ACTIVITY REPORT
2019
Global Antibiotic Research & Development Partnership
# ACTIVITY REPORT 2019

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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 biotechs 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 the 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.

As part of our partnership with biotech Entasis Therapeutics, we launched a global phase 3 trial for zoliflodacin, a new treatment for uncomplicated gonorrhoea – the priority focus of GARDP’s sexually transmitted infections programme. This programme is a good 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 at 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.

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

DR. MANICA BALASEGARAM GARDP EXECUTIVE DIRECTOR

& PROF. RAMANAN LAXMINARAYAN GARDP BOARD CHAIR
Antimicrobial resistance (AMR) 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.

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.

The Global Antibiotic Research and Development Partnership (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 bloodstream infection). We have formed over 50 partnerships in 20 countries 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.

Antimicrobial resistance (AMR) 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.

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.

Antibiotics can save millions of lives and protect the agricultural economy from devastating losses. GARDP brings 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 goal is to deliver five new treatments by 2025 to tackle drug-resistant infections that pose the greatest threat to health and economic security. It is a global crisis that requires global action.

To learn more about our mission and our latest efforts to combat antimicrobial resistance, visit our website.
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 infrastructure 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.
**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 fosfomycin 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 Calibir, 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 Welcome 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.
- 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.

**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.
- The Okyama Declaration of the G20 Health Ministers welcomes the recent work done by AMR R&D initiatives such as GARDP and renewed calls for further investment.

**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 zolidofloxacin. Zolidofloxacin is a new, first-in-class oral antibiotic being developed for the treatment of uncomplicated gonorrhea.
- 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 gonorrhea.

**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 gonorrhea.
- GARDP partnered with Takeda and Eisai, two leading pharmaceutical companies, to launch a global phase 3 pivotal trial of flodacin as a new, first-in-class oral antibiotic being developed for the treatment of uncomplicated gonorrhea.
- The Okayama Declaration of the G20 Health Ministers welcomes the recent work done by AMR R&D initiatives such as GARDP and renewed calls for further investment.

**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.
- 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 Okyama Declaration of the G20 Health Ministers welcomes 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.
- Dr Mercedes Tatas, 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.
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.

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.
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.

“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.

Patience 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.

Winnie Mkare lives with her husband and four children in Matano Manne village, an hour’s drive from the nearest hospital. Winnie Mkare lives with her husband and four children in Matano Manne village, an hour’s drive from the nearest hospital. 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.

Mercelyne Chengo, from the Kwandam 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 knew many babies with sepsis don’t survive. Khalid was treated and Mercelyne and her son were able to return home.

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.

“...”

Globally the infection rate of gonorrhoea is increasing, with 87 million new cases estimated each year.²

² https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections

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

DR. MANICA BALASEGARAM
GARDP EXECUTIVE DIRECTOR
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 antibacterial 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.

The cost of hospital infections leads 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.
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 Calib, 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 antibacterials. 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.
FINANCE – 25

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.

EXPERIMENT

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 DND in 2016

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

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 1 billion (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.

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.

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.

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.

PUBLIC CONTRIBUTORS 2016 - 2024 EUR

<table>
<thead>
<tr>
<th>Country</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany (BMBF and BMG)</td>
<td>55.1 M</td>
</tr>
<tr>
<td>United Kingdom (DFID, DHSC and NIHR)</td>
<td>13.5 M</td>
</tr>
<tr>
<td>The Netherlands (VWS)</td>
<td>7.5 M</td>
</tr>
<tr>
<td>Switzerland (FOPH)</td>
<td>1.2 M</td>
</tr>
<tr>
<td>South African Medical Research Council</td>
<td>0.6 M</td>
</tr>
<tr>
<td>Grand Duchy of Luxembourg</td>
<td>0.1 M</td>
</tr>
<tr>
<td>Principality of Monaco</td>
<td>0.4 M</td>
</tr>
</tbody>
</table>

PRIVATE CONTRIBUTORS 2016 - 2024 EUR

<table>
<thead>
<tr>
<th>Foundation</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bill &amp; Melinda Gates Foundation</td>
<td>1.8 M</td>
</tr>
<tr>
<td>Wellcome Trust</td>
<td>1.1 M</td>
</tr>
<tr>
<td>Others (Médecins Sans Frontières, Leo Model Foundation)</td>
<td>0.7 M</td>
</tr>
</tbody>
</table>

In 2019 donor funding

- 15% Restricted
- 14% Unrestricted
- 71% Portfolio

Fund types (In million EUR)

- Switzerland
- The Netherlands
- Bill & Melinda Gates Foundation
- Others
- United Kingdom
- Germany

2019 donor funding

- 3.1
- 2.8
- 0.9
- 2.8
- 2.5
- 3.3
- 6.5
- 0.1

R&D expenses per programme (In million EUR)

- STI: 46%
- Neonatal sepsis: 35%
- AMREP/D&E: 15%
- Paediatric: 3% 

2018

STI: 38%
Neonatal sepsis: 11%
AMREP/D&E: 35%
Paediatric: 16%

2019

STI: 46%
Neonatal sepsis: 35%
AMREP/D&E: 15%
Paediatric: 3%
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.

ANJA KARLICZEK
GERMAN FEDERAL MINISTER FOR EDUCATION AND RESEARCH

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
TOTAL INCOME 18,924,512 11,180,980

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 6510,041 3,065,379
Children’s Antibiotics - Paediatric 640,190 138,022
Total research & development expenditure 15,438,942 9,762,681
International network 1,049,697 485,349
TOTAL SOCIAL MISSION EXPENDITURE 16,488,639 10,248,031

NON-SOCIAL MISSION EXPENDITURE (EUR) 2019 2018
Fundraising & General and Administration 2,386,869 931,544
Total non-social mission expenditure 2,386,869 931,544
TOTAL EXPENDITURE 18,875,508 11,179,575
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)
TOTAL OTHER INCOME (EXPENSES) (44,764) (49)
Net surplus for the year prior to allocations 2,240 1,356
Allocation to unrestricted operating funds (2,240) (1,356)
NET SURPLUS FOR THE YEAR AFTER ALLOCATIONS – –

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

“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
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
Enai
Takeda

JOINT PROGRAMMING INITIATIVE ON ANTIMICROBIAL RESISTANCE (JIPIAMR)

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)

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)
Paw 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.
**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
  Adinun Therapeutics, India (member until May)
- George DRUSANO
  Institute for Therapeutic Innovation, University of Florida, USA
  (member until May)
- 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)
- Kasuki 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 WALLIA
  Indian Council of Medical Research, India
- Nicholas WHITE
  Mahidol University, Thailand

**OBSERVERS**

- Graeme BILBE
  Drugs for Neglected Diseases initiative, Switzerland
- Jorgen STASSJUNS
  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**

- Monica 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.
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.

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.

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.

GARDP starts screening compound libraries from Eisai, Takeda and Calibra, 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.
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 Louis-Dunant – 1202 Geneva – Switzerland
+41 22 555 19 90 – contact@gardp.org – www.gardp.org

Credits

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