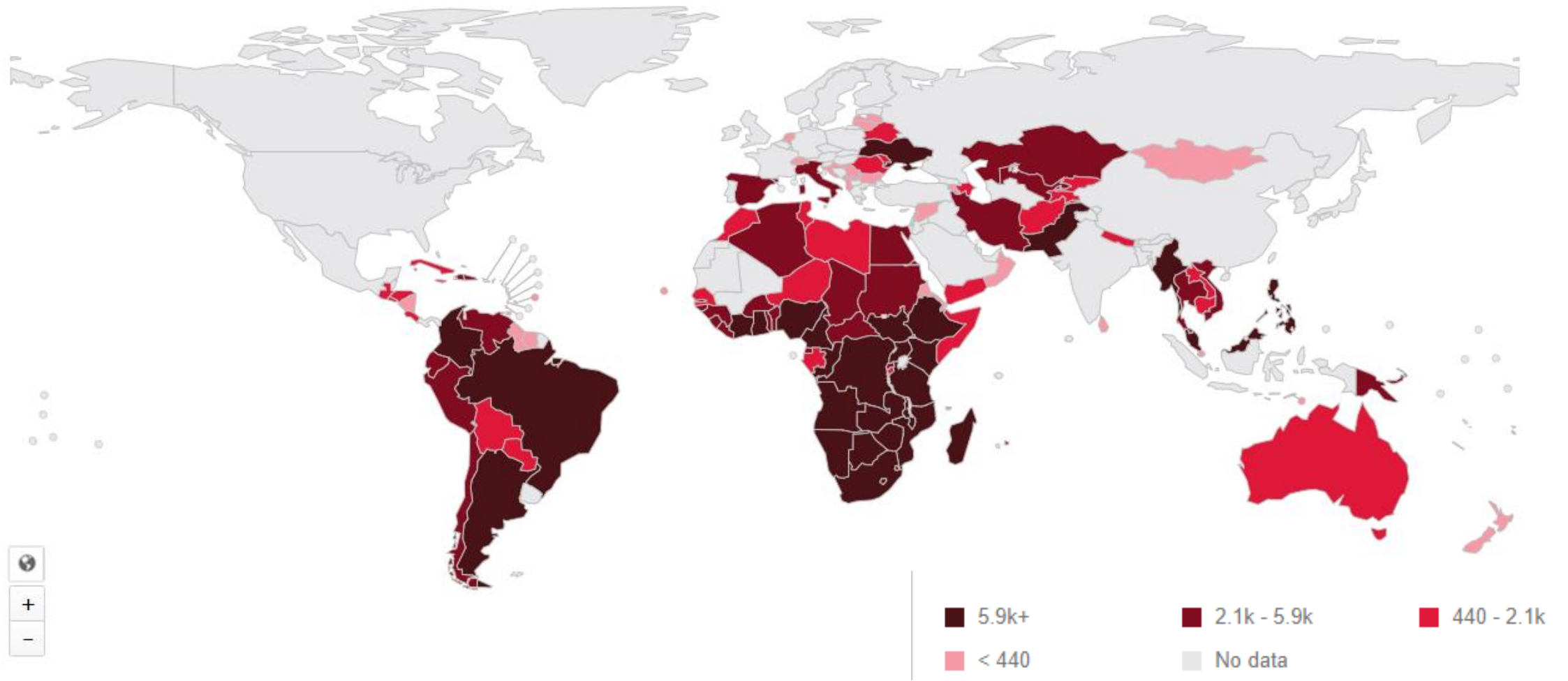
Reaching Global HIV Treatment Targets



HIV Testing and Treatment Cascade

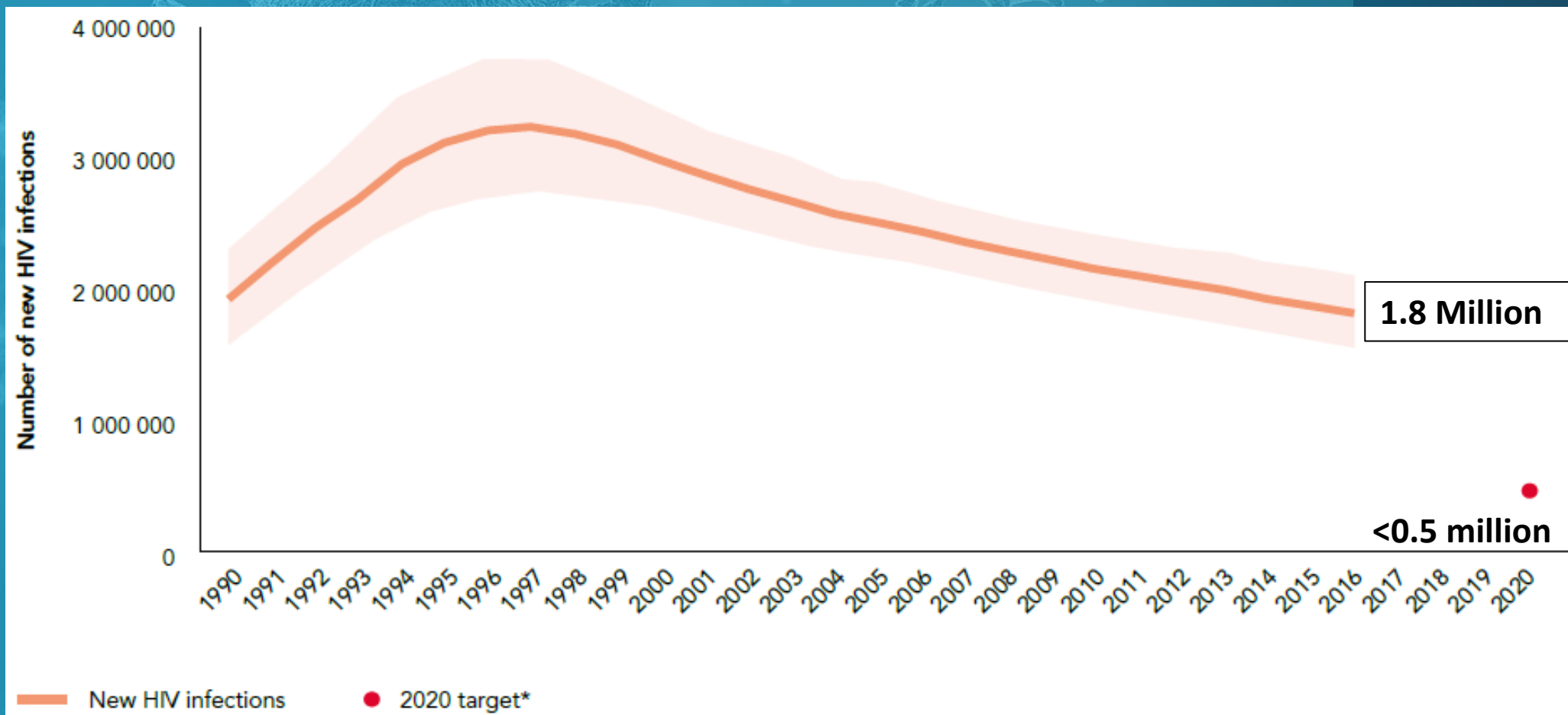


Number of new HIV infections | 2019

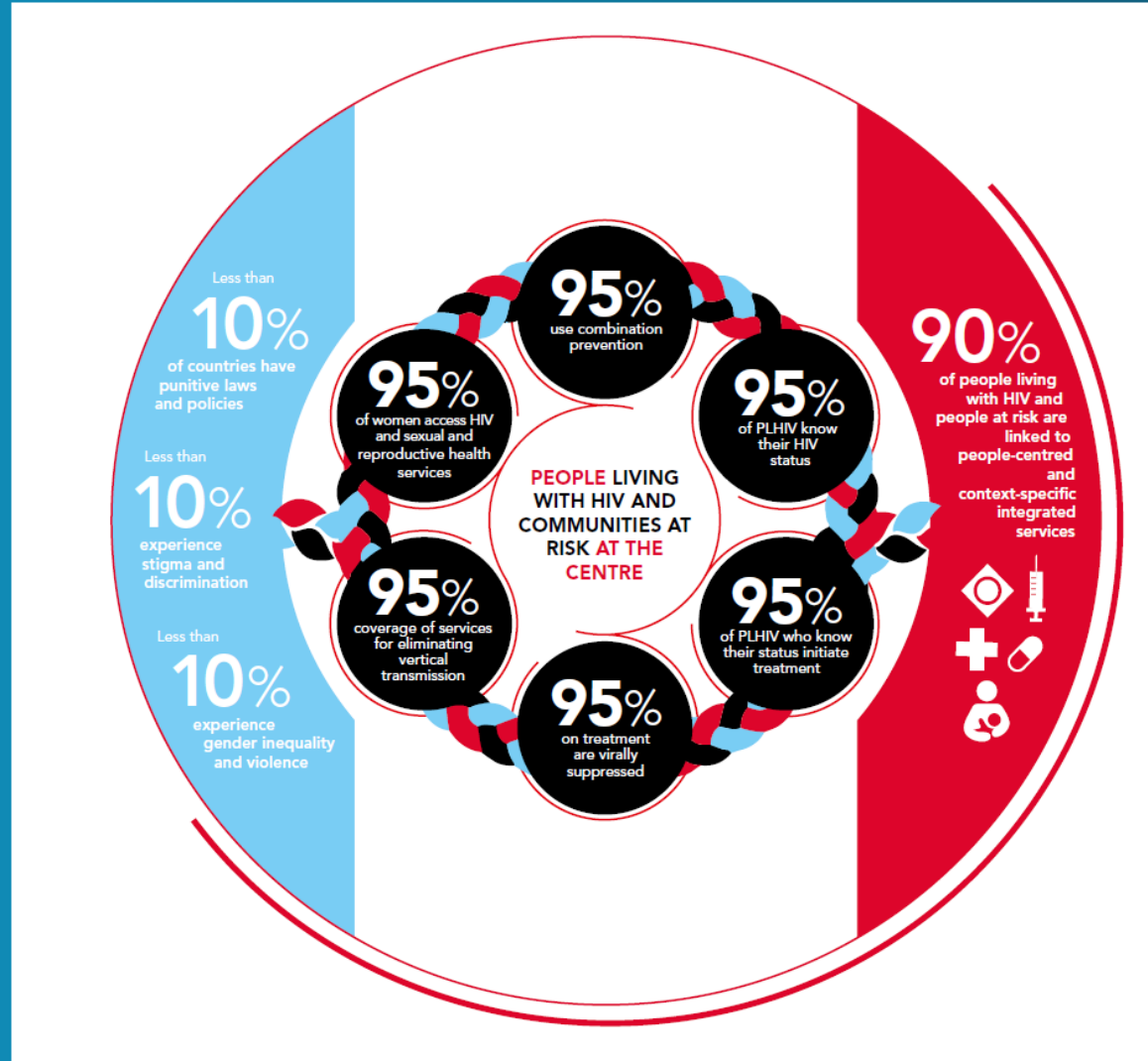


Total: 1.7 million [1.2 million–2.2 million] people

Number of New HIV Infections

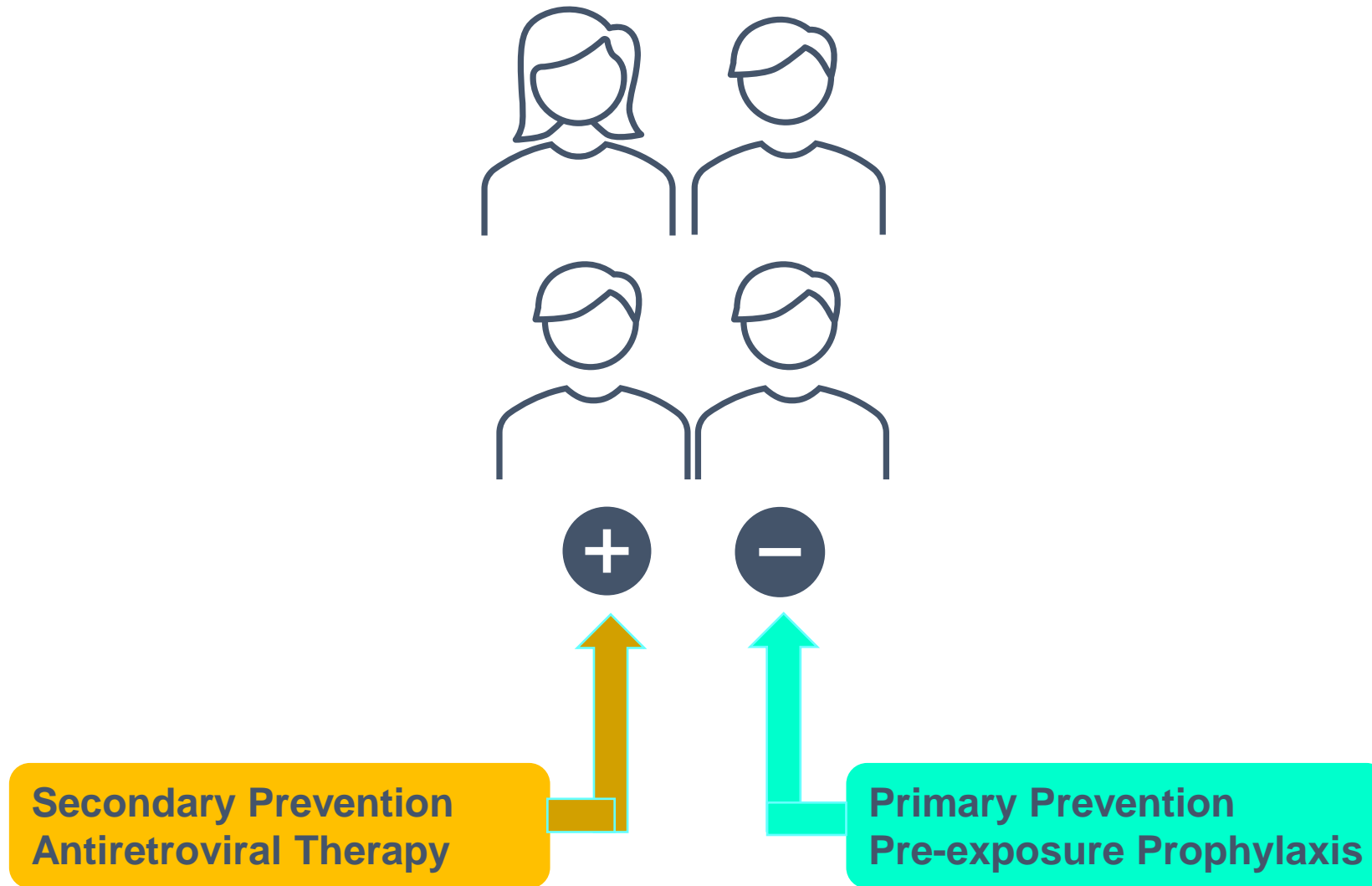


Global Targets for 2025



HPTN Strategic Vision

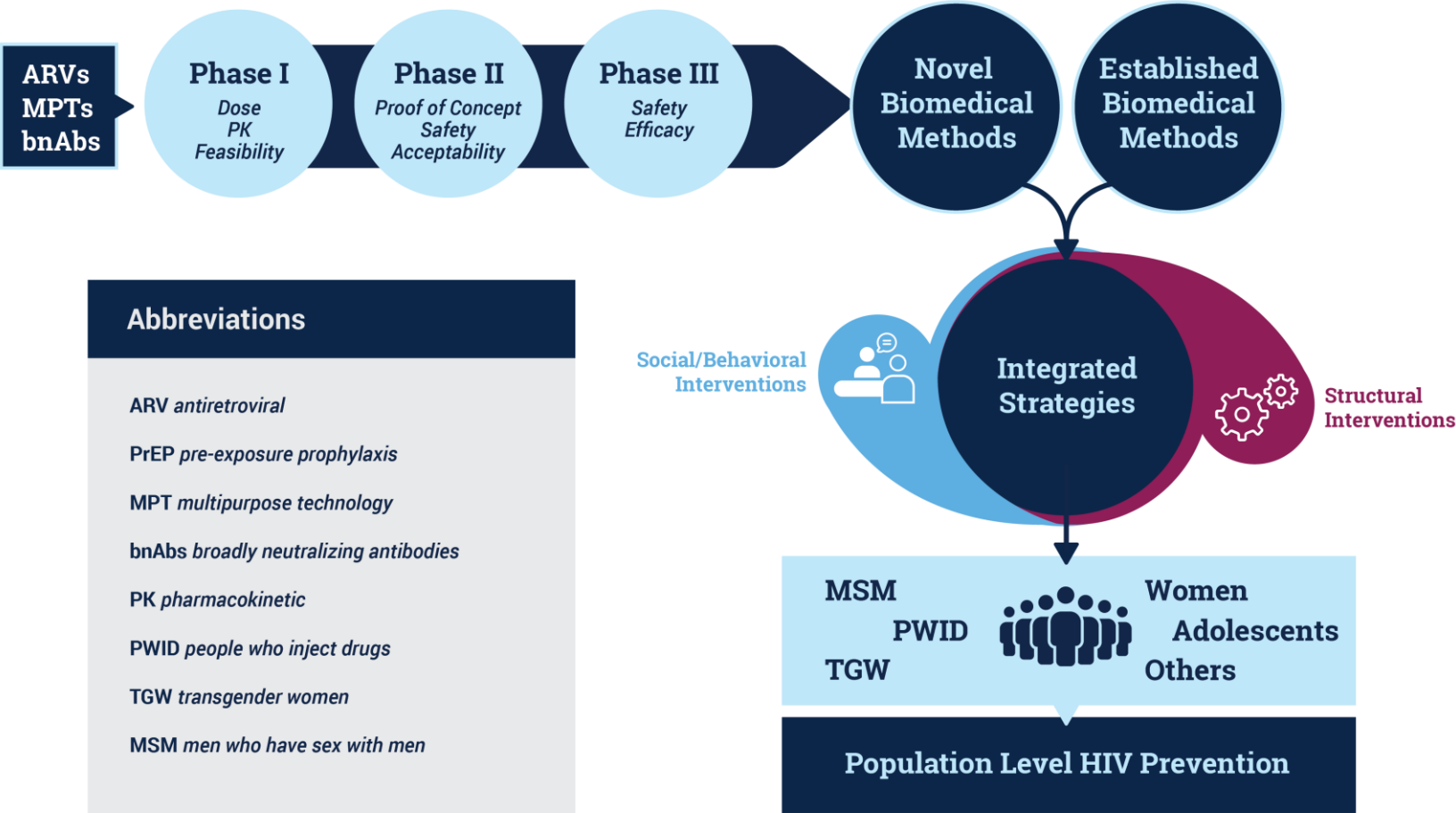
Foundation of HIV Prevention



Scientific Aims

- 1 Identify **novel antiretroviral (ARV)-based methods and delivery systems** for HIV prevention
- 2 Develop **multi-purpose technologies** for HIV prevention as well as for contraception, prevention of other sexually transmitted infections or opioid dependence
- 3 Evaluate **broadly neutralizing antibodies** alone or in a combination that prevent HIV acquisition, in collaboration with the HIV Vaccine Trials Network
- 4 Design and conduct population-specific **integrated strategy studies** that combine biomedical, socio-behavioral, and structural interventions for HIV prevention to maximize their effectiveness.

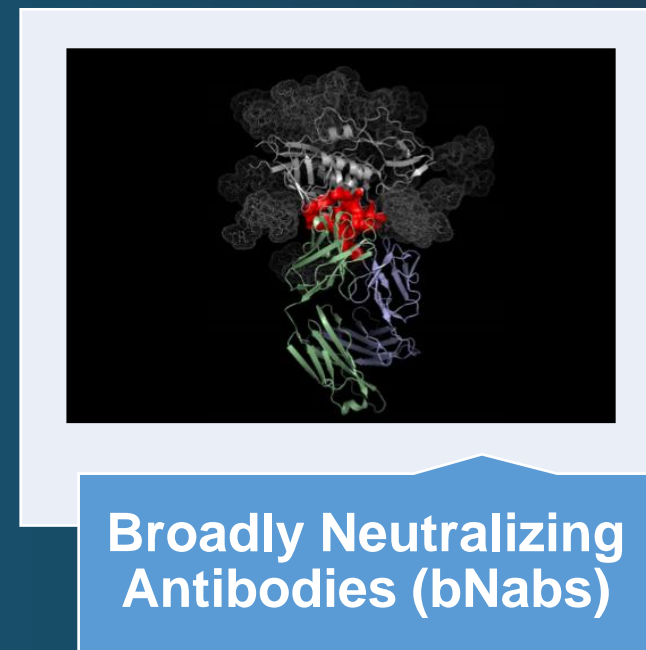
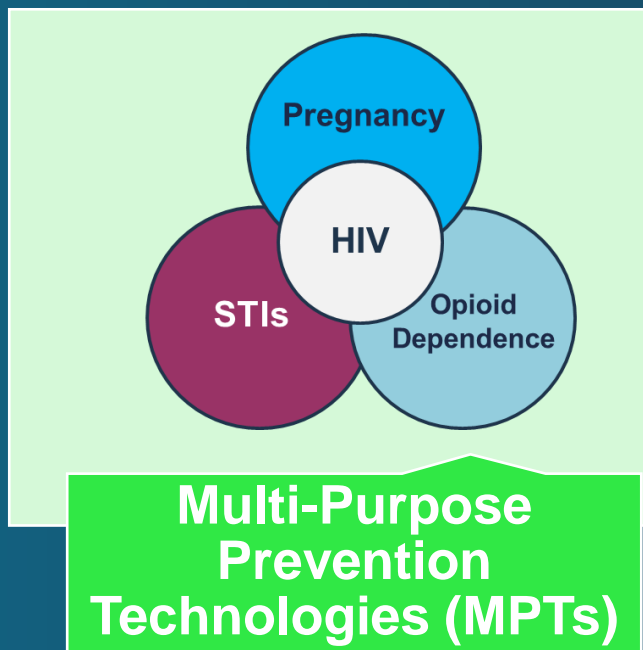
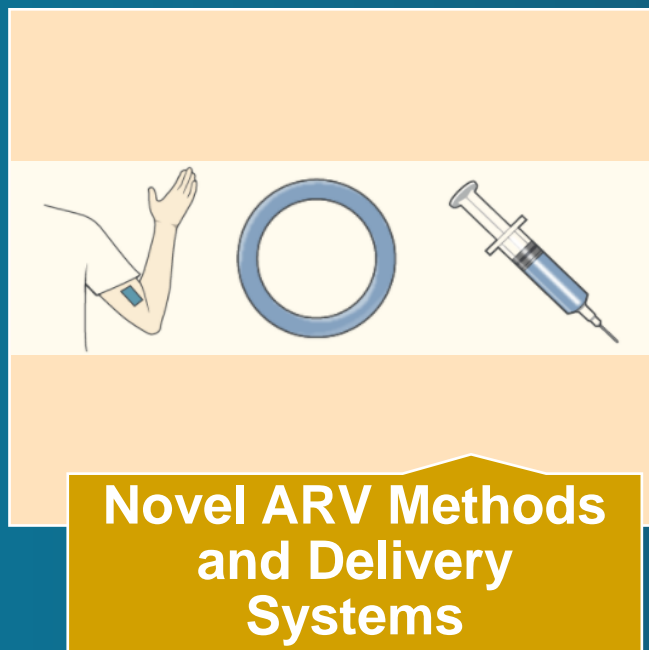
HPTN Scientific Agenda: Conceptual Framework



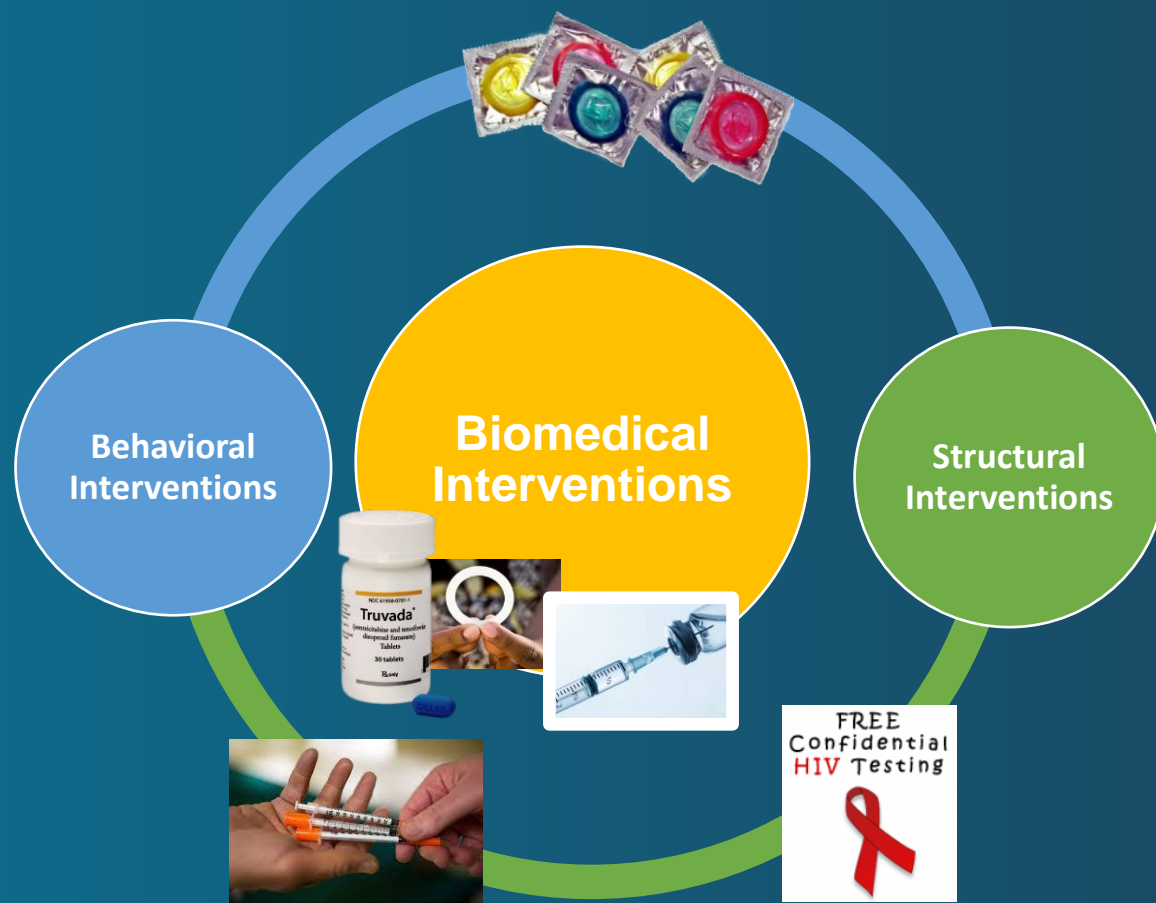
Abbreviations
ARV <i>antiretroviral</i>
PrEP <i>pre-exposure prophylaxis</i>
MPT <i>multipurpose technology</i>
bnAbs <i>broadly neutralizing antibodies</i>
PK <i>pharmacokinetic</i>
PWID <i>people who inject drugs</i>
TGW <i>transgender women</i>
MSM <i>men who have sex with men</i>

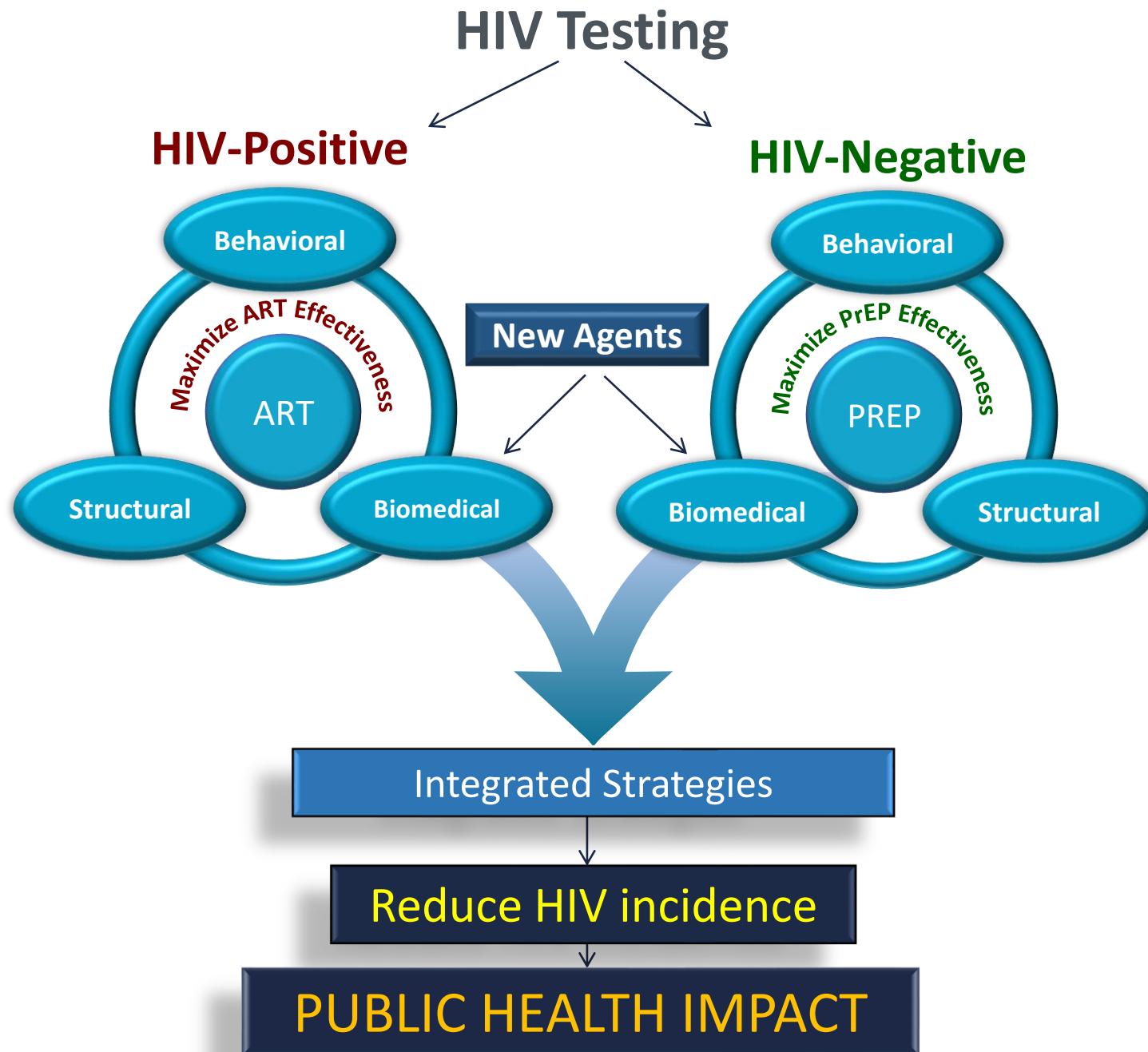
I. Discovery

New Prevention Tools and Methods

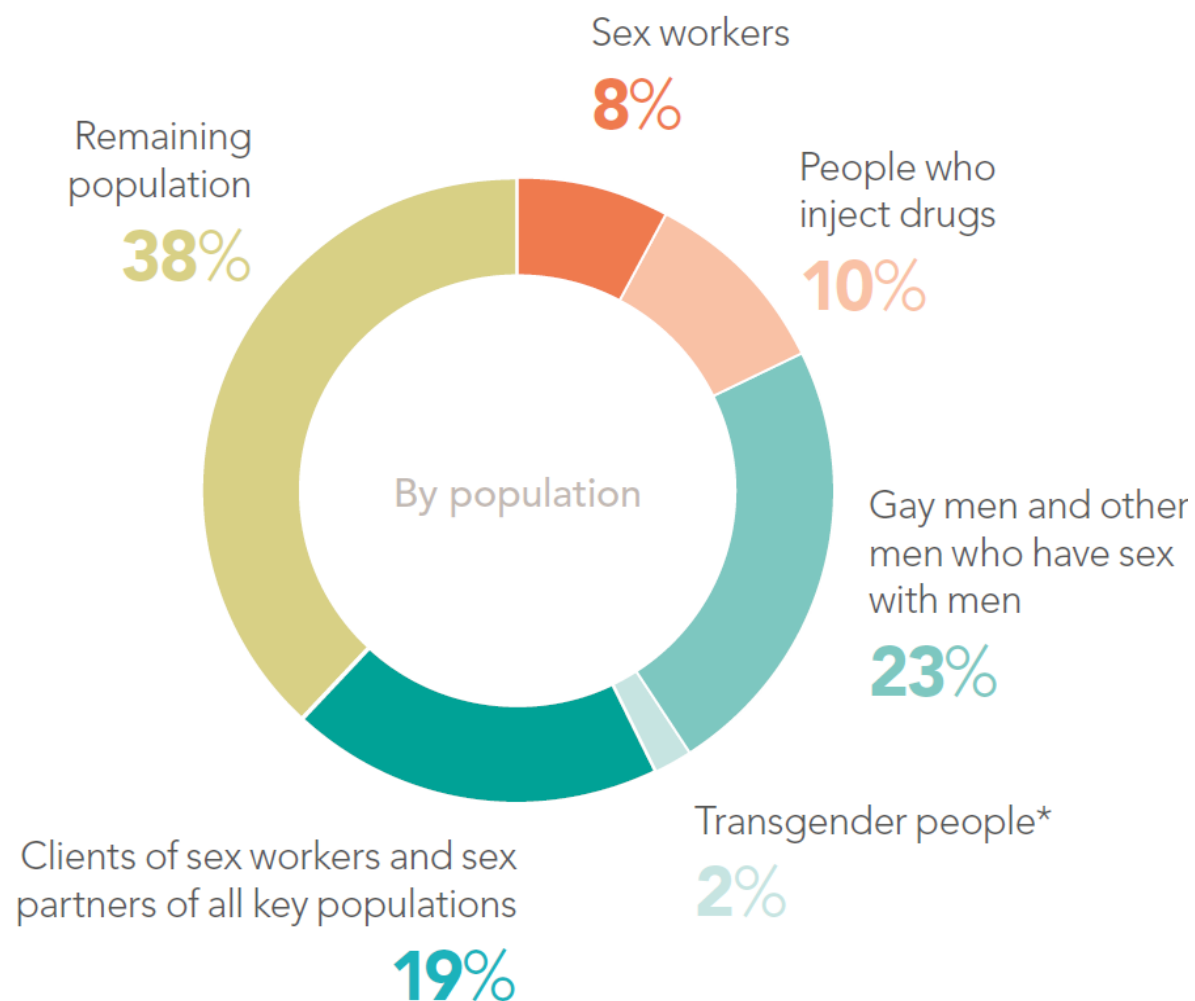


II. Achieving Population Impact Integrated Strategies





Who is getting newly infected?



HPTN Study Updates

HPTN 083

A Phase IIb/III Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC), for Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women who have Sex with Men



HPTN 084

A Phase III Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV Uninfected Women



HPTN 083 Open Label Extension (OLE)

HPTN 084 Open Label Extension (OLE)



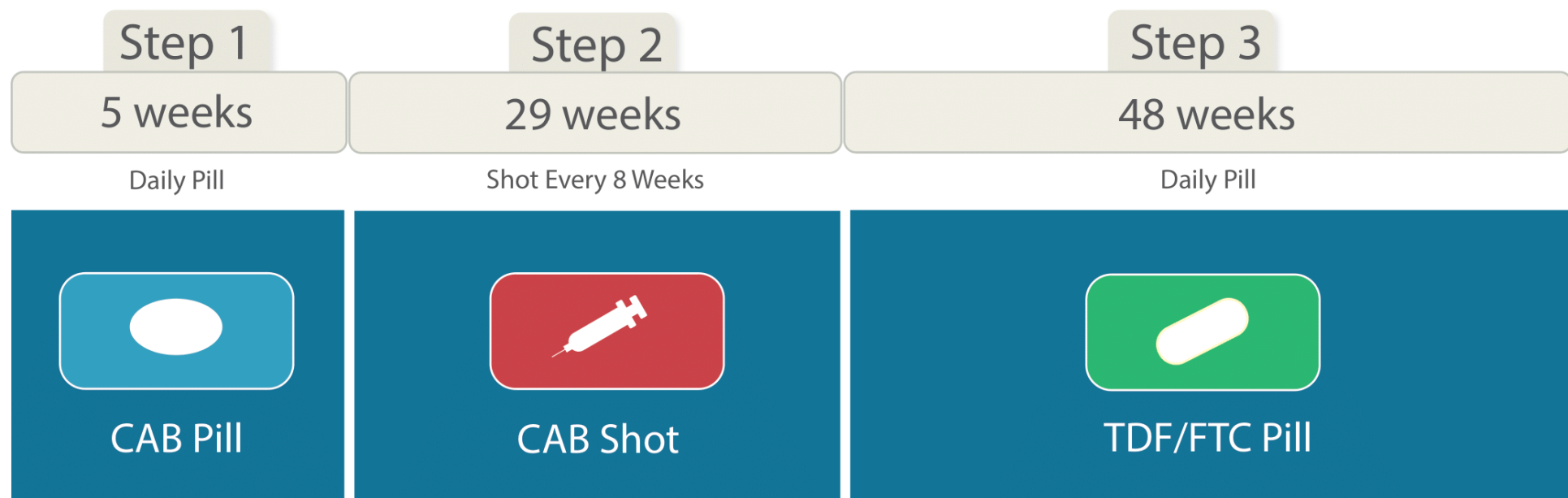
HPTN 083-01

Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescent Males



HPTN 083-01

Study Participant Plan



*In step 2, the first two shots are four weeks apart and 8 weeks apart after that

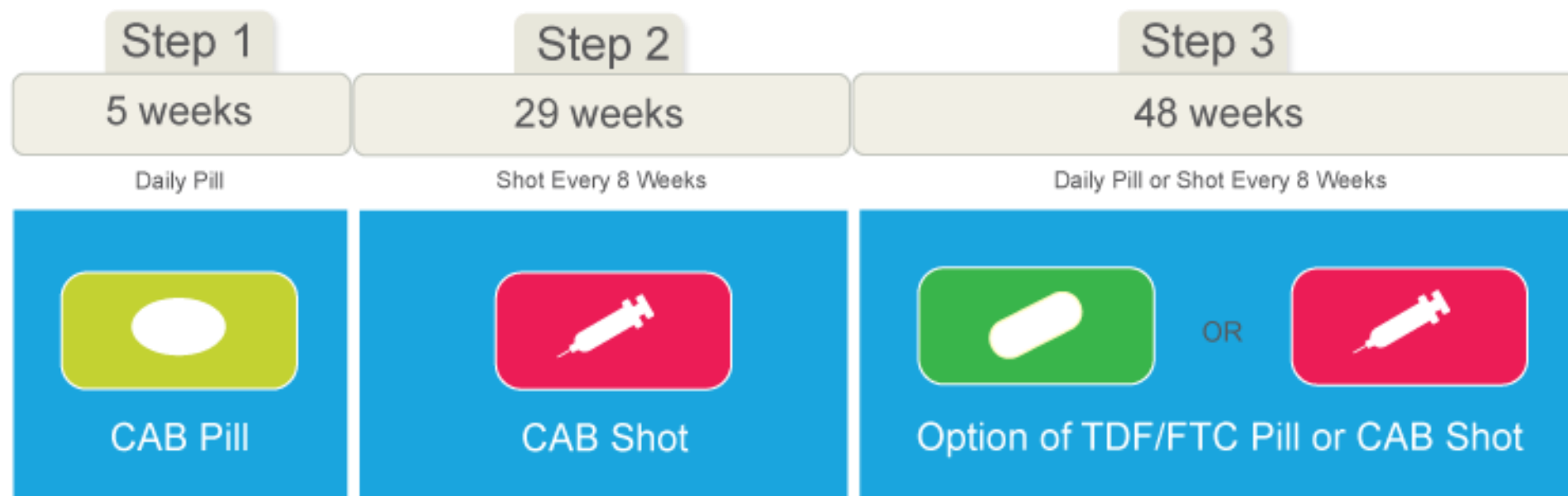
HPTN 084-01

Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescent Females



HPTN 084-01

Study Participant Plan



*In step 2, the first two shots are four weeks apart and 8 weeks apart after that

New and Planned Studies

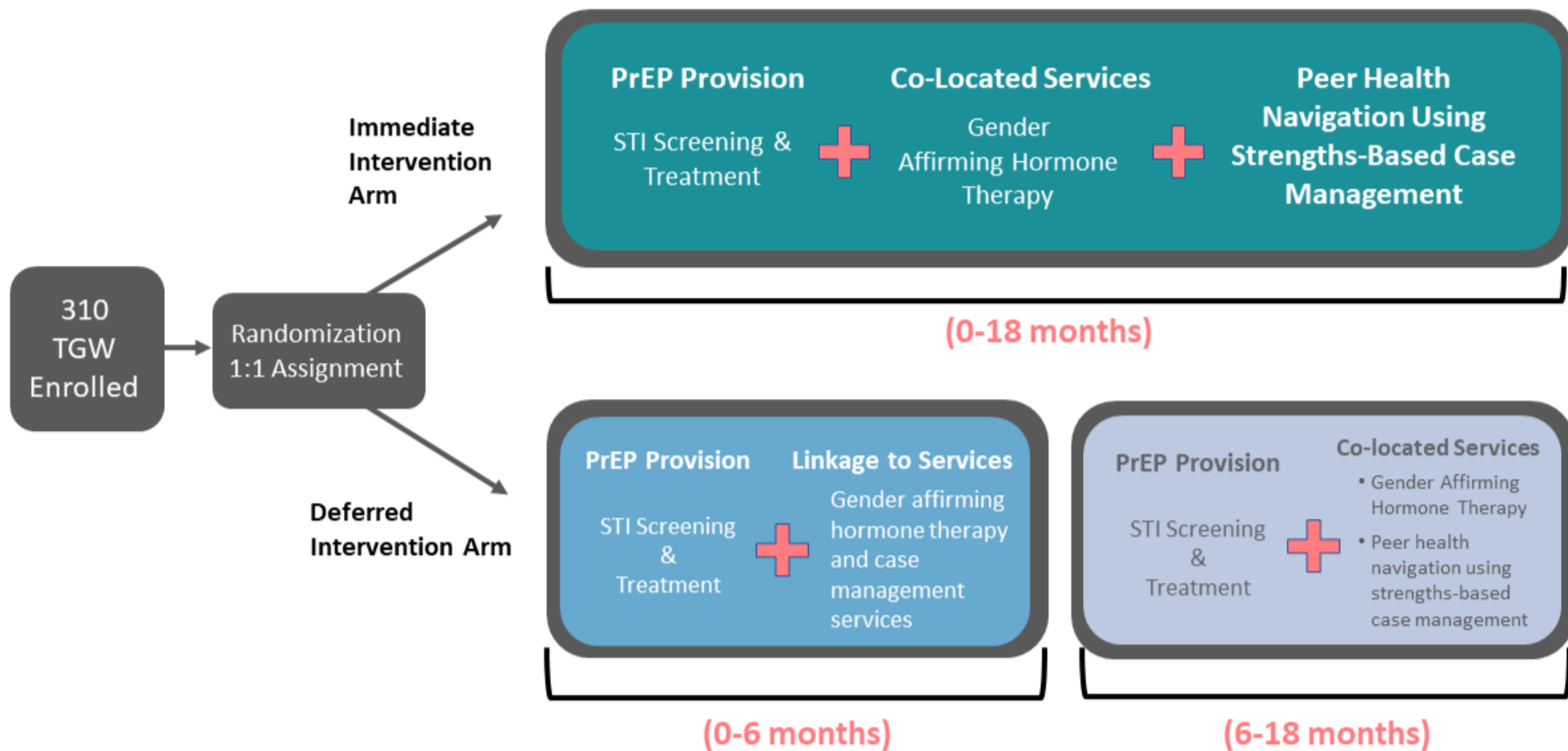
HPTN 091: Integrated Strategy Study Among Transgender Women

To assess the feasibility, acceptability, and preliminary impact of a multi-component strategy to improve pre-exposure prophylaxis (PrEP) uptake and adherence:

- PrEP: biomedical HIV prevention
- Co-located gender-affirming transgender care (hormonal therapy and medical monitoring)
- Peer Health Navigation (PHN) using Strengths-Based Case Management (SBCM) professional supervision



HPTN 091: Study Design



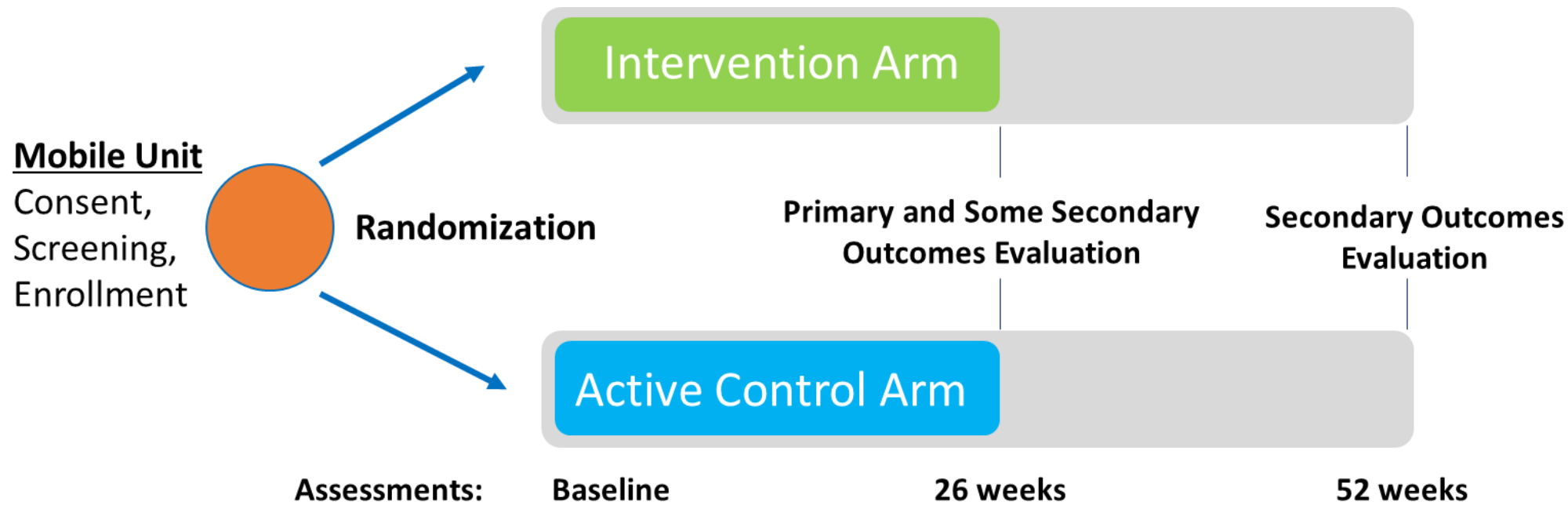
HPTN 094: Integrated Strategy Study Among Persons Who Inject Drugs

INTEGRA: A Vanguard Study of Health Service Delivery in a Mobile Health Delivery Unit to Link Persons who Inject Drugs to Integrated Care and Prevention for:

- Addiction
- HIV
- Hepatitis C
- Primary Care



Study Design



INTERVENTION

“One stop Model” services in van, with peer navigation: MOUD, ART or PrEP, HCV, STI, primary care, and harm reduction

ACTIVE CONTROL

Navigation to health services available at community-based agencies

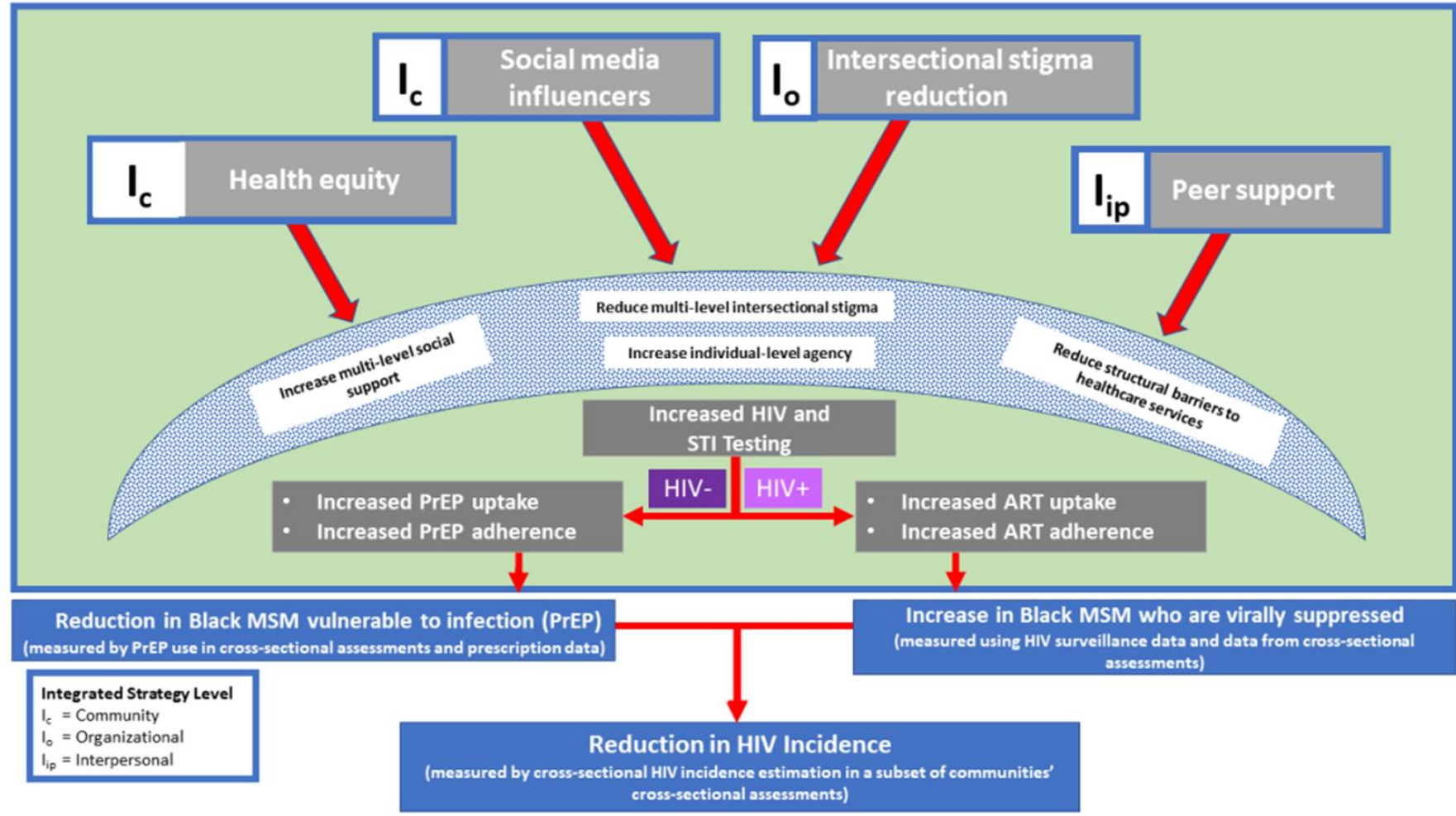
HPTN 096: An Integrated Strategy for Men who have Sex with Men in US South

To evaluate an integrated, HIV status-neutral, population-based approach to reduce HIV incidence among Black men who have sex with men (MSM) in the US South by increasing:

- HIV testing
- uptake and use of pre-exposure prophylaxis (PrEP) among Black MSM living without HIV
- viral suppression rates among Black MSM living with HIV



HPTN 096: Study Design



HPTN 096: Study Population

- 16 communities identified from the southern counties and states included in the Ending the HIV Epidemic plan
 - 8 intervention communities
 - 8 standard of care communities



Looking Ahead

Key updates

- HPTN Leadership
- Working Groups and Science Committees
- Induction of HPTN 2021-2022 Scholars

Network Structure - Leaders

Executive Committee (EC)

- Myron S. Cohen
- Wafaa El-Sadr
- Quarraisha Abdool Karim
- Chris Beyrer
- Sinead Delany-Moretlwe
- Deborah Donnell
- Susan Eshleman
- Sybil Hosek
- Raphael Landovitz
- Nyaradzo Mgodli
- David Serwadda
- Sten Vermund
- Nirupama Sista
- Melissa Turner
- Darrell Wheeler
- 2 NIH Representatives

Leadership and Operations Center (LOC) FHI 360

- Nirupama Sista

Statistical and Data Management Center (SDMC) SCHARP

- Deborah Donnell

Laboratory Center (LC) Johns Hopkins University

- Susan Eshleman

Committee/Working Group Leadership

Science Committees	Chair	Co-Chair
Adolescents at Risk	Audrey Pettifor	Linda-Gail Bekker
Sexual and Gender Minority	Kenneth Mayer	Nittaya Phanuphak
Substance Users	Steffanie Strathdee	Nabila El-Bassel
Women at Risk	Ada Adimora	Philippa Musoke
Working Groups	Chair	Co-Chair
Biomedical Sciences	Jeanne Marrazzo	Joseph Eron
Community	Melissa Turner	Ntando Yola
Ethics	Jeremy Sugarman	Jerome Singh
Socio-Behavioral Sciences	Ariane van der Straten	Julie Pulerwitz
Technical Liaisons		
Susan Buchbinder, Connie Celum, Sharon Hillier		

HPTN 2021-2022 Domestic Scholars



**Noelle M. St. Vil, PhD,
MSW**
University of Buffalo

Mentor(s):
Danielle Haley, Gina Wingood

Project:
An Exploration of the Social
Determinants of Violence
Against Women At-Risk of HIV



**Ndidiamaka Amutah-
Onukagha, PhD, MPH**
Tufts University

Mentor(s):
Audrey Pettifor

Project:
Examining the role of social
support in PrEP uptake and
utilization for young African
women: implications for HIV
prevention



**Donaldson F.
Conserve, PhD, MS**
George Washington
University

Mentor(s):
Chris Beyrer

Project:
Assessment of Case Manager
Intervention Dosage Impact on
Viral Suppression among MSM:
A Mixed Method Study



**Adedotun Ogunbajo,
PhD, MPH**
Harvard University

Mentor(s):
Kenneth Mayer

Project:
Intimate Partner Violence,
Social Support, and
Substance Use among Black
men who have sex with men
(BMSM) in the United States

HPTN 2021-2022 International Scholars



**Manuela Bullo, MD,
MPH**

Mentor(s):
Audrey Pettifor

Project:
Alcohol Use and HIV-HSV2
Incidence in Female Adolescents
in Rural South Africa



**Nomtha Bell-Mandla,
PhD candidate, DTTC**

Mentor(s):
Peter Bond, Lungiswa Nkonki,
Ayana Moore

Project:
Determinants strategies and cost
implications for participant
recruitment, and retention in an
HIV cohort, perspectives from
HPTN 071 (PopART)



Bwalya Chiti, MPH

Mentor(s):
Virginia Bond, Musonda
Simwinga

Project:
Thinking on their feet: Lessons
learnt from the role, identity and
experiences of community-
based HIV service providers in
delivering Universal Test and
Treat within the (PopART) trial
in Zambia and South Africa

HPTN Concept Solicitation

HPTN Concept Solicitation



Focus Areas of Submitted Concepts

Novel ARV Based Methods and Delivery Systems

- Cabotegravir implants for PrEP
- Cabotegravir microneedle patches for PrEP
- Oral islatravir vs. intramuscular cabotegravir for PrEP among MSM and TGW
- On demand rectal vs. oral TFV-based PrEP
- Lencapavir vs TDF/FTC among US women
- Long-active injectable lencapavir vs. oral TD/FFTC for PREP

Multi-purpose Technologies (MPTs)

- Injectable PrEP + contraception
- Tailored STI care + HIV PrEP intervention
- HIV prevention + stimulant and opioid injection treatment
- Fast dissolving non-ARV MPT insert
- MPT for HIV + pregnancy
- MPT for HIV + STI

Integrated Strategies

- Drug use prevention and treatment + HIV prevention
- Social marketing of HIV services to improve uptake & retention in high burden settings
- Digital HIV health intervention among diverse adolescents & young adults
- Daily vs. long-acting PrEP among young adults in SSA
- HIV, STI, and unintended pregnancy prevention in Southern Africa
- Client-centered, status neutral, community-based ARVs for PrEP and ART in high prevalence settings in Southern Africa
- Leveraging HIV self-testing and sexual networking to engage men in HIV services
- PrEP choice and adherence package vs. wait-list in cisgender men, transgender and gender nonbinary persons who have sex with men and TGW
- Tele-PrEP and peer-delivered behavioral risk reduction among TGW and MSM in US
- Integration HIV prevention strategies in US county jails
- Rapid HIV testing to reduce transmission

Conclusions

- Substantial progress has been achieved in confronting the HIV epidemic, but major gaps remain in prevention of new HIV infections
- HPTN aims to identify new HIV prevention tools and to optimize the use of new and existing tools to achieve desired HIV prevention impact in diverse populations
- New ambitious global targets have been set for 2025 in order to achieve the end of AIDS as a public health threat by 2030
- HPTN is poised to contribute the research results that will advance progress towards reaching the 2025 targets

Acknowledgments

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- National Institute on Drug Abuse (NIDA)
- National Institute of Mental Health (NIMH)
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

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