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ClinOps+

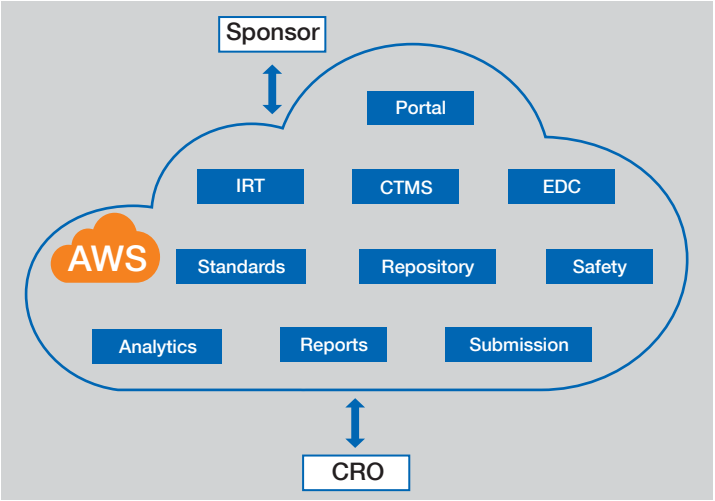
COMPLETE CLOUD-BASED CLINICAL TECHNOLOGY PLATFORM

HCL's ClinOps+ is a comprehensive cloud-based clinical information management platform from study start-up through regulatory submission. ClinOps+ is a natural fit for early phase and late development trials as well as for small and medium businesses as it is a completely self-contained clinical operations platform, which requires no additional application components to fulfill Clinical R&D business functionality.

ClinOps+ cloud platform was developed in collaboration with EDETEK and is served on the Amazon Web Services (AWS) Cloud supporting globalization, on-demand scalability, managed software services, highest levels of information privacy and overall systems controls for GxP compliance.

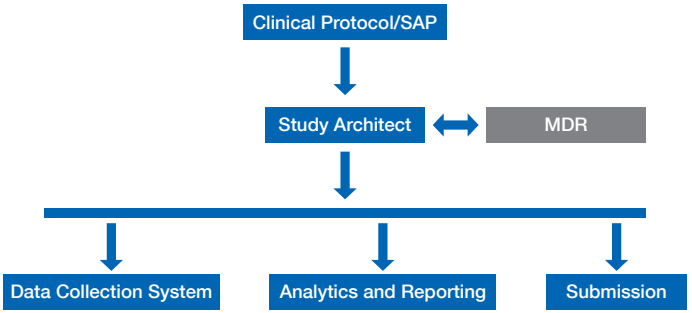
Built on standards and supporting consumption and/or production of industry standards, such as CDISC, HL7, and BRIDG, ClinOps+ leverages the latest technologies in study design and data collection, semantic management, statistical analysis and information visualization.

Our platform utilizes simplistic and yet efficient commercial study-based pricing model. ClinOps+ fully integrates all clinical operational business processes in a computing environment fully consumable from cloud. *It contains all of the technology required for a clinical trial. No additional investment is needed.*



ClinOps+ makes externalization of Clinical Trials more effective by allowing all partners to collaborate on a single information platform. Several biopharmaceutical companies as well as clinical research organizations (CROs) are already using the full-suite or individual components of the platform.

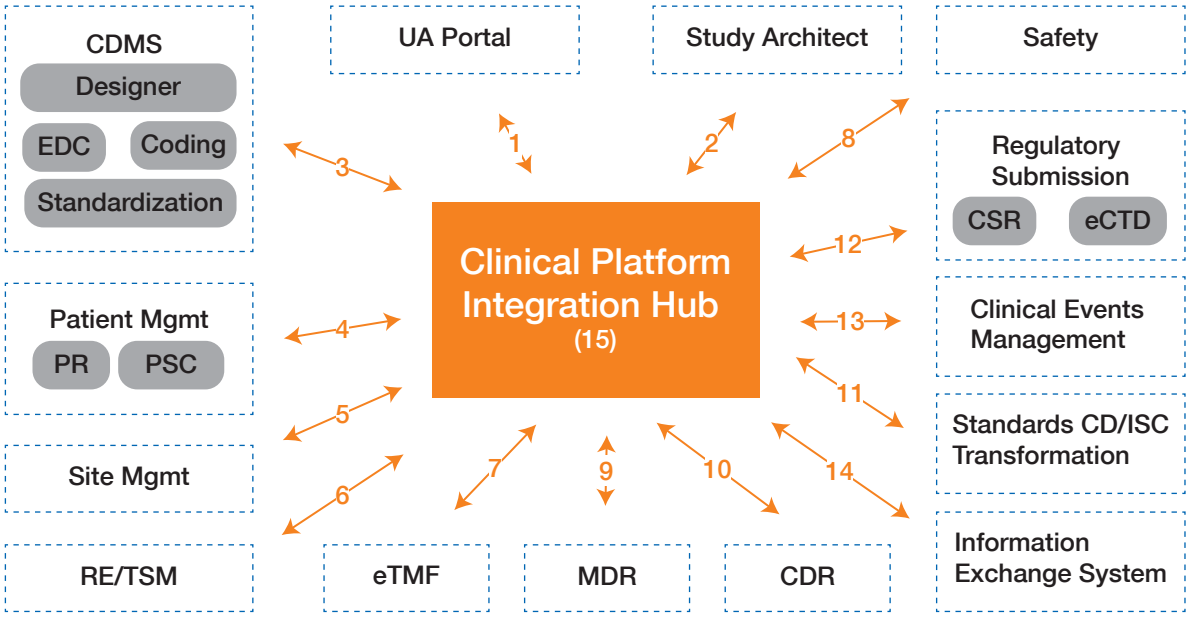
The protocol design driven study engineering automates creation of various study components such as CDASH eCRFs, SDTM and ADaM mapping, data validation routines, TLFs, CTMS milestones, etc. reducing time and improving quality. The ClinOps+ modular design and service-based architecture enable integration with a customer's existing applications via WEB services and clinical data standards.



CLINOPS+ PLATFORM FEATURES

- SaaS Cloud Application Architecture
- Metadata-based automated Study Setup and Application Components engineering
- Out of the box shared database or event-based integrated clinical transactional systems
- Data Standardization across all application components
- Data Exchange and Analytics for Clinical and Operational Data
- Support for Relational Databases and File-based information repository with complete traceability for all data changes and transformations performed within the Platform
- Private Information Repositories for Sponsors
- Industry standards for data privacy and encryption (to meet or exceed on premises corporate standards)
- Choice of Global Locations
- Identity Management and Data Access Optimized for CROs and Pharma
- Robust scalable (up and down) cloud-based infrastructure globally, near real-time processing and support for IoT
- Data and Document Archive
- Global Business Continuity / DR system
- GxP Compliance on the Cloud
- "Pay as you go" Pricing

HCL CLINOPS+ APPLICATIONS



1. **UA Portal (Universal Access Portal)** Provides unified WEB access to the entire Platform, with interface for management, monitoring, data collection, reporting, and administrative functionalities.
2. **Study Architect.** Translates Clinical Protocol and SAP into the metadata set that drives configuration and settings of downstream applications
3. **CDMS (Clinical Data Management System)** eCRF and Study Specific Design, EDC setup and execution, coding, data standardization based on CDISC CDASH CRFs, edit checks, discrepancy management, SDTM output
4. **Patient Management** Provides patient registration, study calendar setup, and activity tracking functionalities.
5. **Site Management** Provides site registration, investigator management, communication, and monitoring functionalities.
6. **RE/TSM (Randomization and Enrollment/Trial Supply Management)** Provides patient randomization and recruitment, trial supply management, drug dispensing, and controlled un-blinding functionalities.
7. **eTMF (Electronic Trial Master File)** Enables centralized management of study documents, including versioning, workflow, and audit trails.
8. **Safety (Adverse Event Reporting System)** Supports adverse event recording and reporting.
9. **MDR (Meta Data Repository).** A multi-level repository of clinical meta data –information about structures that contain actual data. Supports history and auditing.
10. **CDR (Clinical Data Repository)** Provides centralized storage of clinical data, as well as all the associated metadata. It represents the single version of truth for all study information. Supports Relational and File based storage and data lineage information
11. **Standards /CDISC Transformation** Comprehensive product for conversion of patient data into Custom or CDISC standard formats (SDTM, ADaM, etc.)
12. **Regulatory Submission** Support medical writing, CSR development, and eCTD based submission.
13. **Clinical Events Management** Customizable repository, reporting, analysis and workflow of all scientific, business, process integration and systems events occurring during the conduct of clinical trials
14. **Information Exchange Platform** Provides bi-directional data and metadata exchange interface with external systems. Support HL7 V3, XML, SAS, CSV and other formats.
15. **Clinical Platform Integration Hub** A single Computer System responsible for integration of all Clinical Applications of the Platform. Provides interfaces for integration of external applications.

END-TO-END DATA STANDARDIZATION

Fully Integrated; Standards and Metadata Driven				
Protocol and SAP Analysis	CRF Design	Database Setup & Operation	Database Creating and Statistical Analysis	Study Writing and Publishing
PRM	ODM/CDASH	OOM/CDASH	SDTM/LAB/ADaM	eCTD
Study Architect	eCRF Designer	EDC	Study Reporter	Study Writer

- Metadata-driven methodology with industry CDISC and BRIDG standards in its core
- Comprehensive MDR
- Capture of Study settings and SAP analysis from clinical documents, creation of metadata elements
- Built-in CDASH library drives eCRF design creation in EDC and the SDTM Production
- Automation of ADaM data set creation as well as production of TLF shell specifications.
- CDISC transformation engine can transform data on-demand or automatically into targets SDTM, ADaM based standards while maintaining end-to-end traceability from source to target data

HCL CLINOPS+ SUMMARY

- The only “One Stop Shop” for all Clinical Applications on the Cloud
- Resides in the World’s Largest Computing and Information Cloud. GxP compliant
- Common user interface across applications increase adaptability and productivity - the system was designed as a unified and integrated Clinical Platform
- Systematic management of business processes among external and internal study contributors via comprehensive and customizable workflows – we bring sponsors and CROs together into one collaborative computing environment
- Protocol design driven clinical study settings – automated study engineering. Complete study set up in days (not weeks or months)
- “Designed for Cloud Platform” Computing and Consumption (not a typical legacy application ported to cloud).
- Incorporates numerous technological innovations and more are coming
- Industry first Clinical Data Lake repository of information
- The only event – driven clinical platform. Provides actionable business and systems events as well as analysis of events
- Any number of studies and individual study of any size and duration are supported
- Attractive all inclusive commercial model with per study pricing and no capital expenditures
- Typical savings of 25-50% off current spend on clinical technology

HCL LIFE SCIENCES & HEALTHCARE

HCL is a leading provider of Life Sciences and Healthcare Business and Technology services. We are the chosen service provider for enabling new growth drivers for our clients, providing them with industry leading best practices, taking care of their compliance needs and ensuring goldstandard process cycle times. Our clientele includes seven of the top ten global pharmaceutical companies, seven of the top ten medical devices companies, six of the top ten health plans, three of the top five CRO's and two of the top three data providers. Equipped with certified technology experts and domain specialists, HCL offers services in critical areas of the life sciences and healthcare eco system such as drug discovery, clinical development, drug safety, regulatory compliance, manufacturing and plant automation, commercial, Healthcare analytics, Population Health Management [PHM], mHealth, member experience management [MEM], fraud, waste and abuse management [FWA].

Let's connect:

Please feel free to write to us at contact.lsh@hcl.com

ABOUT HCL

ABOUT HCL TECHNOLOGIES

HCL Technologies is a leading global IT services company working with clients in the areas that impact and redefine the core of their businesses. Since its emergence on the global landscape, and after its IPO in 1999, HCL has focused on 'transformational outsourcing', underlined by innovation and value creation, offering an integrated portfolio of services including software-led IT solutions, remote infrastructure management, engineering and R&D services and business services. HCL leverages its extensive global offshore infrastructure and network of offices in 31 countries to provide holistic, multi-service delivery in key industry verticals including Financial Services, Manufacturing, Consumer Services, Public Services and Life Sciences & Healthcare. HCL takes pride in its philosophy of 'Employees First, Customers Second' which empowers its 105,000 transformers to create real value for customers.

HCL Technologies, along with its subsidiaries, had consolidated revenues of US$ 5.8 billion, for the Financial Year ended as on 31st March 2015 (on LTM basis). For more information, please visit www.hcltech.com

ABOUT HCL ENTERPRISE

HCL is a $6.5 billion leading global technology and IT enterprise comprising two companies listed in India – HCL Technologies and HCL Infosystems. Founded in 1976, HCL is one of India's original IT garage start-ups. A pioneer of modern computing, HCL is a global transformational enterprise today. Its range of offerings includes product engineering, custom & package applications, BPO, IT infrastructure services, IT hardware, systems integration, and distribution of information and communications technology (ICT) products across a wide range of focused industry verticals. The HCL team consists of over 100,000 professionals of diverse nationalities, who operate from 31 countries including over 505 points of presence in India. HCL has partnerships with several leading global 1000 firms, including leading IT and technology firms. For more information, please visit www.hcl.com

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Relationship™
BEYOND THE CONTRACT

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