

Sexually Transmitted Infections

R&D PROGRAMME SNAPSHOT

Rising prevalence of sexually transmitted infections (STIs) is a major public health concern. The World Health Organization (WHO) estimates that there are approximately 357 million new cases of curable STIs every year, including 78 million cases of gonorrhoea. To help address this global crisis, GARDP has developed a roadmap to treat STIs, starting with a focus on gonorrhoea.

Rising threat of drug resistant gonorrhoea

Gonorrhoea is one of the most common sexually-transmitted infections (STIs) worldwide, heralded by alarmingly rapid escalation in recent years. The disease can infect women's reproductive organs including the cervix, uterus, and fallopian tubes; as well as the urethra, rectum, mouth, throat, and eyes of both men and women. If left untreated, complications arising from it can lead to infertility, particularly in women. Pregnancy complications include ectopic pregnancies and spontaneous abortions. In up to 40% of cases, predominantly in low and middle-income countries, mothers can pass the infection to their

unborn children at delivery, which can result in neonatal conjunctivitis, which can lead to scarring and blindness. Gonorrhoea can also increase the risk of contracting and transmitting HIV in men and women. Although the African and Western Pacific regions have the highest incidence, the disease's impact is truly global as no country is free from its presence. The spread and incidence of drug-resistant gonorrhoea is rapidly outpacing the development of new medicines, with increasing resistance even to last-resort treatment options. Without action, the world faces a nightmare scenario of untreatable gonorrhoea.



Sexually Transmitted Infections R&D Strategy

MAIN GOALS

By 2023, deliver 1 to 2 new treatments that:

- Are suitable for integration into STI syndromic management
- Work against drug-sensitive and drug-resistant forms of gonorrhoea
- Work in uro-genital and extra-genital infections



Accelerate the development of one to two new chemical entities



Investigate combinations of existing antibiotics



Explore the development of FDCs and co-packaged products



Improve treatment guidelines and promote sustainable use

GARDP's STI R&D Programme

With WHO and international experts, GARDP has now published a peer reviewed article that comprehensively outlines its STI strategy, including short and long-term Target Product Profiles (TPPs). For the first time, this details an R&D road map for new treatments against drug-resistant gonorrhoea.

Key components of the STI strategy include:

- Evaluating the use of existing antibiotics and combination treatments for STIs
- Developing co-packaged and fixed-dose combination treatments
- Supporting the development of simplified treatment guidelines, including for the empiric treatment of STIs
- Accelerated development of a new treatment for gonorrhoea

Global Collaborations

GARDP aims to help fill the R&D gap by partnering with key stakeholders to develop reliable and sustainable treatment options as last-resort treatment options fail.

The STI Programme has established a solid core of collaborators with complementary expertise to ensure that patients living with drug-resistant gonorrhoea will be able to access new treatments. Strong partnerships have been made with the WHO, research and industrial partners, governments, and other key stakeholders to ensure GARDP can deliver on the objectives of the STI programme.

Partnership to co-develop a new antibiotic

In July 2017, GARDP entered its first partnership agreement with biotech company Entasis Therapeutics to co-develop an antibiotic known as zoliflodacin, in a global Phase III clinical trial. Zoliflodacin is from an entirely new class of antibiotic and the only drug in clinical development developed specifically to treat gonorrhoea.

The agreement includes a sustainable access strategy, and if zoliflodacin receives regulatory approval, Entasis will grant GARDP an exclusive license with sublicensing rights in most low- and middle-income countries, while retaining commercial rights in high-income markets. Through its pharmaceutical management programme, GARDP is committed to work on cost and affordability.

If the trials are successful, it is hoped that zoliflodacin will offer a significant opportunity to provide a pilot case study in how to introduce antibiotics into the market to ensure appropriate use. Work will be carried out with the WHO and relevant countries to build on and develop appropriate access and stewardship plans.

This partnership will also play a key part in the first pillar of GARDP's STI R&D strategy – accelerate - the development of a new treatment for gonorrhoea. GARDP is also actively working to develop the other pillars of its STI strategy.

Going Forward

No country in the world has escaped the serious public health effects of gonorrhoea. It is an STI of truly global significance and warrants immediate action. The STI Programme offers a comprehensive means to address the many facets of R&D for this disease – from drug development to registration to affordable and equitable access – to help overcome drug resistance, and ensure patients can access the treatment they need.

Supporting the Sexually Transmitted Infections Programme

The estimated cost of this seven-year programme is €62.8 million. GARDP seeks public, private and in-kind contributions to develop much-needed new antibiotic treatments for important STIs.

About GARDP

Launched in 2016 by WHO and DNDi, the Global Antibiotic Research & Development Partnership (GARDP) aims to develop and deliver new treatments for bacterial infections where drug resistance is present or emerging, or for which inadequate treatment exists, while endeavouring to ensure sustainable access. GARDP is currently operating within DNDi, which provides its governance.