

## **End-to-End Execution of a Large-Scale Rotavirus Vaccine Trial**

DiagnoSearch led the successful execution of a 7,500-infant Phase III vaccine trial in India, using custom-built offline IWRS technology to overcome low-connectivity barriers while ensuring full compliance from start to finish.

### **Situation and Challenge**

A pivotal Phase III trial for a rotavirus vaccine requiring enrolment of 7,500 paediatric participants (aged 6–8 weeks) across 6 sites in India. The study faced key challenges:

- Remote or low-connectivity satellite sites
- High-volume SAE management and reporting
- Intensive protocol training
- Technological customization for seamless dose management

### **Our Solution**

DiagnoSearch provided end-to-end clinical support across all critical areas:

#### **Site Enablement & Training**

- Customized site operational plans
- Face-to-face and virtual training modules
- Train-the-Trainer workshops with evaluations

#### **Project Management & Monitoring**

- Risk-based monitoring framework
- Over 2,100 site monitoring man-days

#### **Core Services**

- Data Management and Biostatistics
- SAE Management with 100% compliance
- IWRS design and implementation
- Lab and site supply management
- Analytical lab oversight

#### **Offline IWRS Innovation**

To address unreliable internet access, DiagnoSearch developed a custom offline IWRS module, enabling uninterrupted randomization and dose dispensation even at remote sites.

## **Results and Impact**

DiagnoSearch's scientific agility and field-driven innovation ensured smooth execution of this high-volume pediatric trial.

Key outcomes included:

- 7,500 infants enrolled across 6 sites within ~10 months
- ~375,000 eCRF pages processed with clean, audit-ready data
- Over 3,300 SAEs managed with 100% compliance
- 22,500 IWRS doses dispensed, powered by the offline module
- 2,100+ monitoring man-days delivered through a risk-based model

DiagnoSearch's blend of scientific rigor and field-driven innovation ensured smooth execution of a large-scale pediatric trial. The study played a critical role in advancing rotavirus vaccine development for infant populations in India and beyond.

## **Preview Version**

### **Rotavirus Vaccine Trial with Offline IWRS Innovation**

6 Sites in India | Phase III | 7,500 infants | ~10 Months

DiagnoSearch delivered full-spectrum support for a high-stakes rotavirus vaccine trial in India. Leveraging operational rigor and offline IWRS technology, the study achieved rapid enrollment, robust safety reporting, and high-quality data across low-connectivity sites.