

AFTER COVID-19? **THE GOLDEN AGE** **OF VACCINOLOGY**

The Future of Vaccine Development

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**BILL & MELINDA GATES
MEDICAL RESEARCH
INSTITUTE**



THE GREAT DIVIDE



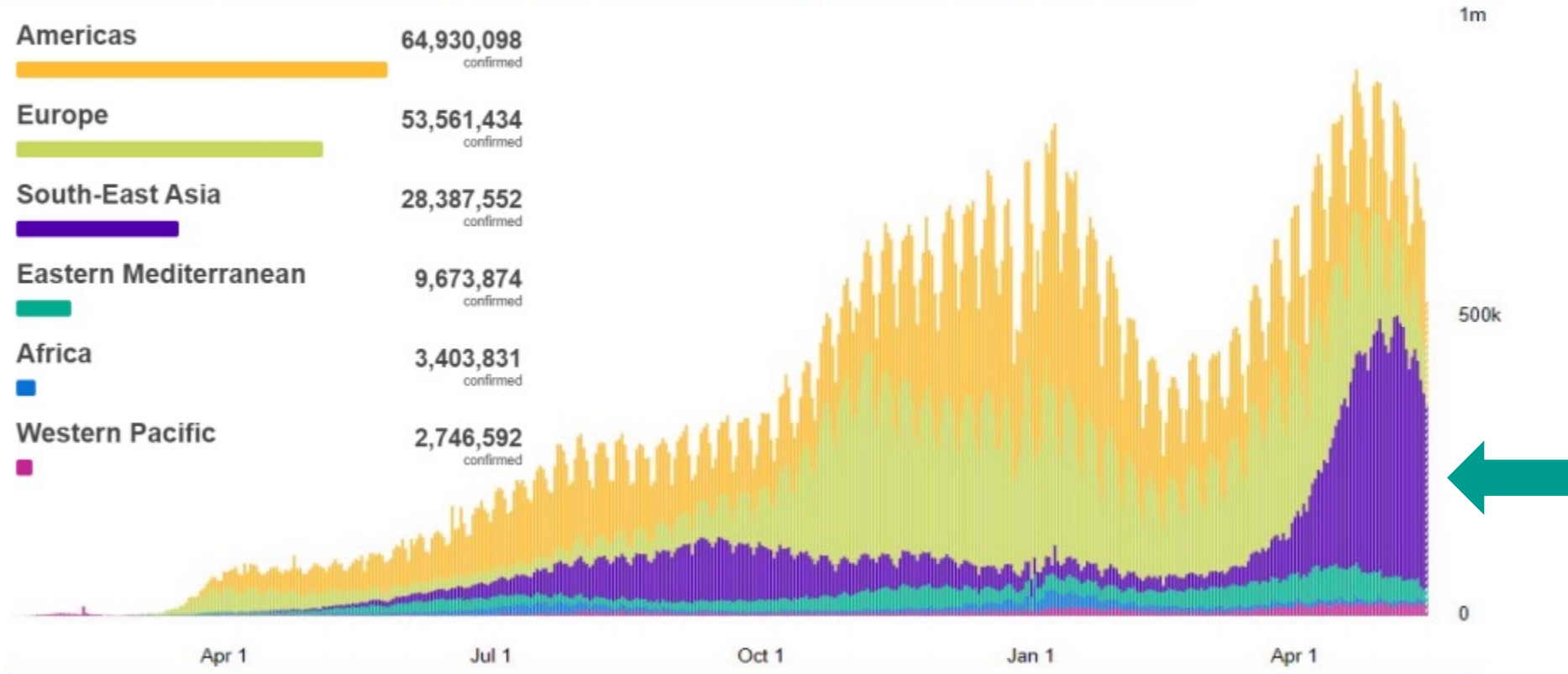
- Technology gap between rich and poor countries has narrowed, but remains large
- Progress in LMIC reflects absorption of pre-existing technologies – not “at-the frontier” inventions
- Cutting-edge technologies and approaches are needed to address immunologically and epidemiologically complex diseases – disproportionately affecting the poor

**How can we
address this?**

THE GREAT DIVIDE? COVID-19

GLOBAL EPIDEMIC CURVE

Number of confirmed COVID-19 cases through May 17, by date of report and region

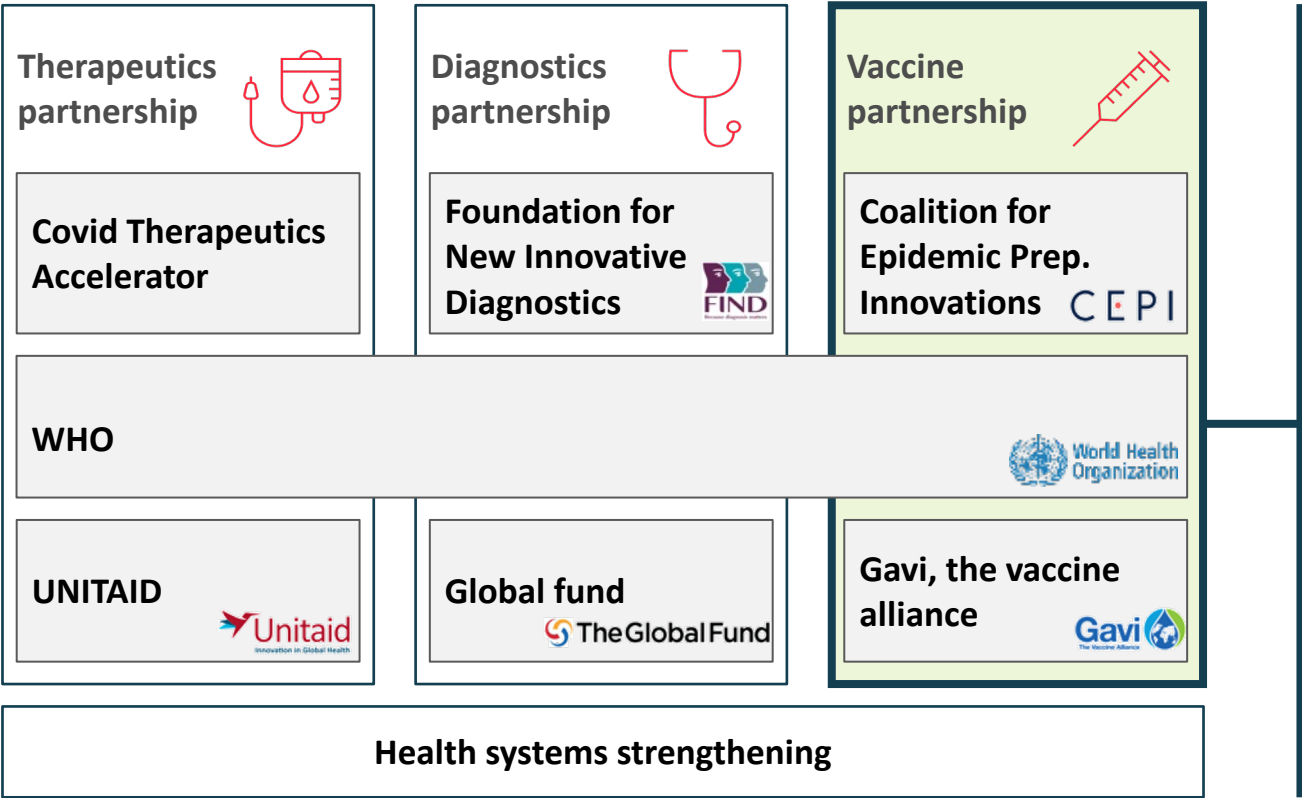


Source: WHO Covid Dashboard

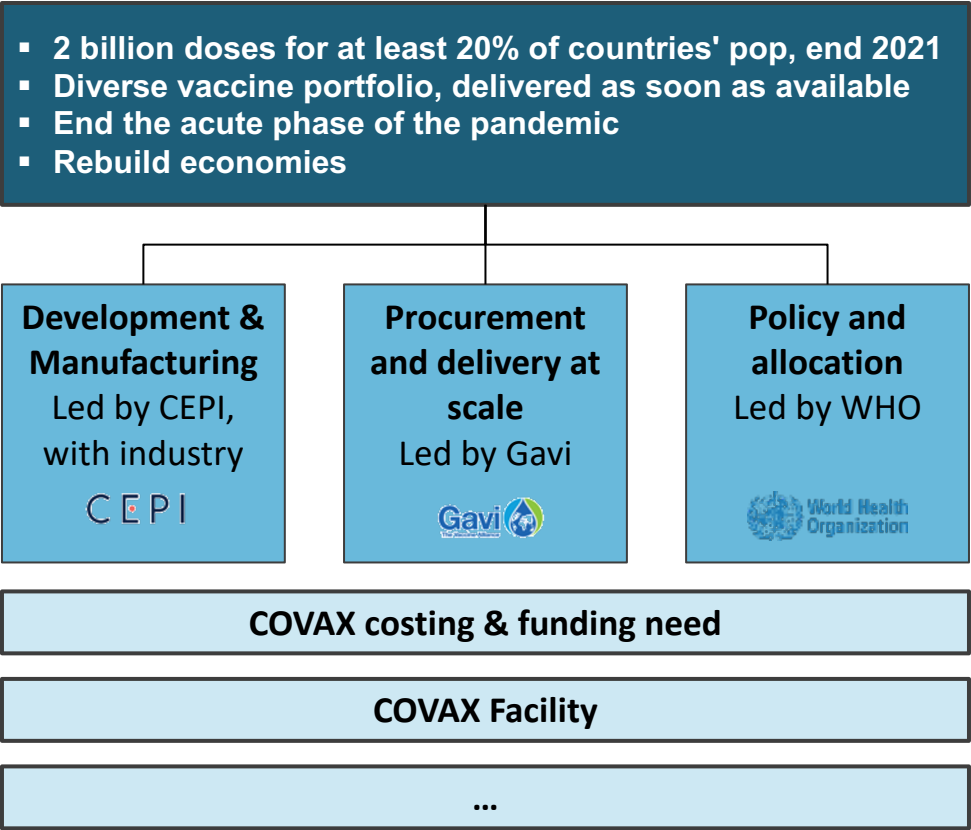
COVID-19 VACCINE STRATEGY FOR LOW RESOURCE SETTINGS



Access to COVID-19 Tools Accelerator (ACT-A)



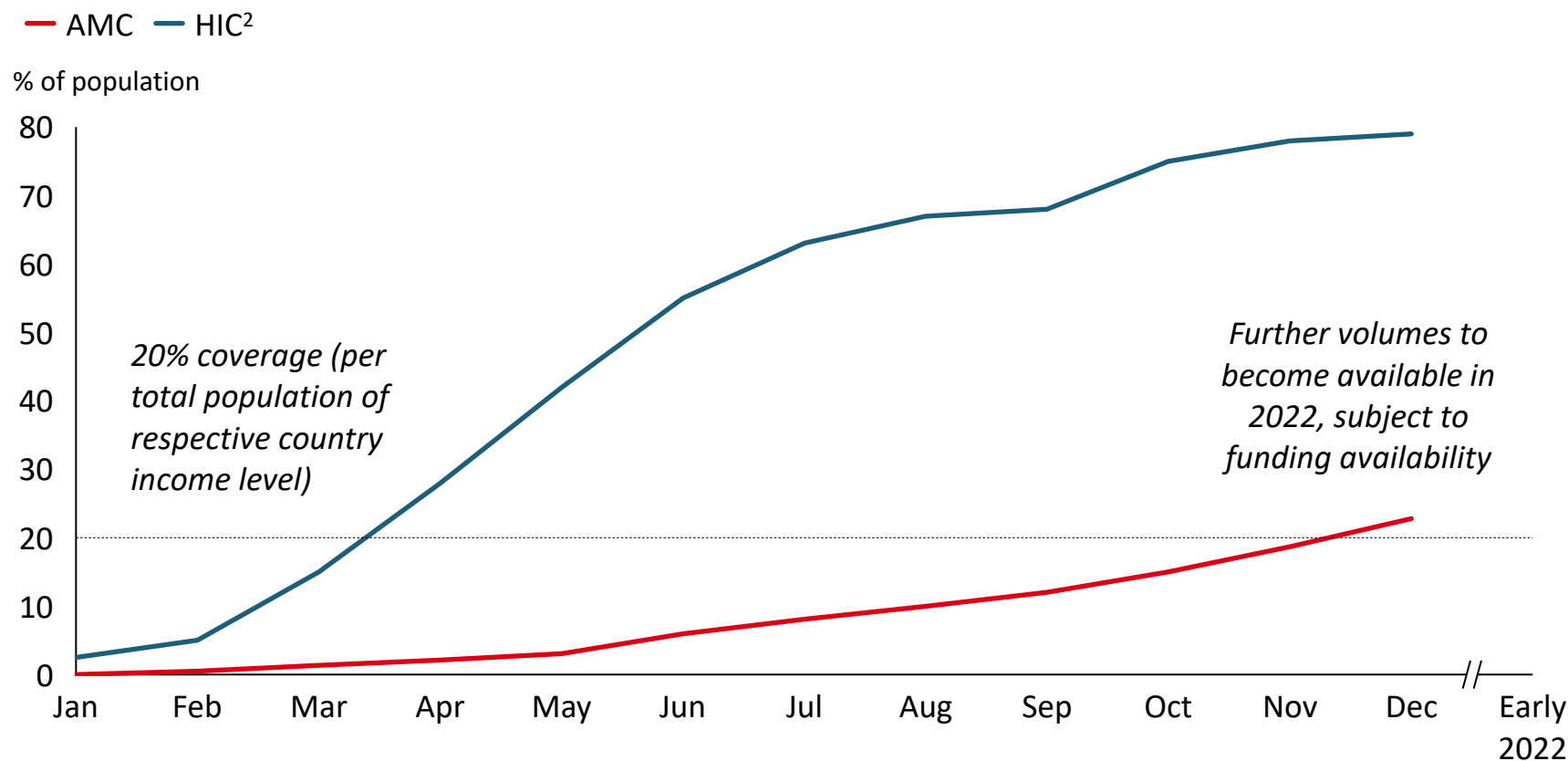
“COVAX” Pillar



GAP IN COVAX FACILITY GLOBAL POPULATION COVERAGE BY COUNTRY INCOME

Most LMIC countries are counting on COVAX, which has reached agreements with five companies for about 2 billion doses

COVAX Available Supply, Cumulative, Mn doses, 2021¹



To date, **68.8M doses** have shipped through COVAX to **124 countries**

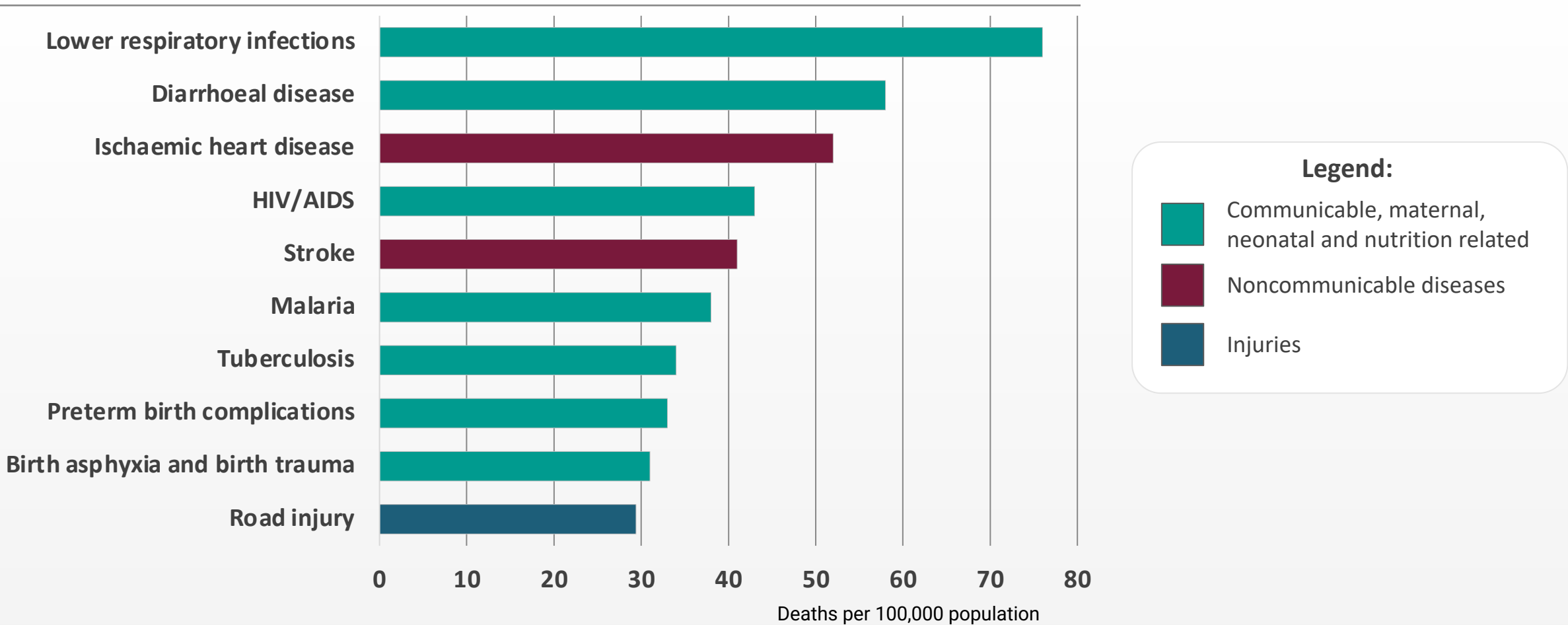
Doses Administered by Income Group

- HIC: 43%
- UMIC: 41%
- LMIC: 16%
- LIC: No Data

PRELIMINARY AND SUBJECT TO ASSUMPTIONS

THREE MILLION INDIVIDUALS STILL DIE OF VACCINE-PREVENTABLE DISEASES EACH YEAR

Top 10 causes of death in low-income countries in 2016¹



/ OUR MISSION

DEVELOP PRODUCTS TO ...



TUBERCULOSIS



**Accelerate the
end of the
tuberculosis
epidemic**



MALARIA



**Eradicate
malaria**



**ENTERIC AND
DIARRHEAL
DISEASES**



**End diarrheal
deaths in
children**



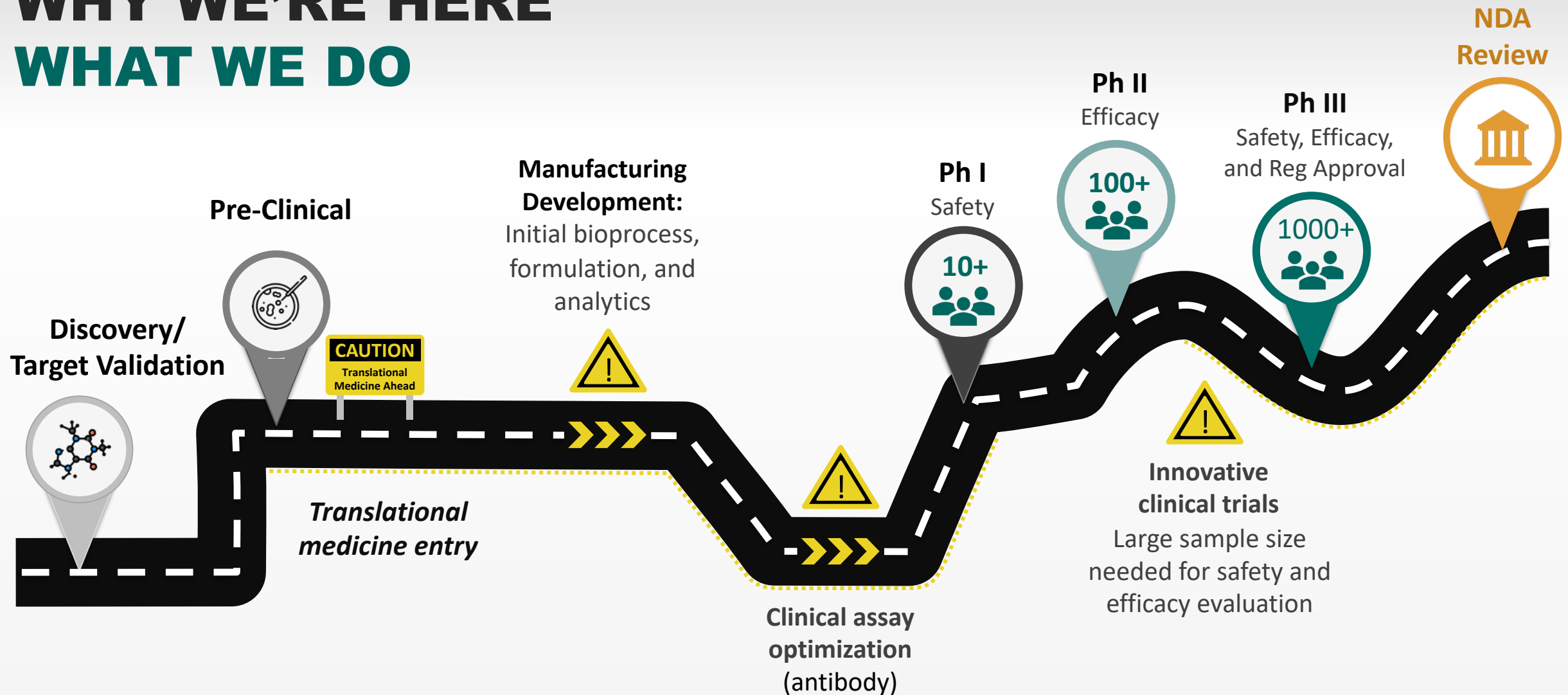
**MATERNAL
NEONATAL &
CHILD HEALTH**



**Reduce adverse
birth outcomes
and mortality**

WHY WE'RE HERE

WHAT WE DO



Nonprofit Biotech Model

Bridging Innovation from Private Sector

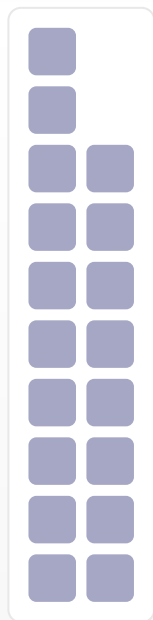
Translating from Preclinical through Development

THE GREAT DIVIDE. PRIORITIES

TUBERCULOSIS, AN OVERLOOKED EPIDEMIC

COVID-19 global
deaths in 2020

□ = 100,000

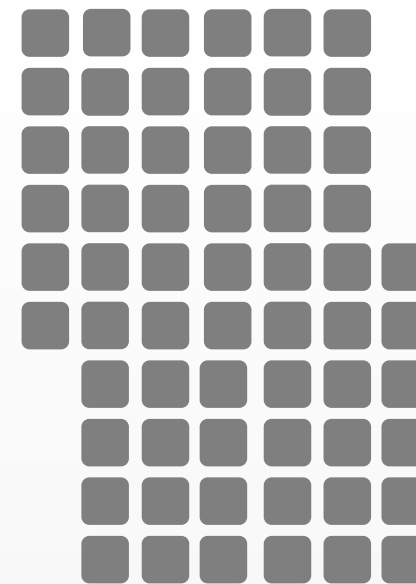


1.8 million in 2020

Tuberculosis global
deaths in 2019



~1.5 million in 2019



'18 '17 '16 '15 ...

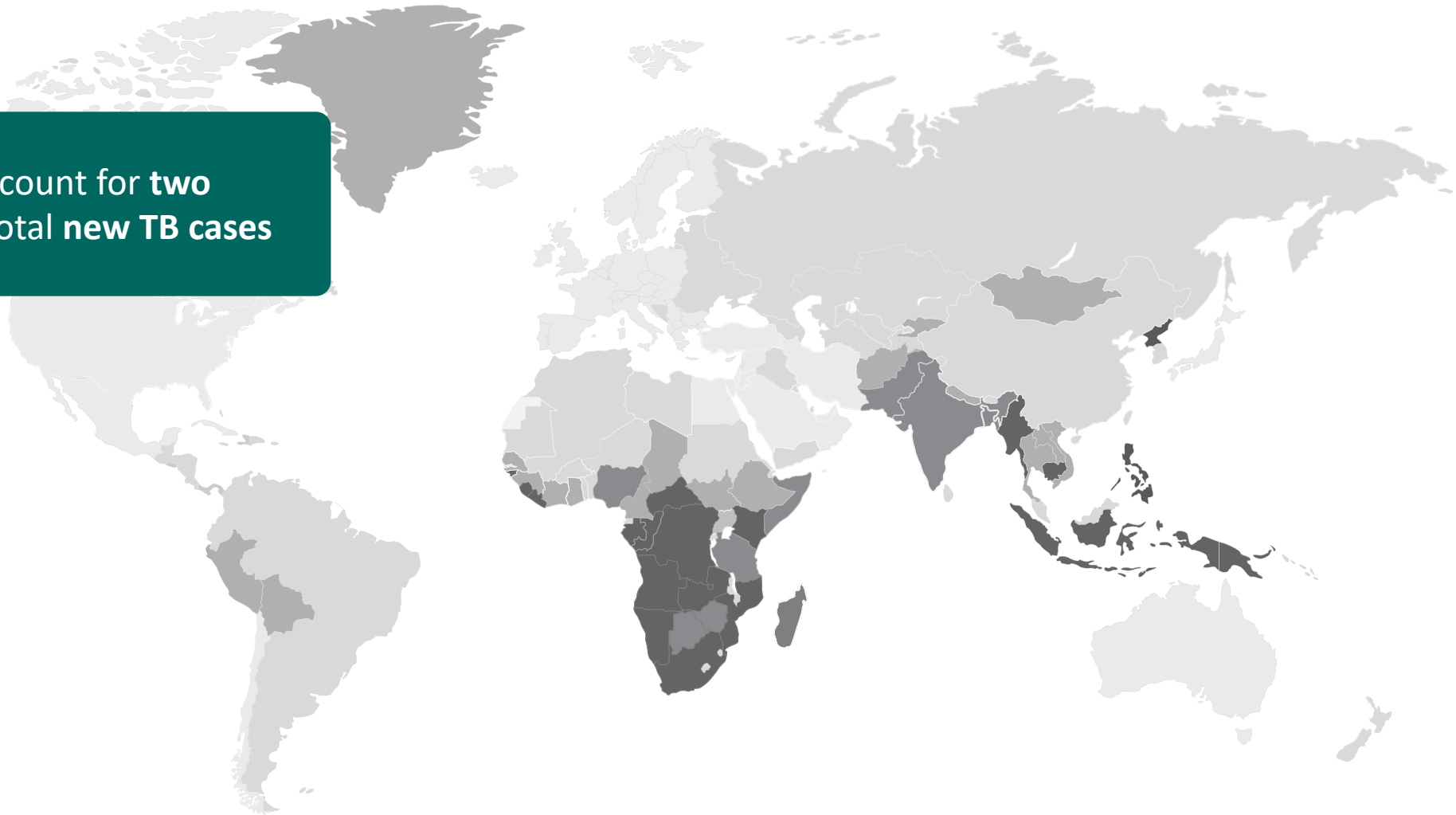
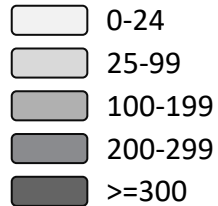
In 2020, Worldwide deaths from COVID-19 were similar to what occurs in Tuberculosis every year

GLOBAL HEALTH BURDEN OF TUBERCULOSIS

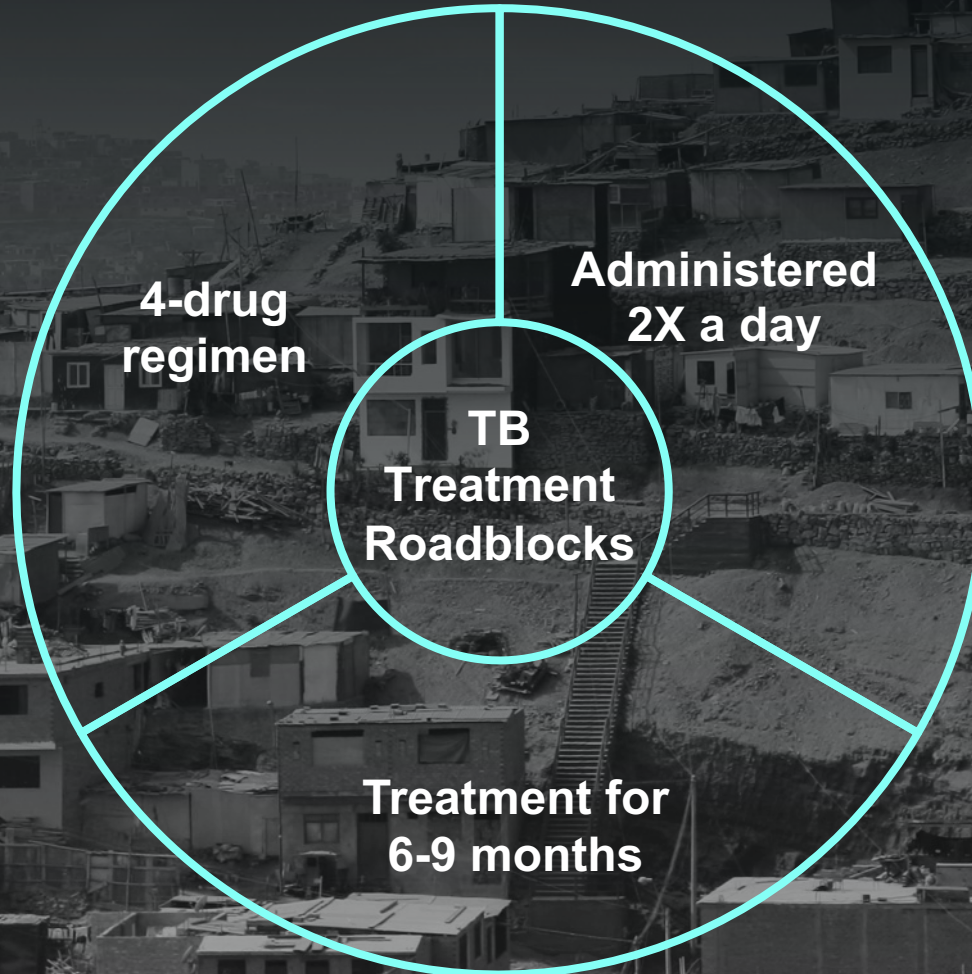
Tuberculosis disproportionately affects low- and middle-income countries

- 8 countries account for two thirds of the total new TB cases

Annual TB incidence
per 100 000



/ CORINA'S...AND MY DAD'S...STORIES



/ 2018: A HISTORIC YEAR FOR TB VACCINES

The NEW ENGLAND JOURNAL of MEDICINE

Phase 2b Controlled Trial of M72/AS01E Vaccine to Prevent Tuberculosis

Olivier Van Der Meeren, M.D., Mark Hatherill, M.D., Videlis Nduba, M.B., Ch.B., M.P.H., Robert J. Wilkinson, F.Med.Sci., Monde Muyoyeta, M.B., Ch.B., Ph.D., Elana Van Brakel, M.B., Ch.B., Helen M. Ayles, M.B., B.S., Ph.D., German Henostroza, M.D., Friedrich Thienemann, M.D., Thomas J. Scriba, Ph.D., Andreas Diacon, M.D., Ph.D., Greta L. Blatner, M.S., M.P.H., et al.

October 25, 2018

N Engl J Med 2018; 379:1621-1634

DOI: 10.1056/NEJMoa1803484

The NEW ENGLAND JOURNAL of MEDICINE

Prevention of M. tuberculosis Infection with H4:IC31 Vaccine or BCG Revaccination

Elisa Nemes, Ph.D., Hennie Geldenhuys, M.B., Ch.B., Virginie Rozot, Ph.D., Kathryn T. Rutkowski, M.Sc., Frances Ratangee, B.N., Nicole Bilek, Ph.D., Simbarashe Mabwe, M.Sc., Lebohang Makhethhe, B.Sc., Mzwandile Erasmus, B.Sc., Asma Toefy, B.Sc., Humphrey Mulenga, M.P.H., Willem A. Hanekom, M.B., Ch.B., et al., for the C-040-404 Study Team†

July 12, 2018

N Engl J Med 2018; 379:138-149

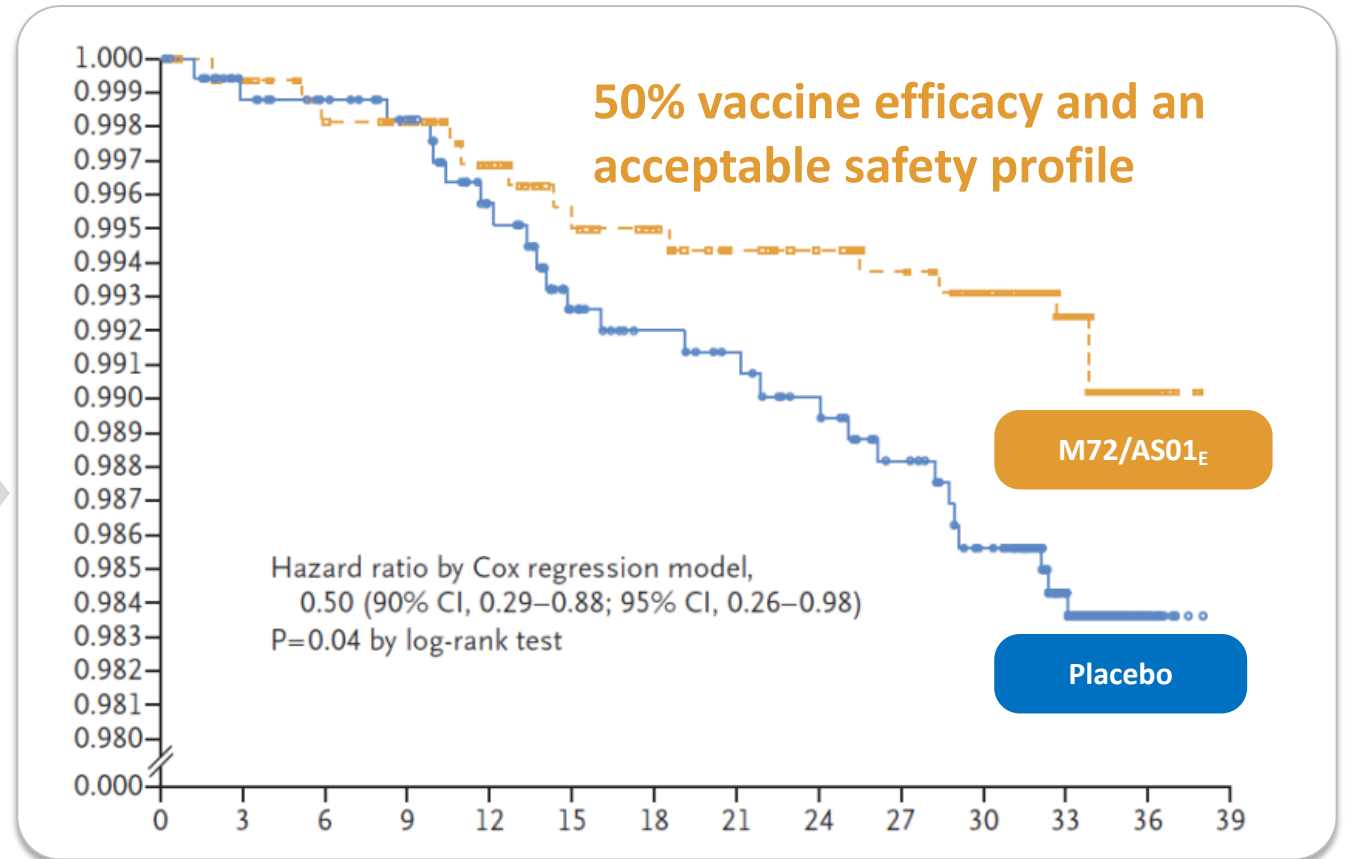
DOI: 10.1056/NEJMoa1714021

THE M72 TB VACCINE IS THE MOST PROMISING NEW TB VACCINE TO BE DEVELOPED IN 100 YEARS

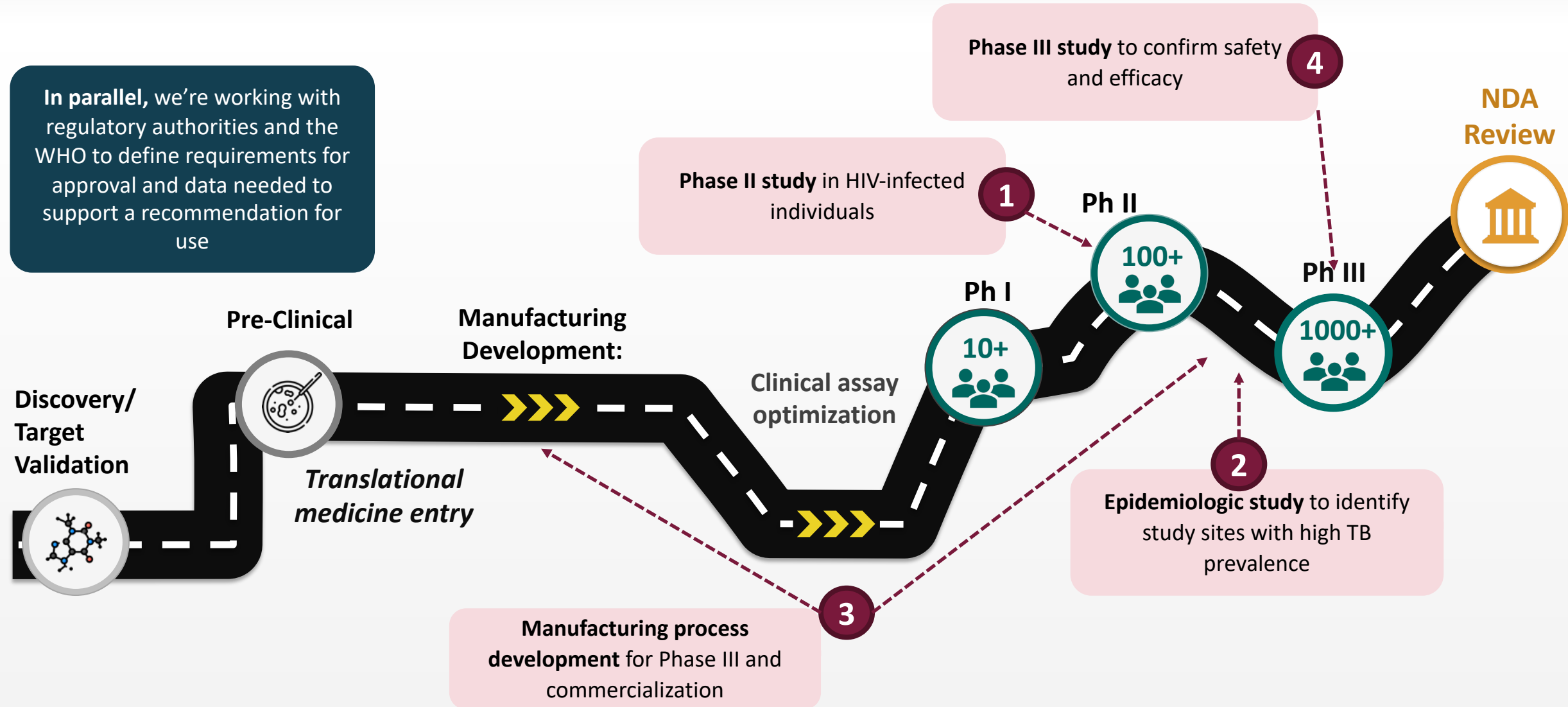
In 2018, the experimental vaccine candidate M72/ AS01E was found to be significantly protective against TB disease in a Phase 2b study

- GSK, supported by Aeras and the Gates Foundation, developed this candidate vaccine through Phase 2B
- Gates MRI obtained a license for M72/AS01E from GSK in 2020
- GSK actively supports technology transfer & provides adjuvant for the program
- This paves the way for continued vaccine development and potential use in LMICs

Phase 2B study of M72/AS01E in MTB-infected individuals:



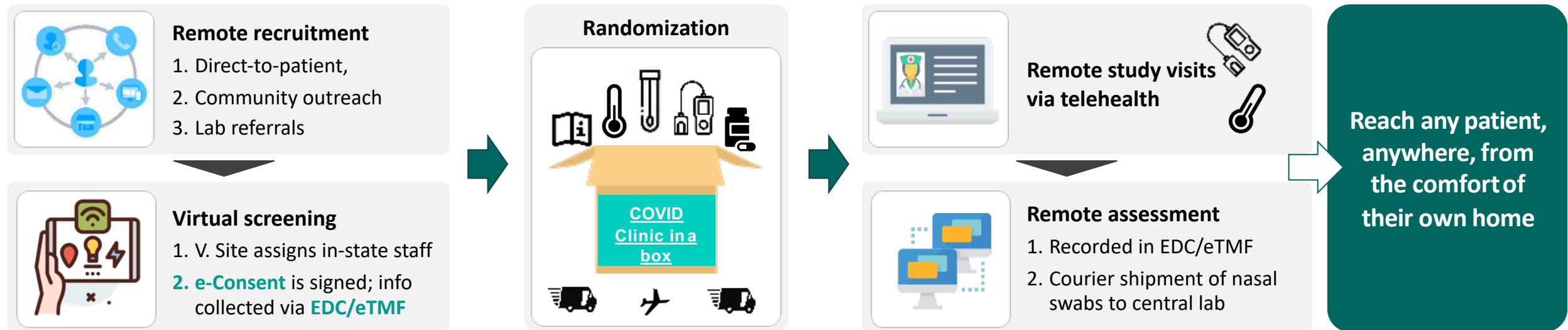
WHAT IS NEEDED FOR M72/AS01E VACCINE APPROVAL AND IMPLEMENTATION





INNOVATING IN A CRISIS: THE GATES MRI COVID-19 THERAPEUTICS PLATFORM TRIAL

Fully remote platform study for mild COVID-19



CLINICAL OPERATIONS INNOVATIONS

Clinical Trial Design



100% Remote Adaptive Trial Design with the Platform Core Protocol

Patient Recruiting



Population Outreach Through **Digital Media**

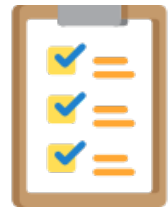


Community Engagement, **Minority Outreach**



National **multi-channel outreach** for COVID-19 testing

Clinical Operations



e-Consent



At-home Protocol Visits



e-Source. Direct, real-time digital capture of source data



Remote Safety Monitoring via Telemedicine/Video Calls



Direct to Patient (DTP) Shipments



Auto-migration of data from e-source to EDC



Self administered Nasal Swabs



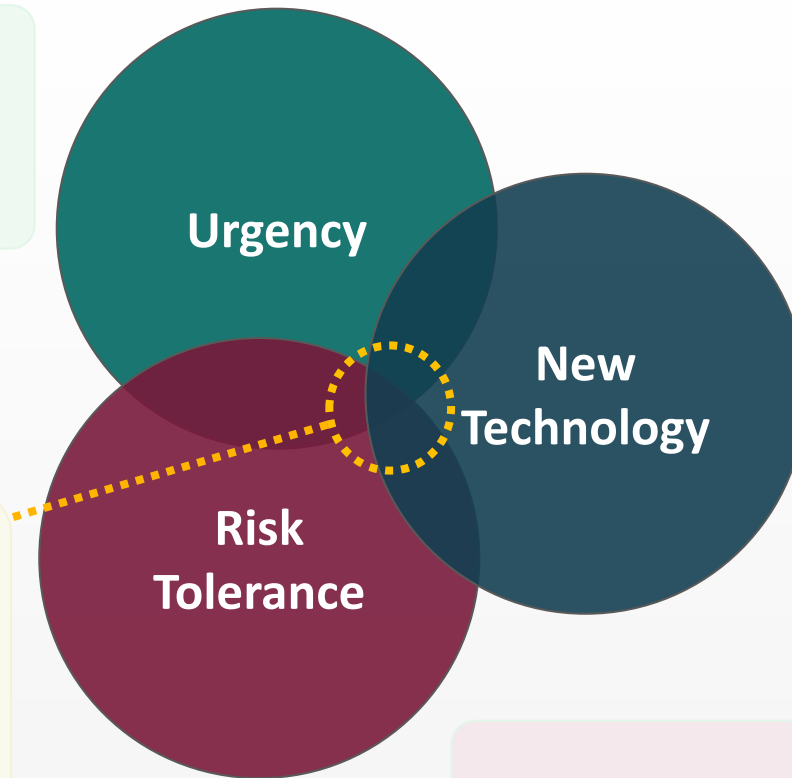
Virtual interactive platform and mobile application

WHAT WILL WE DO MOVING FORWARD?

“A lesson isn’t learned until we decide what we will do differently.”

1. Emergency use authorizations
2. Close engagement and rapid turnaround with regulators

1. Necessity to form novel partnerships
2. Acceleration/willingness to progress new technology
3. The need to adapt clinical trial operations to the reality of the day (e.g., direct delivery)

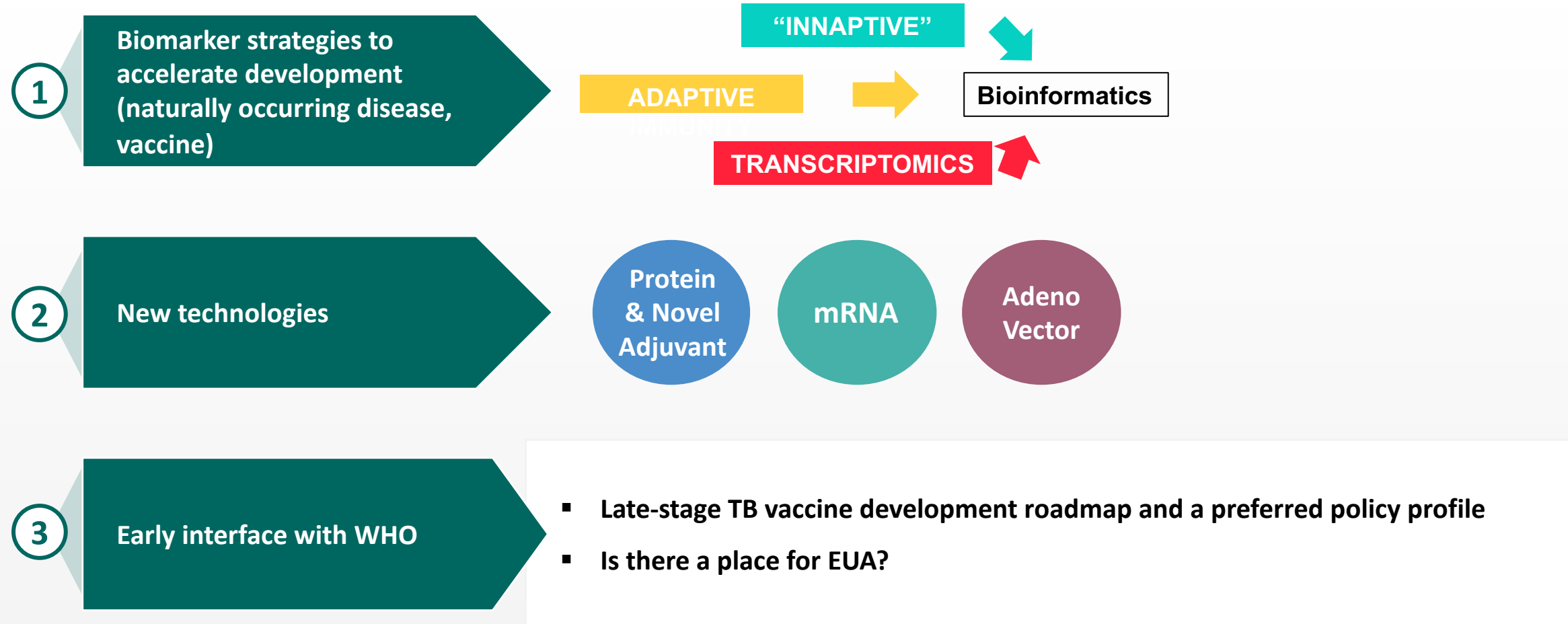


1. High throughput antigen and antibody screening
2. Novel adjuvants
3. New platforms (mRNA)
4. Breakthroughs in existing platforms (e.g., adenovirus)
5. Deep immuno-profiling
6. Advanced manufacturing techniques

1. Scaling manufacturing “at-risk”
2. Risk sharing

THE FUTURE?

M72/AS01E TB VACCINE PROGRAM



A close-up of a person's face, focusing on their eyes and hands. The person's eyes are closed, and a vibrant, colorful landscape scene is visible through them, featuring a body of water, trees, and a bright sky. Their hands are clasped together in front of their mouth, with fingers interlaced. The overall lighting is warm and dramatic, with a strong orange and yellow glow from the landscape scene.

**"The best way to predict the future is to
invent it."**

- Alan Kay