

## **Landmark clinical trial to transform treatment options for newborns with sepsis expands to Asia**

**Geneva, 24 June 2026** — An innovative international clinical trial to evaluate life-saving antibiotic combinations for newborns with sepsis has expanded to India, one of several Asian countries participating in the study.

Sponsored by the GARDP Foundation (known as GARDP), the NeoSep1 clinical trial in India began with the first baby recruited at Jawaharlal Postgraduate Education Institute of Medical and Research (JIPMER) in Puducherry, followed by Pt. B.D Sharma PGIMS in Rohtak. Mumbai's Lokmanya Tilak Municipal College and General Hospital is expected to start enrolling newborns shortly.

The study is also getting underway in hospitals in Vietnam and Pakistan, and will soon start in Malaysia, Bangladesh and Uganda. NeoSep1 aims to enrol 3,000 newborns across Asia and Africa by the end of 2028. So far, newborns have been enrolled in Ghana, Kenya and South Africa.

“With underdeveloped immune systems, newborns are especially prone to life-threatening sepsis,” said Sally Ellis, Children's Antibiotics Project Leader for GARDP. “Today, we stand at a tipping point. The antibiotics for newborns that we have relied on for decades are failing against resistant infections, in many hospital settings. This trial, led by GARDP and partners, is about giving neonatologists new tools, and giving babies with sepsis a fighting chance at life.”

Part 2 of the NeoSep1 trial is pioneering the use of a Personalised Randomised Controlled Trial (PRACTical) design, which will evaluate and rank multiple antibiotic regimens for newborns with sepsis. This approach will help clinicians choose effective treatments best suited to their local context.

The goal of the trial is to identify one or more safe, effective, and affordable treatments that can reduce the high number of newborn deaths caused by drug-resistant sepsis, especially in low- and middle-income countries. The trial will provide critical data to inform much-needed updates of international and national treatment guidelines for neonatal sepsis.

Part 1 of the NeoSep1 trial, conducted in South Africa and Kenya in 2023, assessed and validated the appropriate dose for fosfomycin and flomoxef for use in newborns, when used in combination with other antibiotics.

“Every day doctors face the heartbreaking reality of losing babies to sepsis due to lack of safe and effective treatments,” said Dr Nishad Plakkal, Principal Investigator of the NeoSep1

trial in India and Associate Dean (Research) and Professor and Head, Department of Neonatology at JIPMER. “Having the right antibiotics at the right dose can tip the balance between life and death. This trial offers hope to change that.”

Each year, up to three million newborns around the world develop neonatal sepsis, a life-threatening bloodstream infection that is especially common in Asia and sub-Saharan Africa. In these regions, the burden is felt most acutely, as access to timely diagnosis and effective antibiotic treatment is often limited.

In 2019 alone, an estimated 238,500 newborn deaths across South Asia, Southeast Asia, and Oceania were associated with antimicrobial resistance (AMR). Of these, 63,200 newborn deaths were directly caused by infections that no longer responded to the standard antibiotics available. These findings, from the Global Research on Antimicrobial Resistance (GRAM) study, underscore a growing crisis: infections that were once treatable are becoming increasingly difficult - and sometimes impossible - to treat, placing the world’s most vulnerable patients at even greater risk.

NeoSep1 is sponsored by GARDP in collaboration with the UCL Innovative Clinical Trials Unit; City St George’s, University of London (SGUL), and Penta Foundation.

## **GARDP**

GARDP (the Global Antibiotic Research & Development Partnership) is a not-for-profit global health organization driven to protect people from the rise and spread of drug-resistant infections, one of the biggest threats to us all. By forging the public and private partnerships that matter, we develop and make accessible antibiotic treatments for people who need them. Vital support for our work comes from the governments of Germany, Japan, Monaco, the Netherlands, Switzerland, the United Kingdom, the Canton of Geneva, the European Commission, as well as the Gates Foundation, Global Health EDCTP3, GSK, the RIGHT Foundation, the South African Medical Research Council (SAMRC) and Wellcome. GARDP is registered under the legal name GARDP Foundation in Switzerland. [www.gardp.org](http://www.gardp.org)

## **Press contact**

Kim Cloete, GARDP - [kcloete@gardp.org](mailto:kcloete@gardp.org)

Laura Keenan, GARDP - [lkeenan@gardp.org](mailto:lkeenan@gardp.org)