Stop TB Partnership
Working Group on New TB Vaccines

Working Group on New TB Vaccines Open Meeting

New TB Tools Summit: Towards a World Free of TB

14 November 2023

Paris, France

Agenda

Introduction to WGNV

- David Lewinsohn, Ann Ginsberg, Shaun Palmer, Simon Mendelsohn

State of the Field of TB Vaccine R&D

- Ann Ginsberg

Panel Discussion

- Moderators: Richard White, Gopa Kumar
- Panelists: Birgitte Giersing, Michele Tameris, Shaun Palmer, Elly van Riet

Summary and Closing

- David Lewinsohn

Stop TB Partnership
Working Group on New TB Vaccines

Introduction to the Working Group on New TB Vaccines

David Lewinsohn
Shaun Palmer
Simon Mendelsohn
Ann Ginsberg

WGNV Open Meeting | 14 November 2023, Paris, France

About Us

Stop TB Partnership
Working Group on New TB Vaccines

Our mission

The mission of the Working Group on New TB Vaccines is to facilitate research and development of new TB vaccines by providing an inclusive forum for stakeholders to engage in scientific exchange, build consensus on key issues, and advocate for greater support and investment in TB vaccine R&D.

How we work

The WGNV is an informal network of stakeholders engaged in all aspects of TB vaccine R&D and from all constituencies, including academics, product developers, clinicians, advocates, funders, policymakers, and affected communities. Membership is open to anyone who is interested in being engaged and involved in TB vaccine R&D.

Who we Are - Leadership

Stop TB Partnership
Working Group on New TB Vaccines

Chair

David Lewinsohn (Oregon Health & Science University, USA)

Core Group

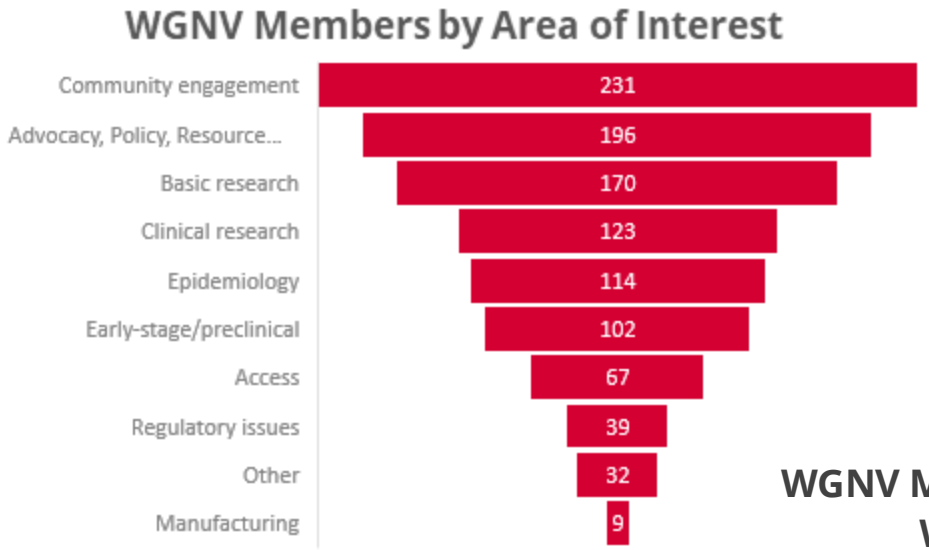
- **Academic Institutions:** Richard G. White, London School of Hygiene and Tropical Medicine (UK)
- **Affected Communities:** *Vacant, in process of being filled*
- **Clinical Trial Sites:** Michele Tameris, South African Tuberculosis Vaccine Initiative (South Africa)
- **Developed Country NGOs/Advocacy Networks:** Shaun Palmer, TB Vaccine Advocacy Roadmap (TB Vax ARM) (Netherlands)
- **Early Career Researchers:** Puck Pelzer, IAVI (Netherlands); Paul Ogongo, University of California San Francisco (USA)
- **Funders:** Ann Ginsberg, Bill & Melinda Gates Foundation (USA)
- **Global TB Vaccine Partnership:** Michael Makanga (Netherlands)
- **IAVI:** Lewis Schrager (USA)
- **TBVI:** Elly van Riet (Netherlands)
- **Public Sector:** Katrin Eichelberg, National Institute of Allergy and Infectious Diseases/National Institutes of Health (USA)
- **Private Sector/Industry:** Eileen Foy, Vir Biotechnology (USA)
- **World Health Organization:** Brigitte Giersing, Vaccine and Product Delivery Research, WHO (Switzerland)

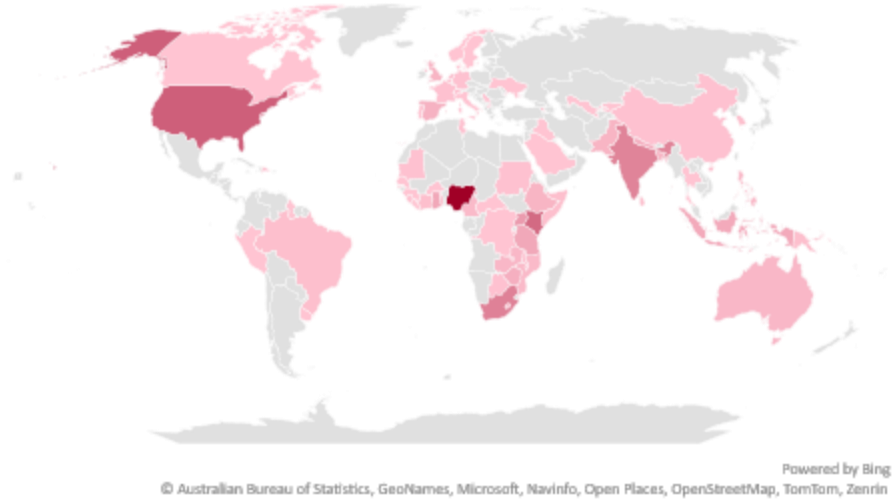
Secretariat

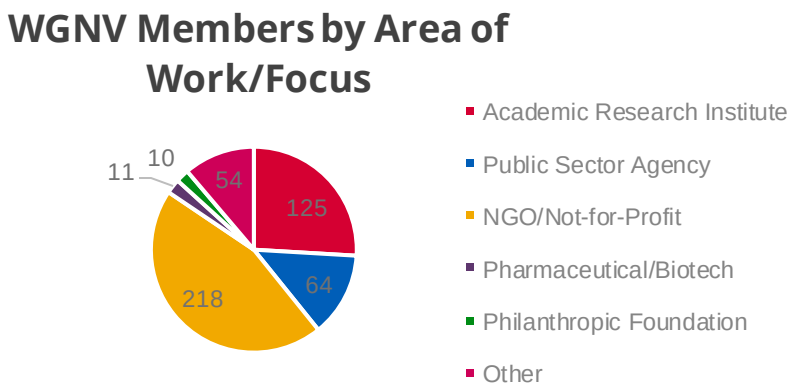
Hosted by IAVI | Jennifer Woolley, Head of Secretariat | Erick Auma, Intern

Who We Are – Members

423 members from 69 countries | 132 members identify as Early Career Researchers







As of 6 November 2023

WGNV Resources

Stop TB Partnership
Working Group on New TB Vaccines

Website (newtbvaccines.org)
- Publications, fact sheets, and other resources
- Upcoming meetings and events
- Global TB Vaccine Pipeline
- Jobs, funding, opportunities
- Take Action!

Email updates to members and subscribers

Online workshops, webinars, and discussion sessions

Active social media presence
- X (@newtbvaccines)
- LinkedIn (Stop TB Partnership Working Group on New TB Vaccines)

Online TB Research Curriculum (in collaboration with Working Groups on New Drugs and Diagnostics, and Affected Communities and NGO Delegations

WGNV Priority Areas

Stop TB Partnership
Working Group on New TB Vaccines

Advocacy

Fostering discussion

Supporting early career researchers

Sharing knowledge

Addressing issues in product development

WGNV Priority: Advocacy

Stop TB Partnership
Working Group on New TB Vaccines

The Need

- Meeting the global goal to develop new TB vaccines will require significantly increased funding and political will
- Preparing for equitable access to new TB vaccines will require collaboration and engagement with countries and communities way in advance of implementation

WGNV Contribution

- Participates in TB Vaccine Advocacy Roadmap (TB Vax ARM) for global efforts
- Develops and shares fact sheets and materials for advocacy, research literacy, and community engagement

How to Get Involved

- Join WGNV and indicate your interest in advocacy
- Join the **TB Vax ARM** to get information and be involved in global advocacy efforts
- Visit the “Take Action” page of the WGNV website
- Participate in WGNV/TB Vax ARM events related to advocacy

WGNV Priority: Fostering Discussion

Stop TB Partnership
Working Group on New TB Vaccines

The Need

- Developing and implementing new TB vaccines is complex; success will require alignment and coordination on key issues, concepts, and gaps in TB vaccine R&D

WGNV Contribution

- Virtual workshops on identified gaps in knowledge
  - June 2023: *Recognition of the Mtb infected cell: From basics to the clinic*
  - Oct 2023: *Generating Key TB Vaccine Epidemiological, Impact, Feasibility and Acceptability Data to Support the Introduction of New TB Vaccines at the Country Level*
  - Planned 2024: *Fit for Purpose Animal Models*

How to Get Involved

- Join WGNV and indicate an interest in Fostering Discussions
- Review resources on the WGNV website; if you are aware of additional resources, share them with us
- Participate in WGNV workshops and online discussions on key topics in TB vaccine R&D

WGNV Priority: Sharing Knowledge

Stop TB Partnership
Working Group on New TB Vaccines

The Need

- A platform for compiling and sharing information about TB vaccine R&D, from basic and discovery research through to access and implementation

WGNV Contribution

- Sharing resources about TB vaccine R&D through our website, including journal articles, reports, and other publications
- Compiling a global pipeline of TB vaccines in development
- Convening the Global Forum on TB Vaccines series

How to Get Involved

- Join WGNV and indicate your interest in Sharing Knowledge
- Review resources on the WGNV website; if you are aware of additional resources share them with us
- If you are developing a TB vaccine, let us know (from proof of concept in animal models stage)
- Participate in the Global Forum and other WGNV events related to sharing knowledge

WGNV Priority: Supporting Early Career Researchers

Stop TB Partnership
Working Group on New TB Vaccines

The Need

- Encourage and support the next generation of TB vaccine researchers
- Assist Early Career Researchers in navigating career paths, building critical skills, and providing a network of support

WGNV Contribution

- Supports an Early Career Researcher Network,
- Organizes virtual discussion sessions for ECRs, most recently a series on career paths and opportunities in TB research
- Other activities for ECRs being planned for 2024

How to Get Involved

- Join WGNV and indicate that you are an ECR or a support of ECRs
- Participate in ECR Network activities
- Suggest activities to WGNV and ECR that would benefit ECRs

WGNV Priority: Addressing issues in product development

Stop TB Partnership
Working Group on New TB Vaccines

The Need

- Translating concepts for novel TB vaccines into potential products is a challenging process unfamiliar to many researchers
- The vaccine product development pathway is lengthy and complicated

WGNV Contribution

- Compiling resources on product development (available on newtbvaccines.org)
- Organizing informational webinars and workshops on key issues (planned for 2024 and beyond)

How to Get Involved

- Join WGNV and indicate your interest in Issues in Product Development
- Review resources on the WGNV website; if you are aware of additional resources share them with us
- Participate in WGNV events related to Product Development

Get Involved!

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Email us **wgnv@iavi.org**

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TB VACCINE R&D: STATE OF THE FIELD

Ann M. Ginsberg

Stop TB Working Group on New Vaccines Annual Meeting

Paris, France

November 14, 2023

WHY ARE BETTER TB VACCINES URGENTLY NEEDED?

TB IS A LEADING CAUSE OF DEATH GLOBALLY

*Effective vaccines are a critical unmet public health need**

In 2022: 10.6 million new cases of TB and 1.3 million deaths

- 8-9% of TB cases and ~13% of TB deaths are in persons living with HIV

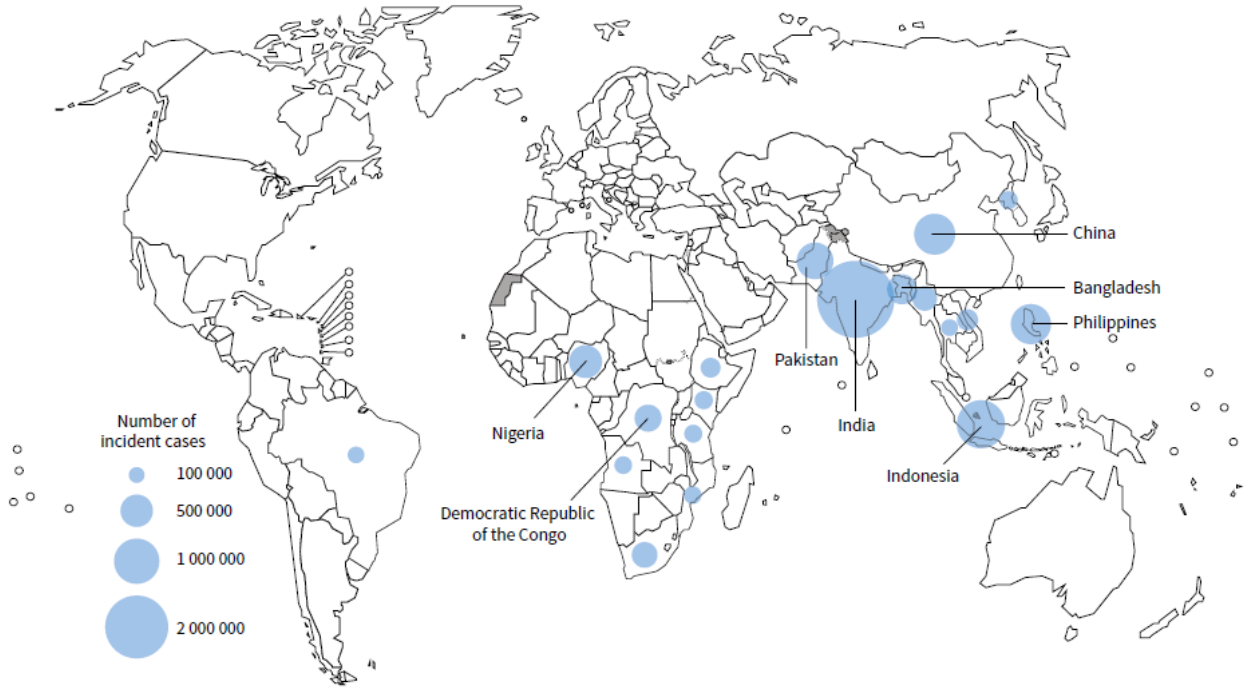
TB incidence **increased** by ~3.9% from 2020-2022

- follows ~2% per year **declines** from 2010-2020

BCG helps protect young children from severe forms of TB

- but does not reliably protect adolescents and adults and is not controlling the epidemic

Estimated number of incident TB cases in 2022, for countries with at least 100 000 incident cases[a]



[a] The eight countries ranked in order from first to last in terms of numbers of cases, and that accounted for about two thirds of global cases in 2022, are India, Indonesia, China, the Philippines, Pakistan, Nigeria, Bangladesh and the Democratic Republic of the Congo.

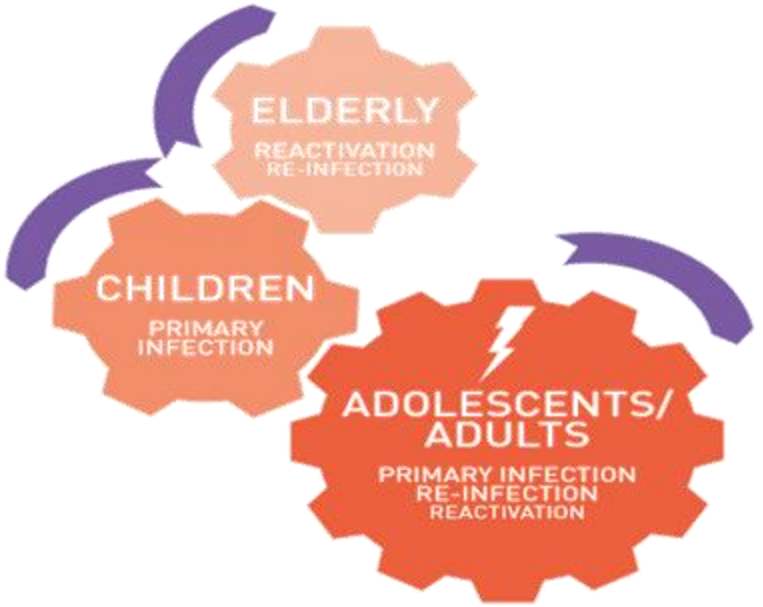
GLOBAL TUBERCULOSIS REPORT 2023

*WHO Preferred Product Characteristics for New Tuberculosis Vaccine; https://www.who.int/publications/i/item/WHO-IVB-18.06

ADOLESCENTS AND YOUNG ADULTS ARE THE HIGHEST PRIORITY TARGET FOR TB VACCINES

because they are the main source of M.tb transmission

Global estimates of TB incidence (black outline) and case notifications of people newly diagnosed with TB disaggregated by age and sex (female in purple; male in orange), 2022



Nyabadza et al, South African J Science 2013;109(9/10)
WHO Preferred Product Characteristics for New Tuberculosis Vaccine; https://www.who.int/publications/i/item/WHO-IVB-18.06

THE GLOBAL CLINICAL PORTFOLIO OF TB VACCINE CANDIDATES

17 CANDIDATES IN CLINICAL DEVELOPMENT

TB Vaccine Pipeline

Vaccine candidates under clinical development

There are 16 vaccine candidates in the pipeline as of September 2023, of which 11 are in active trials. The candidates are placed under the phase which corresponds to the most advanced ongoing or completed trial.

Platform

- Mycobacterial - Live attenuated
- Mycobacterial - Inactivated
- Viral vector
- Protein/Adjuvant
- RNA

Trial staus

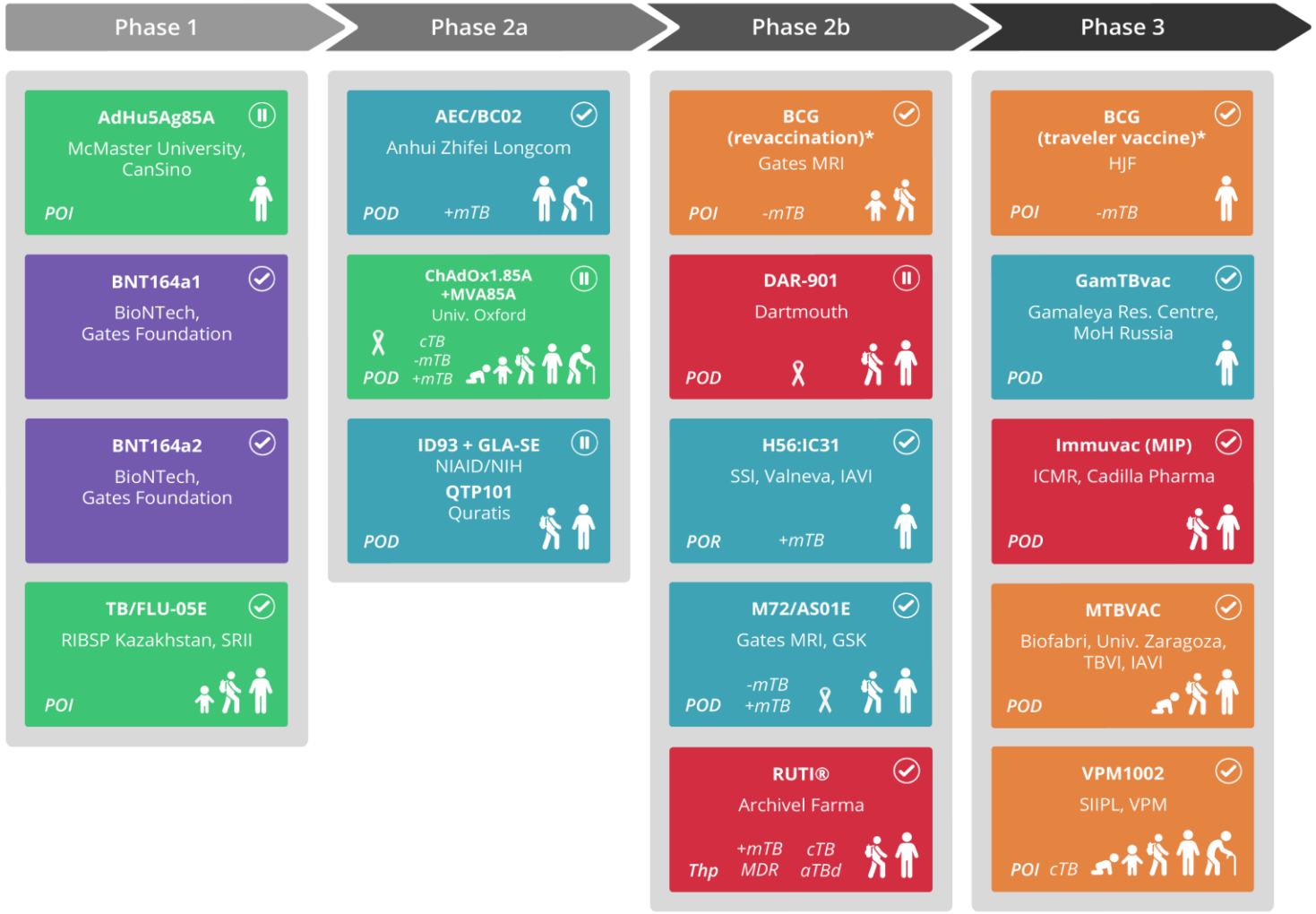
- Active trials
- No active trials

Candidate target population

- Elderly
- Adults
- Adolescents
- Children
- Infants
- People living with HIV
- -mTB — People without mTB infection
- +mTB — People with mTB infection
- aTBd — People with active TB disease
- MDR — People with MDR-TB
- cTB — People cured of active TB

Primary candidate indication

- *POI* — Prevention of Infection
- *POD* — Prevention of Disease
- *POR* — Prevention of Recurrence
- *Thp* — Therapeutic



**BCG appears twice in the pipeline to distinguish between the investigation of its use in BCG-naïve individuals (traveler vaccination) and in individuals who have previously been vaccinated with BCG (revaccination).*

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Information reported by vaccine sponsors or found in clinical trial registries or other public sources.

For the full list of completed trials for each candidate, visit www.newtbvaccines.org/tb-vaccine-pipeline/

Last update: 28 September 2023

TB Vaccine Pipeline

Active clinical trials of TB vaccine candidates

There are 11 active clinical trials across nine candidates as of October 2022.

Platform

- Mycobacterial - Live attenuated
- Mycobacterial - Inactivated
- Viral vector
- Protein/Adjuvant
- mRNA

Trial target population

	Elderly
	Adults
	Adolescents
	Children
	Infants
	People living with HIV
-mTB	People without mTB infection
+mTB	People with mTB infection
aTBd	People with active TB disease
MDR	People with MDR-TB
cTB	People cured of active TB

Primary trial indication

Sf	Safety
POI	Prevention of Infection
POD	Prevention of Disease
POR	Prevention of Recurrence
Thp	Therapeutic

Trials in planning:

- H107/CAF10b Ph1a/b
- MTBVAC Ph2b (adols/adults)
- M72/AS01E Ph 3

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Last update: 02 February 2023

A ROBUST DEVELOPMENT PIPELINE

PRECLINICAL

PHASE 1

PHASE 2

PHASE 3

TB Vaccine Pipeline

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Last update: 02 February 2023

ANTICIPATED BOLUS OF EFFICACY RESULTS 2024-2028

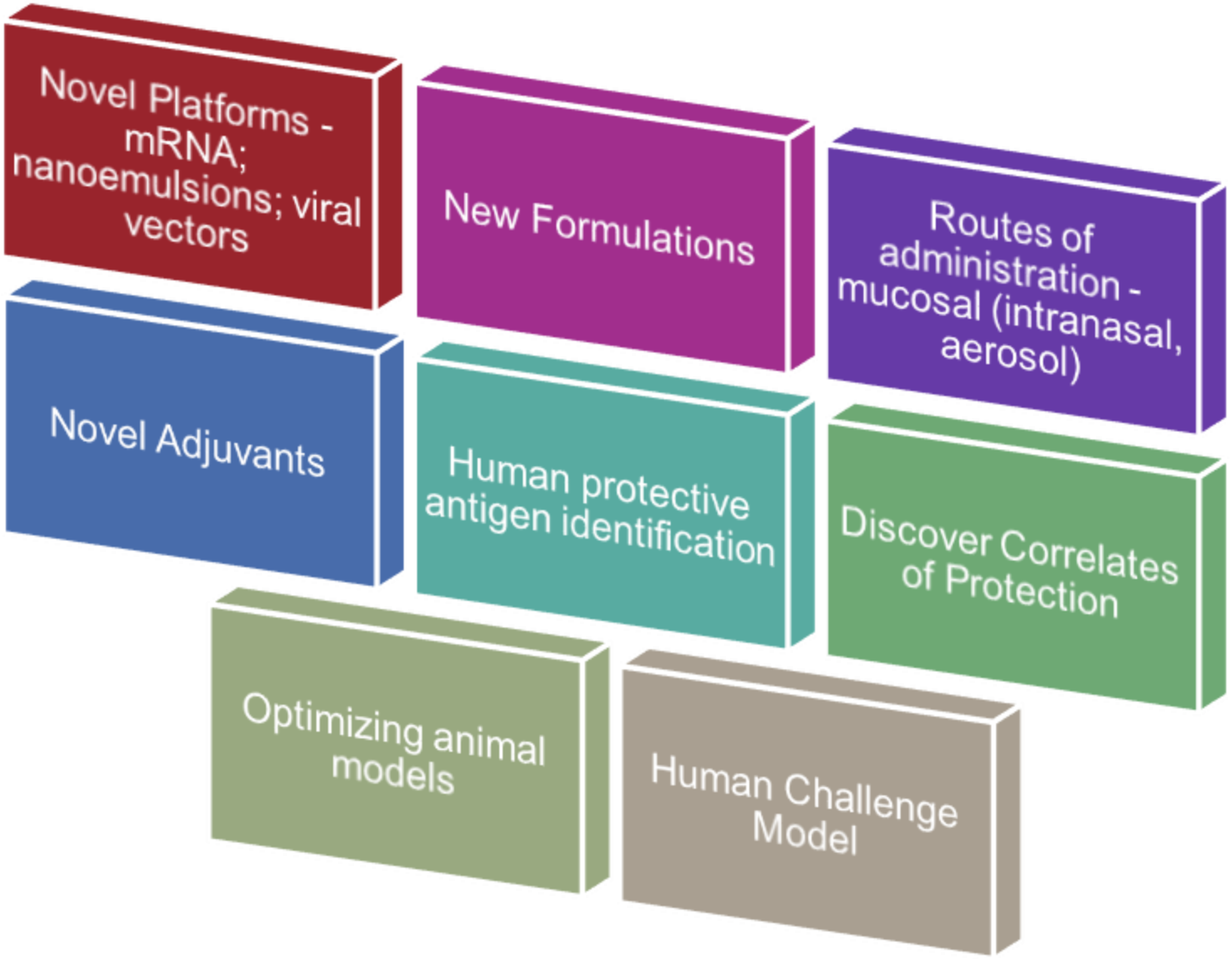
Vx candidate	Trial endpoint	Trial phase	Trial population	Results due	Comments
VPM1002					
also, IMMUVAC (MIP)	POD	Ph3	HHC (~13,000)	2024	
	POR	Ph2/3	Adults on rx (~2000)	2024	
	POI	Ph3	Infants (~6900)	2026	Non-inferiority to BCG
MTBVAC					
	POD (infants)	Ph3	Infants (~7100)	4Q 2028	Superiority to BCB
	POD (adol/adult)	Ph2b	Adol/adult (14-45; ~4300)	IA:2027?	*In planning* – starting mid-2024-T
BCG revac	POI			Primary – 2024; final - 2026	
M72/AS01$_E$	POD	Ph3	Adol/adult (15-44; ~26,000)	IA: 2027-8?	Powered on HIV-IGRA+ *T-starting 1Q 2024*
H56:IC31	POR	Ph2b	Cured adults	2023-4	
ID93+GLA-SE / QPT101	POD	Ph2b/3	Adol/adult in S. Korea	?	*In planning* - Starting 4Q2023-T
	Rx-shortening	Ph2b	Adults on rx	?	*In planning*
RUTI	Adjunct to rx (improved outcomes)	Ph2b	Adults on rx	4Q 2025	
GAMTBVAC	POD	Ph3	HIV-, Mtb- adults 18-45 (~7100); TB incid.>30/100,000)	4Q 2025	Substantially under-powered?

GAPS AND CHALLENGES

MAJOR CHALLENGES AND GAPS IN TB VACCINE R&D

- Complex pathogen expressing ~4000 antigens; protective epitopes/antigens largely unknown
- To date, no identified vaccine-induced Correlate(s) of Protection in humans
- Human protective immune responses only partially understood
- No reproducibly predictive animal model(s) human challenge model established
- Pipeline of candidates not adequately robust – inverted pipeline
- Effects of HIV status, infection (IGRA/TST) status, age and geography on vaccine efficacy must be determined for each vaccine
- Inadequate capacity for multiple, overlapping registration-quality efficacy trials
- Preparation for access, adoption and delivery to end users just beginning
- Inadequate funding and political will

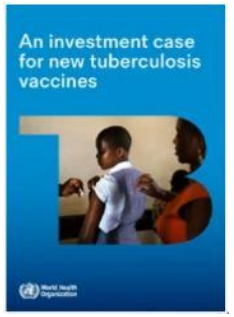
BUILDING A MORE ROBUST “NEXT GENERATION” PIPELINE



END-TO-END DEVELOPMENT OF TB VACCINES

Groundwork being laid:

Selected examples:



- Preferred Product Characteristics
- R&D Roadmap to Phase 3 (AIGHD, EDCTP)
- Roadmap from Licensure to Implementation (WHO)
- Investment Case for a New TB Vaccine (full value assessment) (WHO)
- Evidence Considerations for Vaccine Policy (WHO)
- TB Vaccine Market Analysis (Wellcome Trust)
- National TB Vaccine Policy Project (BMGF)
- TB Vx Implementation Planning Landscape and Gap Analysis *(underway with WHO)*

THANK YOU!

ann.ginsberg@gatesfoundation.org

Stop TB Partnership
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Panel Discussion

Richard White
Gopa Kumar
Birgitte Giersing
Shaun Palmer
Michele Tameris
Elly van Riet

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Follow us on @GlobForumTBVax

SAVE THE DATE!

tbvaccinesforum.org/rio-de-janeiro

7TH GLOBAL FORUM ON TB VACCINES

8-10 October 2024
Rio de Janeiro, Brazil

An international convening of the

Stop TB Partnership
Working Group on New TB Vaccines

Organized in collaboration with

iavi
Translating science into global health impact

TBVI
TuBerculosis Vaccine Initiative

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