



Project Management

Project Management at GVK BIO is led by skilled and highly motivated executives with experience averaging 6-7 years. Our Project Managers (PMs) employ proven planning, time management, problem solving and communication skills to ensure timely project delivery, determined to exceed customer expectations. PMs are supported by Team Leads and Monitors, which assures GCP and regulatory compliance, data integrity and delivery of quality metrics. Our teams strive to promote positive personal relationships with a high level of mutual trust and self-confidence. Collectively, GVK BIO Project Management team has had a vast experience of working with a diverse set of customers across the Pharmaceutical, Biotech and Medical Device industries.

Services Offered

- Study Feasibility
- Site & Investigator Selection
- Site Monitoring
- Project Management
- Clinical Trial Supply Management
- Vendor Management

We offer customized services which can be availed on a standalone basis or as part of an integrated full service offering.

Regulatory Affairs

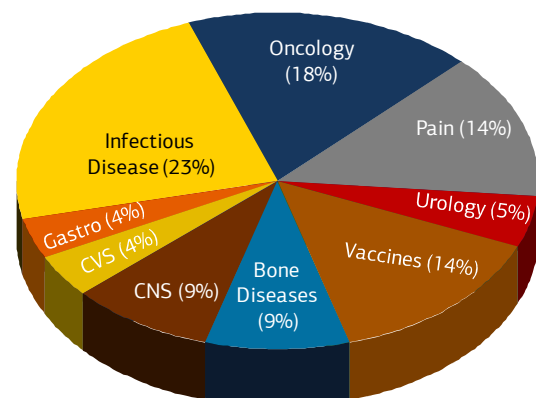
We have an experienced in-house team that provides consultancy and local regulatory liaison. The team manages submission of the Clinical Trial Application, follows up to obtain approval for conduct of the study and licenses for import/export of the investigational product, submits safety updates, annual status reports and troubleshoots on behalf of the client. In association with our US partners, we are capable of managing submissions to the US FDA for studies to be conducted under a US IND.

Therapeutic Expertise

GVK BIO has successfully worked in diverse therapeutic areas with studies that often have had stringent enrollment criteria, and tight timelines for submission to the USFDA, WHO or local regulatory authorities.

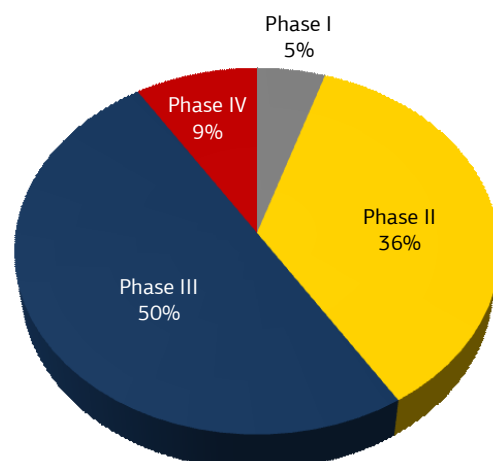
Therapeutic Expertise

Number of Studies (Percent)



Study Phases

Number of Studies (Percent)



Training and e-learning

Training activities are driven by a Training SOP that mandates regular training of all employees. New employees receive training in three phases:

- Mandatory and immediate
- Mandatory and extended
- Supplemental and refresher

Training is tracked and assessed through an electronic learning management system.

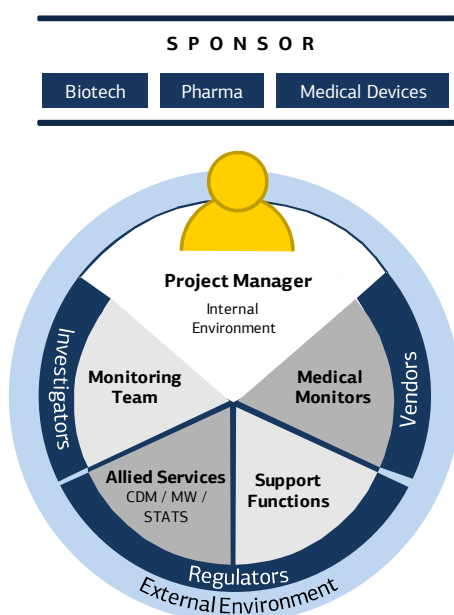
GVK BIO Presence

The GVK BIO Clinical Research unit is headquartered in Gurgaon, (Delhi, National Capital Region) with easy access to federal regulatory offices as well as to key investigators and institutions in the north of the country. In addition, a segment of clinical study management and monitoring staff are located regionally in Mumbai, Hyderabad and Chennai to ensure comprehensive coverage of sites along the critical North-West-South axis. Project Managers play a pivotal role through the course of the study, maintaining constant communication with sites, sponsors and regional monitoring staff.

Global Footprint

Membership in a consortium of CROs allows us to offer global recruitment capabilities across North and South America, Central and Western Europe, Russia, the Middle East, Africa and the Indian subcontinent.

Project Management



Every individual at GVK BIO is aligned to deliver highest value to clients, which is further reinforced by the quality of our Senior Management. Compliance, timeliness and cost consciousness are ingrained in GVK BIO personnel and processes to achieve highest level of client satisfaction.

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

Contact: bdcrd@gvkbio.com

Visit: www.gvkbio.com