

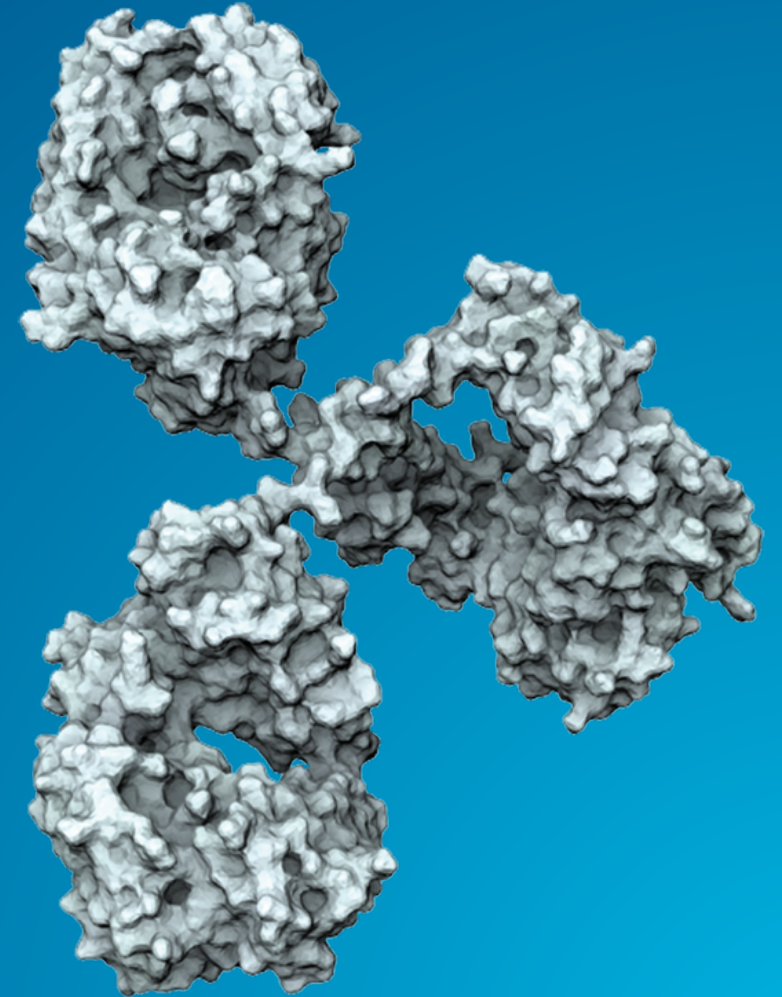


Translating **science** into  
**global** health impact

# TB vaccine R&D: An overview

**Ben Coates, Advocacy Manager, Europe**

TBEC Webinar| 28<sup>th</sup> September 2020



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As of September 2020

# IAVI's Mission

*Translating scientific discoveries into affordable, accessible public health solutions to help the people who need them most*

## What We Do:

**Discover** new approaches to developing vaccines and other global health tools

**Accelerate** translational and clinical research through our laboratories in the U.S., India, and the U.K.

**Build Capacity** in-country for researching vaccine candidates while strengthening local public health and scientific expertise.

**Share** our resources with other innovators to help the global health community as a whole succeed.

**Extend** our core capabilities to solving disease prevention and treatment challenges.

# An expanded mission

For more than 20 years, IAVI has been a leading force in HIV vaccine research. That mission continues unabated, and now we're also leveraging HIV and TB expertise\* to generate innovative solutions to the world's most intractable infectious and neglected diseases by building new partnerships and coalitions.

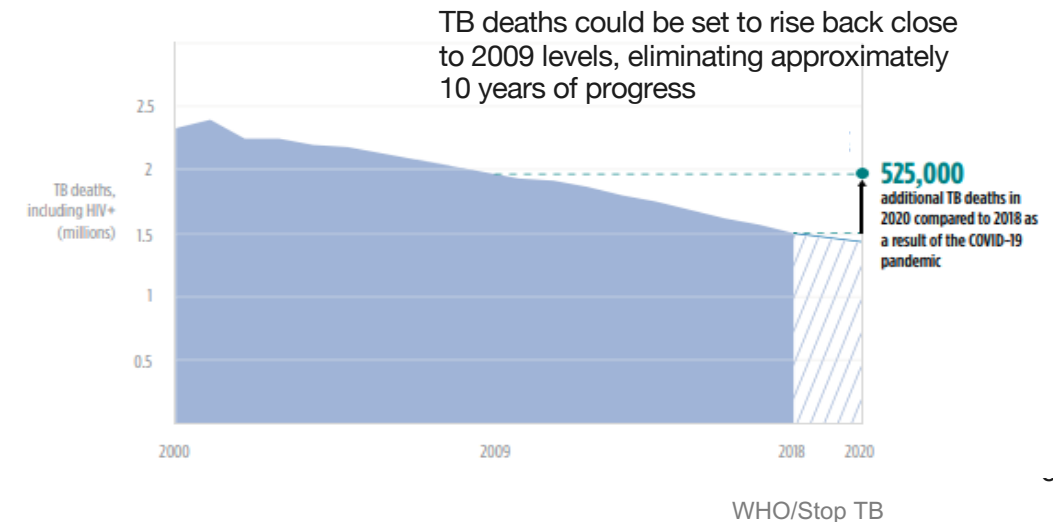
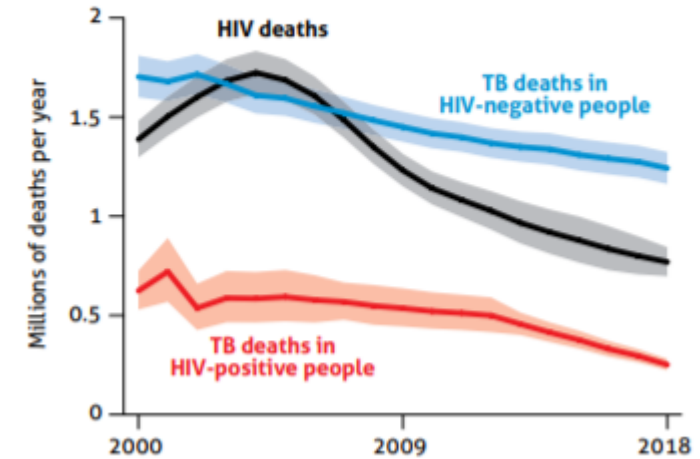
\*In October 2018, IAVI acquired tuberculosis vaccine clinical research programs and assets, including clinical staff, from Aeras, the product development nonprofit focused on TB vaccines.



# TB is still a major threat to global health

- In 2018, an estimated 10 million people fell ill with TB and at least 1.2 million people died – the equivalent of over three thousand lives lost every single day.
- According to the WHO, “TB is ... a major cause of ill health, one of the top ten causes of death worldwide and the leading cause of death from a single infectious agent, ranking above HIV/AIDS”.
- In 2018, the 30 high TB burden countries accounted for 87% of new TB cases. Eight countries (including India, China and Indonesia) account for two thirds of the total.
- MDR-TB is a growing problem. In 2018, there were about half a million new cases of rifampicin-resistant TB, of which nearly four hundred thousand involved multidrug-resistant TB.
- COVID-19 risks making things far worse: Stop TB estimates between 2020 - 2025 an additional 1.4 million TB deaths could be registered as a result of the pandemic

Global trends in the estimated number of deaths caused by TB and HIV, 2000–2018.<sup>a,b</sup> Shaded areas represent uncertainty intervals.





# New TB vaccines are needed



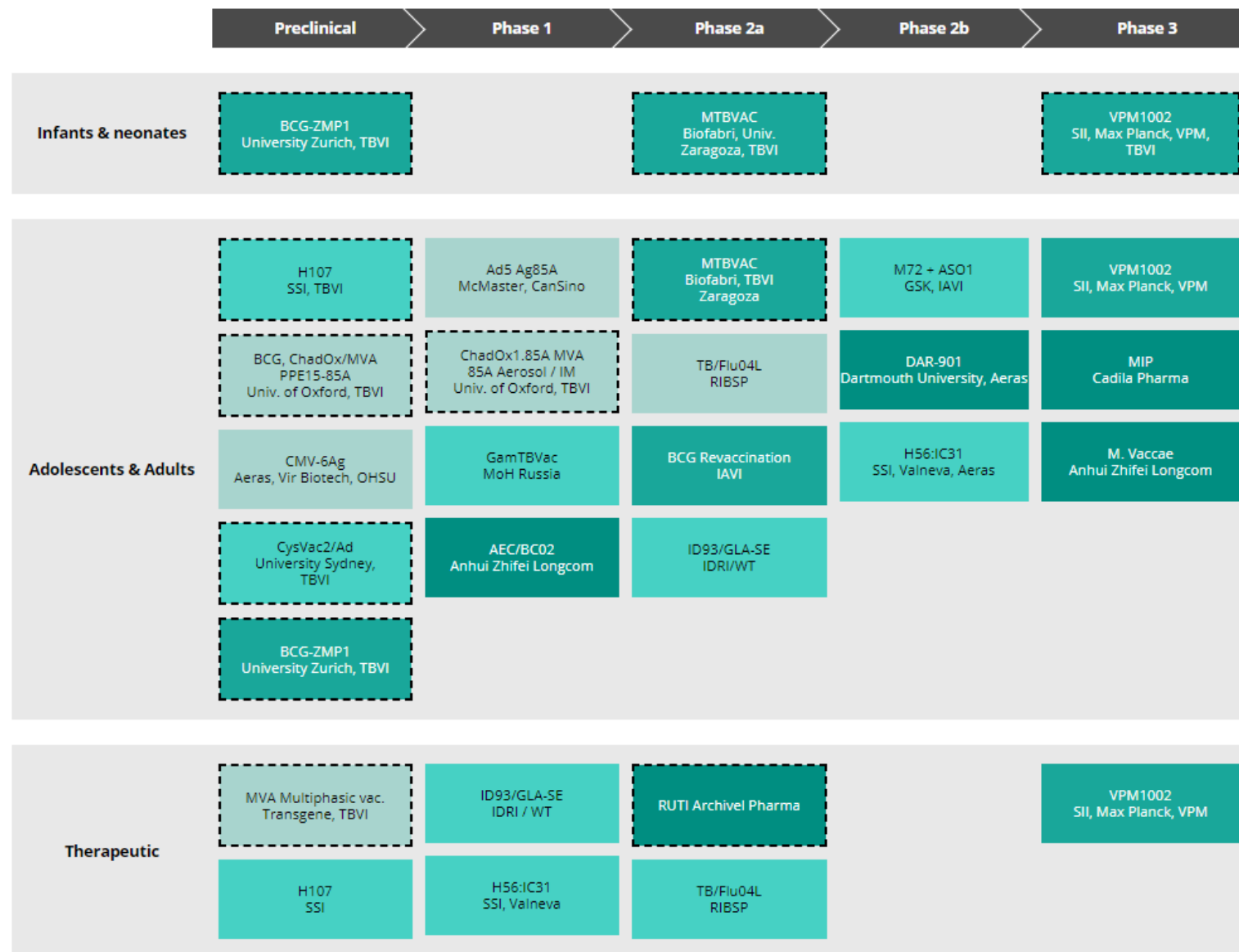
- The only existing TB vaccine, BCG, was first used around 100 years ago, and while partially effective in preventing severe forms of TB in infants and young children, does not adequately prevent pulmonary TB in adolescents and adults. If you get vaccinated against TB today, the doctor will be using a vaccine which is roughly the same age as the Model T Ford.
- We don't have new TB vaccines partly because developing them is difficult, but mostly because their development hasn't been prioritized. In 2018, the world spent a total of around \$750 million on R&D for new HIV/AIDS vaccines and around \$160 million on malaria vaccines – but only about \$65 million on developing TB vaccines.
- One study estimated that only 1.1 percent of new drugs approved between 1975 and 1999 were for poverty-related and neglected diseases, despite them represented 12 percent of the global disease burden.

# Exciting advances



- The last few years have seen some genuine breakthroughs in the development of TB vaccines, with numerous candidates advancing through the pipeline.
- In late 2019 GSK and IAVI reported that the **M72/AS01<sub>E</sub> candidate vaccine** was significantly protective against pulmonary TB in HIV-negative adults with latent TB infection.
  - The trial was conducted in TB-endemic regions (Kenya, South Africa and Zambia) and involved about 3,500 people, who were given either the M72 vaccine or a placebo. 13 people who got the vaccine went on to develop active pulmonary TB, compared to 26 in the placebo group – meaning the overall vaccine efficacy was 50%, with an immune response sustained for three years. This represents the first time in almost a century that a new vaccine has been shown to help provide protection against TB disease
- Separately, another trial found that revaccination with the **BCG vaccine** could help significantly reduce sustained TB infections in adolescents.
- Research into the use of TB vaccines to treat and prevent Covid-19 is also underway.
- Several other candidates are also moving through clinical trials – we are arguably closer than ever to having a new vaccine

# The pipeline



Live
  Wholecell
  Subunit
  Vector

TBVI



# Challenges remain

- TB vaccine development is at a critical juncture. In order to bring game-changing new vaccines to market, we need to conduct late stage efficacy trials for the M72 candidate, prepare for licensure and use of a new TB vaccine, build understanding the epidemiology of TB, and continue advancing a diverse portfolio of vaccine candidates.
- Some of the scientific obstacles are complex, but one of the biggest barriers is funding – later-stage clinical trials can run to hundreds of millions of dollars.
- Globally, R&D funding is concentrated on a few large donors - the NIH, the Gates Foundation and a few pharmaceutical firms collectively provide nearly three-quarters of TB vaccine R&D funding
- There's also a problem of the pipeline drying up –after decades of underinvestment, if current leading candidates fail, we don't have a large number of alternatives in advanced development.
- We need to advance TB vaccine candidates in late stage efficacy trials and prepare for TB vaccine implementation – but also develop next generation candidates to address current and future unmet needs and facilitate human correlate identification to streamline TB vaccine development.
- Sustained investment in R&D is therefore essential.

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