

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.

GARDP's mission is to accelerate the research and development (R&D) of new and effective antibiotics to replace those lost to resistance, while improving appropriate global access to essential antibiotics that remain effective. India is uniquely positioned to partner with GARDP to achieve these objectives, both within the country and beyond, given its scientific expertise, clinical capacity and thriving pharmaceutical sector, alongside a strong track record in delivering affordable medicines and vaccines during the HIV/AIDS epidemic, the COVID 19 pandemic and the polio eradication effort.

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.

GARDP'S PARTNERSHIPS IN INDIA

INDIAN COUNCIL OF MEDICAL RESEARCH

Through our 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 characterize the epidemiology and treatment of severe bacterial infections.

SUPPORTING ACCESS IMPLEMENTATION NETWORKS

In alignment with ICMR's objective of strengthening the AMR response in India, GARDP is building on the Indian AMR Implementers Network initiated in 2024 in collaboration with Holy Family Hospital, New Delhi. In partnership with **ReAct Asia Pacific**, we are taking this work forward through state-level implementers networks, with a particular

focus on states where implementation of AMR action plans and access to appropriate antibiotics remain challenging. These networks aim to bring together stakeholders across the public and private sectors to identify and address practical barriers related to antibiotic access, diagnostics, stewardship, supply and affordability, while supporting the introduction and responsible use of new and Reserve antibiotics.

In parallel, GARDP has partnered with the **Public Health Foundation of India (PHFI)** to develop a pooled procurement strategy for quality-assured Reserve antibiotics in India. The initiative will explore innovative procurement approaches to improve affordability, availability and sustainable access, particularly for private sector hospitals, while ensuring that access is aligned with appropriate stewardship and clinical use.

NEOSEP1 - NEONATAL SEPSIS TRIAL IN INDIA

NeoSep1 is an international, open-label randomised controlled trial evaluating new antibiotic combinations for the empiric treatment of neonatal sepsis, a leading cause of death in newborns. The trial is sponsored by GARDP and implemented in collaboration with the UCL Innovative Clinical Trials Unit, City St George's, University of London, and Penta Foundation, with participating sites across Africa and Asia. In India, the trial began in 2026, with the first infant enrolled at JIPMER, Puducherry, followed by Pt. BD Sharma PGIMS, Rohtak and Lokmanya Tilak Municipal Medical College and General Hospital, Mumbai. The study aims to generate evidence on safe and effective treatment options that can help address the growing challenge of drug-resistant neonatal sepsis and inform treatment guidance in India and other high-burden settings. GARDP aims to enroll approximately 3,000 newborns across Asia and Africa by the end of 2028.

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. In December 2025, it was approved by the US Food and Drug Administration (FDA) under the brand name NUZOLVENCE® and then by the Thai FDA just six months later. 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.

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.

LEARN MORE ABOUT GARDP: WWW.GARDP.ORG

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