OVERVIEW

HCL helps global life science companies accelerate the drug development process through conduct of clinical trials using innovative solutions, provided by its Asian Clinical Trials-CRO division that has done **75+** trials over the last **12+** years, in multiple therapeutic areas, in all phases. These high quality back office services are provided to support the sponsors and CROs clinical trial support needs cost efficiently.

The challenge today is to get products faster to market in a complex business and regulatory environment. HCL helps its partners to pass through rigorous clinical programs successfully to reach the launch stage and thereafter. HCL provides technical and scientific expertise to ensure a quality trial outcome.

REGULATORY SERVICES

Recently, India has undergone a regulatory transformation. In March 2011, the Drugs Controller General of India (DCGI) office formed the “New Drug Advisory” committee for each therapeutic area. This changed the review cycle and the process for new clinical trial applications. To further streamline the processes, on 01 Dec 2011, the DCGI initiated a new process to pre-screen applications for any missing documents and administrative requirements. With the objective to enhance the Rights and Safety of the clinical trial subjects, the DCGI made further amendments to the regulations that have an impact on submission documents. HCL has complete understanding of this transition and has the capability to facilitate the new process. Our capabilities for filing clinical trial applications and supporting applications like Import and Export Licenses in India are:

- Submission Dossier preparation
- Submission Dossier Quality Check for completeness and compliance
- Submission and Tracking
    - Filing of all submissions
    - Submission Tracking
    - Submission query resolution

HCL Life-Sciences unit also supports global sponsors in regulatory submissions. This is a bid to provide quality, cost effective and speedy submissions to sponsors globally.

Our state of art support center for global submissions has the following capabilities:

To support eCTD, NeeS and Paper format submission for the below submission types:

- Investigational New Drug Application
- Global Marketing Approvals
- Submissions for Maintenance of Marketing Approvals
- Structured Product Labeling

PROJECT MANAGEMENT

HCL’s CRO Project Management team provides the leadership to plan and integrate cross functional activity to keep projects on time and on budget with a dedication to quality assurance through every phase.

- Client interface
- Team management and leadership
- Financial management and resource planning
- Supply chain management
- Ensure timelines and milestones are met
- Risk analysis and contingency planning
- Monitor project metrics
- Facilitate team communication, escalation and reporting

SITE MANAGEMENT

HCL provides a wide range of clinical research services at the study site to meet quality and ICH-GCP compliance standards at the highest level.

- Study feasibility
- Investigator identification, selection and contracts
- Investigator meetings
- Site initiation
- Site support and interactions
- Routine Onsite monitoring
- Remote Central Monitoring
- Risk Based Monitoring
- Study close out
- Compliance with Protocol and ICH-GCP Guidelines
- Site performance metrics and Database Maintenance in Future Studies and Contract Negotiations

MEDICAL MONITORING

HCL's medical monitoring team brings in broad therapeutic expertise and has experience in understanding study challenges and manages the study outcome to ensure highest safety as follows

- Manage and maintain investigator database
- Create protocol-specific feasibility questionnaire
- Therapeutic area / indication training of project team
- Provide medical oversight and support to project team
- Site support for medical, protocol and subject related issues
- SAE management (Triage, causality assessment and narrative writing)
- Review safety lab data and / or other safety data
- Medical review of statistical analysis plan and integrated report

MEDICAL WRITING

HCL's medical writers have a strong academic, pharmaceutical and biotechnology industry background and can help clients' prepare clear, concise and high quality:

- Clinical study reports
- Investigator's brochure
- Clinical trial protocols
- Informed Consent Forms
- Risk Profiles
- Patient Narratives
- Clinical Sections of CTD/NDA
- Manuscripts
- Abstracts
- Posters • Slide Kits • Literature Searches

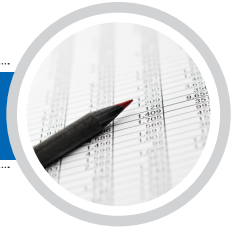
SAFETY SURVEILLANCE

HCL's medical monitors are available on a 24/7 response line to take medically related questions or for reporting Adverse Events.

The Safety surveillance services include:

• Review of protocol , investigator brochure, informed consent form and case report form • Safety monitoring • SAE collection, evaluation, classification and reporting to central IRBs/Sponsors /Regulatory authorities • Safety database development • Organize independent data monitoring board • Periodic Safety Update Reports (PSUR) • Drug Safety Update Reports (DSUR) • Periodic Adverse Drug Experience Reports (PADER)

CLINICAL DATA MANAGEMENT



HCL provides sophisticated solutions using various platforms. These solutions are complete end to end processes, with the integrated Electronic Data Capture; allowing companies to rethink some of the traditional paper based clinical data management processes.
HCL automates database design, data collection, data management and regulatory submission, using an architecture that can scale to handle hundreds of studies per year. This helps its customers to bring medical products to market faster with significant cost savings.
HCL's data management team brings in their wide expertise in a range of therapeutic areas in different phases using multiple platforms. The team is well equipped to provide data management support for studies of different sizes and complexity. They deliver accurate, clean and locked database on time. HCL's data management services include:

- Database & eCRF design
- CRF management
- Double data entry
- Electronic data capture
- Data validation and review
- Medical coding using MedDRA & WHO Drug
- Data processing and migration
- Data generation for analysis
- Trial scalability and site flexibility
- Transparent/seamless data conversion
- Quick setup time and economical cost
- CDISC

Platforms:

- Oracle Clinical
- OC RDC
- eTrials
- RAVE
- InForm
- ThinkClinical
- Panther
- Trial Master

BIOSTATISTICS

HCL's in-house biostatisticians provide crucial analytical expertise for coordinating clinical trials and are involved in trials from study design to total analysis or published manuscript, and beyond.
HCL's biostatistical services include:

- Protocol development, including sample size and power calculations
- Randomization schedules
- Statistical analysis plans
- CDISC® Study Data Tabulation Model (SDTM) Mapping and Conversion, Generation of ADaM (Analysis of Data Models). HCL has pioneered CDISC Metadata BRIDG Conversions
- Analysis Dataset Programming and Documentation
- Clinical and Statistical SAS® programming(Generation of Tables, Listings and Figures Programming)
- Interim analysis for early decision making
- Tables, Listings and Figures Validation and Quality Control
- Integrated summary of safety (ISS) and efficacy(ISE) summaries
- Adhoc Statistical Support
- Interpretation and reporting of data for clinical trial reports and publications

QUALITY ASSURANCE

HCL's Quality Assurance Program is delivered with scientific and mathematical precision. HCL is committed and focused on meeting its clients' QA needs.

The array of Quality services HCL provides is:

- GCP, GLP and GMP audits
- Investigator Site Audits
- Vendor Audits
- SOP Management
- Quality Systems Training & Development