**Market Demand Assessment for HIV bnAbs in Infant Prophylaxis**

**Request for Proposals (RFP)**

**Background:**

As of 2019, infants constitute roughly 10% of new HIV infections globally, and rates of vertical transmission remain as high as 10-25% in several African countries. Unknown or delayed HIV diagnosis; challenges in ART initiation and adherence amongst pregnant and breastfeeding people and infants; and difficulties with the daily administration of infant prophylaxis all present critical challenges for the prevention of vertical transmission.

Broadly neutralizing antibodies could afford several advantages for infant HIV prophylaxis relative to current ARV-based alternatives given their long half-life and generally good safety profile. In non-human primate studies, subcutaneous administration of antibodies (VRC07 and PGT121) beginning 24 hours after SHIV exposure prevented infection, even from sites of initial replication (Hessell, 2017).

Primate studies suggest that bnAb post-exposure prophylaxis may also be effective in preventing breast milk HIV transmission. It is possible that a single subcutaneous injection of bnAbs to neonates at birth could provide long-acting protection, simplifying administration and opening the door for potential vaccine-like implementation during breastfeeding.

In addition to safety and efficacy evaluations in infants, evidence is needed in order to establish the market viability of bnAbs for infant HIV prophylaxis, including the potential market size and demand for preventive antibodies. Clarity on the potential market for bnAbs for infant prophylaxis can inform clinical development strategy, commercial investment decisions, and eventual implementation planning. Additionally, market size has bearing on overall potential manufacturing scale and costs—with implications in terms of commercial feasibility and affordability.

**Project Description & Outputs:**

IAVI is seeking a collaborator to develop a market forecast to help clarify both the overall market size and potential demand for bnAbs for infant HIV prophylaxis.

It is expected that the forecast will:

- Integrate the latest available and validated demographic and HIV epidemiological models to determine overall potential market,\(^1\) including transmission parameters over time and factors such as births, fertility rates among general population and in women living with HIV, rates of breastfeeding,
maternal ANC and ART/PMTCT coverage, and rates of new HIV incidence and diagnosis among young mothers at delivery and during breastfeeding.

- Include assumptions on portion of the existing market or relative growth in the overall prevention market with the introduction of bnAbs based on:
  - Consultations with key informants with knowledge of the PMTCT landscape and/or HIV prevention market.
  - The literature and existing market intelligence

The anticipated outputs include:

- A power point presentation summarizing results on:
  - The estimated total need for infant prophylaxis in sub-Saharan Africa (SSA) over time (short-term [2-5 years] and long-term-- time horizon to be determined)
  - The anticipated demand for HIV bnAbs in infant prophylaxis (base case, low and upside forecasts) as a portion of the overall PMTCT market, according to the following scenarios:
    - Scenario 1: Use in HIV-exposed infants (sub-Saharan Africa)
    - Scenario 2: Use in all infants (high HIV prevalence areas only)
    - Scenario 3: Use in HIV-exposed infants in SSA and in all infants in high prevalence areas.

- Excel spreadsheet with underlying data and outputs of the model, with a user-friendly interface to adjust assumptions for select parameters as mutually determined, including for market share, for country-specific views, or for different implementation scenarios.

**Collaborative Approach:**

It is anticipated that IAVI and the Partner will work closely together and with the guidance of USAID in implementing this project. IAVI and USAID’s anticipated involvement would include:

- Reviewing and advising on the proposed approach for implementing the project
- Advising on assumptions and epidemiological parameters for input into the market sizing and forecasting effort
- Jointly identifying key informants to inform modeling assumptions
- Facilitating and participating in select consultations
- Reviewing progress toward project deliverables
- Reviewing and providing feedback on final deliverables
- Disseminating results to relevant stakeholders
**Project Timelines:**

A draft of the market forecast presentation will be delivered by Feb 1, 2022 with final outputs will be delivered by March 15, 2022.

**Qualifications:**

Track record developing high quality demand forecasts for global health commodities required, particularly forecasts that integrate demographic, epidemiological, and market evidence. Experience developing market assessments in the HIV prevention and/or infant vaccination space preferred. Proposals with a strong technical approach that represent value for money will be prioritized.

**Submission process:**

Proposals should be submitted by September 17th by email to kchapman@iavi.org, with the RFP title included in the email subject line. Submissions should include a description of the technical approach for implementing the work, approach for collaborating with IAVI, relevant qualifications, budget and project timelines.

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1 Spectrum AIM model national estimates, and Naomi model sub-national estimates, produced by national Ministries of Health and submitted to UNAIDS, version of May 2021; available publicly through AIDS Info Online.