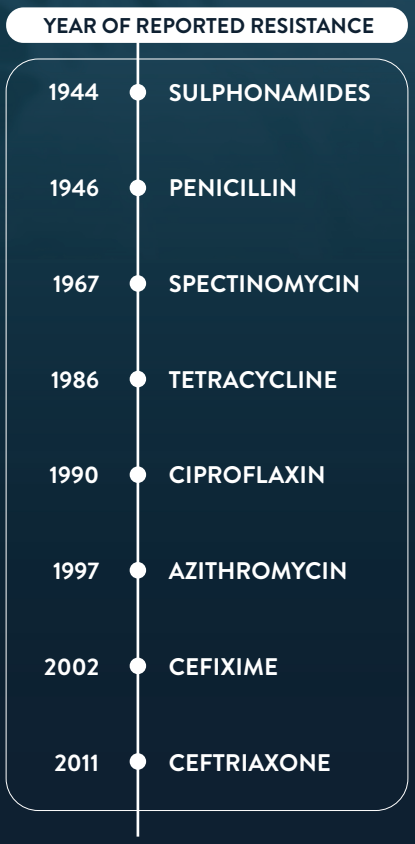
GARDP
Global Antibiotic Research & Development Partnership

GLOBAL CHALLENGES

SEXUALLY TRANSMITTED INFECTIONS

GONORRHOEA — Towards an untreatable disease?

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



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

CHALLENGES OF TREATING DRUG-RESISTANT STIs

A little over a century ago when syphilis became the very first disease to be treatable with antibiotics, it triggered a new golden era in modern medicine and a significant decline in sexually transmitted infections (STIs). However, today STIs are at record high levels, with more than one million potentially curable sexually transmitted infections acquired every day. A major contributing factor to this trend is the rise and spread of antimicrobial resistance (AMR), because drug-resistant infections are making it increasingly difficult to treat some bacterial STIs.

With the decline of antibiotic research and development (R&D) in recent decades, treatments that have been lost to resistance have not been replaced with new antibiotics that are effective against multidrug-resistant infections. As a result, treatment options for once-curable STIs, like gonorrhoea, are now running out. Without the development and access to new and effective antibiotic treatments, diseases like gonorrhoea were in danger of becoming one of the first once-curable diseases to be no longer treatable.

NEGLECTED DISEASES

STIs can affect the sexual and reproductive health of both men and women in a wide range of ways, with serious and potentially permanent impacts on fertility, ectopic pregnancy, pelvic inflammatory disease and more. If not effectively treated they can also affect the nervous system, cause cardiovascular disease and increase the risk of HIV transmission. Babies born while a mother is infected with gonorrhoea are at risk of severe eye infections that can result in blindness. All this not only affects the lives of patients, their families and communities, but it also comes with broader economic impacts.

According to the US Centers for Disease Control & Prevention (CDC), the US has been experiencing an STI epidemic with more than 2.2 million STI cases reported in 2024. And the annual cost of treating STIs exceeded $16 billion. In low- and middle-income countries (LMICs), where the burden of disease is greatest, the situation is even more profound. According to the World Bank, the economic burden of STIs in LMICs is so high that the treatment of curable STIs is considered one of the most cost-effective ways to improve health worldwide.

Despite this, R&D into new STI treatments remains neglected and underfunded. For example, even though there are now more than 82 million new cases of gonorrhoea each year, it has been more than four decades since ceftriaxone, the last new treatment was introduced. In the face of rising resistance to other antibiotics, ceftriaxone has become the last available recommended treatment for gonorrhoea globally, and now cases are emerging that are also resistant to this. In some countries, we have seen a six-fold increase of these infections in recent years.

GARDP'S APPROACH

Bacterial STIs rarely kill people, but the potential public health benefits of treating them, and the contribution this has towards addressing AMR, are significant. For this reason, a core part of GARDP's work is focused on the development of new and effective antibiotic treatments that target multidrug-resistant STIs, and ensuring that people in need get access to them.

GARDP aims to do this by identifying potential drug candidates and use its unique antibiotic R&D and access model to complete their development, and bring them to market, ensuring that high-risk populations have access to them. This model includes a partnership approach that integrates key access requirements in the clinical development of appropriate treatments. GARDP uses innovative licensing to manufacture and commercialize affordable treatments once approved.

Since access is a key part of GARDP's mission, we carry out surveillance and prevalence studies in high-risk populations in LMICs. We work with local partners to develop introduction strategies aimed at using the treatments optimally to both improve outcomes and reduce the rate of resistance against new treatments. We also carry out work to develop novel access pathways with partners at the national level to ensure treatments are affordable, quality-assured and meet the public health need.

With an initial focus on *Neisseria gonorrhoeae*, one of the World Health Organization (WHO) priority pathogens, GARDP supports the WHO goal of reducing the global incidence of *N. gonorrhoeae* by 90% by 2030, through the development of innovative antibiotic treatments for gonorrhoea infections, such as zoliflodacin (see box). GARDP's long-term goal extends beyond gonorrhoea and aims to contribute to the overall reduction of incidence of STIs caused by other key bacterial pathogens prioritized by the WHO, including *Treponema pallidum* (syphilis), *Mycoplasma genitalium* and *Chlamydia trachomatis*.

ZOLIFLODACIN

In December 2025, the US Food and Drug Administration (FDA) approved zoliflodacin (branded as NUZOLVENCE® in the US), a new first-in-class, single-dose, oral antibiotic for the treatment of uncomplicated urogenital gonorrhoea. Co-developed by GARDP through a public-private partnership with Innoviva Specialty Therapeutics (IST), this was the first new treatment to be developed solely for gonorrhoea in decades. It was also the first to be developed using a novel not-for-profit approach to antibiotic R&D aimed at tackling the rise and spread of AMR.

Zoliflodacin has been shown to be active against all multidrug-resistant strains of *N. gonorrhoeae* tested, with no cross-resistance with other antibiotics. Zoliflodacin belongs to a new class of antibiotics, called spiropyrimidinetriones, which has a unique mechanism of action in the way that it inhibits a crucial bacterial enzyme called type II topoisomerase, which is essential for bacterial function and reproduction.

The approval followed the positive results of a pivotal phase 3 clinical trial, the findings of which were published in *The Lancet*. Sponsored and funded by GARDP, this was not just the largest clinical trial ever conducted for a new treatment against gonorrhoea, it was also one of the most geographically and demographically diverse. Involving 930 participants across 16 trial sites within five countries in four continents – including Belgium, the Netherlands, South Africa, Thailand, and the US – the trial was designed to be conducted in regions with high prevalence of gonorrhoea and include underrepresented populations, such as women, adolescents and people living with HIV.

GARDP has the right to register and commercialize zoliflodacin in more than three-quarters of the world's countries, including all low-income countries, most middle-income countries and several high-income countries. GARDP is taking steps to obtain market authorization initially in Thailand and South Africa. These countries were selected not only because they are important partners for GARDP, but also because they played a key role in the phase 3 trial. Once approval is obtained in these two countries, we will expand access to zoliflodacin through a process of collaborative approvals within a number of countries. GARDP is also working with partners to advance filings with the European Medicines Agency.

As part of its long-term strategy, GARDP is also looking to have additional options once resistance emerges. So, in addition to its work on zoliflodacin, GARDP is looking at new treatment options for gonorrhoea and is also assessing the need for more optimal treatments for syphilis. In this context, in January 2026 GARDP entered into a collaboration and licence agreement with Swiss-based pharmaceutical company Debiopharm to pursue the development of Debio 1453, a novel compound targeting *N. gonorrhoeae* and part of the CARB-X portfolio.