



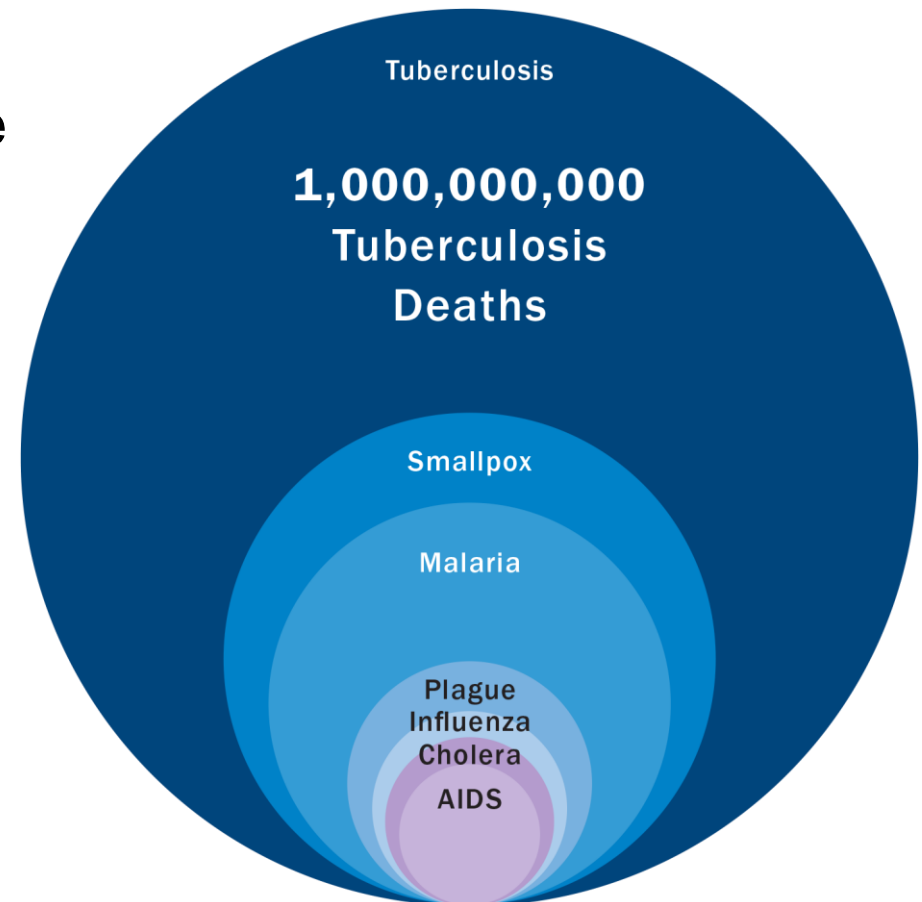
December 1, 2015

# Tuberculosis

Dr. Sharon Chan, Head of Asia

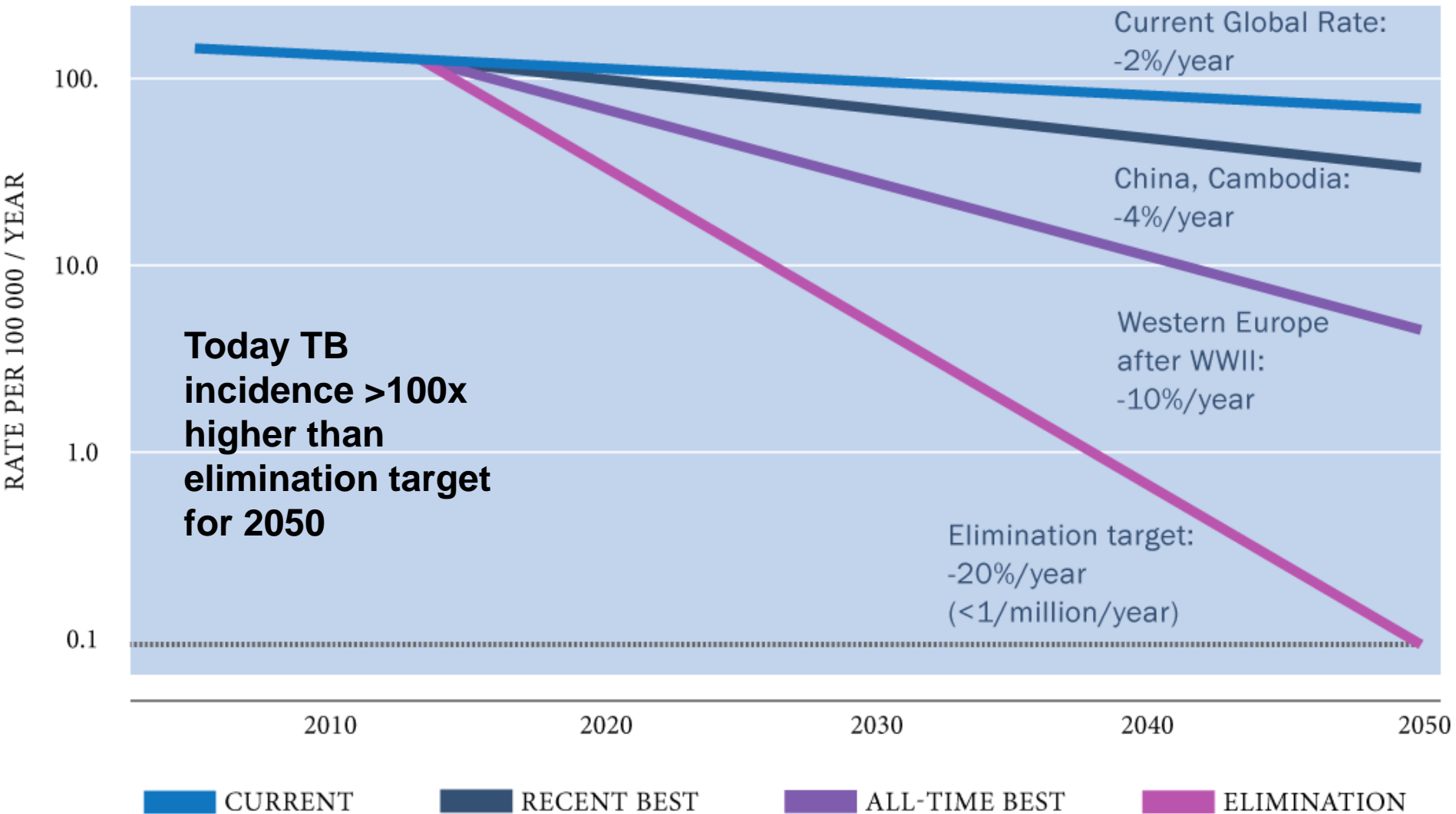
# TB is Mother Nature's number one killer over the past centuries

- TB is spread through the air like a common cold
- 9.6 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

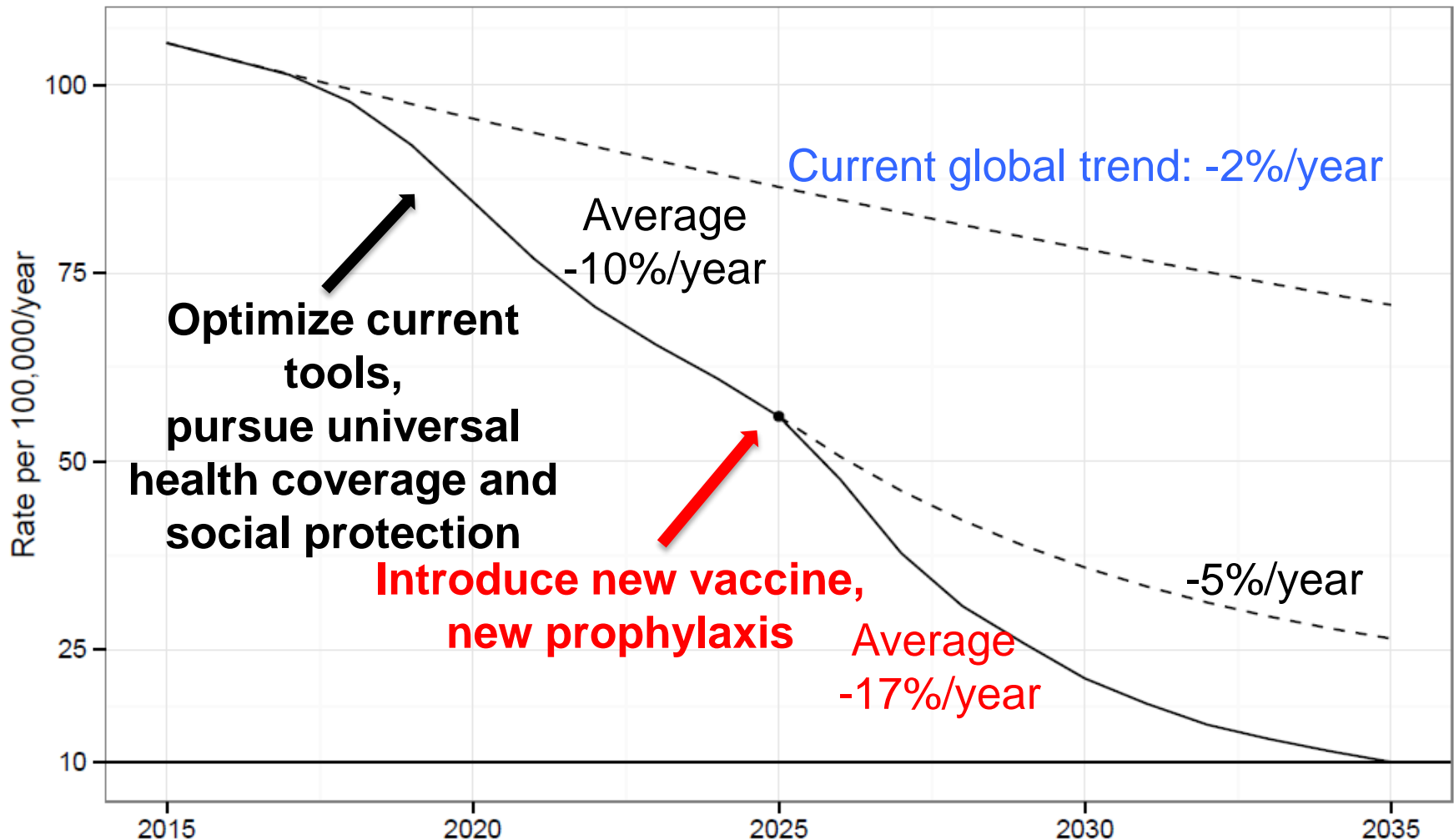


Source: Nature/ World Tuberculosis Report, 2013

# TB will not be eliminated by 2050



# Projected acceleration of TB incidence decline to target levels





**THE NEED FOR**

**A NEW VACCINE**



# THE NEED FOR A NEW VACCINE

“Vaccines are the most effective and cost-effective health tool ever invented. I like to say vaccines are a miracle”

**Bill Gates**

Bill & Melinda Gates Foundation

2011 Annual Letter

# 90-year-old BCG vaccine is the most widely used vaccine in the world


Reduces the risk of severe pediatric TB disease, but:

- Unreliable protection against adult pulmonary TB, which accounts for most TB worldwide
- No significant impact on the global TB epidemic
- Not known to protect against latent TB
- Not recommended for use in infants infected with HIV



# 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
  - High disease-burden, middle-income countries with manufacturing largely operating independently from efforts by the EU/US scientific community

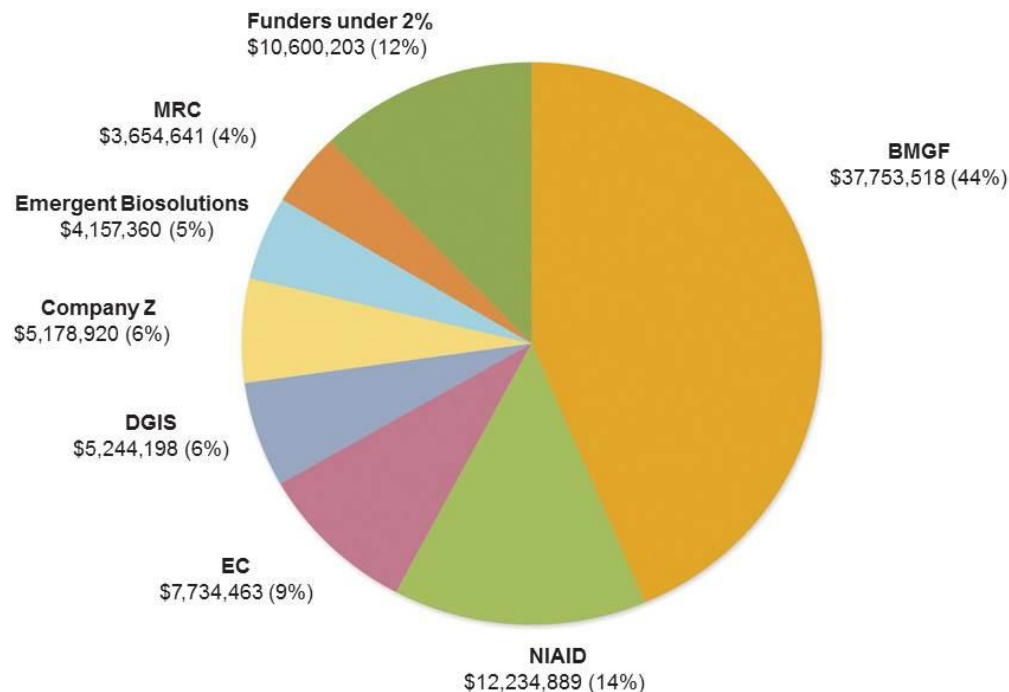


# Major challenges facing the TB vaccine field

## Financial

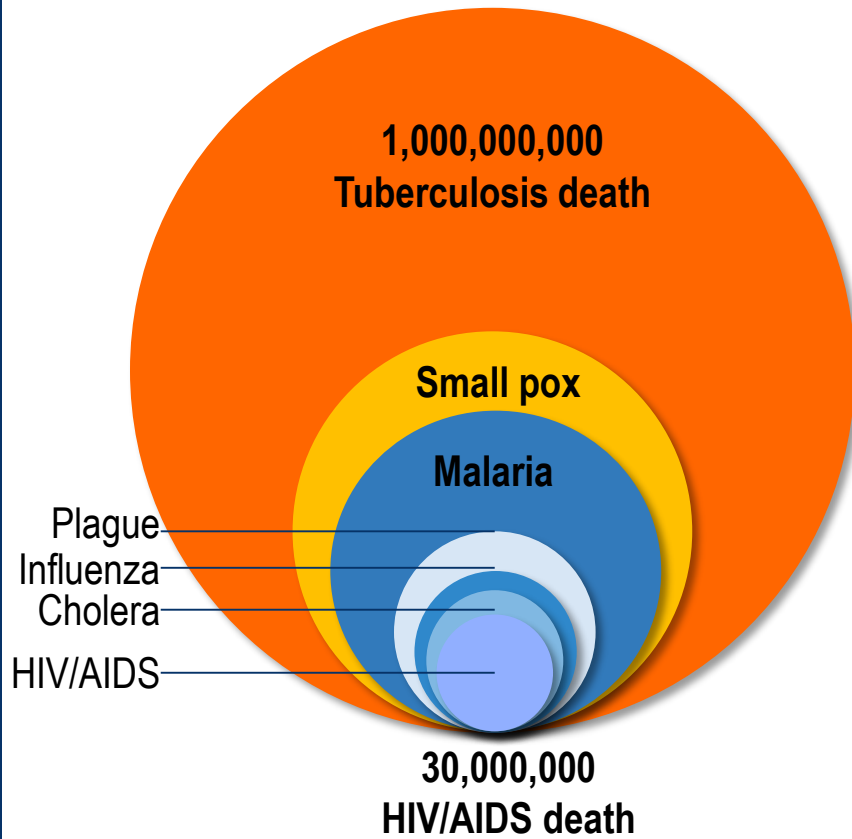
- Small group of funders (5 funders comprise 80% of global resources)
- Limited number of new governments coming on board to support PDPs
- Alignment around a scientific strategy among major donors is poor

TB Vaccines: \$86,558,192

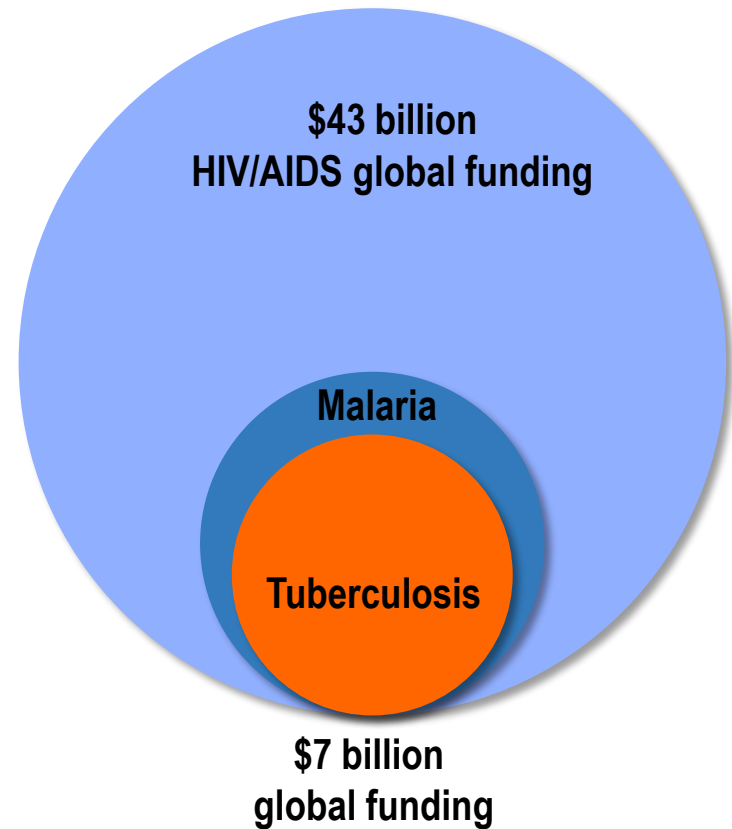


# Funding priorities have lagged relative to the morbidity and mortality of tuberculosis

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

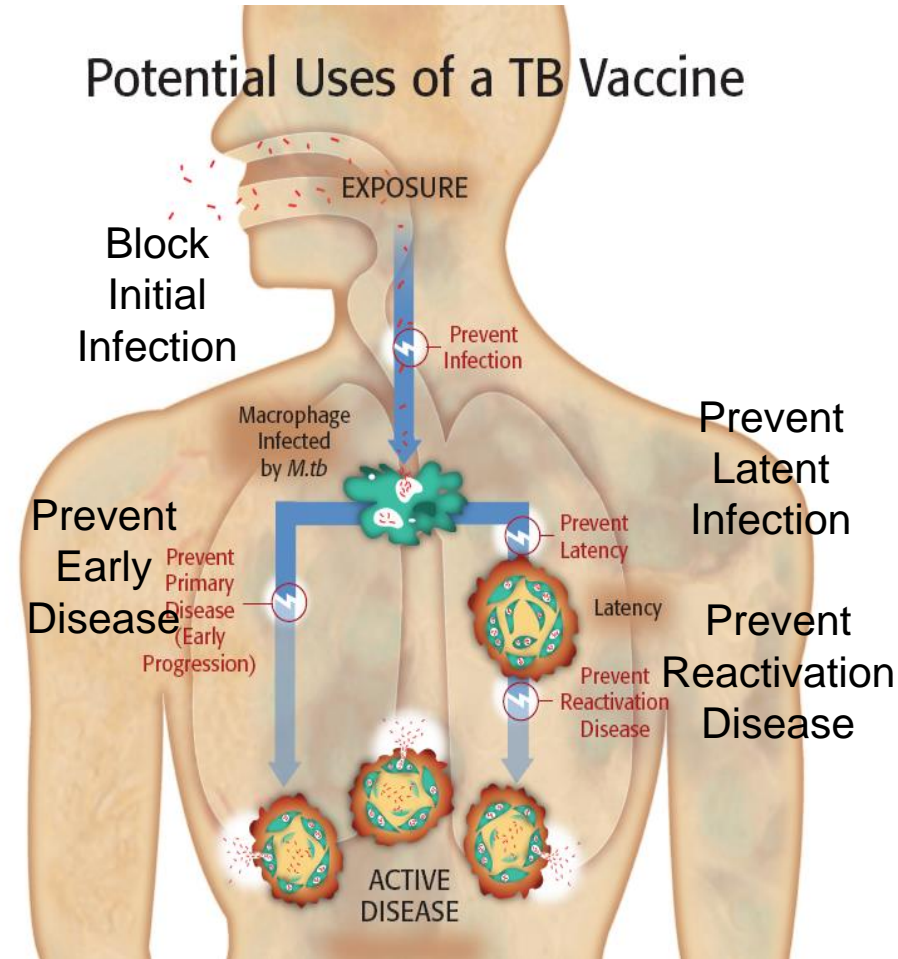


... but has received significantly less funding in the last 10 years compared to HIV and malaria<sup>1</sup>



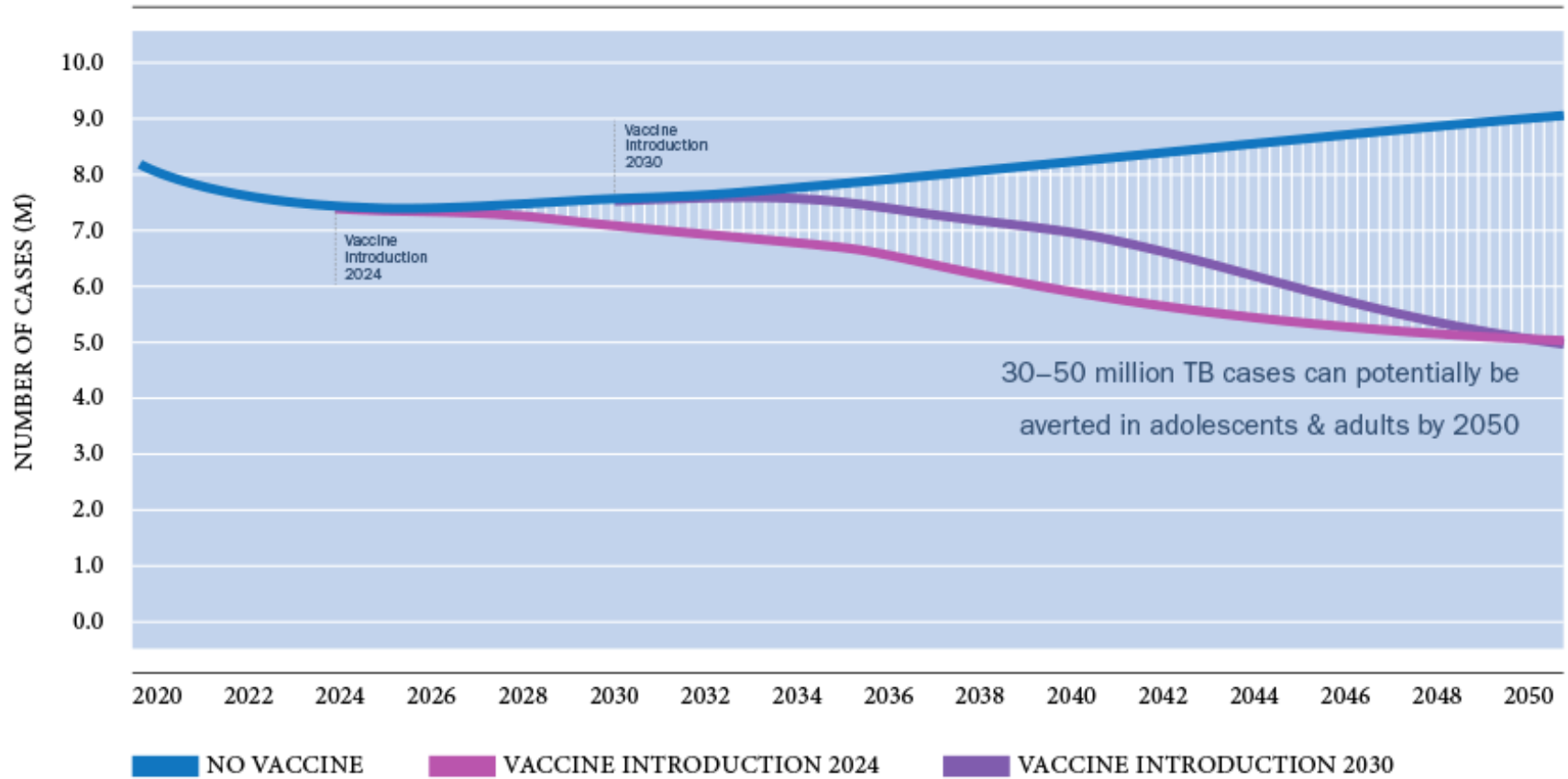
# Strategies for TB Vaccine Development

- **Pre-infection:** to prevent infection
- Either initial infection or establishment of the granuloma
- **Post-infection:** to prevent disease
- after initial infection (most animal data to date)
- reactivation from latency (minimal animal data)
- **Immunotherapeutic:** treatment
- Shorten the course of chemotherapy for active TB
- Decrease relapse or reinfection rates (may correlate to latency)



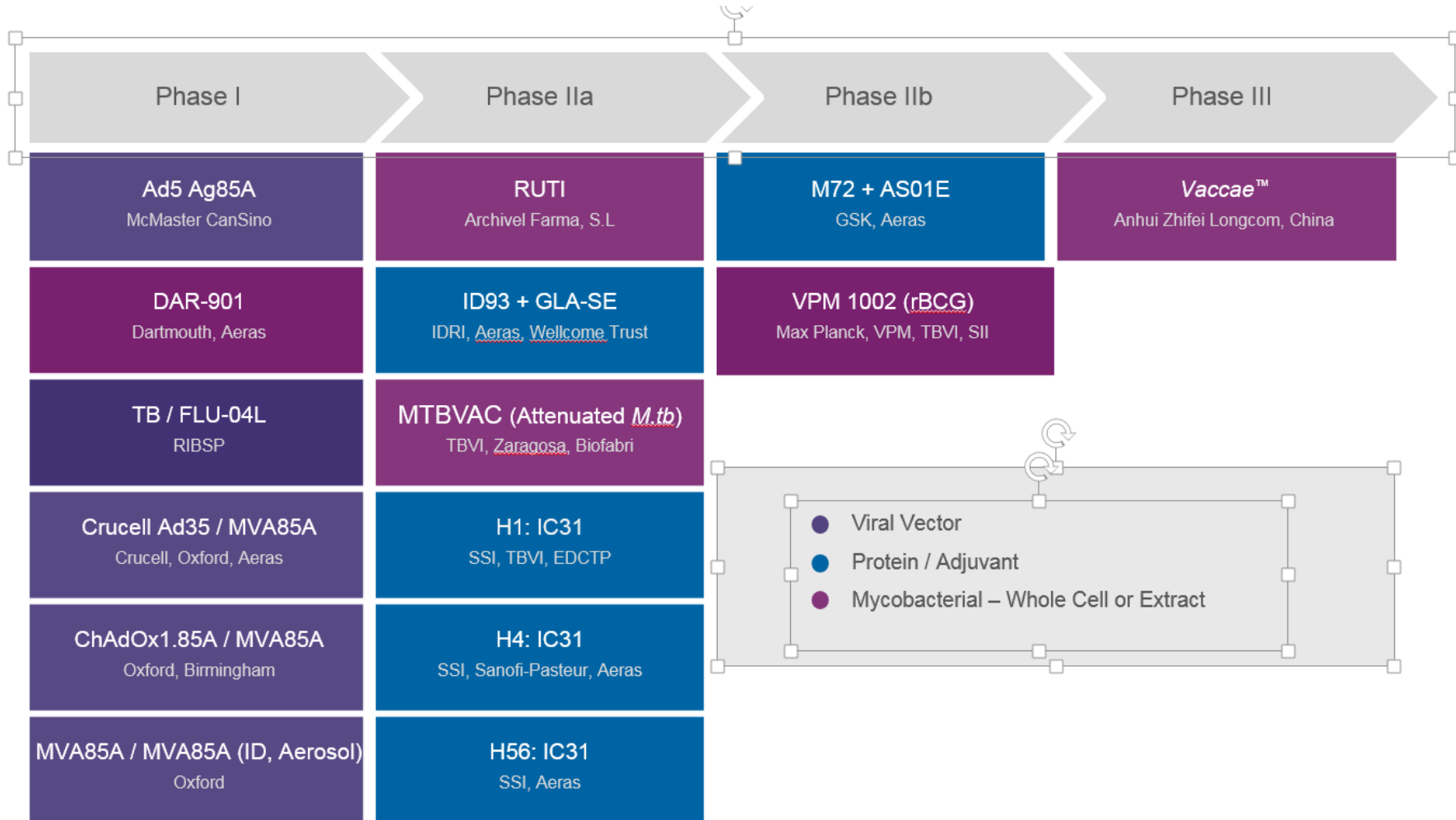
# Focusing on making vaccines that will have the greatest impact

Range of TB Adolescent & Adult Incident Cases Averted



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

# Global Clinical Pipeline of TB Vaccine Candidates



Please note: Information is self-reported by vaccine sponsors

# What's happening in today basic science?

## Antigen Discovery & Selection

- Antibody-based approaches
- Non-classical T cells
- Classical T cells

## Novel Platform Development

- CMV, Aerosol, Chimp Ad, mucosal delivery
- RNA, EP-DNA, Combinations
- Whole cell mycobacteria

## Animal Studies

- Low dose challenge
- Natural transmission models
- Modern imaging technology

## Experimental Medicine

- Intensive, small immunologic studies
- Human challenge model development
- Biologically relevant endpoints

# Collaboration is key in an unprecedented effort





BILL & MELINDA  
GATES *foundation*





# Thank you.

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

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