

Global Antibiotic Research and Development Partnership (GARDP)

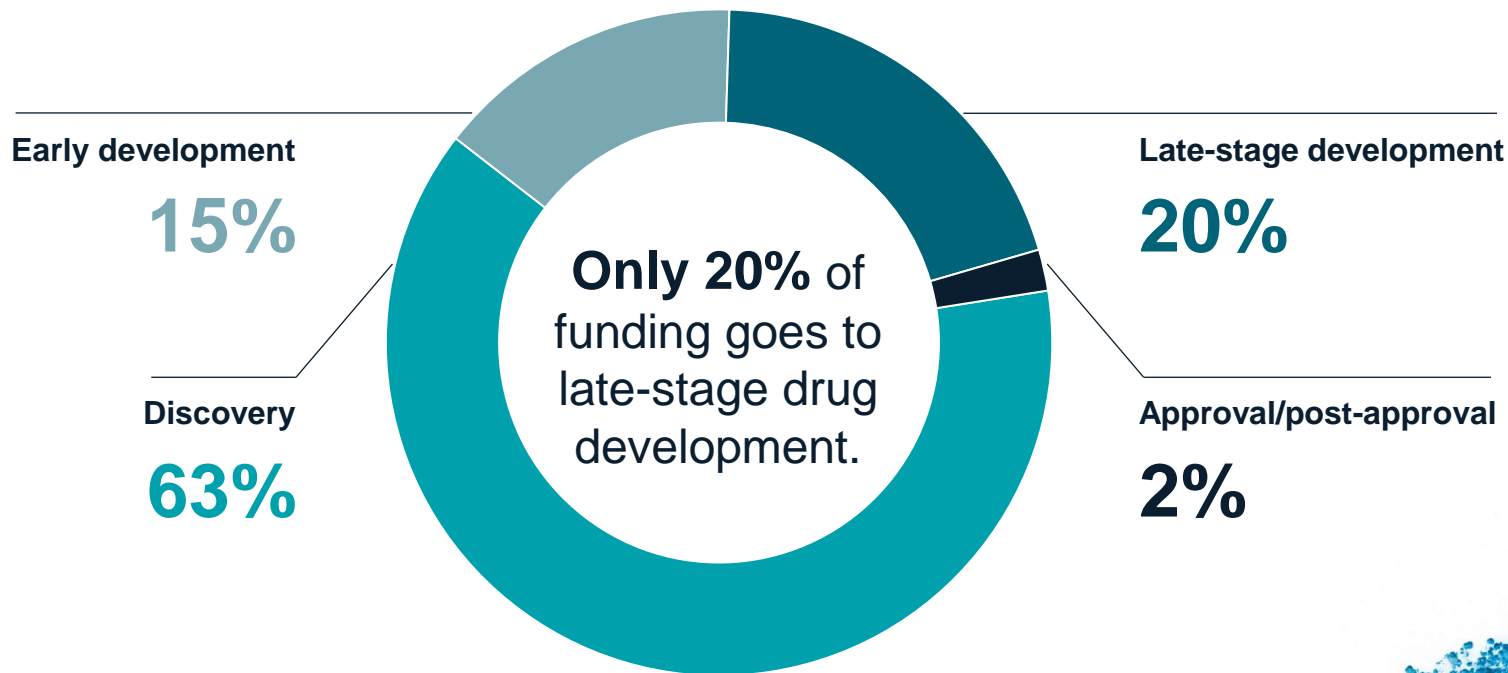
UN Global Leaders Group Briefing

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Public and philanthropic funding for late-stage R&D development is inadequate

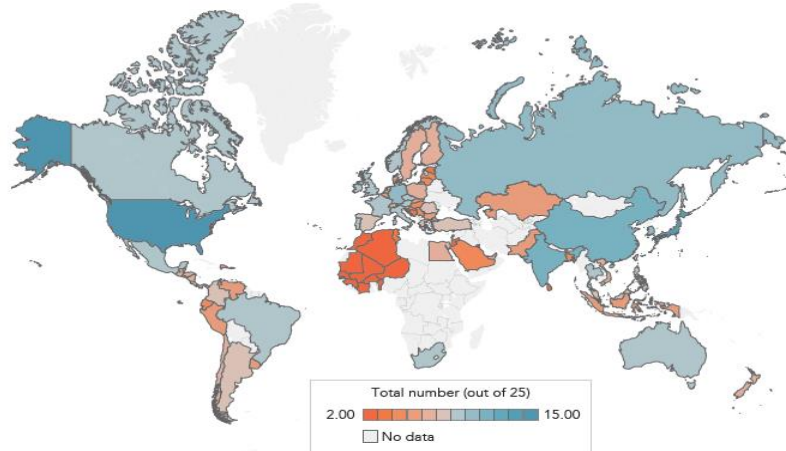


Total therapeutic investments in million USD by R&D stage (source: 2020 Global AMR R&D Hub Report)

Two trends in antibiotic access

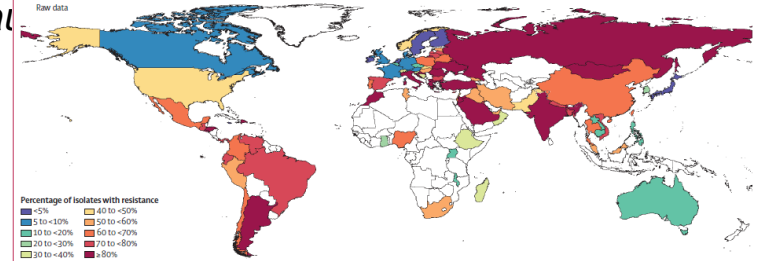
1. Not widely registered

Number of antibiotics registered 1999-2014

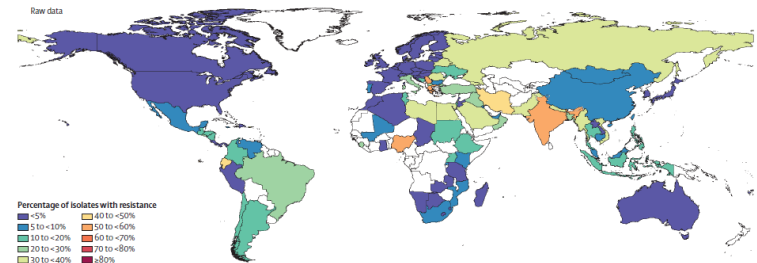


2. Growing antibiotic resistance

Carbapenem-resistant *Acinetobacter baumannii*



Carbapenem-resistant *Klebsiella pneumoniae*





Our Vision

All infections are treatable
for everyone, everywhere

Our Mission

We work with partners
to **accelerate the development
and access to treatments** for
drug-resistant infections

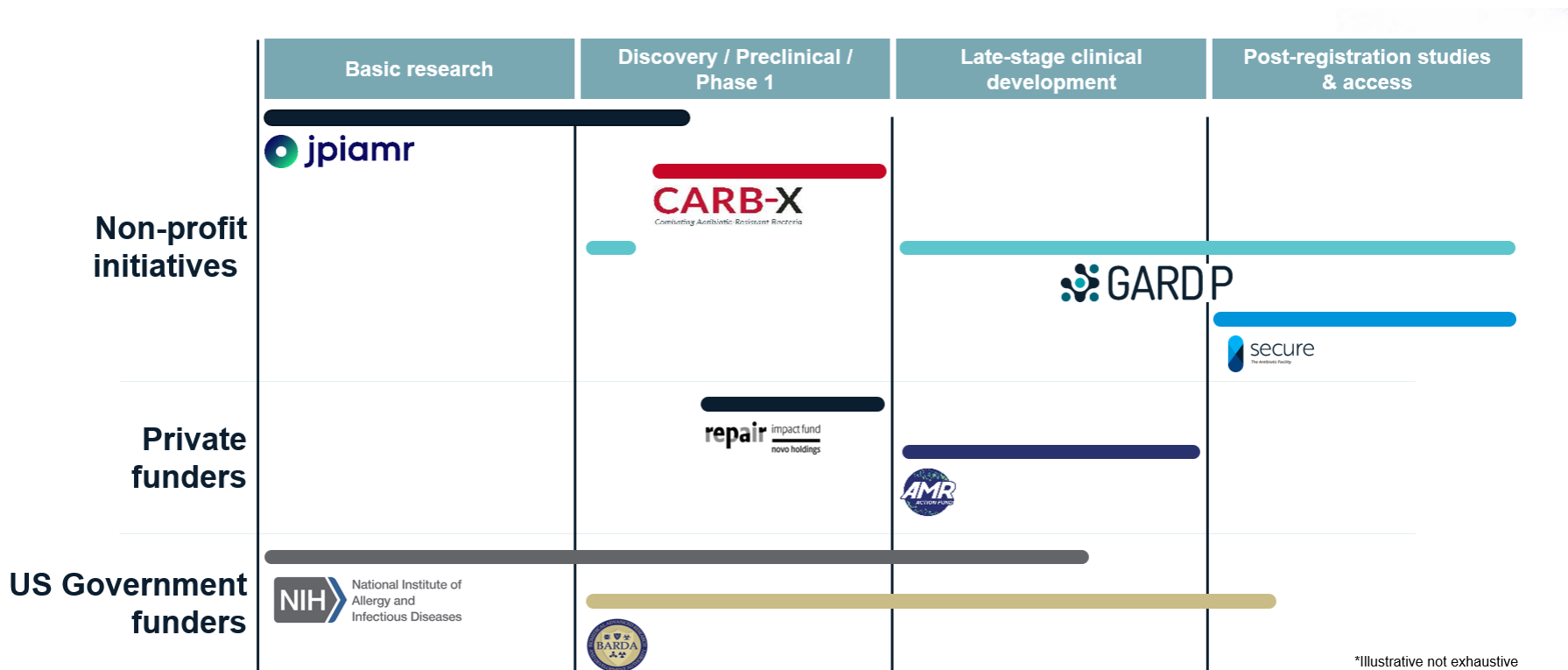
Tackling antibiotic resistance together



A global organization working with **70 partners** across **16 countries** including governments, academic institutions, civil society and the private sector




GARDP in the AMR Landscape





Benefits of a not-for-profit model

- Investment in projects with little or no commercial value, but fulfilling a public health need
 - Focus on populations, including children, and geographies worldwide for R&D with a public health perspective
 - Less risk averse
 - Perceived as a neutral, trusted partner by the public and private sectors
 - Motivation and capacity to mobilize resources to foster R&D and access infrastructure
- 

Addressing the most urgent threats to public health



Sepsis in children and newborns

1 in 5 deaths due to antibiotic resistance occur in children.
140,000 newborns die each year.



Serious bacterial infections in adults

Patients undergoing common medical procedures, such as C-section, hip replacement, or chemotherapy, are at risk of acquiring bacterial infections that cannot be easily treated with commonly used antibiotics.



Sexually transmitted infections

Sexually transmitted infections caused by bacteria may become untreatable with the rise of superbugs, especially gonorrhoea.

Our programmes

1. Antibiotic research & development

Developing new antibiotic treatments to address the most urgent public health threats

CHILDREN'S
ANTIBIOTICS

SERIOUS BACTERIAL
INFECTIONS

SEXUALLY
TRANSMITTED
INFECTIONS

DISCOVERY AND
EXPLORATORY
RESEARCH

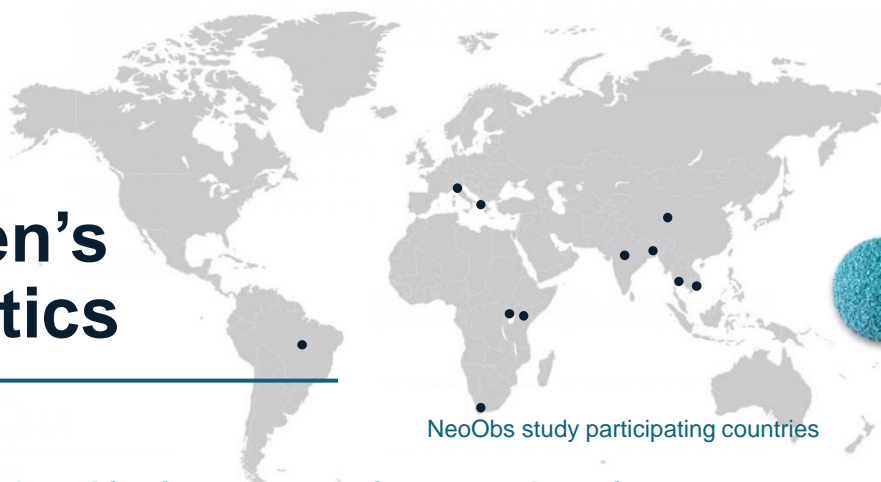
2. Accelerating access

Securing access to a portfolio of novel and generic antibiotics for all people, everywhere

3. REVIVE

Preserving and sharing scientific knowledge

Children's antibiotics



NeoObs study participating countries



3 potential combination treatments for neonatal sepsis

Completed one of the largest studies on babies with sepsis—3,200 newborns in 11 countries—and identified 3 promising antibiotics for use in combination (amikacin, fosfomycin, and flomoxef)



Public health trial to test treatment combinations

A multinational trial of new antibiotic combinations to treat neonatal sepsis should recruit the first patients in Feb/Mar 2023



Paediatric studies of new antibiotics

Supporting paediatric studies for cefepime-taniborbactam

TOMORROW



Provide new treatment options for 20 million children (including 3 million newborns) with sepsis and help prevent up to 3 million deaths each year

HOW?

By obtaining paediatric indications, sharing global recommendations on treatment options and dosage, and facilitating access to new—and the right—antibiotics

Sexually transmitted infections



- Phase 3 zoliflodacin trial participating countries

TODAY



A new innovative treatment for gonorrhoea in late-stage development (zoliflodacin)

GARDP and Entasis are finalizing a global phase 3 trial in 16 sites across 5 countries to evaluate zoliflodacin, an innovative oral treatment for gonorrhoea

The final trial results will become available in the course of 2023

Completed the manufacturing of the final drug product for registration and commercialization



TOMORROW

Provide a new oral treatment option for 82 million people who contract gonorrhoea each year and limit its global spread

HOW?

By expanding access to this new treatment, upon approval, in countries around the world

Serious bacterial infections



TODAY

- Observational study participating countries



A promising new antibiotic treatment on track for regulatory submission (cefepime-taniborbactam)

Welcomed positive results in a phase 3 trial of cefepime-taniborbactam by Venatorx Pharmaceuticals. If approved, this will be the first antibiotic treatment to be launched in collaboration with GARDP



An approved antibiotic treatment (cefiderocol)

Signed an agreement with Shionogi and CHAI to facilitate access to this new antibiotic in 135 countries, mostly low- and middle-income countries



An observational study of priority pathogen infections in hospitalized patients in high priority countries

Launching an observational study at 11 sites across India and South Africa to record current treatment practices for infections caused by carbapenem resistant infections



TOMORROW

Provide new treatment options for 29 million adults with sepsis and help prevent up to 8 million deaths each year

HOW?

By developing new antibiotic treatments and making them accessible to anyone who needs them

Accelerating access

TODAY



Access agreements with:

- **Groundbreaking license agreement with Shionogi** to make an antibiotic (cefiderocol) accessible in 135 countries, mostly low- and middle-income countries (LMICs)
- **Venatorx Pharmaceuticals** for a new antibiotic combination (cefepime-taniborbactam) in 66 LMICs upon approval
- **Entasis Therapeutics** for a new gonorrhoea antibiotic (zoliblodacin), upon approval, in all LMICs (150)



A global access initiative: **SECURE**

A joint initiative by WHO and GARDP in collaboration with UNICEF and CHAI to accelerate access to essential antibiotics for countries in need



Policy support

Supporting policies to address antibiotic shortages and add existing antibiotics – such as flomoxef – to the WHO Essential Medicines List



TOMORROW

Provide equitable access to effective antibiotics for everyone, everywhere

HOW?

By working with medical professionals, policymakers, antibiotic developers, non-profit groups and others to expand antibiotic access in a responsible way

The cefiderocol access project:

A comprehensive approach to access

An agreement signed with Shionogi and CHAI to improve access to cefiderocol in 135 LMICs is paving the way for **sustained access to this and other antibiotics**.



Manufacturing

Affordable and quality-assured products from a licensed manufacturer



Registration

Support for commercialization in high-burden countries



Implementation

Partnerships to co-develop and introduce robust implementation plans



Guidelines

Evidence-based guidance to steward appropriate use






SECURE: The Antibiotic Facility

A joint initiative of WHO and GARDP, with support from UNICEF and the Clinton Health Access Initiative, **SECURE** seeks to accelerate access to a portfolio of essential antibiotics, while ensuring their sustainable use.

A four-year pilot is expected to be launched in 2024 in participating countries.



An overview of GARDP's 5 treatments by 2025

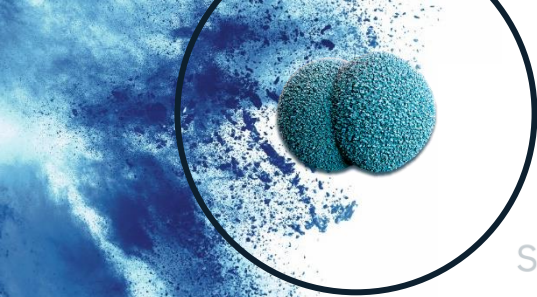
Disease area	GARDP programme area	Treatment	Target pathogens* (WHO priority pathogens)	Description	Investments to date (EUR)
Sepsis		Treatment 1: neonatal sepsis empiric treatment regimen (Shionogi & Co., Ltd and InfectoPharm)	ESBL	Treatment for sepsis in newborns: <ul style="list-style-type: none"> • flomoxef-fosfomycin • fosfomycin-amikacin • flomoxef-amikacin 	25 million
Sepsis		Treatment 2: cefiderocol (Shionogi & Co., Ltd)	CRE CRPA CRAB	Reserve treatment for hospital and community-acquired bacterial infections in: <ul style="list-style-type: none"> -adults -children -newborns 	3 million
Sepsis		Treatment 3: cefepime-taniborbactam (Venatorx Pharmaceuticals, Inc.)	CRE CRPA	See above.	14 million
STI		Treatment 4: zolidodacin (Entasis Therapeutics Limited)	<i>Neisseria gonorrhoeae</i>	Oral treatment for uncomplicated gonorrhoea.	45 million
Sepsis or STI		Treatment 5: TBD	TBD	TBD	

* ESBL: extended spectrum beta-lactamases – producing Enterobacteriales; CRE: carbapenem-resistant *Enterobacteriaceae*; CRPA: carbapenem-resistant *Pseudomonas aeruginosa*; CRAB: carbapenem-resistant *Acinetobacter baumannii*.



Five Joint Recommendations to the GLG on R&D and Access

1. WHO should formalize a numerical target of “highly-impactful” antibacterial treatments (including innovative products as well as paediatric formulations and combinations of new and existing antibiotics) for the next decade so that governments and philanthropic organizations, with the support of the Global AMR R&D Hub, can compare needed and expected investments to guide their long-term funding
2. Governments should close the funding gap for early-stage product development in order to replenish the clinical pipeline with much-needed innovative and “highly-impactful” projects
3. **Governments should close the funding gap for clinical development, registration, manufacturing, post-approval trials and sustainable access in high-burden LMICs**
4. Government should implement pull incentives that bring private investors back into antibacterial R&D while ensuring equitable and sustainable access globally
5. Provided there are adequate funding and financing mechanisms in place, pharmaceutical companies should align their R&D programs to address unmet needs defined under the WHO Priority Pathogen List, and assure equitable and sustainable access to new and existing antibiotics

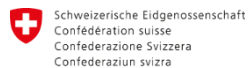


Ministry of Health, Welfare and Sport



Leo Model Foundation

BILL & MELINDA
GATES foundation



Swiss Confederation



LE GOUVERNEMENT
DU GRAND-DUCHÉ DE LUXEMBOURG

Thank you

