Request for Proposal

Acceptability, Feasibility and Costing Study for TBAJ-876-based regimen

Global Alliance for TB Drug Development

31 March 2025

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1. Background to the project

The TB Alliance is a non-profit, product development partnership committed to discovering, developing, and delivering improved regimens to fight tuberculosis. A novel anti-tuberculosis (TB) compound, TBAJ-876 is a member of the diarylquinoline class, the same class of drugs to which bedaquiline belongs. Bedaquiline is a component of the WHO-recommended six-month BPaL/M regimens for treating drug-resistant TB. Preclinical studies suggest that TBAJ-876 can be more efficacious and potent against TB than bedaquiline, with a potential improved safety profile.

TBAJ-876 is currently in a pan-Phase 2 clinical trial called NC-009 (combining components of Phase 2a, 2b, and 2c) which began enrollment in October 2023 and closed enrollment (last patient first visit) in August 2024. To ensure eventually a successful market introduction and inform further research, it is critical to develop an understanding of key market considerations. Hence, TB Alliance wishes to commission a feasibility and costing study aimed at assessing the market landscape, regulatory requirements, pricing models, competitive positioning, and implementation challenges across select representative countries. The study findings will inform planning for further research and access strategies, ensuring that a potential TBAJ-876-based pan-TB regimen for all forms of active TB meets the needs of and can be implemented smoothly in both public and private TB treatment sectors.

2. Project objectives

The primary objective of this study is to gather insights into market feasibility, acceptability, pricing, implementation and policy considerations for a potential TBAJ-876-based pan-TB regimen for all forms of active TB and identifying regimen attributes to be kept in mind when designing a follow-on study to NC-009. The study will focus on:

Objective 1: Landscaping analysis: The study will identify, assess and prioritize unmet clinical, programmatic, patient and program needs in the current DS-TB and DR-TB treatment landscape. It will evaluate the strengths and weaknesses of existing drugs and regimens, and to the extent possible with available data, pipeline DS-TB and DR-TB compounds and regimens in development (phase-2 onwards) across key parameters such as treatment duration, efficacy, safety, tolerability.

Objective 2: Evaluating the feasibility, acceptability, and implementation pathways for a potential TBAJ-876-based pan-TB regimen in public and private sectors: This study aims to assess the feasibility and acceptability of adopting a TBAJ-876-based pan-TB regimen in place of

or alternative to current DS-TB and DR-TB treatments across public and private health sectors. It will explore the likelihood of adoption, key barriers, and potential mitigation strategies.

Specifically, the study will:

- Identify critical regimen attributes (e.g., efficacy, safety, treatment duration, adverse events, dosing, pill burden) that influence adoption as:
    - Alternative to current DS- and DR-TB regimens
    - New SOC replacing current DS- and DR-TB regimens.
- Determine the minimum thresholds for these attributes required to drive a switch to TBAJ-876-based regimen and assess what level of improvement would be considered significant for health systems to transition. Additionally with respect to safety, are there any no-go's?
- Examine trade-offs between different regimen attributes and how they might impact acceptability.
- Evaluate different scenarios of how acceptability of new regimens may vary based on key attributes. For example, how will acceptability vary be if treatment is shortened by 1, 2, 3 months?
- Analyze the changes required for public and private health systems to successfully implement TBAJ-876-based regimen, particularly in transitioning to a pan-TB regimen.
- Explore barriers to adoption of a new regimen respectively in DS-TB and DR-TB spaces, specifically a pan-TB regimen and identify mitigation strategies to overcome them. Barriers may include technical, related to implementation challenges as well as attitudinal, emanating from potential irrelevance or disruption of current mechanisms.
- Recommend a prioritized list of regimen attributes with ranges and trade-offs to guide further studies involving TBAJ-876 in a pan-TB regimen.

Objective 3: Costing analysis: The study will examine the financial implications of introducing TBAJ-876-based regimen. It will assess the cost-effectiveness of TBAJ-876-based regimen compared to SOCs respectively in DS- and DR-TB segments under different hypothetical scenarios. The study will further explore price thresholds at which TBAJ-876-based regimen would be considered cost-saving, cost-neutral, or cost-effective in different sectors, and assess stakeholder perceptions on affordability and willingness to pay across diverse market settings. The study will also estimate the costs for public sector and private sectors to switch to TBAJ-876-based regimen.

Objective 4: Estimate the market potential of TBAJ-876-based regimen and identify key market drivers and barriers: The study will assess the potential market share that TBAJ-876-based regimen could achieve respectively in current DS-TB and DR-TB segments, and private

and public sectors under various scenarios. It will analyse key drivers of market growth, as well as risks and challenges to market access. The study will also estimate potential adoption in public and private markets and identify the critical enablers and constraints that will shape TBAJ-876-based regimen's uptake.

Objective 5: Identifying regulatory and policy considerations for the adoption of TBAJ-876-based regimen: The study will identify potential regulatory and policy challenges that may impact the adoption of TBAJ-876-based regimen at global level (by WHO) and in different countries. It will determine which countries require local studies for regulatory approval and policy development, and which such studies would be required. Additionally, it will evaluate whether new clinical guidelines will be necessary for private market adoption and analyse the broader policy implications of introducing a pan-TB regimen. The study will also assess the feasibility of respective countries being early adopters of TBAJ-876 based a pan-TB regimen and of pursuing accelerated regulatory approvals and outline the specific requirements needed for such pathways.

3. Research plan

3.1. Potential research sample

It is expected that the chosen partner will be able to engage respective national TB programs of target countries and confirm willingness to be interviewed before commencing substantive work, which will be subject to such agreement.

Study design, approach, and data collection tools will be developed in collaboration with TB Alliance with input from advisors and, if required, partners such as WHO. Research should be designed and conducted in a manner that is systematic, objective, robust, adequately sourced, and conducive to the ultimate publication of findings. If more than one group is contracted to execute this work (though this is not TB Alliance's preferred plan), it is anticipated that partners will work with TB Alliance to ensure adequate coordination and standardization across data collection tools and approaches.

The study will utilize a combination of expert interviews, focus groups, and desk research. At least 4 representatives from each country will be included and key stakeholders will include:

- National TB program managers and policy decision-makers
- Heads of TB units in referral hospitals, heads of TB hospitals
- Key opinion leaders (KOLs) from both public and private sectors

- Community members and patient advocacy groups
- WHO representatives where applicable.

Desk research will complement primary research to assess pricing models, procurement structures, and treatment pathway feasibility.

3.2. Preliminary target countries

The study will focus on a subset of 5-6 countries preferably from among top-20 TB incidence countries, including as many of the following as possible: India, Brazil, S. Africa, Philippines, Ukraine, Indonesia, Vietnam, Nigeria, Pakistan, Ethiopia.

The selected representative countries should ideally have a mix of countries with:

- High DR- and DS-TB burden countries
- High DS-TB burden, moderate/low DR-TB burden countries
- Markets with a significant private sector TB treatment market

4. Deliverables

Deliverables will include:

- Report summarizing methodology, stratified research results, conclusions, and challenges/limitations with study implementation
- Strategic implications and guidance for access strategies and prioritization of regimen attributes and trade-offs for further research studies, especially the next stage and Phase 3 trials.
- Power-point synthesizing key highlights from the report
- Excel spreadsheet capturing data outputs from qualitative and quantitative data collection/interviews

5. Project timing

Further scoping of the assignment will be finalized following the RfP process and supplier selection, with an aim to have the project completed by October 2025 (no/very limited possibility for extension) and the following anticipated timelines for key milestones:

	04. 2025	**05. 2025**	**06. 2025**	**07. 2025**	**08. 2025**	**09. 2025**	**10. 2025**

Contract established	√						
Document/literature review	√	√					
Methods meeting		√					
Research tools developed		√					
Data collection		√	√	√			
Data aggregation and analysis				√	√	√	
Interim Read-out					√		
Preparation of deliverables						√	√
Final Read-out							√

6. Proposal format and requirements

To be considered as a potential supplier, the proposal must meet the stated requirements described in this section. Proposals are due to the TB Alliance by email by close of business on April 15th, 2025. All material submitted must be in English.

Proposals (maximum 20 pages) should include the following components:

- Executive summary
- Description of the services to be provided, including the scope of activities, approach, methodology, interview sampling approach, and timelines
- Proposed countries & applicant's footprint in these countries
- Justification for the countries proposed for the study, with information on existing country networks and platforms that will be leveraged to deliver the work
- Description of the plan for ensuring adequate coordination with TB Alliance
- Description of the end product/s to be delivered
- Detailed budget including spreadsheet (budget spreadsheet not in 20 pages limit)
- Overview of roles, responsibilities, and relevant experience of project personnel, summary of staff expertise
- Curriculum vitae of project personnel (not included in the 20 pages limit)
- Discussion of how this project will link with and complement other related initiatives (optional)

7. Proposal evaluation criteria

Proposals will be evaluated based on the following criteria:

- Strength of proposal and responsiveness to RFP

- Availability of the right team members to execute the project
- Knowledge of TB landscape in target countries and understanding of issues related to TB diagnosis and treatment
- The ability to leverage relationships with key stakeholders to expeditiously and effectively gather required information and ensure cost effectiveness of study
- Experience producing publication-quality research
- Availability to participate in key meetings, information gathering opportunities, and briefings, as deemed necessary

8. Submission of proposals

Completed applications and supporting documentation should be submitted electronically to:

Market Research Team
MarketResearch@tballiance.org

&

Aastha Gupta
aastha.gupta-consultant@tballiance.org

9. Presentations at the pitch day

TB Alliance will invite the shortlisted suppliers to present their proposal at a virtual meeting with the following (expected) agenda:

- Presentation of the team
- Presentation of the RfP including Q&A
- Next steps

Please notice that TB Alliance expects that the proposed team will be presenting the proposal. Key members expected to work on this project should participate in the pitch meeting.

10. RfP process timeline

The following is the timeline for activities relevant to the RfP process. TB Alliance reserves the right to change these dates and will notify the suppliers in such circumstances.

Activity	Deadline 2025	Responsible party
RFP released	31 March	TB Alliance

Notice of intent Please inform whether your organization intends to participate in this proposal no later than the stated deadline.	7 April	Supplier
Q&A session (optional) An optional, one virtual Q&A call per applicant prior to proposal submission deadline (max. 30 mins). Interested applicants should contact TB Alliance Market Research team at MarketResearch@tballiance.org to arrange a session.	Between 7-11 April	TB Alliance & Supplier
Binding Proposal submission deadline Please submit according to requirements.	15 April	Supplier
Pitch Day with TB Alliance - Virtual • If your organization is shortlisted, the pitch will take place at the expected date. • An exact date and time will be decided based on mutual availability. • Presentation of your pitch proposal including Q&A's.	Between 16-18 April	TB Alliance & Supplier
Final supplier selection Based on the submitted responses to the questions asked in this RfP and the supplier's performances at the pitch TB Alliance will evaluate and select the supplier.	23 April	TB Alliance