



# TB Vaccine Development Strategy Overview

October 28, 2014

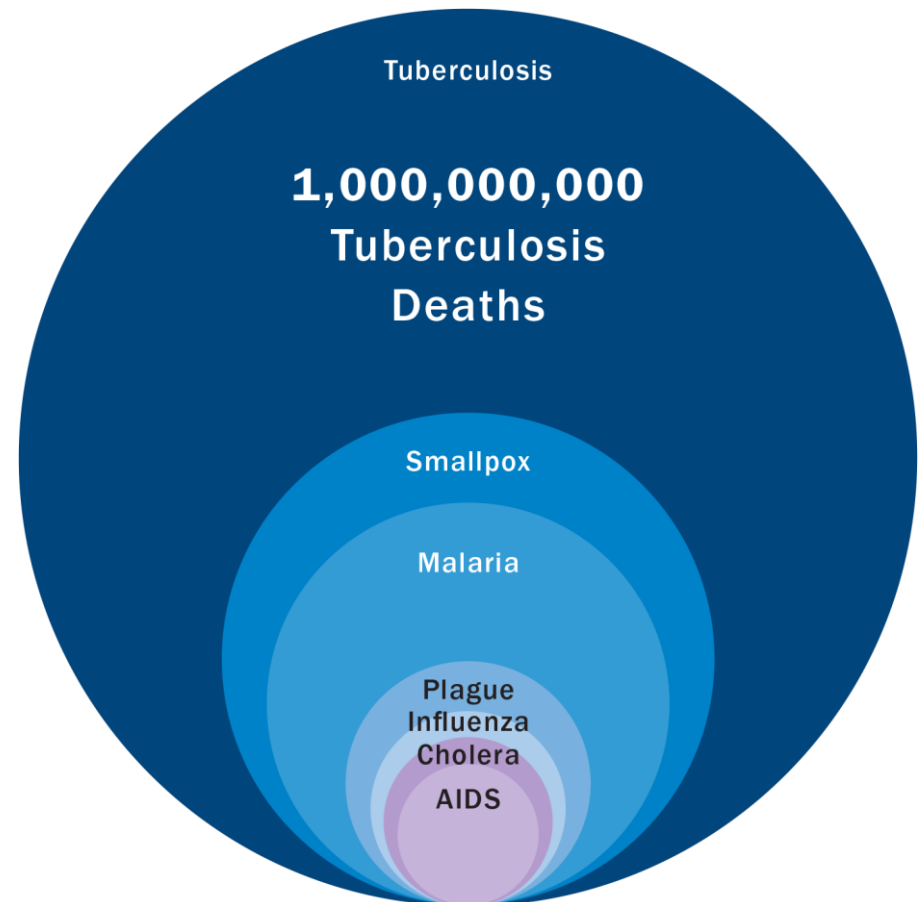
Angeline Nanni, MBA, MS

Aeras

Director, Global Access

# TB is Mother Nature's number one killer over the past centuries

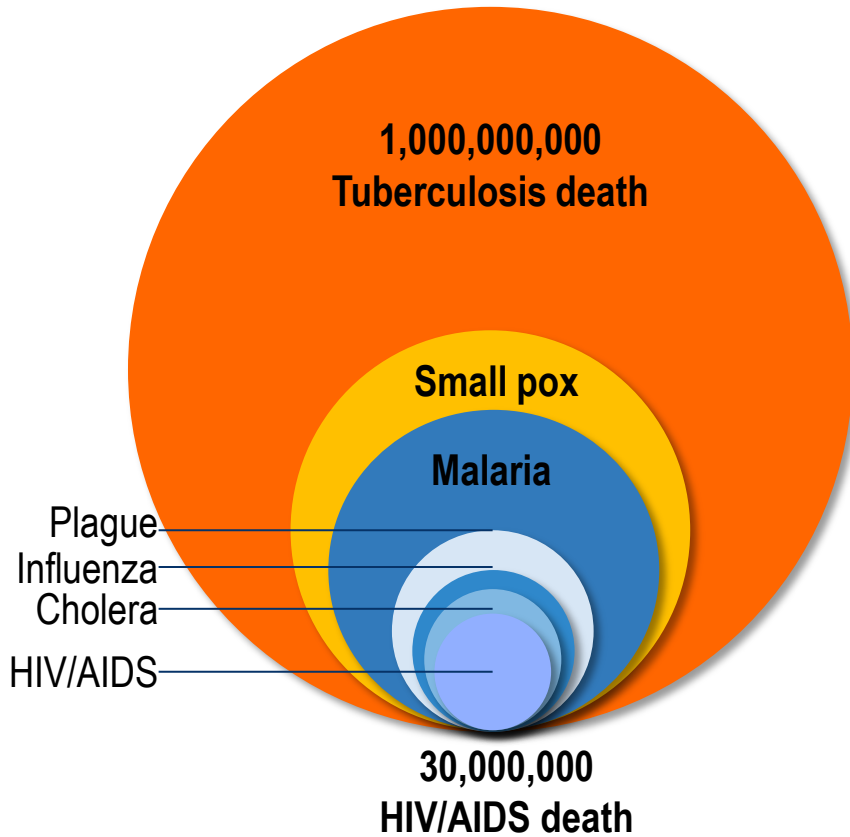
- TB is spread through the air like a common cold
- Nearly 8.5 million people become sick with TB each year
- TB kills 1 in 4 people infected with HIV
- 530,000 annual cases among children aged under 15
- 410,000 women killed annually by the disease



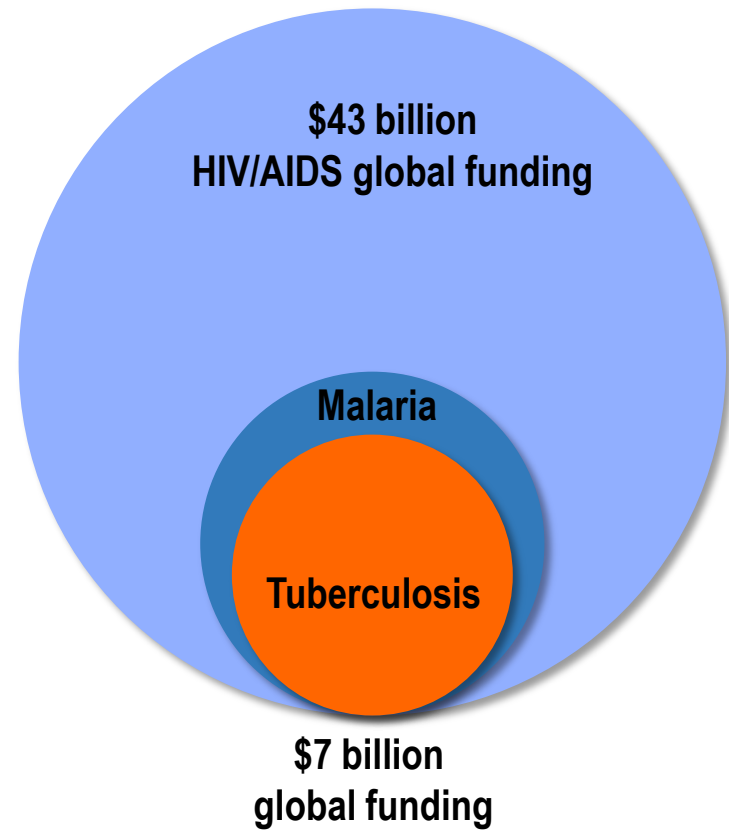
Source: Nature/ World Tuberculosis Report, 2013

# Yet, funding priorities have lagged relative to the morbidity and mortality of tuberculosis

Tuberculosis has led to more deaths in the last 200 years than any other infectious disease...



... but has received significantly less funding in the last 10 years as compared to HIV and malaria<sup>1</sup>



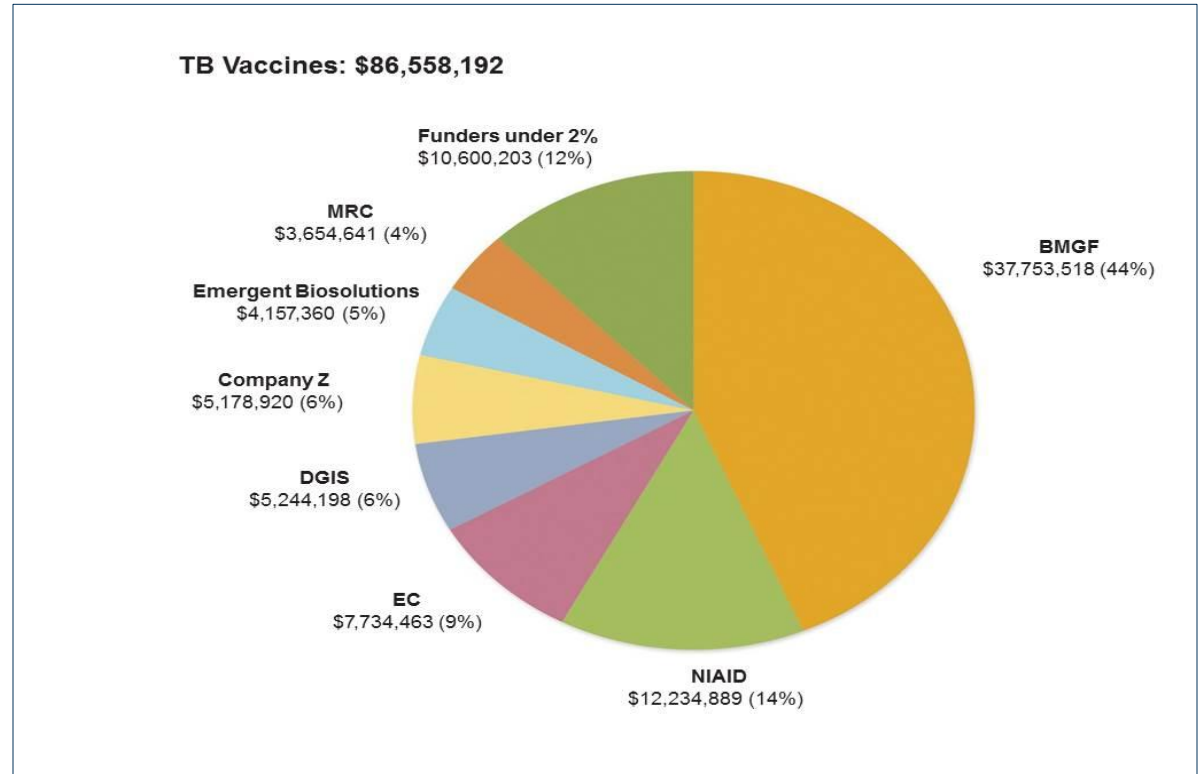
<sup>1</sup> Based on OECD and IHME Development Assistance for Health (DAH) funding data

Source: Global Tuberculosis Report 2012, WHO (2012), Nature Vol 502, No. 7470 Suppl, S2 (2013), Financing Global Health 2012, IHME

# Who is funding the TB vaccine field?

## 5 funders comprise 80% of global resources

- Limited number of new governments coming on board to support PDPs
- Alignment around a scientific strategy among major donors is poor



- Estimated <\$500 million required to strengthen and advance the global portfolio - highly cost-efficient portfolio management approach through 2021
  - Today, <22% of the total needed funding is earmarked/committed
  - Only 2 major donors (BMGF & DFID) committed through 2016

# The cost of underfunding TB vaccine development: economic impacts

## COUNTRIES

TB costs the global economy an estimated \$1Billion each day

## GROWING COST OF DRUG-RESISTANT TB\*

Cost of treatment for MDR - \$6,772 per patient in South Africa and \$113,000 in the U.S.

Treatment for one XDR patient - US\$250,000 in the Industrialized countries

## BUSINESS SECTOR

Emerging economies, for example, China estimated to be up to \$1.182 Trillion from 2006-2015

Annual cost to the South African mining sector is over \$880 million

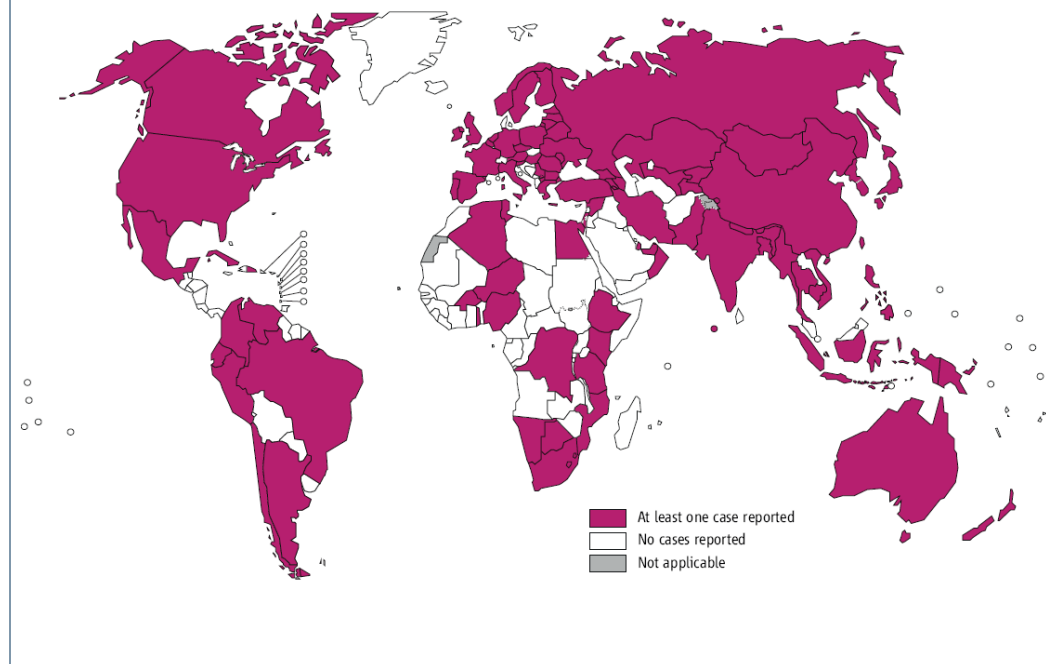
## FAMILY

TB primarily strikes down working-age adults

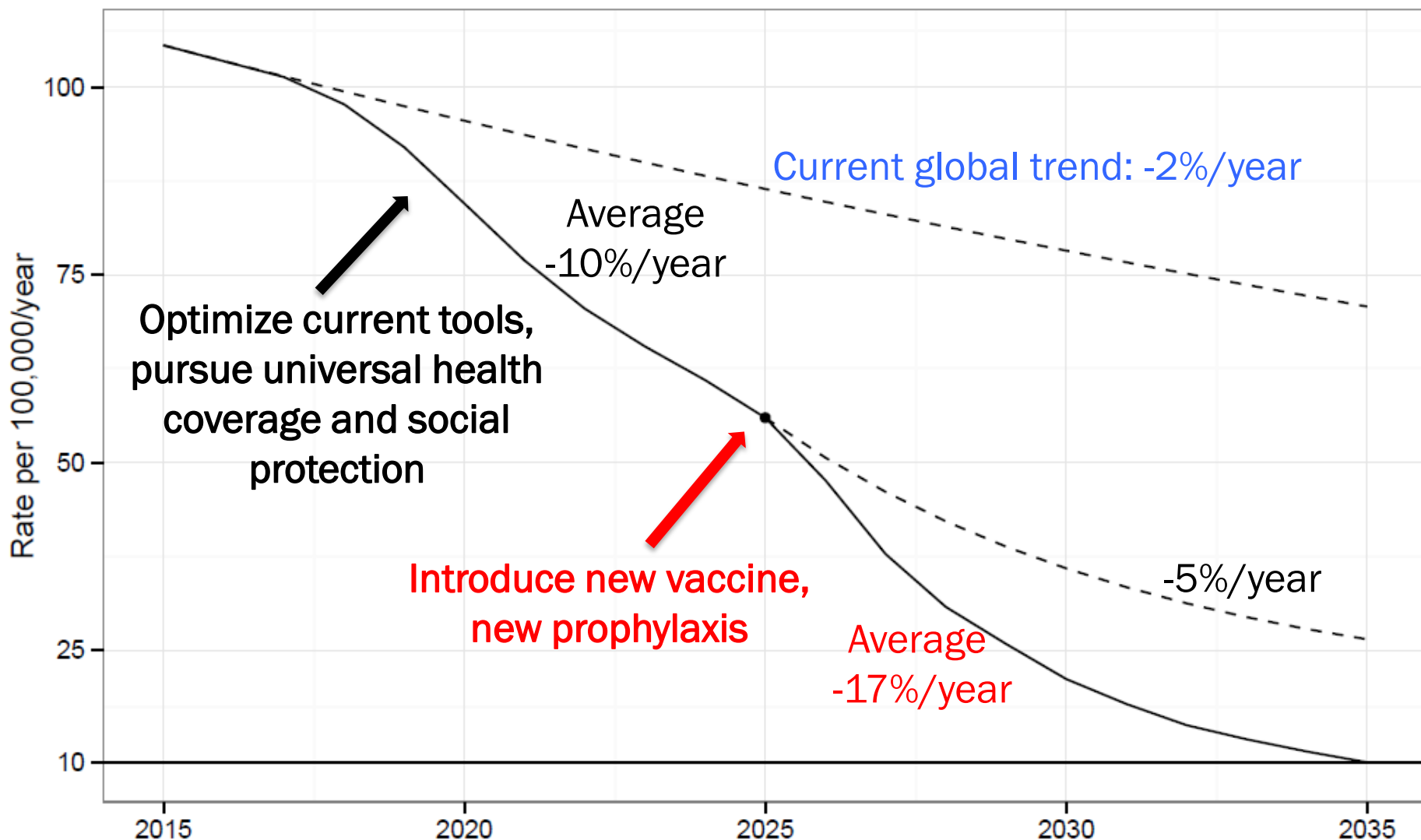
# Antimicrobial Resistance is Confounding Global Efforts to Control the Epidemic

- ~ 650,000 drug-resistant cases in 2013
- 1 in 5 individuals with drug-resistant TB are being accurately diagnosed and even fewer are receiving appropriate treatment
- Current treatments for drug-resistant strains require a minimum of 2 years using highly toxic drug regimens
- Evolving with some strains becoming virtually untreatable

92 countries have reported at least one case of XDR-TB



# Vaccines feature prominently in the Post-2015 Global Agenda: Targets approved by World Health Assembly in May, 2014



# Major challenges facing the TB vaccine field

## Scientific

- Lack of correlate or biomarker of protection
- Current preclinical portfolio lagging and lacks sufficient diversity
- Human challenge model not yet developed
- Development timelines long and expensive
- Animal models not validated



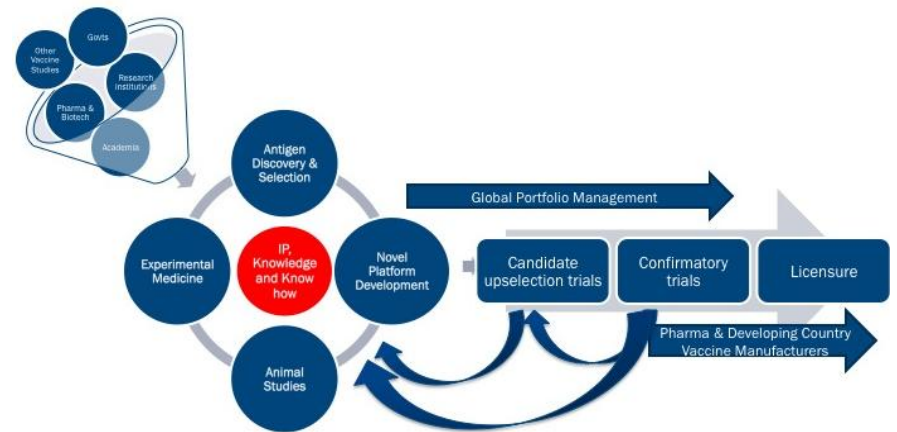
- Discovery field lacks mechanisms to address gaps and opportunities generated by findings from clinical development



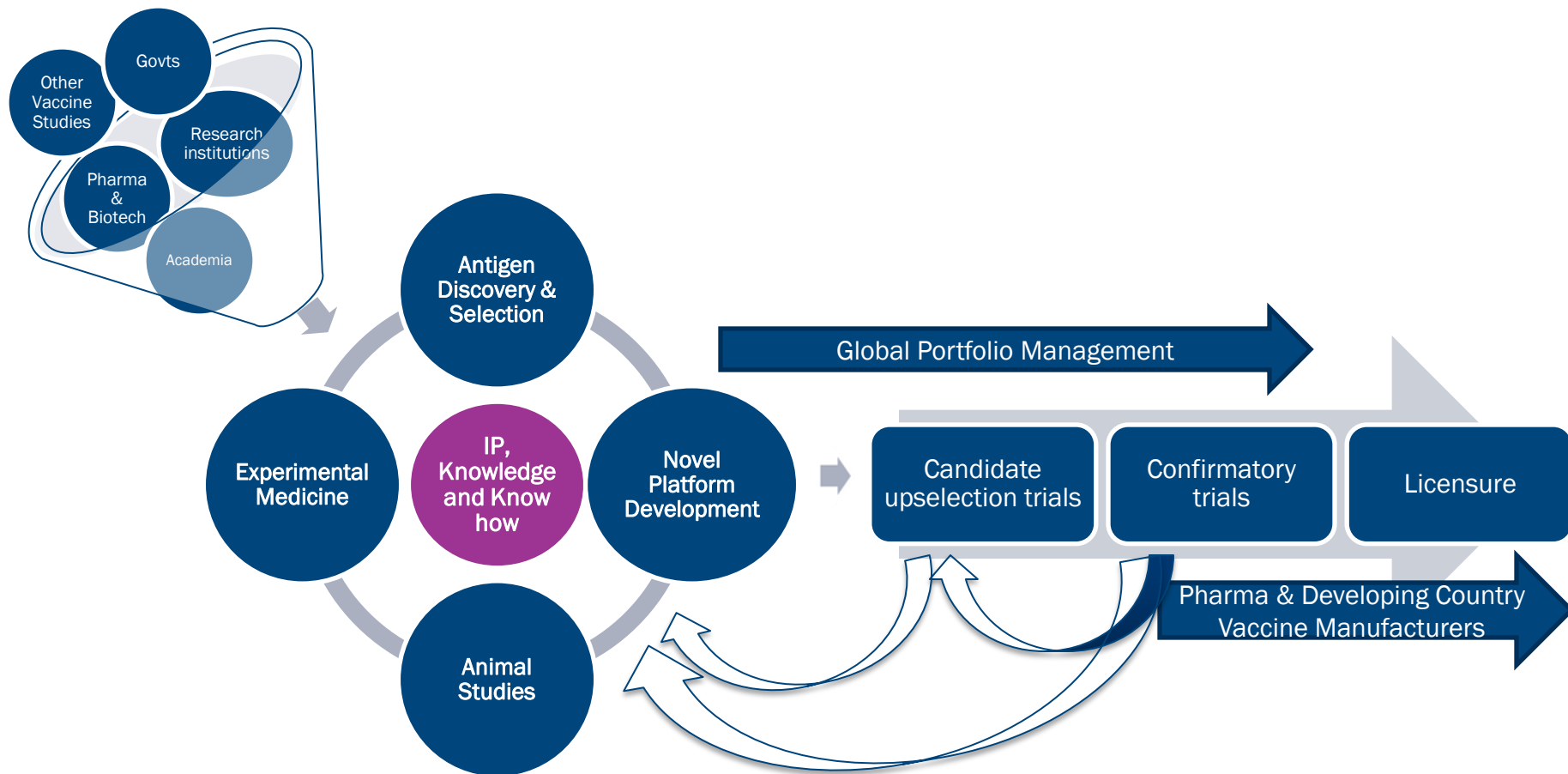
# Aeras strategic objectives to address challenges

Through enhanced collaboration with key stakeholders:

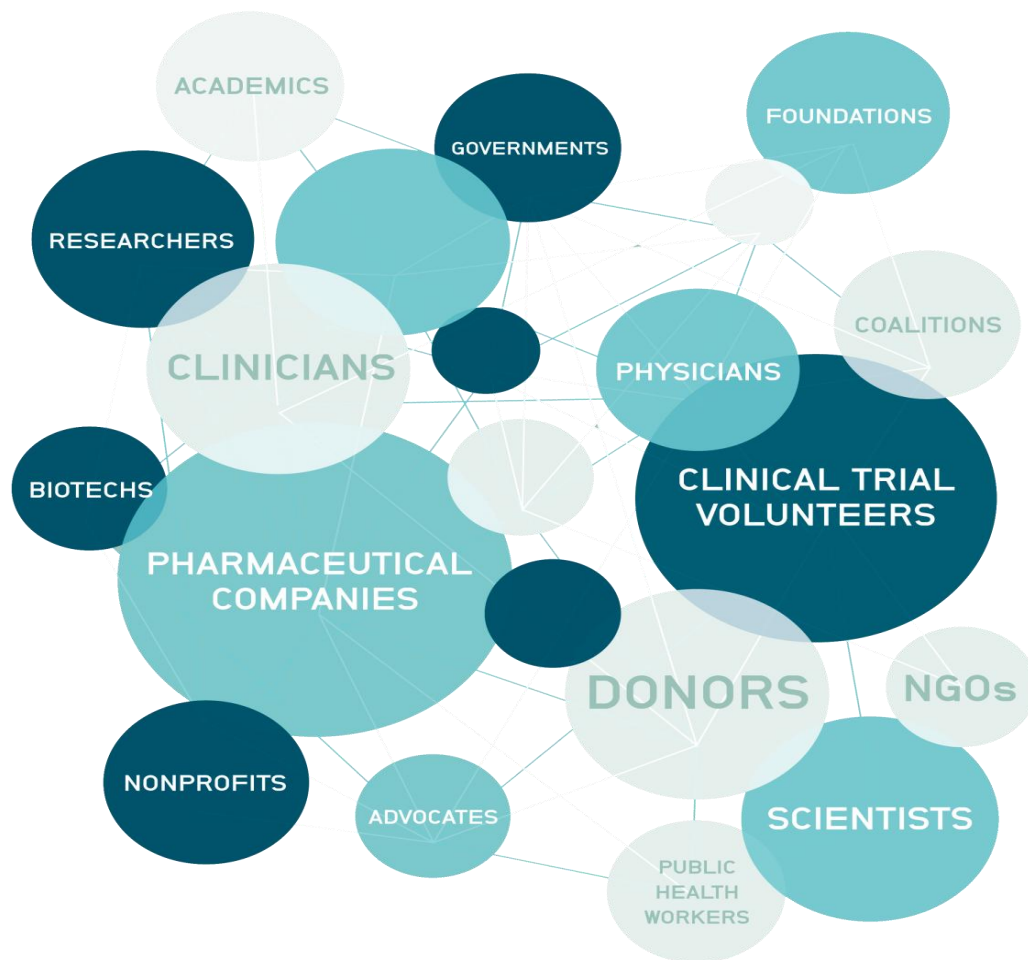
1. Strengthen and diversify the preclinical pipeline
2. Employ an iterative cycle of preclinical, animal model and experimental trials in humans to define the strengths and weaknesses of a variety of platforms and approaches
3. Advance diverse and novel candidates into innovative trials to assess for biological effect
4. Utilize a cost-effective portfolio management approach, advance selected candidates into larger Proof-of-Concept studies
5. Expand the worldwide support of TB vaccines through advocacy, outreach and education



# Aeras 'field of engagement' includes collaboration with partners and a dynamic feedback loop

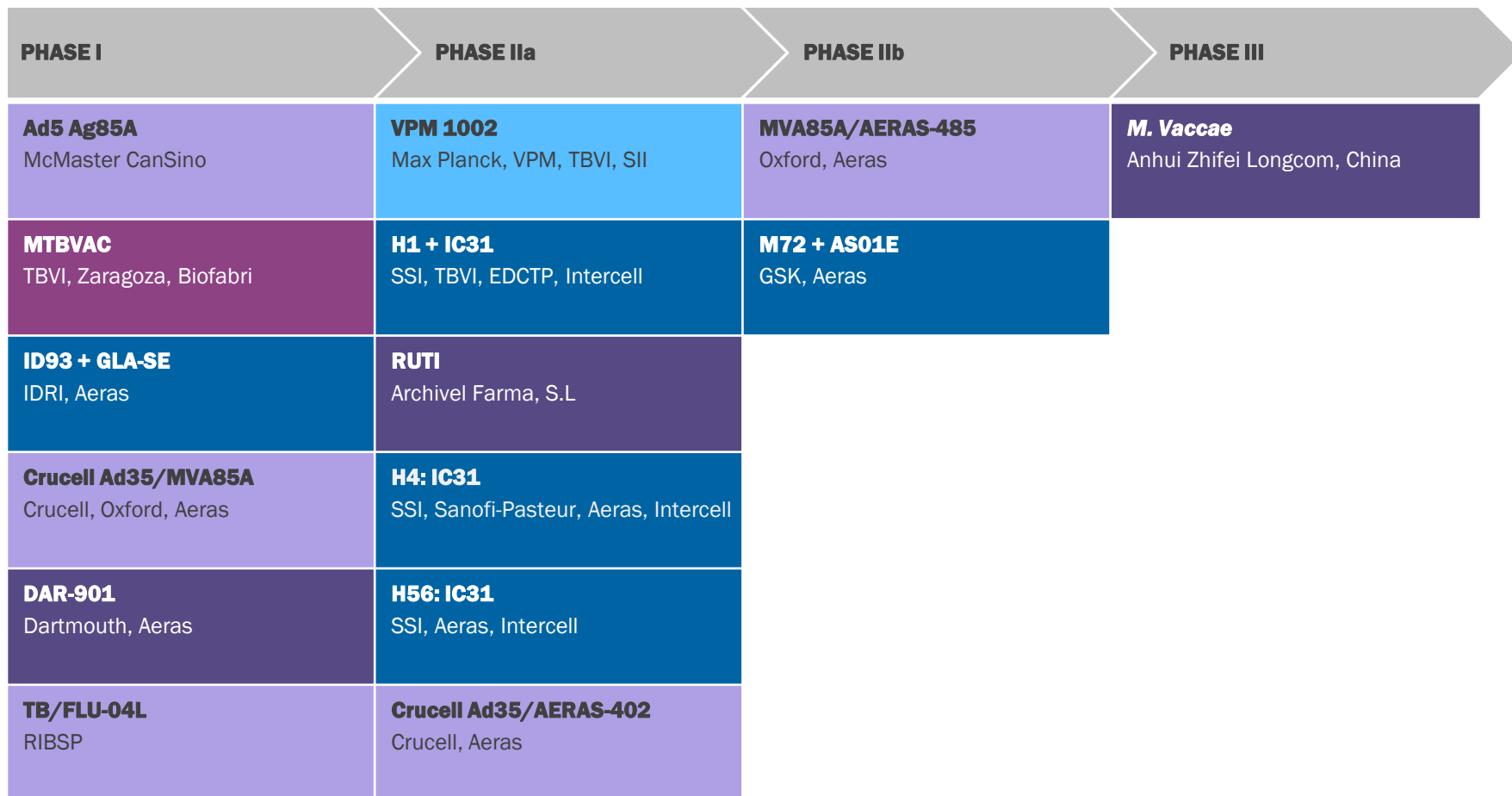


# Engagement of strategic partners is critical




- Engage, listen and learn in affected countries and regions
- Network with a wide variety of stakeholders
- Only enter areas in which Aeras represents added value
- Develop local offices and expertise- SA and China

# The Global Clinical Pipeline of TB Vaccine Candidates



 VIRAL VECTOR

 PROTEIN/ADJUVANT

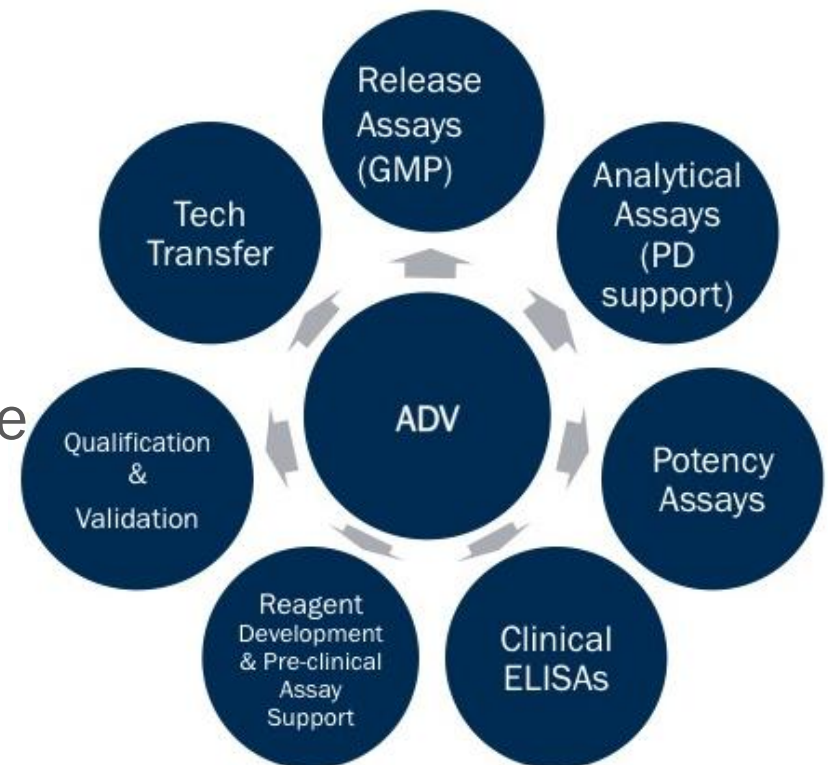
 MYCOBACTERIAL – WHOLE CELL OR EXTRACT

 rBCG

 ATTENUATED *M. Tb*

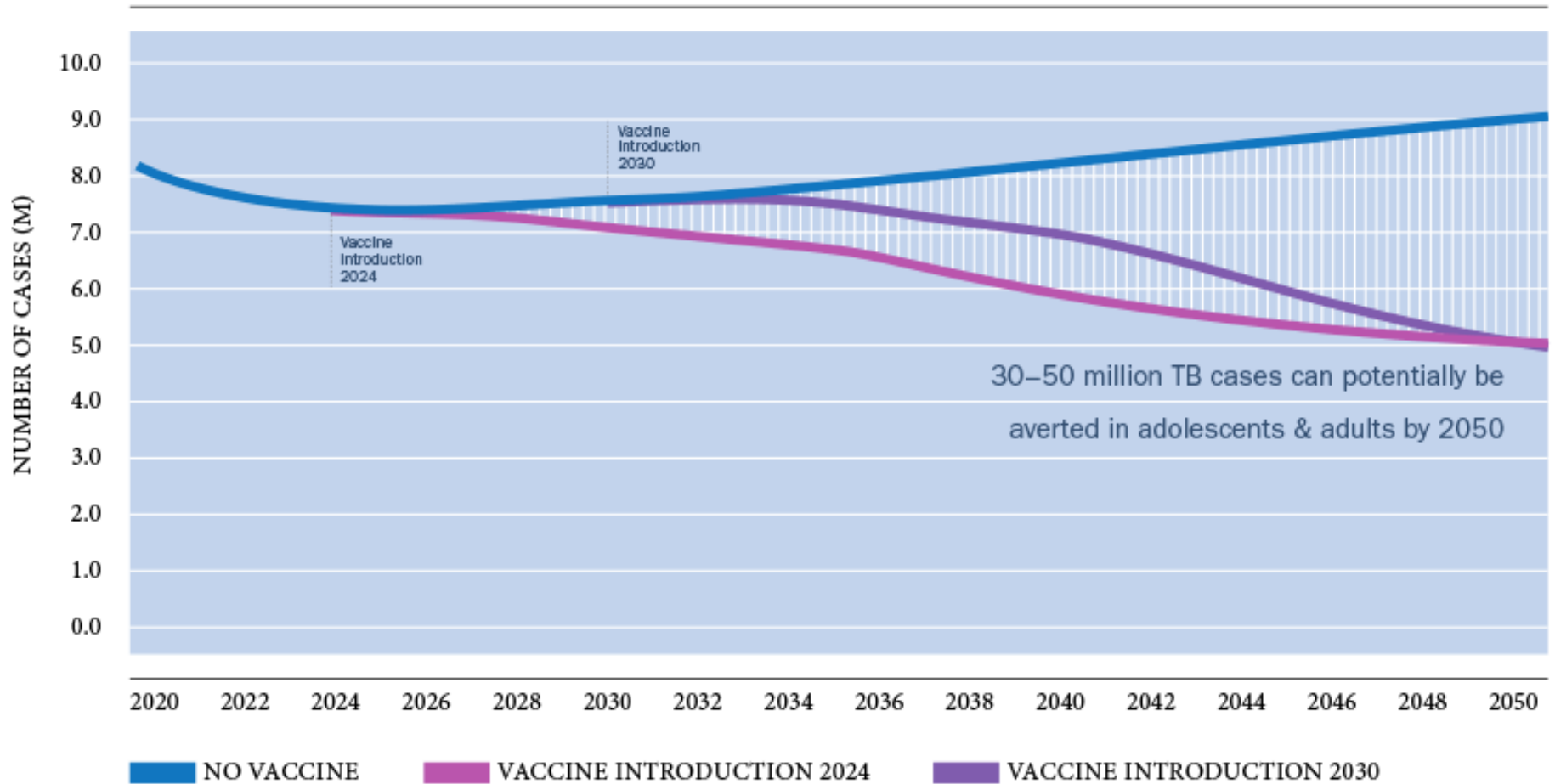
# Aeras serves as a critical translational bridge for product development in the area of CMC

- Characterization of the GMP manufactured product
  - Potency, identity and stability
- Providing quality control mechanisms and risk assessment characterizations that more closely resemble more experienced manufacturers
- Assay development and qualification to determine immunogenicity



# Potential Health Impact of New TB Vaccines

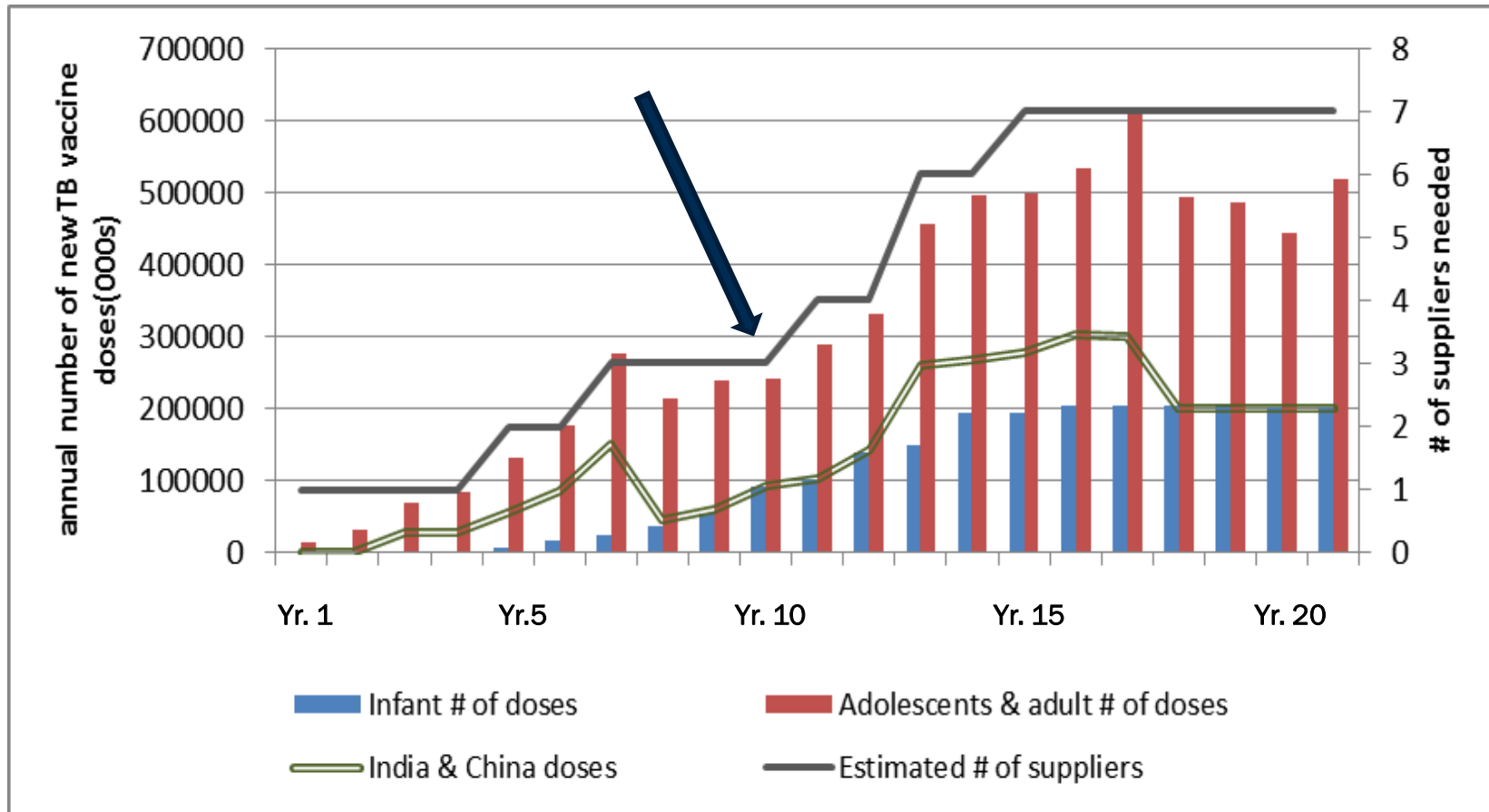
Range of TB Adolescent & Adult Incident Cases Averted



30–50 million TB cases can potentially be averted in adolescents & adults by 2050

An additional 7–10 million TB cases can be averted in infants by 2050

# TB vaccines early estimates of global supply & demand potential

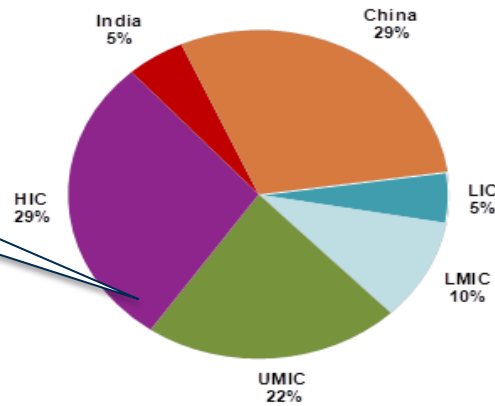


A minimum of 3 suppliers would be required to meet potential demand within 10 years after vaccine introduction (~250,000 M - 300,000 M)

# Overall market revenue potential

HICs & China dominate the market returns

Market Revenues 1st 10 Years by Segment - Conservative Case

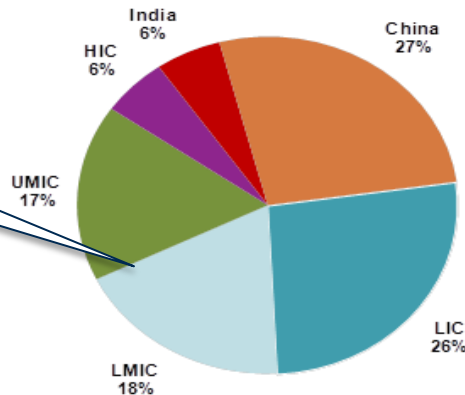


Total Market Potential (\$000)

13,626,873

MICs & China dominate the vaccine supply

# of Doses 1st 10 Years by Segment - Conservative Case



Total # of Doses (000)

1,658,432



# So how can the DCVMN support TB vaccine development

**DCVMN - over 40 vaccine manufacturers representing 17 countries**

- China
- India
- Indonesia
- Thailand
- South Africa
- Viet Nam
- Bangladesh
- Brazil

**High degree of interest for TB vaccine development**

**- high burden of disease**

**or**

**- existing partnerships**

**or**

**- manufacturing capacity**

**or**

**- clinical trial capacity**

# Major Funders and R&D Partners



Rijksoverheid



# Thank you.

[www.aeras.org](http://www.aeras.org)

**AERAS** | Advancing Tuberculosis  
Vaccines for the World