Tuberculosis vaccine R&D roadmap

EDCTP — The power of sharing science

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THEMES

I Diversifying the pipeline	II Accelerating clinical development	III Ensuring public health impact

R&D ACTION LINES

1 Basic and translational science	2 Animal models	3 Clinical trials	4 Epidemiology and modelling	5 Research to ensure optimal implementation
1.1 Mechanisms and biomarkers of protection 1.2 New approaches to vaccine discovery 1.3 Improved vaccine formulation and delivery 1.4 Controlled human infection model	2.1 Optimised animal models 2.2 Comparison of vaccine candidates within and across animal models	3.1 Trial endpoints 3.2 Correlates of protection 3.3 Trial harmonisation and design 3.4 Trial site capacity	4.1 Country-specific data and projections 4.2 Post-licensure studies	5.1 Health system conditions for vaccine introduction 5.2 Barriers and enablers of vaccine uptake

KEY ENABLING CONDITIONS

a Funding

A1 Attract new investments in TB vaccine R&D
- Develop a comprehensive global value proposition for TB vaccines
- Broaden the funding base with governments, philanthropy and donors
- Attract new entrants

A2 Develop innovative financing mechanisms for TB vaccine R&D
- Establish partnerships for joint funding of trials
- Customise calls to the clinical development pathway

A3 Create mechanisms that attract investment in early stages of development
- Market shaping to reduce commercial uncertainty
- Manage intellectual property

b Open science

B1 Promote timely and open access of data, specimens and results
- Promote open-access publication and open-access databases
- Promote sharing of biospecimens
- Establish publicly searchable patent databases

B2 Create a mechanism for coordinating open science
- Establish a platform for data sharing
- Develop and coordinate systems and procedures

c Stakeholder engagement

C1 Create a supportive environment for TB vaccines
- Increase political commitment
- Advocate for development and uptake
- Harmonise and fast-track regulatory review
- Create innovative incentives

C2 Overcome barriers to delivery and uptake
- Engage with end-user communities
- Develop approaches for community-level delivery

C3 Promote TB vaccine and research literacy
- Create a global programme for community engagement and training
- Foster strategic and reciprocal partnerships

The European & Developing Countries Clinical Trials Partnership