

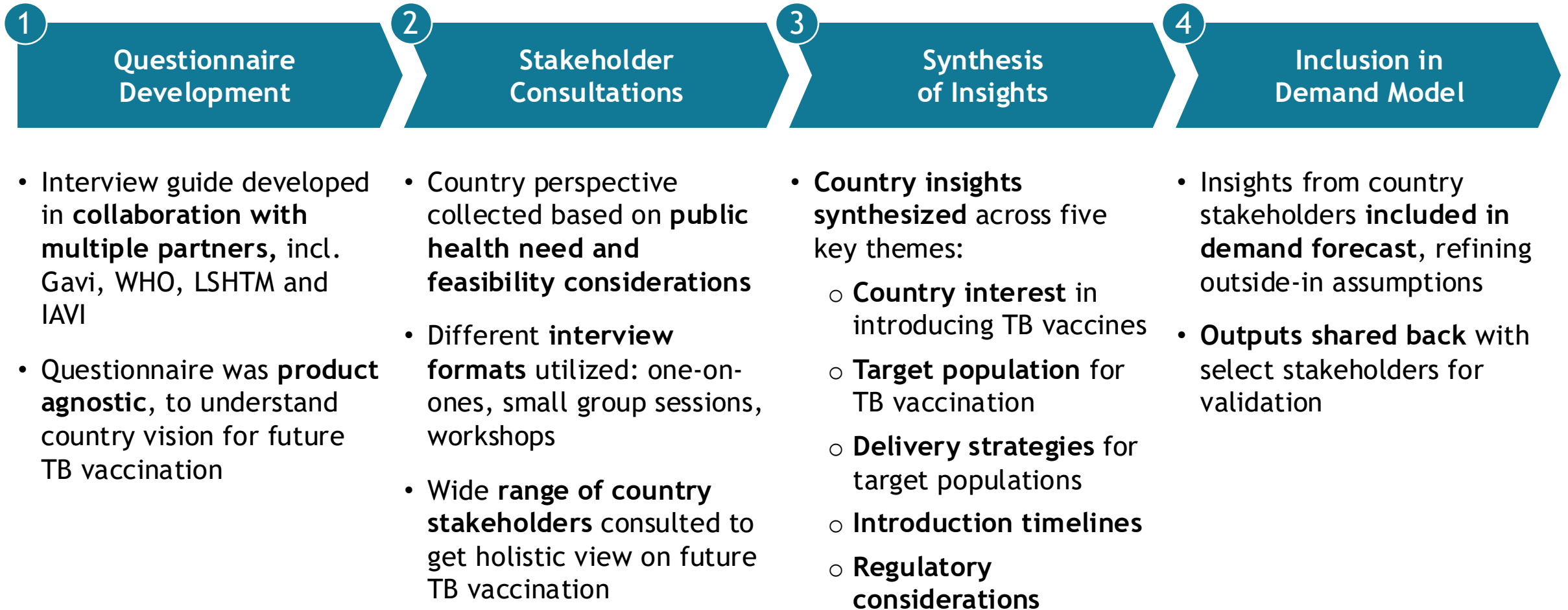


Forecasting global demand for novel TB vaccines

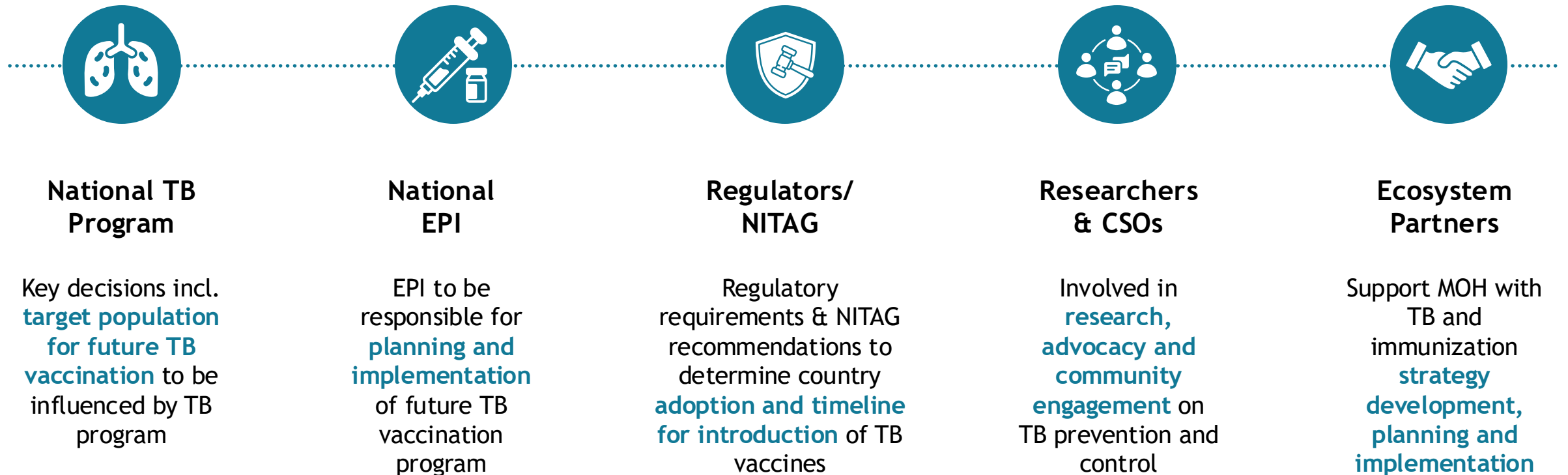
Insights from country consultations

November 2025

CONTEXT: Country-level consultations were conducted to inform a global demand forecast for novel tuberculosis (TB) vaccines



CONTEXT: Wide range of country stakeholders consulted to get holistic country position on future TB vaccination



Over 120 stakeholders engaged to understand country interest in future TB vaccination... if? when? who? how?

China interested in TB vaccines, but local trial & domestic manufacturing requirements will delay NIP introduction



Country adoption

- **China interested in TB vaccines** due to high TB burden, government classification of TB as a critical infectious disease and alignment with China CDC's **National TB Prevention & Control Plan**.
- Factors to be considered include **minimum efficacy of 70% preferred**, **affordability**, National Immunization Program (NIP) historical preference for **childhood vaccination** due to limited resources, **local phase 3 trials** are highly likely to be required for vaccine registration, **local production** mandatory for NIP inclusion.

Target populations

- **Broad population-based** and **targeted risk-group** approach for maximum public health impact
 - Broad population: **Adolescents (15-17 years)** and **elderly (≥65 years)**.
 - High risk groups (HRGs): **household contacts**, **healthcare workers in designated TB hospitals**, **people living with diabetes**, and **people in high-risk areas** such as prisons, drug rehabilitation centers, nursing homes, social welfare institutions, psychiatric hospitals, and rural migrant settlements.

Delivery strategies

- **Leverage existing systems** for TB vaccine delivery - school based vaccination networks for adolescents, elderly health check ups, HIV program for PLHIV, TB program (follow up/ case mgt) for household contacts etc.

Timeline & regulatory considerations

- **Timeline for NIP introduction unknown** due to local clinical trial and local production requirements.
 - **At least 2 local manufacturers** required for NIP inclusion, with **all vaccine components manufactured locally**.
 - **The standard timeline for local registration is 200 working days**. However, this requires **local phase 3 trials** typically conducted over **~5-10 years**.
- Roll-out in the **private market** is expected, alongside **phased introductions in high TB burden & high-income provinces**, like the approach to the PCV & HPV vaccine introductions. However, these phased introductions depend on the timeline for local registration.
- China **strictly adheres to product labelling**. Product evaluation for off-label use is more stringent for vaccines compared to medications used in clinical settings.



DRC is interested in novel TB vaccines, but stakeholders expressed uncertainty about budget sustainability



Country adoption	- Interested in introducing a TB vaccine due to rising burden in country, especially multi-drug-resistant TB. - Preference mentioned around key vaccine characteristics including efficacy (50+% in line with WHO preferred product characteristics), dosage schedule (preference for 1 dose) and route of administration (intramuscular to introduce acceptability, general preference for oral administration). Local clinical trials are not required, while local production would be preferred but not required.
Target populations	- Most stakeholders voiced preference for high-risk group approach focused on: household contacts, health workers, people living with HIV (PLHIV), miners, prisoners and security personnel (military, police). - Some stakeholders suggested a broader population-based approach focused on: Routine immunization focused on adolescent age cohort for long-term effect. Catch-up of adults/general population starting with high-prevalence provinces (e.g., Kasai Oriental) - However, exact target populations to consider for vaccination will ultimately depend on country-level TB epidemiology - initial insights from National TB Program would need to be further quantified. - In addition, need for early awareness campaigns to ensure willingness to get vaccinated among the general population.
Delivery strategies	- Where possible, integrate vaccination into existing programs (e.g., contact tracing for household contacts, HIV care for PLHIV). - Need for campaigns to reach target populations without existing health touchpoints. - Start with pilot phase in few cities (block-by-block) before roll-out to the wider population.
Timeline & regulatory considerations	- DRC regulator (ACOREP) likely to follow WHO recommendations on vaccine authorization. Post WHO prequalification, authorization in country can be gained in 90 days. - DRC unlikely to be first-mover for vaccine intro, likely to wait 3-5 years to observe introduction in other African countries and wait for more evidence. Uncertainty exists around long-term (Gavi) funding and national budget allocation given likely high costs of TB vx. - Openness to introduce vaccine without IGRA testing. Less certainty around introduction of live attenuated vaccines for PLHIV, would likely wait for additional evidence.



High certainty/ convergence of stakeholder feedback



Some uncertainty/ divergence in stakeholder feedback



Low certainty/ convergence in stakeholder feedback

India has strong interest in introducing novel TB vaccines given high relative and absolute TB burden



Country adoption	• India interested in introducing a TB vaccines due to the high TB burden, and strong political will. • Key requirements for TB vaccine adoption include local clinical trial results, and vaccine price/ affordability for the government. • While these may not hinder adoption, there was a preference for high efficacy TB vaccines (50+%), local production for supply sustainability, 1-dose schedule for full vaccination, and intramuscular route of administration. TB vaccine cold chain requirements to also be considered.
Target populations	• Preference for broad population-based approach in addition to targeting specific high-risk groups especially. if there are price or supply constraints ○ Broad groups: adolescents & adults ○ High risk groups: household contacts, undernourished, health workers, people living with HIV, people living with diabetes • In broad population, start with highest TB burden states incl. Uttar Pradesh, Maharashtra, Bihar, Madhya Pradesh, Rajasthan, for operational efficiency and accelerated impact
Delivery strategies	• Integrate TB vaccination into existing programs - TB program for household contacts, schools for adolescents (e.g., touch points for tetanus or HPV vaccination), nutrition screening for malnourished etc. • Start with campaigns and then routinize delivery. Campaigns critical to reach target populations with no existing service delivery touchpoints especially healthy adults
Timeline & regulatory considerations	• Country ambition is to introduce TB vaccines within 0-2 years of vaccine availability • Results of local clinical trials or immuno-bridging studies required for local registration and about 8-12 months needed for local registration • Off-label approval of TB vaccine for HIV+/ IGRA- without efficacy data is not within the regulator's remit. The NITAG could make required recommendations including regarding use of live-attenuated vx in PLHIV, after rigorous evaluation of the clinical trial data



Nigeria has strong interest in novel TB vaccines, subject to funding, regulatory & programmatic factors



Country adoption

- Interested in TB vaccines due to high TB burden (almost 500,000 new cases per year), and high prevalence of TB drivers, e.g., malnutrition, overcrowding, poverty.
- Factors to be considered include clinical trial data showing **efficacy ($\geq 50\%$)**, **safety**, **limited side effects**; **cost effectiveness**/ projected lives saved vs status quo; **low price**/ long term affordability for the government, long duration of **protection**/ need for boosters, **2-8°C** vaccine storage temperature.

Target populations

- Majority of EPI & TB stakeholders suggested a **focus on high-risk populations** (especially under current efficacy assumptions) with a **nationwide roll-out** from the outset.
 - Priority groups: **household contacts**, **people living with HIV**, **healthcare workers**, **people with diabetes**, **prisoners**.
 - Additional groups: internally displaced persons, malnourished persons in nutrition clinics.
- Fewer stakeholders expressed preference for a **general population approach**. This approach will require a **phased roll-out**, starting with high burden states (Kano, Lagos, Bauchi, Rivers, Niger, Anambra).

Delivery strategies

- Integration of vaccination into **existing services for high-risk populations** (e.g., contact tracing for household contacts, antiretroviral therapy clinics for people living with HIV).

Timeline & regulatory considerations

- Possibility of **fast-tracked regulatory approval** (~60 business days instead of 120 days).
- However, expected **introduction timeline is 3-5 years after WHO prequalification**, to learn from introductions in other countries (citing novelty of the TB vaccines), except evidence of cost effectiveness compared to TB preventive treatment is very high.
- Regulator expressed **unwillingness to approve TB vaccines for IGRA negative persons & PLHIV** without efficacy data. Also unwilling to approve use of live-attenuated vaccines in immuno-compromised persons. **NITAG or EPI may make necessary recommendations** after detailed consideration of the available evidence.



High certainty/ convergence of stakeholder feedback



Some uncertainty/ divergence in stakeholder feedback



Low certainty/ convergence in stakeholder feedback

Pakistan has strong interest in novel TB vaccines, subject to efficacy & access to funding



Country adoption

- **Pakistan interested in TB vaccines** due to high TB burden and rising incidence of drug-resistant TB.
- The two most critical factors that will determine adoption of TB vaccines are
 - **Efficacy**, Pakistan will follow the WHO recommendations on efficacy.
 - **Access to funding**, especially. given limited domestic funding for TB programs. Country stakeholders need clarity on the extent of Gavi funding to expect for TB vaccination.
- Other preferences (which will not prevent adoption) include fewer dose schedules, and intramuscular route of action.

Target populations

- Vaccination likely to **start with a targeted approach, prioritizing high-risk groups** first and scaling up to the broader population later
 - Broad groups: adolescents, adults, elderly.
 - High risk groups: **close contacts of TB cases, health workers, people living with HIV, miners, prisoners, people living with diabetes**. Other groups mentioned by few stakeholders include refugees and malnourished persons.
- In the longer-term, country could adopt a **broad population** approach, i.e., implement **phased roll-out** starting with high burden provinces including **Punjab, Sindh and Khyber Pakhtunkhwa**.

Delivery strategies

- **Integrate TB vaccine delivery** with existing non-communicable disease and maternal, neonatal and child health services.
- Possible to reach **adolescents through schools**, but this delivery platform is untested as HPV vaccines have not yet been introduced.
- Challenging to reach general adults and elderly but achievable through **campaigns** and appropriate **incentives**, like during COVID-19 vaccination.

Timeline & regulatory considerations

- Stakeholders expect accelerated introduction **within 1-2 years** of TB vaccine availability, assuming presence of the right level of advocacy and access to funding.
- The standard **regulatory approval** process lasts **~12 months**. TB is considered a high priority, so TB vaccines may qualify for the **fast-tracked regulatory process**, potentially reducing the registration timeline to **~3 months**.
- The NITAG can make appropriate **off-label recommendations** after evaluating the available evidence.



South Africa has strong interest in introducing novel TB vaccines, given high TB/ HIV co-infection rates



Country adoption	• RSA strongly interested in TB vaccine due to high TB burden. The EPI is working to include life course vaccination in the new immunization strategy. • Factors to be considered include clinical trial results, affordability for the government, cost effectiveness relative to TB preventive therapy. A detailed cost-benefit analyses will be required for mobilization of domestic funding for TB vaccines. • Preference for high efficacy (RSA will consider WHO recommendation), one dose vaccination schedule, local manufacturing (although not mandatory), cold chain storage temperature between 2-8°C, multidose vial packaging, and no prefilled syringes.
Target populations	• Broad population-based approach preferred but risk-group-based approach might be more practical in case of limited efficacy, funding and supply. Stakeholders may prioritize adolescents & high-risk groups first. ○ Broad population: adolescents (additional population: adults). ○ High risk groups: people living with HIV, healthcare workers, household/close contacts of TB cases, miners, prisoners, people living with diabetes.
Delivery strategies	• RI and campaigns leveraging existing systems for TB vx delivery - schools for adolescents, health check-ups/ hospital visits for adults with chronic conditions, HIV service delivery for PLHIV, TB prog (case mgt, contact investigation) for contacts of TB patients etc. • Start with high burden provinces/ districts where feasible. Note: district-level targeting might fuel hesitancy.
Timeline & regulatory considerations	• Goal is to introduce TB vx immediately. Majority of stakeholders believe this is possible while some think delivery planning & procurement processes might delay intros by at least 12-24 months. • TB vaccines will qualify for priority regulatory review process (180 instead of 350 business days). • Regulator will only approve products for use in specific groups based on clinical trial results; extra scrutiny of safety data will be conducted, in case of live attenuated vaccines for use in immunocompromised persons. • However, off-label use is possible if recommended by the National Advisory Group on Immunization, after careful assessment of the evidence, risks and benefits.



Vietnam interested in novel TB vaccine adoption, especially among high-risk groups



Country adoption

- Vietnam is interested in TB vx intro due to the high TB burden & rising drug resistance.
- Most critical factors to be considered are **high efficacy, strong safety evidence and affordability** for the government.
- Additionally, stakeholders highlighted **preference** for vaccines with **single dose** regimens, **intramuscular** vaccines, local clinical trials and **locally manufactured** products.

Target populations

- Most stakeholders suggested prioritization of high-risk groups (HRGs) for **initial NIP roll-out**, like the COVID-19 vaccination approach
 - **Main HRGs: people living with HIV, household contacts, healthcare workers, people living with diabetes, prisoners.**
 - Other HRGs: migrants, persons who use drugs and people with chronic obstructive pulmonary disease.
- A **broad population approach** is **desirable**, but funding will be limited, hence the focus on HRGs.
- In case of **broad pop vaccination** later, **adolescents** will be prioritized. Adults and the elderly can be reached through the HRG approach and others may opt for vaccination through private providers, supplementing the government's efforts.

Delivery strategies

- Deliver TB vaccines through routine immunization & campaigns, **integrated with existing services** such as HIV care, active TB case finding, non-communicable disease management programs/ diabetes clinics, and work closely with private facilities.
- Where relevant (in broad populations & some HRGs), implement phased **sub-national roll-out** starting with priority provinces¹ and then slowly scale-up nationwide.

Timeline & regulatory considerations

- Most stakeholders expect **TB vaccines would be introduced at least 3-5 years** after availability, citing time needed for **market authorization & strategic planning**, and to learn from other countries.
- TB vaccines to go through the standard **market authorization process** which typically takes **>1 year**.
- Local clinical trial requirements may be waived if TB vaccines are approved by stringent regulatory authorities in developed countries.
- The Drug Administration of Vietnam (DAV) **follows label guidelines** and is unlikely to approve TB vaccines for use in HIV positive/ IGRA negative individuals without efficacy data, though NITAG may recommend use in these groups after weighing the benefits and risks.

1. High priority provinces: An Giang, Can Tho, Dong Thap, Tay Ninh, Vinh Long, Khanh Hoa, Hue, Ho Chi Minh City

