



2024–2028

STRATEGY

Putting public health needs
at the centre of antibiotic
drug development

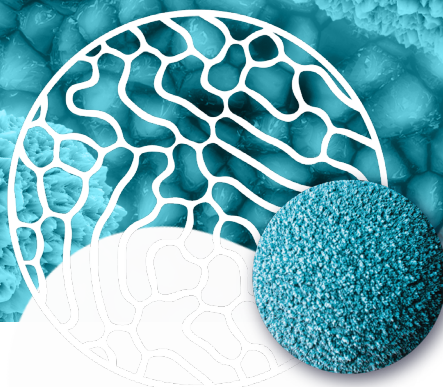




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SECTION 1

INTRODUCTION

WHO/Christopher Black



Foreword

Dr Tedros Adhanom Ghebreyesus
Director-General of the World Health Organization

Antimicrobial resistance (AMR) represents one of the most severe global health threats facing humanity. The latest estimates are that in 2019, nearly 5 million deaths were associated with, and 1.3 million deaths attributable to, drug-resistant bacterial infections. AMR has the potential to reverse decades of progress in fighting infectious diseases and undermine many aspects of modern medicine.

Successful action on AMR in the human health sector must address the whole continuum of preventing infections, ensuring access to health services, strengthening diagnostics and surveillance, and appropriate use of safe and effective medicines. The World Health Organization (WHO) is supporting countries to take this forward as part of comprehensive multi-sectoral action and a One Health approach.

In this context, it is critical that we address the failing pipeline for development of new antibiotics. Traditional drug development incentives are not meeting the needs of populations that are most vulnerable to serious bacterial infections, such as women, children and newborns. There is an urgent need for new antibiotics against drug-resistant bacteria.

In response to this, WHO and the Drugs for Neglected Diseases initiative (DNDi) created the Global Antibiotic Research & Development Partnership (GARDP) in 2016 to address both the global market failure and public health failure that contribute to this escalating global health crisis.

Tackling the antibiotic crisis goes beyond financial incentives; it requires a concerted effort to bridge the gaps in research, development and access that disproportionately affect vulnerable populations and countries. As we learned from the COVID-19 pandemic, addressing these issues requires global collaboration based on core principles of collaboration, solidarity and equitable access in the face of a global threat that does not respect national borders.

This new strategy outlines GARDP's commitment to fostering collaborations, engaging diverse stakeholders and promoting open knowledge sharing. WHO values its partnership with GARDP, including the SECURE initiative, which aims to improve equitable access to new and existing antibiotics. Together with governments, civil society, researchers and the private sector, we can collectively address the urgent health needs of the most vulnerable populations and develop innovative solutions that can be readily accessible to all. This is an essential contribution to progressing towards universal health coverage and the other health-related targets in the Sustainable Development Goals.

I therefore warmly welcome GARDP's 2024–2028 strategy and its vision of building a world in which everyone, everywhere can access life-saving antibiotic treatments. By fixing the public health failure, addressing the needs of the most vulnerable populations and designing trials that overcome historic inequities, we can make meaningful strides in combating AMR and safeguarding the health and well-being of future generations.



Opening message

Prof Ramanan Laxminarayan
GARDP Board Chair

AMR is no longer a silent pandemic—it is already one of the biggest global killers and one of the 10 greatest threats to global health according to WHO. However, even with billions of dollars of public investment now flowing into antibiotic research and development (R&D), the degree and breadth of the global response still does not reflect the scale of the problem, nor its urgency. Despite the significant clinical need for new antibiotics to replace those that no longer work reliably, there are many challenges to building a new model to bring new antibiotics to market.

GARDP was created by WHO and the Drugs for Neglected Diseases initiative (DNDi) precisely for this reason—to demonstrate and scale up a new R&D model for the scientific discovery, research and development of new antibiotic treatments, and to ensure that they protect people in the highest burden regions from priority pathogens, those multidrug-resistant bacteria that pose the greatest public health threat.

GARDP has brought donor funding and deep scientific and technical expertise to the problem. Our solution is to work with private pharmaceutical companies to de-risk the clinical phase of drug development using our funding, scientific capabilities and networks in exchange for obtaining market access rights in low- and middle-income countries, thereby enabling access for millions of patients in need. In

the short five years of GARDP's existence as an independent organization, there is clear evidence that this approach is working to address the crisis of the broken antibiotic pipeline.

Bringing new drugs to market in this way is a cost-effective and responsible use of donor funding. With support from governments and private foundations, we can prioritize projects that maximize impact and ensure a return for public health.

Along the way, we have made significant progress towards establishing the global ecosystem needed to address AMR. We have done this through the creation of a global network of partnerships involving pharmaceutical and biotech companies, research institutions, generic manufacturers and representatives from academia and civil society. Over the next five years we plan to build on that progress to take our antibiotic treatments to registration for global access, and to invest in the next set of potential treatments. This will pave the way so that people across the world—particularly vulnerable populations, like cancer patients, women and children—can access much-needed antibiotic treatments sooner and continue to benefit from antibiotics for generations to come.

For 2024–2028 we have two principal objectives. The first is to help address the immediate AMR

crisis by improving access to much-needed antibiotic treatments in the short term. The second is to demonstrate how this new R&D partnership model can help to address the public health failure, and in doing so provide a long-term solution to AMR.

We call on governments, including G7 and G20 nations, to renew, expand, or initiate their support for GARDP and to recognize the full extent of the challenges posed by AMR. The world urgently needs a better global pipeline for antibiotics, one that is driven by public health need and serves everyone.

We have estimated that the cost of this next phase will be €220 million. With a demonstrated track record of success, GARDP stands ready to help solve the world's antibiotic crisis with respect to research, development and enabling access to the newest antibiotics for the millions of patients in need worldwide.

GARDP is grateful for financial support from the governments of Australia, Canada, Germany, Japan, Monaco, the Netherlands, South Africa, Switzerland, the United Kingdom, as well as the European Union (via the Health Emergency Preparedness and Response Authority), the RIGHT Foundation, the Canton of Geneva, Wellcome and private foundations.



Executive Summary

GARDP: Addressing the global crisis of drug resistance

It is well understood what is at stake if we fail to develop new treatments for drug-resistant bacterial infections. If we ultimately fall into a post-antibiotic era, the 23-year increase in life expectancy that antibiotics have helped us achieve could steadily be reversed.¹ But what is less well understood about this grim reality is what needs to be done to prevent it, and the sense of urgency required to act. AMR is not a looming threat that will happen suddenly. It is a global crisis that is already upon us.

According to data based on the 2022 GRAM study, AMR is directly responsible for the deaths of nearly 1.3 million people a year and associated with almost 5 million deaths, making it one of the biggest global killers. If AMR is left unchecked, its annual death toll is expected to rise considerably, and according to some estimates could cost as much as US\$3.4 trillion to the global economy by 2030.² Over time its impact on humanity is expected to be further compounded by other global trends, including climate change, human migration, conflict and urbanization.

The Global Action Plan on AMR (2015) underscored the need for new initiatives to develop new antibiotic treatments. In response, WHO and DNDi partnered in 2016 to create a new organization: the Global Antibiotic Research & Development Partnership, or GARDP. Legally established as an independent foundation in 2018, GARDP responds to the urgent need for antibiotic research, development and access.³

Through its partnership model, GARDP has successfully developed a portfolio of antibiotic treatments to make progress towards delivering five treatments by 2025, as set out in our previous strategy (published in 2019). We are also excited to pioneer new access initiatives with our innovator, manufacturing and distribution partners.

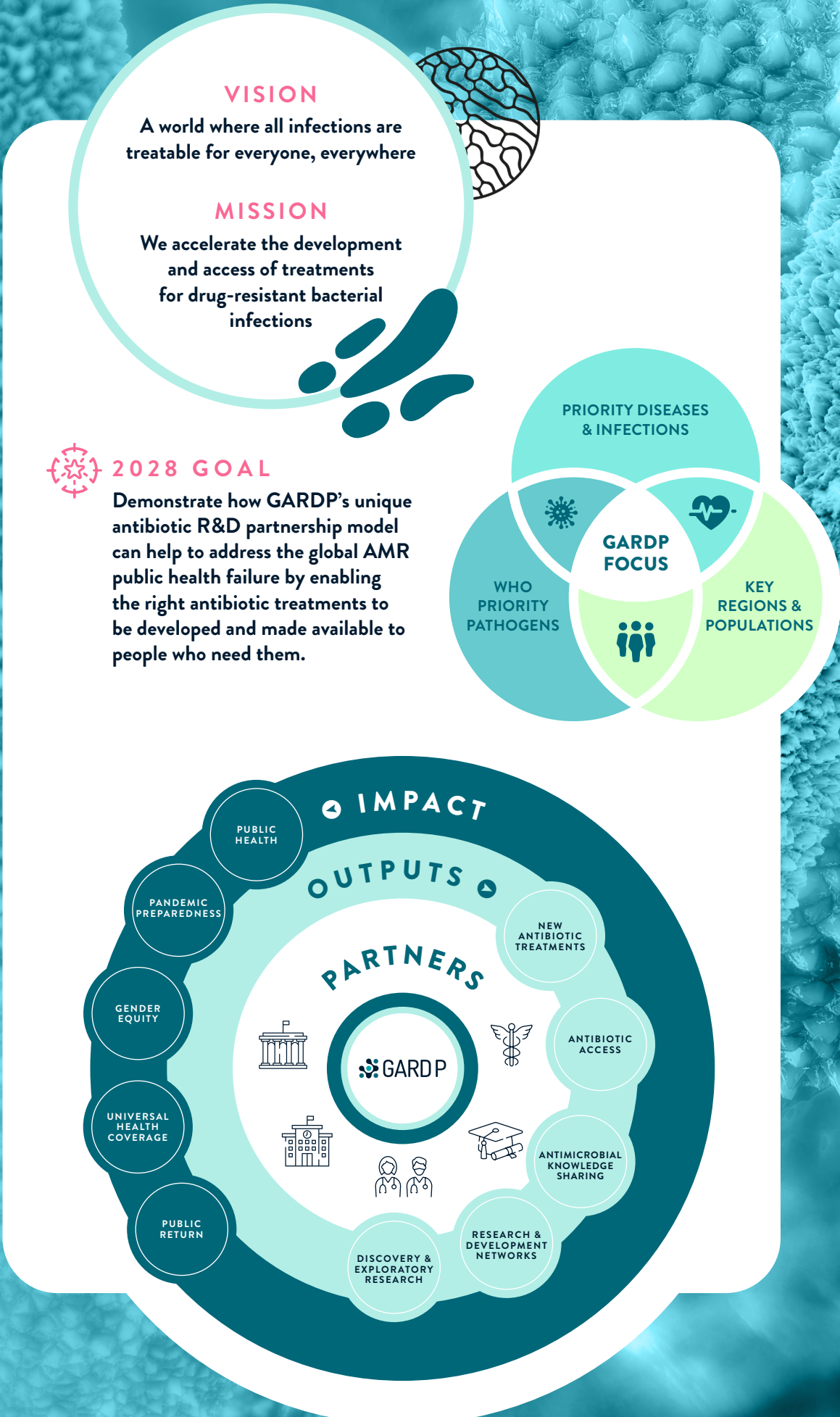
The progress is part of GARDP’s “Start-Up” and “Growth” phases, during which GARDP has put in place all the pieces needed to address this global crisis. In particular we’ve developed a strong team with extensive cross-sector R&D experience and brought together all the key public and private sector stakeholders, such as the research and development community, donors, industry and implementing countries.

Now as GARDP enters its next strategic five-year phase, it will build on this progress. Having laid the foundations, it aims to bring together its different workstreams, along with global partners, to establish an ecosystem for antibiotic R&D and access. We want to ensure that, when promising new antibiotics are found, their research, development and commercialization receive adequate investment and support and have a clear pathway to make it to market, ultimately reaching the people who need them most, no matter where they live. At the same time, by supporting good stewardship, GARDP will contribute to the sustainable use of these antibiotics. This new strategy highlights the key milestones we have achieved to date and maps out how GARDP will attain its goals for 2028.

ANTICIPATED DELIVERABLES 2024–2028

- 2 new innovative antibiotic treatments authorized for market
- 3-4 new treatments available for use
- 1-2 new treatments in late-stage development

1. Hutchings MI, Truman AW, Wilkinson B. Antibiotics: past, present and future. *Curr. Opin. Microbiol.* 2019;51:72-80. <https://pubmed.ncbi.nlm.nih.gov/31733401/> [accessed 28 November 2023].
2. The World Bank. *Drug-Resistant Infections: A Threat to Our Economic future.* March 2017. <https://www.worldbank.org/en/topic/health/publication/drug-resistant-infections-a-threat-to-our-economic-future> [accessed 28 November 2023].
3. GARDP is a Swiss foundation registered under the legal name “GARDP Foundation.”





SECTION 2

GARDP'S IMPACT ON ANTIMICROBIAL RESISTANCE

GARDP: Who we are and what we do

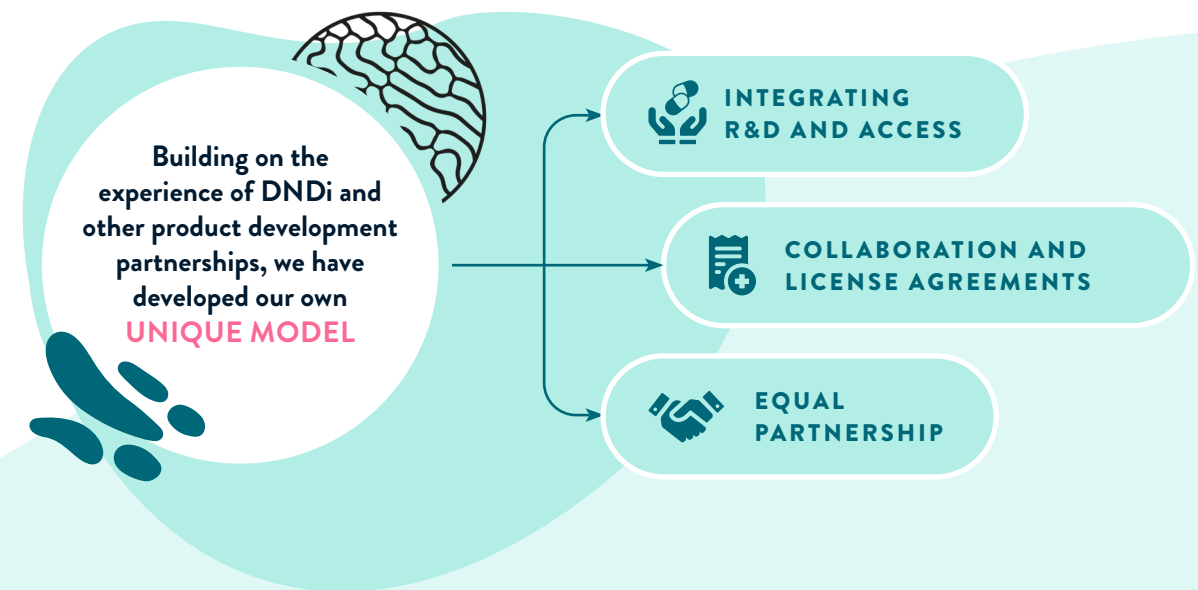
OUR GOAL

By 2028, we will demonstrate how GARDP's unique antibiotic R&D partnership model can help to address the global AMR public health failure by enabling the right antibiotic treatments to be developed and made available to people who need them.

OUR PROGRAMMATIC AREAS

GARDP is a not-for-profit organization that works in partnership to develop new antibiotic treatments and expand access to them. We focus on serious bacterial infections and sepsis in adults, children and newborns, as well as sexually transmitted infections (STIs).

FIGURE 1: **OUR UNIQUE MODEL**
PUTTING PUBLIC HEALTH NEEDS AT THE CENTRE OF ANTIBIOTIC DRUG DEVELOPMENT



INTEGRATING R&D AND ACCESS

GARDP engages in carefully selected antibiotic drug development and access projects to address urgent public health needs. More than just a funder, GARDP is able to take a leading or complementary role in the drug development process, according to the demands of each particular project. We are directly involved in pharmaceutical and clinical development to ensure that every treatment we develop is safe, effective, affordable and suitable for use in diverse settings, including those with high AMR burden and limited resources.



COLLABORATION AND LICENSE AGREEMENTS

We de-risk antibiotic drug development projects by negotiating collaboration and license agreements with pharmaceutical companies. In exchange for our expertise and financial support, we seek the rights to manufacture and distribute treatments, especially in regions with high morbidity and mortality due to antibiotic resistance. We sublicense these rights to manufacturers for registration and distribution in our territories to facilitate access at affordable prices.



EQUAL PARTNERSHIP

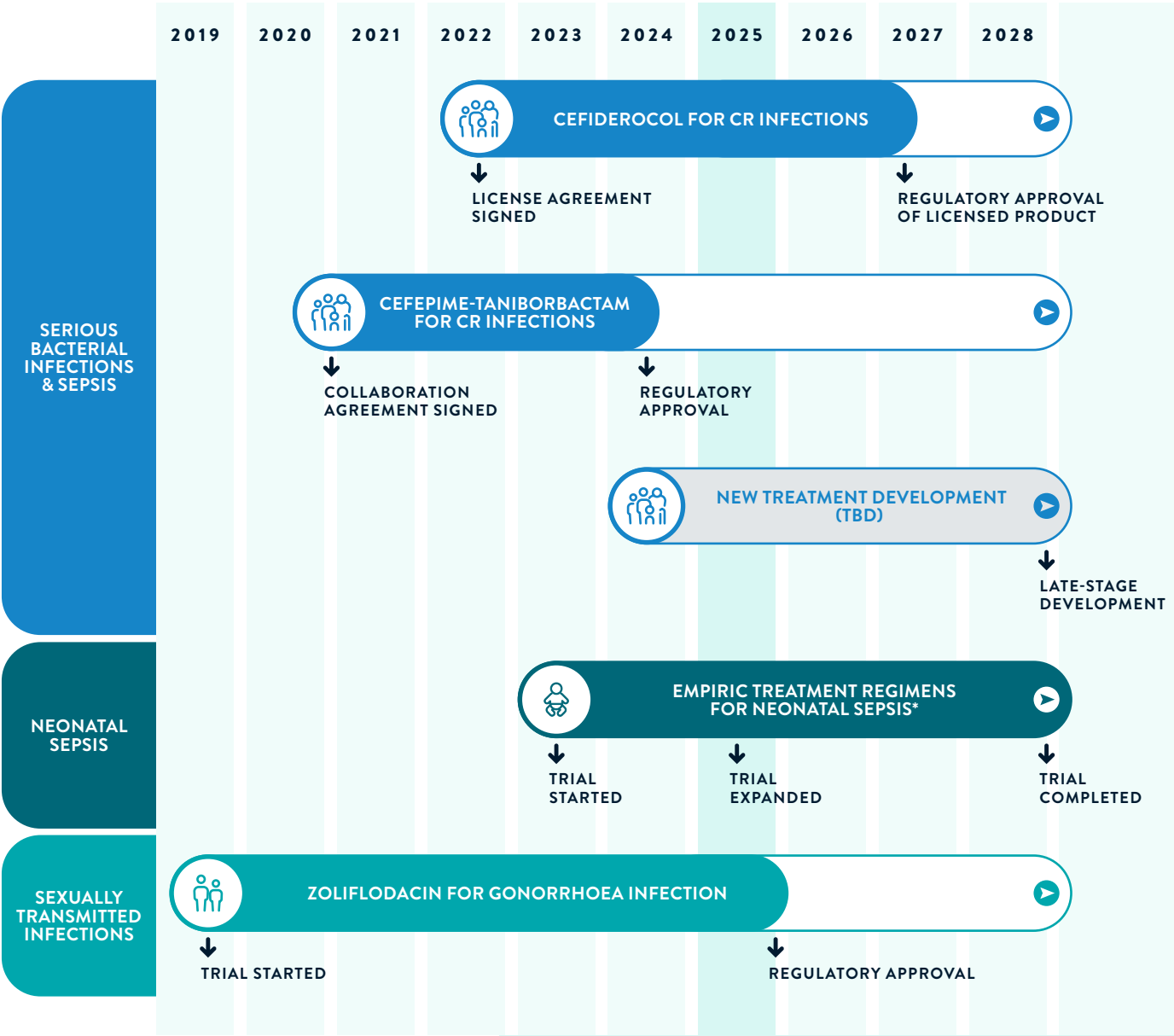
Many low- and middle-income countries have expertise that is critical to address the global antibiotic crisis. Our public-private partnership approach involves working with these individuals and all key stakeholders from the get-go—including scientists, clinicians, industry, manufacturers, governments, donors and civil society—to coordinate efforts in the antibiotic pipeline of drug development and access. To each of these relationships, we bring a range of skills, knowledge and resources, including financial and scientific resources, as well as geographic reach. We are able to do so thanks to our diverse, experienced team and global network.

5 treatments by 2025: Where do we stand now?

At the World Health Summit in Berlin in 2019, GARDP announced an ambitious goal to deliver five new antibiotic treatments by 2025. We have made notable progress since then, as shown in **Figure 2**. GARDP’s portfolio now includes one approved treatment and several investigational treatments for serious bacterial infections and sepsis in adults, children

and newborns, as well as an investigational treatment for drug-resistant gonorrhoea. Three of these treatments—cefiderocol, cefepime-taniborbactam and zoliflodacin—are licensed to GARDP, which has the responsibility for providing access to the products, upon approval, through sublicensees in a large number of countries.

FIGURE 2: STATUS OF 5BY25



CR: carbapenem-resistant * fosfomycin-amikacin / flomoxef-amikacin / fosfomycin-flomoxef

CEFIDEROCOL

As of 2023, cefiderocol, a treatment for certain Gram-negative infections, had been approved by the US Food and Drug Administration (US FDA) and the European Medicines Agency (EMA). Shionogi & Co., Ltd. (Shionogi) licensed the rights for manufacturing and distribution in 135 countries to GARDP, and GARDP then sublicensed the rights for manufacturing to Orchid Pharma.

CEFEPIME-TANIBORBACTAM

Cefepime-taniborbactam was submitted for US FDA approval by our industrial partner Venatorx Pharmaceuticals, Inc. (Venatorx). The US FDA’s decision is scheduled for early 2024.

NEONATAL SEPSIS

GARDP has launched an international public health trial to evaluate new treatment regimens for neonatal sepsis in the context of widespread drug resistance to the currently recommended option. This trial could confirm the safety and efficacy of up to three new treatment regimens.

ZOLIFLODACIN

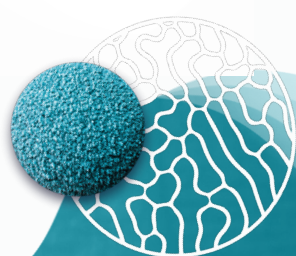
Zoliflodacin is a potential novel oral treatment for gonorrhoea infection. We have successfully completed a global phase 3 trial, which allows us to move to registration, in collaboration with Entasis Therapeutics Limited (Entasis), now a subsidiary of Innoviva Inc. (Innoviva).



GOAL BY 2028

- As an initial step towards broader access, we aim to make cefiderocol accessible in at least five countries, none of which currently has access.
- We hope to welcome the approval of cefepime-taniborbactam as a treatment for adults with carbapenem-resistant Enterobacterales infections, and we will strive to develop this treatment for use in children.
- Our ambition is to identify at least one effective new treatment regimen for neonatal sepsis.
- We anticipate the approval of zoliflodacin in the United States and Europe, as well as in GARDP’s priority countries, South Africa and Thailand.

For further details on these projects and our objectives, see section 4.

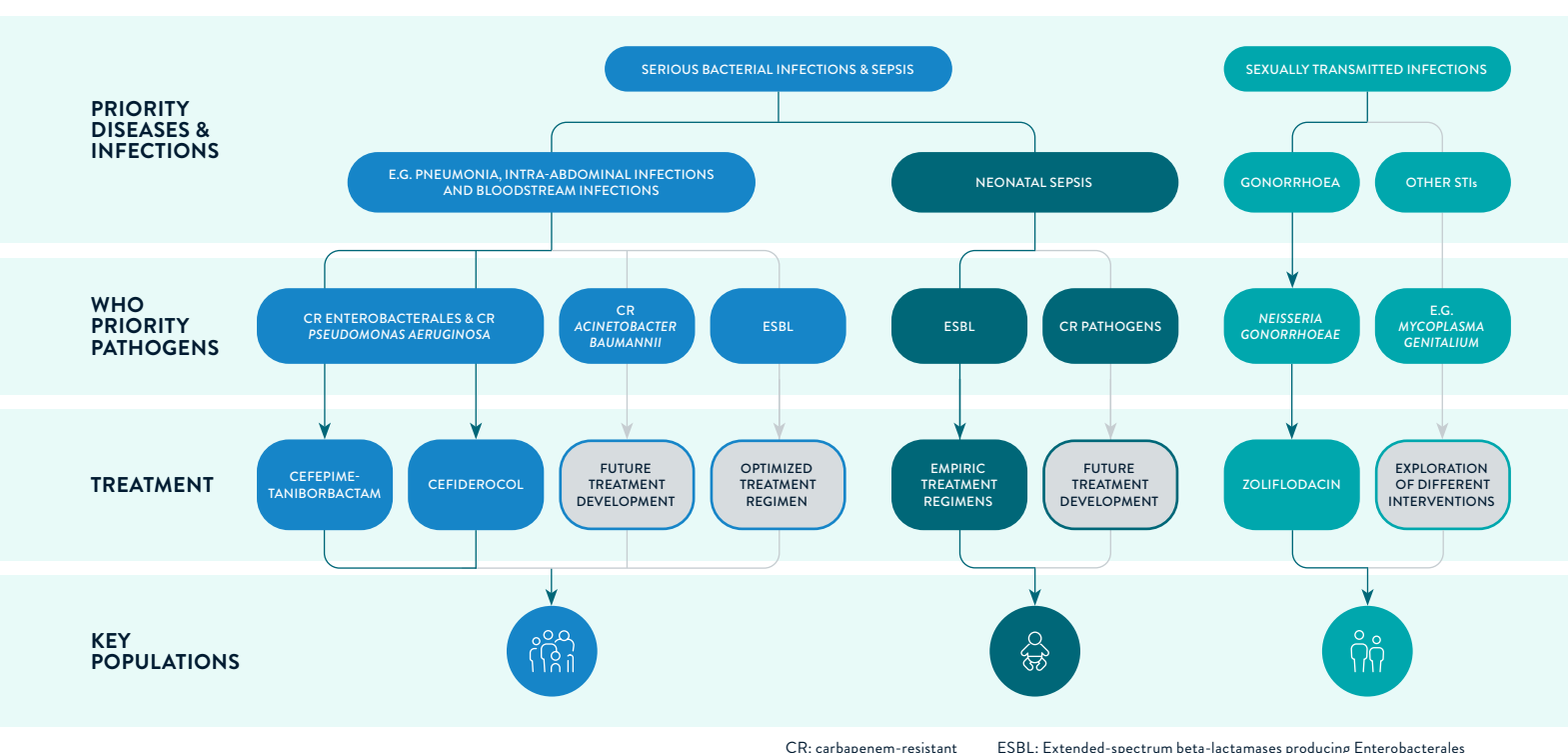


Expanded portfolio 2024–2028

Building on this progress, GARDP now seeks to complement the current portfolio, as shown in **Figure 3**. Our portfolio will remain centred on bacterial pathogens that cause serious bacterial infections and sepsis in adults, children and newborns, and on sexually transmitted infections, as outlined in section 3 below. We have identified four new projects (in grey) that we believe to be essential to addressing these priority diseases and infections. GARDP will also consider any new priorities identified by WHO and related areas such as antifungal resistance.



FIGURE 3: GARDP'S EXPANDED PORTFOLIO 2024–2028



NOVEL BROAD-SPECTRUM TREATMENT FOR SERIOUS BACTERIAL INFECTIONS

We aim to develop a novel broad-spectrum antibiotic treatment for infections caused by carbapenem-resistant Gram-negative pathogens such as Enterobacterales, *Acinetobacter* species and *Pseudomonas* species.

OPTIMIZED TREATMENT REGIMEN FOR INFECTIONS CAUSED BY DRUG-RESISTANT ENTEROBACTERIALES

GARDP envisages developing a new treatment regimen for infections caused by drug-resistant Enterobacterales, including extended-spectrum beta-lactamase-producing Enterobacteriaceae (ESBL-PE).

FUTURE TREATMENT DEVELOPMENT FOR CARBAPENEM-RESISTANT INFECTIONS IN NEWBORNS

With this project, GARDP will accelerate the development of new treatments for infections caused by carbapenem-resistant *Acinetobacter baumannii* (CRAB) and carbapenem-resistant Enterobacterales (CRE) in newborns.

EXPLORATION OF DIFFERENT INTERVENTIONS FOR STIs

GARDP is considering the development of a new treatment for difficult-to-treat gonorrhoea and related STIs. GARDP may also expand its portfolio to preventive measures for STIs and target additional pathogens that cause STIs like *Mycoplasma genitalium* and syphilis.

For further details on these projects and our objectives, see section 4.

Funding need: €220 million

Since initial incubation by DNDi in 2016, GARDP has invested €126.3 million to develop and make accessible treatments to counter antibiotic resistance. This investment has come from public funders (96%) and private foundations (4%). For the period 2024–2028, GARDP is seeking €220 million to continue addressing the immediate public health needs for antibiotics, while working towards the creation of an ecosystem of antibiotic research, development and access for the world's future antibiotic needs. As of 2023, GARDP had secured €63 million towards its financial goal.

FIGURE 4: GARDP'S EXPENDITURE BY YEAR⁴
(INCLUDING ESTIMATED EXPENDITURE 2024–2028)

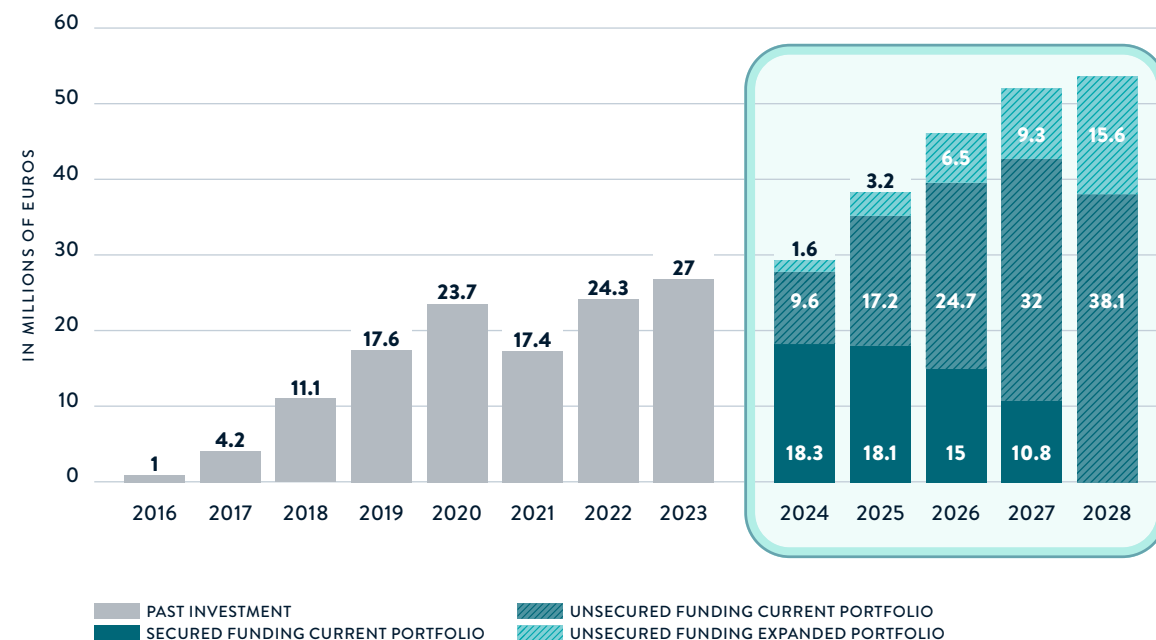
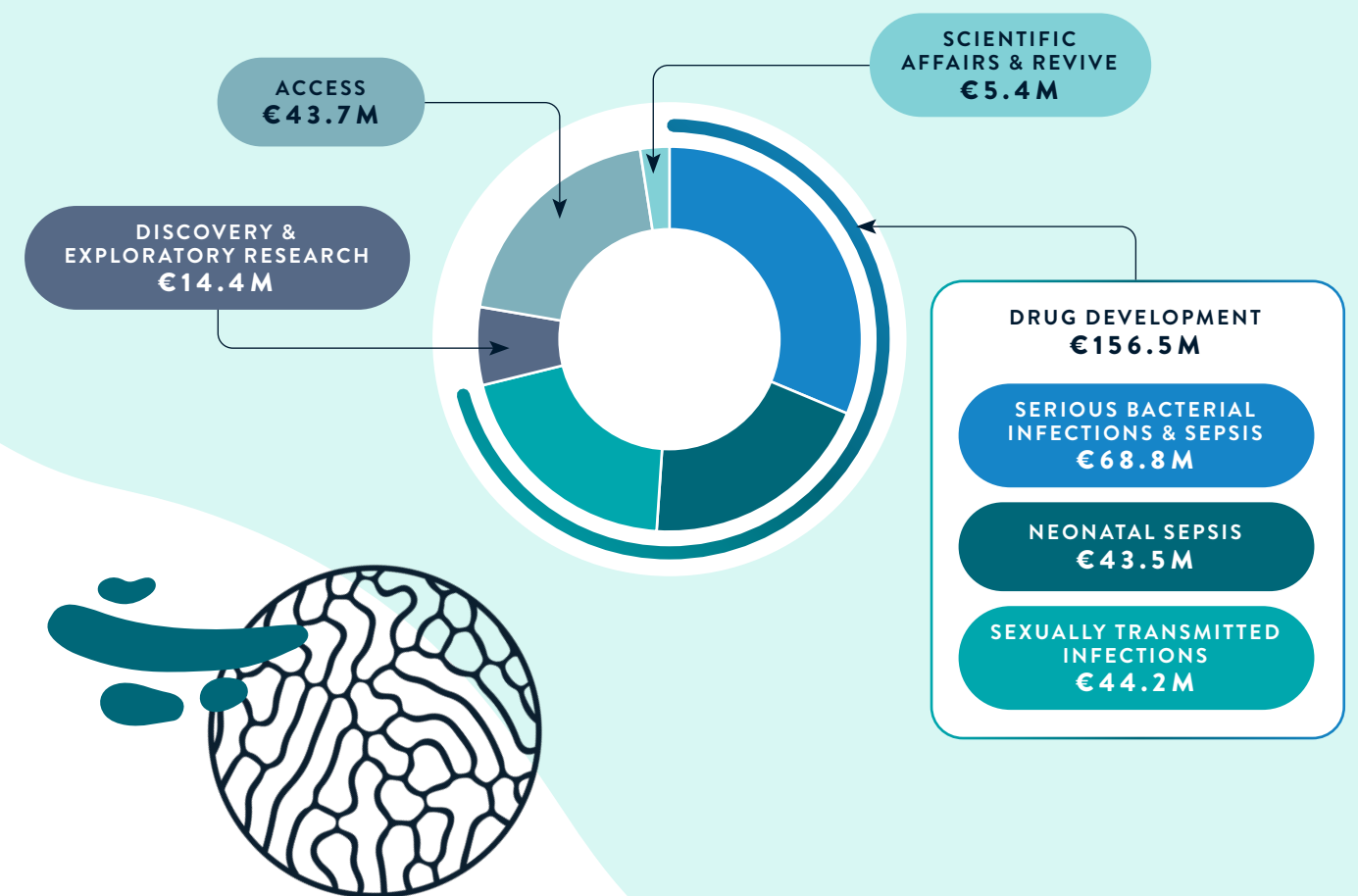


FIGURE 5: BUDGET BY PROGRAMME 2024–2028



To ensure our spending has as much impact as possible, we aim to keep our overhead at or below 13% of total spending. This ensures that the vast majority of our resources is used to fund the direct costs of our R&D, access and scientific programmes.

COST OF CURRENT PORTFOLIO: €183.8 MILLION

With full funding for our current work, GARDP will continue to develop up to five treatments in its existing portfolio, and will facilitate initial access to at least three treatments.

COST OF EXPANDED PORTFOLIO: €36.2 MILLION

Additional funding to expand our work will allow GARDP to develop at least one new treatment and launch innovative and critical partnerships aimed at establishing a reliable ecosystem of antibiotic R&D and access.

TOTAL FUNDING NEED 2024–2028: €220 MILLION

MAXIMIZING IMPACT WITH CORE FUNDING

To achieve our goal of developing a pipeline of priority antibiotic treatments while strengthening the overall ecosystem for R&D and access, we must ensure that every part of the GARDP model is funded. Core funding allows us to take a strategic approach to our financial and operational planning, rather than to manage the stops and starts associated with earmarked project funding. The flexible nature of core funding also allows us to take advantage of new opportunities that offer exceptionally good value in terms of impact and help drive our mission forward.

For relatively moderate investment compared to other global health priorities, funders can support GARDP's proven, cost-effective model that focuses on delivering a global public good: new, priority antibiotic treatments the world needs most.

4. The 2023 investment is the forecast as of November 2023. In 2021 and 2022, the COVID-19 pandemic meant that GARDP invested less than originally planned due to delays, for example in trial recruitment and site activation.



SECTION 3

HOW WE WORK

A product development and access partnership

The traditional R&D model has failed to address many of the world's pressing public health needs due to the uncertainty of commercial returns. Many specialized product development partnerships (PDPs) have been set up over the past few decades to close this R&D gap. PDPs partner with actors across the public, private and non-profit sectors to develop and provide access to new vaccines, therapeutics, diagnostics and other health products for diseases and populations that are neglected or underserved. And they have kept their promise:

“PDPs have now developed a total of 79 new health technologies since 2010, delivering more than 2.4 billion treatments, tests, and other health tools to people around the world.”⁵

Part of GARDP's unique model has been to adapt this approach to address antibiotic resistance, integrating R&D and access to focus on areas that most of the major pharmaceutical players have abandoned for lack of profitability. With diverse partners, GARDP has developed an antibiotic pipeline driven by public health needs.

5. *Amid Unprecedented Challenges, PDPs Continue to Develop and Deliver Lifesaving New Medical Technologies*. 6 April 2023. <https://www.keepingthepromisereport.org/2023-update> [accessed 2 August 2023].

FIGURE 6: GARDP'S PARTNERS, OUTPUTS AND IMPACT



Return on public investment

In recent years, the product development partnership (PDP) model has proven to be of tremendous value, using public money cost-effectively to drive innovation in areas where private investment is insufficient or ineffective.⁶

With its progress towards reaching 5 treatments by 2025, GARDP has already demonstrated that with a relatively small budget it can considerably accelerate development and access to antibiotic treatments. A case in point is zoliflodacin, the development of which has been led by GARDP (following the phase 2 proof of concept study).

We estimate that our total costs for the development of zoliflodacin—including carrying out the full phase 3 trial involving nearly 1,000 patients across five countries, the pharmaceutical development of the final formulation of the drug, the preparation of the regulatory submission to the US FDA (anticipated for 2024), registration in at least two priority countries, and future expansion of the safety database in specific populations (e.g. those who are pregnant or breastfeeding)—will amount to approximately €80 million.

6. PDPs Develop Cost-Effective Medical Innovations with High Returns on Investment. https://static1.squarespace.com/static/5fa16fcb053b490d0db02488/t/642d979d6ed254045ecf05c9/1680709534251/Keeping_the_Promise_2023_Cost-Effectiveness.pdf [Accessed 19 October 2023].



Focusing on key diseases, populations and pathogens to maximize impact

The 2022 GRAM study gives us important insights into what kind of infections are becoming more difficult to treat. To significantly reduce mortality and morbidity related to drug resistance around the world, GARDP has developed a disease area strategy based on three criteria:

PRIORITY DISEASES AND INFECTIONS

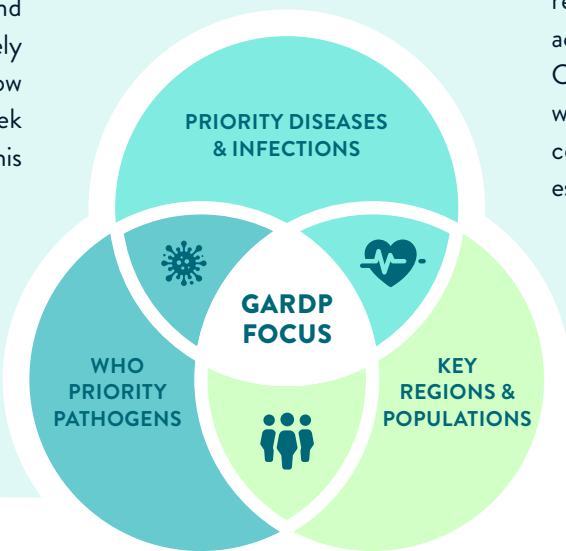
GARDP prioritizes serious bacterial infections and sepsis (including neonatal sepsis) and sexually transmitted infections (with a focus on gonorrhoea). Bacterial sepsis, the body’s life-threatening response to serious bacterial infections, results in close to five million deaths each year, according to the GRAM study. Newborns represent the highest burden group. Gonorrhoea, in turn, can cause serious, lifelong consequences for men and women, although it disproportionately harms women, who often fail to show early symptoms and thus do not seek treatment. Mothers may also pass this disease to newborn babies at birth.

THE DEADLIEST DRUG-RESISTANT BACTERIAL PATHOGENS

Just six of the WHO priority pathogens are responsible for most of the deaths due to antibiotic resistance each year, causing 50,000+ deaths each.⁷ R&D efforts should focus on developing new treatments for infections caused by these pathogens.

REGIONAL NEEDS AND VULNERABLE POPULATIONS

Resistance to first-line treatments across the globe is high, but there are clear differences between countries with the highest burden in sub-Saharan Africa, South Asia and Eastern Europe. More than 99.5% of children under five years old who die from drug-resistant infections are in low- and middle-income countries. These data reveal great disparities in the impact of drug resistance and access to antibiotics across regions and population groups. Children of all ages, pregnant women, the elderly and people with compromised immune systems are especially vulnerable.



These priorities are in line with the WHO Global research agenda for antimicrobial resistance in human health.⁸

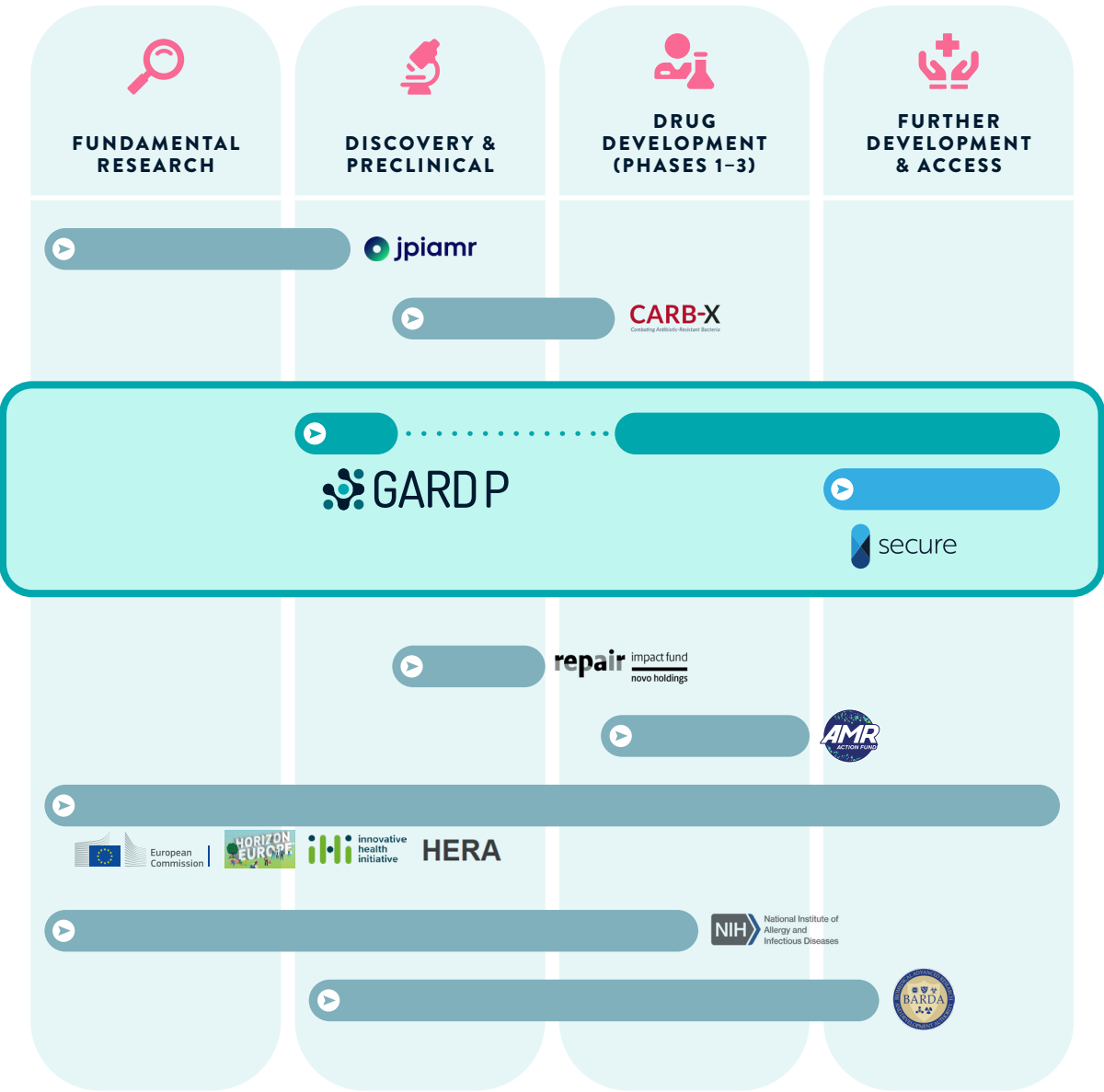
To understand how this focus shapes our programmes, see section 4.

7. WHO. “WHO publishes list of bacteria for which new antibiotics are urgently needed.” <https://www.who.int/news/item/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed> [accessed 20 October 2023]. N. B. *Mycobacterium tuberculosis* was not included in the study.
8. WHO. *Global research agenda for antimicrobial resistance in human health*. 22 June 2023. <https://www.who.int/publications/m/item/global-research-agenda-for-antimicrobial-resistance-in-human-health> [accessed 6 November 2023].

GARDP in the antibiotic R&D and access landscape

Since the adoption of the Global Action Plan on AMR in 2015, the R&D landscape to develop new treatments for drug-resistant infections has evolved considerably. The increased engagement by governments and other players has led to new initiatives and organizations that address important gaps in the antibiotic R&D landscape.

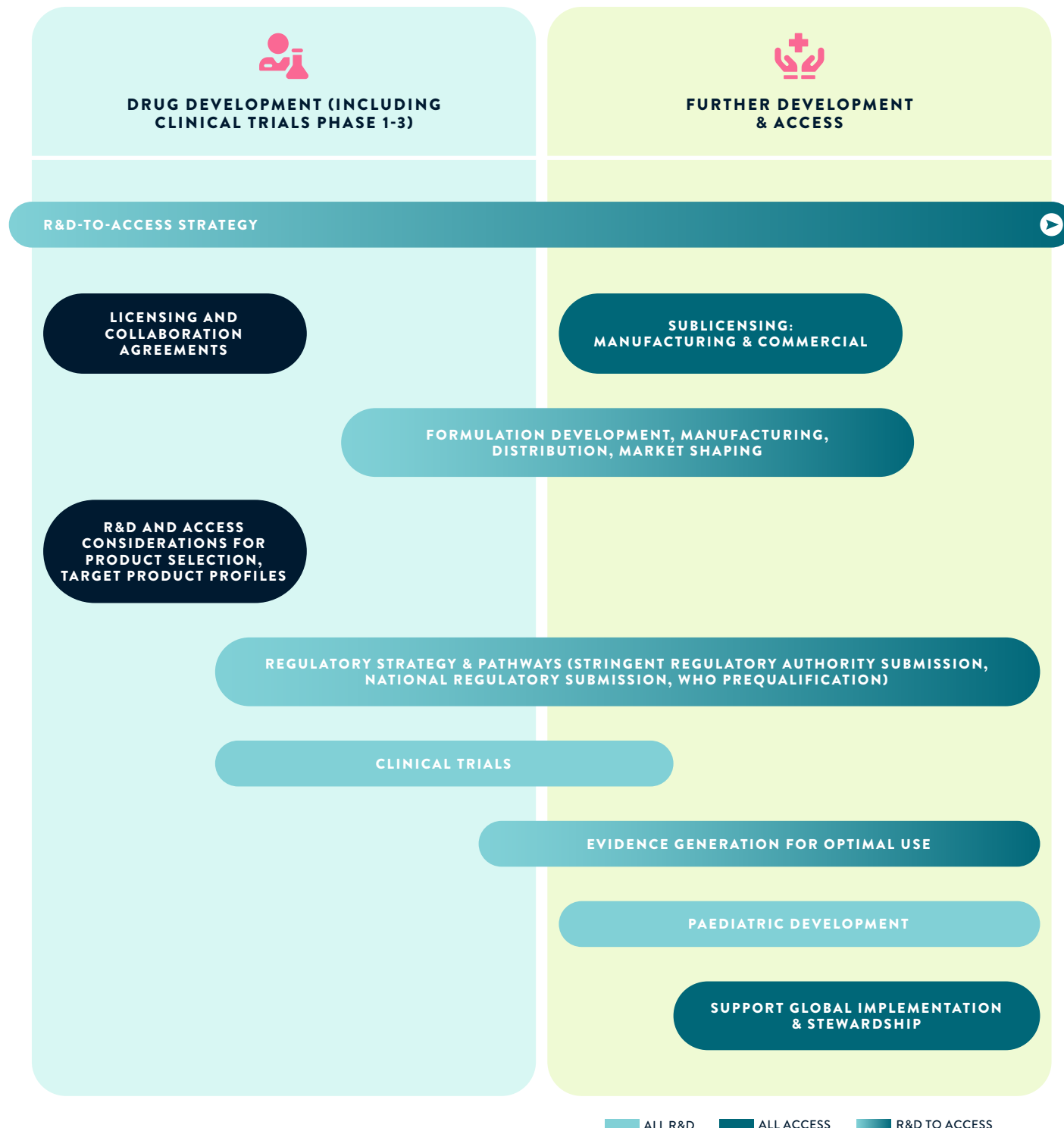
Within this landscape, GARDP helps to balance investments so that the later stages of antibiotic development and access are appropriately funded and supported. It collaborates with other players in the field—including CARB-X, the REPAIR Impact Fund, the AMR Action Fund, BARDA and pharmaceutical companies—to avoid duplicating efforts and use funds efficiently.



*Illustrative not exhaustive

An integrated R&D-to-access approach

We integrate as early as possible the constraints of public health needs and access challenges into our projects, so that these projects eventually benefit patients globally.



GUIDING PRINCIPLES OF GARDP'S APPROACH

- **Clear access rights** are key provisions—not afterthoughts—in our collaboration and license agreements.
- **Scientific and clinical evidence of effectiveness and safety** is needed to both register the product and support its optimal and appropriate use as a treatment.
- **Pharmaceutical development**—including initial formulation of the active pharmaceutical ingredient leading to an affordable high-quality final drug product—is at the core of our approach.
- **Availability and affordability** rely in part on activities initiated during the development phase, e.g. investing in manufacturing efficiencies to promote affordability.
- **Partnerships** are key at all steps of our integrated approach from innovative trial design and conduct to working with country-level partners to develop and demonstrate antibiotic introduction.
- **GARDP's integrated R&D and access approach** supports broad registration of antibiotic products.
- **Market intelligence and market shaping** are important for affordable supply and product introduction.
- **Post-approval data** helps support the utility and effectiveness of new and existing antibiotics as treatments for as many patients who need them, with children as a priority.




Catalyzing antibiotic access

Affordable and reliable access to the right antibiotics at the right time is integral to GARDP’s work and mission. Indeed, developing new antibiotic treatments is only beneficial if they reach the populations that need them. Today this is not the case.

Novel antibiotics have very seldom been registered outside of high-income countries, and quite often registration does not even occur in all high-income countries. In addition, there are antibiotic shortages or supply interruptions, due in part to the commercial unsustainability of antibiotic manufacturing, which suffers from unpredictable and limited demand.

To change this situation, GARDP engages in catalytic activities to support access, as shown in **Figure 7**.

“One of the most frustrating experiences you can have as a doctor is not to be able to treat a seriously ill patient because of a drug-resistant infection. If we had access to the right drugs, many tragic deaths would be preventable.”



Nishad Plakkal
Additional Professor of Neonatology and Associate Dean at the Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, India



STEWARDSHIP IS INTEGRAL TO ACCESS

Every step in the journey from product development to patient care has a stewardship component, including ensuring that the product is quality-assured, reducing/eliminating environmental discharge of active pharmaceutical ingredients (APIs), developing evidence for appropriate use, and securing commercialization contracts that reduce/eliminate rewards based on sales volumes.

FIGURE 7: GARDP’S CATALYTIC ROLE IN ANTIBIOTIC ACCESS

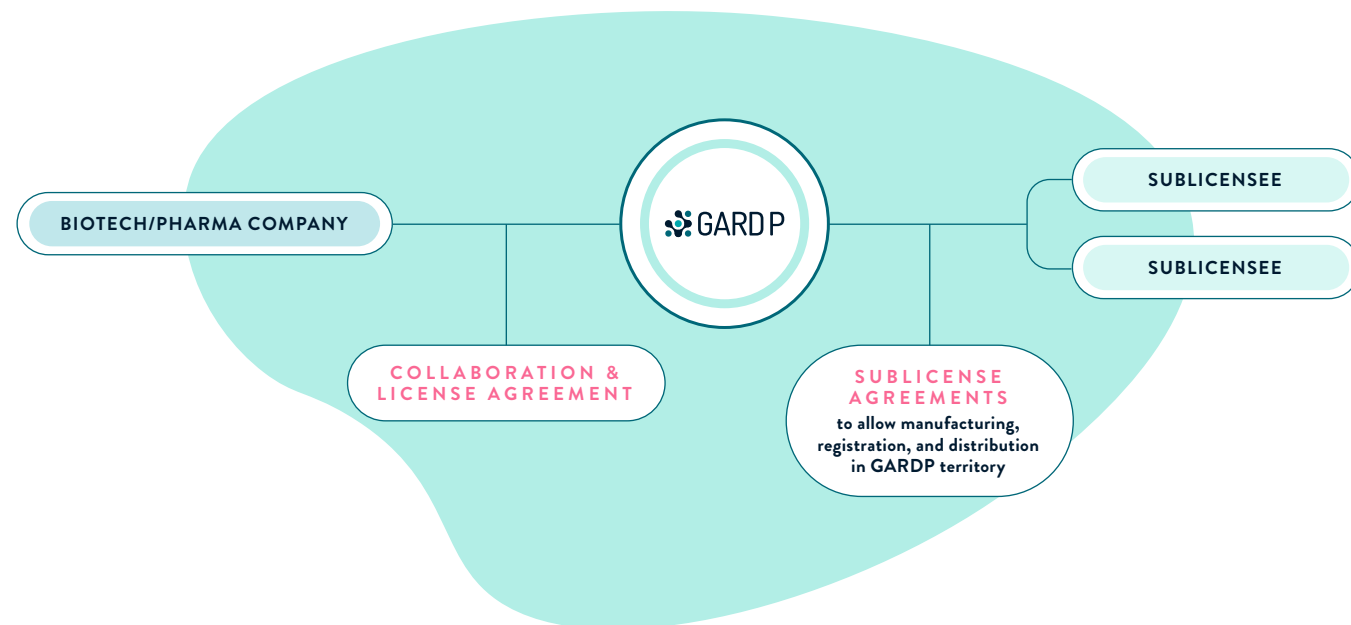


Manufacturing and distribution partnerships

Supply and distribution partnerships are central to GARDP's catalytic access activities. **Figure 8** shows how GARDP establishes collaboration and license agreements with our R&D and access partners to de-risk antibiotic development and secure the rights to manufacture and distribute products in our treatment portfolio in low- and middle-income countries, with a focus on high-burden countries. We then sign sublicense agreements with carefully selected companies that manufacture, register and distribute these new treatments in our territory.

In the absence of a global buyer such as GAVI or the Global Fund, GARDP seeks to develop models that are self-sustaining, meaning that our agreements with manufacturers make it possible for them to generate sufficient income to sustain quality production and distribution.

FIGURE 8: SUPPLY AND COMMERCIALIZATION PARTNERSHIPS



GARDP ENSURES THAT THESE PARTNERSHIPS MEET THE FOLLOWING REQUIREMENTS:

- The terms of the license and sublicense align with GARDP's access strategy
- Supply capacity matches projected appropriate demand in a subset of high-burden countries, at a minimum
- The pricing strategy is transparent, for example based on a cost-plus approach
- Treatments will be available in a number of high-burden countries, at a minimum
- Quality-assurance standards are met
- Manufacturing processes respect high environmental standards

Ensuring manufacturing of safe and affordable products

Through innovative license and sublicense agreements, GARDP aims to bring together innovators and manufacturers to deliver quality-assured products for patients in need. Central to this effort are Chemistry, Manufacturing and Controls (CMC) activities, which involve both innovators and manufacturers.

WHAT IS CMC?

CMC refers to the design, development and scale-up of manufacturing processes for drug substances (e.g. APIs) and drug products (e.g. final tablet or granules), as well as the development of quality control tests and the conduct of stability studies. CMC activities are an essential component of drug development, registration and manufacturing.

WHY GARDP IS RAMPING UP ITS CMC & PHARMACEUTICAL DEVELOPMENT ACTIVITIES

Although all antibiotic developers will carry out baseline CMC activities for registering a drug product and supporting manufacture, they do not prioritize CMC activities that streamline manufacturing processes for lower production costs. Lowering these costs can contribute to more affordable products for patients.

GARDP carries out CMC and pharmaceutical development activities—including manufacturing and commercial formulations—to ensure safety, efficacy, product approval and lower production costs. It develops processes so that drugs can be administered in diverse settings, including those with limited resources, thus reducing costs for patients and health systems everywhere.



WHY DOES GARDP PRIORITIZE CMC AND PHARMACEUTICAL DEVELOPMENT ACTIVITIES?

- **Safety:** to deliver the active ingredient to the target organ or tissues at an optimum rate and concentration in patients and to ensure that the manufactured drug works the way it is supposed to
- **Efficiency:** to refine manufacturing processes for increased efficiency
- **Approval:** to ensure the final drug products meet stringent regulatory standards for registration
- **Accessibility:** to develop manufacturing processes and drug formulations that are appropriate for low-resource settings
- **Savings:** to develop efficient manufacturing processes that lower costs for manufacturers that in turn help lower prices for patients and health systems around the world
- **Sustainable supply:** to identify and work with quality manufacturers to supply global needs, including high-burden regions and low- and middle-income countries



SPOTLIGHT: ZOLIFLODACIN

Zoliflodacin, an oral treatment for gonorrhoea, is a prime example of GARDP's engagement in Chemistry, Manufacturing and Controls (CMC) and pharmaceutical development for safe, affordable products. Since the successful phase 2 proof of concept study, GARDP has led all remaining clinical and pharmaceutical development activities, including developing the formulation and manufacturing the final drug product for registration, access and global commercialization. GARDP has led this work through partnerships with the innovator and manufacturers.

These activities contribute to safe, effective products at lower prices that will benefit patients worldwide.

For more information on zoliflodacin, see section 4.

A global network created through our alliance with DNDi

Based in Geneva, GARDP is committed to expanding its global presence by creating a collaborative network of research, development and access partners across various regions to ensure that our portfolio of treatments reaches patients in countries where the need is critical.

Since our foundation, we have had an alliance with DNDi, our co-founder. **This mutually beneficial collaboration allows us to pool resources for efficient use of funds. It also facilitates our ability to establish and consolidate partnerships and initiatives globally.**

GARDP teams are currently hosted in several locations worldwide through DNDi, including Brazil, India, Japan and Thailand. To advance engagement in Africa, an independent collaborative entity known as DNDi GARDP Southern Africa Plc (DGSA) was established in 2018.

BENEFITS:

- **A shared office in Geneva and shared IT infrastructure** for efficient use of resources
- **Geographic diversity** to better position us to respond to emerging challenges
- **Synergies in pharmaceutical development** and Chemistry, Manufacturing and Controls (CMC) activities, which is a fully shared function and strategic collaboration between the two organizations, who have internal expertise and access to a network of expert consultants
- **Contributing to scientific and healthcare communities** by bolstering local research capacity
- **Awareness raising and policy changes** to address stewardship and health disparities
- **Sharing DNDi's network** of strategically located offices and teams around the world



“**THE JAPANESE GOVERNMENT** has pledged to support GARDP during the period 2020–2025, and Japanese companies have worked with GARDP with the aim of improving children’s antibiotics and expanding antibiotic access, as well as discovering new antibiotics. These contributions by the government and by industry are beneficial for the world as well as Japan.”

Kaori Nakatani
Director of DNDi Japan



“When it comes to antimicrobial resistance, **INDIA** has a problem as well as the potential to manage the problem. The highest levels of government have recognized the challenge presented by AMR, and the AMR surveillance and research network (AMRSN) generates regular, reliable and accessible data. In addition, the Indian pharma industry produces generic antibiotics for countries around the world. Overall, GARDP has worked extremely well with the different stakeholders responsible for AMR treatment in India.”

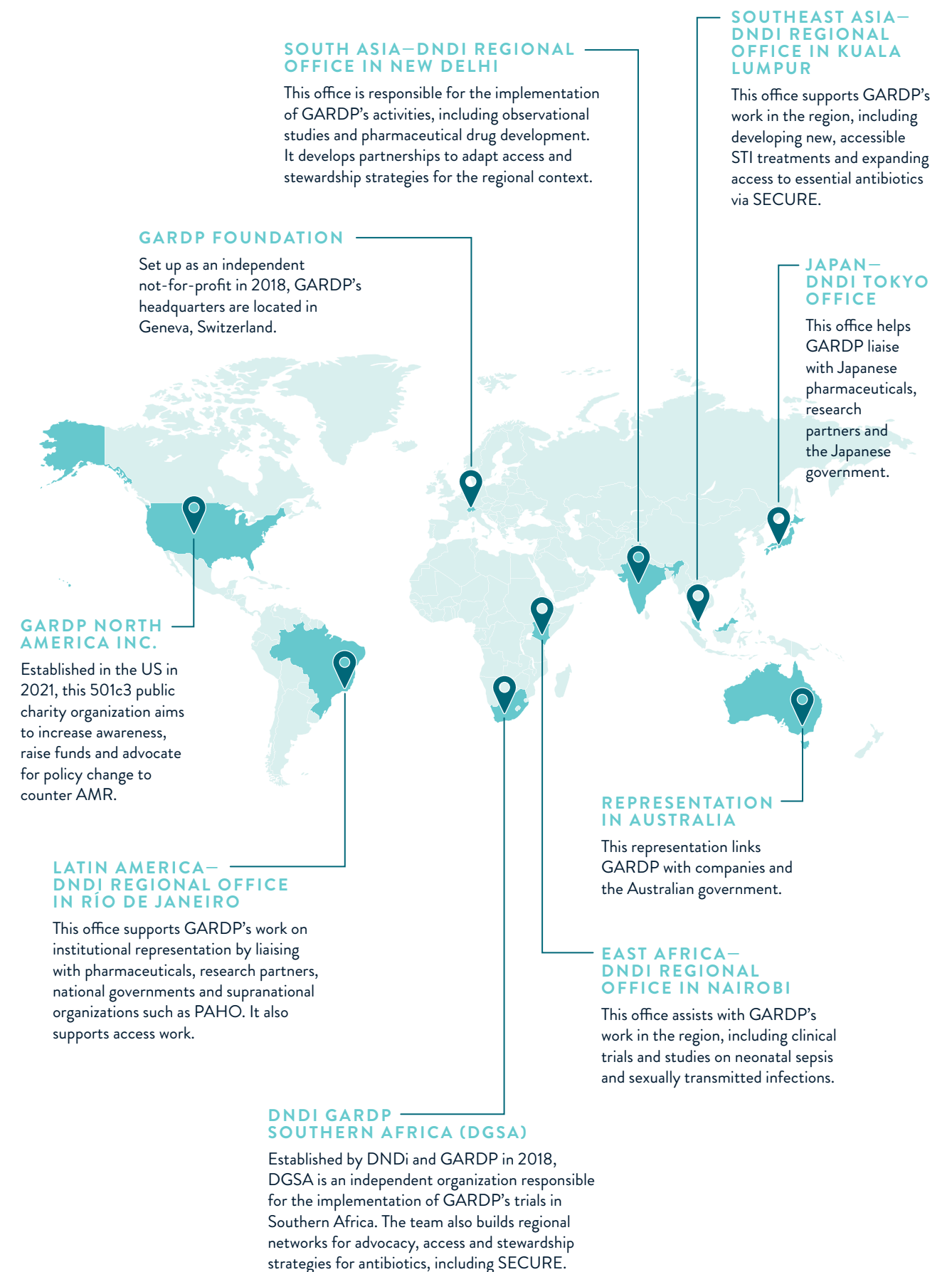
Kavita Singh
Director of DNDi South Asia / India



Carol Ruffell
Director of DNDi GARDP Southern Africa

“**THE AFRICAN CONTINENT** is particularly hard-hit by drug-resistant infections and does not have reliable access to effective antibiotics in many settings. We have the opportunity to play our part to change this inequitable situation through developing new and improved antibiotics and ensuring they are made accessible to people in countries which clearly need them.”

FIGURE 9: GARDP GLOBAL NETWORK



Partnering with study and trial leaders around the world

Research and healthcare institutions in India, South Africa, and many other low- and middle-income countries are leading efforts in clinical trials, pharmaceutical development, and data collection to inform guidelines. GARDP partners with these research and healthcare institutions in regions that are heavily affected by drug resistance, drawing on local expertise and skills and building local capacity as needed.

ZOLIFLODACIN GLOBAL PHASE 3 PIVOTAL CLINICAL TRIAL

With our local partners, we tapped into and expanded capacity for gonorrhoea trials in South Africa and Thailand. This network now has broader experience in undertaking clinical trials for regulatory submission and in generating data to support optimal treatment of patients. GARDP will continue to invest in trial capacity in additional countries/settings to further assess the safety and effectiveness of zoliflodacin in specific populations.

NEONATAL SEPSIS OBSERVATIONAL STUDY AND CLINICAL TRIAL

Conducting trials in children and especially newborns is particularly challenging and requires both specialist clinical knowledge and experience. Through GARDP and partners' neonatal sepsis observational study, we have consolidated an international network of sites, primarily in limited-resource settings, that will be further expanded with the international interventional trial NeoSep1 to evaluate new treatments for neonatal sepsis.

OBSERVATIONAL STUDY OF CARBAPENEM-RESISTANT INFECTIONS

GARDP is working with local partners and sites in India and South Africa to understand how high-priority resistant infections are managed. As necessary, GARDP assists partners to acquire additional research capacity for potential future interventional trials that will generate high-quality data on the effectiveness of novel treatments for carbapenem-resistant infections.

GARDP will continue to collaborate with R&D institutions to develop and deepen sustainable clinical research capabilities and capacity, especially in countries with a high burden of AMR. We will also work with existing clinical trial networks such as Penta, Advance-ID and potentially Ecraid to further advance the clinical development of new antibiotic treatments.

FIGURE 10: GARDP STUDY AND TRIAL PARTNERS



ZOLIFLODACIN TRIAL SITES

The largest phase 3 trial of a first-in-class oral antibiotic to treat uncomplicated gonorrhoea, involving 930 patients at 16 sites across 5 countries.



NEONATAL SEPSIS OBSERVATIONAL STUDY SITES

One of the largest ever studies on newborns with sepsis, including 3,200 newborns in 11 countries.



CARBAPENEM-RESISTANT INFECTIONS OBSERVATIONAL STUDY SITES

A study to shed light on the management of antibiotic-resistant infections in hospitals in India and South Africa.



NEONATAL SEPSIS TRIAL SITES

An international clinical health trial to rank the safety and effectiveness of new combination treatment regimens for newborns with sepsis.





SECTION 4

PROGRAMMATIC AREAS

Introduction

Across all our programmes, we focus on two disease areas:

SERIOUS BACTERIAL INFECTIONS & SEPSIS

Throughout our lives, each of us will suffer from bacterial infections, most of which are uncomplicated and easily treated. However, when such infections do not respond to antibiotic treatments and/or get into the blood, heart, lungs or brain, they may lead to sepsis, a life-threatening complication. Bacterial sepsis associated with AMR results in close to 5 million deaths each year.⁹ The availability of effective antibiotics is critical to prevent and treat bacterial sepsis in patients. GARDP therefore has a dedicated programme to address serious bacterial infections and bacterial sepsis.

Children are especially vulnerable to growing antibiotic resistance. Every year, 1 in 5 deaths associated with antibiotic-resistant infections worldwide occurs in children under the age of 5. That number is 1 in 2 in sub-Saharan Africa.¹⁰ The development of antibiotics and other medicines for children lags behind that for adults by nearly a decade.¹¹ GARDP thus invests additional resources specifically in antibiotic development for children.

Newborns, especially those who are malnourished or born prematurely, are vulnerable to neonatal sepsis, a life-threatening bloodstream infection which affects up to 3 million newborns every year.¹² GARDP singles out the importance of advancing treatments for neonatal sepsis, which aligns with the WHO Global research agenda for antimicrobial resistance in human health.¹³

SEXUALLY TRANSMITTED INFECTIONS

Gonorrhoea is among the most common bacterial STIs in the world, with 82 million new cases documented each year.¹⁴ Resistant strains of gonorrhoea are on the rise all around the world, raising concern about the ability to treat this disease in the future.^{15,16} For this reason, *Neisseria gonorrhoeae* is included on WHO's list of priority pathogens in urgent need of new treatments.¹⁷ GARDP is working to develop a new treatment option for gonorrhoea to contribute to the sexual and reproductive health of people everywhere. These efforts align with the WHO Global research agenda for antimicrobial resistance in human health, and they will contribute to the WHO 2030 target of reducing the incidence of gonorrhoea infections by 90%.¹⁸








For more information on our focus, see section 3.

9. Antimicrobial Resistance Collaborators. "Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis." *Lancet*. 2022 Feb 12;399(10325):629-655.
10. Antimicrobial Resistance Collaborators. "Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis." *Lancet*. 2022 Feb 12;399(10325):629-655.
11. WHO. *Shaping the global innovation and access landscape for better paediatric medicines: global accelerator for paediatric formulations 2022-2024 strategy*. 2022. <https://apps.who.int/iris/handle/10665/352200> [Accessed 6 November 2023]
12. Fleischmann-Struzek C, Goldfarb D M, Schlattmann P, Schlapbach L J, Reinhart K, Kissoon N. "The global burden of paediatric and neonatal sepsis: a systematic review." *Lancet Respir Med*. 2018 Mar;6(3):223-230.
13. WHO. *Global research agenda for antimicrobial resistance in human health*. 22 June 2023. <https://www.who.int/publications/m/item/global-research-agenda-for-antimicrobial-resistance-in-human-health> [accessed 6 November 2023].
14. WHO. *Sexually transmitted infections (STIs)*. 22 November 2021. [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)) [accessed 6 November 2023].
15. Unemo M, Golparian D, Eyre DW. "Antimicrobial Resistance in *Neisseria gonorrhoeae* and Treatment of Gonorrhea." *Methods Mol Biol*. 2019;1997:37-58.
16. WHO. *Multi-drug resistant gonorrhoea*. 11 July 2023. <https://www.who.int/news-room/fact-sheets/detail/multi-drug-resistant-gonorrhoea> [accessed 6 November 2023].
17. WHO. "WHO publishes list of bacteria for which new antibiotics are urgently needed." 27 February 2017. <https://www.who.int/news/item/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed> [accessed 6 November 2023].
18. WHO. *Global research agenda for antimicrobial resistance in human health*. 22 June 2023. <https://www.who.int/publications/m/item/global-research-agenda-for-antimicrobial-resistance-in-human-health> [accessed 6 November 2023].

DRUG DEVELOPMENT

Portfolio overview

CURRENT PORTFOLIO

TREATMENT	CLASS	PARTNER	STAGE OF DEVELOPMENT	WHO PRIORITY PATHOGENS	GARDP'S COMMERCIAL RIGHTS
SERIOUS BACTERIAL INFECTIONS & SEPSIS					
Cefiderocol	Siderophore cephalosporin	 SHIONOGI	Approved by US FDA (2019) and EMA (2020). Included on WHO Essential Medicines List. PIP and PSP ongoing.	CRE CRPA	135 countries
Cefepime-taniborbactam	β -lactam / β -lactamase inhibitor	 Venatorx	Positive cUTI phase 3 results. PIP/PSP initiated.	CRE CRPA	64 countries (plus the public market in India and South Africa)
NEONATAL SEPSIS					
Flomoxef	Generic cephamycin	 SHIONOGI	Approved in 4 Asian countries since 1998	ESBL	Generics
Fosfomycin	Generic phosphonic	 INFECTOPHARM Wissen wirkt.	Approved in Europe and in some low- and middle-income countries	ESBL	Generics
Amikacin	Generic Aminoglycoside	N/A	Generic, introduced in 1977	ESBL	Generics
SEXUALLY TRANSMITTED INFECTIONS (GONORRHOEA)					
Zoliflodacin	Spiropyrimidinetrione	 INNOVIVA Specialty Therapeutics	Positive phase 3 results	Ceftriaxone- and multidrug-resistant <i>N. gonorrhoeae</i>	¾ of countries worldwide (~150)

EXPANDED PORTFOLIO

SERIOUS BACTERIAL INFECTIONS & SEPSIS					
New treatment	TBD	TBD	TBD	CR infection, including CRAB	TBD
Optimized treatment regimen	TBD	TBD	TBD	ESBL	TBD
NEONATAL SEPSIS					
New treatment	TBD	TBD	TBD	CRAB CRE	TBD

CR: Carbapenem-resistant
CRE: Carbapenem-resistant Enterobacterales

CRPA: Carbapenem-resistant *Pseudomonas aeruginosa*
CRAB: Carbapenem-resistant *Acinetobacter baumannii*

ESBL: Extended-spectrum beta-lactamases producing Enterobacterales
cUTI: Complicated urinary tract infection
PIP/PSP: Paediatric Investigation Plan (Europe) and Paediatric Study Plan (US)

CURRENT PORTFOLIO

SERIOUS BACTERIAL INFECTIONS & SEPSIS



CEFIDEROCOL ACCESS PROJECT

Cefiderocol is an innovative antibiotic approved by the US FDA and EMA, and it is listed on WHO's Model List of Essential Medicines as a Reserve antibiotic. As of 2021, cefiderocol was the only recently authorized antibiotic agent with activity against all three Gram-negative bacteria on the WHO critical priority pathogen list.¹⁹ In 2022, GARDP signed a license and technology transfer agreement with Shionogi that gives GARDP the rights to manufacture and commercialize cefiderocol in 135 countries, most of which tend to have limited or no access to recently approved antibiotics. At the same time, GARDP signed a collaboration agreement with Shionogi and the Clinton Health Access Initiative, Inc. (CHAI). In 2023, based on a tendering process, GARDP signed a sublicense agreement with Orchid Pharma to manufacture cefiderocol for its territory.

KEY ACTIVITIES AND MILESTONES 2024–2028



- **Support the technology transfer** from Shionogi to Orchid Pharma and the manufacture of cefiderocol by Orchid Pharma
- **Identify commercial partners** and sign sublicense agreement(s) with distributors to cover the GARDP territory
- **Support evidence generation, affordable pricing, registration, implementation and evaluation** of cefiderocol in early adopter countries
- **Launch pilot programme for distribution** of cefiderocol through the Stop TB Partnership's Global Drug Facility (GDF)

OUTCOMES 2024–2028

- **Cefiderocol** registered by partners and **accessible in at least five countries** in GARDP's territory
- **WHO Prequalification approval** of Orchid's cefiderocol product

As an oncologist in the UK, **Dr Hilary Thomas** had treated thousands of patients for cancer over the years. She had seen first-hand the threat that bacterial infections pose for cancer patients. When she herself was diagnosed with breast cancer in 2006, that threat was on her mind.



"I saw my white blood cell count was going down and I was very aware of the risk of sepsis," said Hilary, who completed her treatment successfully. **"We need to be having conversations with people across society about the dangers of antimicrobial resistance for cancer patients and others."**

19. WHO. 2021 Antibacterial agents in clinical and preclinical development: an overview and analysis. 27 May 2022. <https://www.who.int/publications/i/item/9789240047655> [accessed 6 November 2023].



CEFEPIME-TANIBORBACTAM DRUG DEVELOPMENT

PRIORITY 17 in the WHO Global research agenda for antimicrobial resistance in human health²⁰
(N.B. Priority numbers do not imply order of priority.)

Cefepime-taniborbactam is a potential antibiotic treatment with activity against two of the three critical WHO bacterial priority pathogens (carbapenem-resistant Enterobacterales and carbapenem-resistant *Pseudomonas aeruginosa*). In 2020, GARDP signed a collaboration agreement with Venatorx through which GARDP has the rights to distribute cefepime-taniborbactam in 64 low- and middle-income countries, as well as in the public markets in India and South

Africa. Following the successful phase 3 trial of cefepime-taniborbactam for complicated urinary tract infections (cUTI)—for which GARDP provided significant financial investment and technical advice—Venatorx filed a New Drug Application (NDA) seeking US FDA regulatory approval for cefepime-taniborbactam for cUTI. In August 2023, the US FDA accepted the NDA for review and set a target action date for 22 February 2024.

KEY ACTIVITIES AND MILESTONES 2024–2028



- **Lead the paediatric clinical development** of cefepime-taniborbactam to ensure a safe and effective dose in children of all ages
- **Complete observational/feasibility study** in hospitalized patients with carbapenem-resistant infections
- **Generate evidence on the safety and efficacy** of cefepime-taniborbactam in patients with infections caused by carbapenem-resistant pathogens
- **Support access activities** in high-burden countries in the GARDP territory

OUTCOMES 2024–2028

- **Approval of cefepime-taniborbactam for use** in adults by US FDA (in partnership with Venatorx) planned for February 2024
- **Publication of results of observational/feasibility study** of patients with carbapenem-resistant infections in hospitals in India and South Africa
- **Submission of application** for marketing authorization in additional territories
- **Cefepime-taniborbactam accessible** in some high-burden countries within GARDP territory

20. WHO. Global research agenda for antimicrobial resistance in human health. 22 June 2023. <https://www.who.int/publications/m/item/global-research-agenda-for-antimicrobial-resistance-in-human-health> [accessed 6 November 2023].

**FIGURE 11: SOURCES OF GARDP'S
TREATMENT PORTFOLIO**



EXISTING GENERIC ANTIBIOTICS

We evaluate existing generic antibiotics to identify their potential for use in new combinations or new indications.

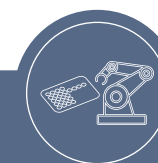
e.g. Treatment regimens for neonatal sepsis



NEW ANTIBIOTICS

We evaluate the current antibiotic pipeline and partner with companies to co-develop innovative treatments that cover priority diseases & infections, WHO priority pathogens, and key regions & populations.

e.g. Cefepime-taniborbactam, zoliflodacin



DISCOVERY & EXPLORATORY RESEARCH

We screen compounds that have never been tested for antibiotic activity to identify any substances that could become the basis of new drugs or improve the efficacy of existing antibiotics.

Research in progress



NEONATAL SEPSIS EMPIRIC TREATMENT REGIMENS

PRIORITY 19 in the WHO Global research agenda for antimicrobial resistance in human health²¹

From 2018, GARDP started to work with Penta, an independent scientific network dedicated to child health, and other partners to evaluate the possibility of using antibiotics in novel combinations to expand effective and safe treatment options for neonatal sepsis. GARDP and partners carried out a global observational study of neonatal sepsis (2018–2020), involving 3,200 newborns across 19 hospitals in 11 countries, to understand the current treatments and outcomes of newborns with sepsis. In parallel scientific and clinical studies, GARDP demonstrated that fosfomycin, amikacin and flomoxef—three existing antibiotics with a licensed indication to treat neonates—have the potential to be active in combination to treat neonatal sepsis resistant

to current recommended regimens, and to reduce the emergence of further resistance. Based in part on these results, GARDP, St George's, University of London (SGUL), and the Medical Research Council Clinical Trials Unit at University College London (MCR CTU at UCL) designed a large public health interventional trial to rank the safety and efficacy of new antibiotic combinations to treat neonatal sepsis (fosfomycin-amikacin, fosfomycin-flomoxef and flomoxef-amikacin). In early 2023, the trial "NeoSep1" was launched in Kenya and South Africa. It will expand to other countries and continents with the expected target of enrolling more than 3,000 newborns.

KEY ACTIVITIES AND MILESTONES 2024–2028

- **Complete the initial pharmacokinetic confirmatory phase** of the NeoSep1 trial in Kenya and South Africa
- **Expand and complete the NeoSep1 trial**, and publish preliminary results
- **Expand availability** of quality-assured and affordable flomoxef and injectable fosfomycin

OUTCOMES 2024–2028

- **Based on the results of NeoSep1 trial:** Identify one or more effective treatment regimens for neonatal sepsis
- **Establish two sources** of quality-assured and affordable supply of the identified treatment regimens

21. WHO. Global research agenda for antimicrobial resistance in human health. 22 June 2023. <https://www.who.int/publications/m/item/global-research-agenda-for-antimicrobial-resistance-in-human-health> [accessed 6 November 2023].

FIGURE 12: A PASSIONATE TEAM ADDRESSING NEONATAL SEPSIS AROUND THE WORLD

"GARDP is focusing on neonatal sepsis because it's an area of concern when it comes to antibiotic resistance. It's particularly important with neonates to have the data that shows you're treating the baby with the right drug at the right dose at the right time."

Sally Ellis, Children's Antibiotics Project Leader, UK



"As a doctor in a public hospital in Kenya, I witnessed unacceptable morbidities and mortalities due to few options for treating neonatal sepsis. I am glad that GARDP is prioritizing solutions for children vulnerable to drug-resistant infections."

Borna Nyaoke, Head of Mycetoma Disease, DNDi, Kenya (formerly part of GARDP's neonatal sepsis team)

"I am honoured to be part of GARDP's R&D team, implementing clinical trials that can make a difference to the lives of neonates and children suffering from drug-resistant infections."

Erika Correia, Clinical Trial Manager, Switzerland



"In a country with one of the highest rates of resistance to antibiotics, treating babies with bacterial infections is extremely challenging. Being part of GARDP's initiatives in India gives me the opportunity to closely work with experts in this area of research and understand the actual burden caused by antimicrobial resistance in healthcare settings."

Raji Devarajan, Clinical Research Manager, India

"Sepsis is a leading cause of neonatal deaths. I am proud to work on clinical trials that aim to find antibiotic treatments for this vulnerable population in desperate need of effective and accessible treatments."

Nathalie Khavessian, Clinical Trial Manager, Switzerland



"Without timely treatment, neonatal sepsis can lead to organ failure and death. It is particularly fulfilling to be working on research studies that aim to improve the outlook for babies and children."

Sibongile Ratlhogo, Clinical Trial Manager, South Africa



ZOLIFLODACIN DRUG DEVELOPMENT

PRIORITY 21 in the WHO Global research agenda for antimicrobial resistance in human health²²

In 2014, WHO recommended making gonorrhoea a research priority, anticipating that resistance to recommended treatments would develop and spread over the coming years. Indeed, as of July 2023, several countries reported resistance to recommended treatments for gonorrhoea, including Australia, Austria, Cambodia, Canada, China, Denmark, France, Ireland, Japan, Singapore, the UK and Vietnam.²³

Zoliflodacin, if approved, may play a critical role in addressing this situation and reducing the global burden of gonorrhoea. It could be the first agent of a new antibiotic class active against resistant strains of *N. gonorrhoeae*, including those resistant to the last-line treatment ceftriaxone. Zoliflodacin is conveniently administered via a single oral dose, setting it apart from the current standard of care that requires intramuscular injections.

Since the phase 2 proof of concept study, GARDP has led all remaining clinical and pharmaceutical development activities for zoliflodacin, such as developing and manufacturing the final drug product for registration and global commercialization. Under a collaboration agreement signed in 2017 with Entasis, now an affiliate of Innoviva

Specialty Therapeutics, GARDP holds the rights to register and market zoliflodacin in more than three-quarters of countries worldwide, including all low-income countries, a majority of middle-income countries and several high-income countries.

In November 2023, GARDP announced positive results in its pivotal phase 3 trial of zoliflodacin at 16 sites across five countries. A total of 930 patients with uncomplicated gonorrhoea were recruited, making it the largest clinical trial ever conducted for a new treatment against this infection.

GARDP placed special emphasis on the involvement for the first time of high-burden countries in this trial, with South Africa and Thailand leading the recruitment. GARDP also emphasized the inclusion of women, who represented 14% of all trial participants, a figure which is relatively high for gonorrhoea trials (which typically recruit high-risk males). This underrepresentation is particularly problematic given that women bear a disproportionate impact of gonorrhoea, with potential consequences more severe than those faced by men, including pelvic inflammatory disease, infertility, complications in pregnancy as well as the transmission of infection to newborns.

KEY ACTIVITIES AND MILESTONES 2024–2028



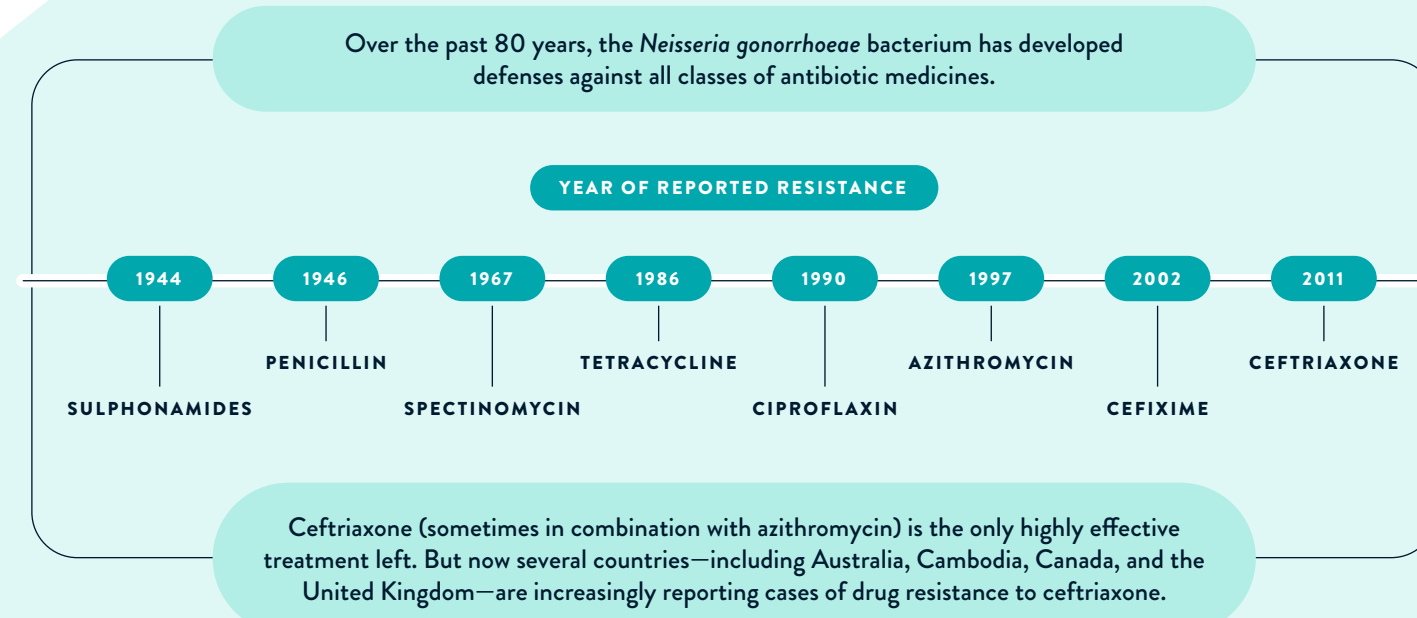
- **Compile registration dossier** for zoliflodacin for submission in high-burden countries
- **Generate additional evidence** to support the optimal and appropriate use in priority populations, including the use of supporting diagnostics where possible
- **Expand safety database in specific populations** (those pregnant and breastfeeding); drug-drug interaction studies with medications commonly used in target population
- **Surveillance activities:** Model future resistance development and regular surveillance studies
- **Development and implementation of an early access programme** based on physician request process
- **Launch of a pilot for distribution and stockpiling** with the Global Drug Facility or other entity
- **Reducing the cost of goods** by improvements to the manufacturing process

OUTCOMES 2024–2028

- **Approval of zoliflodacin** in the US and Europe
- **Completion of evidence generation activities**
- **Implementation of an early access programme pre-registration** in GARDP territories
- **As soon as possible:** Zoliflodacin registered and accessible for appropriate use in South Africa and Thailand as priority countries in GARDP's territory and if possible additional high-burden countries
- **Zoliflodacin included in international and national treatment guidelines**
- **A functioning rotating stockpile** for outbreak response and use in areas with high burden of resistant gonorrhoea infection



FIGURE 13: GONORRHOEA—TOWARDS AN UNTREATABLE DISEASE?



22. WHO. Global research agenda for antimicrobial resistance in human health. 22 June 2023.

<https://www.who.int/publications/m/item/global-research-agenda-for-antimicrobial-resistance-in-human-health> [accessed 6 November 2023].

23. WHO. "WHO releases new guidance to improve testing and diagnosis of sexually transmitted infections." 24 July 2023.

<https://www.who.int/news/item/24-07-2023-who-releases-new-guidance-to-improve-testing-and-diagnosis-of-sexually-transmitted-infections/> [accessed 6 November 2023].



NOVEL BROAD-SPECTRUM TREATMENT FOR SERIOUS BACTERIAL INFECTIONS

Target: Carbapenem-resistant Gram-negative pathogens such as *Enterobacterales*, *Acinetobacter* species and *Pseudomonas* species, causing healthcare-associated infections/sepsis.

PRIORITY 17 in the WHO Global research agenda for antimicrobial resistance in human health²⁴

GARDP is screening the pipeline for promising antibiotic drug candidates with the potential to become a broad-spectrum treatment for patients with serious bacterial infections, such as complicated urinary tract infections, complicated intra-abdominal infections, hospital- and ventilator-acquired pneumonia, and bloodstream infections, including those caused by carbapenem-resistant *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae* and *Escherichia coli*.

PLANNED START DATE

2024

KEY ACTIVITIES AND MILESTONES 2024–2028

- Project launched
- Depending on the terms of the collaboration agreement and the successful completion of phase-gated milestones:
 - Phase 1 clinical trial
 - Proof of concept phase 2 clinical trial to determine initial efficacy and safety of the compound in infected patients
 - Manufacturing of phase 3 clinical trial material

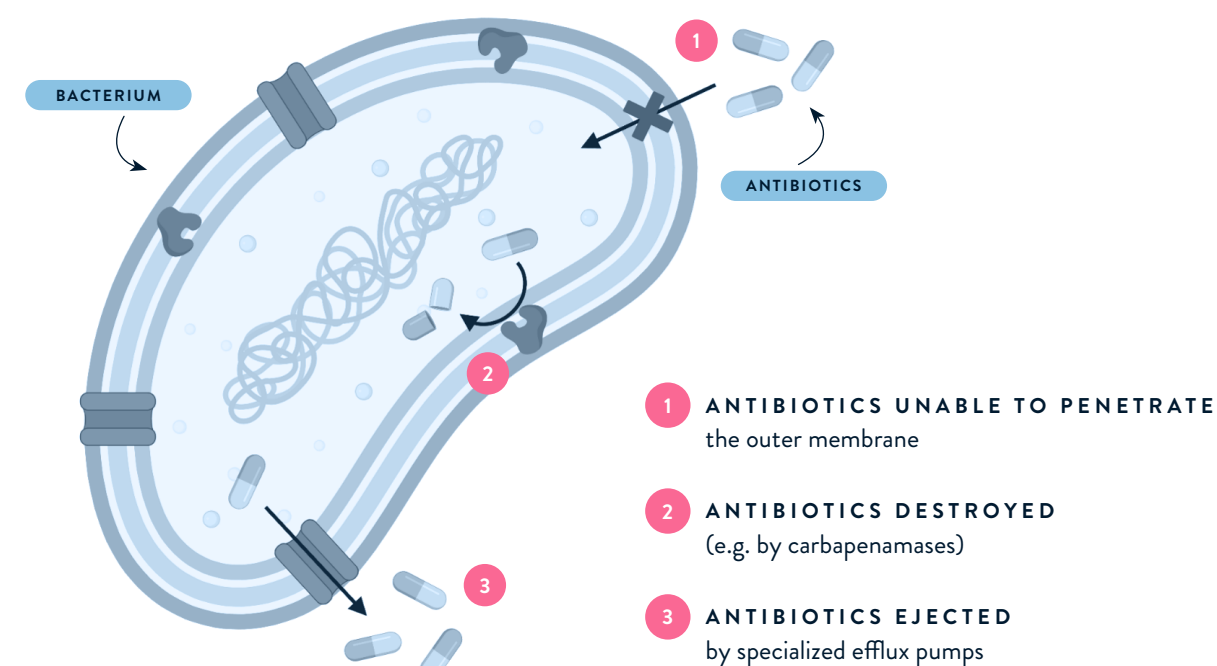
OUTCOME 2024–2028

- Compound reaches late-stage clinical development



FIGURE 14: MECHANISMS OF RESISTANCE

HOW BACTERIA COUNTER “LAST-RESORT”
CARBAPENEM ANTIBIOTICS



24. WHO. Global research agenda for antimicrobial resistance in human health. 22 June 2023. <https://www.who.int/publications/m/item/global-research-agenda-for-antimicrobial-resistance-in-human-health> [accessed 6 November 2023].



OPTIMIZED TREATMENT REGIMEN FOR DRUG-RESISTANT BACTERIAL INFECTIONS

Target: *Enterobacterales* producing extended-spectrum beta-lactamases (ESBL), resistant to 3rd generation cephalosporins responsible for community-acquired sepsis and related infections.

PRIORITY 17 in the WHO Global research agenda for antimicrobial resistance in human health²⁵

Drug-resistant *Enterobacterales* infections may cause life-threatening pneumonia, bloodstream infections and sepsis. In many countries and regions where resistance rates are high, such infections are treated empirically—that is, without a laboratory verification of diagnosis—with last-resort carbapenem antibiotics. To reduce the usage of these carbapenem antibiotics while ensuring effective care, GARDP envisages developing a new treatment regimen for sepsis caused by a drug-resistant *Enterobacterales*, including extended-spectrum beta-lactamase-producing

Enterobacteriaceae (ESBL-PE), which is a big problem and major killer, particularly in low- and middle-income countries. GARDP will assess different potential treatments (including combinations of new and existing antibiotics) and generate evidence for potentially carbapenem-sparing regimens to deliver a cost-effective alternative treatment that provides better outcomes for community-acquired sepsis and, most importantly, address the high burden of disease associated with these drug-resistant infections.

“Until now, carbapenem antibiotics have been the antibiotic class of last resort to treat hospitalized patients with bacterial sepsis. But resistance to carbapenems is growing fast around the world, and we have very few alternative treatments. We can’t afford inaction—we must invest right now in new treatments. If we don’t, the number of lives lost to antibiotic-resistant infections will increase dramatically.”

François Franceschi

Head of Asset Evaluation and Development and Serious Bacterial Infections Project Leader, GARDP



PLANNED START DATE

2024 (preparatory activities)

2027 (for potential evidence generation and/or interventional study or studies)

KEY ACTIVITIES AND MILESTONES 2024–2028

- **Assess current treatment practices and access for antibiotics** to treat infections caused by ESBLs, including availability and price of therapeutic options, guidelines and inclusion of products on national essential medicines lists
- **Evaluate level of unmet need** and potential role for revised treatment options in priority countries
- **Advance studies to confirm the role for new treatment options** and to demonstrate effectiveness as carbapenem-sparing regimens for community-acquired bacterial sepsis
- **Advance partnerships to address access requirements** for products that are part of the new treatment regimens

OUTCOMES 2024–2028

- **Share progress and outcomes from studies of ESBL treatment option** for scale-up in high-burden countries
- **Identify access challenges and options** for the prioritized antibiotics



25. WHO. Global research agenda for antimicrobial resistance in human health. 22 June 2023. <https://www.who.int/publications/m/item/global-research-agenda-for-antimicrobial-resistance-in-human-health> [accessed 6 November 2023].



NEW TREATMENTS FOR CARBAPENEM-RESISTANT INFECTIONS IN NEWBORNS

Target: Carbapenem-resistant pathogens that cause neonatal sepsis

PRIORITY 17 in the WHO Global research agenda for antimicrobial resistance in human health²⁶

Carbapenem-resistant *Acinetobacter baumannii* (CRAB) and carbapenem-resistant Enterobacterales (CRE) cause infections for which there are very limited or no safe and effective treatment options for children and newborns, who are disproportionately affected by antibiotic resistance. With this project, GARDP strives to improve outcomes for newborns by accelerating the development of new treatments for these drug-resistant infections, thus making a significant contribution to reducing AMR-related morbidity and mortality around the world.

“The biggest challenge when treating neonatal sepsis now is that there are only a few common drugs and there is very high resistance to them. Finding options is becoming harder and harder every day. And second-line drugs are more expensive—not everyone can afford them.”

Dr Flavia Namiro

Paediatrician,
Mulango Specialized
Women and Neonatal
Hospital, Uganda



PLANNED START DATE

2024 (preparatory activities)

2028 (clinical studies)

KEY ACTIVITIES AND MILESTONES 2024–2028

- **Confirmation of a cefepime-taniborbactam dose** for regulatory approval for use in neonates
- **Identification of potential regimens** for the use of cefiderocol and/or cefepime-taniborbactam for neonatal sepsis, including specific patient pharmacokinetic studies where required
- **Initial assessment of the effectiveness** of either antibiotic in a regimen for second-line treatment for neonatal sepsis in NeoSep1 or a later version of the study
- **Development of the paediatric investigation plan** (PIP, required in the European Union) and paediatric study plan (PSP, required in the United States) for the new candidate(s)/treatment(s) prioritized for *Acinetobacter baumannii*
- **Submission of the PIP and PSP** to the EMA and US FDA respectively
- **Initiation of the clinical development** as planned and agreed with both regulatory agencies

OUTCOMES 2024–2028

- **Initial outcomes on the potential effectiveness** of cefiderocol and cefepime-taniborbactam for neonatal sepsis in the setting of carbapenem resistance
- **Identification and initiation of the assessment** of a new treatment for carbapenem-resistant (priority *Acinetobacter baumannii*) infections in newborns

EXPLORATION OF DIFFERENT INTERVENTIONS FOR STIs

PRIORITY 21 in the WHO Global research agenda for antimicrobial resistance in human health²⁷

As we work towards actively supporting WHO’s 2030 objective of diminishing the incidence of gonorrhoea by 90%, GARDP is considering the inclusion of an additional candidate in its portfolio to be developed as a treatment to address difficult-to-treat gonorrhoea and related STIs. Currently, GARDP is in the process of evaluating multiple potential candidate drugs.

GARDP may also expand its portfolio to preventive measures for STIs and target additional pathogens that cause STIs like *Mycoplasma genitalium* and syphilis. We will also invest in improving diagnostic capabilities to support clinical use and antibiotic stewardship.

“To keep pace with the inevitable emergence of drug resistance to the few treatments currently available, we must invest now in developing new antibiotics, researching further existing antibiotic regimens, and accelerating equitable antibiotic access.”

Alison Luckey

Senior Medical Lead,
GARDP



PLANNED START DATE

2024

KEY ACTIVITIES AND MILESTONES 2024–2028

- **Identification of new opportunity**—final recommendation
- **Due diligence** on selected project

OUTCOMES 2024–2028

- **New partnership launched**
- **Project commenced**

26. WHO. Global research agenda for antimicrobial resistance in human health. 22 June 2023. <https://www.who.int/publications/m/item/global-research-agenda-for-antimicrobial-resistance-in-human-health> [accessed 6 November 2023].

27. WHO. Global research agenda for antimicrobial resistance in human health. 22 June 2023. <https://www.who.int/publications/m/item/global-research-agenda-for-antimicrobial-resistance-in-human-health> [accessed 6 November 2023].



DISCOVERY & EXPLORATORY RESEARCH

In 2021, the review of the antibiotic pipeline by WHO confirmed that the current drug development pipeline is insufficient to address antimicrobial resistance. GARDP takes on crucial discovery and exploratory activities that no other actor is filling, including examining libraries of compounds that have never been tested for antibiotic activity. GARDP aims to identify new substances (compounds), either unaffected by current drug resistance mechanisms or able to restore activity to clinically approved drugs, with potential for drug development (see **Figure 15**). These discoveries will contribute to the global antibiotic pipeline for further development and, if aligned with our strategy, be incorporated into our portfolio.

KEY ACTIVITIES AND MILESTONES 2024–2028

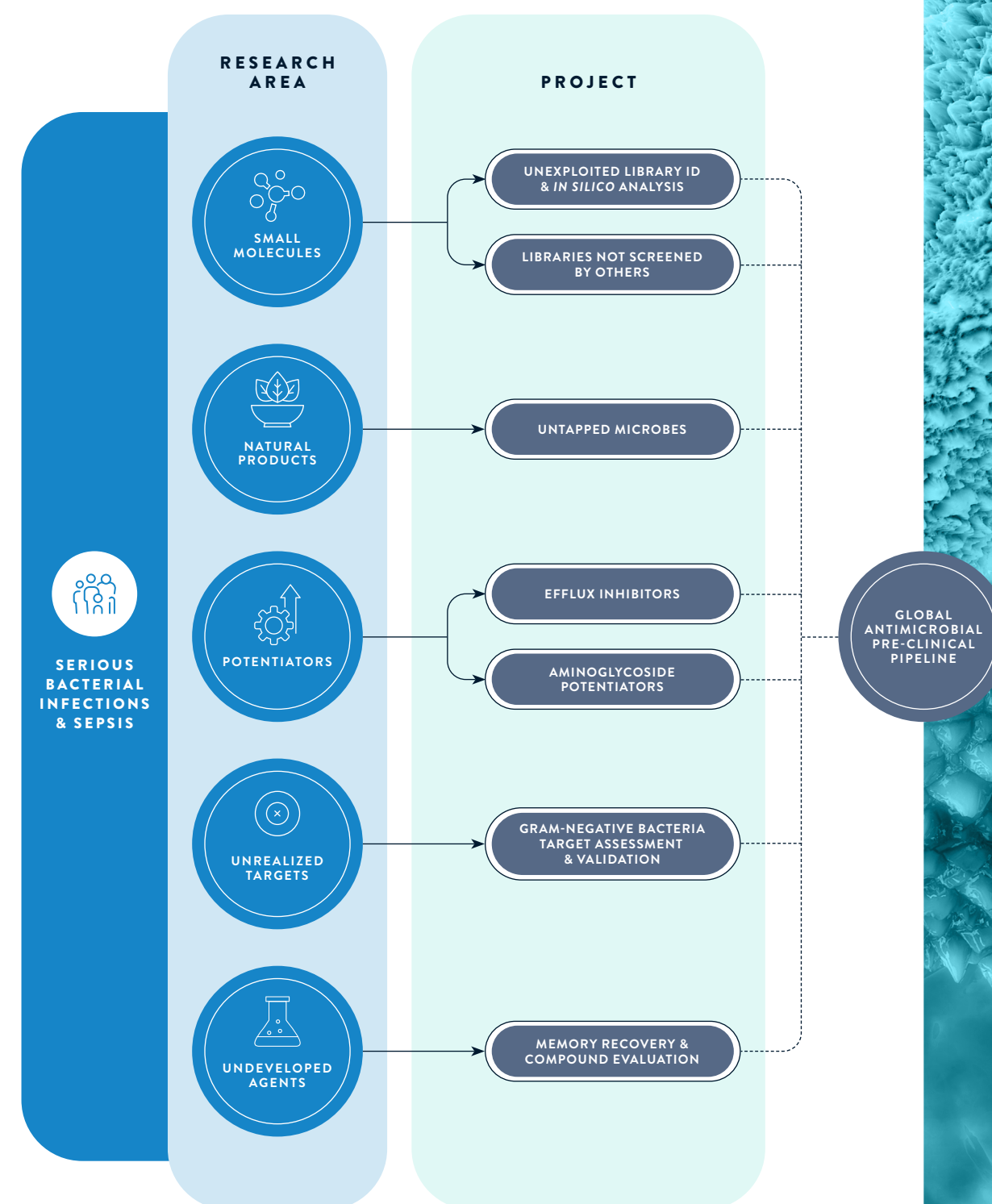
- **High-throughput computational and phenotypic screening of new libraries** increased to more than 50,000 novel compounds per year involving in part the latest artificial intelligence discovery tools, with 10 or more potential antibiotic or antibiotic-enhancing candidates entering hit-expansion per year
- **Development of new global consortium** for discovery research on an unrealized target

OUTCOME 2024–2028

- **At least one compound** with antibiotic or antibiotic-enhancing potential identified as a **lead-optimization candidate by 2028**

FIGURE 15: DISCOVERY & EXPLORATORY RESEARCH PORTFOLIO

FROM TARGET ASSESSMENT, TO HIT IDENTIFICATION AND VALIDATION, TO LEAD CANDIDATE





SECURE

Many health systems, particularly in LMICs, do not have reliable access to antibiotics. Only 10 of the 25 new antibiotics that entered the market between 1999 and 2014 were registered in more than 10 countries.²⁸ Shortages of antimicrobials are increasingly common, contributing to preventable suffering and death and raising the threat of antibiotic resistance.²⁹ GARDP is collaborating with WHO on SECURE, an initiative to expand access to essential antibiotics. SECURE will work with participating countries to establish a relevant portfolio of quality-assured and affordable antibiotics driven by local public health needs. If treatments in GARDP's portfolio match the needs of participating countries, then they may become part of the SECURE portfolio.



KEY ACTIVITIES AND MILESTONES 2024–2028

- **Implement SECURE** in participating countries
- **Review** early implementation phase of SECURE

OUTCOMES 2024–2028

- **Development of SECURE portfolio** of prioritized antibiotics in 3 countries/regions
- **Development and testing of SECURE tools in 3 countries/regions:** Forecasting model, procurement mechanism, rotating stockpile, financial levers

28. Källberg C, Årdal C, Salvesen Blix H, Klein E, M Martinez E, Lindbæk M, Outtersson K, Rettingen JA, Laxminarayan R. "Introduction and geographic availability of new antibiotics approved between 1999 and 2014." *PLoS One*. 2018 Oct 16;13(10):e0205166.
29. Shafiq N, Pandey AK, Malhotra S, et al. "Shortage of essential antimicrobials: a major challenge to global health security." *BMJ Global Health*. 2021;6:e006961.



SCIENTIFIC AFFAIRS & REVIVE

Antimicrobial research and development is not keeping pace with the need for new antibiotics. Many companies and academic groups have abandoned this work to pursue less risky, more profitable endeavours. In the process, invaluable scientific knowledge and expertise is being lost. Since 2018, through its scientific affairs activities and the launch of REVIVE (revive.gardp.org), GARDP has helped build a global scientific community and one of the biggest global competence knowledge hubs for antibiotic research and development. By convening this global community with free-to-access resources and events, GARDP is leading efforts to preserve and freely share scientific knowledge and tools for antimicrobial R&D at the global level.

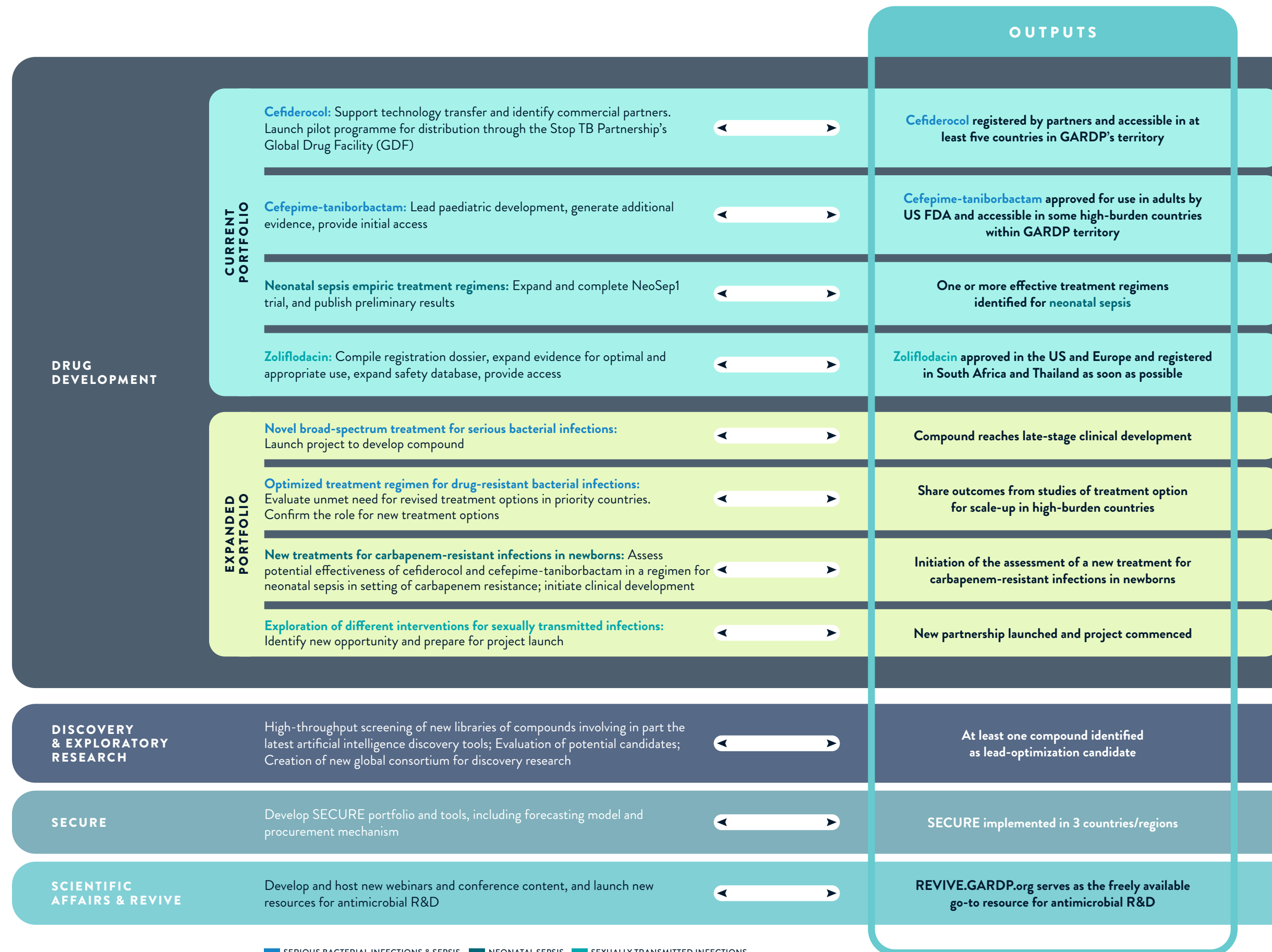
KEY ACTIVITIES AND MILESTONES 2024–2028

- **Launch the Antibiotic Discovery and Development Roadmap**—an interactive tool with resources on the entire process of antibiotic drug discovery and development—and continue to add content to the REVIVE platform
- **Relaunch and expand a new more user-friendly version of GARDP's open-access database, AntibioticDB**, containing the details of antibiotics past and present at all stages of the pipeline
- **Launch a Massive Open Online Course (MOOC)** on antimicrobial R&D
- **Increase the global reach of the annual Antimicrobial Chemotherapy Conference** to 3,000+ registrants, with improved representation from currently under-represented regions like Africa and South America

OUTCOME 2024–2028

- **REVIVE.GARDP.org** serves as the go-to resource for freely available, high-quality technical information and research tools for antimicrobial R&D

Summary of R&D activities and outputs 2024–2028



■ SERIOUS BACTERIAL INFECTIONS & SEPSIS ■ NEONATAL SEPSIS ■ SEXUALLY TRANSMITTED INFECTIONS



SECTION 5

ORGANIZATION AND GOVERNANCE

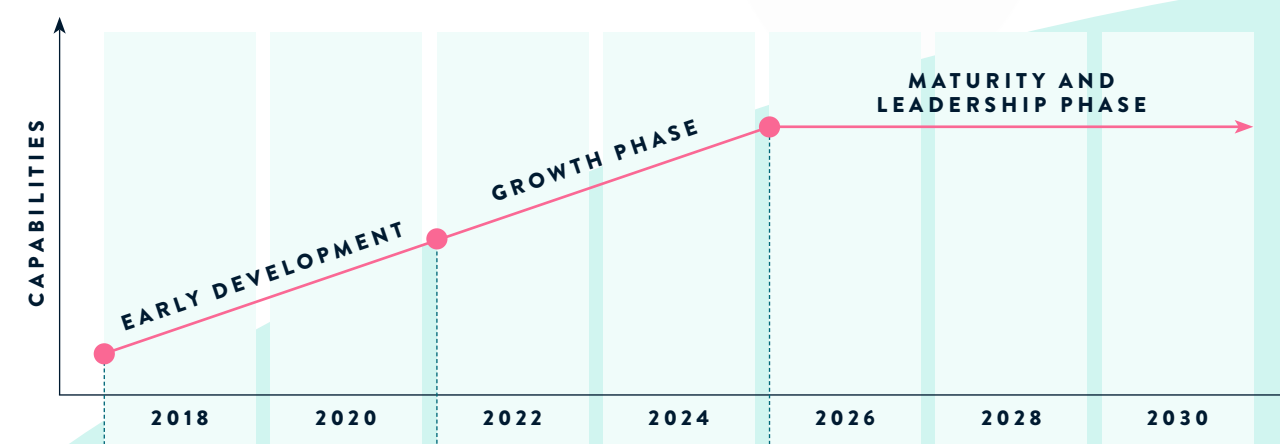
Organizational development for impact

Since its early development, GARDP has grown steadily and is now on course to further mature and consolidate its success. Looking ahead, GARDP will carefully expand its portfolio and manage its growth to deliver more fully on its core mission from 2024 to 2028 (see **Figure 16**).

As of 2023, GARDP had 97 full- or part-time staff within the GARDP global network. In the past years, we have hired staff in Brazil, India, Japan, South Africa, Spain and the United Kingdom. We will continue to increase our presence in key geographies which support our clinical trials and access activities.

GARDP is committed to transparency regarding diversity, equality and inclusion in all our activities, including gender balance in the organization, particularly in organizational leadership. As of 2023, our male to female ratio at the leadership level (including heads and directors) was 1:1.

FIGURE 16: ORGANIZATIONAL DEVELOPMENT



EARLY DEVELOPMENT

- GARDP is created in 2016 and legally established in 2018
- DNDi incubates GARDP
- Initial strategic concept and first R&D projects
- Focus on new assets and support from funders

GROWTH PHASE

- Development of disease area and access strategies
- Strengthening of R&D portfolio with new assets and projects
- Expansion of R&D capacity and in-house capabilities
- Development of SECURE
- Intensification of partnerships with companies, non-profits and others
- Growth of global network

MATURITY AND LEADERSHIP PHASE

- Expansion of a mature R&D portfolio
- Establishment of access and production capabilities through local and cross-national partnerships
- Implementation and expansion of SECURE into full-scale programme
- Development of new income streams
- GARDP as a key partner for governments and industry
- GARDP as a catalyst in the AMR R&D and access ecosystem

Governance and management

As GARDP grows and matures, GARDP’s governance will continue to ensure accountability, transparency and effectiveness:

- The Board, which serves as the ultimate decision-making body of our organization, determines GARDP’s strategic goals and ensures that management works diligently and efficiently.
- The Board receives guidance from the Observers of the Board, the Scientific Advisory Committee, and the Donor Partnership Advisory Committee. It also gets input from various Board subcommittees (i.e., the Strategic Partnerships Committee; the Nomination, Remuneration and Safeguarding Committee; and the Audit Committee).
- Our co-founders WHO and DNDi remain key partners for us and are both represented in our governance structure.
- GARDP strives for equal representation within its governance structures, including regional and gender balance. From 2024 to 2028, GARDP will ensure organic growth of the Board and take steps to increase the representation of key partners from low- and middle-income countries.

“GARDP Board members bring rich insight from their various professional backgrounds that span scientific, non-profit and governmental sectors. As a truly international Board, we share a deep commitment to guiding and governing a non-profit organization built for the 21st century to address one of the greatest health challenges of our time.”

Prof Ramanan Laxminarayan
GARDP Board Chair



BOARD MEMBERS

Ramanan Laxminarayan	Chair (until 30 June 2024)	One Health Trust, USA
John-Arne Rottingen	Vice-Chair (until 31 December 2023)	Ministry of Foreign Affairs, Norway
Stanislas Zuin	Board Treasurer	Independent
Glenda Gray	Board member / Vice-Chair (1 January 2024 to 30 June 2024) / Chair (from 1 July 2024)	South African Medical Research Council, South Africa
Chieko Ikeda	Board member	Independent
Veronika von Messling	Board member	Federal Ministry of Education and Research, Germany
Bernard Pécoul	Board member	Independent

OBSERVERS OF THE BOARD

Gregg Alton	Board observer	Independent
Hanan H. Balkhy	Board observer	World Health Organization, Switzerland
Herman Goossens	Board observer	University of Antwerp, Belgium
Luis Pizarro	Board observer	DNDi, Switzerland
Nora Kronig Romero	Board observer	Federal Office of Public Health, Switzerland

GARDP DIRECTORS

Manica Balasegaram	Executive Director
Peter Beyer	Deputy Executive Director
Jennifer Cohn	Global Access Director
Vincent Constantin	General Counsel
Pierre-Yves Delhez	Director of Internal Operations
Yann Ferrisse	Business Development & Partner Engagement Director
Seamus O'Brien	R&D Director
Laura Piddock	Scientific Director
Jeffrey Rowland	External Relations Director
Carol Ruffell	Director of DNDi GARDP Southern Africa
Subasree Srinivasan	Medical Director

SCIENTIFIC ADVISORY COMMITTEE

Herman Goossens	Chair	University of Antwerp, Belgium
Karl-Heinz Altmann	Committee member	ETH Zurich, Switzerland
Marc Bonten	Committee member	University Medical Centre Utrecht, the Netherlands
Anthony Coates	Committee member	St George's Hospital, University of London, UK
Angela Dramowski	Committee member	Stellenbosch University, South Africa
Ana Cristina Gales	Committee member	Universidade Federal de São Paulo, Brazil
Mark J. Goldberger	Committee member	formerly AbbVie, USA
Roy Jamieson	Committee member	OkerPharma Consultancy AB, Sweden
Rudo Mathivha	Committee member	University of Witwatersrand and Chris Hani Baragwanath Hospital, South Africa
Marc Mendelson	Committee member	University of Cape Town, South Africa
Malcolm Page	Committee member	formerly Roche, Switzerland
Sumathi Nambiar	Committee member	Johnson and Johnson, USA
Kamini Walia	Committee member	Indian Council of Medical Research, India
Valeria Gigante	Ex-officio member	World Health Organization, Switzerland
Nicholas White	Ex-officio member	DNDi, Switzerland

THE DONOR PARTNERSHIP ADVISORY COMMITTEE

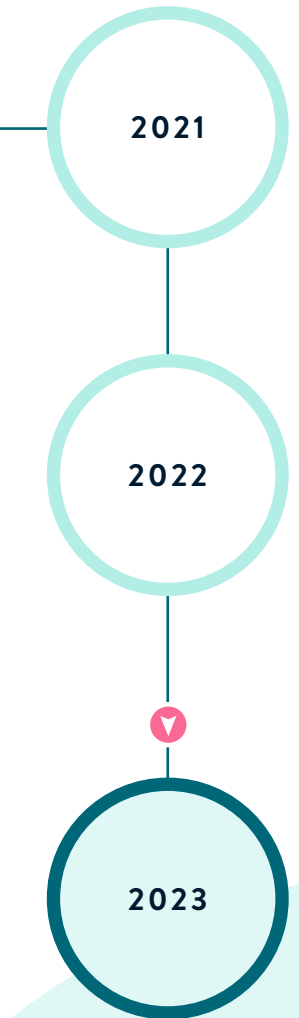
Nora Kronig Romero	Chair	Federal Office of Public Health, Switzerland
Nireesh Bhagwandin	Committee member	South African Medical Research Council, South Africa
Jasper Claessen	Committee member	Ministry of Health, Welfare and Sport, the Netherlands
Eiji Hinoshita	Committee member	Ministry of Health, Labour and Welfare, Japan
Louise Norton-Smith	Committee member	Department of Health and Social Care, UK
Dagmar Reitenbach	Committee member	Federal Ministry of Health, Germany

THE STRATEGIC PARTNERSHIPS COMMITTEE

Glenda Gray	Chair	South African Medical Research Council, South Africa
Gregg Alton	Committee member	Independent
Dominique Carouge	Committee member	Independent
Rachel Christinat	Committee member	Independent
Chieko Ikeda	Committee member	Independent
Veronika von Messling	Committee member	Federal Ministry of Education and Research, Germany

Additional governance committees and their members are listed on [GARDP.org](https://gardp.org)

GARDP's history



SCAN TO FIND
OUT MORE ABOUT
OUR PARTNERS



SPONSORED BY THE



OUR WORK IS
MADE POSSIBLE
WITH ESSENTIAL
SUPPORT FROM
OUR FUNDING
PARTNERS.
THANK YOU.



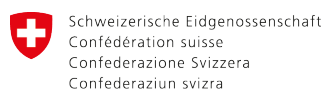
Ministry of Foreign Affairs



Ministry of Health, Welfare and Sport



Co-funded by
the European Union



Swiss Confederation



Global Antibiotic Research & Development Partnership (GARDP)

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The Global Antibiotic Research & Development Partnership (GARDP) is a not-for-profit organization that develops new antibiotic treatments for drug-resistant bacterial infections that pose the greatest threat to human health, and makes them accessible to the people who need them. It puts public health needs at the centre of antibiotic drug development to address the immediate crisis of antimicrobial resistance (AMR). GARDP was created by the World Health Organization and the Drugs for Neglected Diseases initiative (DNDi) in 2016 and legally registered as the GARDP Foundation in Geneva, Switzerland in 2018.

