



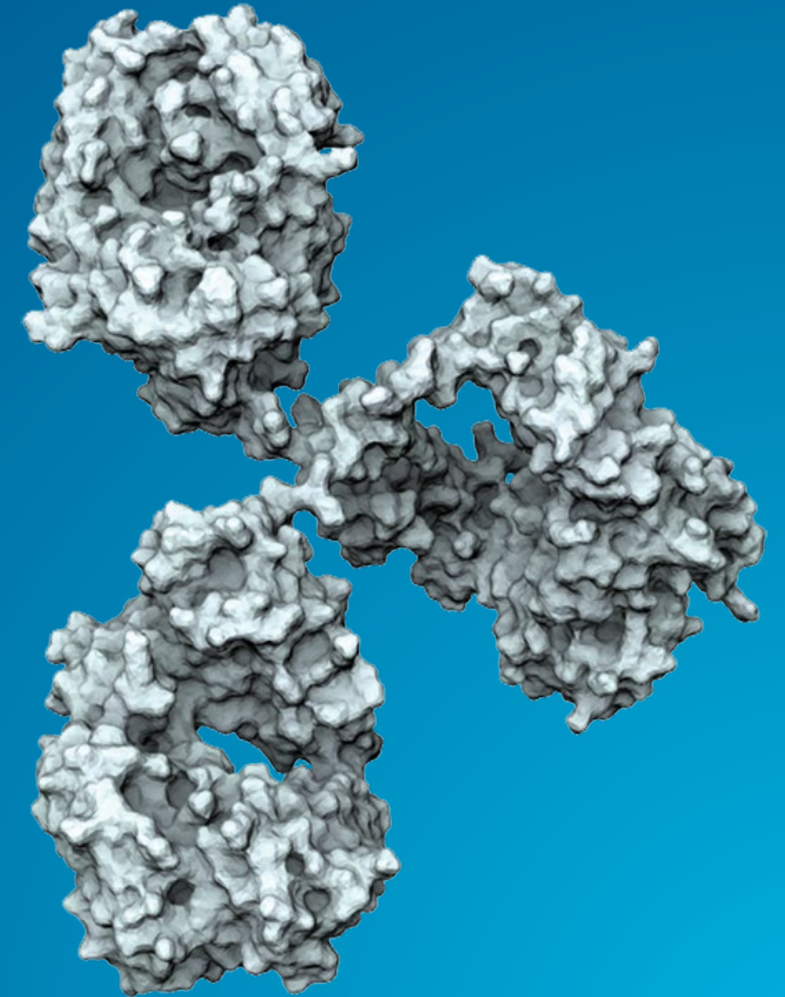
Translating **science** into
global health impact

bnAbs for HIV prevention

Shelly Malhotra

NURHT Caucus Webinar

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As of April 2022

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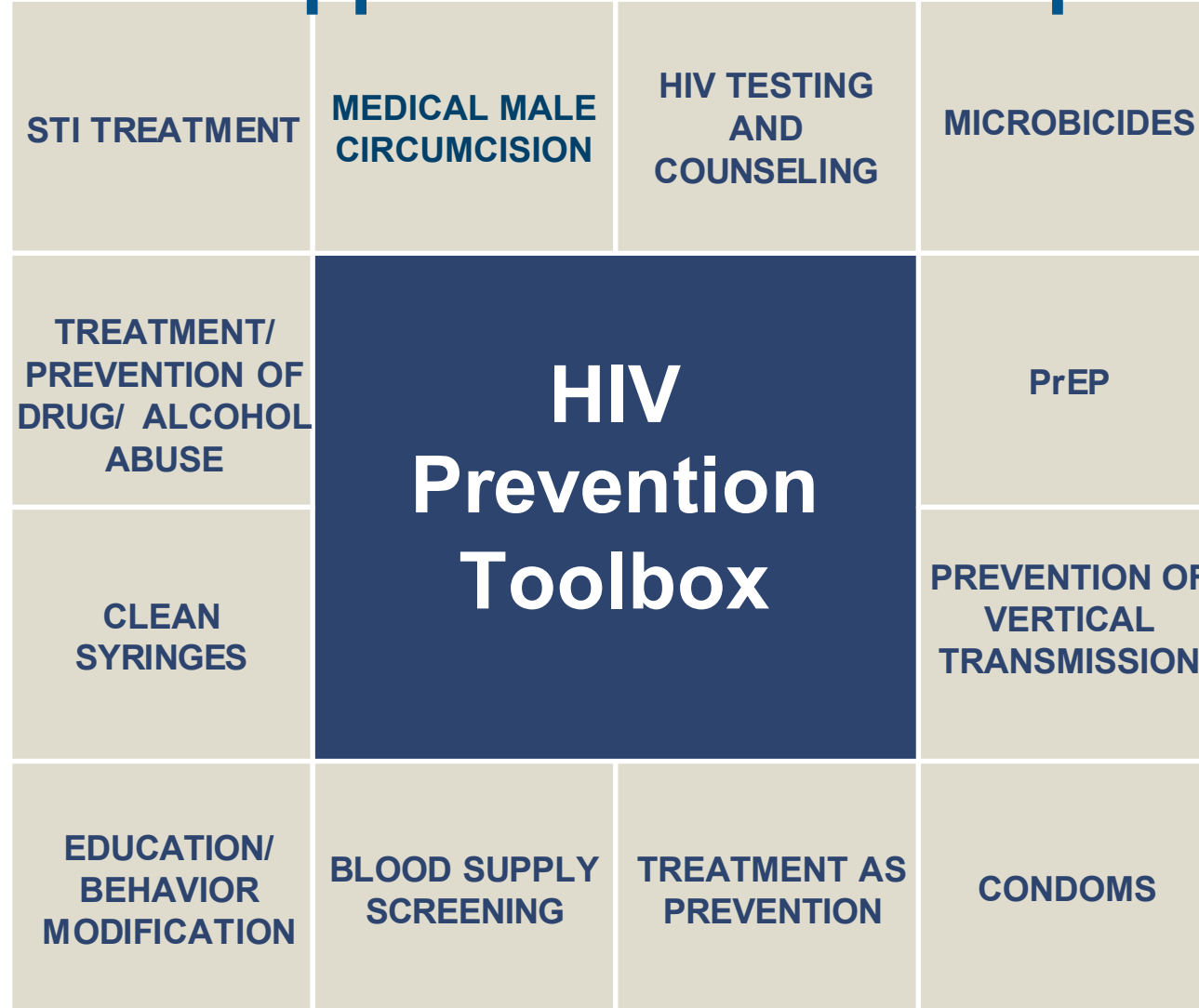
HIV

An Unmet Need

- The HIV pandemic continues to **cause extensive morbidity and mortality** globally and is a top public health priority
- Despite progress in reaching 73% of people living with HIV with antiretroviral therapy, gaps in HIV prevention and treatment contributed to **1.5 million new infections and 680,000 HIV-related deaths in 2020**
- **Adolescent girls and young women (AGYW)** in low- and middle-income countries (LMICs), especially in sub-Saharan Africa (sSA) remain **disproportionately affected**
- **Young children** accounted for **150,000 new HIV infections**, the vast majority during infancy

HIV Prevention Toolbox

A single product or approach will not stop the pandemic



We need a diversity of prevention options and programs to address the diverse needs of individuals at risk for HIV infection

HIV bnAbs for prevention (and treatment)

CASE FOR ADDING ENHANCED BNABS TO PREVENTION TOOLBOX

STI TREATMENT	MEDICAL MALE CIRCUMCISION	HIV TESTING AND COUNSELING	MICROBICIDES
TREATMENT/ PREVENTION OF DRUG/ ALCOHOL ABUSE	HIV Prevention Toolbox		Oral PrEP
CLEAN SYRINGES			BROADLY NEUTRALIZING ANTIBODIES
EDUCATION/ BEHAVIOR MODIFICATION	BLOOD SUPPLY SCREENING	PREVENTION OF VERTICAL TRANSMISSION	CONDOMS

We need a diversity of prevention options and programs to address the diverse needs of individuals at risk for HIV infection

LONG-ACTING

- Reduced frequency of administration

MECHANISM OF PROTECTION

- AMP trials provided a proof of concept for use of bnAbs for prevention of HIV
- Protection at the site of infection
- Elimination of infected cells distally from the site of infection

LOW TOXICITY

- Very few cases of adverse side effects, generally well-tolerated

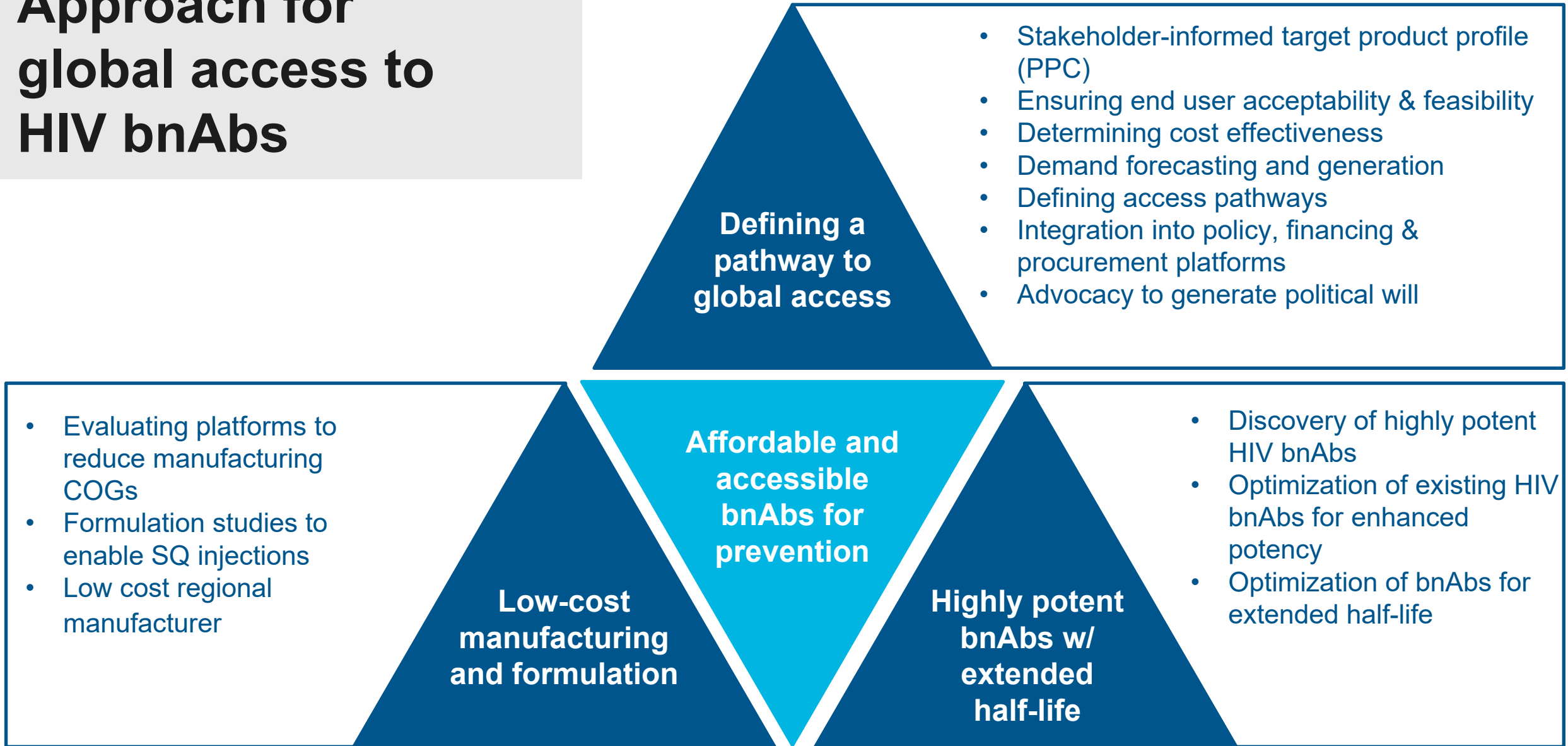
DISCREET

- Subcutaneous delivery every 3 to 4 months for next generation ebNAb

Potential role of ebnAbs to prevent vertical transmission

- Favorable potential **dosing schedules**
- Lower **COGS** for the pediatric indication
- **Cost effectiveness**; bNAbs for infant prophylaxis would offer good value in various sub-Saharan African settings and implementation scenarios (Alba, et al. forthcoming)
- Potential to align with schedule for **routine pediatric vaccines**
- Plan is to initiate a **Phase 1 in Q1 2023**, followed by initiating the Pediatric Program in sub-Saharan Africa once an adult dosing schedule (2024)
- Access work to define a use case, potential demand, acceptability, & implementation strategies for infant indication is underway

Approach for global access to HIV bnAbs



IAVI has Created a Public-Private Partnership to Advance an HIV bnAb Prevention Product and Collectively Map Out a Pathway to Global Access



USAID-PEPFAR and IAVI Strategic Partnership

- ✓ Engagement with high-risk populations
- ✓ Sustainable research capacity
- ✓ Antibody R&D for HIV prevention in African/global communities



IAVI-NIAID (VRC/DAIDS) Memorandum of Understanding

- ✓ Selection and advancement of antibody and antibody combinations for HIV
- ✓ Development experience



IAVI-Serum Institute Collaboration Agreement

- ✓ Low-cost and high-volume manufacturing process for antibodies
- ✓ Distribution and access channels in LMIC



Expanding Access to Monoclonal Antibodies: A Global Call to Action

- ✓ Engagement to analyze gaps in global access to antibodies and enable innovative solutions



World Health Organization

HIV antibody guidance documents

- ✓ Collaboration on Preferred product characteristics (PPC), Vaccine Value Profile

Summary

- The HIV pandemic continues to cause extensive morbidity and mortality globally and is a top public health priority
- There is a good case for adding long acting and potent bnAbs to the HIV prevention toolkit
- Alongside our product development, activities to enable broad access to bnAbs post-licensure are ongoing and include plans for prevention of vertical transmission and use by pregnant women

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