



GARDP

Global Antibiotic Research
& Development Partnership

Uniting against antibiotic resistance

Working in partnership
to develop new treatments
for bacterial infections;
safeguarding their
sustainable access
so they are available
to everyone,
everywhere

5BY25



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About GARDP

What is GARDP?

The Global Antibiotic Research and Development Partnership (GARDP)

is a not-for-profit public health research and development (R&D) organization.

GARDP was co-founded by the World Health Organization (WHO) and the Drugs for Neglected Disease *initiative* (DNDi) in 2016 and is a core element of the Global Action Plan on Antimicrobial Resistance (AMR).

We develop new and improved treatments

focusing on areas of greatest public health need. Our focus is on WHO's priority pathogens list and incorporates the needs of priority populations, targeting infections less likely to be addressed by other actors. We work with our public and private sector partners to ensure sustainable access, promoting responsible use and affordability to all in need.

What do we mean by antibiotics, treatments and sustainable access?

Antibiotic: is a substance that either kills bacteria or stops them from growing.

Treatment: is a formulation and/or regimens of either a single or combination of (antibiotic) drugs that is used to treat infections.

Sustainable access: refers to treatments which are of a required quality (i.e. relating to active compounds and manufacturing standards); affordable for patients and/or health systems; supplied in a timely and appropriate manner; and having the required stewardship in place to ensure they are used in a responsible manner (avoiding over-prescription and unnecessary use).

GARDP's vision

All infections are treatable for everyone, everywhere

GARDP's programs

OBJECTIVES

1



SERIOUS BACTERIAL INFECTIONS

Accelerate development of new antibiotics to deliver at least one new treatment addressing priority **hospitalized adult populations** due to infections caused by **WHO priority pathogens**.

Assess new antibiotics, 'recovered' drugs, and combinations.

2

CHILDREN'S ANTIBIOTICS



NEONATAL SEPSIS

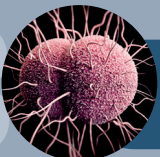
Develop an **alternative first-line treatment for clinically diagnosed cases of sepsis** and a new treatment for confirmed **multidrug-resistant pathogens**.



PAEDIATRIC

Repurpose and optimize use of old antibiotics and **accelerate** development of new antibiotics for at least one new and **improved treatment** for children.

3



SEXUALLY-TRANSMITTED INFECTIONS

Accelerate development of **new antibiotics** and **develop at least one new treatment** for difficult to treat and drug-resistant infections.

4



DISCOVERY & EXPLORATORY

Identify novel antibiotics for new and under-exploited targets to translate into treatments for drug-resistant infections.

GARDP's mission

We bring together the public and private sectors to develop new treatments for bacterial infections.

We ensure responsible and sustainable access, addressing the public health impact of antibiotic resistance.

ACHIEVEMENTS

Identified a drug as a candidate of interest for serious bacterial infections on hospitalized adults and ready to launch new partnerships.

Reviewed 100+ treatment candidates from new and 'recovered' antibiotics.

Developed two target product profiles (TPP) for new treatments: clinically-diagnosed sepsis (TPP1); neonatal multidrug-resistant infections (TPP2)

Completed a pharmacokinetic clinical trial to evaluate a generic drug candidate in TPP1 (fosfomycin)

Launched and enrolled 2000+ patients in a neonatal sepsis observational study in 11 countries to inform phase III trials

Identified old drugs and new chemical entities in the pipeline & launched an in vitro pharmacokinetic/ pharmacodynamic project to evaluate candidates for both TPPs.

Initiated a paediatric antibiotic development platform building on existing networks in high-burden countries.

Identified candidates of interest for paediatric serious bacterial infections.

Developed with WHO and other key stakeholders a strategy and TPP to guide our program.

Established a partnership to develop a first-in-class drug (zoliflodacin) for the treatment of gonorrhoea.

Developed a robust commercial formulation for zoliflodacin; advanced late-stage clinical development including the launch of phase III pivotal trial to support registration.

Screened compound libraries.

Launched REVIVE, hosted webinars, co-hosted workshops at international conferences, and published blogs.

Addressing the crisis of antibiotic resistance

The discovery of antibiotics heralded the start of a new medical era. Thanks to these treatments, millions of lives have been saved and previously fatal infections such as bacterial pneumonia and sepsis were cured. Thanks to antibiotics, and the protection they offer, it is possible to perform cancer chemotherapy, hip and knee replacements, and organ transplants.

Unfortunately, the rise of antimicrobial resistance (AMR), or drug-resistant infections, is outpacing drug discovery at an alarming rate. The natural process of microorganisms evolving to survive exposure to antimicrobial drugs, as well as the lack of tools to counter the phenomenon, is

causing a dramatic increase in human morbidity and mortality.

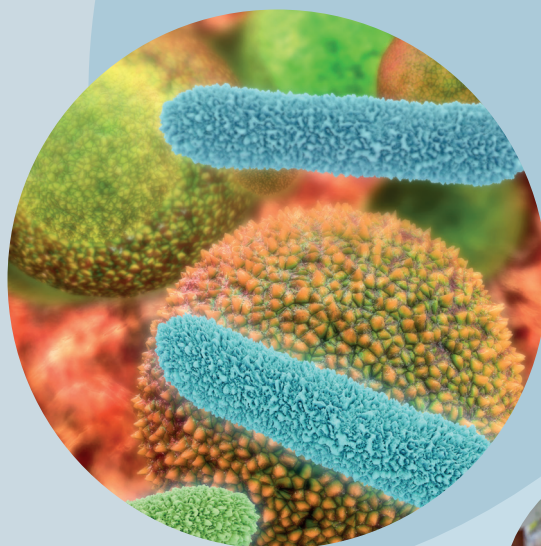
Previously, many common bacterial infections – whether caused by a simple cut, an open wound or complex surgery – were easily prevented or treated. Due to drug resistance, this is no longer the case for many infections.

This has a massive impact on the health of people and economies of countries, around the world. However, it's the most vulnerable – women, children, the elderly, immunocompromised, and those in countries with weak health systems – who are most at risk.

“ The rise of drug-resistant bacteria is jeopardizing decades of progress and threatening our ability to prevent and treat infections that were once easy to treat. GARDP is an essential element of delivering the Global Action Plan on AMR. ”

Dr. Tedros Adhanom Ghebreyesus,
WHO Director-General





The growing impact of AMR

Each year, an estimated **700,000 people die** worldwide as a result of **antimicrobial-resistant infections**¹.

In 2015, it was estimated that around **214,000 newborn babies died due to infections resistant** to first line antibiotics².

High rates of resistance to WHO recommended beta-lactams and aminoglycosides have been reported worldwide including sub-Saharan Africa.

In 2015, **670,000 people in the European Union contracted antibiotic-resistant infections** resulting in around 33,000 deaths. The burden was highest in babies under the age of one, and adults over the age of 65³. In 2018, total deaths in the USA due to AMR were re-estimated to >150 000 people⁴.

¹ IACG. (2019). No Time to Wait: Securing the future from drug-resistant infections.

² Laxminarayan, R. et al. (2016). Access to effective antimicrobials: a worldwide challenge. The Lancet. Vol 387, Issue 10014 (168-175).

³ Cassini, A. et al. (2019). Attributable deaths and disability-adjusted life-years caused by infections with antibiotic-resistant bacteria in the EU and the European Economic Area in 2015: a population-level modelling analysis. The Lancet Infectious Disease. Vol 19, Issue 1 (56-66).

⁴ Burnham, J. P. et al. (2019). Re-estimating annual deaths due to multidrug-resistant organism infections. Infection Control & Hospital Epidemiology. Vol 40, Issue 1 (112-113).

In low - and middle - income countries (LMICs), the situation is worse:

In 2019, in hospitals in Bangladesh, Columbia, Ghana, India, Lebanon, Nepal, Nigeria, Pakistan and Vietnam **death rates in patients with bloodstream infections (BSIs) due to carbapenem-resistant (CR) bacteria was 35% versus 20% in patients with drug-susceptible infections**⁵.

In South Africa (2018), the bacterium most often found in blood, *Klebsiella pneumoniae*, is usually resistant to common antibiotics (~68% resistant to extended spectrum beta-lactams). **One in 12 isolates of bacteria are also resistant to carbapenems (used to treat multidrug-resistant infections)**⁶.

In Thailand in 2010, **there were an additional 19,122 deaths in patients with hospital-acquired infections** due to multidrug-resistant bacteria⁷.

AMR is not just something that affects health – it is a global development issue.
The impacts of drug-resistant infections are far-reaching.

In 2017, the World Bank quantified the losses caused by drug-resistant infections and the impact they may have on the global economy between now and 2050⁸.

- ▶ **28.3 million** more people will fall into extreme poverty
- ▶ Healthcare costs will increase by up to **\$1 trillion**
- ▶ The volume of global real exports would shrink by at least **1.1%**
- ▶ Livestock production will reduce by up to **7.5%** per year.

⁵ Stewardson, A. J. et al. (2019). Effect of carbapenem resistance on outcomes of bloodstream infection caused by Enterobacteriaceae in low-income and middle-income countries (PANORAMA): a multinational prospective cohort study. The Lancet Infectious Diseases. Vol 19, Issue 6 (601-610).

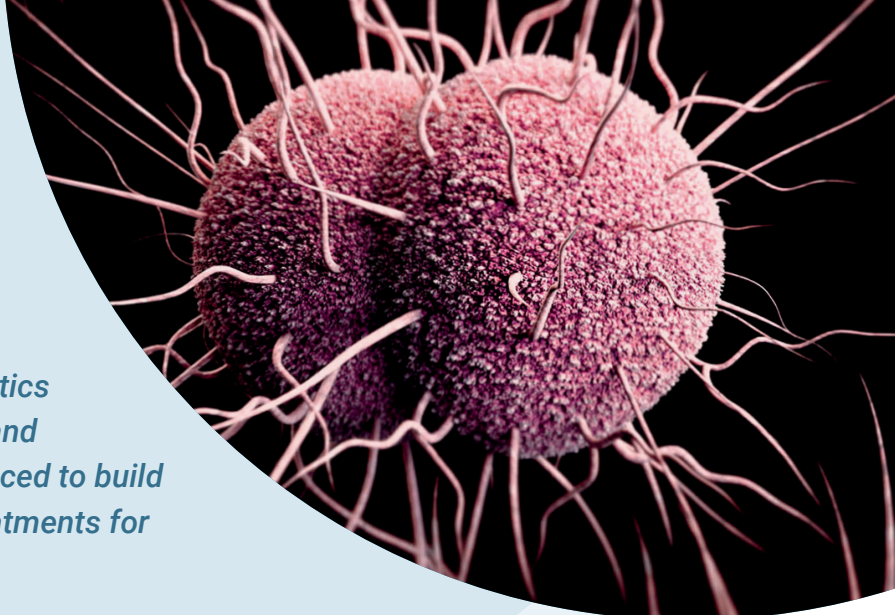
⁶ Department of Health Republic of South Africa. (not dated). Antimicrobial Resistance.

⁷ Lim, C. et al. (2016). Epidemiology and burden of multidrug-resistant bacterial infection in a developing country. eLife. 5:e18082.

⁸ Jonas, O. B. et al. (2017). Drug-resistant infections: a threat to our economic future (Vol. 2): final report (English). Washington, D.C. World Bank Group.

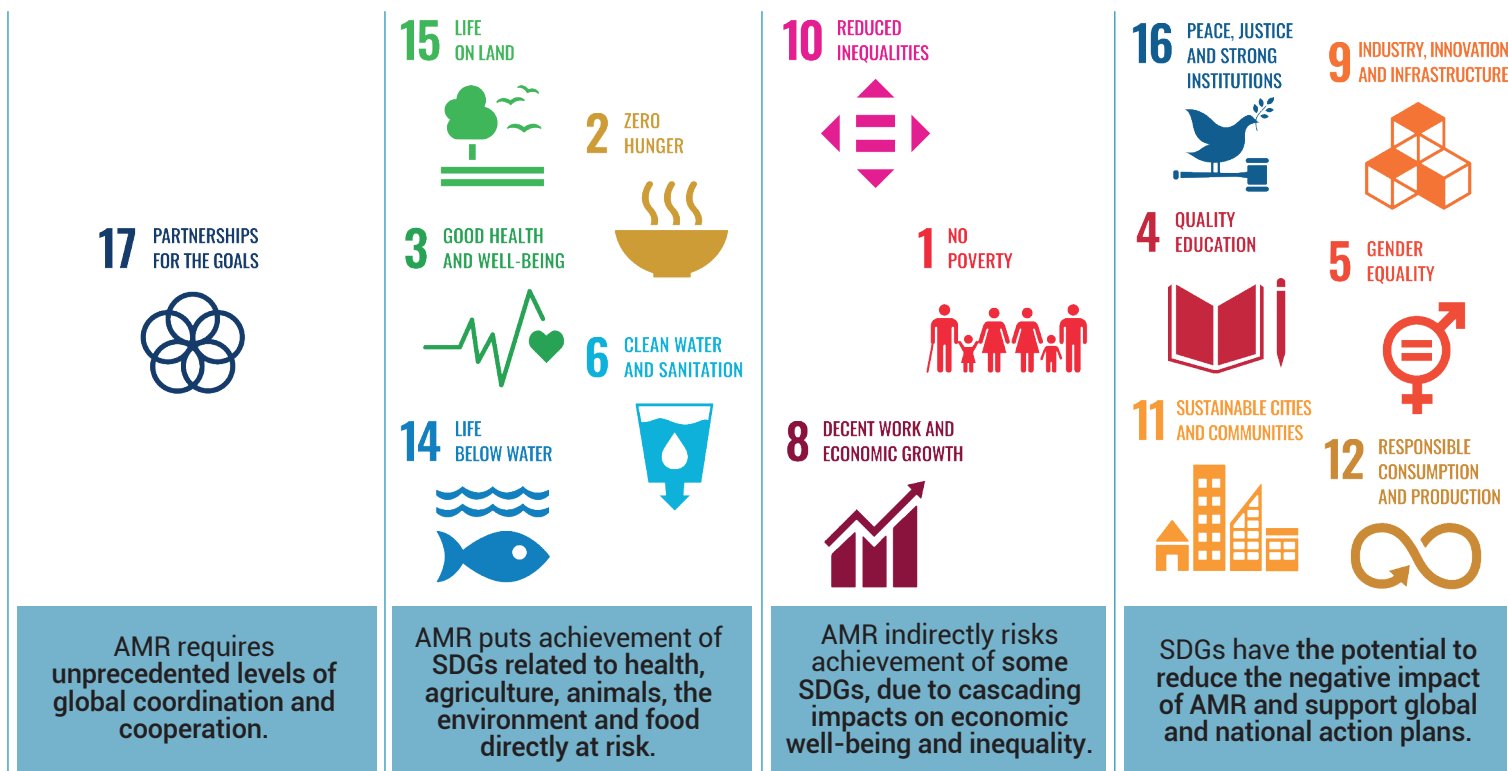
“ *Drug-resistant infections pose significant health challenges to us as a global society. To deliver solutions for patients, new effective treatments, diagnostics and prevention measures are urgently needed. Preventing the very real scenario of a world without effective antibiotics will require particularly enhanced research and development activities. GARDP is ideally placed to build the required partnerships to deliver new treatments for priority public health needs.* ”

Anja Karliczek, Federal Research Minister
German Federal Research Ministry of Education and Research



Drug resistance and the SDGs

Making progress on AMR has been recognized by the UN General Assembly as critical to achieving the Sustainable Development Goals (SDGs).



Over the last few years, a number of initiatives have been launched to reinvigorate the antibiotic research and development pipeline. Despite this, we need to significantly scale-up our efforts to address the magnitude of the public health challenges we face today.

Why is there a crisis?

While drug resistance is a phenomenon which occurs naturally due to genetic changes in bacteria cells, there are many other reasons why we've reached a crisis point in drug resistance.

- 1 **Bacteria are easily transferred** between people, animals, and the environment, increasing the risk of drug-resistant infections.
- 2 Antibiotics are often used when not needed. **Antibiotic use in humans increased 36% globally between 2000 and 2010⁹**. Animals in the USA take more than twice as many medically important antibiotics as humans¹⁰.
- 3 **17% of the substandard or falsified medicines reported to the WHO are antibiotics**, which contribute further to AMR¹¹.
- 4 Good hygiene and sanitation are essential in reducing the spread of infectious diseases, especially in hospitals. In many countries, there are barriers to good Infection, prevention & control – from **lack of access to vaccination, to a lack of guidelines or their effective implementation**.
- 5 **Very few new antibiotics have been developed over the past number of years** and the pipeline is very limited due to:

Challenges in complex science to discover antibiotics that work against priority Gram-negative bacteria, which are responsible for the most serious and resistant infections.

Significant time and cost to produce the clinical and pharmaceutical development data required to support regulatory approval and guidance on how to best to use new antibiotics.

Lack of a suitable economic model with appropriate reimbursement to support sustainable development and access for new antibiotics.

GARDP is focusing its work on one key area which we believe will have a long-term and significant impact on public health: **the clinical development of treatments and their sustainable and responsible access**.

⁹ Boecklet, T. V. et al. (2014). Global antibiotic consumption 2000 to 2010: an analysis of national pharmaceutical sales data. *Lancet Infectious Diseases*. Vol 14, Issue 8 (742-750).

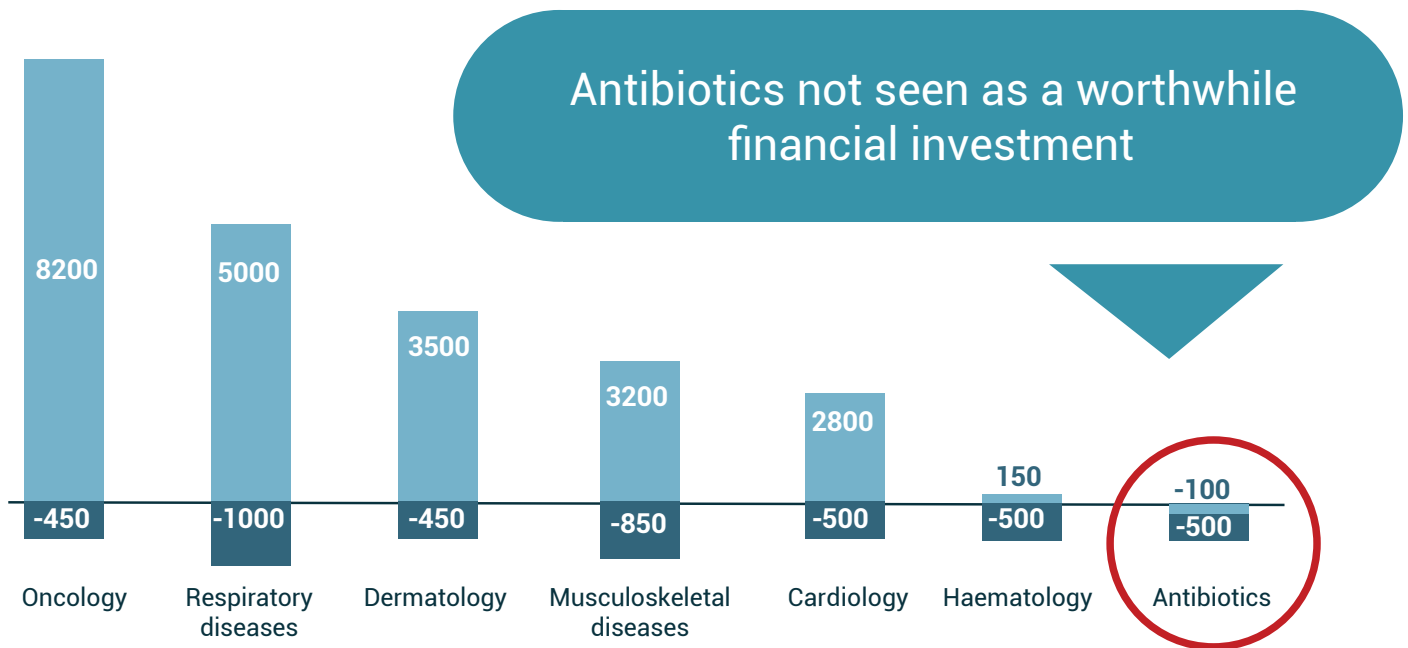
¹⁰ <https://amr-review.org/infographics.html>

¹¹ Healthline. (not dated). What Are Nosocomial Infections?

Antibiotics: a high investment for public health but with no market return

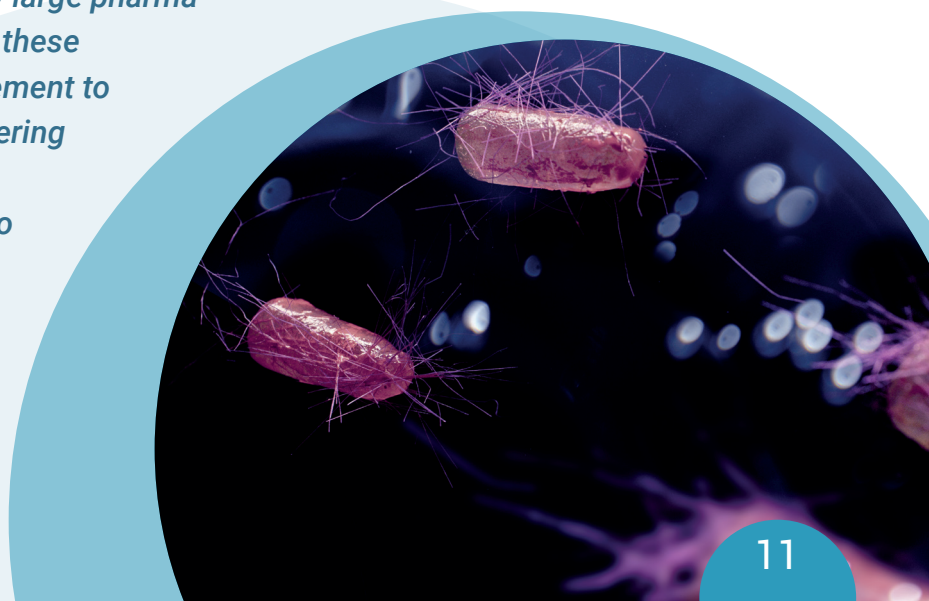
- ▶ R&D of new antibiotics can be risky
- ▶ The R&D is scientifically challenging
- ▶ Novelty in new drugs is relatively rare
- ▶ Antibiotic R&D is not an attractive investment
- ▶ A blockbuster model is not sustainable for antibiotic R&D

Expected net present value in US\$ million (range)



“ *Drug-resistant bacteria are jeopardizing most medical advances of the past century and pose an incredible threat to human health and wealth. At the same time, the broken economic model for antibiotics has led to the abandonment of the field by large pharma and the private financial sector. In light of these challenges, GARDP is a very important element to support the remaining companies in delivering much needed novel antibiotics to market and ensuring access to these medicines to patients in need around the world.* ”

Dr. Marc Gitzinger,
Vice-President of BEAM Alliance and CEO &
Co-founder of BioVersys



Innovation to access

While there are a number of critical factors in the rise of drug-resistant infections, GARDP's mission is clear. We are focusing our efforts on developing new treatments, safeguarding their responsible use, and ensuring sustainable access.

No single actor or group can deliver a solution alone. **To successfully address the public health impact of AMR, we need to work in partnership with both the public and private sector.** The private sector brings significant experience and innovation in the development and delivery of treatments. However, a purely market-driven approach has not delivered enough innovative antibacterial treatments.

Public sector involvement is needed to identify public health needs, set priorities, inject funding and reshape incentives for the private sector. **A public-private partnership like GARDP leverages the best of both sectors** and provides a transparent vehicle for collaboration, focused on achieving a mutually beneficial objective: new treatments for drug-resistant infections, for every person who needs them.

Why GARDP?

The problem we face	How we help	Where we're concentrating
Increasing drug resistance Access gaps A precarious pipeline Market failure Inadequate financing	Concentrating on developing a public-health oriented portfolio through global public-private partnerships Investing in and co-developing clinical and pharmaceutical development with partners to offset costs and derisk projects Leveraging public and private funding Developing sustainable access strategies Promoting sustainable reimbursement models	5 NEW TREATMENTS DIRECTED TOWARDS: SERIOUS BACTERIAL INFECTIONS NEONATAL SEPSIS PAEDIATRIC SEXUALLY-TRANSMITTED INFECTIONS addressing WHO priority pathogen list

KEY PARTNERS

Patients | Donors | Civil Society/NGOs | Governments | Pharma/biotech/manufacturers

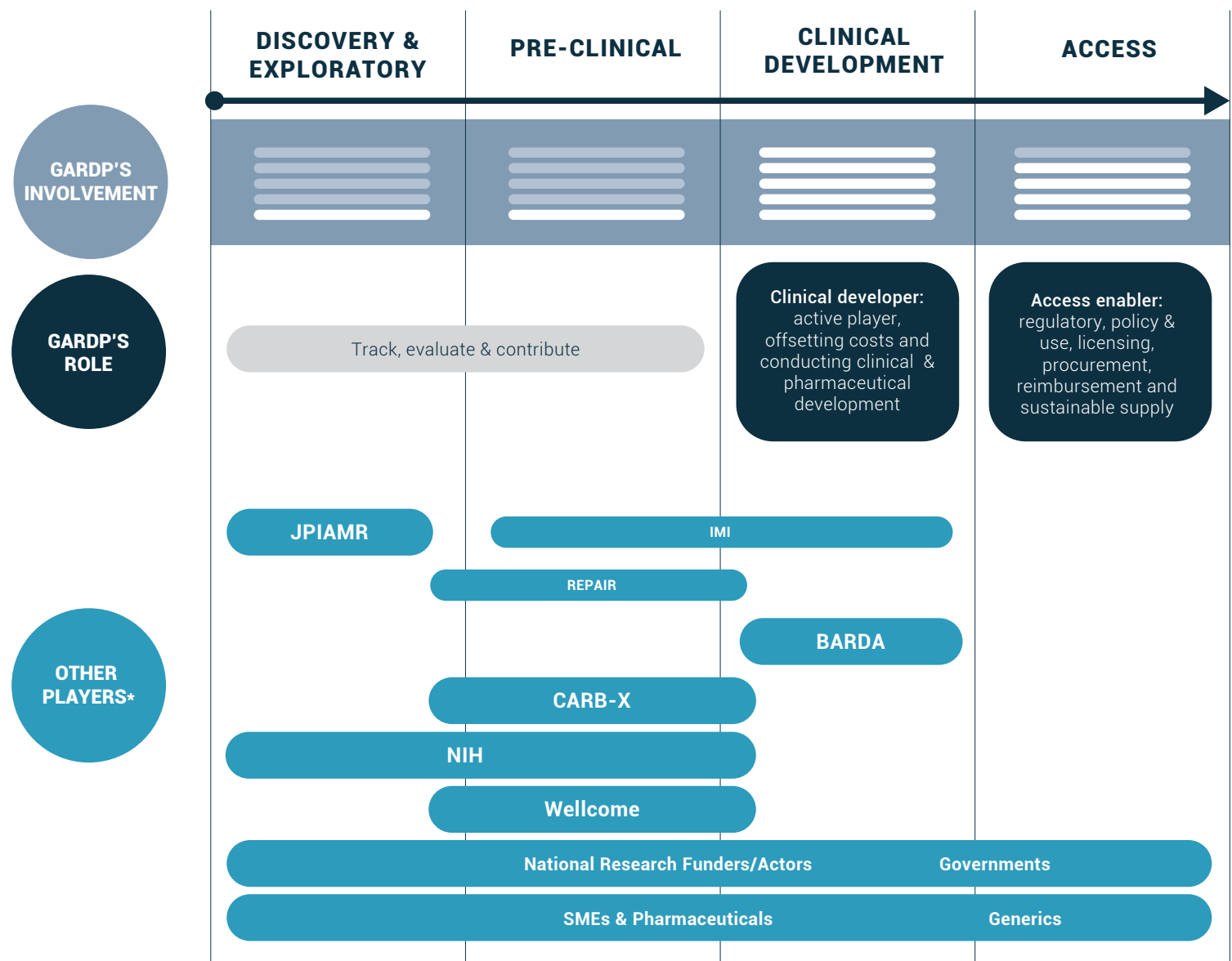
“ Tackling the threat of drug-resistant infections requires an urgent and truly global response. Critical to achieving this is GARDP’s public-private partnership approach and commitment to ensuring new and improved antibiotics are available for every person who needs them, wherever they live. ”

Glenda Gray,
President & CEO, South African Medical Research Council

GARDP can bridge the gap between R&D and access by:

- 1 Delivering antibiotic R&D through bespoke partnerships: accelerating R&D projects to tackle AMR including in countries with a high burden of drug-resistant infections, creating a network of stakeholders and strategic public-private partnerships.
- 2 Sharing expertise: bringing in GARDP’s unique expertise and connecting companies and researchers, ensuring the right people have the support they need to accelerate the development of new treatments, and ensure responsible use.
- 3 Ensuring funding streams link the value chain between R&D and access: investing government, not-for-profit and other funding in drug development partnerships, lowering the cost (and risk) associated with late stage R&D and early access interventions, enabling long-term, sustainable access.
- 4 Safeguarding the future: supporting the WHO, national governments and regional networks in developing guidelines and drug stewardship policies to ensure responsible antibiotic access.

Where does GARDP fit in the drug development landscape?



*Illustrative not exhaustive

GARDP's focus: delivering 5 BY 25 and building an antibiotic portfolio

GARDP's commitments 2020-2025

With an additional **€500 million in funding** GARDP and its partners aim to have developed **five new treatments** to address **the burden of antibiotic-resistant infections by 2025.**



All infections are treatable for everyone, everywhere

What will GARDP develop treatments for?

- ▶ Serious bacterial infections
- ▶ Children
 - Neonatal sepsis
 - Paediatric antibiotics
- ▶ Sexually-transmitted infections

WHO priority pathogen list for which there is a critical and high need for new antibiotics.

How will GARDP accomplish its ambition?

The main focus will be on developing new and improved treatments in late stage clinical development and ensuring responsible and sustainable access.

GARDP's 5 BY 25 goal will focus on:

- ▶ Bacteria on the WHO priority pathogen list.
- ▶ Diseases and populations disproportionately affected by drug resistance.
- ▶ Late-stage clinical development and access.

Our approach encompasses pathogens, populations, and specific infections.

Serious bacterial infections

Program

WHO priority pathogens for which there is a high or critical need for new antibiotics.

Serious and potentially life-threatening infections in hospitalized adults such as hospital-acquired pneumonia, intra-abdominal infections, complicated urinary tract infections and bloodstream infections.

The serious bacterial infections program is the newest GARDP program. It aims to develop, in partnership with innovators, new treatments to address serious hospital-associated bacterial infections for which there are limited or no treatment options. GARDP's efforts will be directed towards accelerating the initial regulatory approval, generating new evidence, extending a regulatory indication, and updating clinical guidelines. The end goal is to improve outcomes in patients with drug-resistant infections, with a global perspective, and a focus on the needs of high-burden settings. This program will be important to help accelerate development of new treatments for infections in children and babies.

Why is this important?

Serious bacterial infections are among the major causes of death for people in hospitals and other health-care settings. These bacterial infections can enter the body through wounds and operation sites, ventilators or urinary and intravenous catheters. This can lead to pneumonia and infections of the blood, bones, joints, and urinary tract. These infections disproportionately affect the ill and are often difficult to treat.

Across high-income countries, up to 10 percent of all hospital patients will contract some form of infection, a figure that rises for patients admitted to intensive care units¹². These levels are even higher in LMICs, where medical procedures such as surgery, organ transplants, cancer chemotherapy, and diabetes management are very high risk with health-care facilities facing significant constraints.

In Europe, over 400,000 people a year contract health care-associated infections caused by drug-resistant bacteria¹³.

GARDP's response

We have evaluated the late-stage clinical pipeline and old antibiotics to identify any potential treatments which may address our priorities and have a global health impact.

We have identified drug candidates of interest and are developing new partnerships in the upcoming months.

We will partner to conduct a number of activities on chosen candidates to support primary registration and ensure responsible use. These activities include clinically evaluating candidates against multidrug-resistant bacteria to both support label extension, and provide evidence to support the appropriate use of the drug as a treatment for patients with serious multidrug-resistant infections. This work will provide the data to support further development for children/babies and deliver at least one new treatment for adult serious bacterial infections.

Over the next six years, we intend to take on additional drug candidates to build our portfolio, allowing us to deliver further new treatments to cover multidrug-resistant infections in adults.

¹² Healthline. (not dated). What Are Nosocomial Infections?

¹³ Cassini, A. et al. (2018). Attributable deaths and disability-adjusted life-years caused by infections with antibiotic-resistant bacteria in the EU and the European Economic Area in 2015: a population-level modelling analysis. The Lancet Infectious Diseases. Vol 19, Issue 1 (56-66).

Children's antibiotics

Program

Neonatal sepsis
Paediatric antibiotics, including appropriate formulations

Why is this important?

More than **214,000 newborn babies die each year** from drug-resistant infections.

Approximately **40% of infections in newborn babies resist standard treatments**¹⁴.

Most of these deaths occur in low-income countries. Reports of **infections in newborn babies are three to 20 times higher in low-income countries**, compared to high-income countries¹⁵.

There is little effort to develop new treatments for babies and children; **paediatric clinical trials are rare, especially in babies** – a group disproportionately affected by drug-resistant infections.

GARDP's response

Neonatal sepsis

We have developed two target product profiles for a new empiric treatment for neonatal sepsis (TPP1) and a new treatment for multidrug-resistant infections caused by carbapenem-resistant organisms (TPP2).

We have launched a global observation study in 11 countries to address major knowledge gaps prior to launching phase III trials.

We have conducted a pharmacokinetic and safety clinical trial on a drug candidate for TPP1, fosfomycin.

We are conducting in vitro pharmacokinetic/pharmacodynamic evaluations of other drug candidates in TPP1 (these are generic drugs).

We are making preparations to start a phase III trial, which we hope will develop a new treatment to address TPP1.

We have identified potential old drugs and new chemical entities in the pipeline which could be developed as new treatments for TPP2. We plan to conduct relevant development programs and trials over the next six years to ensure we can deliver at least one new treatment.

Paediatric sepsis

We are working with partners to build a Paediatric Antibiotic Development Platform.

The platform will include a paediatric clinical trial network covering high-burden countries. It will also bring together a group of experts (regulatory, medical, statistical, pharmacokinetic, and clinical trial) to support future activities.

We have identified an old drug and a new chemical entity to conduct paediatric development programs; we are continuing to evaluate the pipeline for future opportunities.

We will expedite the development of at least one new paediatric treatment (based on old or new antibiotics) for children of all ages. Through that, we will update paediatric evidence-based guidelines to treat severe infections in children.

¹⁴ Costello, A. and Peterson, S. S. (2016). Birth in a time of antibiotic-resistant bacteria. WHO Media Center.

¹⁵ Zaidi, A. K. et al. (2005). Hospital-acquired neonatal infections in developing countries. The Lancet. Vol 365 (1175-88).



Sexually-transmitted infections

Program

Gonorrhoea
Extend to other pathogens over time

Why is this important?

Global infection rates of gonorrhoea are increasing, with 87 million new cases each year¹⁶. **If left untreated, gonorrhoea can have serious consequences for reproductive health** and increases the transmission risk of HIV and other sexually-transmitted infections.

Gonorrhoea has developed resistance to globally recommended treatments, with cases of drug resistance reported throughout the world.

Women, marginalized, and vulnerable groups are disproportionately affected by the consequences of sexually-transmitted infections.

GARDP's response

With WHO, **we have developed a strategy and target product profiles** to guide our program.

We have started a phase III trial and pharmaceutical development program on a first-in-class drug, zoliflodacin (Entasis Therapeutics). We are evaluating other potential candidates in the pipeline.

We will conduct additional studies and phase IV trials. We will generate the evidence needed to develop a treatment that will work against both drug-sensitive and -resistant gonorrhoea as well as urogenital and extra-genital infections.

We will work to ensure a new treatment can be integrated into international and national guidelines.



¹⁶ [https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-\(stis\)](https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis))

Discovery and exploratory

Program

WHO priority pathogens for which there is a high or critical need for new antibiotics.

Feed drug candidates into GARDPs clinical programs.

Why is this important?

There is an urgent need for renewed antibiotic R&D to build a pipeline of treatments which focus on bacteria – in particular multidrug-resistant Gram-negative bacteria identified as a priority by WHO.

Discovery and exploratory research to find novel compounds and formulations is a critical component of this.

There is a need for more exploratory research focused on the discovery of novel antimicrobials. Part of the solution may also lie in long-forgotten compounds. It may be possible, with emerging science and technological advances, to further rescue and repurpose under-used or forgotten compounds.

GARDP's response

Through discovery and exploratory research, and antimicrobial memory recovery and asset evaluation, GARDP aims to:

continue screening activities with public and private sector partners. We have also explored and evaluated numerous potential candidates – both old drugs and new chemical entities for our portfolio.

continue working with partners on numerous educational and knowledge-sharing activities in antibiotic drug R&D to disseminate knowledge to the latest generation of experts.

identify up to two new chemical entities for preclinical or clinical development.



How is GARDP going to achieve its vision?

GARDP was created because developing and ensuring access of new and improved antibiotics can only be achieved collaboratively. We are working to leverage the best available innovation, experience, and resources from organizations and funding partners in the public and private sector. However, we require significant investment to achieve our 5 BY 25 goal and further build a portfolio that will deliver for the world.

We call on governments, philanthropic, private, and public organizations to support us in our 5 BY 25 goal by contributing to our funding requirement of €500 million.

We can address this crisis by working together, acting as a catalyst in innovation for new candidates, optimizing the use of existing drugs, and securing sustainable investment in antibiotic development.

By acting now, collectively, and with urgency, we can protect our health today and that of future generations.

GARDP's strategic plan

Bridging the gap between R&D and access:
GARDP's approach

TARGETING PUBLIC HEALTH NEEDS

Building public health-oriented portfolio

Conducting, sponsoring, supporting
and/or financing R&D programs
(direct/in-kind investments)

Securing sustainable access via
negotiated partnerships: in and out
licensing, returns for public investments

Facilitating global registration & use

LEVERAGING THE PUBLIC AND PRIVATE R&D ECOSYSTEM

Private

SMEs
Pharma
Manufacturers
Funders
NGOs/ CSOs
Patient groups
Professional
bodies

Public

Funders
Research
institutions
Clinical trial
networks
Academia
International
organizations
National
regulators

Accelerating
access to all in need

Our approach to address drug resistance recognizes that by working together, we are more than the sum of our parts. Since our inception, we have formed over **50 partnerships in 20 countries**.

We work with the pharmaceutical and biomedical industry, research institutions, governments, not-for-profits, civil society, and people affected by infectious diseases. GARDP is uniquely positioned to focus our **5 BY 25 efforts on late-stage development and sustainable access** – an area where few others are active. However, thanks to our structure and expertise, we can work from any stage along the development pipeline through to access.



Strategic pillars

To achieve our vision, we are working across three strategic pillars. Each pillar allows us to accelerate the development and delivery of treatments to address significant threats to public health. It also means we can build a long-term portfolio of future treatments.

1 Research and development

Public health needs

In-house expertise

Clinical and pharmaceutical development

Label extension and evidence generation

Discovery and exploratory research

2 Public health orientated portfolio and partnerships

Build a portfolio with the public and private sectors

In-kind and direct contributions with returns for access

Rights to develop, register and deliver new tools

Strengthen clinical trial networks

Enrich the R&D ecosystem

Advocate for public needs driven and sustainable R&D ecosystem

3 Sustainable access (through our portfolio)

Global regulatory approach

Outsourcing strategies

Reimbursement models

Procurement strategies

Policy and guidelines

Out-licensing

Pillar one: research and development

Drug-resistant infections are outpacing the development of new treatments. **There is an urgent need for dedicated antibiotic R&D to help build a pipeline to secure the delivery of new treatments in the future.**

GARDP's R&D priorities are the clinical and pharmaceutical development of antibiotics, and driving sustainable access including for those most in need – the elderly, the young, and vulnerable populations. **GARDP will fill gaps in the discovery and exploratory research pipeline** by tracking, evaluating, and contributing where others are not.



Priority populations

Newborns and children, hospitalised adults impacted by AMR, vulnerable & marginalized populations



Priority pathogens

WHO critical & high priorities for which new treatments are needed



Priority infections/syndromes

Serious bacterial infections, neonatal sepsis, sexually-transmitted infections



Core activity: antibiotic development

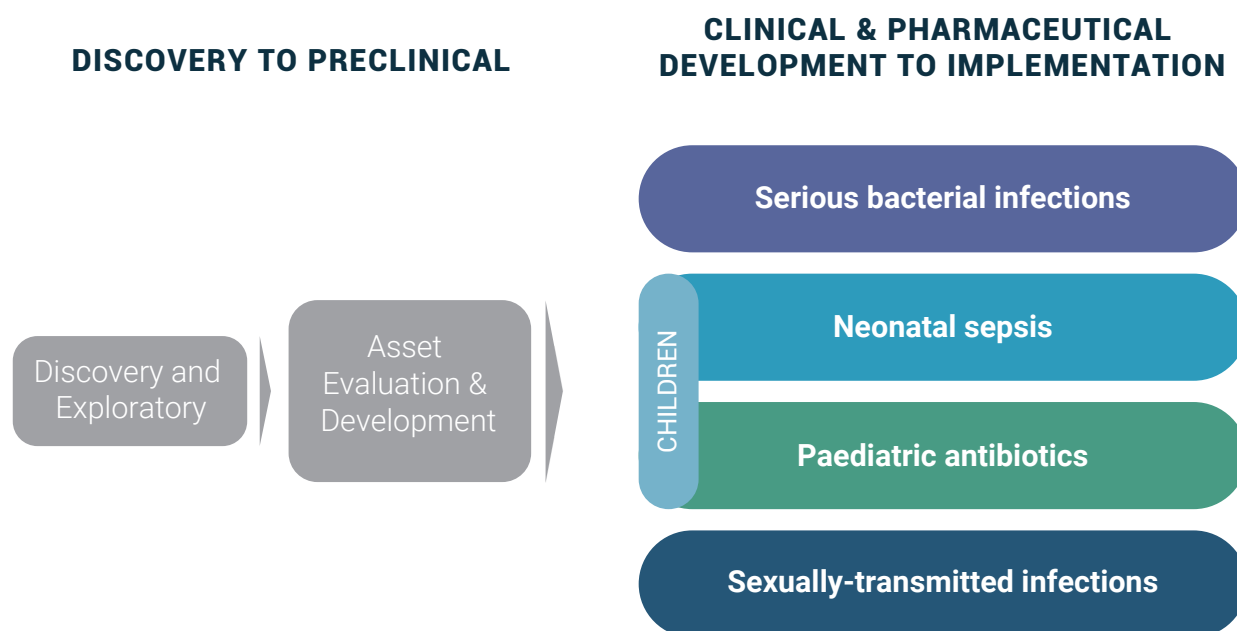
Clinical and pharmaceutical (recovered and new)*
Activity: Discovery & exploratory research

* Clinical development will focus on phase II onwards.



GARDP's resources will be focused on the development of new treatments in our priority R&D areas: serious bacterial infections, children's antibiotics, sexually-transmitted infections, and our discovery & exploratory program.

GARDP R&D operations



Within antibiotic development, GARDP concentrates on:

Clinical development:

executing clinical development projects from phase II through to initial primary regulatory approval and post-approval evidence requirements. Accelerate the design and delivery of paediatric development programs.

Regulatory pathways:

defining the route from initial primary approval to broader country-level submission through consultation with stringent regulatory authorities, national agencies, and the WHO.

Enabling science:

non-clinical science supporting the evaluation of potential new treatments and supporting regulatory approval through determining and filling data gaps (e.g., determining optimal dose via pharmacokinetic and pharmacodynamic models, evaluation of spectrum of activity, resistance studies and other non-clinical studies of antibacterial drugs).

Public health evidence:

generating post-approval evidence for policy, guidelines, and appropriate clinical use – ensuring new treatments can be successfully launched for priority infections and populations thus supporting sustainable access.

Formulation and manufacturing development:

addressing key issues in the development of appropriate drug formulations, ensuring affordability, adaptability, and effective distribution.

Sustainable access:

developing appropriate-use pathways (including the role of diagnostics) to support the sustainability of new antibiotics; working with partners such as the Foundation for Innovative New Diagnostics (FIND), and the WHO.

GARDP portfolio

With the support of the WHO and our Scientific Advisory Committee, **we identify priorities for new treatments for drug-resistant infections.** We actively support and conduct R&D around key priority pathogens and infections, building a robust portfolio of projects.

GARDP is building a public health-oriented portfolio to deliver its 5 BY 25 goal and provide new treatments for the world in the longer term. This portfolio is being built with several key principles in mind:

- **Developing new treatments for unmet clinical needs**, rather than merely just developing drugs.
- **Ensuring potential new treatments match target product profiles** (TPP) to treat relevant infections (for example, neonatal sepsis).
- Considering both old antibiotics and new chemical entities (NCEs) in the pipeline, and potentially **evaluating combinations of antibiotics**.
- Working on potential new treatments and **ensure regulatory approval** as well as appropriate sustainable access and use.

GARDP is currently building a pipeline of both NCEs and old antibiotics covering its priority programs. Several potential new treatments are currently being evaluated and GARDP is in discussions to develop new partnerships to support their development.

GARDP requires funding and support to build this pipeline to deliver new treatments and guard against natural attrition.

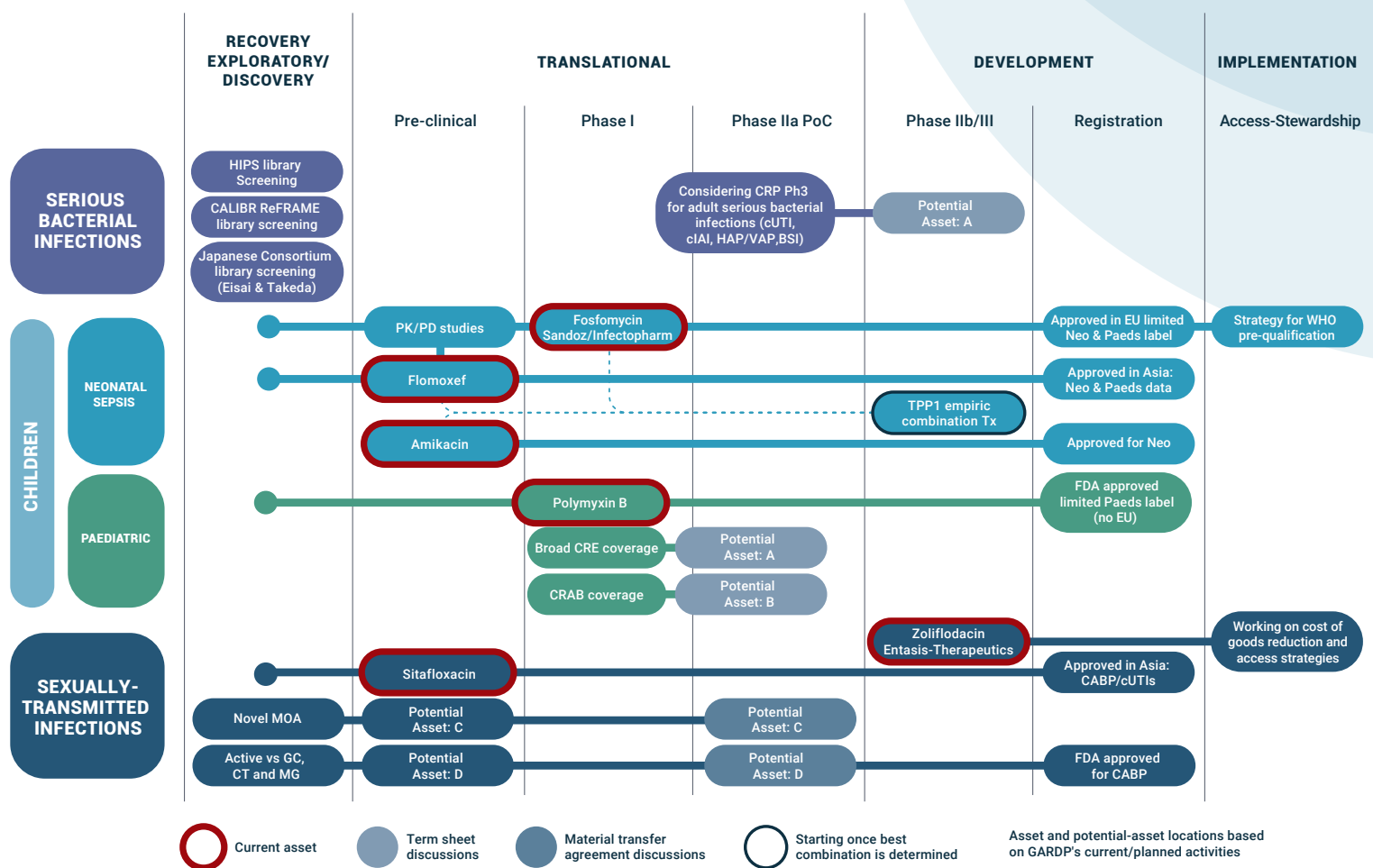
“ *The world is facing an antibiotic apocalypse. Unless action is taken to halt the practices that have allowed antimicrobial resistance to spread and ways are found to develop new types of antibiotics, we could return to the days when routine operations, simple wounds or straightforward infections could pose real threats to life.* ”

Dame Sally Davies,
Former Chief Medical Officer for England



GARDP Pipeline

(October 2019)



Pillar two: developing a public health-oriented portfolio

No country, organization or stakeholder group can solve the drug resistance crisis alone. GARDP's success is dependent on partnerships with the private sector, academics, governments, and civil society. These collaborative relationships are critical to delivering on 5 BY 25 and there is a clear need for a sustainable and global public-private mechanism.

1 Multiple actors are needed to fill skill and knowledge gaps in the R&D pipeline

GARDP, with its multi-disciplinary team, builds partnerships from both the private and public sectors to fill critical gaps in knowledge and expertise.

2 The public sector needs to prioritize an R&D agenda based on public health needs

GARDP, as an advocate for public health needs-driven R&D, supports this objective via a portfolio-based approach targeting priority pathogens, populations, and infections as part of the Global Action Plan on AMR.

3 The private sector is an important partner for delivering solutions to antibiotic R&D

GARDP focuses on late-stage development, working with and linking together private sector entities holding assets or expertise (e.g. small- and medium-sized enterprises & manufacturers). We contribute to conducting complex R&D and ensuring sustainable access of treatments.

4 Sustainable and predictable funding and incentives are needed to address market failure

GARDP, as a global mechanism and an advocate for sustainable incentives, can act as a trusted partner for funders and governments, ensuring a public health return for investments while allowing private sector partners to leverage its support for further financing.



We are working to build collaborative public-private partnerships, leveraging a wide range of actors, including:

- Small - and medium-sized enterprises (SMEs)
- Government funders
- Government research institutions
- WHO and Ministries of Health who set norms and policy
- Other foundations with expertise in key areas (e.g. diagnostics, paediatrics)
- Preferred academic partners with strong experience and expertise
- Clinical trial networks (including in high-burden countries)
- Clinical, public health and drug development experts
- Pharmaceutical companies and manufacturers, including generic companies, and entities with expertise in formulation development
- Local partners, including not-for-profits and civil society organizations to support access and delivery

Many of these partners bring significant direct and in-kind support to GARDP's work.

Others bring specific capacities (such as manufacturing, marketing) that are key in the value chain. A significant part of GARDP's work is building and coordinating this global network in order to co-develop a public health-oriented portfolio to advance R&D in areas currently underfunded or untapped.

One of the key barriers to antibiotic development in the private sector is the lack of funding.

Small- and medium-sized companies have difficulty raising the required capital to push their candidates through the long development process. Even if they manage to reach the final stages of development, they are often unable to find investors to commercialize the treatment.

Our work is a direct complement to the work of government funders and important organizations

such as CARB-X, the Biomedical Advanced Research and Development Authority (BARDA) and the National Institutes of Health (NIH). For example, GARDP will work with relevant CARB-X therapeutic graduates as they move into phase II, supporting these entities in their R&D and access strategies and acting, with major players like BARDA, as a 'post-CARB-X' clinical developer.

Focusing partnerships for a portfolio with public health impact

GARDP is building, investing in, and co-developing a public health-oriented portfolio which advances R&D in areas currently underfunded or untapped.

Unfortunately, many of the antibiotics currently in development will not add significant value to the current treatment portfolio. This is why we focus on projects and partnerships that will deliver significant impact – helping to orientate the R&D pipeline towards public health needs. We ensure direct and in-kind contributions are used more effectively – supporting and connecting people with research. We develop projects with flexible and bespoke partnerships, through:

Sponsorship of clinical and pharmaceutical development

- Conduct of post-regulatory activities (such as phase IV, label extension, global registration, and reimbursement).
- Provision of in-house expertise and access to the GARDP network, including in high-burden countries.
- Upfront funding as part of a broader collaborative partnership.
- Involvement of national and international institutions (WHO, ministers of health & science).

In return, GARDP will use the following criteria to assess partner suitability:

- Strategic fit with the GARDP mission, vision, and strategy.
- Clear ability to comply with international research standards and good business practices.
- Agreement for monitoring performance and change of control protection.
- Agreed public health-driven R&D and access strategy.
- Commitment to appropriate use, stewardship policies and affordable access.
- Licensing rights in specific territories when relevant.
- Willingness to provide a return on GARDP investment to support R&D and sustainable access activities, where consistent with global access.

GARDP's objective is to ensure the rapid introduction of any new treatment globally, especially in high-burden countries. We need to support efficient distribution and equitable pricing to ensure sustainable access for those in need.

In all cases, GARDP will ensure the R&D of treatments critical to meet global health needs is not lost.

Pillar three: delivering sustainable access

For GARDP, sustainable access refers to treatments that are of required quality, affordable for patients, and/or health systems, supplied in a timely and appropriate manner, and with the required stewardship in place to ensure they are used in a responsible manner. If we are to ensure the sustainable availability of treatments, we need to develop innovative solutions around access and stewardship. As GARDP works across geographies, products, populations, and partnerships, each R&D project must have a bespoke approach.

New drugs alone will not address the antibiotic crisis. Unavailable drugs, insufficient supplies, and other challenges put lives at risk and jeopardize progress. Every year, 5.7 million people die due to a lack of availability of antibiotics.

Low- and middle-income countries are worst affected by limited access to treatments, leading to higher mortality rates and increased health care and societal costs¹⁷. Of the 25 new antibiotics that entered the market between 1999 and 2014, only 12 of them were registered in more than 10 countries¹⁸.

Some of the leading barriers to access include:

- Difficulties in market entry for new antibiotics¹⁹.
- Lack of registration, including in countries where treatments are needed most.
- Inappropriate use of antibiotics due to uncontrolled distribution, lack of knowledge, shortages of the appropriate treatments, the lack of guidelines, stewardship protocols, and supporting interventions such as diagnostics.
- Falsified and substandard products.
- Unreliable drug supply chains and poor quality control protocols – both in the public and private sectors.
- A lack of market for antibiotics and inappropriate pricing and reimbursement models.
- A limited market for supply and distribution partners.



“ Just the mere existence of an effective antibiotic does not mean that they are available in countries where they are most needed. ”

Professor Ramanan Laxminarayan, Board Chair GARDP

- Lack of affordability/ high prices for certain antibiotics.

Overcoming these barriers requires a holistic and flexible approach. Access to treatments varies globally and is dependent on strong regulatory frameworks, robust health systems, political will, and leadership

Collaboration between inter-governmental organizations, national governments, and those implementing and advocating on the ground is needed. Alongside our partners and in-country stakeholders, GARDP plays an important role in ensuring the sustainable and affordable access to essential treatments for everyone, everywhere.

¹⁷ Cars, O. (2014). Securing access to effective antibiotics for current and future generations. Whose responsibility? Upsala Journal of Medical Sciences. Vol 119, Issue 2 (209–214).

¹⁸ Källberg, C. et al. (2018). Introduction and geographic availability of new antibiotics approved between 1999 and 2014. PLoS One. Vol 13, Issue 10.

¹⁹ Frost, I. et al. (2019). Access barriers to Antibiotics. The Center For Disease Dynamics, Economics & Policy.

The GARDP access framework

Ensuring access to treatments implies GARDP's involvement across several areas – each requiring varying degrees of engagement, which may include advocating, facilitating and/or directly implementing. GARDP is taking a practical, project-based approach to access through:

Licensing: focusing on in- and out-licensing strategies supporting quality manufacturing, early access, affordability, and responsible marketing.

Regulatory: collaborating with the WHO and national regulators to ensure optimal regulatory pathways for GARDP drug candidates, including facilitating global registration and label extension; and sharing GARDP's experience to advocate for increasing coherence between key regulatory authorities for antibiotic drug development.

Public health, policy and appropriate use: generating evidence for guidelines to ensure sustainable access for each treatment in the GARDP portfolio; supporting monitoring programs for the emergence of resistance; outlining the basis for antibiotic stewardship; developing and supporting the implementation of early access programs in high-burden countries.

Outsourcing strategies: defining best practice in manufacturing which can be used as a benchmark across industry; optimizing the cost of goods of GARDP drug candidates; and building and maintaining a core group of partnerships with manufacturers.

Procurement: a better understanding of national needs, and facilitating cost-saving procurement mechanisms, which support predictable demand.

Reimbursement models: supporting equitable reimbursement models that promote win-win scenarios ensuring long-term sustainable supply and appropriate use of GARDP treatments.



Licensing

In and out-licensing supporting:

- ▶ Quality manufacturing
- ▶ Early access across high-burden countries
- ▶ Appropriate marketing



Regulatory

Collaborating with WHO and national regulators for:

- ▶ Public health evidence (need and use)
- ▶ Global registration
- ▶ Label extension



Public Health Policy & Use

- ▶ Early access programs
- ▶ Guidelines to ensure appropriate access
- ▶ Surveillance for resistance emergence
- ▶ Diagnostics for stewardship



Outsourcing Strategies

- ▶ Cost of goods focus
- ▶ Defining best practice in manufacturing
- ▶ Maintaining a core network of partners



Procurement

- ▶ Better understanding national needs in key high-burden countries
- ▶ Facilitating cost-saving procurement mechanisms to support demand



Reimbursement Models

- ▶ Non-volume based sustainable reimbursement models

GARDP's intensity of engagement will vary for each of these interventions and will include:

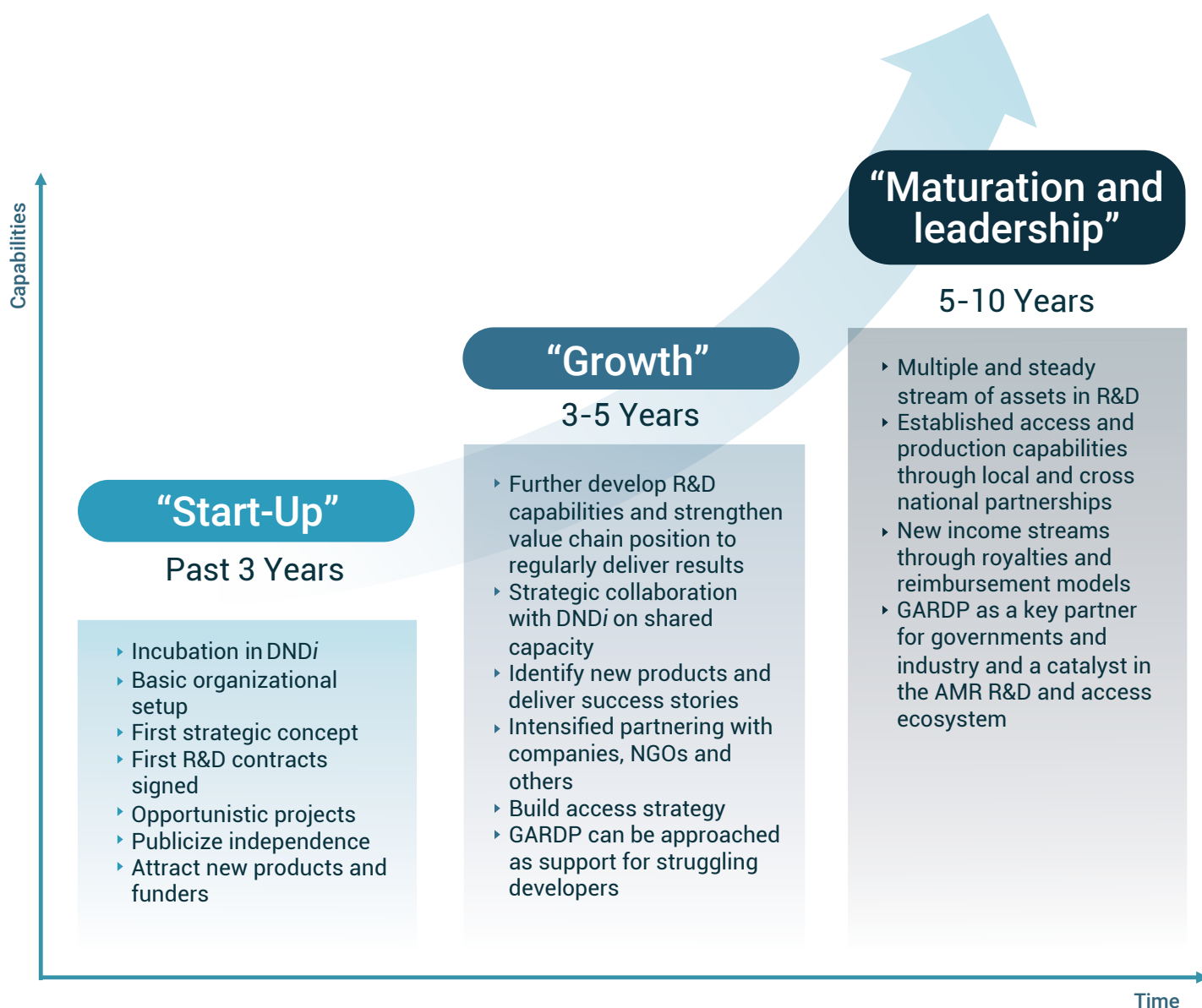
Advocating

Facilitating

Implementing

Roadmap for growth

Over the next five years, as we deliver 5 BY 25, GARDP will grow out of its start-up phase. With this maturity comes a number of expectations with regards to capabilities, partnership, funding, and leadership.



Governance

For GARDP to thrive, **it needs robust governance**. As an organization, we must have rules and processes in place to ensure **accountability, transparency, and effectiveness**.



The Board



Executive Team



Scientific Advisory Committee



Donor Partnership Advisory Committee

As GARDP works in partnership with many different organizations across the public and private sectors, we have developed **a transparent, relevant, and open governance structure**. Alongside the leadership team, who is responsible for the day to day running of the organization, **we are governed by our Board**. The Board meets at least twice a year and is GARDP's ultimate policy and decision-making authority. **The Board is made of up to 15 members**.

The Board determines GARDP's strategic goals and ensures the management works strategically and efficiently to meet these goals.

Procedures for the appointment of Board members are guided by GARDP's statutes and by-laws as approved by the **Swiss Supervisory Board for Foundations**.

The Board is made up of leading international figures in global health and observers including representatives of WHO, DNDi, the Chairs of GARDP's Scientific Advisory Committee and Donor Partnership Advisory Committee.

The Board has set up three sub-committees:

- **Strategic partnerships sub-committee:** ensures private sector partnerships are made in accordance with GARDP's mission, vision, and objectives.
- **Nominations, remunerations, and safeguarding sub-committee:** responsible for overseeing the size and makeup of the Board, as well as rules for the Executive.
- **Audit sub-committee:** responsible for the quality and integrity of the accounting, auditing, and reporting practices of GARDP.

The Board has also set up two advisory committees:

- **Scientific Advisory Committee:** providing independent expert advice to GARDP's Board. Made up of scientists with expertise in various disciplines across public health, drug development, infectious diseases and microbiology.
- **Donor Partnership Advisory Committee:** representing the interests and experience of our funding partners and providing advice to GARDP's Board (to be convened in early 2020).

Current Board members and Observers:

MEMBERS

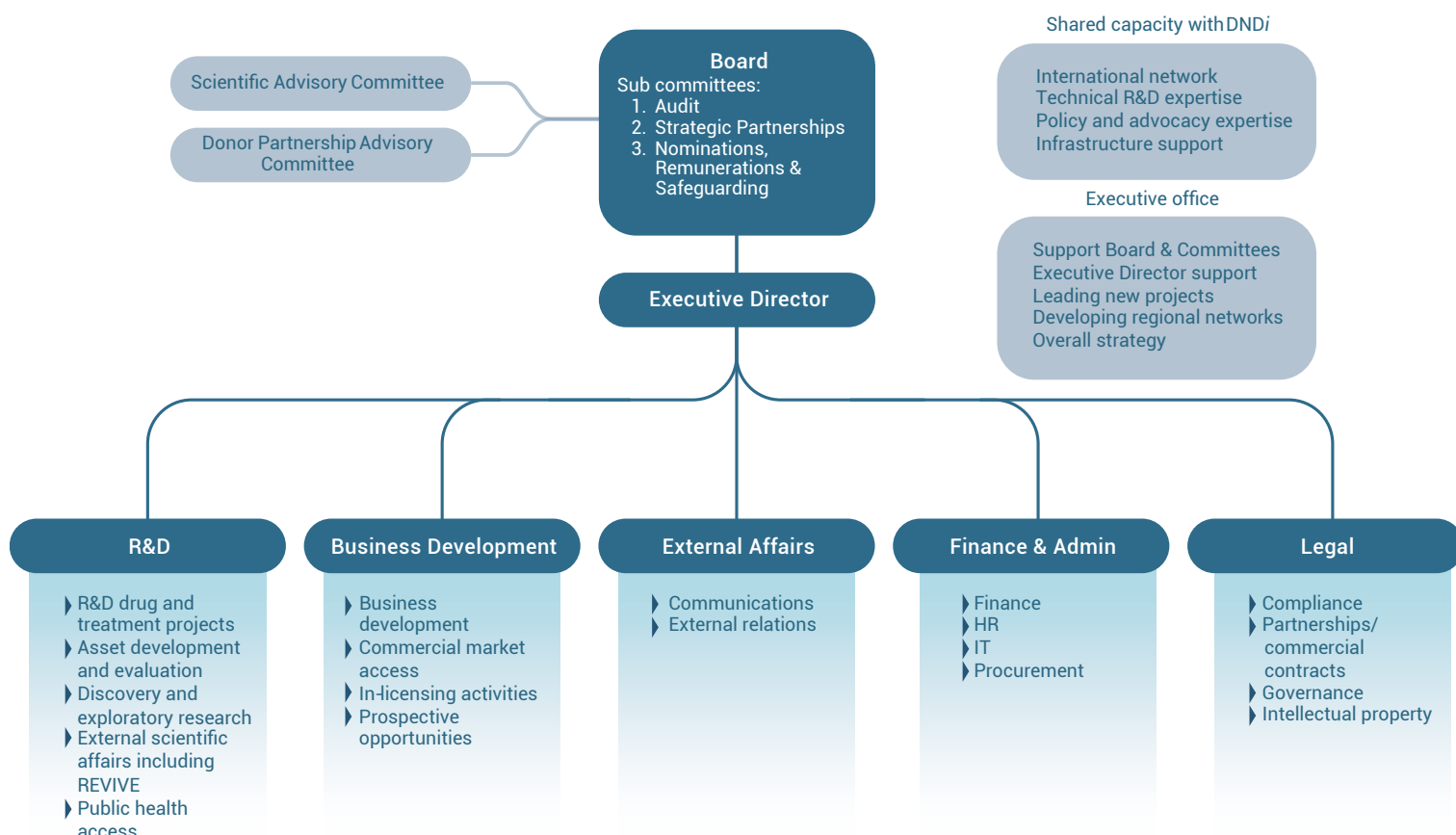
Glenda Gray, South African Medical Research Council, South Africa
Marie-Paule Kieny, Vice-Chair
Institut National de la Santé et de la Recherche Médicale, France
Ramanan Laxminarayan, Chair
Centre for Disease Dynamics, Economics and Policy, USA
Joanne Liu,
Médecins Sans Frontières
Veronika Von Messling,
Federal Ministry of Education and Research (BMBF), Germany
Frédéric Vallat, Treasurer
Ville de Genève, Switzerland

OBSERVERS

Manica Balasegaram, *Ex officio*
GARDP
Prabha Fernandes, Chair of GARDP
Scientific Advisory Committee (incoming)
Jutta Heim, Chair of GARDP
Scientific Advisory Committee (outgoing)
Bernard Pécoul,
Drugs for Neglected Diseases *initiative*,
Soumya Swaminathan,
World Health Organization

Executive structure

Our leadership team and employees work to deliver on our vision by supporting the R&D ecosystem while developing and securing sustainable access to new treatments. Our Executive Director reports directly to, and is held accountable by, the Board.



Over the next six years, we propose to double the size of our global team to deliver our **5 BY 25 goal**. Most of this headcount will be in our R&D and business development functions (increasing to around 70 people). We will strengthen our internal capabilities in pharmaceutical and

clinical development and with our partners, advisors, and vendors. Alongside this, we will proportionately reinforce our operations and management functions, ensuring we effectively manage our resources.

GARDP will continue collaboration with its founding partners, DNDi and WHO. DNDi, who has a track record in delivering treatments and building a robust R&D pipeline, and will continue to provide expertise and capacity to GARDP through its R&D team, policy advocacy, and established international network (including a joint DNDi GARDP office in South Africa). To drive efficiencies, we will continue to share some infrastructure and support services.

GARDP will also continue its close partnership with the WHO. We will leverage the WHO's expertise and leadership in determining public health priorities, developing target product profiles, strengthening stewardship and access, connecting to regional networks, as well as benefiting from access to Member States and international experts.

Investing in antibiotic R&D

Over the last two years (2017-2018), the annual expenditure of GARDP more than doubled from €4m to €11m. It is expected to reach €20m in 2019 (totaling about €36m since its launch in 2016).

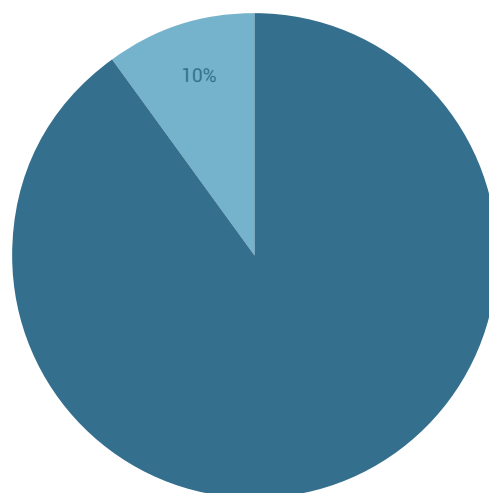
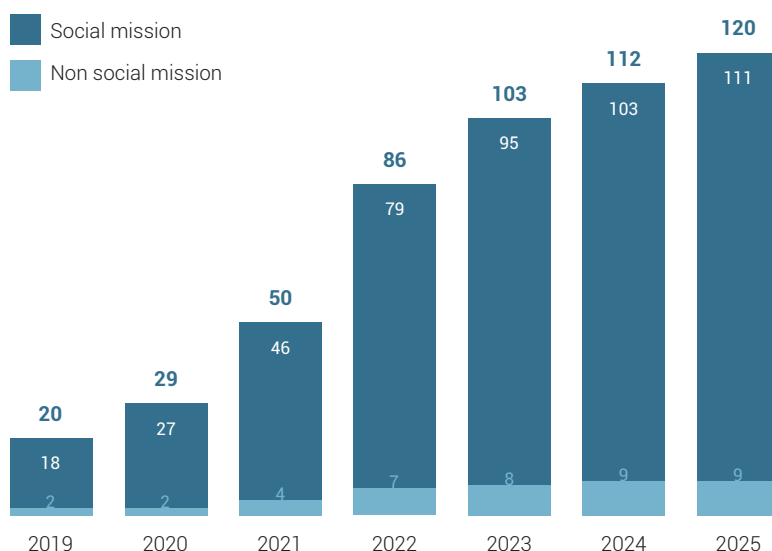
To achieve the objectives laid out in this business plan, we need to secure a total of €500m in funding. Ninety-eight percent of our current funding comes from governments. This funding will need to diversify over time to include private donors (including large and small foundations, high net worth individuals, and the general public), and alternative financing mechanisms. Where relevant, GARDP will look to supplement funds through royalties, licensing fees, and loans from development banks, consistent with our public health mission and priorities.

The 2020-2025 vision, 5 BY 25, relies on the development of five new treatments. We will expand our sexually-transmitted infections and paediatric programs and develop a new serious bacterial infections program. Together, our work will focus on treatments for both adults and children.

Based on our current business plan, our annual expenditure – including that on new treatments – is expected to increase from about €30m in 2020 to over €100m by 2023. Over the period 2020-2025, our funding will be spent on achieving our ultimate goal – making sure new treatments for bacterial infections are responsibly and sustainably accessible to all. We estimate an average of 10 percent of funding will be used for general administrative costs over the new business plan period.

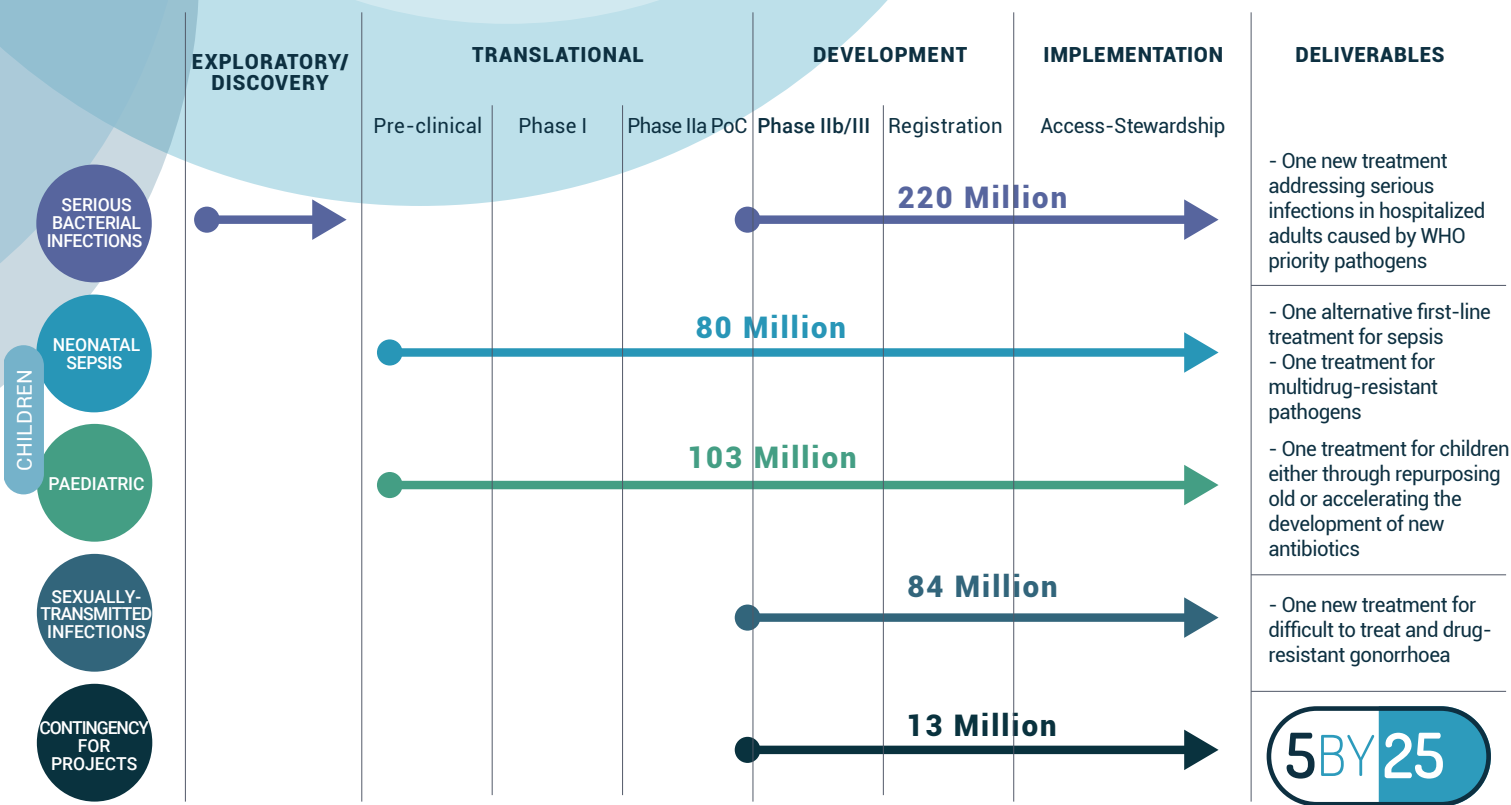


The following figure shows the breakdown of our investments in our existing and proposed R&D programs. We plan to invest about €220m in our new serious bacterial infections program, a further €183m in children's antibiotics (neonatal sepsis and paediatrics), and €84m in our sexually-transmitted infections program.



■ Research & development ■ General administration and fundraising

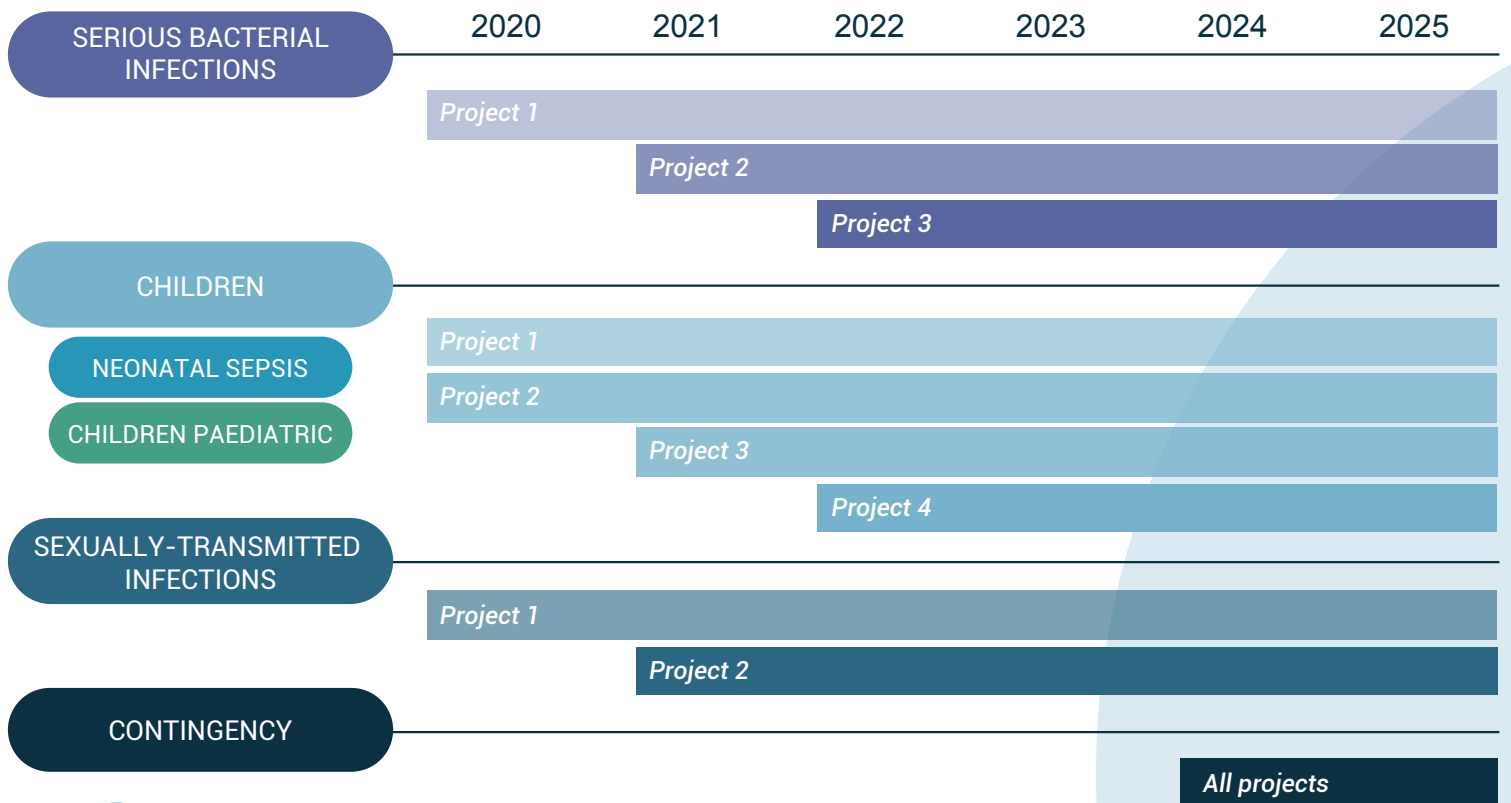
Estimated costs of GARDP portfolio - EUR 500M



It is currently estimated that 25 to 50 percent of the new projects, those assigned as serious bacterial infections and those not assigned yet, will be funded via cost sharing agreements. This is reflected in the above figures, but it does mean the costs could change significantly.

GARDP program timetable

The following highlights a likely breakdown of projects per program. It should be noted that this will be dynamic as the antibiotic pipeline will evolve and attrition will occur.



GARDP will continue initiatives

aimed at minimizing costs and increasing value for its beneficiaries and donors.

This includes:

Leveraging the willingness of partner organizations (including pharmaceutical companies) for additional in-kind contributions at all stages of development.

Continuing to improve processes to accelerate delivery and reduce associated costs through our partnerships.

Further developing activities for clinical development in high-burden settings to reduce time and costs.

Strengthening our procurement and project management capabilities to **reduce costs and delays**.

Exploring further pro bono partnerships (e.g. with academia and industry) and individual expert contributions.

Investing in our collaboration with DNDi to make the most of our shared R&D technical expertise, international network and infrastructure, therefore driving efficiencies.

Developing alliances, especially with other public-private and product development partnerships, to minimize costs.

Contingency planning to mitigate risks.



The GARDP journey

2014

In 2014, the idea of GARDP was born. After consultation with the WHO Member States and key stakeholders, the WHO and DNDi set up GARDP as a new initiative to promote the research, responsible use, and access of new antibiotics.

2015

The 2015 World Health Assembly endorses a global action plan to tackle antimicrobial resistance, including antibiotic (antibacterial drug) resistance.

G7 endorses the WHO Global Action Plan and commits to developing national action plans.

The WHO holds a technical consultation with Member States and other key stakeholders on the concept of a product development partnership. Following this meeting, the DNDi Board of Directors approve the incubation of GARDP.

2016

GARDP launches at the 2016 World Health Assembly as a joint initiative between the WHO and the DNDi; first activities are incubated within DNDi.

Development of first GARDP business plan.

First scientific consultation at Institut Pasteur.

2017

GARDP secures €6.5m in seed funding and has a team of 10 people.

By the end of 2017, the team has increased to 17 people.

GARDP publishes its first business plan outlining an R&D strategy.

GARDP launches its first programs on sexually-transmitted infections and neonatal sepsis. Two further programs – paediatrics and an antimicrobial exploratory program – follow.

GARDP announces first agreement with Entasis Therapeutics to develop novel oral antibiotic for gonorrhoea.

GARDP conducts a survey on the current antibiotics used to treat late-onset neonatal sepsis.

Joint DNDi/GARDP office set up in South Africa with support from South African Medical Research Council.

2018

GARDP set up as an independent not-for-profit foundation with headquarters in Geneva, Switzerland.

GARDP starts its first antibiotic development activities in various countries including:

A partnership with Penta – the paediatric infectious diseases network – on a clinical trial in Kenya confirming dose and safety of fosfomycin to combat neonatal sepsis.

Starting of a global observational study in hospitals and neonatal units across Africa, Asia, Europe, and South America. The study, in partnership with St George's, University of London and Penta, focuses on collecting clinical information on babies with significant/clinical sepsis.

GARDP completes a phase I pharmacokinetic and safety study on zoliflodacin, allowing appropriate dose selection for the pivotal phase III trial.

Secures regulatory advice for phase III clinical trials on zoliflodacin in the Netherlands, South Africa, Thailand, and the U.S.

GARDP signs its first multi-actor partnership with Eisai, Takeda and the Institut Pasteur Korea (IPK) to support antibiotic discovery.

GARDP announces a partnership with the Helmholtz Centre for Infection Research (HZI/HIPS).

GARDP signs public-private partnerships with a number of entities including with Evotec AG and Sandoz focused on new or improved antibiotics.

GARDP completes recruitment of key R&D positions and is present in 16 countries.

REVIVE (GARDP's education, training, and outreach activities resource center for the antimicrobial R&D community) launches, hosting four webinars to participants across the world, publishing two blogs, and co-hosting three sessions at international conferences.

2019

GARDP completes its incubation period in DNDi. A new collaboration is agreed for the next three years.

GARDP is fully operational as a new independent not-for-profit foundation with a skilled team of 40+ employees with expertise from a wide variety of sectors.

Phase III clinical trial on zoliflodacin, investigating the efficacy and safety of a new drug for gonorrhoea, launched with first patients recruited.

New data from GARDP pharmacodynamic and clinical studies allows selection of candidate treatments for a sepsis efficacy study in newborn babies (neonates).

GARDP starts screening compound libraries from Eisai, Takeda and Calibr, and natural products from HIPS, at screening facilities in Australia (UQ) and Korea (IPK).

REVIVE hosts 10 webinars to participants across the world, publishes seven blogs, and co-hosts one conference, plus three sessions at international conferences.

GARDP reviews over 100 potential treatment candidates amongst new and 'recovered' antibiotics.

Updated business plan launches reflecting progress and outlining plan for 5 BY 25.

5BY25

Looking ahead...

Since its inception in 2016, GARDP has secured €72 million in funding. However, we still need to secure an additional €464 million in funding if we are to deliver our 5 BY 25 ambitions. Over the next six years, the GARDP Board will continue to evolve, new partnerships will be created, and together, GARDP and its partners will have developed five new treatments and a solid portfolio to address antimicrobial resistance.

“ *Developing new treatments to address drug resistance cannot be done in isolation. Our partners are the key to our success and I truly believe that by working together, we can be more than the sum of our parts.*

Because we work with experts in both the public and private sectors, we can take advantage of the best available innovation, expertise, and resources. Since our inception, we have formed over 50 partnerships in 20 countries. We are proud to work with governments, the biomedical and pharmaceutical industry, research institutions, not-for-profits, civil society, and, of course, patients affected by infectious diseases. We would like to thank all our partners and funders – in the public and private sectors – for their support. None of our achievements would have been possible without them.

GARDP is committed to building, investing in, and co-developing a public health-oriented portfolio with a focus on late-stage development and sustainable access. Unfortunately, many of the antibiotics currently in development will not add significant value above current treatment options. This is why we need to direct our attention and resources on projects and partnerships that will deliver the most significant impact. It is important to acknowledge those who have helped us put our new strategy together. I believe this new direction will make a real and relevant contribution in addressing the growing problem of AMR.

We want to develop new treatments for unmet clinical needs, rather than just developing drugs. We want to help those most in need – the elderly, the young, and the most vulnerable populations. We want to ensure everyone, everywhere, has access to the treatment they need in a responsible and sustainable manner. And, with your support, I know we can deliver. ”

Dr. Manica Balasegaram,
GARDP Executive Director

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