

# Accelerating TB Vaccine Research & Development Through Partnership



**TBVI**

TuBerculosis Vaccine Initiative

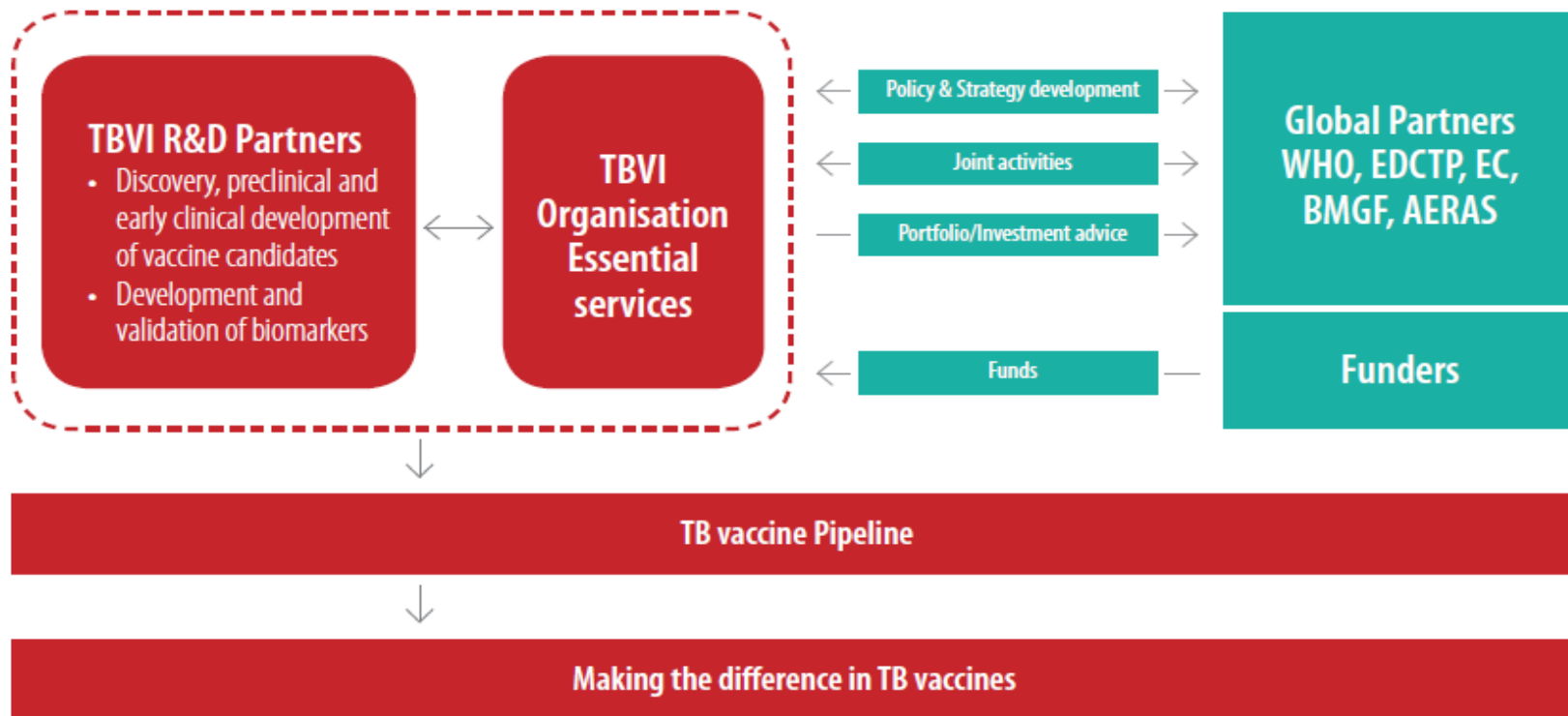
[www.tbvi.eu](http://www.tbvi.eu)

Dr. Nick Drager

# TBVI Business Model

## Mission:

To innovate and diversify the TB vaccine and biomarker pipeline through effective collaboration with partners, and to support and accelerate the development of the most promising vaccine candidates through early development stages



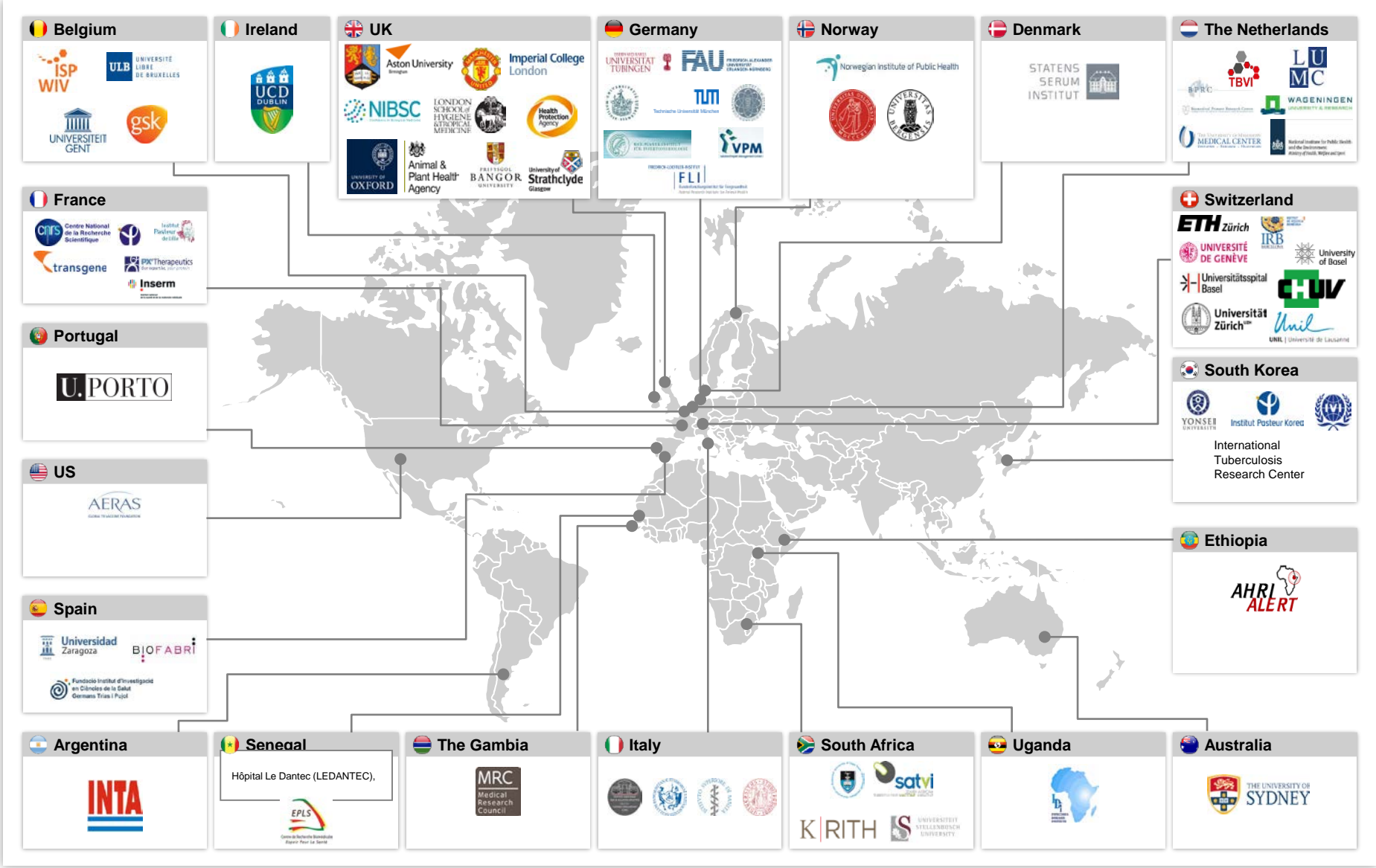
## Vision:

Available safe, effective and affordable TB vaccine contributing to the global goal of the elimination of TB by 2050

# TBVI operating principles

- Vaccine R&D through partnership
- Promoting an enabling R&D environment
- Ownership of vaccine candidates and biomarkers and any IP rights remain with researchers and vaccine developers
- Access and affordability of vaccines a guiding principle and is a commitment that is part of each project grant agreement supported by TBVI

# We have worked together with our 72 partners worldwide in the last 10 years



# TBVI – Accelerate the discovery and development of new TB vaccines that are safe, effective and affordable.

## TBVI organisation

- Pools resources, provides project management and technical support to allow its R&D partners to focus on the science
- Leverages public sector funding to gain private sector investment.
- Provides the knowledge platform which enables its R&D partners to share unpublished data and convenes the brightest minds in TB research, bio-pharma and the public sector to bring a new vaccine to the market.
- Gives cutting edge expert, unbiased scientific advice to both scientists and funders.
- Acts as an “honest broker” between scientists and funders (IP rests with R&D partners; TBVI does not take equity/ownership)
- Provides funders with portfolio and investment advice. It engages with its global partners in developing up-to-date policy, strategy and priority setting in TB vaccine R&D

# TBVI – Services to R&D partners

- As a **Product Development Partnership (PDP)**, TBVI integrates, translates and prioritizes Research and Development (R&D) efforts to discover and develop new TB vaccines and biomarkers for global use. The TBVI organization provides essential services that support the efforts of its 50+ R&D partners from academia, research institutes and private industry in the TB vaccine field. These services include:
  - Technical advice and support for product and clinical development
  - Resource mobilisation
  - Knowledge exchange and networking
  - Project identification, design and development
  - Project management
- TBVI provides funders with portfolio and investment advice. It engages with its global partners in developing up-to-date policy, strategy and priority setting in TB vaccine R&D.

## 4 We are mindful about how to allocate our funds

*We manage our projects in a way to reduce any financial risks*

### General governance principles

**TBVI manages ongoing projects to keep them on track**

#### Transparency



- All TBVI's articles, policies, rules, decisions and recommendations are published to show transparency among stakeholders and public

#### Conflicts of interest



- TBVI uses safeguards to manage possible conflicts. All workers and experts are to declare their conflict of interests and comply with TBVI's conflict interest policy

#### Standards and codes of conduct



- All clinical trials participated by TBVI will be performed in a way accepted by ICH guidelines along with ethical and regulatory requirements

#### Confidentiality



- TBVI treats data received from its collaborators with strict confidentiality. Confidentiality agreements are a standard with handling sensitive information

#### TBVI acts as the gatekeeper

- Controls the financial status
- Checks if the research milestones are achieved

If there any problems TBVI will help out



### 3 Our collaborative partnership model improves the quality of TB research

*Partners regularly get together to share their knowledge*

In total TBVI has organized over 40 scientific events on TB vaccine R&D<sup>1</sup>

This have led to cross learning, avoiding overlap and building ther on each other's knowledge

Example events	Location	# participants
4 global forums on TB vaccines	<ul style="list-style-type: none"> <li>China</li> <li>South-Africa</li> <li>Estonia</li> <li>Switzerland</li> </ul>	<ul style="list-style-type: none"> <li>Up to 300 participants, including policy makers, pharmaceuticals</li> </ul>
22 specific project meetings	<ul style="list-style-type: none"> <li>Netherlands</li> <li>Germany</li> <li>Switzerland</li> </ul>	<ul style="list-style-type: none"> <li>With annual 150+ researchers from specific projects                             <ul style="list-style-type: none"> <li>– TBVAC</li> <li>– NEWTBVAC</li> <li>– TBVAC 2020</li> <li>– Les Diablerets</li> </ul> </li> </ul>



“  
*It was for me really useful to know what is going on to **avoid overlap and build further on others' knowledge***  
 ”

“  
*After the presentations regarding the latest data and research findings, we had the opportunity to **engage in discussion** and debate about the path forward for this critical research*  
 ”

“  
*For me it is now **easier to connect** with all the stakeholders in the world ( the leading researchers, product developers, pharmaceutical companies, government officials, advocates and others)*  
 ”

TBVI creates an enabling environment for its consortium partners and other relevant stakeholders to promote knowledge sharing on events, but also outside events

<sup>1</sup> Since 2004



# 4 We are mindful about how to allocate our funds

*We end projects that do not show enough relevance*

TBVI developed quality decision making process to ensure the most promising candidates are being advanced

This led to endings of some candidates in the last 10 years

**Objective**

- To ensure that
  - the most promising candidates are being selected and further developed
  - duplications are avoided at a global level

**Tools**

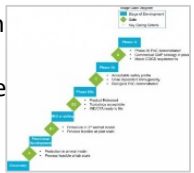
- State gating**
  - Framework to aid decision-making in advancing and investing further in candidates through the R&D pipeline
- Priority setting**
  - A matrix process to prioritize candidates competing for available resources

**Process**

- A formal assessment on the new vaccine discoveries and the existing portfolio is taking place twice a year carried out by the P&CDT team and presented to the steering committee

**Independent view**

- The intellectual property rights of the candidates main with researchers/developers
- This enables the TBVI to give independent, unbiased expert advice to its partners and funders and being an honest broker



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	
1. Conceptualisation																					
2. Feasibility																					
3. Research																					
4. Business case																					

	Discovery phase	Pre-clinical phase	Clinical phase <sup>1</sup>
<b>Currently supported candidates</b>	20	6	5
<b>Past supported candidates</b>	<b>Moved forward</b>	10	5
	<b>Ended</b>	30	5
<b>Total supported</b>	<b>60</b>	<b>16</b>	<b>6</b>

**Biomarkers:**

- ✦ 15-20 candidate biomarkers were further characterized and validated
- ✦ 18 novel candidate biomarkers were identified
- ✦ 3 were selected for further assay development

1 Currently 3 candidates in Phase I, 2 candidates in phase IIa, 1 candidate in phase IIB and 1 project ended in phase IIB

Discovery	Preclinical	Phase I	Phase IIa	Phase IIb	Phase III
Approximately 20 novel TB vaccine strategies in development, several R&D partners, TBVI	<b>Combination vaccines prime-boost</b> GSK, TBVI	<b>MVA85A (ID, Aerosol)</b> University of Oxford, TBVI	<b>VPM1002</b> VPM, SII, MPIIB, TBVI	<b>M72 + AS01E</b> GSK, Aeras	<b>M. Vaccae</b> AnHui Longcom
	<b>H64 + CAF01</b> SSI, TBVI	<b>MTBVAC</b> Biofabri, University of Zaragoza, TBVI	<b>RUTI</b> Archivel Pharma	<i>M72 + AS01E</i> GSK, Aeras	
	<b>rBCGΔais1/zmp1</b> University of Zurich, Aeras, TBVI	<b>ChAdOx1.85A MVA85A</b> University of Oxford,	<b>H1/H56 : IC31®</b> SSI, Valneva, Aeras		
	<b>ChAdOxPPE15</b> University of Oxford, TBVI	<b>Ad5 Ag85A</b> McMaster University, Can Sino	<b>H4 : IC31 ®</b> SSI, Sanofi Pasteur, Aeras		
	<b>Therapeutic vaccine –MVA platform</b> Transgene SA, TBVI	<b>MVA85A-IMX313</b> University of Oxford, Imaxio	<b>ID93 + GLA-SE</b> IDRI, Aeras		
	<b>CysVac2/Advax</b> University Sydney, TBVI	<b>TB/FLU-04L</b> Research Institute for Biological Safety Problems, Kazakhstan	<b>DAR-901</b> Dartmouth University, Aeras		

- Vaccine candidates currently receiving technical and / or financial or other support from TBVI
- Vaccine candidates formerly receiving technical and / or financial support from TBVI
- Other candidates in the global pipeline

Source: Phase I-III: TAG pipeline report  
Update: December 2016

