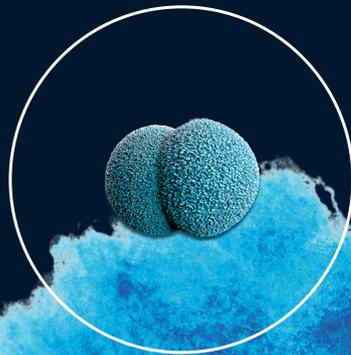


# ACTIVITY REPORT 2019

Global Antibiotic  
Research & Development  
Partnership



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## MESSAGE

# FROM THE BOARD CHAIR & EXECUTIVE DIRECTOR

The 2019 Activity Report shows GARDP's remarkable progress and promise in the fight against the most serious drug-resistant infections. It also demonstrates why more partnerships and investment are critical to address the scourge of antibiotic resistance and achieve the Sustainable Development Goals.

For decades, antibiotic research and development has been in flux, with large pharmaceuticals abandoning the field and small biotech firms failing. Moreover, new antibiotics that are introduced are not reaching the countries and populations where they are most needed. Where incentives have been introduced, they often fail to address stewardship to ensure these powerful drugs are used appropriately. Through partnerships, GARDP aims to change that narrative.

In 2019, we worked to reshape the landscape for late-stage development of new antibiotics targeting areas of greatest need as identified by the World Health Organization (WHO). We completed a phase 1 clinical trial to evaluate the safety of a drug (fosfomycin) to treat newborns with sepsis and rolled out one of the largest studies to date on the care of newborns with bloodstream infections. Given the overall lack of research and development for children, as well as the difficul-

ties involved, these programmes promise to provide evidence to fill knowledge gaps, help transform treatment and save lives.

As part of our partnership with biotech Entasis Therapeutics, we launched a global phase 3 trial for uncomplicated gonorrhoea – the priority focus of GARDP's sexually transmitted infections programme. This programme is a ground-breaking example of a public-private

partnership approach to initially developing a novel antibiotic that prioritizes market access in countries that have high rates of gonorrhoea and for patients who need the treatment most.

The impact of drug-resistant infections is often worst in hospitals, because they are high-risk environments for the spread of infections. We have introduced a programme and undertaken extensive consultations to develop a new treatment for serious bacterial infections (SBIs) for hospitalized adults, a significant step towards tackling difficult and sometimes impossible-to-treat infections. The SBI programme seeks to develop treatments for bacteria identified by the WHO as a 'critical priority' and among the greatest threats to health. GARDP will finalize a new partnership to develop an innovative new treatment in 2020 that will be a significant step towards addressing these threats.

From treatments for neonatal sepsis, to gonorrhoea and SBIs in hospitalized adults, the work GARDP is championing requires clinical and academic researchers equipped with the best possible skills and knowledge. Our REVIVE project seeks to capture old and new knowledge and skills in antimicrobial drug discovery and development, as well as support and connect this community worldwide. The global reach of REVIVE continued to expand throughout 2019,

as our webinars reached people from over 60 countries. Underpinning all these activities was the launch of our goal to deliver five treatments that address high-priority drug-resistant infections by 2025. With a focus on late-stage clinical development and sustainable access, our strategy sets out how we plan to develop treatments for those infections posing the greatest threat to health.

The strategy follows our successful three-year incubation at the Drugs for Neglected Diseases initiative (DNDi). Built on the shared missions of our founding partners - DNDi and WHO - we are truly grateful for their leadership and support during our early years and look forward to continued collaboration.

As a newly independent legal entity, it is important GARDP continues to build a robust governance structure with leading figures in global health. In 2019 we were delighted to welcome Prof Veronika von Messling and Dr Mercedes Tatay to our Board of Directors and Dr Prabhavathi Fernandes as the new Chair of our Scientific Advisory Committee.

None of what we have achieved in the past year could have been done by GARDP alone. Partnership is in our DNA and we are now working with more than 50 organizations in 20 countries. This includes governments, the pharmaceutical and biotech industries, academia and

civil society. We thank the governments of Germany, Japan, Luxembourg, Monaco, Switzerland, the Netherlands and the United Kingdom for their financial commitments in 2019, and all our public and private donors and partners for their remarkable support and dedication to the mission. We also thank GARDP staff for the passion they bring to this critical work.

Antibiotic resistance is a complex problem that poses an immediate threat to health, prosperity and security. The coronavirus disease (COVID-19) pandemic is an unfortunate reminder of the urgency of addressing such risks. Tackling the growing antibiotic resistance crisis will require unified political action at national and international levels, as well as increased investments from the public and private sectors. Investing now in essential technologies and treatments will prevent us from paying a premium in years to come as infectious disease outbreaks and the spread of drug-resistant pathogens worsen.

By acting today, collectively and with urgency, we can deliver novel treatments to safeguard our health now and for generations to come.

**DR. MANICA BALASEGARAM**  
GARDP EXECUTIVE DIRECTOR

**& PROF. RAMANAN  
LAXMINARAYAN**  
GARDP BOARD CHAIR

*"The rise of drug-resistant bacteria is jeopardising decades of progress and threatening our ability to prevent and treat infections that were once easy to treat. GARDP is an essential element of delivering the Global Action Plan on Antimicrobial Resistance."*

**DR. TEDROS ADHANOM GHEBREYESUS**  
DIRECTOR-GENERAL OF THE WORLD HEALTH ORGANIZATION

Antimicrobial resistance (AMR)<sup>1</sup> is a major and rapidly growing global public health threat that risks undermining the attainment of the Sustainable Development Goals (SDGs), in particular SDG3, which aims to ensure healthy lives and promote wellbeing for all.

Approximately **700,000** people worldwide die of drug-resistant infections every year and this number is expected to increase significantly in the future.

Antibiotic resistance is one of the **biggest threats** to global health, food security, and development today.

Very few antibiotics have been developed in the last **25 years.**

## CRISIS

# A GROWING CRISIS

Thanks to the discovery of antibiotics, millions of lives have been saved and previously fatal infections such as bacterial pneumonia and sepsis were cured. Unfortunately, antibiotic resistance is outpacing antibiotic development. Globally, we are seeing an alarming increase in deaths caused by once-treatable infections. These bacteria have been placed on the WHO priority pathogens list, highlighting the critical need for new treatments to be developed.

Previously, many common bacterial infections – whether caused by a simple cut, an open wound, or routine surgery – were easily prevented or treated. Due to drug

resistance, this is no longer the case for many infections. This has a massive impact on the health of people and economies of countries around the world. It is often the

most vulnerable – women, children, the elderly, people with weakened immune systems, and those in countries with weak health systems – who are most at risk.

<sup>1</sup>Antimicrobial resistance happens when microorganisms (such as bacteria, fungi, viruses, and parasites) change when they are exposed to antimicrobial drugs (such as antibiotics, antifungals, antivirals, antimalarials, and anthelmintics). Microorganisms that develop antimicrobial resistance are sometimes referred to as "superbugs" (WHO)

## GOAL

# COMBATING THE ANTIBIOTIC RESISTANCE CRISIS

The Global Antibiotic Research and Development Partnership (GARDP) is a not-for-profit organization developing new treatments for drug-resistant infections that pose the greatest threat to health. We were created to ensure that everyone who needs antibiotics receives effective and affordable treatment, no matter where they live.

GARDP was established in 2016 by WHO and DNDi to deliver on the Global Action Plan on Antimicrobial Resistance. After four years in operation, GARDP has already built a pipeline to tackle sexually transmitted infections as well as infections in hospitalized adults and children, including newborns with sepsis (a blood-stream infection). We have formed over 50 partnerships in 20 coun-

tries that span governments, the biomedical and pharmaceutical industries, research institutions, non-profits, and civil society.

GARDP bridges the gap between innovation and access by focusing on developing candidates in late-stage clinical development. This requires identifying the barriers to access and finding innovative ways to overcome them. We are also

exploring ways to ensure there is a viable market and sustainable supply of treatments in the long-term.

To combat the growing antibiotic crisis, GARDP has set the 5 BY 25 goal, which seeks to deliver five new treatments by 2025 to tackle drug-resistant infections that pose the greatest threat to health and economic security.

## OUR VISION

All infections are treatable for everyone, everywhere.

## OUR MISSION

We bring together the public and private sectors to develop new treatments for bacterial infections. We ensure responsible and sustainable access, addressing the public health impact of antibiotic resistance.

## OUR FOCUS

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

## ADDRESSING STEWARDSHIP AND ACCESS



Efforts to tackle antibiotic-resistant infections must focus on responsible and sustainable access to lifesaving drugs and address issues of stewardship to ensure treatments are used appropriately. **GARDP** strives for a world where everyone who needs antibiotics receives effective, appropriate and affordable treatment, no matter where they live. We continue to work with partners, governments and other agencies to help ensure appropriate policies are

in place to safeguard sustainable access, including within each of our programmes.

In 2019 **GARDP** hosted a workshop on sustainable access to antibiotics, advocated for the development of innovative reimbursement models, and held a meeting in India with regulators from various regions to discuss approaches to clinical trials and registration.



## ENABLING AMR CLINICAL TRIALS IN INDIA

In November 2019, **GARDP**, together with **DNDi** India, and the Indian Council of Medical Research (ICMR) hosted a two-day workshop exploring the practical steps required to develop an AMR clinical trials network in India. This included investigating the evolving regulatory landscape in India and internationally, as well as trial and laboratory site capacity for indication and pathogen-resistant clinical research. The workshop brought

together key Indian stakeholders and international partners including the Food and Drug Administration (FDA), European Medicines Agency (EMA) and **WHO**. **GARDP** and the ICMR agreed to partner together to develop adult and paediatric antibiotic clinical trials with new candidates to treat drug-resistant infections in India.

*“We are in a race against time to develop new antibiotics and make them accessible to the millions of people who need them. **GARDP**’s remarkable progress over the last four years in building strong partnerships and a talented team positions it well to meet this ambitious new goal. We need to work together with all stakeholders, including governments, academia and civil society, philanthropic organizations and the private sector, to make this goal a reality.”*

**PROF. RAMANAN LAXMINARAYAN**  
GARDP’S CHAIR OF THE BOARD

## GARDP AND ITS FOUNDERS: A CLOSE COLLABORATION

Built on the shared missions of **WHO** and **DNDi**, **GARDP** draws its strength from both **WHO**’s mandate to drive the global response to AMR and set health priorities, and **DNDi**’s expertise in harnessing partnerships with the public and private sectors and building a research and development (R&D) pipeline focused on public health needs.

As **GARDP**’s host, **DNDi** provided **GARDP** with its initial governance and support necessary for an effective start-up phase. Going forward, **DNDi** and **GARDP** will continue to collaborate, sharing specialized R&D expertise and capacity, policy advocacy expertise, and some infrastruc-

ture and support services to drive efficiencies. In-country implementation of **GARDP**’s programmes will be supported by **DNDi**’s regional network and a joint **DNDi-GARDP** office in Southern Africa.

**WHO** and **GARDP** will continue their close collaboration. **WHO** provides support in setting public health priorities, defining target product profiles, and developing strategies for regulatory approval and access and appropriate use. **WHO** will also continue to garner more Member States support, and ensure effective liaison with relevant **WHO** technical departments.



## HIGHLIGHTS

# 2019 HIGHLIGHTS

2019 has been a landmark year for GARDP. We have built on last year's successes and made significant progress in addressing drug-resistant infections in children and newborns, and sexually transmitted infections. 2019 also marked the creation of a new GARDP programme focused on tackling serious bacterial infections in hospitalized adults and children, as well as the launch of our new business plan and 5 BY 25 goal.

## JANUARY

- GARDP organized a session on developing a new treatment for sexually transmitted infections at the Antimicrobial Chemotherapy Conference in London.
- GARDP launched its Twitter and LinkedIn channels.

## FEBRUARY

- GARDP and partners completed recruitment for a clinical study to better understand the pharmacokinetics and safety of the antibiotic fosfomicin in newborns (less than 28 days) with clinical sepsis. This study, conducted in Kilifi (Kenya), will provide evidence to support the development of new antibiotic treatments for this vulnerable population.

## MARCH

- GARDP partnered with Penta, the paediatric infectious diseases research network based in Italy, to tackle drug-resistant infections in children and newborns. The strategic collaboration aims to accelerate paediatric development of antibiotic treatments.
- GARDP joined forces with Evotec to tackle the growing threat of drug resistance. This strategic partnership focuses on accelerating the development of first-in-class antibiotic treatments for hard-to-treat bacterial infections by establishing a platform that spans the length of the drug development value chain as well as developing a joint pipeline.

## APRIL

- GARDP partnered with Calibr, the Helmholtz Institute for Pharmaceutical Research Saarland (HIPS), and the University of Queensland's Community for Open Antimicrobial Drug Discovery (CO-ADD) in its efforts to discover novel compounds or combinations of drugs that will treat the priority drug-resistant infections identified by the WHO.
- GARDP becomes an independent legal entity following a successful three-year incubation by DNDi. GARDP continues close relationship with its founders, securing a new 3-year collaboration with DNDi and maintaining strong ties with WHO.
- The report to the Secretary-General of the United Nations by the Interagency Coordination Group (IACG) on Antimicrobial Resistance acknowledged the important and encouraging role of GARDP and other initiatives and recommended full and sustained funding.

## MAY

- The Principality of Monaco announced an investment of EUR 400,000 to GARDP. The funds will be used to support the programme to combat neonatal sepsis in South Africa.
- GARDP organized an event during the World Health Assembly addressing the global antibiotic resistance crisis, featuring talks from South African and German government representatives, WHO and the Wellcome Trust.

## JUNE

- GARDP announced its 5 BY 25 goal to deliver five new treatments by 2025 in response to the growing threat of antibiotic resistance. GARDP's five treatments will focus on the priority drug-resistant infections identified by WHO.

5BY25

## JULY

- Switzerland invested an additional CHF 500,000 to support GARDP's activities, bringing its total funding to CHF 1.4 million.
- GARDP, in collaboration with the Medicines Patent Pool and WHO, organized a workshop on sustainable access to antibiotics. Over 50 stakeholders from across the antibiotic R&D value chain came together to identify ways to transform principles into practical access and stewardship interventions.

## AUGUST

- GARDP and FIND welcomed the creation of an Australian Research Council Research Hub to Combat Antimicrobial Resistance, led by the Kirby Institute. GARDP will contribute AUD 400,000 over the next five years to the hub, which will focus on sexually transmitted infections - a critical area of concern in Australia.

## SEPTEMBER

- GARDP joined forces with Entasis Therapeutics, a clinical-stage biopharmaceutical company, to launch a global phase 3 pivotal trial of zoliflodacin. Zoliflodacin is a new, first-in-class oral antibiotic being developed for the treatment of uncomplicated gonorrhoea.

## OCTOBER

- GARDP launched its new business plan for 2020-2025 at the World Health Summit in Berlin. "Uniting against antibiotic resistance: delivering 5 BY 25" maps out how GARDP plans to develop five new treatments for drug-resistant infections by 2025. GARDP is seeking EUR 500 million from governments, philanthropic, public and private organizations to develop these treatments.
- Japan made a multi-year pledge to GARDP of JPY 1 billion, the Netherlands renewed its commitment with an investment of EUR 5 million, and the United Kingdom announced GBP 3.5 million of continued funding to develop new treatments for gonorrhoea.

- Prof Veronika von Messling, who heads the Life Science Directorate-General of Germany's Federal Ministry of Education and Research, joined the GARDP Board and Dr Prabhavathi Fernandes, an expert in drug discovery and development, was selected as Chair of GARDP's Scientific Advisory Committee.
- The Okayama Declaration of the G20 Health Ministers welcomed the recent work done by AMR R&D initiatives such as GARDP and renewed calls for further investment.

- GARDP and partners achieved the first milestone in the AMR Screening Consortium by completing the screening of Takeda's and Eisai's compound libraries for new antibiotics.

## NOVEMBER

- GARDP's Executive Director was a key speaker at the World Conference on Access to Medical Products - Achieving the SDGs 2030, held in New Delhi, India.
- GARDP and the Indian Council of Medical Research organized a workshop to map out the opportunities and challenges of carrying out clinical trials of new antibiotics in India. Participants discussed the potential for India to take a greater role in the clinical evaluation of new treatments.

## DECEMBER

- GARDP and partners enrolled 3000 babies in one of the largest international observational studies on neonatal sepsis, reaching 90% of the recruitment target. This study conducted at 19 sites in 11 countries will provide key data on how neonatal sepsis is managed and the impact of antibiotic resistance on treatment and outcomes.
- Dr Mercedes Tatay, International Medical Secretary for Médecins Sans Frontières, joined the GARDP Board for a three-year term.
- Germany and the United Kingdom invested additional funding in GARDP, signalling their leadership in tackling antibiotic resistance - Germany with EUR 1 million, bringing their total funding to GARDP to EUR 55.1 million; and the United Kingdom with GBP 4 million (focus on neonatal sepsis), bringing their total funding to GARDP to GBP 11.5 million.

BUSINESS PLAN

# GARDP BUSINESS PLAN & 5 BY 25

At the World Health Summit in Berlin in October 2019, GARDP launched its new business plan for 2020-2025 outlining how it will deliver the 5 BY 25 goal, which seeks to deliver five new treatments by 2025 to tackle drug-resistant infections that pose the greatest threat to health and economic security.

We call on governments, philanthropic, private and public organizations to help us raise the **EUR 500 million** needed to reach the **5 BY 25 goal**.

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

| RESEARCH & DEVELOPMENT                  | PORTFOLIO AND PARTNERSHIPS                                     | SUSTAINABLE ACCESS         |
|---|--|----------------------------|
| Public health needs                     | Build a portfolio with the public and private sectors          | Global regulatory approach |
| In-house expertise                      | In-kind and direct contributions with returns for access       | Outsourcing strategies     |
| Clinical and pharmaceutical development | Rights to develop, register and deliver new tools              | Reimbursement models       |
| Label extension and evidence generation | Strengthen clinical trial networks                             | Procurement strategies     |
| Discovery and exploratory research      | Enrich the R&D ecosystem                                       | Policy and guidelines      |
|   | Advocate for public needs driven and sustainable R&D ecosystem | Out-licensing              |



*“WHO strongly welcomes the progress of **GARDP** to date and its new ambitious 5 BY 25 goal which complements **WHO**’s Global Action Plan on AMR. We call on all key actors to support and collaborate with **GARDP** in line with the UN Interagency Coordination Group on AMR.”*

**DR. HANAN H. BALKHY**  
ASSISTANT DIRECTOR-GENERAL FOR ANTIMICROBIAL RESISTANCE,  
WORLD HEALTH ORGANIZATION

## GARDP WILL DEVELOP TREATMENTS FOR

- Serious bacterial infections
- Children – neonatal sepsis and paediatric antibiotics
- Sexually transmitted infections

### HOW?

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

## CHILDREN'S ANTIBIOTICS

# TACKLING DRUG-RESISTANT INFECTIONS IN CHILDREN & NEWBORNS

Tackling drug resistance and its effects on children is critical to achieving the Sustainable Development Goals (SDGs), particularly the children's health targets under SDG 3, which aims to ensure healthy lives and promote wellbeing for all. Prioritising the development of child-friendly antibiotics is an essential component of this.

Children, particularly babies and infants, need medicines that are adapted to their specific needs. Scarce evidence means child-friendly antibiotic treatment options are often limited, with paediatric evaluation of antibiotics only happening years after treatments are registered for use in adults, if at all.

To address this, **GARDP** partnered with Penta, the paediatric infectious diseases research network based in Italy, to develop a global children's antibiotic platform. By leveraging Penta's international network of clinical trial sites and paediatric experts, **GARDP** has strengthened its relationships with academic and government institutions across Asia, Africa, Europe and Latin America.

Activities include a pharmacokinetic clinical trial in Kenya to assess safety and dosing of the antibiotic fosfomycin in newborns, which recently completed enrolment (results to be announced in 2020); and one of

the largest observational studies on neonatal sepsis, collecting clinical information from more than 3,000 newborns in 19 hospitals in 11 countries. Outcomes such as antibiotic use, duration of treatment and mortality rates have been recorded and analysed.

The observational study will help build the evidence base needed to evaluate future interventions that could be used to treat neonatal sepsis. **GARDP** has also begun testing possible combination treatments – amikacin, fosfomycin and flomoxef – that will inform the design of the clinical trial for neonatal sepsis.

In 2019 **GARDP** also submitted a paediatric investigation plan for polymyxin B – a priority antibiotic identified for paediatric development – to the European Medicines Agency (EMA). Initial registration in Europe will help facilitate access to polymyxin B in other parts of the world, including countries with a high burden of drug resistance in Africa and Asia.

## PUTTING CHILDREN FIRST: A HARD-TO-TREAT POPULATION

More than **3 million** childhood deaths result from infectious diseases every year.

Infectious diseases are the leading cause of death and disability in children. **More than half** of all deaths in children under five are in newborns.

In Europe, a recent study found that **infants under the age of 1** bear the highest burden of drug-resistant infections.

Sepsis is a leading cause of death and disability in children under 5. About **3 million** newborns suffer from it every year.

*“Clinical trials in children involve highly complex ethical, regulatory and study-design issues. This partnership consolidates existing efforts between **GARDP** and **Penta**, allowing us to maximise our expertise in the fields of paediatric treatments and AMR, including Penta’s strong partnership with the Medical Research Council’s Clinical Trial Unit in London.”*

**PROF. CARLO GIAQUINTO**  
PRESIDENT, PENTA FOUNDATION

## CHILDREN'S ANTIBIOTICS

# A LIFESAVING TREATMENT FOR NEONATAL SEPSIS

Every year, up to 3 million newborns are diagnosed with neonatal sepsis, a life-threatening bloodstream infection. Most of these infections happen in low- and middle-income countries

Despite the high death rate from newborn infections, there are few antibiotics specifically licensed for use with babies and children. **GARDP** is working with partners, including the **KEMRI/Wellcome Trust Research Programme** based in Kilifi, Kenya, to evaluate the dosage and safety of the existing antibiotic fosfomycin to treat neonatal sepsis.



Mercelyne Chengo, from the Kiwandani area of Kilifi, holds her son Khalid, who was treated at the Kilifi District Hospital for neonatal sepsis. A first-time mother, Mercelyne explains she was terrified when the hospital told her that her son had sepsis. She knows many babies with sepsis don't survive. Khalid was treated and Mercelyne and her son were able to return home.

Winnie Mkare lives with her husband and four children in Matano Manne village, an hour's drive from the nearest hospital. Shortly after the birth of her daughter, Patience, the baby developed a dangerously high temperature. Patience was rushed to the paediatric ward of the Kilifi District Hospital where she was diagnosed with neonatal sepsis. Winnie says she didn't know if her daughter would survive. Patience was able to receive treatment and is today recovering at home with her family.



Patience is held by her sister, Grace. While Patience was successfully treated for neonatal sepsis, around 1 million babies die every year due to this condition. The World Health Organization has called for urgent action on neonatal sepsis to achieve Sustainable Development Goal 3: Ensure healthy lives and promote well-being for all.

## SEXUALLY TRANSMITTED INFECTIONS

# TACKLING THE RISE OF DRUG-RESISTANT GONORRHOEA

Global infection rates of drug-resistant gonorrhoea, a common sexually transmitted infection (STI), are on the rise and rapidly outpacing the development of new medicines. If left untreated, gonorrhoea can have serious consequences for reproductive health and can increase the transmission risk of HIV and other STIs. Vulnerable populations, such as women, and marginalised groups, are disproportionately affected.

In 2019, **GARDP** and Entasis Therapeutics, a clinical-stage biopharmaceutical company, significantly advanced the development of zoliflodacin, a new, first-in-class oral antibiotic for the treatment of uncomplicated gonorrhoea. Following positive phase 2 results published in the *New England Journal of Medicine*, Entasis and **GARDP** partnered to complete late-stage development, with **GARDP** sponsoring and funding the global phase 3 trial.

Clinical pharmacology and pharmacokinetic modelling studies were completed to confirm a safe and effective dose of zoliflodacin for evaluation in patients with uncomplicated gonorrhoea.

In September, the global phase 3 trial of zoliflodacin was launched with the first sites activating in the United States. **GARDP**, which is fully-funding and sponsoring the global phase 3 trial, supported the formulation and manufacturing activities to ensure clinical supplies were

available for the trial. This work will in turn allow for the regulatory acceptability of manufacturing the final drug product in 2020.

Novel laboratory models were established and work began to assess possible combinations of zoliflodacin for the syndromic management of gonorrhoea and associated infections. These clinical studies will also establish the potential of such combinations to delay the emergence of resistance to zoliflodacin.

The phase 3 trial is expected to enrol approximately 1,000 adults with urogenital gonorrhoea from clinical trial sites in the United States, Netherlands, Thailand and South Africa.

In parallel to the clinical trials, **GARDP** launched several activities to define its zoliflodacin sustainable access and stewardship strategy targeting low- and middle-income countries.

Gonorrhoea is a common STI affecting both men and women, particularly between **15 and 24 years old**.

Globally the infection rate of gonorrhoea is increasing, **with 87 million** new cases estimated each year.<sup>2</sup>

*“The initiation of the phase 3 trial of zoliflodacin is an important milestone and brings hope for people affected by this disease. Our partnership with Entasis is critical for preventing the dire scenario of untreatable gonorrhoea and controlling this infection. The global nature of the trial, across four continents, represents our commitment to ensuring this treatment is available to anyone who needs it, wherever they live.”*

**DR. MANICA BALASEGARAM**  
GARDP EXECUTIVE DIRECTOR

<sup>2</sup> [https://www.who.int/en/news-room/fact-sheets/detail/sexually-transmitted-infections-\(stis\)](https://www.who.int/en/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis))

SEXUALLY TRANSMITTED INFECTIONS

# SEX DETECTIVE

Globally the infection rate of gonorrhoea is increasing, with 87 million new cases each year. Gonorrhoea has progressively developed resistance to recommended treatments and has been identified by the WHO as among a family of drug-resistant priority pathogens posing the greatest threat to public health.

GARDP is working on a novel antibiotic called zoliflodacin, the only drug being developed specifically to treat gonorrhoea. The treatment is currently being evaluated in a global phase 3 trial. One of the sites where the drug is being trialled is in the US city of Birmingham, Alabama.

*Melissa Nelson is a disease intervention specialist with the Jefferson County Department of Health, in Birmingham, Alabama. When she is alerted that someone in her county has been diagnosed with a sexually-transmitted infection (STI), her job is to investigate where the infection has come from and to stop it from being spread further. "People will affectionately call us 'sex detectives,'" she says.*

*Melissa's day typically starts in her Birmingham-based office, where she receives notification of STI cases like gonorrhoea. However, much of her time is spent on the road, tracing people in order to provide them with education, counseling and linkages to care and treatment.*



*Outbreaks of STIs can be especially difficult to contain because of stigma: people might not want official records of their infections, or they might not know or be unwilling to report the names of sexual partners. This means the work of a disease intervention specialist requires tact and discretion, alongside strong relationships with the local community. "We're community workers in a sense," says Melissa. "Whether it be at churches or at mosques, people know us and trust us."*

SERIOUS BACTERIAL INFECTIONS

# PRIORITIZING HOSPITAL INFECTIONS

Serious bacterial infections are among the major causes of death for people in hospitals. Each year, about 1.7 million hospitalized people in the US acquire secondary bacterial infections while being treated for other health issues. Bacteria can enter the body through wounds and surgery sites, ventilators and catheters, leading to pneumonia, urinary tract, abdominal and bloodstream infections.

The impact of drug-resistant infections is often worst in hospitals, because they are high-risk environments for the spread of infections. This is particularly the case for infections caused by drug-resistant Gram-negative bacteria. The threat of drug resistance is more severe in low- and middle-income countries, where healthcare facilities can face constraints on hygiene and sanitation, including access to sterilizing equipment. GARDP is developing new treatments for the most resistant Gram-negative infections.

## COST OF HOSPITAL INFECTIONS

Serious bacterial infections lead to longer hospital stays, long-term disability and more preventable deaths. In Europe alone, hospital infections cause 16 million extra days of hospital stay and 37,000 deaths every year. Hospital infections also hurt economic growth, costing the European economy EUR 7 billion and US economy USD 6.5 billion annually. In low- and middle-income countries, where less data is available,

indicators suggest the financial impact is even more severe. Developing new treatments to fight hospital infections frees up more money to invest in healthcare and fuels economic development.

## GARDP'S RESPONSE

GARDP aims to develop, in partnership with innovators, new treatments to address serious bacterial infections in hospitalized adults and children for which there are limited or no treatment options. These include hospital-acquired pneumonia, intra-abdominal infections, complicated urinary tract infections and bloodstream infections.

To date, GARDP has evaluated the late-stage clinical pipeline and old antibiotics to identify any potential treatments which may address our priorities and have a global health impact. We have identified drug candidates and are developing new partnerships to evaluate their efficacy against multidrug-resistant bacteria.

In high-income countries, **7%** of all hospitalized people will contract some form of infection, including one in three people in intensive care units. In low- and middle-income countries this figure rises to at least **10%** of hospitalized people, and up to half of people in intensive care units.

DISCOVERY & EXPLORATORY

# ADVANCING ANTIBIOTIC R&D

GARDP's discovery and exploratory programme focuses on three activities - discovery and exploratory research; asset evaluation and development; and external scientific affairs and REVIVE.

## DISCOVERY & EXPLORATORY RESEARCH

GARDP's discovery and exploratory research programme is screening natural product extracts and compounds as well as chemical compound libraries for activity against drug-resistant infections that urgently require new treatments.

In April, GARDP partnered with Calibr, the Helmholtz Centre for Infection Research (HZI), and the University of Queensland's Community for Open Antimicrobial Drug Discovery (CO-ADD) in its efforts to discover novel compounds or combinations of drugs that will treat priority drug-resistant infections identified by WHO.

GARDP, together with the Institut Pasteur Korea, achieved the first milestone in its AMR Screening Consortium by completing the screening of Takeda's and Eisai's compound libraries for new antibiotics. Exciting results have been obtained, which are being followed up in 2020.

These are our first discovery collaborations and contribute to the expansion of GARDP's R&D ecosystem by linking partners in Australia, Germany, Japan, Korea and the US.

## ASSET EVALUATION & DEVELOPMENT

Using new science and technological advances, GARDP is also working to repurpose under-used or forgotten compounds alone or in combination. GARDP completed a thorough evaluation of antibiotic candidates both in development and registered and selected priority candidates to enter into its paediatric and serious bacterial infections programmes.

## EXTERNAL SCIENTIFIC AFFAIRS & REVIVE

REVIVE, GARDP's online knowledge sharing platform on antimicrobial R&D, enables all researchers in the antimicrobial field to benefit from the experience and knowledge of recognized experts. Our external scientific affairs activities, including REVIVE, are

helping to advance the development of new antimicrobial drugs by capturing and sharing the knowledge and skills of experts and making it freely accessible by all.

In 2019 alone, over 1,500 participants from more than 60 countries took part in 13 REVIVE webinars led by experts in their field. Thirteen international experts from various fields, including economics, antimicrobial stewardship and drug development, published Antimicrobial Viewpoints on the REVIVE website.

GARDP developed content and co-organized symposia, bootcamps and workshops with the British Society for Antimicrobial Chemotherapy, CARB-X, JPIAMR, REPAIR Impact Fund and the Wellcome Trust at leading international scientific conferences.

GARDP provides these resources to the global health community free of charge to everyone worldwide. All conference sessions were recorded and hosted on the REVIVE website - [revive.gardp.org](http://revive.gardp.org).



## THREE AIMS OF REVIVE



FINANCE

# INCOME

## RENEWED FUNDING SHOWS COMMITMENT TO GARDP MISSION

The German Federal Ministry of Health (BMG), the UK's Department of Health and Social Care (DHSC), the Netherlands Ministry of Health, Welfare and Sport (VWS), the Swiss Federal Office of Public Health (FOPH) and the Grand-Duchy of Luxembourg all renewed their financial support to **GARDP** in 2019 by contributing a total of EUR 10.6 million to **GARDP** programmes. The Leo Model Foundation also extended its support to **GARDP** with an additional USD 50,000.

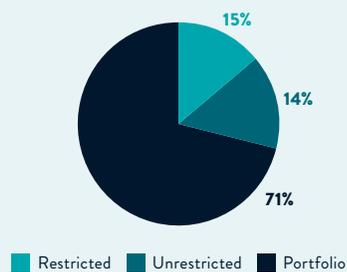
| PUBLIC CONTRIBUTORS 2016 - 2024        | EUR    |
|--|--------|
| Germany (BMBF and BMG)                 | 55.1 M |
| United Kingdom (DFID, DHSC and NIHR)   | 13.5 M |
| The Netherlands (VWS)                  | 7.5 M  |
| Switzerland (FOPH)                     | 1.2 M  |
| South African Medical Research Council | 0.6 M  |
| Grand Duchy of Luxemburg               | 0.1 M  |
| Principality of Monaco                 | 0.4 M  |

| PRIVATE CONTRIBUTORS 2016 - 2024                        | EUR   |
|---|-------|
| Bill & Melinda Gates Foundation                         | 1.8 M |
| Wellcome Trust  | 1.1 M |
| Others (Médecins Sans Frontières, Leo Model Foundation) | 0.7 M |

## NEW DONORS COMMIT FUNDS

The Principality of Monaco became a new donor in 2019 contributing EUR 400,000. The Japanese government made a multi-year pledge of JPY 1billion (EUR 8.3 million), and the UK's National Institute for Health Research (NIHR) invested EUR 4.5 million. By the end of the year, **GARDP** had secured a cumulative total of EUR 90 million in commitments and pledges.

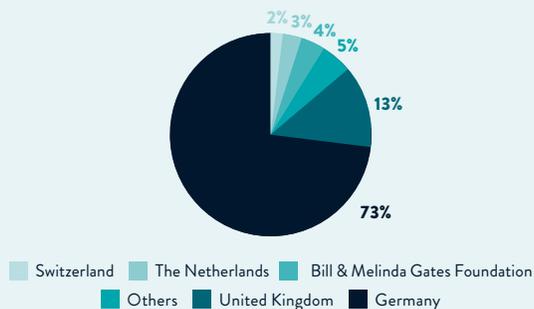
Fund types  
(In million EUR)



## 71% PORTFOLIO FUNDING

**GARDP** aims to maintain a balance between restricted and unrestricted grants. However, a strong trend of portfolio funds still puts **GARDP** in a good position to respond quickly to research opportunities within a broad portfolio of projects. In 2019, **GARDP** increased both its restricted and unrestricted funding. Balanced and flexible funding allows **GARDP** to effectively manage its priorities at both programmatic and portfolio levels.

2019 donor funding



FINANCE

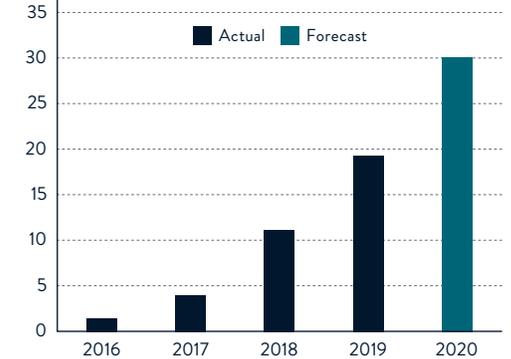
# EXPENDITURE

## STEADY GROWTH IN SPENDING, CONCENTRATED ON R&D

- Expenditure totalled EUR 18.9M in 2019, an increase of 69% (+ EUR 7.7 M) compared to 2018
- Spending on social mission equated to 87% of the EUR 18.9M with R&D expenditure totalling EUR 15.4M
- GARDP** expenditure totals EUR 35.3M since the start of its incubation within DNDi in 2016

An increase in 2020 expenditure is expected due to new collaborations and increased clinical research activity.

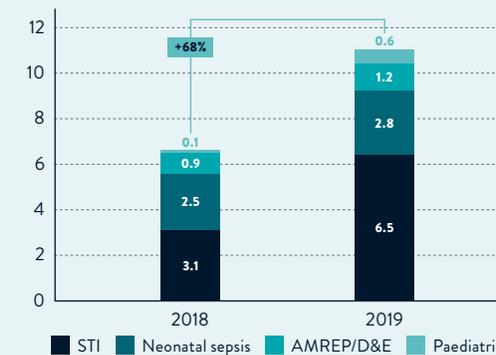
Actual expenditure 2016-2019 and forecasted 2020  
(In million EUR)



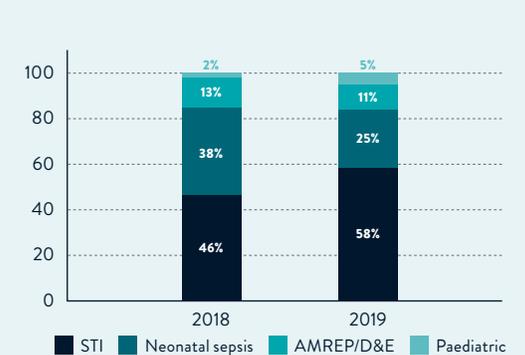
## R&D EXPENDITURE

R&D spending per programme increased significantly in 2019 over 2018 (+ EUR 4.6M), with the largest proportion still being spent within the Children's Antibiotics - Neonatal Sepsis and Sexually Transmitted Infections programmes.

R&D expenses per programme  
(In million EUR)



R&D expenses per programme  
(In %)



In 2019 the AMREP programme was renamed Discovery & Exploratory including: Asset Evaluation & Development, Discovery & Exploratory Research, and External Scientific Affairs and REVIVE. **GARDP** is also in the process of initiating a new Serious Bacterial Infections (SBI) programme with development of capabilities and capacity to undertake hospital-based adult clinical trials via **GARDP** bespoke networks.

## FINANCE

# STATEMENT OF OPERATIONS

## AT 31 DECEMBER 2019 WITH COMPARATIVE FIGURES

| INCOME (EUR)  | 2019              | 2018              |
|---|-------------------|-------------------|
| Total public institutional funding                  | 17'402'268        | 10'213'611        |
| Total private funding                               | 1'515'832         | 965'964           |
| Other income  | 6'412             | 1'406             |
| <b>TOTAL INCOME</b>                                 | <b>18'924'512</b> | <b>11'180'980</b> |
| SOCIAL MISSION EXPENDITURE (EUR)                    | 2019              | 2018              |
| Research & development coordination and supervision | 4'250'544         | 3'215'581         |
| Antimicrobial Memory Recovery and Exploratory       | 1'236'462         | 862'708           |
| Children's Antibiotics - Neonatal Sepsis            | 2'801'705         | 2'480'991         |
| Sexually Transmitted Infections                     | 6'510'041         | 3'065'379         |
| Children's Antibiotics - Paediatric                 | 640'190           | 138'022           |
| <b>Total research &amp; development expenditure</b> | <b>15'438'942</b> | <b>9'762'681</b>  |
| International network                               | 1'049'697         | 485'349           |
| <b>TOTAL SOCIAL MISSION EXPENDITURE</b>             | <b>16'488'639</b> | <b>10'248'031</b> |
| NON-SOCIAL MISSION EXPENDITURE (EUR)                | 2019              | 2018              |
| Fundraising & General and Administration            | 2'386'869         | 931'544           |
| <b>Total non-social mission expenditure</b>         | <b>2'386'869</b>  | <b>931'544</b>    |
| <b>TOTAL EXPENDITURE</b>                            | <b>18'875'508</b> | <b>11'179'575</b> |
| Operating surplus / (loss)                          | 49'004            | 1'405             |
| OTHER INCOME (EXPENSES) (EUR)                       | 2019              | 2018              |
| Financial income, net                               | 572               | (37)              |
| Exchange gain (loss), net                           | (47'336)          | (11)              |
| <b>TOTAL OTHER INCOME (EXPENSES)</b>                | <b>(46'763)</b>   | <b>(49)</b>       |
| Net surplus for the year prior to allocations       | 2'240             | 1'356             |
| Allocation to unrestricted operating funds          | (2'240)           | (1'356)           |
| <b>NET SURPLUS FOR THE YEAR AFTER ALLOCATIONS</b>   | <b>-</b>          | <b>-</b>          |

Extracted from the unaudited GARDP "2019 Financial and Performance Report". The full report, audited by Deloitte, will be available in July 2020 on [www.gardp.org](http://www.gardp.org)

## PARTNERS

# THE POWER OF PARTNERSHIPS

## A WORD OF THANKS

No single country or actor can fight drug resistance alone. It can only be done in partnership. **GARDP** brings together the public and private sectors, leveraging their resources and expertise to deliver new treatments for drug-resistant infections. By investing in **GARDP**, governments are investing in the future well-being of their citizens and the rest of humanity. Together with private sector partners, including philanthropists, we are working towards a world where all infections are treatable for everyone, everywhere. Thank you for your loyal commitment and support.



*“AMR is a global problem that affects all countries, rich and poor alike. Because no country can solve this alone, joint efforts across different sectors are crucial. All nations must take responsibility and come together with innovative R&D solutions to address this global issue. This is why Germany strongly supports **GARDP** in bringing together all relevant stakeholders to achieve the ambitious goals that have been set. We encourage other countries to join in tackling **AMR**.”*

**ANJA KARLICZEK**

GERMAN FEDERAL MINISTER FOR EDUCATION AND RESEARCH

## PARTNERS

# AT THE HEART OF GARDP'S WORK

Partnerships with governments, academia, research centres and industry are at the heart of GARDP's work. Without the support of partners, GARDP would not have been able to make the progress it has made so far:

**AUSTRALIA**

Australian Research Council (ARC)  
Research Hub to Combat Antimicrobial Resistance

University of Queensland's Community for Open Antimicrobial Drug Discovery (CO-ADD)

Kirby Institute

Melbourne Sexual Health Clinic

**BELGIUM**

University of Antwerp

**DENMARK**

REPAIR Fund

**GERMANY**

Evotec

InfectoPharm

Helmholtz-Institute for Pharmaceutical Research Saarland (HIPS)

**INDIA**

The All India Institute of Medical Sciences

The Indian Council of Medical Research

Dr Reddy's

**ITALY**

Penta Foundation

**JAPAN**

Eisai

Takeda

## JOINT PROGRAMMING INITIATIVE ON ANTIMICROBIAL RESISTANCE (JPIAMR)

**KENYA**

KEMRI-Wellcome Trust Research Programme

**KOREA**

Institut Pasteur Korea

**THE NETHERLANDS**

Department of Infectious Diseases, Public Health Service Amsterdam

**SOUTH AFRICA**

National Institute for Communicable Diseases

South African Medical Research Council

Stellenbosch University

University of KwaZulu Natal

Wits RHI, University of Witwatersrand

Wits Health Consortium

**SPAIN**

European Society of Clinical Microbiology and Infectious Diseases

**SWEDEN**

WHO Collaborating Centre for STIs, University Hospital Örebro

**SWITZERLAND**

Foundation for Innovative New Diagnostics (FIND)

Sandoz (Novartis generics division)

World Health Organization (WHO)

Drugs for Neglected Diseases initiative (DNDi)

**THAILAND**

Bureau of AIDS, TB, and STIs

Department of Disease Control

Thai Ministry of Public Health

Thailand US CDC Collaboration

Thai Red Cross AIDS Research Center

University of Mahidol, Tropical Medicine Hospital

**UNITED KINGDOM**

British Society of Antimicrobial Chemotherapy

St George's, University of London

Institute of Child Health, University College, London

The Medical Research Council – Clinical Trial Unit at University College, London

The University of Liverpool

The Wellcome Trust

Oxford University

**UNITED STATES**

American Society of Microbiology CARB-X

Entasis Therapeutics

National Institute of Allergy and Infectious Diseases (NIAID)

National Institutes of Health (NIH)

Pew Charitable Trusts

University of Alabama

University of Florida

## Research centres collaborating with GARDP on specific studies in the following countries:

Bangladesh, Brazil, China, Greece, India, Italy, Kenya, Netherlands, South Africa, Thailand, Uganda, the United States and Vietnam.

## EXECUTIVE STRUCTURE

# GOVERNANCE & MANAGEMENT

## BOARD OF DIRECTORS

GARDP's Board of Directors is the ultimate policy and decision-making authority and includes leading international figures in global health. The Board determines GARDP's strategic goals and ensures the management works efficiently to meet these goals. In 2019, a new governance structure was developed as GARDP became an independent legal entity. The Board set up three subcommittees – strategic partnerships; nominations; remunerations and safeguarding; and audit. Two advisory committees have also been set up: Scientific Advisory Committee and the Donor Partnership Advisory Committee (to be convened in 2020).

## BOARD MEMBERS

**Ramanan LAXMINARAYAN**

*Chair, Centre for Disease Dynamics, Economics and Policy, USA*

**Marie-Paule KIENY**

*Vice-chair, Institut national de la santé et de la recherche médicale, INSERM, France*

**Frédéric VALLAT**

*Treasurer, Ville de Genève, Switzerland*

**Glenda GRAY**

*South African Medical Research Council, South Africa*

**Mercedes TATAY**

*Médecins Sans Frontières*

**Veronika VON MESSLING**

*Federal Ministry of Education and Research (BMBF), Germany*

## OBSERVERS

**Manica BALASEGARAM**

*Ex officio, GARDP*

**Bernard PÉCOUL**

*Drugs for Neglected Diseases initiative, Switzerland*

**Soumya SWAMINATHAN**

*World Health Organization*

**Prabhavathi FERNANDES**

*Chair of GARDP Scientific Advisory Committee*

## SCIENTIFIC ADVISORY COMMITTEE

**GARDP's** Scientific Advisory Committee (SAC) is made up of scientists with expertise in various disciplines within infectious diseases and microbiology. The SAC has a consultative function: its members advise **GARDP's** Board of Directors in order to carry out **GARDP's** scientific objectives, assess its scientific strategy and projects and provide guidance and medical and scientific expertise to **GARDP's** programmes.

### MEMBERS

**Prabhavathi FERNANDES**

*Member and incoming Chair*

**Karl-Heinz ALTMANN**

*Swiss Federal Institute of Technology, Switzerland*

**Rashmi H BARBHAIYA**

*Advinus Therapeutics, India (member until May)*

**George DRUSANO**

*Institute for Therapeutic Innovation, University of Florida, USA (member until Oct)*

**David SHLAES**

*formerly Case Western Reserve University, USA (member until Nov)*

**Anthony COATES**

*St George's University, UK*

**Mark J GOLDBERGER**

*formerly AbbVie, USA*

**Jutta HEIM**

*University of Basel, Switzerland (Chair until Nov)*

**Kazuki HOSHINO**

*Daiichi Sankyo Biotech, Japan*

**Rudo MATHIVHA**

*Chris Hani Baragwanath Hospital, South Africa*

**Marc MENDELSON**

*University of Cape Town, South Africa*

**Malcolm PAGE**

*formerly Roche, Switzerland*

**Kamini WALIA**

*Indian Council of Medical Research, India*

**Nicholas WHITE**

*Mahidol University, Thailand*

### OBSERVERS

**Graeme BILBE**

*Drugs for Neglected Diseases initiative, Switzerland*

**Jorgen STASSIJNS**

*Médecins Sans Frontières, Belgium*

**Tim JINKS**

*The Wellcome Trust, United Kingdom (observer until May)*

**Andreas RUMMELT**

*InterPharmaLink AG, Switzerland*

**Nicola MAGRINI**

*WHO, Switzerland*

## GARDP LEADERSHIP & PROGRAMMES

**GARDP's** leadership team and staff work to deliver on our vision by supporting the R&D ecosystem while developing and securing sustainable access to new treatments.

**GARDP** has a flexible R&D operating model that enables cross-functional project leadership integrating technical disciplines from across **GARDP** and our partners. At the core of the model is a collaborative project team focussing on the development of a drug and delivery of an antibiotic treatment. The collaborative project teams lead by **GARDP** project leaders follow development plans underpinned by target treatment/product profiles with progress reviewed via **GARDP** R&D governance and a **GARDP** Board-appointed Scientific Advisory Committee.

### MANAGEMENT TEAM

**Manica BALASEGARAM**

*Executive Director*

**Seamus O'BRIEN**

*Research & Development Director*

**Jean-Pierre PACCAUD**

*Business Development and Corporate Strategy Director*

**Jennifer KATZ**

*External Affairs Director*

**Laura PIDDOCK**

*Scientific Affairs Director*

**Pierre-Yves DELHEZ**

*Internal Operations Director*

### PROGRAMME LEADS

**Emilie ALIROL**

*Sexually Transmitted Infections Project Leader*

**Sally ELLIS**

*Children's Antibiotics Project Leader*

**François FRANCESCHI**

*Asset Evaluation and Development Project Leader*

**Julie MIRALVES**

*R&D Portfolio and Planning Lead*

## INTERNATIONAL NETWORK

**GARDP**, through DNDi, has a global presence with offices in several regions, including Africa, North America, Latin America and South Asia, and country offices in Japan and India. In-country implementation of **GARDP's** programmes is supported by these offices and a joint DNDi-**GARDP** office in Southern Africa. **GARDP** also has representation in Australia.



## TIMELINE

# GARDP JOURNEY

## ACTION PLAN

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

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

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

2015

2014

## BIRTH

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

2016

## LAUNCH

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

First scientific consultation is held at Institut Pasteur.

2017

## FUNDING

GARDP secures EUR 6.5M in seed funding; the team has increased to 17 people by the end of the year.

First GARDP business plan outlining an R&D strategy is published.

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

## PROGRAMMES

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

First GARDP programmes on sexually transmitted infections and neonatal sepsis are launched. Two further programmes – paediatrics and an antimicrobial exploratory program – follow.

## INDEPENDENCE

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

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

Phase 3 clinical trial on zoliflodacin, investigating the efficacy and safety of a new drug for gonorrhoea, is launched with first patients recruited.

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

GARDP starts screening compound libraries from Eisai, Takeda and Calibr, and natural products from Helmholtz-Institute for Pharmaceutical Research Saarland (HIPS), at screening facilities in Australia (University of Queensland) and Korea (Institut Pasteur Korea).

GARDP and partners enrol 3000 babies in one of the largest international observational studies on neonatal sepsis, reaching 90% of the target. This study conducted in 11 countries will provide key data on how neonatal sepsis is managed and the impact of antibiotic resistance on treatment and outcomes.

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

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

GARDP launches new business plan for 2020-2025, outlining its 5 BY 25 goal.

2018

## ACTIVITIES

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

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

- A clinical trial in Kenya confirming the dose and safety of fosfomycin to treat neonatal sepsis.
- A partnership with Penta – the paediatric infectious diseases network in Italy – including the launch of a global observational study in hospitals and neonatal units across Africa, Asia, Europe, and Latin America. The study, in partnership with St George's, University of London and Penta, focuses on collecting clinical information on babies with sepsis.
- Completion of phase 1 pharmacokinetic and safety study on zoliflodacin, allowing appropriate dose selection for the pivotal phase 3 trial.
- Securing regulatory advice for phase 3 clinical trials on zoliflodacin in the Netherlands, South Africa, Thailand, and the US.
- Partnerships with pharmaceutical companies and research institutes to support antibiotic discovery, focusing on new or improved antibiotics.
- Launch of REVIVE - GARDP's online knowledge sharing platform on antimicrobial R&D - hosting four webinars with participants across the world, publishing two blogs, and co-hosting three sessions at international conferences.

2019

## LOOKING AHEAD

# 2020 MILESTONES

## CHILDREN'S ANTIBIOTICS

In October 2020, GARDP and its partners – St George's University of London and the Penta Foundation – are expected to announce the final results of the global observational study on neonatal sepsis. The results of the pharmacokinetic clinical trial in Kenya assessing the safety and dosing of the antibiotic fosfomycin in newborns will also be released towards the end of the year. Information from both of these studies will be used to confirm the design concept for a clinical trial to evaluate the efficacy and safety of the alternative treatment options identified for sepsis in neonates in 2020.

GARDP has successfully identified one possible antibiotic combination of fosfomycin and amikacin and continues to evaluate others to undergo clinical evaluation, with the objective of developing an alternative to ampicillin-gentamicin, the current WHO recommended treatment for sepsis in neonates. Half of the infections that cause neonatal sepsis are now reported to be resistant to ampicillin-gentamicin, which means an alternative is urgently needed.

## SERIOUS BACTERIAL INFECTIONS

At the end of April 2020, GARDP announced it was joining forces with Venatorx Pharmaceuticals to accelerate the development of a critically needed new treatment to fight antibiotic-resistant, hospital-associated infections in adults and children. Cefepime-taniboractam is a new, broad-spectrum beta-lactam/beta-lactamase inhibitor combination that restores the activity of the antibiotic cefepime against carbapenem-resistant *Enterobacteriaceae* (CRE) and carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), which are largely responsible for some of the most serious bacterial infections in hospitals.

Clinical trials will be conducted in adults to demonstrate safety and efficacy for clinically relevant bacterial infections including those which are resistant to other antibiotics. Additional development activities including clinical trials to ensure the treatment is safe and effective for use with children and babies with serious bacterial infections, including neonatal sepsis, will be planned in 2020 and begin before the end of the year. Traditionally it has taken seven to ten years after an antibiotic has been registered for use in adults for the paediatric formulation to be made available.

## SEXUALLY TRANSMITTED INFECTIONS

The global phase 3 trial of zoliflodacin, ongoing in the USA, is expected to be activated in the Netherlands, South Africa, and Thailand with sites commencing recruitment in 2020. Work will continue to manufacture the final drug product for eventual regulatory approval. A stewardship and sustainable access strategy for zoliflodacin will be further developed including public health and market access pathways.

## DISCOVERY & EXPLORATORY

In January 2020, GARDP signed an agreement with Daiichi Sankyo, a Japanese pharmaceutical company, to access and screen compounds from the Daiichi Sankyo chemical library with activities starting in 2020. GARDP hopes to identify novel compounds that could be used to develop new treatments against drug-resistant infections.

REVIVE - GARDP's online knowledge sharing platform on antimicrobial drug R&D - will continue to expand with more webinars led by experts in their field and a wide range of Antimicrobial Viewpoints published by doctors, researchers in industry and academia and policy makers. To date, over 2,400 participants from around the world have joined more than 19 webinars.



## COVID-19 & ANTIBIOTIC RESISTANCE

The coronavirus disease (COVID-19) pandemic has shown how a virus can disrupt health systems, economies and threaten vulnerable populations. It has also highlighted the critical importance of pandemic preparedness, particularly the need to invest in research and development for new diagnostics, treatments and vaccines.

The link between COVID-19 and drug-resistant infections is more troubling than many realize. Antibiotics, while not effective against viruses, have been used in people

with the novel coronavirus to prevent or treat secondary bacterial infections, including bacterial pneumonia and bloodstream infections like sepsis. However, many of these infections are increasingly resistant to existing treatments.

Just like COVID-19, antibiotic resistance is a health security crisis that moves silently within populations and knows no boundaries. No single country, company or organization can fight drug resistance alone. It can only be done in partnership. We must act now to prevent drug-resistant infections from becoming the next global public health emergency.

## 5 BY 25

GARDP is calling on governments, philanthropic, private and public organizations to support the delivery of five new treatments by 2025 to tackle the drug-resistant infections that pose the greatest threat to global health and economic security. We are seeking EUR 500 million to develop these treatments and ensure their responsible use and sustainable access.

## CONTACT

# FOR MORE INFO

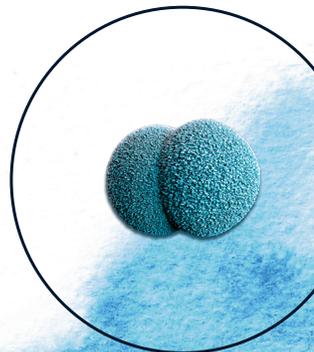
## Global Antibiotic Research & Development Partnership (GARDP)

15 chemin Camille-Vidart – 1202 Geneva – Switzerland

+41 22 555 19 90 – [contact@gardp.org](mailto:contact@gardp.org) – [www.gardp.org](http://www.gardp.org)

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Design: ©Enigma



 GARDP

   in