THE TUBERCULOSIS VACCINE R&D ROADMAP

DCVMN 22ND ANNUAL GENERAL MEETING FORUM
CAPE TOWN, 19-21 OCTOBER 2021

Frank Cobelens
f.cobelens@aighd.org

The EDCTP2 programme is supported under Horizon 2020, the European Union’s framework programme on research and innovation
Tuberculosis is a leading cause of illness and mortality

WHO estimates (2020):
9.9M new TB cases
1.0M in children
1.5M TB deaths
TB is primarily a problem in low- and middle-income countries.

WHO target = 90% reduction in incidence by 2035.

This is unlikely to be achieved without an effective vaccine.

BCG (current TB vaccine) is effective against severe TB in children but not against adult pulmonary TB and transmission.
1. A safe, effective and affordable TB vaccine for adolescents and adults

2. An affordable TB vaccine for neonates and infants with improved safety and efficacy compared to BCG

3. A therapeutic vaccine to improve TB treatment outcomes

Need for a Global Roadmap for Research and Development for TB vaccines that:

- Lists the short- and long-term strategic objectives for global TB vaccine development
- Provides global stakeholders with key actionable priorities that could help guide their actions
- Focuses on affordable vaccines for use in low- and middle-income countries
Roadmap consultation process

Stakeholder interviews
N = 22

Consent workshop
N = 34 (+)

WHO
PDVAC
draft 1-2

EDCTP
SAB
draft 3

Public consultation
finalize

Advocacy & community representatives
Donors of TB control and immunization
Global policy bodies
Health economists & modelers
National TB program managers/policy makers
National EPI managers/policy makers

Product Development Partnerships
Regulators
Research funders
Researchers involved in TB vaccine development
Technical assistance agencies
Vaccine manufacturers

Stakeholders consulted
<table>
<thead>
<tr>
<th><strong>Barriers to TB vaccine R&amp;D</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diversifying the pipeline</strong></td>
</tr>
</tbody>
</table>
| **Accelerating clinical development** | Lack of validated animal models that predict efficacy in humans  
Lack of validated laboratory correlates for protection  
Need for large-scale phase III trials with disease endpoint |
| **Ensuring public health impact** | Lack of clear value proposition for countries to introduce a TB vaccine  
Limited insight in how a TB vaccine for adults would be used & accepted  
Poor insight in global and national demand and willingness to pay |
| **Enabling conditions** | Limited and fragmented funding  
Siloed science  
Limited stakeholder engagement |
Diversifying the pipeline – R&D Action Lines

1. Basic and translational science
   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
Accelerating clinical development – R&D Action Lines

2. Animal models
   2.1 Optimised animal models
   2.2 Comparison of vaccine candidates within and across animal models

3. Clinical trials
   3.1 Trial endpoints
   3.2 Correlates of protection
   3.3 Trial harmonisation and design
   3.4 Trial site capacity
Ensuring public health impact – R & D Action Lines

4 Epidemiology and modelling
   4.1 Country-specific data and projections
   4.2 Post-licensure studies

5 Research to ensure optimal implementation
   5.1 Health system conditions for vaccine introduction
   5.2 Barriers and enablers of vaccine uptake
Key enabling conditions

**FUNDING**
Attract new investments in TB vaccine R&D
Develop innovative financing mechanisms for TB vaccine R&D
Create mechanisms that attract investments in early stages of development

**OPEN SCIENCE**
Promote timely and open access of data, specimens and results
Create a mechanism for coordinating open science

**STAKEHOLDER ENGAGEMENT**
Create a supportive environment for TB vaccines
Overcome barriers to delivery and uptake
Promote TB vaccine and research literacy
Recent and next steps

Launch of the R&D Roadmap at TB Vaccine Forum April 2021

Complement with **WHO Roadmap on Global Introduction of New TB Vaccines**

*country value propositions, regulatory strategy, global policy making, commercialisation*

Introduce the Roadmap with all relevant stakeholders & help coordinate actions

Monitor Roadmap implementation

https://www.aighd.org/?s=roadmap
This project is part of the EDCTP2 programme. The EDCTP programme is supported under Horizon 2020, the European Union’s Framework Programme for Research and Innovation.

Expert panel
Rajinder K. Suri
Mark Hatherill

Remko van Leeuwen
Britta Schaffmeister
Frank Deege

Nebiat Gebreselassie
Johan Vekemans
Matteo Zignol

THANK YOU