HCL

DIaaS
(DATA INTEGRATION AS A SERVICE)
CDISC CONVERSION PLATFORM

HCL DIAAS (DATA INTEGRATION AS A SERVICE) – CDISC CONVERSION PLATFORM

INDUSTRY PERSPECTIVE

The majority of commercially available clinical study data conversion solutions and services for CDISC (SDTM, ADaM) and/or custom derived clinical data standards are resource intensive. Manual execution steps and poorly executed re-usable components prevent efficient processing and need to be repeated for each conversion endeavor. Data quality and validation tasks are cumbersome and rarely automated, which leads to increased costs. Complete end-to-end workflows and collaboration tools with the sponsor are often non-existent. Comprehensive Metadata Repositories (MDRs) either are in development stages or poorly integrated.

This prolongs the execution time. Consequently, economies of scale are difficult to achieve as more and more clinical studies need transformations. As a result, quality, delivery and functionality issues exist resulting in unmet business needs.

HCL SOLUTION

We believe as sponsors focus on CDISC SDTM conversion of legacy and live studies, it is important to use automated CDISC conversion tool with reliable and consistent quality to reduce workload on operational tasks while minimizing time required for conversion. HCL offers conversion of legacy and live clinical study data to SDTM and other popular formats format by leveraging its own Data Integration as a Service (DIaaS) platform comprising of CDISC registered tool which adopts a cost-effective factory-based, and MDR- driven metadata approach to automated CDISC conversion tools.
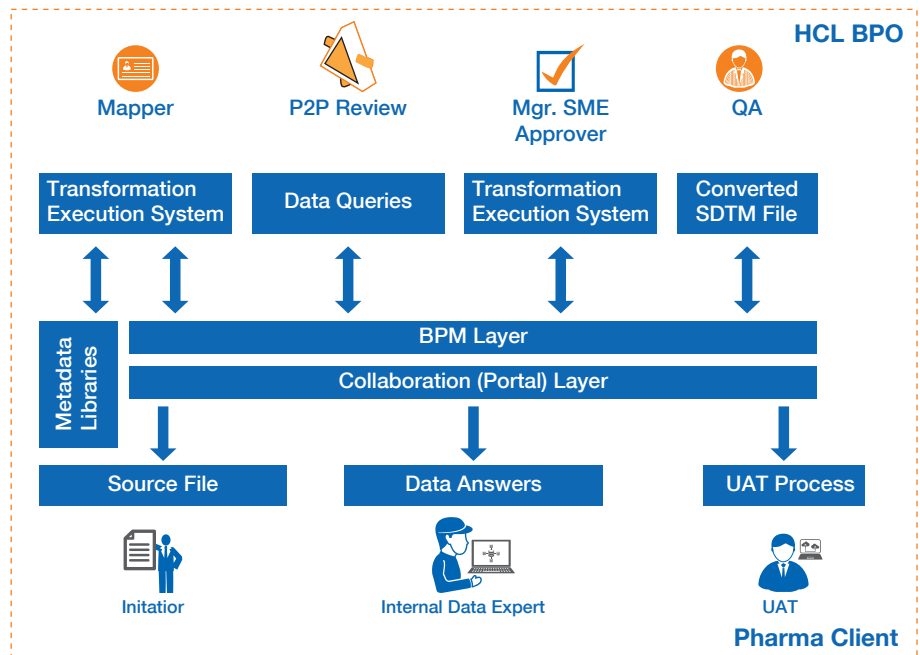
The following graphic depicts the HCL industrial assembly line approach process for SDTM:
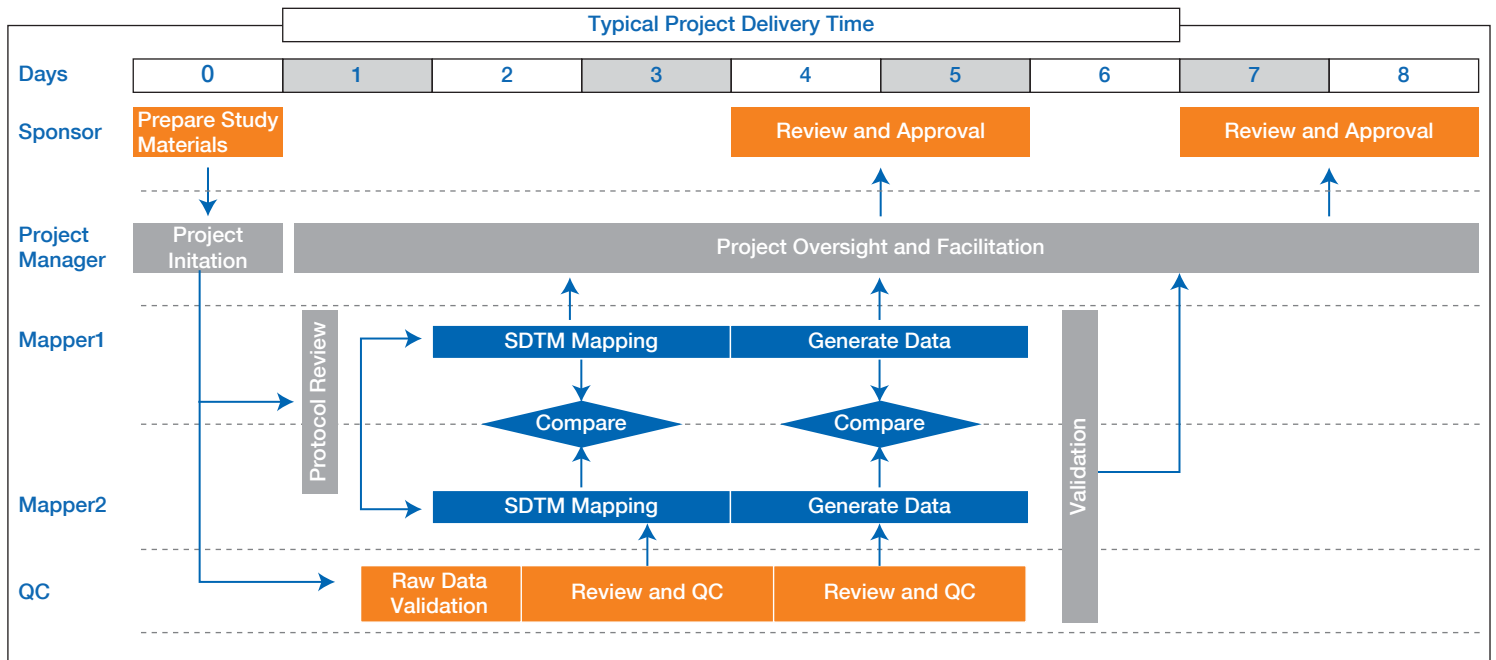
A well-defined centralized access management system proactively manages multi-partner user's access to specific studies while supporting assigned user-specific business functions across systems in all phases of study conduct as well as to facilitate regulatory inspections.

CDISC SDTM "ASSEMBLY LINE"

DIaaS is a combination of the state of the art clinical technologies and HCL's CDISC center of excellence with 100+ trained individuals operating in the USA, Europe and Asia.

DIaaS customers typically received converted data sets in a fraction of time the industry is accustomed to seeing. Displayed below is a representation of an average new study conversion process/timeline (with no mapping inheritance from MDR):

Typical Project Delivery Time

Days	0	1	2	3	4	5	6	7	8

Sponsor: Prepare Study Materials | Review and Approval | Review and Approval

Project Manager: Project Initation | Project Oversight and Facilitation

Mapper1: Protocol Review | SDTM Mapping | Generate Data | Validation

Compare | **Compare**

Mapper2: SDTM Mapping | Generate Data

QC: Raw Data Validation | Review and QC | Review and QC

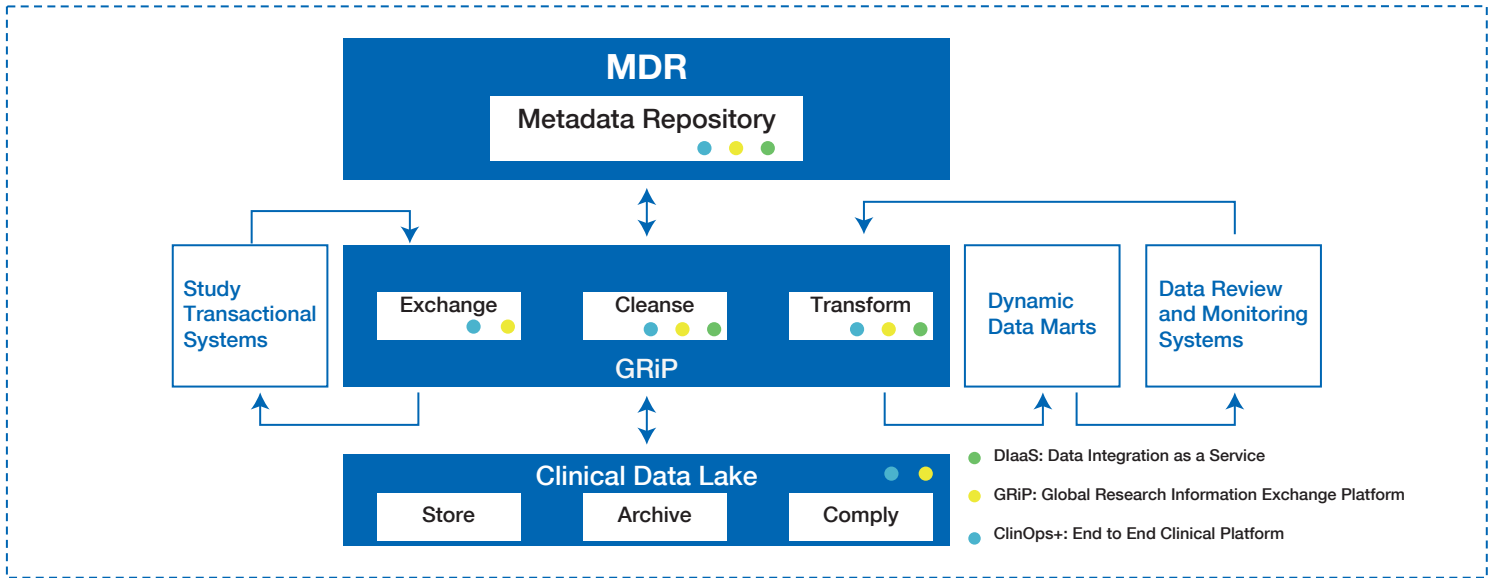## KEY FEATURES OF THE HCL DIAAS SOLUTION ARE:

- Cloud based offering with virtually unlimited scalability and complete security
- GxP Compliance
- Metadata driven to manage the intelligence and automate the mechanics
- Comprehensive MDR integrated within the product
- Structured and workflow managed processes for enhanced coordination
- Systematic and comprehensive QA process ensuring high quality of deliverables

- 100% transparency and traceability with consistent and comprehensive documentations
- Independent double data mapping with automatic results comparison
- Built-in validation framework with automated and custom edit checks
- Reduction in time/resource requirements
- Supports ODM, CDASH, SDTM, ADaM and BRIDG standards
- Application Integration via WEB Services: CDISC conversions can be executed automatically via included WEB Services API

BUSINESS BENEFITS

Cost
- Reduction in time/resource requirements
- Error reduction

Control
- Elimination of "black box processes"
- Elimination of bottle necks
- Process visibility for sponsors

Performance
- Streamlined processes
- Parallel processing of operations
- Automated Programming (Code generation)

Quality
- Single Version of Truth
- Enhanced communication
- Reduction in human error

Flexible Implementation

- Per Study Service Subscription (HCL Performs service)
- Enterprise Licensing (for product in sourcing)
- Bundles. DIaaS can also be purchased as an integrated part of the larger HCL Products that offer more enterprise-class business and technical capabilities
  - GRiP: Global Research Integration and Exchange Platform
  - ClinOps+: End-to-End clinical application platform

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

NOTES

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Relationship
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