



**HERA** HEALTH EMERGENCY  
PREPAREDNESS AND  
RESPONSE AUTHORITY  
#HealthUnion

# **HERA Industry days**

## **H**ealth **E**mergency Preparedness and **R**esponse **A**uthority

2 & 3 June 2025, Brussels

## Plenary panel

**Breaking barriers to effective funding  
for innovative medical countermeasures**

# Breaking barriers to effective funding for innovative medical countermeasures



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Chief Executive Officer at  
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Unit Head, MCM WHO

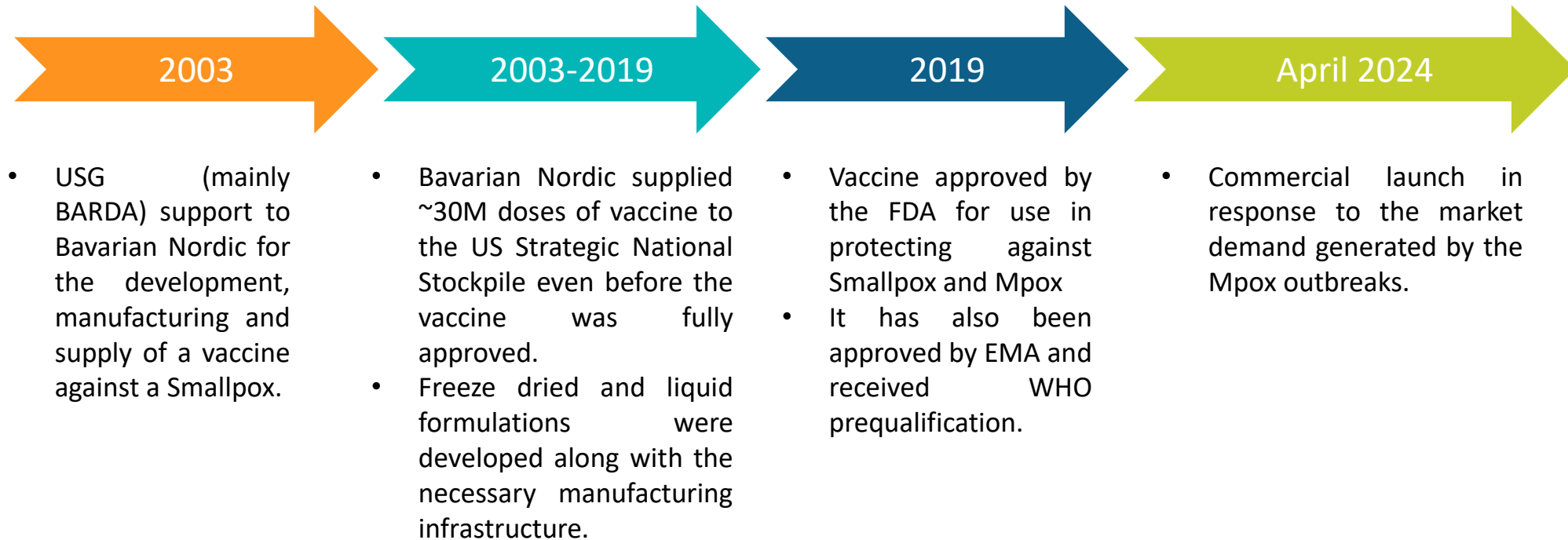
# Industry perspective on barriers to R&D for medical countermeasures (MCM)

*Magda Chlebus - Executive Director Science & Regulatory Policy, EFPIA*



HERA Industry Days, 2 & 3 June 2025,  
Brussels

# Mpox vaccine



It is only because of more than 20 years of support by the USG that the vaccine is currently available to allow vaccination campaigns in Europe, the US, Africa and elsewhere.

**Collaboration with industry will drive early through late-stage R&D with the goal of developing new MCMs that will be ready to use in the event of a health crisis**



**R&D**



**CAPACITY BUILDING**



**MARKET DEMAND**

**Attract & fund the best partners globally**

**Appropriate funding for each  
development stage**

**Ensure market demand and support infrastructure building and use**

**Appropriate risk and cost-sharing**

**Monitoring of project progression and the ability to adapt in response  
to the data generated**

**Contracting – initiate R&D quickly**



## Next MFF: A fit for purpose tool for late-stage development of MCMs

- **Contract** based with **single accountable lead contractor**
- **Joint governance**
- **Adequate funding** (e.g. 50+ mln per project, min. 50% funding rate)
- Open to **companies of all sizes** and **geographical origins**, and possibility to **conduct studies and manufacturing** ex-EU
- **IP rights with the innovator** (and march-in right as last resort)
- Flexibility to **rapidly amend contracts** as needs evolve and data is generated
- **Hands-on support and long-term collaborations** that may span more than one funding cycle

## As of now: Continued and efficient engagement with the private sector

- **Clear communication early engagement** at sector and company level on needs
- **Technology Watch**
- **Dialogue on "creating the market" (pull conditions)**
- **Continued reduction of red tape**



# **Funding AMR countermeasures: SMEs' perspectives**

**Dr. Marc Gitzinger, CEO BioVersys and President BEAM Alliance**



# Why funding AMR countermeasures is important

- The AMR market is broken, the pipeline is dry with 80% of the assets in the hands of (mostly) pre-revenue SMEs
- No new class of drugs for 30 years
- The happy few SMEs that made it to the market closed down

						
<i>Bankrupt in 2019</i>	<i>Acquired in 2022</i>	<i>Bankrupt in 2019</i>	<i>Ceased op. in 2023</i>	<i>Acquired in 2023</i>	<i>Acquired in 2020</i>	<i>Active, 41% force reduction in 2023</i>

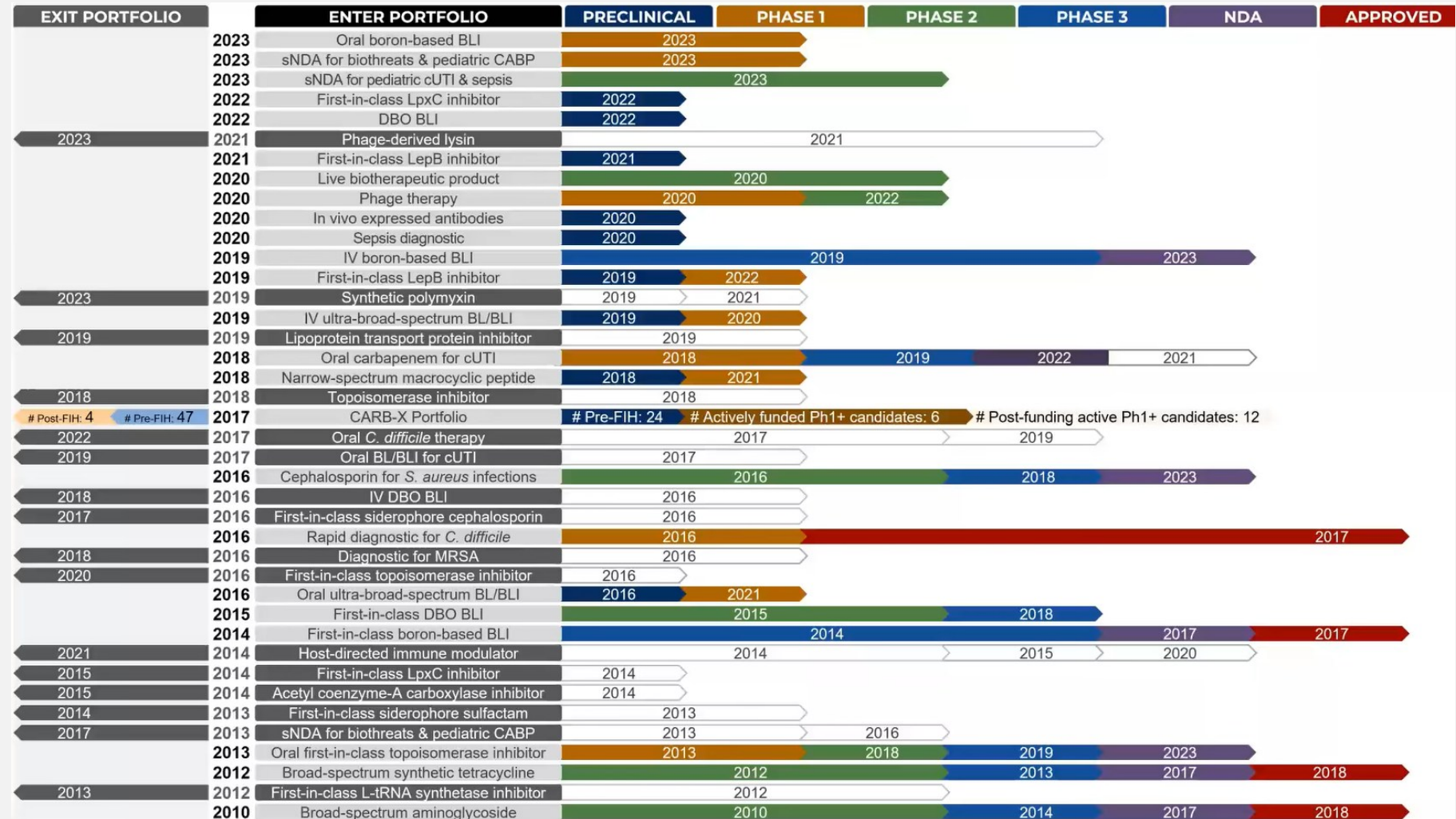
- Public funding is key to help develop the antimicrobials that are essential to modern medicine

# SMEs' perception of EU funding vehicles on AMR

- **Horizon Europe**
  - Health cluster: Too few relevant calls, too large consortia
  - IHI: Same + pre-competitive + need for EFPIA appetite in the topic
  - EDCTP: Works well but only with calls rather than proposal driven
  - EIC: Relevant design, limited size for late-stage trials, competitive for areas with limited market opportunity such as MCMs
- **EU4Health**
  - Tenders: limited experience
- **InvestEU**
  - HERA Invest: Large loans are suboptimal in the balance sheet of non-revenue making companies, 2 awardees in 2 years...

# A good example: BARDA (the US HERA)

BARDA's proven public-private partnership model has supported the development of **over 130 antimicrobial products** through a combination of direct investment and its partnership with **CARB-X**



# The strength of BARDA's model

- **People:** dedicated, expert, experienced staff and SMEs; a shared common goal
- **Product:** non-dilutive milestone-based funding; cost-share with shared risk
- **Process:**
  - 2 party contract, no consortium or other external stakeholders
  - pharma contractor retains responsibility and control
  - every spend requires BARDA approval; contractor must demonstrate value to USG BARDA
  - biweekly oversight meetings form a strong cross-functional expert team, laser-focused on the ultimate goal of FDA approval with target labelling
- **Result:**
  - Approx. 6 FDA approved drugs with approx. 1.5bn US\$ invested
- **Outlook:**
  - Hera could do the same, likely more cost effective
  - Stockpiling for MCMs especially in early years after approval could help to have a more predictable market upon launch

# Funding innovative SMEs: the basics

*Avoid large consortia  
and/or allow SMEs to  
select partners afterwards*



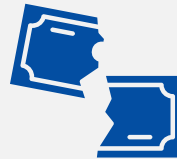
*Significant funding amounts  
(in terms of budget and funding  
rate)*

*Safeguarding IP ownership  
and avoid forced dilution –  
thus ensuring private  
sector to invest more*



*Focus on scientific core tasks  
towards **product development**  
with a **success-driven mindset***

*Dedicated to actors facing  
**market failure***



***Expert staff** following the project  
with the ambition to **provide**  
**guidance** for later stages*

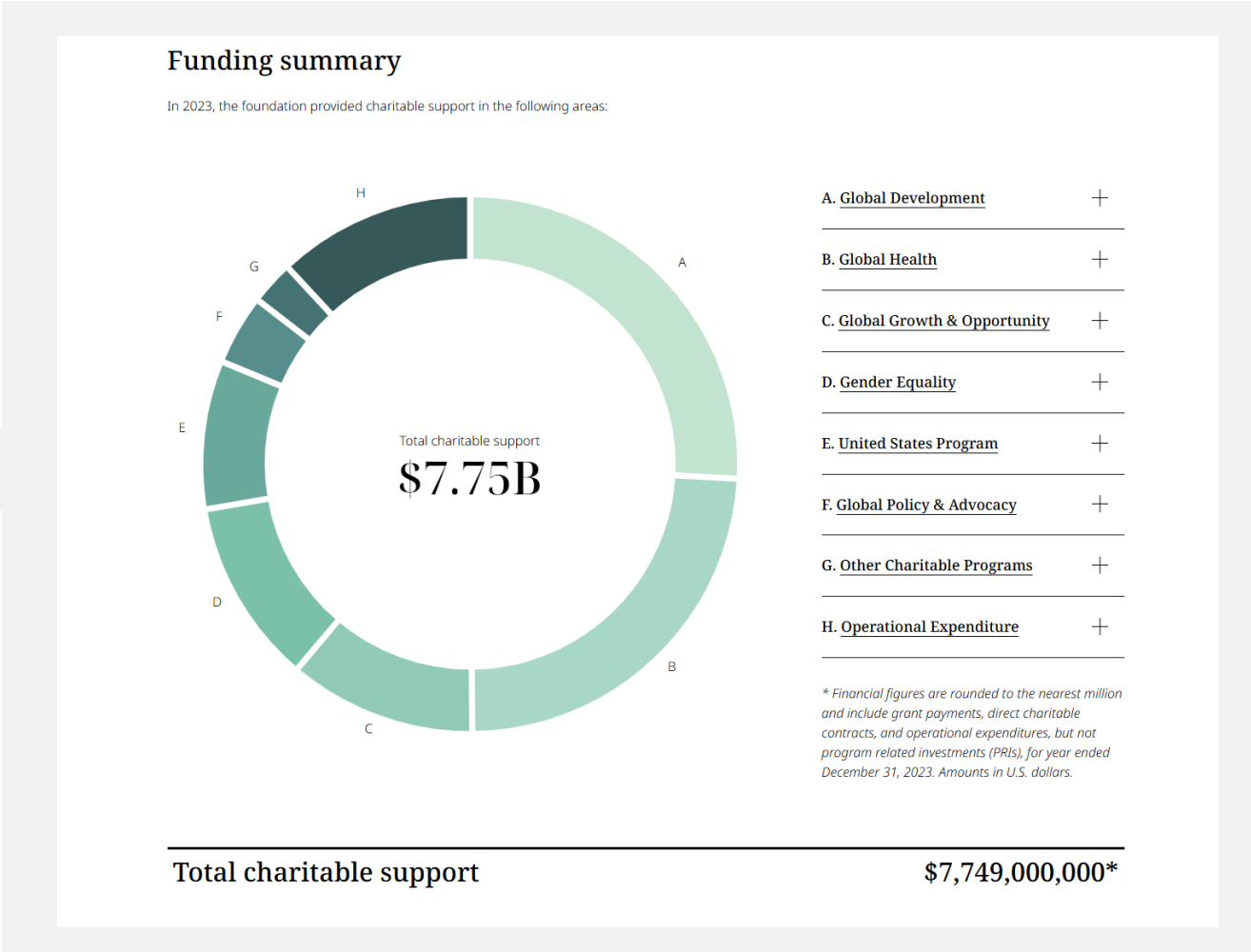
# The Gates Foundation is one of a number of philanthropic donors investing in global health R&D

## Gates Foundation Key Facts

- Non-profit, private foundation launched in 2000
- Total charitable support \$7.75B (2023)
- Over 1,200 grantees
- Primarily grant funding
- Strategic Investment Fund can support via innovative financing options

Our **Global health R&D** program focusses on

- 1) Maternal, child health and nutrition
- 2) Infectious diseases impacting LMICs

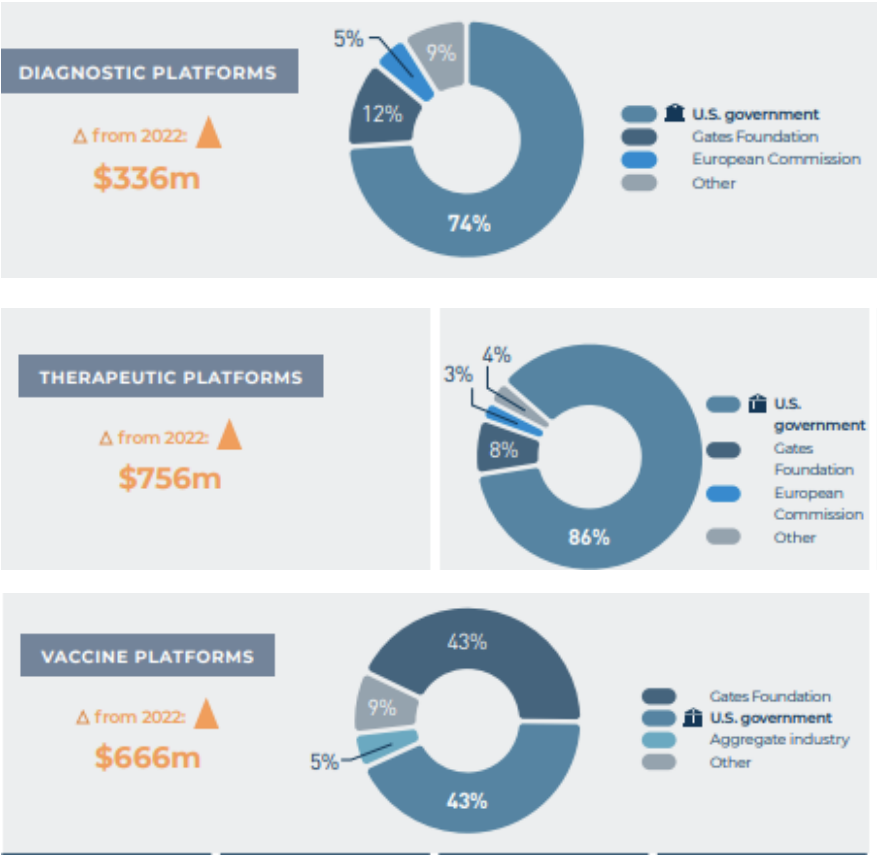


# Research for pathogens of pandemic potential is primarily government funded

*But the Gates Foundation contributes significant funding for the development of platform technology*



## Disease X



R&D funding for diagnostics, therapeutics and vaccines (2020-2023), as reported in the 100 day mission progress report, Jan 2025



# Several challenges exist in financing the development of innovative MCMs



**There is often insufficient commercial market to attract R&D investment in product development for infectious diseases predominantly affecting low and middle income countries:**

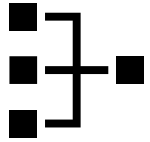
- Lack of data on burden and product demand in low-resource settings
- High cost of late-stage clinical trials
- Real or perceived lack of viable route to patient/route to market in LMICs



**R&D and product development for epidemic and pandemic diseases is typified by additional challenges and uncertainty**

- Target pathogen unknown
- Sporadic epidemiology creates uncertainty over when MCMs will be needed and how they will be used
- Added complications for product development increases risk (Regulatory issues, Feasibility of late stage trials)
- Lack of 'pull' mechanisms to procure and deploy tools in case of outbreaks
- Limited supply, logistical issues or high prices impact access to those that need it most

# Innovative financing and novel forms of collaboration are required



***Pooled funding mechanisms*** such as CEPI and PDPs combine resources effectively from public and philanthropic donors. Alternatively public and philanthropic partners can jointly fund calls for proposals or coordinate their funding around specific health challenges.



***Innovative approaches to sharing costs and risk burden*** across public and private sector, especially for expensive later stage trials- e.g. forgivable loans or equity investments



***Demand signals incl. pull mechanisms*** give confidence for private sector and funders to invest e.g. dual market, advanced market commitment



***Incentives for private sector investments in neglected areas of research*** – including mechanisms like the priority review voucher (PRV) scheme



***Funders may have different motivations, but can partner towards a shared goal.*** Building partnerships requires intention and flexibility on all sides.

# HERA Industry days

Brussels, 2<sup>nd</sup> of June 2025



**GARDP (Global Antibiotic Research & Development Partnership)**  
**An Integrated Approach to Antibiotic R&D & Access**

**Yann Ferrisse**

*Business Development & Partner Engagement Director*

# Antibiotic resistance, a global public health priority requiring new solutions



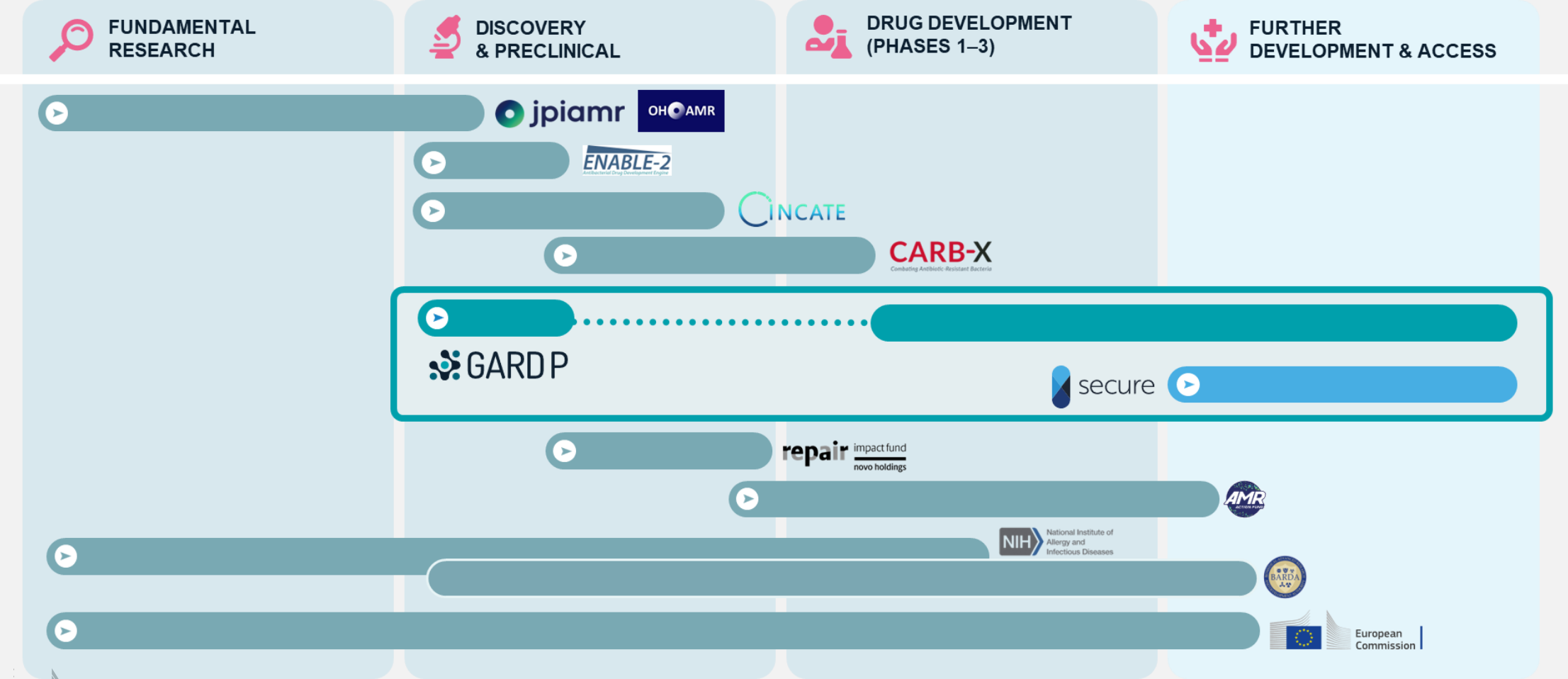
**Our Vision**

**All infections are treatable**  
for everyone, everywhere






**Our Mission**

We accelerate the **development and access of treatments** for drug-resistant bacterial infections

# GARDP in the antibiotic R&D and access landscape



# GARDP portfolio

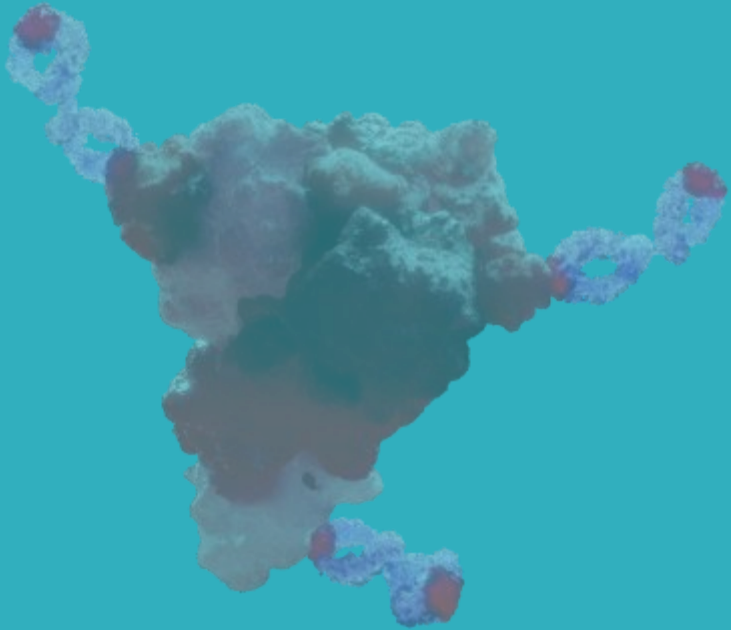
TREATMENT	CLASS	PARTNER	STAGE OF DEVELOPMENT	WHO PRIORITY PATHOGENS	GARDP'S COMMERCIAL RIGHTS
SERIOUS BACTERIAL INFECTIONS & SEPSIS					
<b>Cefiderocol</b>	Siderophore cephalosporin	 <b>SHIONOGI</b>	Approved by US FDA (2019) and EMA (2020). Included on WHO EML. PIP and PSP ongoing.	CRE CRPA	135 countries
<b>Cefepime-taniborbactam</b>	$\beta$ -lactam / $\beta$ -lactamase inhibitor	 <b>Venatorx</b> PHARMACEUTICALS	Positive cUTI phase 3 results. NDA in submission process	CRE CRPA	64 countries + India and South Africa (public market only)
<b>Investigational compound BWC0977</b>	Pyrazino-oxazinone	 <b>bugworks</b>	Phase 1	CR infections, including CRAB	146 countries
NEONATAL SEPSIS					
<b>Flomoxef</b>	Cephalosporin	 <b>SHIONOGI</b>	Approved in 4 Asian countries since 1998	ESBL	Generic
<b>Fosfomycin</b>	Generic phosphonic	 <b>INFECTOPHARM</b> <i>Wissen wirkt.</i>	Approved in Europe and in some LMICs	ESBL	Generic
<b>Amikacin</b>	Generic Aminoglycoside	N/A	Generic, introduced in 1977	ESBL	Generic
SEXUALLY TRANSMITTED INFECTIONS (GONORRHOEA)					
<b>Zoliflodacin</b>	Spiropyrimidinetrione	<b>INNOVIVA</b> Specialty Therapeutics™	Positive phase 3 results	Ceftriaxone- and multidrug-resistant <i>N. gonorrhoeae</i>	¾ of countries worldwide (~150)

## Time to discuss the relative efficiency and effectiveness of different financing options

- **No single push- or pull-incentive** will solve all funding needs;
- Prioritize **public health impact** including needs of underserved populations;
- Anchor an **end-to-end model** & then **coordinate EU funding** across discovery, clinical development, manufacturing, and access;
- **‘Innovation’**: Fund compounds based on expected population-level outcomes, not just novelty;
- Reconsider **the role of public institutions and governments in global health** – to lead or to follow.



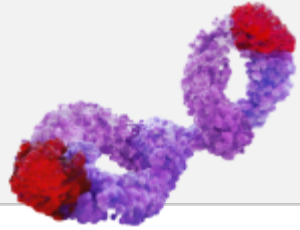
# Broad-spectrum Antibodies for Emergency Situations



*Treatments for biodefence solutions  
and emerging infectious diseases*

# Fabentech ID

15 years of experience in development and production of medical countermeasures



► **Established in**

2009 in Lyon, France

► **Technology**

Immunoglobulins F(ab')<sub>2</sub> (Sanofi)

► **Employees**

50 FTE, 20% PhD

► **Bioproduction site**

One proprietary GMP-ready facility

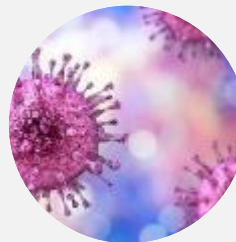
Building the European leader in emergency treatments  
against biothreats



## BIODEFENCE

Antidotes against bioterrorism agents

Toxins, viruses



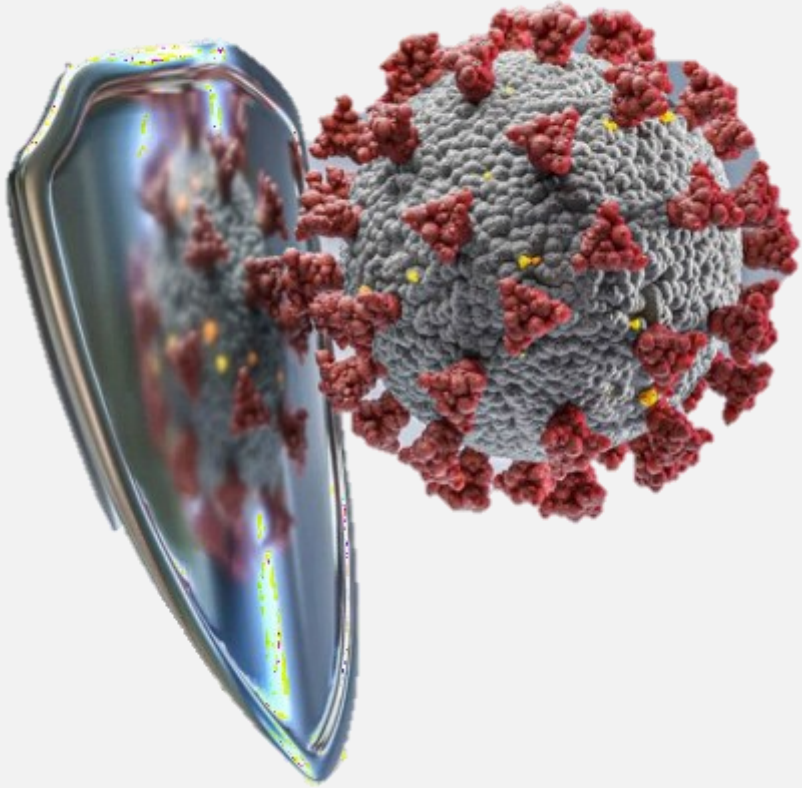
## PANDEMIC PREPAREDNESS

Anti-infectives against Emerging Infectious Diseases

Nipah – H5N1 – Ebola – Sarbecoviruses

# FabShield® platform – BE READY

## The European shield against biothreats



### ✓ **Robust and reliable technological platform**

With integrated R&D and production capabilities



### ✓ **5 antidotes in développement**

against deadly biological agents



*Toxins*



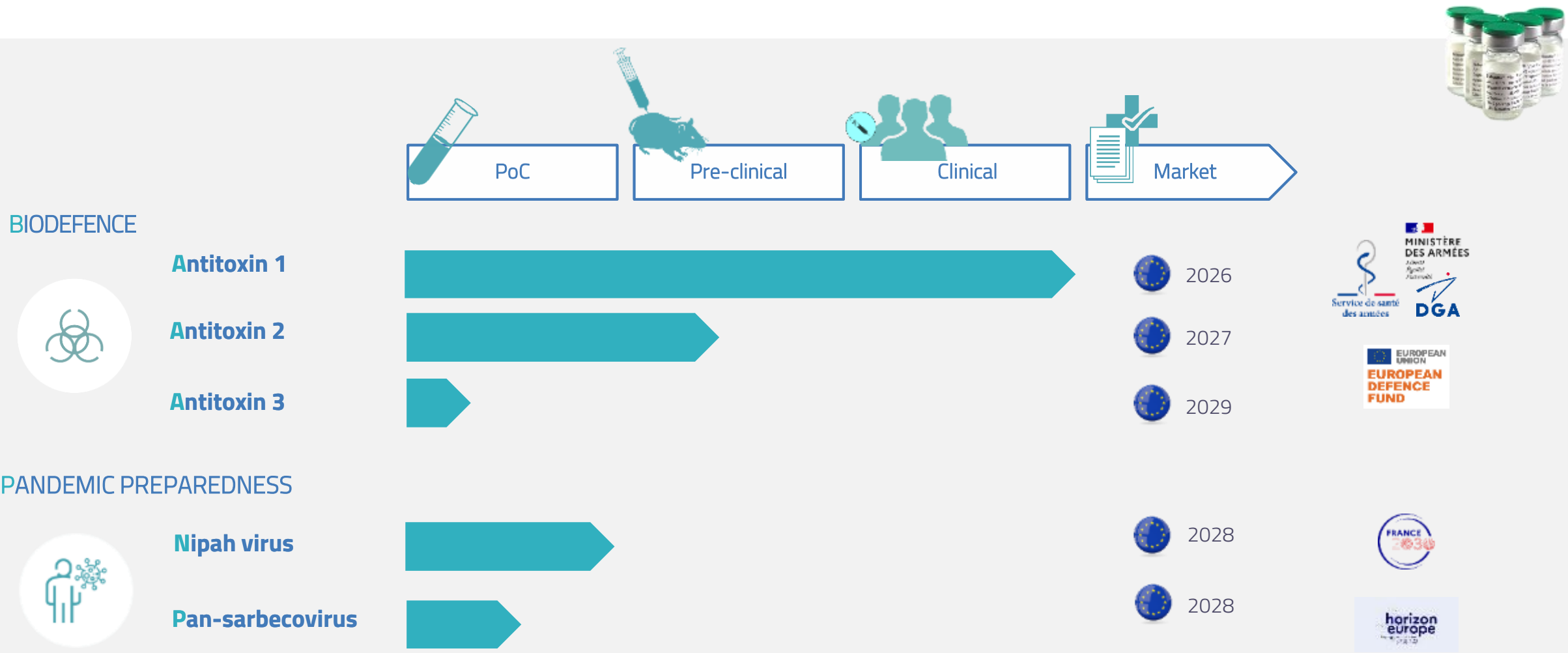
*Nipah, Sarbecovirus, H5N1*



### ✓ **Anticipation of future risks**

for an immediate response when the threat appears

# A diversified pipeline of broad-spectrum therapeutics

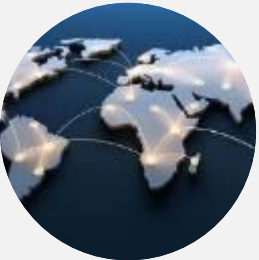


On hold programs : H5N1, Ebola and Sars-Cov-2

# HERA invest financing : 20 m€ to accelerate deployment & support the transformation



Product development & new technologies



International expansion and commercial activities



Industrial process optimizations



**Profitable** by 2027



**5 antidotes** on the market by 2030



**Sovereign**, reliable and sustainable production in Europe

# Breaking barriers to effective fundings for MCMs

*Given the exceptional circumstances for use of MCMs, SMEs need*



- Market predictability and transparency
- **A Stockpiling strategy**



- Long-term contracts with end-to-end fundings
- Unified funding pathways to avoid fragmented tools
- Attract private investors



- Regulatory flexibility to accelerate approvals or
- Early access programs



- A « buy EU approach » to support **EU strategic autonomy**
- Coordination between EU institutions and MS

# Health Emergency Preparedness & Response Global Financing Landscape Analysis

*Tim Nguyen, Head of Unit Medical Countermeasures  
WHO Health Emergencies Programme*

HERA Industry - Breaking barriers to effective funding for innovative medical countermeasures

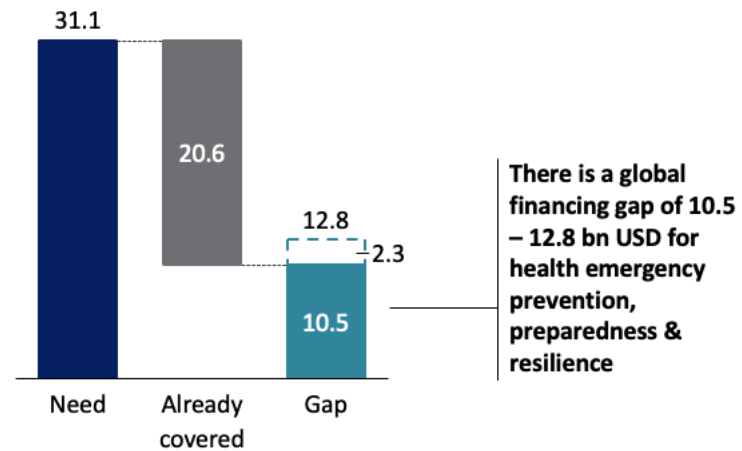
*3 – 4 June 2025*



# Health emergency financing landscape analysis identifies **two key issues** ...

## 1 \$10Bn per preparedness financing gap

Total (National/Global/Regional levels)

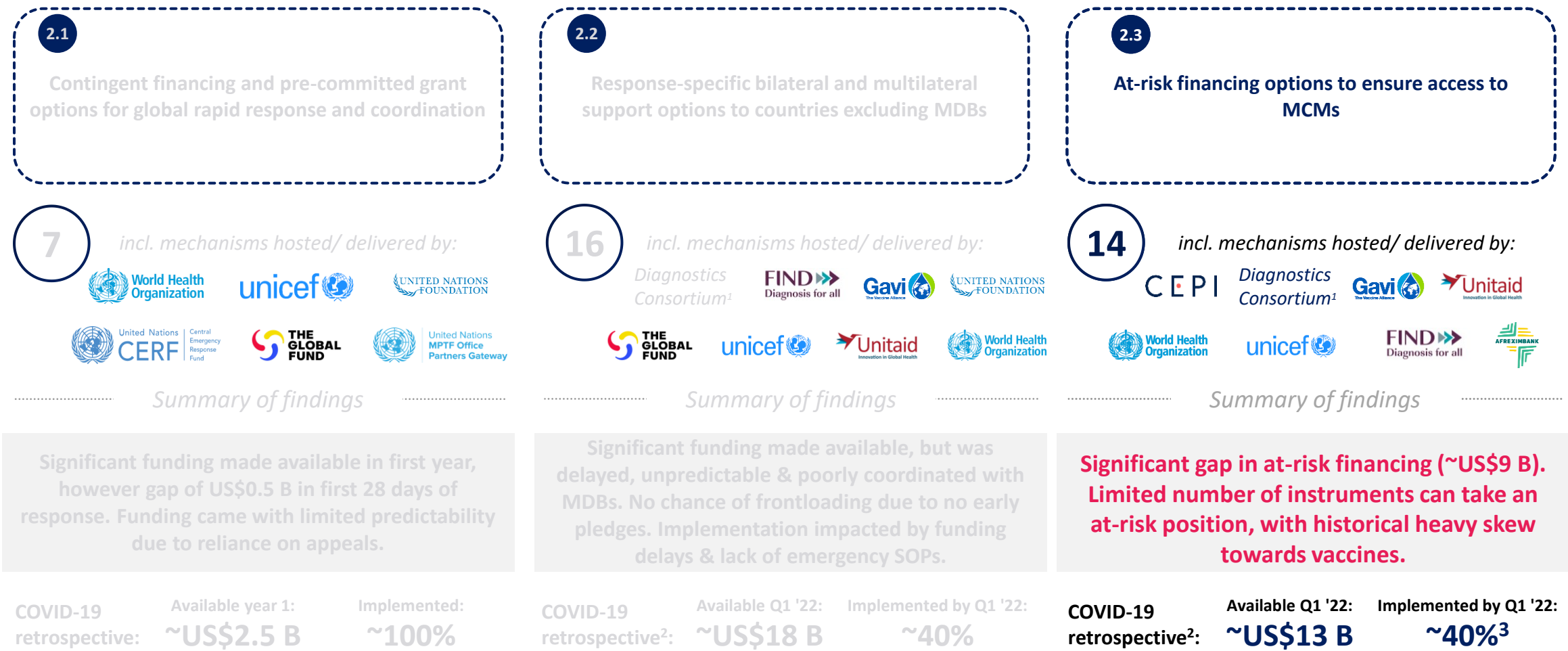


## 2 Fragmented & uncoordinated donor-led financing landscape





# During the pandemic large amounts were made available, lack of coordination and timeliness impacted response with **key gap in at-risk financing**

## Mapping & Gap Analysis Global and Regional COVID19 Response



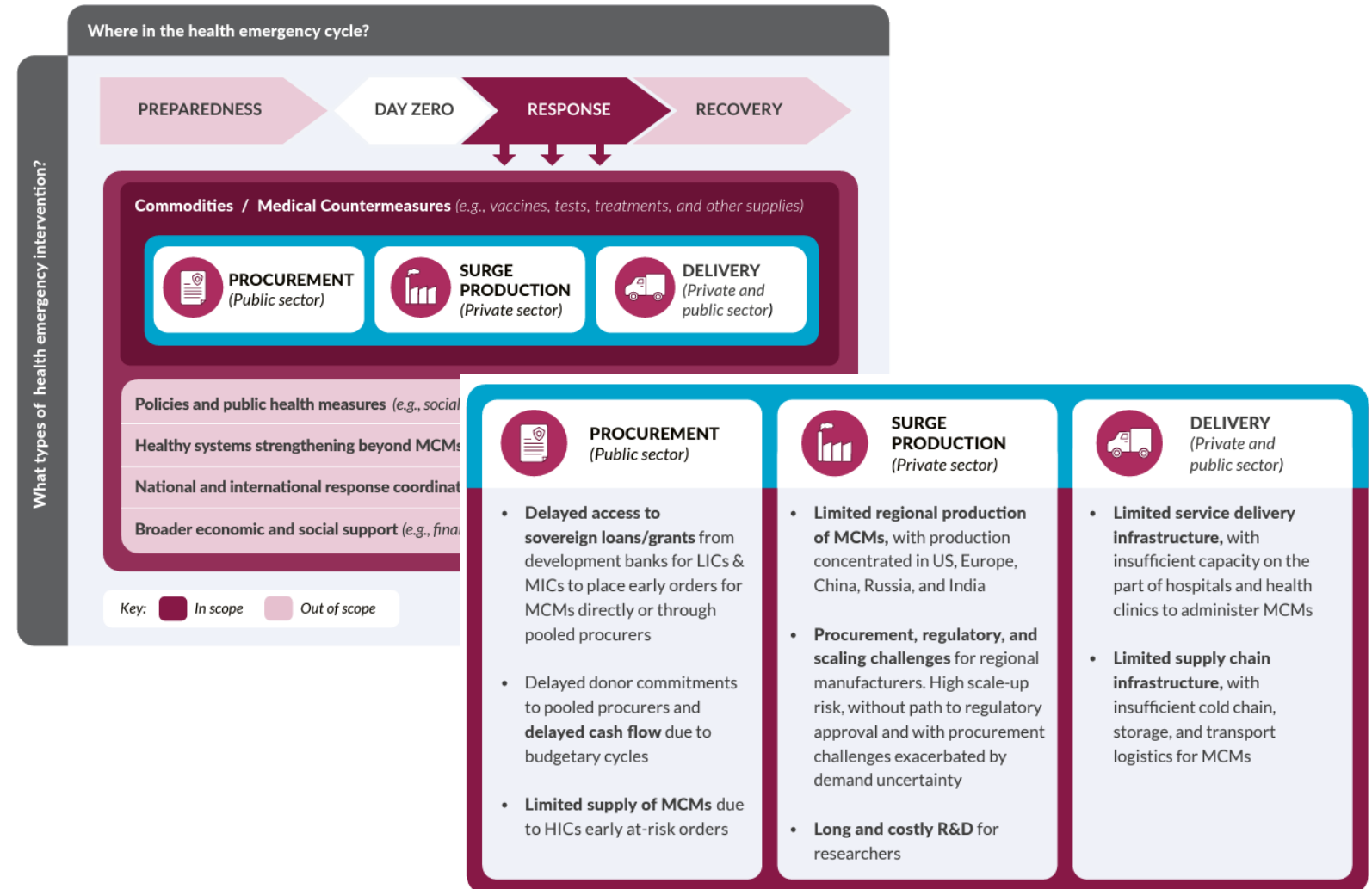
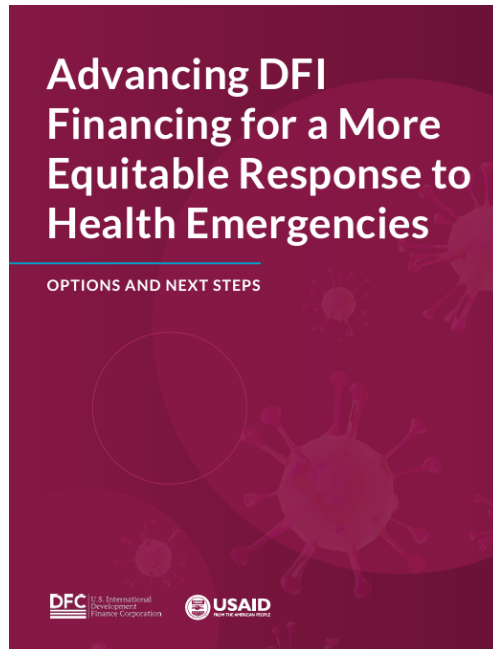
1. The Diagnostics Consortium for COVID-19 was an inter-agency mechanism created at the request of the UN Secretary General to secure volumes of COVID-19 tests and allocate them among over 160 countries with limited market access, according to agreed principles. Over 50 members were involved 2. Based on HSRC analysis Q1 2022 3. Based on Gavi, Unitaid, CEPI, AVAT, FIND Dx

 WORLD BANK GROUP

 World Health Organization

31

# Example: DFI Initiative - Focus on accelerating financing for MCMs in response to a health emergency, but the **Oversee Development Assistance** landscape has changed



# WHO Pandemic Agreement approved at WHA78 - Article 18 Sustainable financing



A78/10

Annex

3

## Appendix

**Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response**

### Proposal for the WHO Pandemic Agreement

**Outcome of the Intergovernmental Negotiating Body:  
agreed text on Wednesday, 16 April 2025 at 01:57 CEST**

NOTE: Consistency review (25 April 2025)

- **Green** highlighting indicates text for which agreement has been reached by the Intergovernmental Negotiating Body.

## Key points

- Adopt a Financial and Implementation Strategy for pandemic prevention, preparedness, and response
- Parties, especially financial supporters, should align their funding with the Strategy within and outside WHO.
- **Establish a Coordinating Financial Mechanism to support the WHO Pandemic Agreement in a sustainable and transparent way.**
- The Mechanism aims to increase the effectiveness and efficiency of financial resources for pandemic prevention, preparedness, and response, focusing on developing countries.
- Promote harmonization and coordination in financing for pandemic prevention, preparedness, and response and related capacities.

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# Thank you