European Commission

HERA HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY

#HealthUnion

HERA Industry days

Health Emergency Preparedness and Response Authority

2 & 3 June 2025, Brussels

European Commission

Plenary panel

Shaping the future of vaccines: progress, challenges, and innovation

Shaping the future of vaccines: progress, challenges, and innovation

Rino RAPPUOLI
Project Coordinator,
European Vaccine Hub (SVA)

Aurélia NGUYEN
Deputy CEO, CEPI

Sibilia QUILICI
Executive Director, Vaccines Europe

An VERMEERSCH
GAVI

Eugenia PUENTES
CEO, Zendal/Biofabri

European Vaccine Hub

Rino Rappuoli

Fondazione Biotecnopolo di Siena

HERA industry days

June 2nd 2025

Co-funded by the European Union

Eight Emerging Infectious Diseases In 40 Years
Three Pandemics

Climate change, 8 billion people, Deforestation, Urbanization, Travel, accelerate their frequency

HIV 43 million deaths

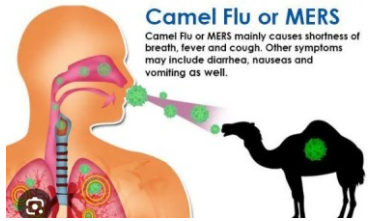
HIV

1981

SARS

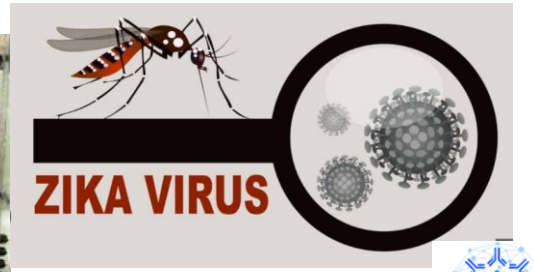
H1N1

MERS



Ebola

Zika



Impact on Health
Economy
National Security

Covid 7 million deaths

SARS-CoV-2

Mpox

2019

Co-funded by the European Union

CEPI, the **Coalition for Epidemic Preparedness Innovations**, a global partnership

Established after Ebola 2014

Mission supported by G7, G20, NIH, WHO ….

Negotiating Pandemic Treaty

Prioritize pathogens with pandemic potential ..

Develop vaccines in 100 days

Equity

EVH EUROPEAN VACCINE HUB

Co-funded by the European Union

ReVAMPP

National Institute of Allergy and Infectious Diseases

Fondazione Biotecnopolo di Siena

350 million $ for a Network of 7 Research Centers

NIAID

ML-PPVA
Neil King, David Veesler, Lynda Stuart
University of Washington

VPPC
Phil Felgner
University of California - Irvine

PABVAX
Tom Geisbert & Chris Broder
University of Texas Medical Branch

CDSC
Greg Sempowski & Sean Hanlon
RTI International

PROVIDENT
Kartik Chandran
Albert Einstein School of Medecine

BP4
Jim Crowe
Vanderbilt University Medical Center

FLARE
Mike Diamond & Richard Kuhn
Washington University in St. Louis

R2P2
Sean Whelan, Anne Moscona, & Rino Rappuoli
Washington University in St. Louis

EVH EUROPEAN VACCINE HUB

Co-funded by the European Union

Biotecnopolo

Fondazione Biotecnopolo di Siena

An Italian Center for Pandemic Preparedness

- A National Center, funded by the Italian Government
- The ambition to be a resource for Europe and for the world
- To be part of a global network of Institutes preparing the world for new pandemics
  (collaborate with CEPI, HERA, NIH, CARBX, BMGF, Wellcome Trust, IVI, Pasteur Network, etc..)
- Focus on **Vaccines and Monoclonal Antibodies**
- Target: **Emerging Viruses and Antibiotic Resistant bacteria (AMR)**
- Discovery, GMP up to phase 2B, for emergency approval

EVH EUROPEAN VACCINE HUB

erc

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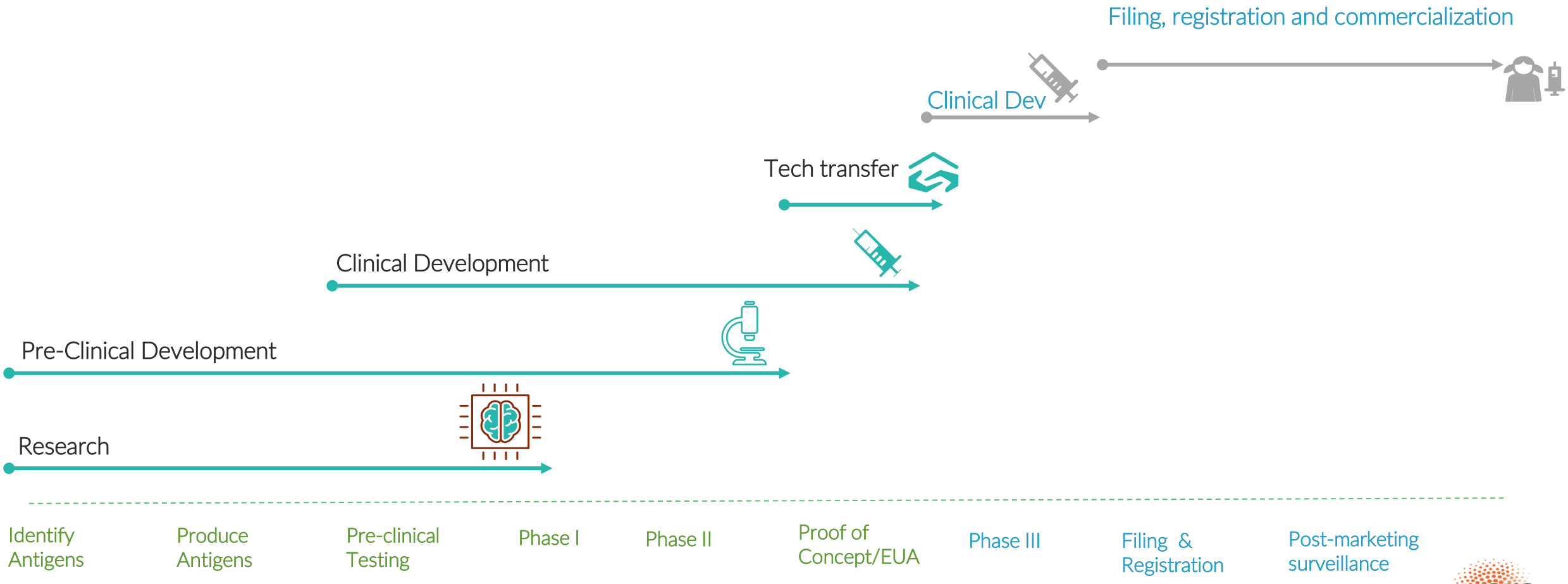
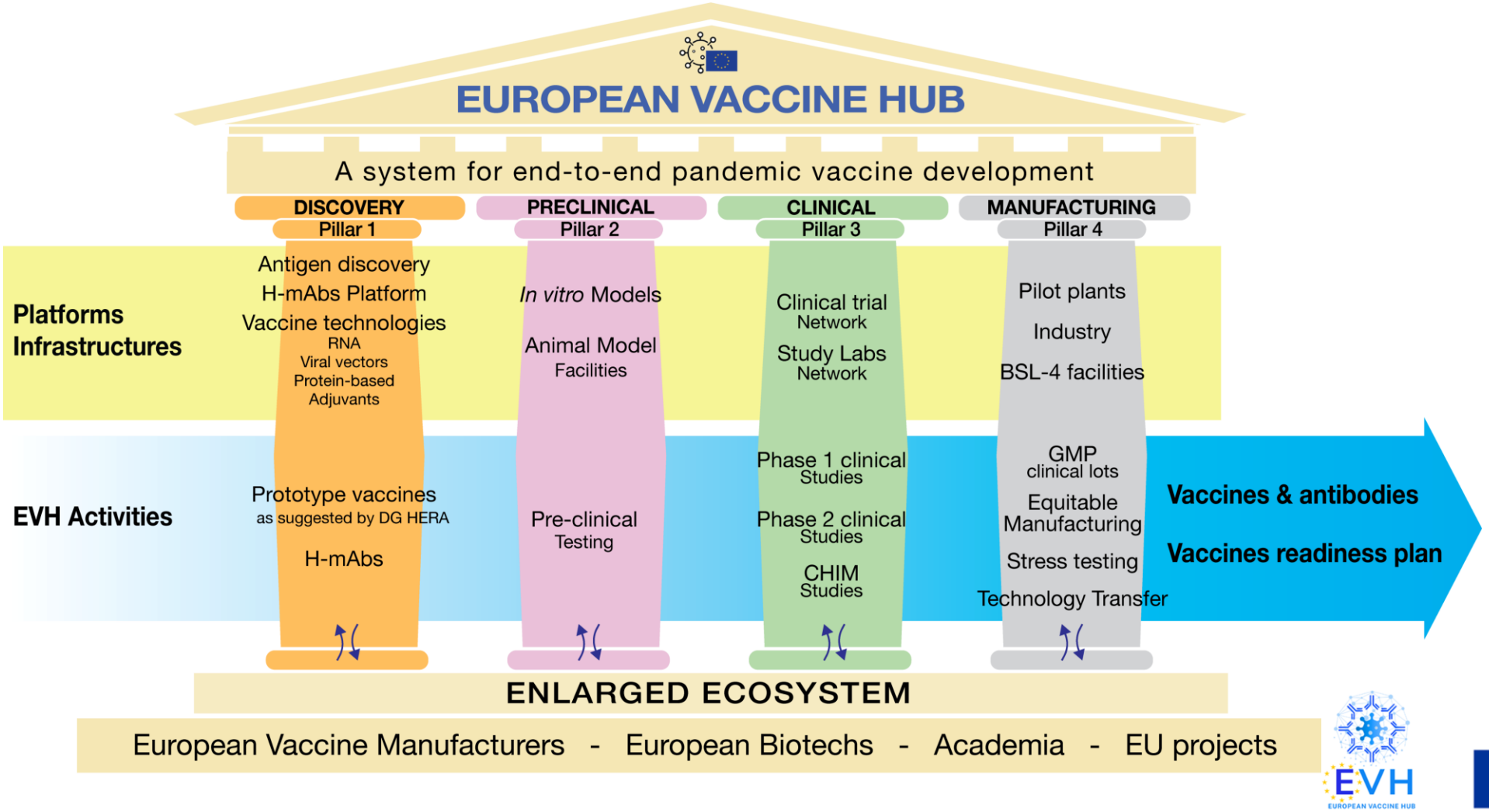
From discovery to phase 2b

Sustainable vaccine development model



European Vaccine Hub (EVH)

Provide EU with a self sustainable and independent ability to discover, develop and manufacture vaccines and monoclonal antibodies against infectious diseases of epidemic and pandemic potential



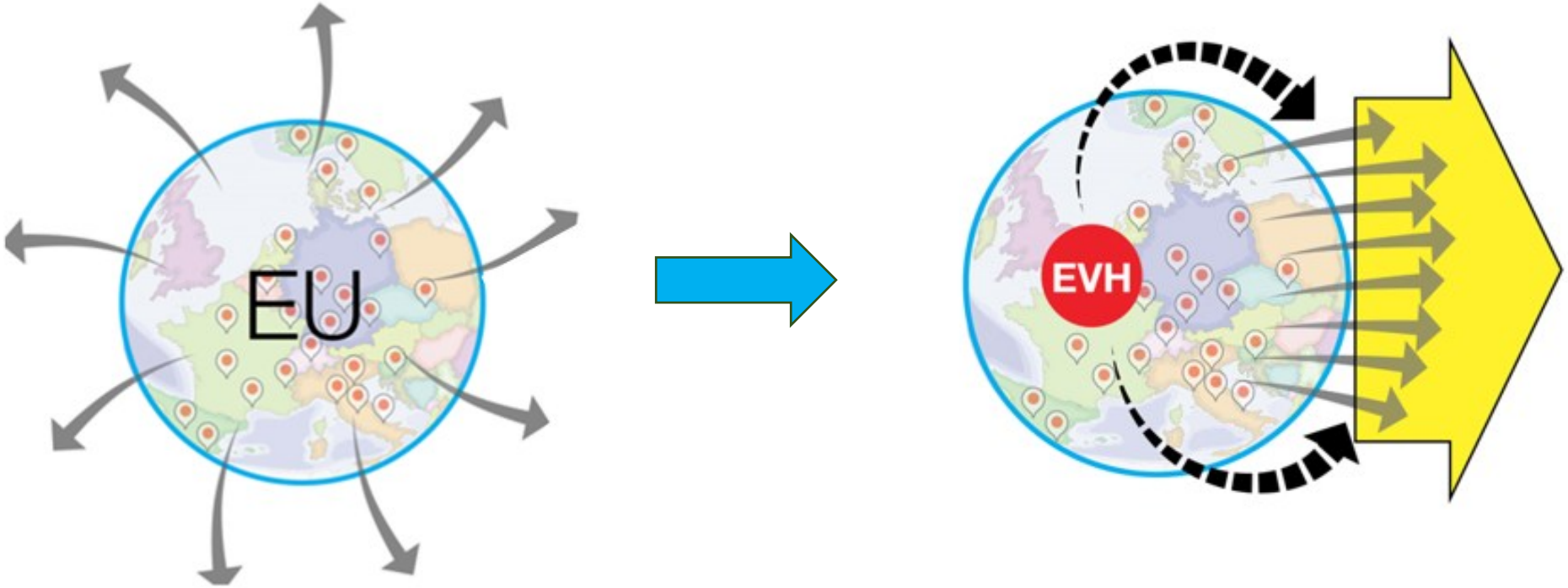
Fondazione Biotecnopolo di Siena

EVH EUROPEAN VACCINE HUB

erc

Co-funded by the European Union

A Unique opportunity to create a leading network



- Pandemic preparedness
- Vaccines
- Monoclonals
- Clinical Trial networks
- Industry
- Biotechs
- Academia

EVH EUROPEAN VACCINE HUB
Co-funded by the European Union

Fondazione Biotecnopolo di Siena

THANK YOU

EVH EUROPEAN VACCINE HUB

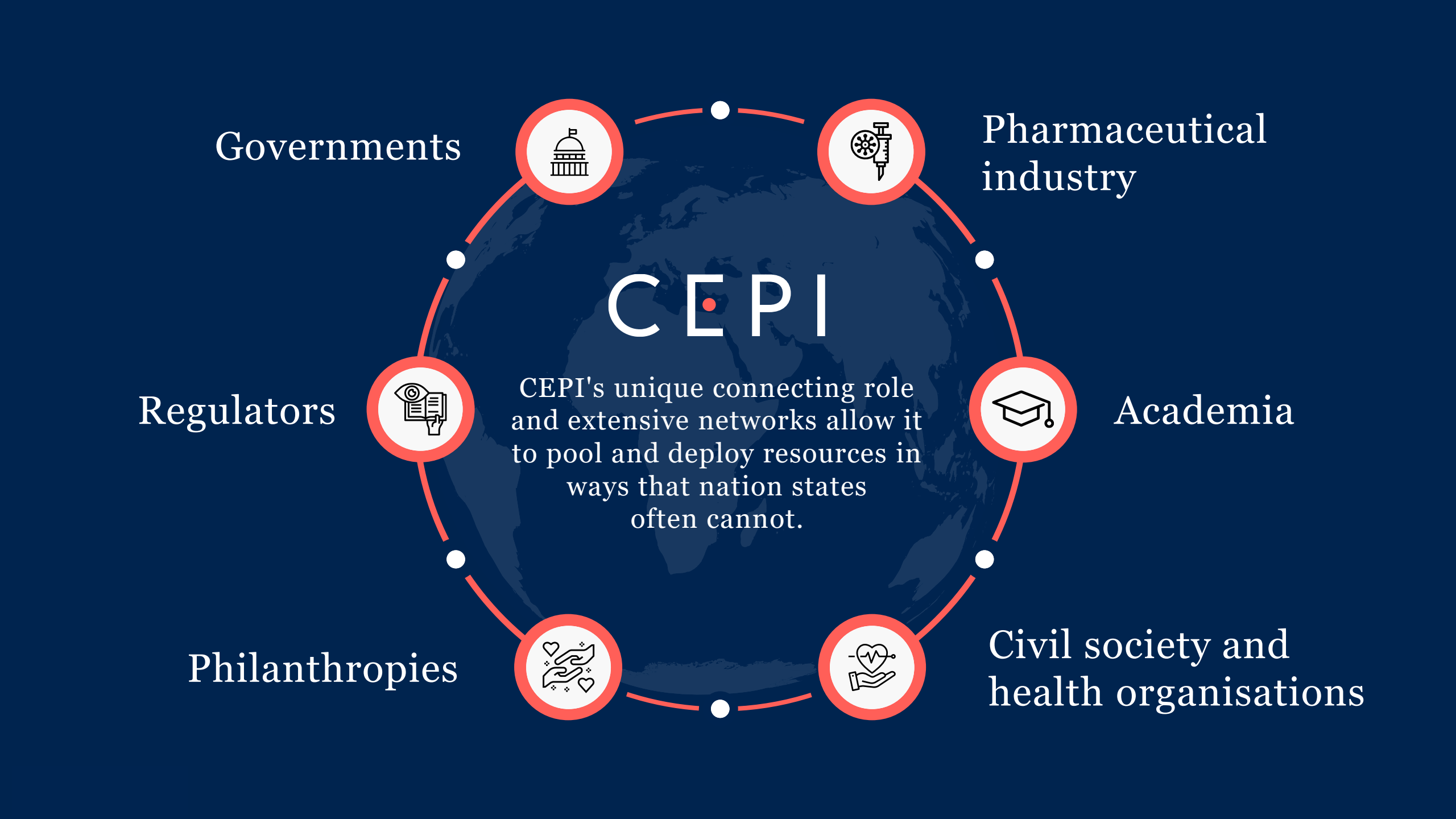
Co-funded by the European Union

CEPI

CEPI, vaccine development and the 100 Day Mission

Aurélia Nguyen
Deputy CEO, CEPI

HERA Industry Day
2 June 2025


Governments
Pharmaceutical industry
CEPI
CEPI's unique connecting role and extensive networks allow it to pool and deploy resources in ways that nation states often cannot.
Regulators
Academia
Philanthropies
Civil society and health organisations

CEPI's 100 Days Mission

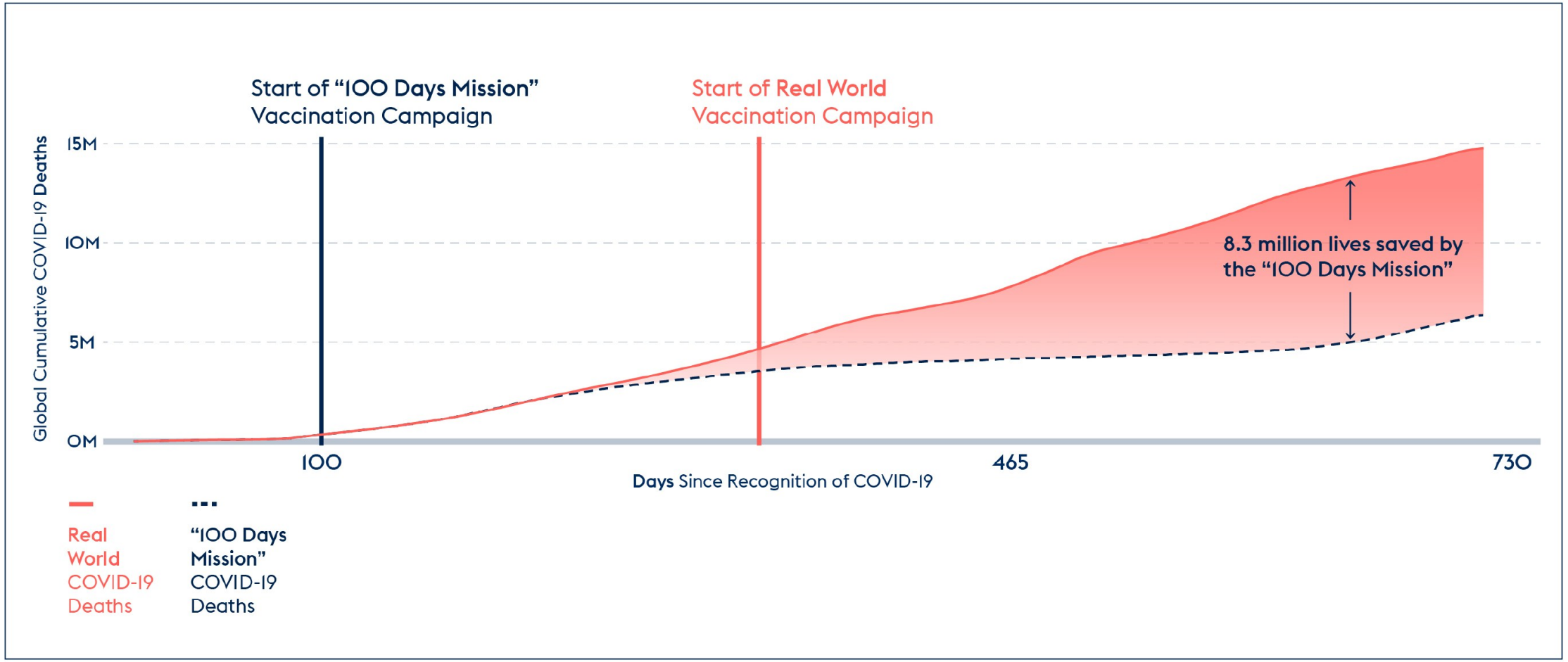
Coupled with improved surveillance, and swift use of non-pharmaceutical interventions, a vaccine in 100 days could defuse the threat of a new pathogen with pandemic potential.

Definition:
'Vaccines should be ready for initial authorisation and manufacturing at scale within 100 days of recognition of a pandemic pathogen, when appropriate.'

#100DaysMission

100 Days to save 8 million lives

Cumulative COVID-19 deaths through 2021



CEPI'S MAJOR PROGRAMMATIC ACHIEVEMENTS

2017 to present

ENABLING PROJECTS

Centralised lab network

Established a global network of **17 laboratories** to support priority pathogen vaccine R&D

Preclinical models network

Established a global network of **16 facilities**

Manufacturing network

Established a network of **5** Global South manufacturing partners

Epidemiology study

Launched ENABLE, the **largest-ever** Lassa epidemiology study

CEPI FIRSTS

Rift Valley fever

Advanced RVF vaccine into **Phase 1** trials

Nipah

Advanced the **first ever** Nipah vaccine into **Phase 1** trials

MERS

Advanced the **first ever** MERS vaccine into **Phase 2** trials

Lassa fever

Advanced the **first ever** Lassa virus vaccine into **Phase 2** trials

Chikungunya

First **licensed** Chikungunya vaccine

Innovations

Supported the **first medical product designed using AI** to be approved for any indication anywhere in the world.

CORONAVIRUSES

COVID-19

Supported **14** COVID-19 vaccine candidates

4 granted **EUL**

3 approved for domestic use

BPCV

World's leading funder of vaccine R&D, investing in 13 broadly protective coronavirus vaccine candidates

COVAX launched and co-led by CEPI

Nearly **2 billion** vaccines

shipped to **146 countries**

2.7 million deaths averted in lower-income countries

FILOVIRUSES

Ebola

Supported generation of data to support expanded access and licensed vaccines

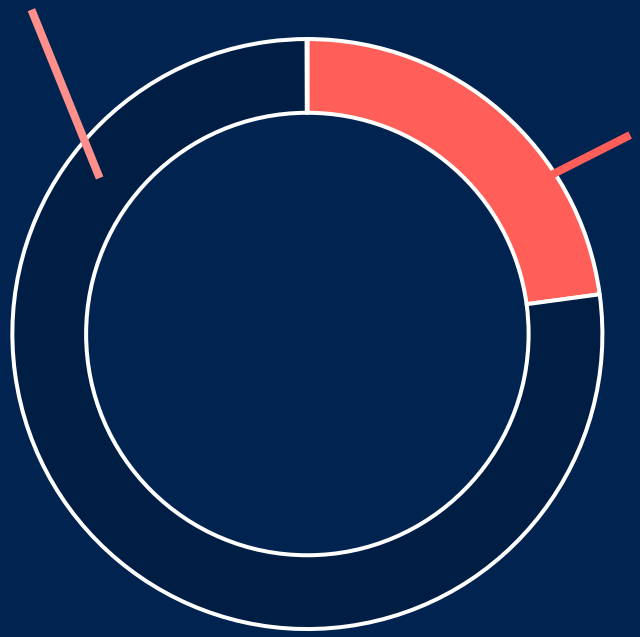
Marburg

9 DAYS

Supported Rwandan led response which deployed vaccine into a clinical trial

CEPI and Europe

CEPI has built a global health vaccine investment portfolio of over **EUR 3.5 billion**



EUR 800 million – with **EU partners** (23%)

125+

Academic, industry, governmental, and civil society partners in the EU

CEPI

CEPI-EC joint portfolio of work

5 Active grant agreements

6 Disease areas: vaccine development projects on Ebola, Rift Valley fever, Chikungunya, COVID-19 and coronaviruses, Lassa fever, and Filoviruses

Enabling Science: Controlled Human Infection Models (CHIM) and Mucosal Immunity, and regulatory support

9 separate contract awardees

28 participating organisations

2 Joint Calls for Proposals with EDCTP3 for programmes on epidemiology and modelling, and clinical trial capacity building are ongoing

CEPI

www.cepi.net

LinkedIn

Facebook

X

Bluesky

Industry perspective on barriers and progress in vaccines innovation

Sibilia Quilici - Executive Director, Vaccines Europe

Vaccines Europe
An industry for healthy lives

2 & 3 June 2025,
Brussels

Vaccines Europe

Vaccines Europe is the specialised vaccines group within the European Federation of Pharmaceutical Industries and Associations (EFPIA).

- **Members**

Our members represent **innovative research-based global vaccine companies operating in Europe**, accounting for a large share of human vaccines used worldwide, as well as European-based small and medium-sized enterprises.

- **Mission**

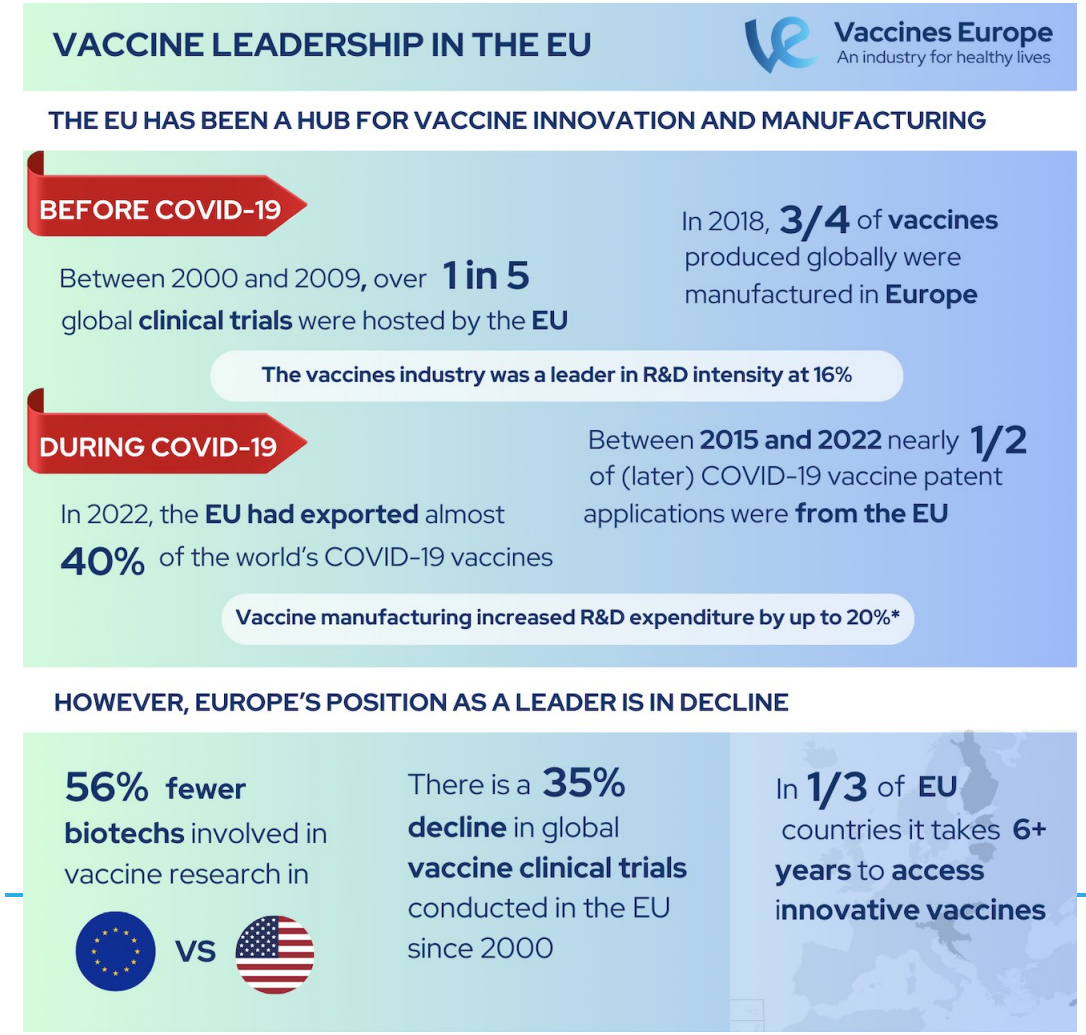
Foster innovation and value recognition of life-course immunisation in Europe to protect people against evolving health challenges.

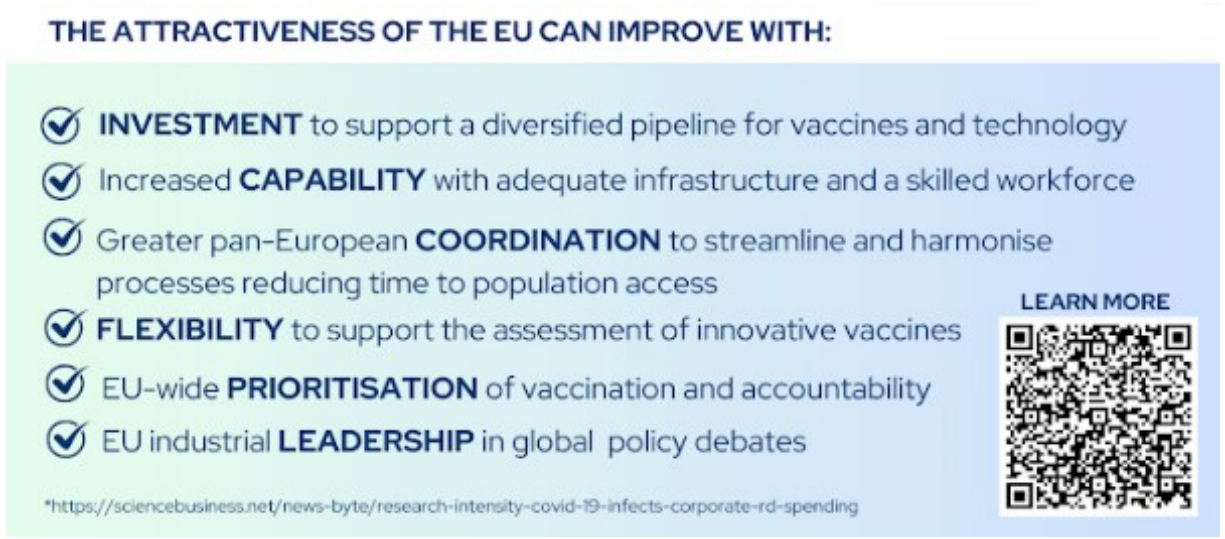
- **What we do**

Raising awareness about the value of vaccines, the innovation taking place and the contribution of the industry in Europe and worldwide.

Abbott
AstraZeneca
GSK
moderna
sanofi
Pfizer
Johnson&Johnson
MSD INVENTING FOR LIFE
Takeda
CSL Seqirus
novavax Creating tomorrow's vaccines today.
valneva
Bilthoven Biologicals Cyrus Poonawalla Group
CUREVAC
VAXCYTE protect humankind
HIPRA

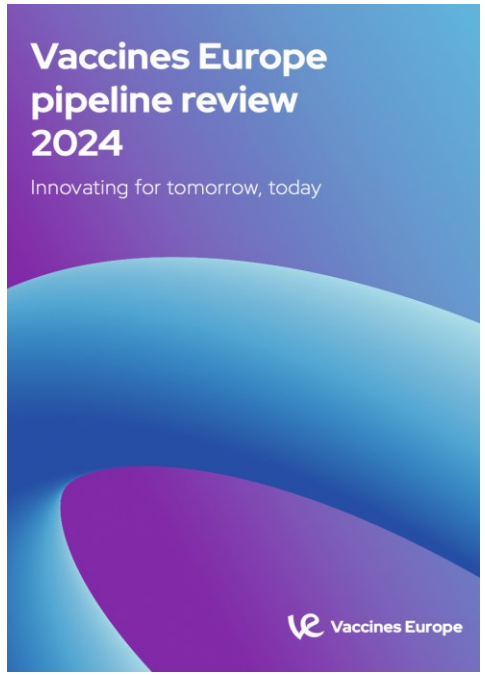
Europe has historically been a leader in vaccine development and manufacturing, however Europe's position is in decline





Vaccines Europe
An industry for healthy lives

98 vaccine candidates in the pipeline



- Identifying new vaccine-preventable diseases

42% OF THE VACCINE CANDIDATES ADDRESS DISEASES FOR WHICH NO VACCINE HAS BEEN REGISTERED

58% VACCINE CANDIDATES AIM TO FURTHER DEVELOP EXISTING VACCINES OR FIND A NEW APPROACH TO ADDRESS A DISEASE

While all authorised vaccines have a positive benefit/risk profile*, Vaccines Europe members are continuously working to improve the knowledge of vaccines' benefits/risks as part of their post authorisation lifecycle development.

- Improving formulations
- Expanding the use to a new population
- Including more target strains in a vaccine
- Developing combination vaccines
- Using a new approach to address a disease

https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines/how-ema-evaluates-medicines-human-use

Vaccines addressing global health threats

CLIMATE CHANGE

The intersection of climate change and infectious diseases is a growing area of concern for global health, with the warming climate altering the distribution, transmission, and severity of various infectious diseases

9 candidates against dengue fever, malaria, typhoidal and non-typhoidal *Salmonella*, *Shigella* sp., yellow fever and Zika

ANTIMICROBIAL RESISTANCE

In 2019, bacterial AMR caused 1.27 million deaths and contributed to 4.95 million deaths. The World Health Organization (WHO) projects that AMR could cause 10 million deaths annually by 2050 if no action is taken to address the issue.

14 candidates against **7** pathogens associated with significant antibiotic resistance

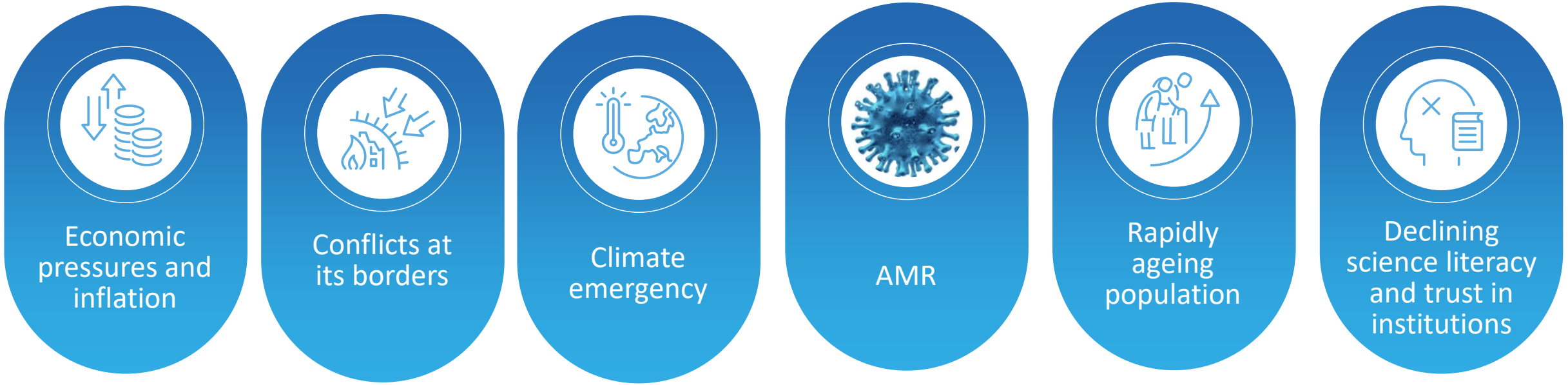
ZOONOSES AND PANDEMIC PREPAREDNESS

Approx. 60% of infectious diseases in humans can be attributed to animal origin. Many of these diseases have high mortality rates and the potential to cause epidemics and pandemics.

34 candidates against coronaviruses, dengue fever, pandemic influenza, Lyme disease, malaria, rabies, Nipah virus disease, salmonellosis and yellow fever

Vaccines Europe
An industry for healthy lives

Strong immunisation policies will be pivotal for Europe to face the major challenges ahead



Yet, many of the challenges we face are interconnected with the spread and rise of existing and new infectious diseases.

This is why immunisation *must* be at the heart of building more resilient and sustainable health systems.

Vaccines Europe
An industry for healthy lives

Reaching the next billion:
Gavi's experience in advancing vaccines through innovation, equity, and preparedness

An Vermeersch

Chief Vaccine Programmes & Markets Officer

Gavi, the Vaccine Alliance

2 June 2025, Brussels

gavi.org

Adan is the first child to receive malaria vaccine in Sudan. 4 November 2024
UNICEF/2024/Ahmed Mohamdeen Elfatih

Malaria vaccination, South Sudan, July 2024 Gavi/2024/Achuoth Deng

Gavi
The Vaccine Alliance

Today, a child in a Gavi-supported country is **more likely to celebrate their fifth birthday** than ever before

#ForOurFuture

The Gavi model

Long-term funding

Market shaping

Donor base

Co-financing

Pooling demand of lowest-income countries

Accelerating access to vaccines

Shaping markets for affordable vaccine products

African Vaccine Manufacturing Accelerator (AVMA)

Strengthening vaccine delivery platforms

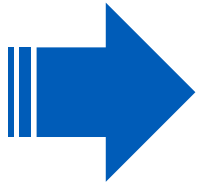
Sustaining immunisation and transition

Gavi The Vaccine Alliance

Market Shaping leads to acceleration of vaccine innovations for greater public health impact

Our market shaping strategy is built on three pillars:

- **A competitive, sustainable supplier base**
- **A supportive demand environment**
- **An enabling space for innovation**



INCREASED EQUITABLE COVERAGE

- Zero Dose Children
- Outbreak, Epidemic, Pandemic

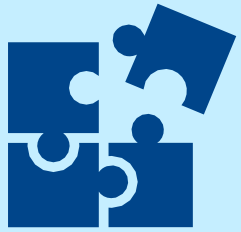
Gavi The Vaccine Alliance | World Health Organization | Gates Foundation | PATH | unicef

Learning from our COVAX experiences, Gavi is adapting its approach to market shaping for outbreak vaccines

Early access to flexible funding

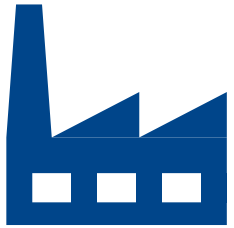
Predictable long-term funding for Board-approved vaccine stockpiles

Launch of $500M First Response Fund for diseases which Gavi doesn't yet have a program – inaugural use to respond to mpox outbreak



Collaboration with R&D funders and risk-sharing with manufacturers

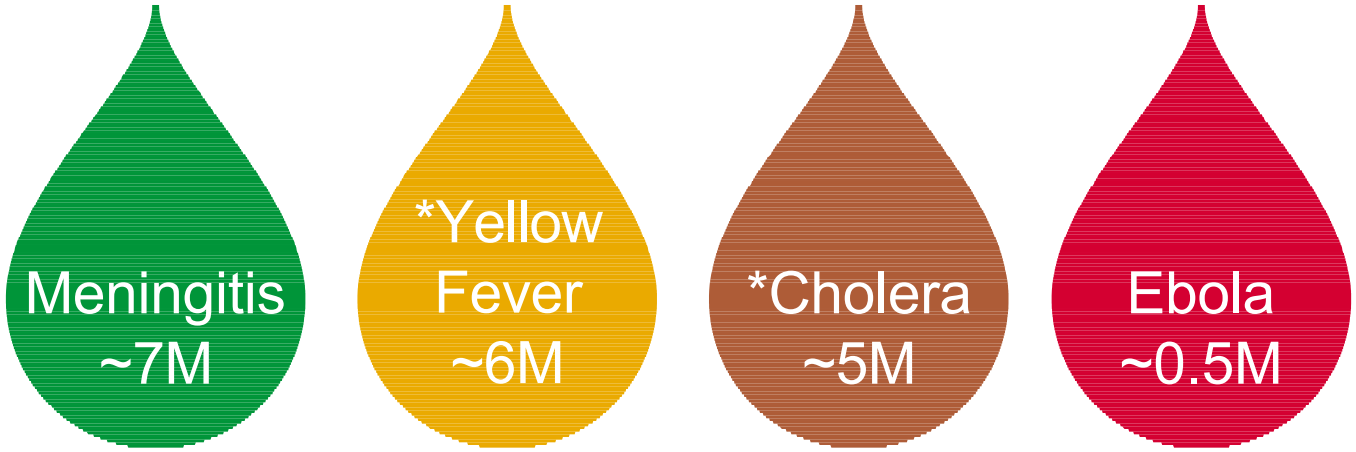
Coordinated push and pull mechanisms and consistent market signalling from funders (e.g. CEPI, BARDA, HERA) to ensure developers / manufacturers invest at scale prior to outbreaks



Regional manufacturing

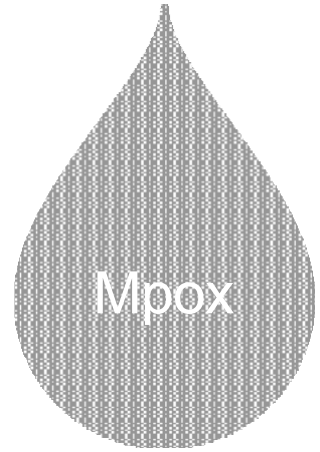
Geographical diversification of vaccine manufacturing capabilities to mitigate against risk of export bans, etc.

Global Health Security is core to our mission – Gavi currently funds five stockpiles; mpox pending approval



International Coordinating Group (ICG) on Vaccine Provision

MEASLES & RUBELLA INITIATIVE

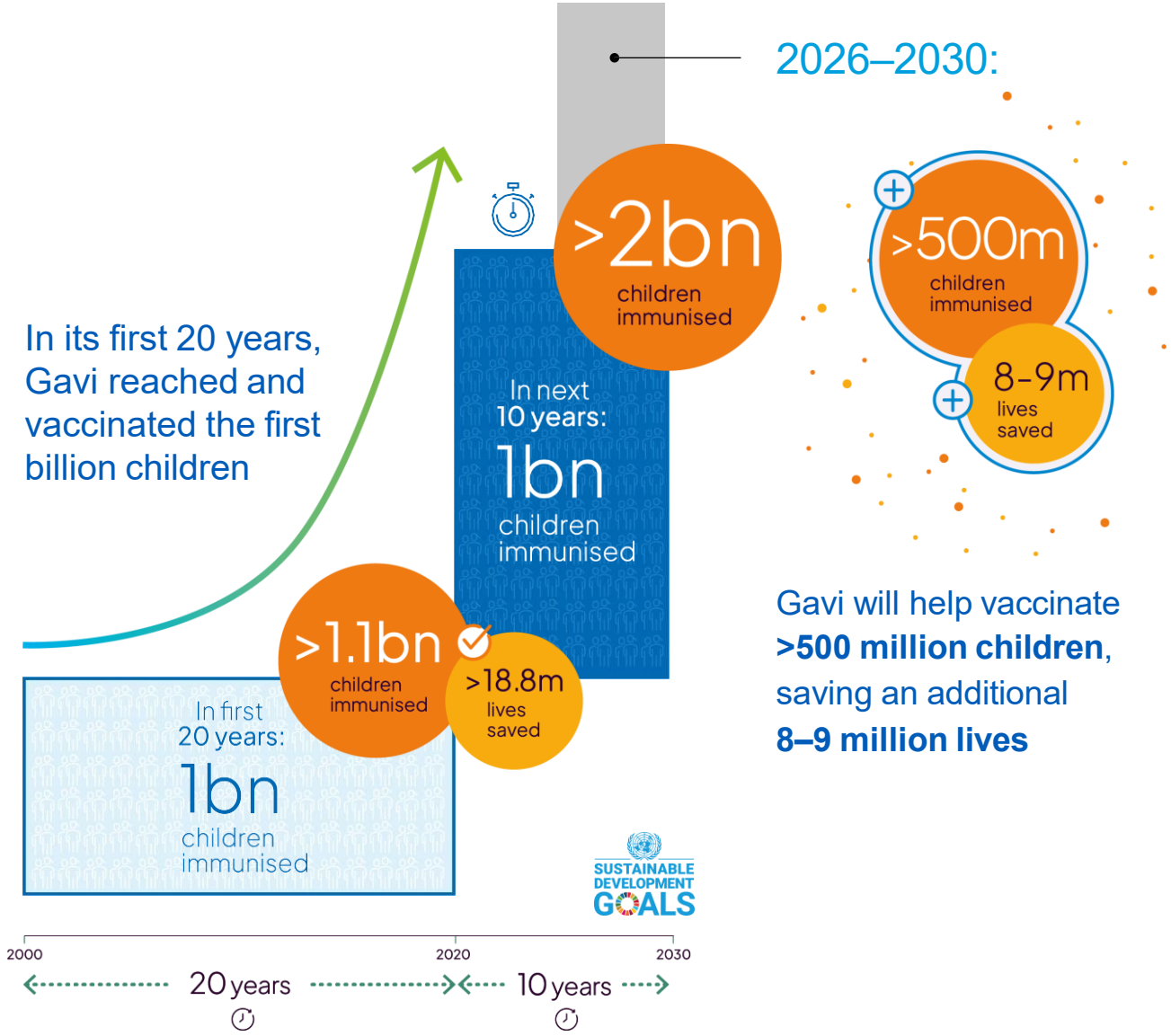


Pending Board approval

*Yellow fever and cholera vaccines are rotating stockpiles, replenished continuously as vaccines are used.

Gavi The Vaccine Alliance

Accelerating our impact: reaching the next billion children in half the time



Gavi will help vaccinate **>500 million children**, saving an additional **8–9 million lives**

This comprehensive package of support will **deliver an unprecedented US $100bn of wider economic benefits for countries** and offer **a proven return on investment for donors.**

Gavi
The Vaccine Alliance

Global Summit: Health & Prosperity through Immunisation
25 June, Brussels

The European Union is a champion of multilateralism, with strong convening power. The EU has contributed more than €3.2 billion since 2003 to Gavi's mission.

Co-hosting by the **European Commission** and the **European Council**. During UNGA, President von der Leyen pledged EUR 260 million for 2026-2027 and sent a strong message: *"Europe will do its fair share"*

The Gates Foundation is instrumental in keeping global attention to immunization and global health.

A Gavi founding member, having committed US$ 6.1 billion since 2000.

European Commission President von der Leyen

European Council President Costa

Co-chair Bill Gates

GLOBAL CITIZEN

Strategic partner
Influencing political leaders and citizens

#ForOurFuture

Thank you!

#ForOurFuture

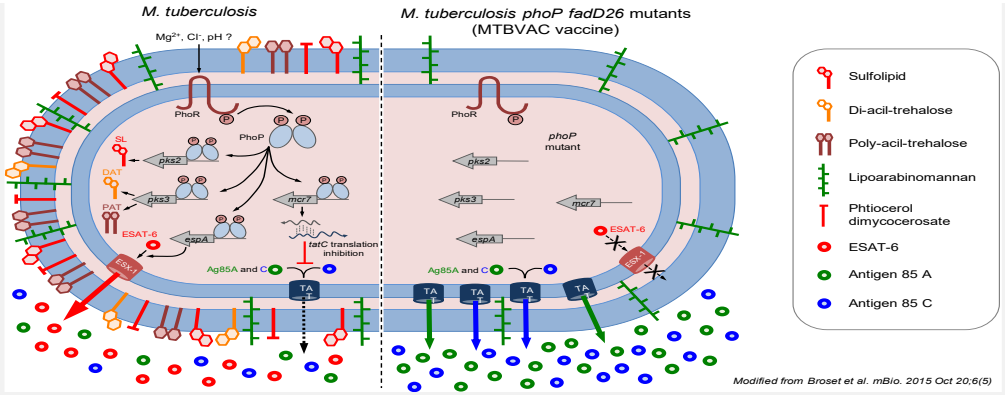
BIOFABRI

Biotechnology and vaccine

MTBVAC, a live freeze-dried Mtb vaccine against tuberculosis: 25 years R&D

E. Puentes

MTBVAC, at the glance



Universidad Zaragoza 1542

BIOFABRI

iavi
Translating science into global health impact

TBVI

MTBVAC is a live attenuated Mtb Vaccine derived from a human clinical isolate.

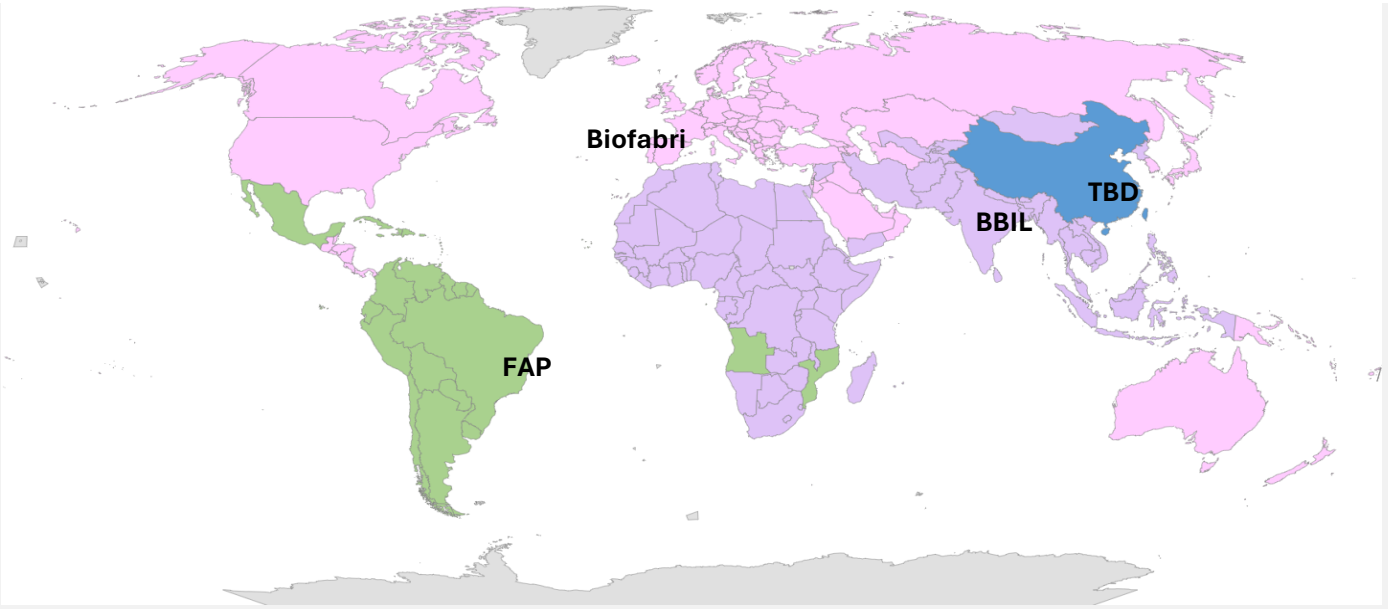
It contains the full repertoire of Mtb antigens that may be involved in generating an immune response against TB.

Preclinical data comparing MTBVAC to BCG shows MTBVAC is as safe as BCG while being more immunogenic and protective.

EMA approved **full prime status** to MTBVAC and will provide accelerated regulatory support to development of MTBVAC as a new TB vaccine.

MTBVAC - Manufacturing & Supply Strategy

Biofabri (Spain)	Zone 1	North America, Europe, North Asia, Australia, New Zealand. **85 countries**
FAP (Brazil)	Zone 2	Central & South America, Portuguese-speaking African Countries **34 countries**
BBIL (India)	Zone 3	South & Southeast Asia, Africa **77 countries**
TBD	**Zone 4**	China, Hong-Kong, Macao, Taiwan

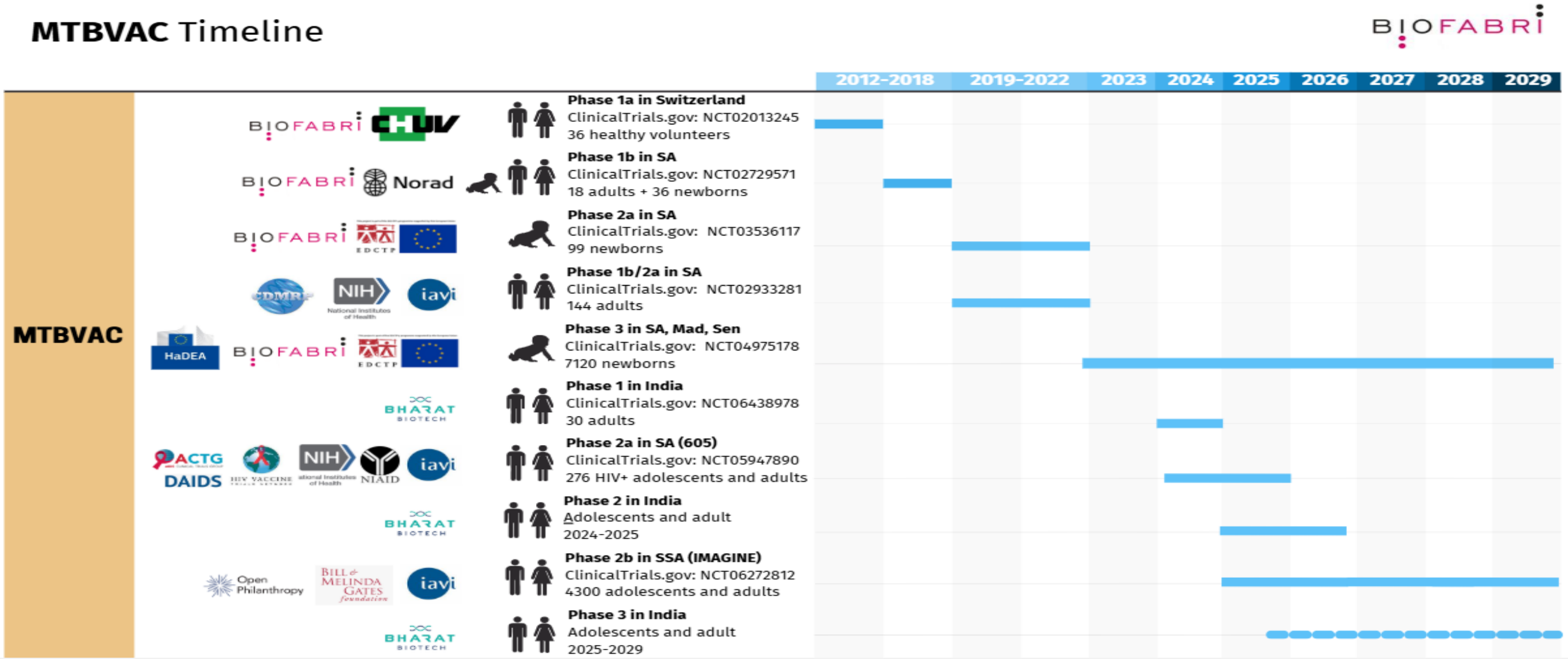


A **commercial scale** production process for MTBVAC has been developed at Biofabri.

Manufacturing and distribution agreements with manufacturing partners with BHARAT and FAP are in place to ensure global supply and availability of MTBVAC.

Our aim: develop a global vaccine affordable and accessible to all.

The History of MTBVAC Vaccine



Zendal Future Challenges and Strategies: Zoonoses and Pandemic Preparedness

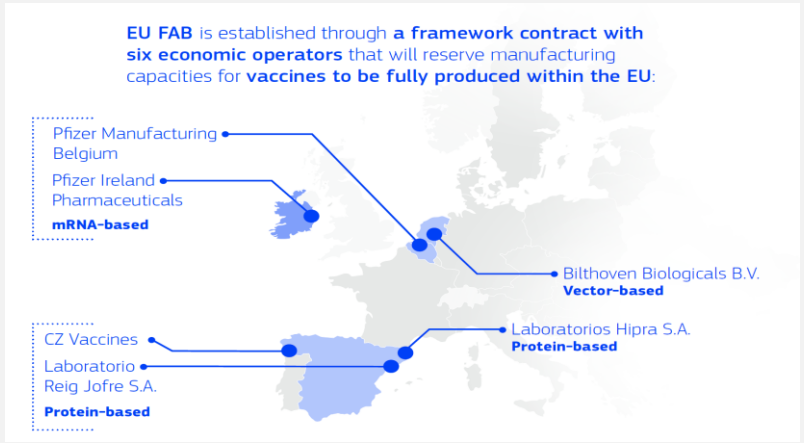
Human health vaccines manufacturing capacity:

CZ Vaccine, Porriño (Spain)

Zendal Portugal, a large-scale manufacturing plant, Paredes de Coura (Portugal)

Warm manufacturing facility for protein-based vaccine:

EU FAB, network of Vaccine producers for Future Health emergencies



Shaping the future of vaccines: progress, challenges, and innovation

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European Commission

Thank you