

GARDP IN INDIA

The Global Antibiotic Research & Development Partnership (GARDP) was created to help stop the rise and spread of drug-resistant infections, and address the rapidly escalating global antimicrobial resistance (AMR) crisis.

With drug-resistant infections already one of the biggest global killers, the number of deaths associated with AMR is now expected to rise sharply, increasing by 70% by 2050 and claiming close to 170 million lives during this time.

The best way to prevent this, and the focus of GARDP's mission, is to accelerate the research & development (R&D) of new and effective antibiotics, to replace those lost to resistance, while increasing appropriate global access to essential antibiotics that remain effective. India is in a unique position to work with GARDP to achieve these objectives, both within the country and beyond.

That is because India has the scientific expertise, clinical resources and thriving pharmaceutical sector needed, and a strong track record of success. During the HIV/AIDS epidemic and the COVID-19 pandemic, it established itself as one of the foremost producers and global suppliers of affordable medicines and vaccines, and through its elimination of wild poliovirus, it demonstrated its ability to increase access to vaccines. Now, India is in a strong position to do the same with AMR, because it has all the essential ingredients needed to develop much-needed antibiotic treatments, and to ensure that people who need them get access.

INDIA'S UNIQUE POSITION

- **Population** - The fact that India has a high burden of drug-resistant infections means that when studies are conducted they can be carried out on large and highly relevant populations, making the results more robust. This is important to ensure the right antibiotics are developed and for the right people.
- **Expertise** - Filling the data and knowledge gaps on disease burden and antibiotic usage is an important part of developing and introducing new treatments. India has the vast and expansive medical and scientific communities, and civil society organizations needed to carry out trials, studies and strategies.
- **Industry** - India's cutting edge biotech and pharmaceutical industry has a long history of innovative R&D, commercial partnerships and technology transfers, all of which are essential to develop, manufacture and commercialize affordable new antibiotics.
- **Scale** - The huge population within India, and the high antibiotic need, create the economies of scale needed to make sustainable markets possible, where antibiotics can be both affordable and financially viable.

One of GARDP's key objectives is to support countries with their AMR National Action Plans, by bringing together the public and private expertise needed to address the challenges in ensuring access to essential antibiotics. Our vision is also to flip the current antibiotic R&D model on its head by working with manufacturers and other partners in low- and middle-income countries (LMICs) to address AMR where it exists.

Therefore, our collaborations in India have a key role to play in terms of how we operate, set our priorities, expand our R&D portfolio and ultimately find success. These strategic partnerships span the entire AMR ecosystem and will help GARDP achieve its strategic vision, while providing an opportunity for the Government of India to position itself at the heart of the global response to AMR.



GARDP'S PARTNERSHIPS IN INDIA

Indian Council of Medical Research

Through its partnership with the **Indian Council of Medical Research (ICMR)**, GARDP is supporting national efforts to tackle AMR. This includes clinical studies aimed at improving the use of antibiotics, such as our antibiotic-resistant infections observational study. This enrolled 152 patients across five sites in India to investigate both the epidemiology and treatments used with severe bacterial infections in India. Similarly, the **Neonatal Sepsis empiric treatment trial**¹ will compare new and existing combinations of antibiotic treatments for neonatal sepsis, while the **cefiderocol introduction study**² will evaluate how cefiderocol can be appropriately introduced within the context of a stewardship programme as a viable treatment option for patients with severe multidrug-resistant infections, that have limited treatment options.

Pharmaceutical Industry

GARDP has partnered with several Indian pharmaceutical and biotech companies with the aim of establishing a quality-assured, sustainable and affordable product development, manufacturing and commercialization chain for new antibiotic molecules as well as repurposed generics. Our partnership with **Orchid Pharma**, for example, is focused on ensuring manufacturing, supply and provision of optimal and affordable access to cefiderocol in India and more than 135 countries.

We are working with **Aurigene Pharmaceutical Services Limited** on the manufacture and supply of zoliflodacin, a novel first-in-class single-dose oral antibiotic treatment for gonorrhoea. We are also partnering with **Dr. Reddy's Laboratories** to register and market zoliflodacin in Thailand and South Africa. If zoliflodacin receives regulatory approval from the US Food & Drug Administration, this partnership could help see this drug introduced into more than 160 countries.

GARDP is also collaborating with **Bugworks Research Inc.** to accelerate the development of its novel BWC0977 compound (oral and intravenous form) to treat serious bacterial infections. BWC0977 is currently in a phase 1 clinical trial and is being developed to address unmet needs of serious hospital and community infections, and bacterial biothreats.

Appropriate use

In collaboration with **FIND**, GARDP carried out facility assessments of 30 public and private hospitals in India, with the aim of assessing their existing AMR diagnostic capacity, current antibiotic use and existing stewardship practices. This work was carried out to improve overall understanding of current practices in public and private hospitals for diagnosing multidrug-resistant infections, supply and availability of Reserve antibiotics and evolving regulatory needs, to pave the way for the introduction of cefiderocol and other new Reserve antibiotics in India.

Through another collaboration with **ECHO India**, GARDP is working on the implementation of a **hub and spoke** telementoring model for antibiotic stewardship. This network-driven approach has been designed to strengthen antimicrobial resistance stewardship by empowering frontline heroes like clinicians, nurses and microbiologists across various healthcare facilities by leveraging expertise and resources (from the "hubs") – including educational materials, infection control protocols, and guidance on antibiotic use – to "spoke" hospitals, ensuring consistency in care and stewardship practices. This pilot programme has been launched in two Indian states – Punjab and Andhra Pradesh.

Supporting access implementation networks

In alignment with the **ICMR's** objective of combating AMR in India, GARDP is supporting access implementation networks to foster collaborative efforts across the public and private sectors. The **Indian AMR implementers network** meeting, held in 2024 in collaboration with the Holy Family Hospital in New Delhi, brought together stakeholders from public and private sectors to discuss key challenges in accessing antibiotics, particularly reserve antibiotics, and identify barriers relating to affordability, supply chain, stewardship and antibiotic development. These networks will be key to: identifying which new drugs need to be introduced and how to do so; improving laboratory infrastructure and workforce to strengthen diagnostics; and implementing novel procurement models for new antibiotics, such as pooled procurement. As part of the next phase, implementers network meetings will be held at the state level in collaboration with **ReAct Asia Pacific**. GARDP has also joined forces with the **Public Health Foundation of India** on a project that aims to design a pooled procurement model to improve access to quality-assured reserve antibiotics in India, particularly in private sector hospital settings.



¹ Currently under development.

² Currently under development.