Urgent Need for Global Investment in TB Vaccines

Stop TB Partnership Board Meeting

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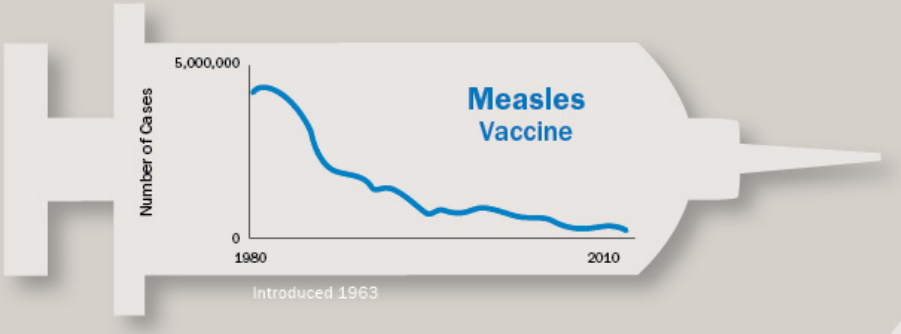
Aeras

Vaccines: An Extraordinary Track Record

"A more effective vaccine would be the single most powerful tool to reduce the incidence of TB."

— The Bill & Melinda Gates Foundation



Introduced 1963

Measles Stats

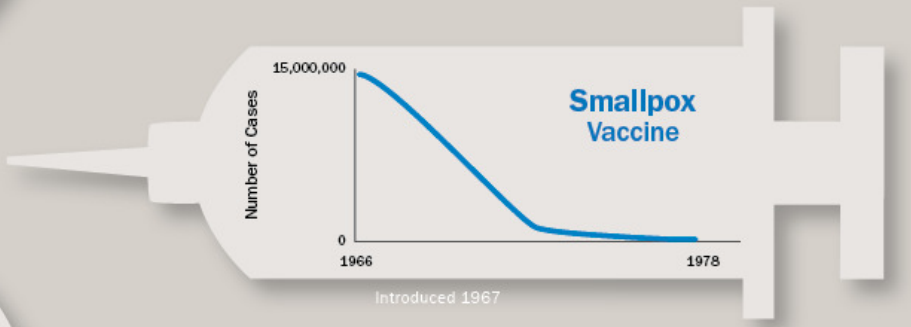
2000 — 853,480 cases[1]
2012 — 226,722 cases[2]

73.5% decline worldwide between 2000–2012, after global increase in immunization

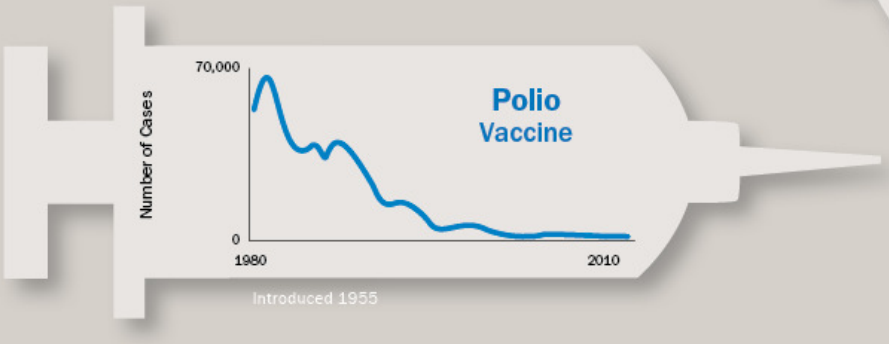
Smallpox Stats

1950s — 50,000,000 cases every year[3]
1980 — 0 cases[4]

100% reduction (eradicated)



Introduced 1967



Introduced 1955

Polio Stats

1988 — 350,000 estimated cases
2013 — 406 reported cases

99% decrease since the launch of the Global Polio Eradication Initiative in 1988[5]

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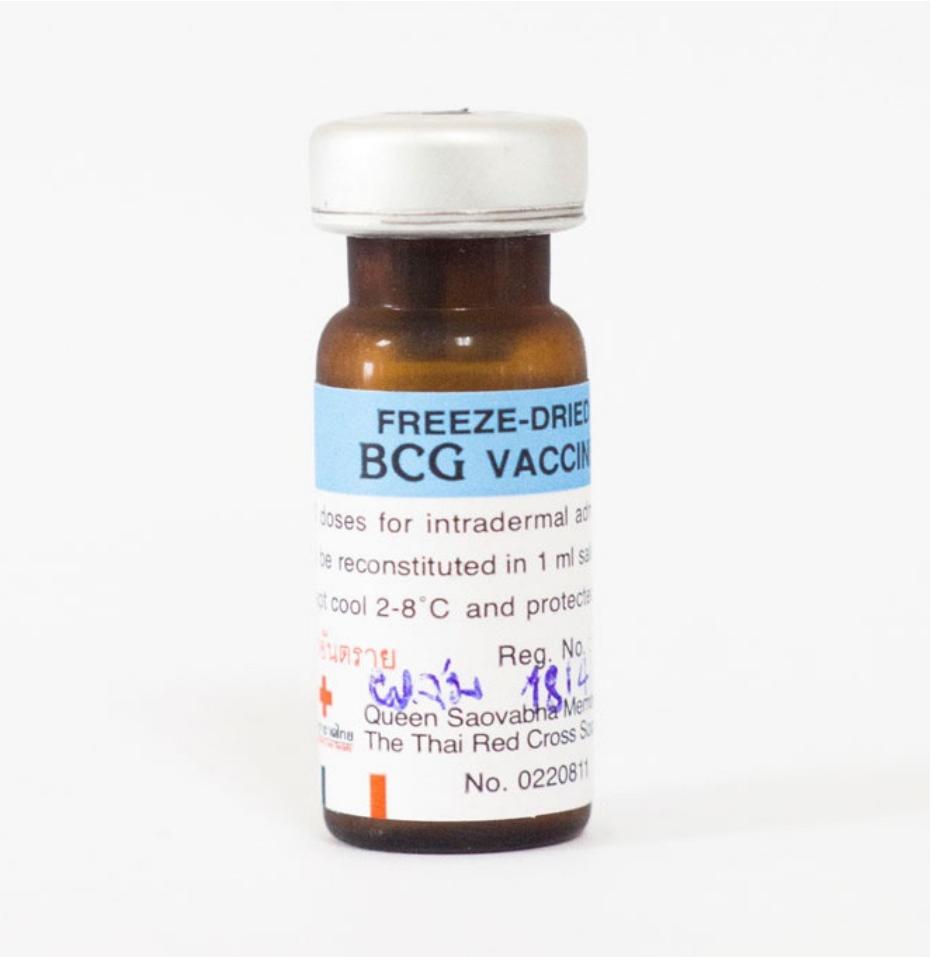
We need a more effective vaccine than BCG



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Global Strategies

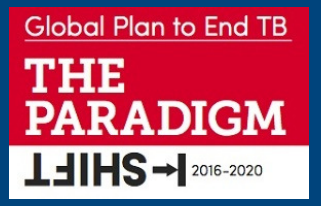
All rely on new tools, including better:

- **Vaccines**
- **Drugs**
- **Diagnostics**

UN Sustainable Development Goals

WHO's End TB Strategy

Global Plan to End TB 2016-2020



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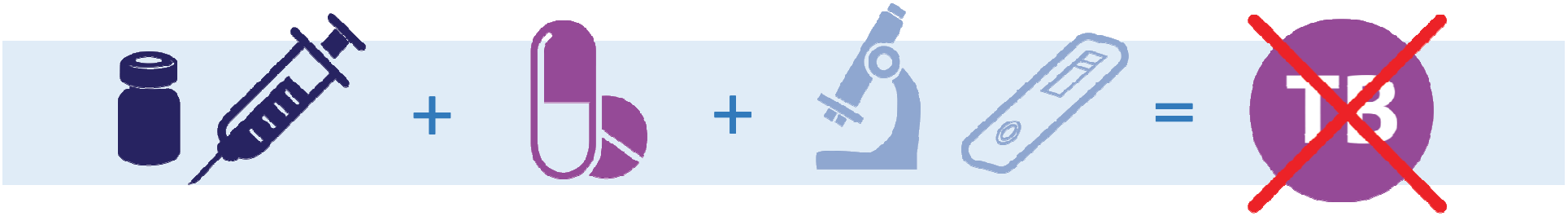
We will not meet our goals and end the TB epidemic without new, more effective vaccines.



New TB vaccine

Drugs with shorter regimens for treatment

Improved point-of-care diagnostics

End TB

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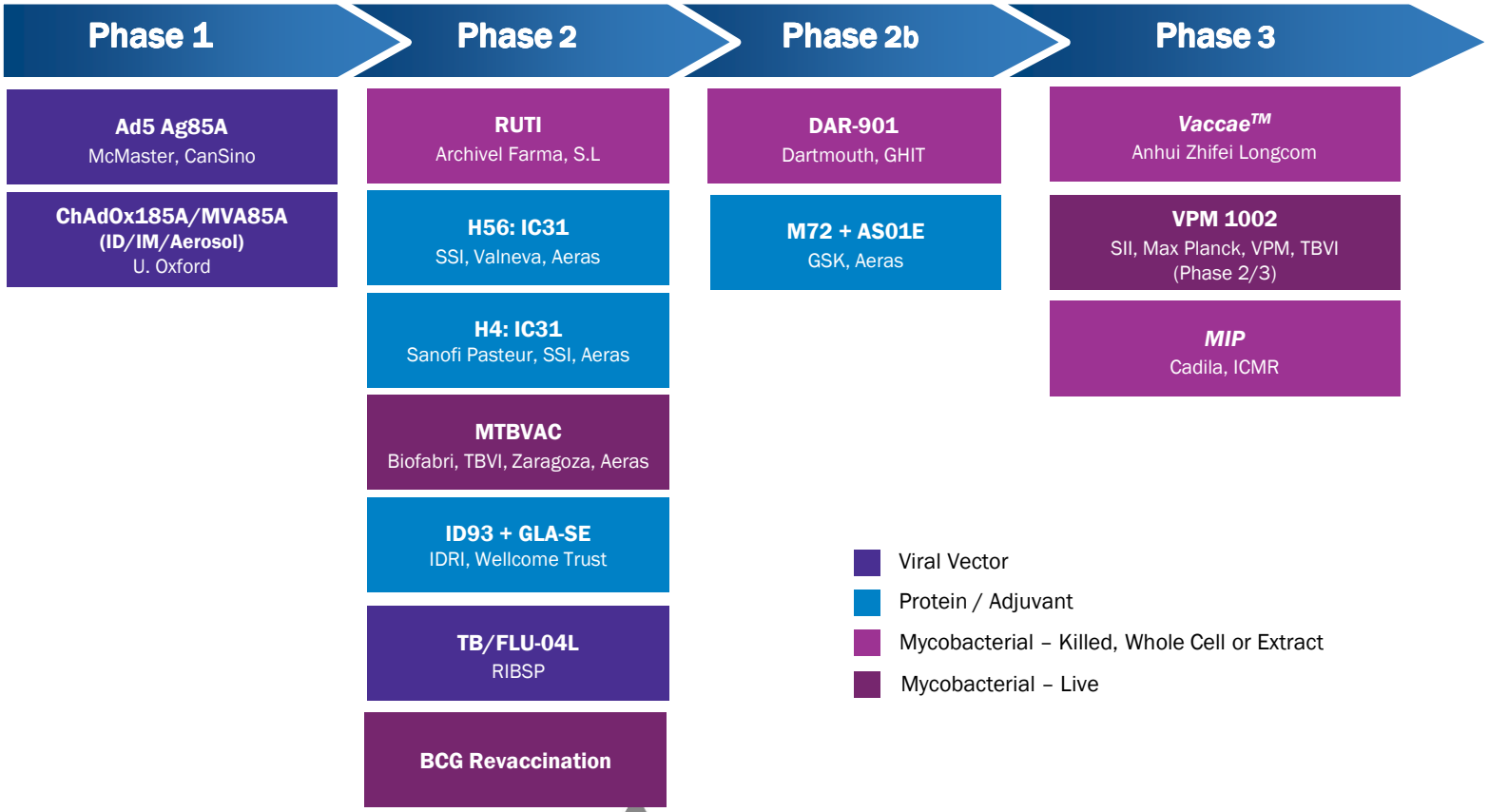
Source: WHO Health Assembly 2014

New Effective TB Vaccines are Achievable

- 14 vaccine candidates in the global TB vaccine clinical pipeline, a growing preclinical pipeline and new tools
- Understand more about the human immune response to TB & risks for developing TB disease
- Recent data from human trials show potential for new vaccination strategies and hope for new vaccines (Ph 2 Study with BCG/H4:IC31)
  - ✓ Additional data coming this summer adding to the growing pool of new knowledge (Ph2 Study M72)
- Novel clinical trial designs opening up new paths to get answers faster and more cost effectively

Global Clinical Pipeline



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Information on candidates in clinical development is self-reported by vaccine sponsors, coordinated by the Working Group on New TB Vaccines and updated February 2018

Severe Economic Impact of TB Disease

- Annual global cost of TB is $18.9B
  - $6.9B = cost of prevention, diagnosis and treatment[1]
  - $12B = economic impact (lost productivity, wages)[2]
- Still not identifying and treating 1/3 of population with TB disease
- Global use of a new, more protective TB vaccine would be a far more cost effective solution

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Sources: 1. WHO. Global TB Report 2017; 2. WHO. Trade, foreign policy, diplomacy and health; Tuberculosis Control

Antimicrobial Resistance: TB is one of top 3 AMR Threats

- WHO estimates ~490K new cases of AMR TB in 2016
  - Only ¼ of these were detected & reported
  - 4.1% of all new TB cases in 2016
- Cost of care is higher due to longer-lasting illnesses, more tests & costlier Rx drugs
  - Only 54% of AMR patients were successfully treated in 2016
- Cost implications if AMR is not controlled:
  - US $100T by 2050 if AMR is not controlled
  - 10M lives lost per year, 2.5M from TB

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Source: WHO Antimicrobial Resistance Fact Sheet, January 2018

Global Under Investment in TB R&D

- TB is #1 Infectious Disease Killer in the World
- A minimum of US $2B per year is needed for all TB R&D, but from 2005-2015, funding has never exceeded $0.7B per year
- TB vaccine R&D investment in 2016 was only ~13% of all TB R&D (US $95M vs $726M)
- 3 funders provided 74% of all global funding for TB vaccine R&D in 2016
  - Diversification and expansion is critical

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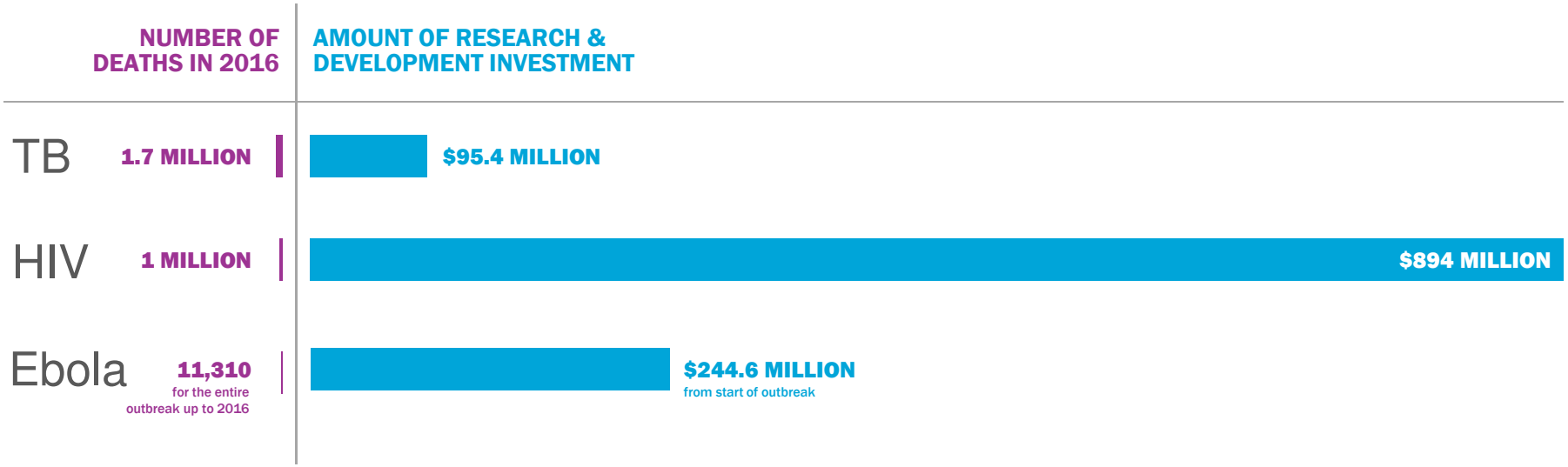
Source: TAG 2017 report "The Ascent Begins"

TB vaccine research is severely underfunded

We cannot afford to *not* invest.



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Sources:
http://www.who.int/mediacentre/factsheets/fs104/en/
http://www.who.int/gho/hiv/en/
https://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html)
http://www.hivresourcetracking.org/wp-content/uploads/2017/07/ResourceTracking2016.pdf
http://www.treatmentactiongroup.org/tbrd2017
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5112007/

What Would it Take to Succeed?

With $1 Billion US we could:

- Accelerate development activities that could impact epidemic
- Attract new researchers to the field
- Accelerate scientific progress and innovation
  - Identify immune correlates of protection
  - Investigate better strategies for use of BCG
  - Confirm predictability of POI trials to prevent disease
  - Advance pipeline candidates toward licensure
  - Further develop tools such as CHIM and refine animal models

The Cost of Inaction

Delaying investing in new tools by just five years could result in a tremendous human and economic toll

By 2030, it would mean:

- 8.4M new cases
- 1.4M more deaths
- US $5.3B more in treatment costs
- US $181B in lost productivity

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Source: The Global Plan to End TB 2016-2020

Summary

Urgent need for TB Vaccine R&D

CHALLENGES	HOW TO ADDRESS
1 Severe under-investment in vaccine R&D	Make **new vaccines** a **key piece** of any strategy to end TB
2 Lack of awareness that new TB vaccines are essential to stop the epidemic within target timelines	Ensure **innovation, investment** and **inclusion**

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Requests for the Stop TB Partnership Board

- To ensure the inclusion of the WGNV and partners in the preparation work leading to the UN HLM
- To advocate for the inclusion of vaccines specifically within the UN HLM political declaration

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Thank You

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