2024–2028
STRATEGY
Putting public health needs at the centre of antibiotic drug development
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## ORGANIZATION AND GOVERNANCE
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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-sustaining 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.
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. 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. 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.

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.
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

Section 2
GARDP’s Impact on Antimicrobial Resistance

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.
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.

**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 Entasys Therapeutics Limited (Entasys), now a subsidiary of Innoviva Inc. (Innoviva).

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

**Expanded Portfolio 2024–2028**

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

**Optimized Treatment Regimen for Infections Caused by Drug-Resistant Enterobacterales**

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 gonorrhea and related STIs. GARDP may also expand its portfolio to preventative 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.

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Funding need: €220 million

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.

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.

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

FIGURE 4: GARDP’S EXPENDITURE BY YEAR (INCLUDING ESTIMATED EXPENDITURE 2024–2028)

FIGURE 5: BUDGET BY PROGRAMME 2024–2028

MAXIMIZING IMPACT WITH CORE FUNDING
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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.”

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.
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. 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.
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:

1. **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.

2. **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. R&D efforts should focus on developing new treatments for infections caused by these pathogens.

3. **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.

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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.


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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.
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.
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

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**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**

- **Assist in market shaping** to improve transparency, efficiency and product affordability, including through pooled procurement mechanisms and volume guarantees.
- **Undertake market intelligence and demand forecasting** to reduce market risk and promote reliable and longer-term planning.
- **Sign detailed sublicense agreements** with companies for registration, manufacturing and distribution.
- **Support technology transfer** to accelerate product availability.
- **Support early adopter networks** for antibiotic introduction.
- **Support inclusion in WHO Essential Medicines List and Prequalification Programme** for accelerated country registration.
- **Data to support inclusion of our products in international, country or regional treatment guidelines**.
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.

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**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
**GARDP Global Network**

*Set up as an independent not-for-profit in 2018, GARDP’s headquarters are located in Geneva, Switzerland.*

**South Asia—DNDi Regional Office in New Delhi**

This office is responsible for the implementation of GARDP’s activities, including observational studies and pharmaceutical drug development. It develops partnerships to adapt access and stewardship strategies for the regional context.

**Latin America—DNDi Regional Office in Rio de Janeiro**

This office supports GARDP’s work on institutional representation by liaising with pharmaceuticals, research partners, national governments and supranational organizations such as PAHO. It also supports access work.

**Southeast Asia—DNDi Regional Office in Kuala Lumpur**

This office supports GARDP’s work in the region, including developing new, accessible STI treatments and expanding access to essential antibiotics via SECURE.

**Japan—DNDi Tokyo Office**

This office helps GARDP liaise with Japanese pharmaceuticals, research partners and the Japanese government.

**Representative in Australia**

This representation links GARDP with companies and the Australian government.

**East Africa—DNDi Regional Office in Nairobi**

This office assists with GARDP’s work in the region, including clinical trials and studies on neonatal sepsis and sexually transmitted infections.

**“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

**“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.”**

Carol Ruffell
Director of DNDi GARDP Southern Africa

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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

**“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.”**

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Director of DNDi GARDP Southern Africa

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Carol Ruffell
Director of DNDi GARDP Southern Africa
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.

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.
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.\(^9\) 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.\(^12\)

**SEXUALLY TRANSMITTED INFECTIONS**
Gonorrhoea is among the most common bacterial STIs in the world, with 82 million new cases documented each year.\(^14,15\) 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%.\(^18\)

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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.”

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. 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.

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Cefepime-taniborbactam is a potential antibiotic treatment with activity against two of the three critical WHO bacterial priority pathogens (carbapenem-resistant Enterobacteriales 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
CURRENT PORTFOLIO

NEONATAL SEPSIS EMPIRIC TREATMENT REGIMENS

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

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 (MRC 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

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 health

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.

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 ceftiofuroxime. 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 Innova 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?

Over the past 80 years, the Neisseria gonorrhoeae bacterium has developed defenses against all classes of antibiotic medicines.

YEAR OF REPORTED RESISTANCE


SULPHONAMIDES PENICILLIN TETRACYCLINE AZITHROMYCIN CEFTRIAXONE CEFIXIME CIPROFLAXIN

Ceftriaxone (sometimes in combination with azithromycin) is the only highly effective treatment left. But now several countries—including Australia, Cambodia, Canada, and the United Kingdom—are increasingly reporting cases of drug resistance to ceftriaxone.
EXPANDED PORTFOLIO

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 health.64

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

**OPTIMIZED TREATMENT REGIMEN FOR DRUG-RESISTANT BACTERIAL INFECTIONS**

**Target:** Enterobacteriales 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 health

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

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**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
EXPANDED PORTFOLIO

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 health

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

EXPLORATION OF DIFFERENT INTERVENTIONS FOR STIs

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

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.

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

“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
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
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
• 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

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

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.26 Shortages of antimicrobials are increasingly common, contributing to preventable suffering and death and raising the threat of antibiotic resistance.26 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

OUTCOME 2024–2028
• SECURE.GARDP.org serves as the go-to resource for freely available, high-quality technical information and research tools for antimicrobial R&D

At least one compound identified as lead-optimization candidate

Cefiderocol: Support technology transfer and identify commercial partners. Launch pilot programme for distribution through the Stop TB Partnership’s Global Drug Facility (GDF)

Cefepime-taniborbactam: Lead paediatric development, generate additional evidence, provide initial access

Neonatal sepsis empiric treatment regimens: Expand and complete NeoSep1 trial, and publish preliminary results

Zoliflodacin: Compile registration dossier, expand evidence for optimal and appropriate use, expand safety database, provide access

Novel broad-spectrum treatment for serious bacterial infections: Launch project to develop compound

Optimized treatment regimen for drug-resistant bacterial infections: Evaluate unmet need for revised treatment options in priority countries. Confirm the role for new treatment options

New treatments for carbapenem-resistant infections in newborns: Assess potential effectiveness of cefiderocol and cefepime-taniborbactam in a regimen for neonatal sepsis in setting of carbapenem resistance; initiate clinical development

Exploration of different interventions for sexually transmitted infections: Identify new opportunity and prepare for project launch

High-throughput screening of new libraries of compounds involving in part the latest artificial intelligence discovery tools; Evaluation of potential candidates; Creation of new global consortium for discovery research

Develop SECURE portfolio and tools, including forecasting model and procurement mechanism

Develop and host new webinars and conference content, and launch new resources for antimicrobial R&D

Cefiderocol registered by partners and accessible in at least five countries in GARDP’s territory

Cefepime-taniborbactam: approved for use in adults by US FDA and accessible in some high-burden countries within GARDP territory

One or more effective treatment regimens identified for neonatal sepsis

Zoliflodacin approved in the US and Europe and registered in South Africa and Thailand as soon as possible

Compound reaches late-stage clinical development

Share outcomes from studies of treatment option for scale-up in high-burden countries

Initiation of the assessment of a new treatment for carbapenem-resistant infections in newborns

New partnership launched and project commenced

At least one compound identified as lead-optimization candidate

SECURE implemented in 3 countries/regions

REVIVE.GARDP.org serves as the freely available go-to resource for antimicrobial R&D
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.
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 Nominations, 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**

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<th>Name</th>
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<th>Organization/Institution</th>
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<td>Chair</td>
<td>One Health Trust, USA</td>
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<td>Vice-Chair</td>
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**OBSEVERS OF THE BOARD**

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Organization/Institution</th>
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<tbody>
<tr>
<td>Gregg Afco</td>
<td>Board observer</td>
<td>Independent</td>
</tr>
<tr>
<td>Helen H. Bakky</td>
<td>Board observer</td>
<td>World Health Organization, Switzerland</td>
</tr>
<tr>
<td>Raman Javdega</td>
<td>Board observer</td>
<td>University of Antwerp, Belgium</td>
</tr>
<tr>
<td>Lene Pihl</td>
<td>Board observer</td>
<td>DNDi, Switzerland</td>
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<tr>
<td>Nora Kring Jimenez</td>
<td>Board observer</td>
<td>Federal Office of Public Health, Switzerland</td>
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**GARDP DIRECTORS**

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<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Marcus Balinganer</td>
<td>Executive Director</td>
<td>ETH Zurich, Switzerland</td>
</tr>
<tr>
<td>Peter Bespore</td>
<td>Deputy Executive Director</td>
<td>University Medical Centre Utrecht, the Netherlands</td>
</tr>
<tr>
<td>Carine Gressel</td>
<td>Global Access Director</td>
<td>General Counsel</td>
</tr>
<tr>
<td>Vincent Gervasoni</td>
<td>Director of Internal Operations</td>
<td>University of Paris, France</td>
</tr>
<tr>
<td>Hanns-Olaf Kirsch</td>
<td>R&amp;D Director</td>
<td>University Medical Centre Utrecht, the Netherlands</td>
</tr>
<tr>
<td>Laura Puchert</td>
<td>Scientific Director</td>
<td>Department of Health and Social Care, France</td>
</tr>
<tr>
<td>Jeffery Brookland</td>
<td>External Relations Director</td>
<td>formerly AbbVie, USA</td>
</tr>
<tr>
<td>Carol Ruffell</td>
<td>Director of DNDi GARDP Southern Africa</td>
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</tr>
<tr>
<td>Subasree Srinivasan</td>
<td>Medical Director</td>
<td>Indian Council of Medical Research, India</td>
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**SCIENTIFIC ADVISORY COMMITTEE**

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<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Ramanan Laxminarayan</td>
<td>Chair</td>
<td>University of Antwerp, Belgium</td>
</tr>
<tr>
<td>Karl-Heinz Altmann</td>
<td>Committee member</td>
<td>ETH Zurich, Switzerland</td>
</tr>
<tr>
<td>Alex Bustin</td>
<td>Committee member</td>
<td>University Medical Centre Utrecht, the Netherlands</td>
</tr>
<tr>
<td>Anthony Carbon</td>
<td>Committee member</td>
<td>Sir George’s Hospital, University of London, UK</td>
</tr>
<tr>
<td>Angela Diamandici</td>
<td>Committee member</td>
<td>Stellenbosch University, South Africa</td>
</tr>
<tr>
<td>Ana Cristina Guilles</td>
<td>Committee member</td>
<td>Universidade Federal de São Paulo, Brazil</td>
</tr>
<tr>
<td>Mark A. Goldberger</td>
<td>Committee member</td>
<td>formerly AbbVie, USA</td>
</tr>
<tr>
<td>Roy Akeson</td>
<td>Committee member</td>
<td>ClarPharma Consultancy AB, Sweden</td>
</tr>
<tr>
<td>Jude Mathurika</td>
<td>Committee member</td>
<td>University of Westminster and Chris Hani Bergshooven Hospital, South Africa</td>
</tr>
<tr>
<td>Max Velander</td>
<td>Committee member</td>
<td>University of Cape Town, South Africa</td>
</tr>
<tr>
<td>Madsen Pape</td>
<td>Committee member</td>
<td>formerly Roche, Switzerland</td>
</tr>
<tr>
<td>Sven B. Nerheim</td>
<td>Committee member</td>
<td>Johnson and Johnson, USA</td>
</tr>
<tr>
<td>Kanuva Wales</td>
<td>Committee member</td>
<td>Indian Council of Medical Research, India</td>
</tr>
<tr>
<td>Valeria Gigante</td>
<td>Ex-officio member</td>
<td>World Health Organization, Switzerland</td>
</tr>
<tr>
<td>Nicholas White</td>
<td>Ex-officio member</td>
<td>DNDi, Switzerland</td>
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**THE DONOR PARTNERSHIP ADVISORY COMMITTEE**

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<thead>
<tr>
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<tbody>
<tr>
<td>Nora Kring Jimenez</td>
<td>Chair</td>
<td>Federal Office of Public Health, Switzerland</td>
</tr>
<tr>
<td>Nishita Bhugarad</td>
<td>Committee member</td>
<td>University of Cape Town, South Africa</td>
</tr>
<tr>
<td>Jasper Clemsens</td>
<td>Committee member</td>
<td>Ministry of Health, Welfare and Sport, the Netherlands</td>
</tr>
<tr>
<td>Egil Husemo</td>
<td>Committee member</td>
<td>Ministry of Health, Labour and Welfare, Norway</td>
</tr>
<tr>
<td>Louise Herman South</td>
<td>Committee member</td>
<td>Department of Health and Social Care, UK</td>
</tr>
<tr>
<td>Dagmar Rethwisch</td>
<td>Committee member</td>
<td>Federal Ministry of Health, Germany</td>
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**THE STRATEGIC PARTNERSHIPS COMMITTEE**

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<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Glenda Gray</td>
<td>Chair</td>
<td>South African Medical Research Council, South Africa</td>
</tr>
<tr>
<td>Gregg Afco</td>
<td>Committee member</td>
<td>University of Antwerp, Belgium</td>
</tr>
<tr>
<td>Dominique Carasso</td>
<td>Committee member</td>
<td>University of Antwerp, Belgium</td>
</tr>
<tr>
<td>Rachel Christien</td>
<td>Committee member</td>
<td>Independent</td>
</tr>
<tr>
<td>Charly Heela</td>
<td>Committee member</td>
<td>Independent</td>
</tr>
<tr>
<td>Veronika van Meeling</td>
<td>Committee member</td>
<td>Federal Ministry of Education and Research, Germany</td>
</tr>
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Additional governance committees and their members are listed on GARDP.org
The Swiss government grants GARDP legal privileges and immunities to facilitate GARDP’s collaboration with others working in the field of public health and in recognition of GARDP’s major role in the fight against antibiotic resistance.

Following several studies, GARDP identifies three combinations of existing antibiotics for testing as potential treatments for neonatal sepsis.

The creation of GARDP North America Inc., a 501c3 public charity, expands GARDP’s global network.

Supported by funders, notably Germany’s €50 million pledge for 2023–2027, GARDP strengthens its R&D and access portfolio and intensifies work with its global network.

GARDP launches a groundbreaking access project with Shionogi and CHAI to expand access to ceferodor, a new treatment in its portfolio.

The SECURE initiative receives seed funding from Wellcome (GBP 1 million) and the Canadian government (CAD 300,000).

GARDP’s REVIVE serves as a global knowledge hub for first-rate webinars, viewpoint articles and technical information with support from 150+ experts.

GARDP celebrates its 5-year anniversary and launches a new strategy for the coming 5 years (2024–2028).

Following positive phase 3 trial results announced in 2022 and 2023, GARDP has two products—cefepime-taniborbactam and zoliflodacin—on track for potential regulatory approval by the US FDA.

GARDP and partners launch a global trial to rank new treatments for neonatal sepsis.

GARDP works with more than 100 R&D and access partners in 22 countries, including pharmaceutical and biotech companies, research institutions, generic manufacturers and representatives from academia and civil society.

GARDP’s history

- 2015: In the context of rising AMR and a looming “post-pandemic era,” the World Health Assembly adopts the Global Action Plan on Antimicrobial Resistance. To deliver on this plan, WHO technical consultations with member states and other key stakeholders discuss the development of a new organization for antibiotic development, preservation and access.

- 2016: GARDP is jointly created by WHO and DNDi. For the first three years, it is incubated by DNDi which, like GARDP, engages in public and private sector partnerships to research and develop new drugs for neglected patients to address public health needs.

- 2017: Germany together with a number of countries and foundations pledge €56.5 million as seed funding for GARDP’s activities.

- 2018: On behalf of GARDP, DNDi signs an agreement with Entasis for zoliflodacin, the first treatment in the GARDP portfolio.

- 2019: GARDP is legally set up in Geneva, Switzerland, as a Swiss non-profit under the name GARDP Foundation.

- 2020: GARDP launches REVIVE to convene academics, non-profits, industry and other players who contribute to antimicrobial R&D.

- 2021: GARDP launches a new strategy that outlines its ambitious “5by25” goal to deliver five new antibiotic treatments by 2025. As part of its discovery work, GARDP starts screening compound libraries and natural products for antibiotic activity.

- 2022: GARDP further expands its disease area approach with the launch of the serious bacterial infection programme by signing a collaboration agreement with Venatorx and adding a second treatment, cefepime-taniborbactam, to its portfolio.

- 2023: GARDP initiates a strategy to integrate access into its core activities and also holds initial discussions with WHO and others about the SECURE initiative to expand access to essential antibiotics.
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.