

## Medical Affairs

The Medical Affairs team at GVK Biosciences (GVK BIO) comprises of well trained medical professionals with cumulative Clinical Research experience of about 28 years. Our team is involved in various aspects of the conduct of a Clinical Trial, such as feasibility assessments, scientific development and review of protocol, training, medical monitoring and safety management. Our team has wide domain expertise in therapeutic areas such as vaccines, oncology, infectious disease, respiratory disease, pain management, neurological and psychiatric disorder.

### Service Models

#### Study Feasibility Assessment

Development and Distribution of Feasibility Questionnaire. Discussion on study feasibility with Key Opinion Leaders and other potential Investigators; typically the deliverables would be -

- Epidemiology overview and Standard of Care
- Expected recruitment rate
- Potential regulatory/IEC issues
- Investigator and site experience
- Relevant details of the IRB/IEC
- Other logistics and infrastructure requirements of the study protocol

#### Training

- Protocol and study related training for Investigators and site staff
- Therapeutic area and study related training for staff of related Clinical Research functions

#### Medical Monitoring and Safety Management

- Preparation and upkeep of Medical and Safety related SOPs
- 24x7 Serious Adverse Event (SAE) reporting services in compliance with Indian regulations and the Sponsors' SOPs including preparation of SAE case narratives

- Receiving, processing and archiving of SAE information including CIOMS reports
- Set up and maintenance of a safety database
- Medical support for SAE reconciliation
- Medical review of CRFs
- Coordination with the Sponsor, Investigation Sites and Project Management team for any medical or safety related issues

### Scientific Development and Review

- Preparation of Clinical Development Plan
- Providing therapeutic and scientific content for development of study protocol
- Design and implementation of pharmacoeconomic studies
- Review and approval of regulatory reports, manuscripts, abstracts, posters and other scientific documents
- Therapeutic and Scientific review of study documents (e.g. informed consent, CRF, IB, CSR, etc)
- Review and approval of medical coding using MedDRA /WHO DD

### About GVK BIO

GVK Biosciences (GVK BIO) is Asia's leading Discovery Research and Development organization. GVK BIO provides a broad spectrum of services, stand-alone and integrated, across the R&D value chain.

### Services

- Chemistry Services
- Process R&D and Custom Synthesis
- Biology
- Informatics
- Clinical Research
- Clinical Pharmacology

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