

Market Assessment for HIV bnAbs for prevention and treatment Request for Proposals (RFP) - Organizational Consultancy

Background:

As of 2022, infants constitute roughly 130,000 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. 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, evidence is needed to establish the market viability of bnAbs for infant HIV prophylaxis. In 2023, IAVI and a partner developed a demand forecast for bnAbs for infant prophylaxis, highlighting the 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. To maximize commercialization opportunities and lower costs, IAVI is exploring what an expanded market would look like if treatment were to be added as an indication on top of prevention, and if the adult market was factored alongside the pediatric preventive market. For treatment, bnAbs offer a novel approach to suppress viral replication and potentially clear infected cells (Kumar,2018), particularly in cases where traditional antiretroviral therapy alone may be challenging or ineffective, such as in infants with drug-resistant strains.

Project Description & Outputs:

IAVI is seeking a Company or an organization with an excellent track record (hereinafter referred to as “Consultant”) able to develop a market forecast to help clarify both the aggregate overall market size and potential demand for bnAbs for prevention and treatment, building on forecasting previously done for bnAbs for infant HIV prophylaxis. Additionally, this forecast will feed into a business case that will consider innovative strategies to attract commercial interest. This business case will consist of a pitch deck to share with prospective commercial partners that effectively outlines the opportunity and rationale to partner for commercialization of bnAbs, with the aim of making the bnAbs accessible where and when they are needed most. This deck will be developed in close collaboration with IAVI, additional IAVI content experts, and USAID, leveraging and expanding upon existing inputs. This deck will be tailored to the stage of development, laying out the potential opportunity and rationale for partnership in a compelling manner, despite key uncertainties.

The anticipated outputs include:

1. A power point presentation summarizing results on:



- a. The estimated total need for bnAbs as a prevention and treatment product in sub-Saharan Africa over time.
 - b. The anticipated demand for HIV bnAbs (base case, low and upside forecasts) as a portion of the overall prevention and treatment market.
2. 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.
 3. Business case – Should include the strategic context including assessing opportunities in the market to address public health needs through bnAb development considering factors such as market dynamics and value proposition. Should detail the unique features and advantages of bnAbs for prevention and treatment compared to others in development.

Collaborative Approach:

It is anticipated that IAVI and the Partner will work closely together in implementing this project. IAVI 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 **aggregate market forecast**: delivery of a XLS with database, model calculations, and key scenario results by Sept 30, 2024.

An **interim pitch deck**: including an overview of the market for HIV bnAbs for treatment and prevention and the aggregate demand forecast by October 15th, 2024.

Final pitch deck: final PowerPoint presentation including potential costs, funding opportunities and risk analysis by December 1st, 2024.

Qualifications of a Consultant:

- Excellent track record of developing high quality demand forecasts and market assessment for global health commodities is required, particularly forecasts that integrate demographic, epidemiological, and market evidence.
- Knowledge of the HIV prevention, treatment, and/or infant vaccination space is desirable.
- Proposals with a strong technical approach that represent value for money will be prioritized.

Submission process:

Proposal should include the following:

- Curriculum Vitae of the consultant highlighting the past experiences/projects that are similar to the above
 - Detailed project outline with the timelines
 - Proposed fee and detailed payment schedule
 - Submissions should include a description of the technical approach for implementing the work, approach for collaborating with IAVI, relevant qualifications, budget and project timelines.
 - Proposals should be submitted by July 1st, 2024, by email to kchapman@iavi.org, with the RFP title included in the email subject line.
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