



# THE TUBERCULOSIS VACCINE R&D ROADMAP

### DCVMN 22<sup>ND</sup> ANNUAL GENERAL MEETING FORUM

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Frank Cobelens f.cobelens@aighd.org

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# Tuberculosis is a leading cause of illness and mortality

#### Estimated TB incidence in 2020, for countries with at least 100 000 incident cases





#### WHO estimates (2020):

9.9M new TB cases 1.0M in children

1.5M TB deaths







# Tuberculosis: need for an effective vaccine



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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



# WHO issued TB vaccine Product Profile Characteristics



- **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





Stakeholders	Advocacy & community representatives Donors of TB control and immunization Global policy bodies	Product Development Partnerships Regulators Research funders
consulted	Health economists & modelers National TB program managers/policy makers National EPI managers/policy makers	Researchers involved in TB vaccine development Technical assistance agencies Vaccine manufacturers





# Barriers to TB vaccine R&D



Too narrow approach –antigens, platforms, delivery	
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	
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	
Limited and fragmented funding Siloed science Limited stakeholder engagement	





## Diversifying the pipeline – R&D Action Lines







## Accelerating clinical development – R&D Action Lines









3.2 Correlates of protection3.3 Trial harmonisation and design

3.4 Trial site capacity



## Ensuring public health impact – R & D Action Lines





4.1 Country-specific data and projections4.2 Post-licensure studies



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Research to ensure optimal implementation

5.1 Health system conditions for vaccine introduction5.2 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



https://www.aighd.org/?s=roadmap

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





# THANK YOU

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Remko van Leeuwen Britta Schaffmeister Frank Deege **Expert panel** Rajinder K. Suri Mark Hatherill



Nebiat Gebreselassie Johan Vekemans Matteo Zignol



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