

## Clinical Data Management Services

for Pharmaceuticals, Biologics and Medical Devices

GVK Biosciences (GVK BIO) is a full-service Clinical Research Organization that provides a broad spectrum of research services needed for conducting clinical trials. GVK BIO offers comprehensive clinical data management services on customer friendly business models. We work closely with our clients to assess their needs and customize a business model tailor made to suit their needs.

GVK BIO has the experience and resources needed to successfully design, conduct, analyze and report your clinical trial.

### Service Models

#### Onsite – Offsite Model

This model is specifically designed with customer convenience in mind. The process is based off client servers, and does not require CRFs / data to be sent out of country for processing. The presence of onsite GVK BIO staff allows for direct client- CRO interaction and direct oversight of service delivery. The offsite component allows for cost reduction and utilization of a 24-hour time cycle. Consulting, process identification and transition is then perfected in a quick and phased manner to stabilize and run the operation.



#### Build Operate Transfer (BOT) Model

Clients have come to appreciate the advantages of conducting Clinical Trials in India. However there are several challenges that companies face, like setting up infrastructure, building teams, dealing with geo-political and regulatory issues besides huge capital costs.

GVK BIO enables clients to rapidly start their CDM operations in India, realize cost savings, make them sustainable, and then transfer it as their own subsidiary.

Build, Operate and Transfer are the three stages of this model.

#### Standard Off-Shoring Model

This standard model is designed to offer complete end-to-end Clinical Data Management Solutions to our clients.

This model can also be adapted to function on a transaction / FTE basis.

#### Services

- Protocol review
- Data management plan
- CRF designing, annotation, completion guidelines
- Data validation guidelines
- Data entry guidelines
- Edit check specifications
- Database design, build and test
- Edit check programming and testing
- Data entry (Single and double data entry)
- Data validation and Query management
- Coding services:
  - Adverse event
  - Medication and laboratory
- Quality analysis
- Database lock and transfer
- Generation of data listings
- Database freeze and Transfer

#### Data Management – Technologies

- Oracle Clinical
- Thesaurus Management System
- MedDRA
- WHO DD
- SAS
- SAS Pheedit

## Expertise

- Our global head of Data Management has a rich experience in the clinical research industry. He has worked in the US, and gained hands on experience in understanding client requirements and issues.
  - Spearheaded transition and setup of the CDM division in India for a major US pharmaceutical company
  - Setup CDM Units across India for multiple CROs
  - Is an expert on majority of CDM platforms – Medidata Rave, Oracle Clinical, ClinPlus, Datalabs, and SAS PheedIt
- Our team comprises of outstanding talent drawn from Pharmaceutical and CRO industry with 5 to 10 years of international experience in Clinical Trials and Data Management. Our team members have experience in working across multiple therapeutic areas and all of them are extensively trained in ICH-GCP. Our Data Managers and Data Coordinators hold Doctorates / Postgraduate degrees in Life Sciences / Pharmacy.
- Clinical Data Managers bring more than 5 years of work experience on multiple EDC/ Paper-based platforms.
- Our Therapeutic Areas of Expertise are:
  - CNS
  - Oncology
  - Dermatology
  - Infectious Diseases
  - Women's Health
  - Musculoskeletal
  - CVS
- We have a rich experience in handling data for Phase I through Phase IV studies for submissions to local and international regulatory bodies (DCGI and FDA).

## Quality and Compliance

GVK BIO's CDM facility and systems are 21 CFR Part 11 compliant. Our working procedures are governed by SOPs and Work Instructions, which are routinely audited by our Quality Assurance Team to ensure compliance.

## Experience Snapshot

Therapeutic Area	No. of Studies
Cardiovascular	4
Dermatology	1
Drug Interaction	6
Gastroenterology	3
Gynecology	4
Infectious Disease	3
Neurology	3
Nutraceutical	1
Oncology	2
Vaccines	2

## EDC Capability

GVK BIO CDM works on SAS PheedIt, which is a SAS based Clinical Data Management System (CDMS) ensuring quick and smooth transitioning of data from Data Management to Biostatistics. With Electronic Data Capture (EDC), GVK BIO provides its clients several operational and cost advantages. EDC enables clinical sites to directly access and enter data into the database thereby reducing time and money involved in transferring / shipping / couriering paper CRFs.

- Data entry, review and reconciliation performed at the study sites
- Faster DCF Resolution as the sites directly enter resolutions and close out issues
- On-going cleaning and review of data until database lock without any backlog / delay
- Fast database lock within 15 working days of the last patient's last visit and receipt of last subject's data records

## 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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