Clinical Data Management

BPaaS Approach

HCL Technologies

Leading pharmaceutical companies are estimating new business models— including alternative Clinical data management platforms—to reduce costs, shorten timelines, and maintain quality and compliance. HCL Life-Sciences Business Process Services will help you achieve within cost boundaries with efficacy.

Situation

HCL understands that the client needs a supporting hand for enhancing the speed of the trial; managing the pouring data from the trials and streamlining it to make it available for analysis. Addressing the challenge of handling robust, varied and high quality data by controlling the cost on the same hand, we extend our services in data management by bringing together the best team on to the field and also ensure quality and regulatory compliant services. Our team has the best knowledge on CDISC guidelines, ICH-GCP and applicable regulatory guidelines knowledge, knowledge in industry standard clinical data management systems as well as EDCs

Out sourced Clinical Data Management is a prime growth driver for both you and HCL, therefore you would need HCL as a dedicated partner to efficiently manage your clinical data and help you meet your desired business objectives in cost effective manner.

Overview

Since 2002, HCL Technologies and its CRO partner have provided clinical solutions in Indian and global market which has been helping many biopharmaceutical sponsors, clinical research organizations (CROs) and medical device manufacturers realize the true potential of the Clinical Data Management and its technologies.

HCL Technologies is synonymous with exceptionally competitive and rich functionality, underpinned by the renowned performance, scalability and resilience inherent in clinical technology platform. Uniquely focused on simplifying data/form design process and delivering superior data programming experiences, the HCL Technologies implementation of Oracle Clinical platform help streamline the entire process starting from study design all the way to collection, management, reporting and submission of clinical trial data.

Our CDM Scope of Services

HCL's Clinical Data Management (CDM) practice provides quality data for clinical trials and succeeds on processing improvement through permanent feedback, state-of-the-art systems, training and teamwork. Our practice includes a combination of technology and function expertise.

Our experts work in partnership with sponsors and investigators/sites to cover data collection, database setup and maintenance, data entry, data cleaning and storage in compliance with regulatory submission requirements and project objectives.

STUDY SETUP

Protocol Development	eCRF Design	DMP Development
Edit Checks & Data Validation Specs	IVRS Setup & Integration	Database Testing & UAT

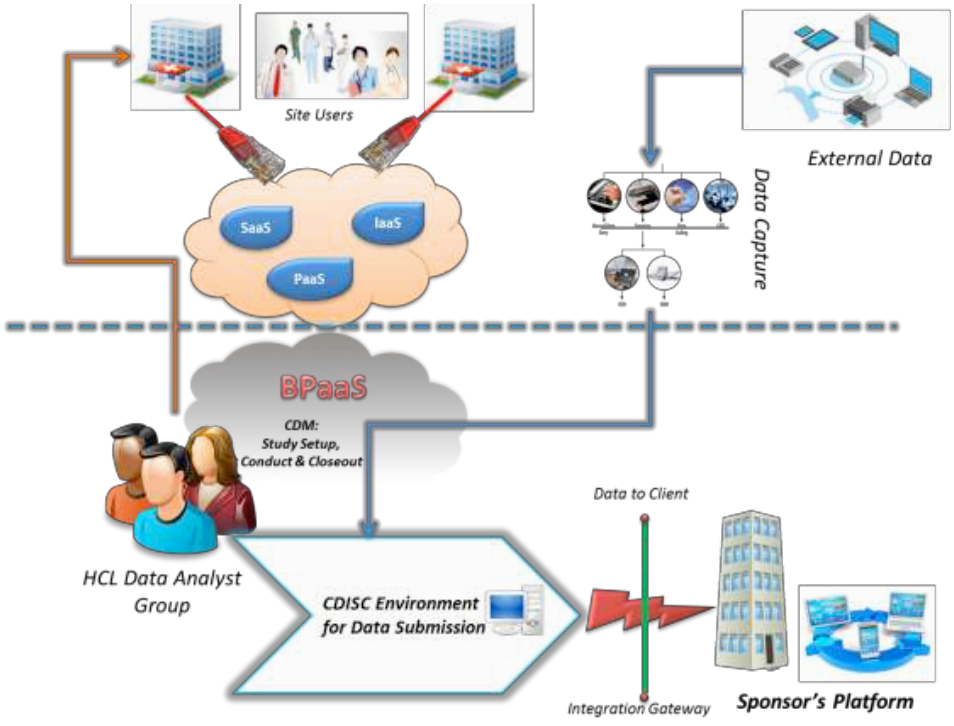
STUDY CONDUCT

Data Entry	External Data Loading & Reconciliation	Discrepancy Management
Query Tracking & Resolution	Interim Analysis / DBMS / Data Analysis	DB QC & Audit
Dictionary Coding & Mapping	SAE Reconciliation	Safety Listing

HCL Global CDM Solution

HCL's experienced Clinical Data Management (CDM) team recognizes the importance of coordination between the CRAs, Project Managers, Sponsors and Investigational sites. The Data Management group is highly experienced in managing clinical data across various Phases of clinical research. Our experienced team ensures that thorough quality checks are performed, as per the CDISC's Data Coding Guidelines that include converting and reporting on specific data collected from Clinical trials.

Our focus in to maintain the BPaaS methodology to share and publish reports while keeping the CDISC's regulations as our priority. Business Process as a Service (BPaaS) refers to a business process layer on top of cloud services such as Software as a Service (SaaS), Platform as a Service (PaaS) and Infrastructure as a Service (IaaS). It encompasses business process services for all horizontals within our Life-Science capabilities as well as different vertical business processes through a feature-rich
platform for delivering automated business outcomes.



An Overview of Proposed Methodology: BPaaS

The need for increasing the alertness of a business process, along with cost control measures is playing a fundamental role in shaping the future of Business Process as a Service. The adoption of these solutions is gaining popularity regardless of cautious approach of organizations and compliance concerns.

BPaaS is expected to enjoy enduring growth and have a pervasive existence across all activities within Clinical Research outsourcing including Clinical Data Management, owing to the growing demand for automation and virtualization of workplace. BPaaS is well-positioned to provide solution specifically for globally spread businesses, despite different organizational structures and business process needs.

HCL Abides by CDISC:

To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.
Our purpose is updating patient care and safety through higher quality medical research.

Advantage HCL:

HCL Technologies have been serving global Pharmaceutical clients, supporting them on various clinical activities and hence we understand the importance and delicacy of clinical trials and patients' safety involved.

You can count HCL on:

- Following FDA regulatory submissions guidelines
- Standardizing predefined collection of submission metadata domains
- Complementing the SDTM submission by detailing the statistical analysis
- Supporting audit trail, XML technology, machine readable storing of ODM
- Establishing a standardized data collection baseline across all submissions