



INVESTING IN GARDP 2024-2028

Why supporting our innovative public health approach is a sound investment to counter antimicrobial resistance

“Tackling the antibiotic crisis requires a concerted effort to bridge the gaps in research, development and access that disproportionately affect vulnerable populations and countries.”

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



WHO/Christopher Black



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ADDRESSING MORE THAN THE MARKET FAILURE



PREVENTION, PREPAREDNESS AND RESPONSE

Climate change, urbanization, migration and conflict are global challenges that exacerbate antibiotic resistance.

The increase in extreme weather events and natural disasters, plus humanitarian crises, will facilitate the spread of drug-resistant microbes through poor access to clean water, sanitation and antibiotics. Such events also lead to increases in human displacement, migration and urbanization – all of which put pressure on health systems and drive demand for and increased use of antibacterial treatments, thus contributing to the evolution and spread of AMR.

Rarely will these outbreaks be contained to one geography. As seen with COVID-19, the spread of drug-resistant infections or any other outbreak-prone infection, can be progressive and predictable, or occur in sudden leaps. As we look to the future, it is clear that antimicrobial resistance is a growing problem in the midst of increasing instability around the globe – and that without a sustainable system and a holistic One Health approach for antibiotic R&D and access, the world will have no effective way to respond.



The challenge

Antimicrobial resistance is a global health crisis that is already upon us.

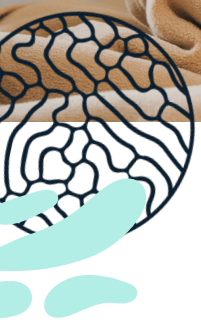
It is well understood what is at stake if the world fails to replace the antibiotic treatments that drug-resistant pathogens continue to render ineffective. **Now one of the top 10 global health threats, antimicrobial resistance (AMR) is responsible for nearly 1.3 million deaths and associated with almost 5 million deaths every year.**¹ Unchecked, the death toll is expected to rise considerably.²

The economic cost is also high, with estimates projecting it to reach US\$3.4 trillion annually by 2030.³ If we do not act, 3.8 percent of global gross domestic product could be wiped out and 28 million people pushed into poverty by 2050.³ Yet despite the urgent need to develop effective treatments for drug-resistant infections, most pharmaceutical companies have left the market to invest in more profitable areas, producing a “market failure”.

The private sector’s large-scale exit from antibiotic R&D and production has hugely exacerbated the AMR crisis. Long before pharmaceutical companies started to withdraw, many clinically important antibiotic drug candidates did not stand a chance of being developed because their fate was determined by profitability rather than public health need. Today as public and philanthropic investments attempt to overcome this failure, it is becoming increasingly evident that addressing market dynamics alone is insufficient. Time and again, promising new treatments fail to reach patients due to the lack of additional investment that is required for research and development, manufacturing, and distribution capacity. And even when treatments are successfully produced,

they rarely focus on the most vulnerable: mainly women, children and infants.

In short, the challenge we face when addressing AMR is both a public health failure as well as a market failure. The greatest burden of AMR is in low- and middle-income countries (LMICs) with weaker healthcare systems and a greater lack of access to effective antibiotics. If this situation is not addressed, the continuous escalation of AMR will impinge on these health systems even further, with the impact disproportionately felt by people of lower economic standing, irrespective of where they live. It is a reality that is set to undo critical progress made towards universal health coverage (UHC) and the Sustainable Development Goals.



Our response

GARDP – an innovative partnership model to tackle the AMR crisis

Established in 2016, GARDP is the only organization in the world working to address the market and public health failures in antibiotic drug development together. Driven by public health need rather than profit, we develop new antibiotic treatments while working to revitalize the antimicrobial R&D ecosystem – making sure that the most needed drugs are developed, and that they are available to the people who need them.

Product development and access

Working with public and private sector partners across the world, GARDP has developed a new model that makes the antibiotic drug development process more efficient and cost-effective.

THE MODEL CONSISTS OF THREE COMPONENTS:



INTEGRATING R&D AND ACCESS

GARDP engages in carefully selected antibiotic drug development and access projects to address urgent public health needs. GARDP can 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 licensing 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. This “third pathway” of drug development – neither wholly private nor wholly public – efficiently uses donor funding to harness private research and creates incentives that deliver a public health goal.



EQUAL PARTNERSHIP

Many LMICs have expertise that is critical to address the global antibiotic crisis. Alongside our collaboration with governments in the countries we work in, our model also involves working across the public and private sectors (scientists, clinicians, industry, manufacturers, donors and civil society) to coordinate efforts in the antibiotic pipeline of drug development and access. Through these relationships, we bring together a range of skills, knowledge and resources, including financial and scientific resources, as well as geographic reach. While our team provides valuable contributions to partners, we in turn benefit from their wealth of knowledge, expertise and experience.

Addressing public health needs

The 2022 GRAM study⁴ provided important data on which pathogens cause the highest mortality rates and the regions and populations facing the most severe consequences. GARDP is focused on investing in and responding to the needs of the people and communities that are most vulnerable, like women, children and babies.

OUR DISEASE AREA STRATEGY IS BASED ON THREE OVERARCHING CRITERIA:



1. PRIORITY DISEASES AND INFECTIONS

To translate resistance in bacteria to diseases that impact patients, GARDP focuses its activities on serious bacterial infections and sepsis in adults, children and babies (including neonatal sepsis), and sexually transmitted infections (e.g. gonorrhoea).



2. THE DEADLIEST DRUG-RESISTANT BACTERIAL PATHOGENS

WHO has identified 12 multidrug-resistant bacteria that pose the greatest threat to human health due to increasing resistance and lack of adequate treatment options.⁵ In line with this, GARDP has prioritized working on solutions for Enterobacterales species including *E. coli*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, and *Pseudomonas aeruginosa*. We are also working to develop solutions to *N. gonorrhoeae* – a strain of gonorrhoea that has developed resistance to last-line antibiotics.



3. REGIONAL NEEDS AND KEY POPULATIONS

While resistance to first-line treatments is a global challenge, the highest rates of AMR are found in sub-Saharan Africa, South Asia and Eastern Europe.⁶ Children, older people and people with chronic disease and compromised immune systems are especially vulnerable. Marginalized and lower socio-economic communities are also particularly impacted by AMR.



TACKLING AMR IS CRUCIAL TO ADVANCING UNIVERSAL HEALTH COVERAGE

By appropriately utilizing antibiotics and vaccines and ensuring access to clean water, healthcare systems can enhance patient survival rates, reduce disease burden, and reduce costs. In addition to improving health outcomes and easing the burden on healthcare providers, this also helps to enhance the overall sustainability of service coverage. Most importantly, by addressing AMR within a comprehensive approach we can better ensure that quality healthcare services are accessible and affordable for all, which, ultimately, saves more lives.



OUR 2028 GOAL

Demonstrate how GARDP's unique 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.





1. CURRENT PORTFOLIO

Achieving success with 5 treatments by 2025

In 2019, GARDP announced an ambitious plan to deliver five new antibiotic treatments by 2025. We have made notable progress since then. Investing a total of €126.3 million through to 2023, our portfolio now includes one approved treatment and several investigational drugs for serious bacterial infections and sepsis in adults, children, and newborns, as well as a new, first-in-class investigational treatment for drug-resistant gonorrhoea.

For three of these antibiotics (cefiderocol, cefepime-taniborbactam and zoliflodacin), GARDP holds the licensing rights in many LMICs. This makes us responsible for ensuring that these products, upon approval, are made accessible to patients through agreements with manufacturers and distributors. As shown in the figure presented on pages 12 and 13, we will continue to develop the five treatments within our existing portfolio and facilitate access to at least three.

THE GARDP STRATEGY 2024-2028

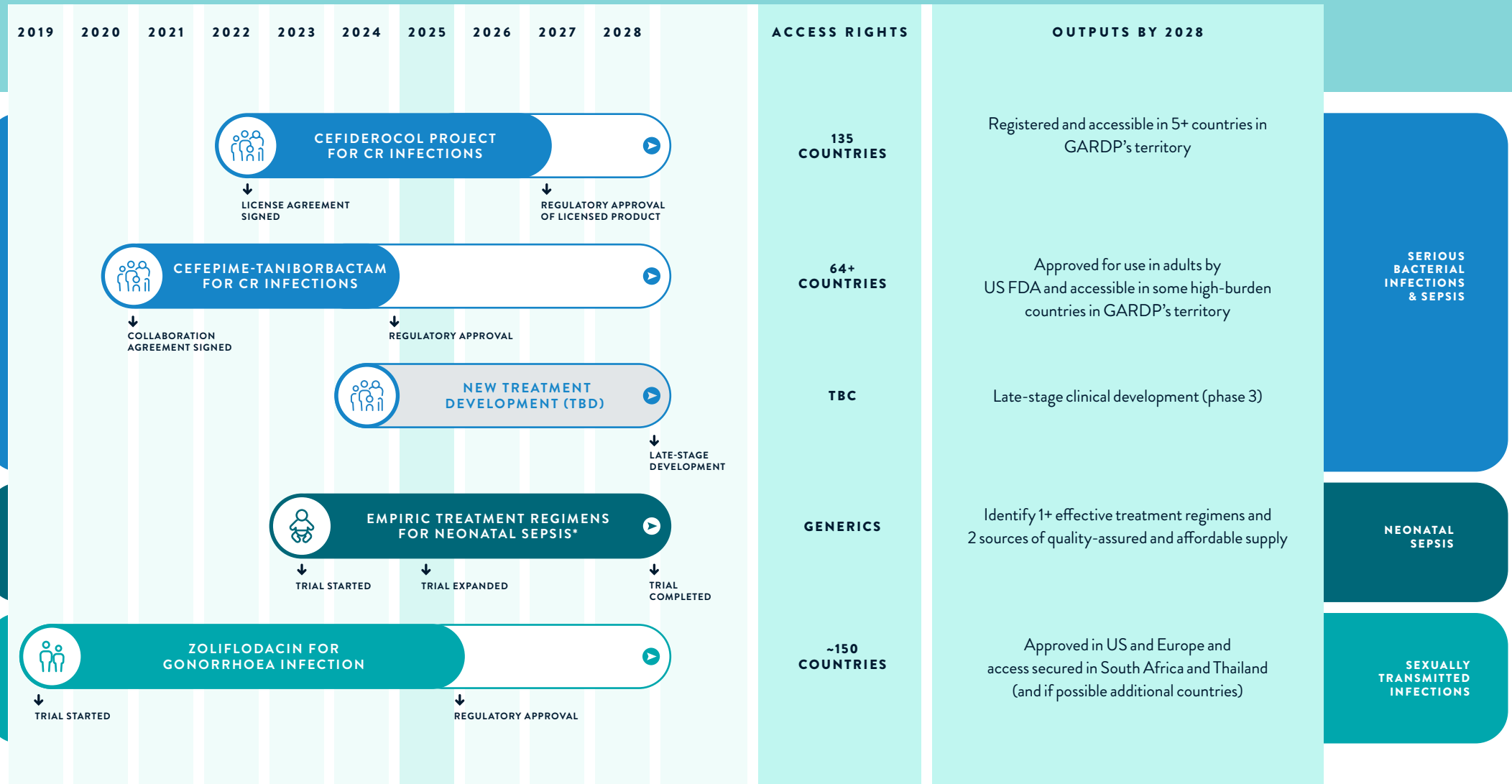
Our strategy focuses on the continued development of our current portfolio and its expansion into new projects deemed essential to addressing current and emerging public health needs.

A COMMITMENT TO COST EFFICIENCY

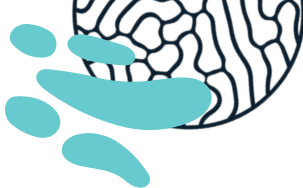
As a non-profit organization, GARDP is continually looking to improve cost efficiency while prioritizing projects that align with our mission and maximize impact. As well as the cost-saving approaches inherent to our unique model, our extensive network of partners and ongoing relationship with our co-founder, the Drugs for Neglected Diseases Initiative (DNDi), allows us to pool knowledge and resources (e.g. shared office, shared IT infrastructure, and synergies in pharmaceutical development) and **keep our overhead costs at or below 13 percent.**

Current portfolio

Delivering critical new treatments



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



2. EXPANDED PORTFOLIO

Towards a long-term supply of treatments for drug-resistant infections

In keeping with our focus on serious bacterial infections and sepsis as well as sexually transmitted infections, we have identified several projects that are essential to addressing current and emerging public health needs for those populations most affected, particularly women, children and babies. These include:



THE DEVELOPMENT OF A NOVEL BROAD-SPECTRUM TREATMENT FOR SERIOUS BACTERIAL INFECTIONS caused by carbapenem-resistant Gram-negative pathogens such as Enterobacterales species, *Acinetobacter* species and *Pseudomonas* species.



THE DEVELOPMENT OF A NEW TREATMENT REGIMEN FOR SEPSIS caused by Enterobacterales, including extended-spectrum beta-lactamase-producing Enterobacteriaceae (ESBL-PE).



THE DEVELOPMENT OF NEW TREATMENTS FOR NEWBORNS with infections caused by carbapenem-resistant *Acinetobacter baumannii* (CRAB) and carbapenem-resistant Enterobacterales (CRE).



EXPLORATION OF DIFFERENT INTERVENTIONS, including the development of a new treatment for difficult-to-treat gonorrhoea and related sexually transmitted infections (STIs). GARDP may also expand its portfolio to preventive measures for STIs and target additional pathogens that cause STIs like *Mycoplasma genitalium* and syphilis.

Alongside these development activities, GARDP will continue its crucial discovery and exploratory work, including examining libraries of compounds that have never been tested for antibiotic activity. The discoveries we make will contribute to the global antibiotic pipeline for further development and, if aligned with our strategy, will be incorporated into our portfolio.

Facilitating access

Recognizing that developing treatments is not enough, our unique and integrated approach allows us to address the challenge of “access” ahead of time. By building access considerations into R&D, we can ensure that promising new products have a clear pathway to market, and that they are available, appropriate and affordable to countries and communities worldwide.

The next strategic period will see GARDP refine and embed existing strategies to support R&D and access through licensing, registration, manufacturing, and distribution. We are committed to testing and deploying new modalities – whether through the creation of novel approaches to pooled procurement, innovative financing, decentralized supply chains, community-based services and/or new healthcare delivery models.



Key to GARDP’s access work is our collaboration with WHO on SECURE, an initiative to improve access to existing and new essential antibiotics. In the next strategic period, SECURE will begin implementation in partnership with participating countries to develop and test tools and establish a relevant portfolio of quality-assured and affordable antibiotics in three countries/regions.



A global AMR knowledge hub and community

A historic lack of investment has left the antimicrobial R&D and scientific community fragmented and disconnected, with urgent action needed to connect, build and expand global knowledge and expertise. To support this process, GARDP will continue to focus on preserving and sharing historic and new knowledge on antimicrobial R&D, supporting and coordinating global research efforts, and ensuring open access to new findings and information.

Much of this work is curated and accessible through the [REVIVE platform and network](#), an online learning and knowledge hub connecting current researchers with established/retired researchers and developers to improve, accelerate and support drug discovery and development. With the right funding, we can expand this programme and bring public and private sector partners in high-, middle- and low-income countries together – breaking down silos, forging new connections, and pooling key skills, resources and expertise.

By uniting the antimicrobial R&D community towards a shared, global objective, we can help unlock critical new developments, reduce duplication, and create efficiencies that make the most of every investment and drive new progress in the fight against AMR.



A COST-EFFECTIVE INVESTMENT THAT OFFERS TRUE VALUE FOR MONEY

With targeted investment from donors, GARDP has enabled the development of new antibiotic treatments and combinations of existing antibiotics in an extremely cost-effective way.

The success of our efforts to develop zoliflodacin as a treatment for multidrug-resistant gonorrhoea is a case in point. We estimate that GARDP's total cost for the development of this first-in-class treatment will amount to approximately €80 million, significantly less than the average estimated cost to develop any type of antibiotic treatment. Working with both public and private partners, GARDP successfully completed a full phase 3 trial in 2023, and plans are being implemented to prepare regulatory submissions, registration in at least two priority countries, and the prospective expansion of the safety database, focusing on specific populations such as women who are pregnant or breastfeeding.

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. Furthermore, by investing in antibiotic development and access, GARDP is helping to meet both immediate public health needs and broader long-term development goals. For the former, the development and delivery of new antibiotics is essential, not just for the treatment of drug-resistant infections in individual patients, but also for disease management strategies as a whole. Without effective antibiotics, the most common infections will become more difficult to treat, and we risk seeing surging healthcare costs and a resurgence of diseases that have long been in decline.

Antibiotics help keep these diseases, and the associated costs, in check, and are a key tool to ensure that healthcare practitioners have the treatment options they need to protect patient health. They also help build resilience against future pandemics, climate change and sociopolitical crises.



INVEST IN ACHIEVING SUCCESS

In its first five years, GARDP has created a new R&D partnership model based on public health needs that delivers effective treatments at considerable savings to funders.

As we embark on a new strategic phase, increased investment will enable us to:

- Deliver greater success and identify and advance new drugs to tackle antibiotic-resistant infections.
- Strengthen the global antimicrobial R&D ecosystem to better ensure future global health security.
- Sustain progress made thus far on the Sustainable Development Goals.

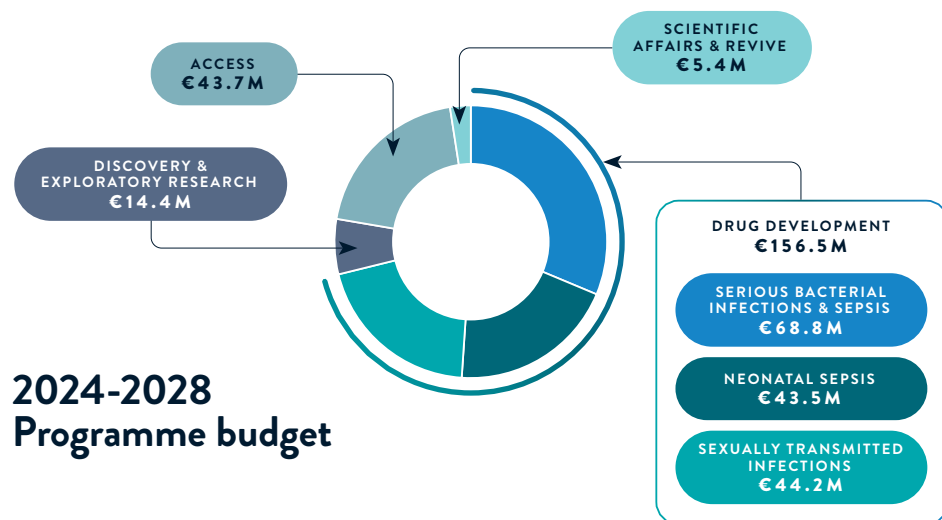
FUNDING REQUIREMENT: ACHIEVING SUCCESS WITH OUR CURRENT PORTFOLIO = €183.8 MILLION

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.

FUNDING REQUIREMENT: EXPANDING OUR TREATMENT 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 creating a reliable ecosystem of antibiotic R&D and access.

TOTAL FUNDING NEED: €220 MILLION



2024-2028 Programme budget



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, unrestricted 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. Fundamentally, unrestricted funds are essential to our ability to implement our unique model and deliver integrated R&D and access.

With flexible funding shrinking every year, GARDP could be at risk of having to convert from a mandate-based organization to one only able to focus on individual projects. **Timely, predictable, and flexible funding are indispensable if we are to seize the opportunities called upon in the Global action plan on antimicrobial resistance⁷** and take advantage of new opportunities that offer exceptionally good value in terms of impact.

For a 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.

“Drug-resistant bacteria represent one of the biggest threats to modern life and it’s on the rise. We must act now, decisively and together, to address this global challenge. Germany is proud to partner with GARDP and will continue to support their work to bring new antibiotic treatments to all.”

Bettina Stark-Watzinger
Federal Minister of Education and Research, Germany

By working in partnership, we can fix the public health failure by ensuring that the right antibiotics are developed and made available to people who need them.

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