HCL

Industrialized Clinical Data Standards Management

Speed of automation, Power of accuracy and Transforming clinical data into business intelligence

Executive Summary

The majority of commercially available legacy clinical study data conversion solutions 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. This prolongs the execution time. Consequently, economies of scale are difficult to achieve as more and more legacy studies are converted. As a result, quality, delivery and functionality issues exist resulting in unmet business needs.

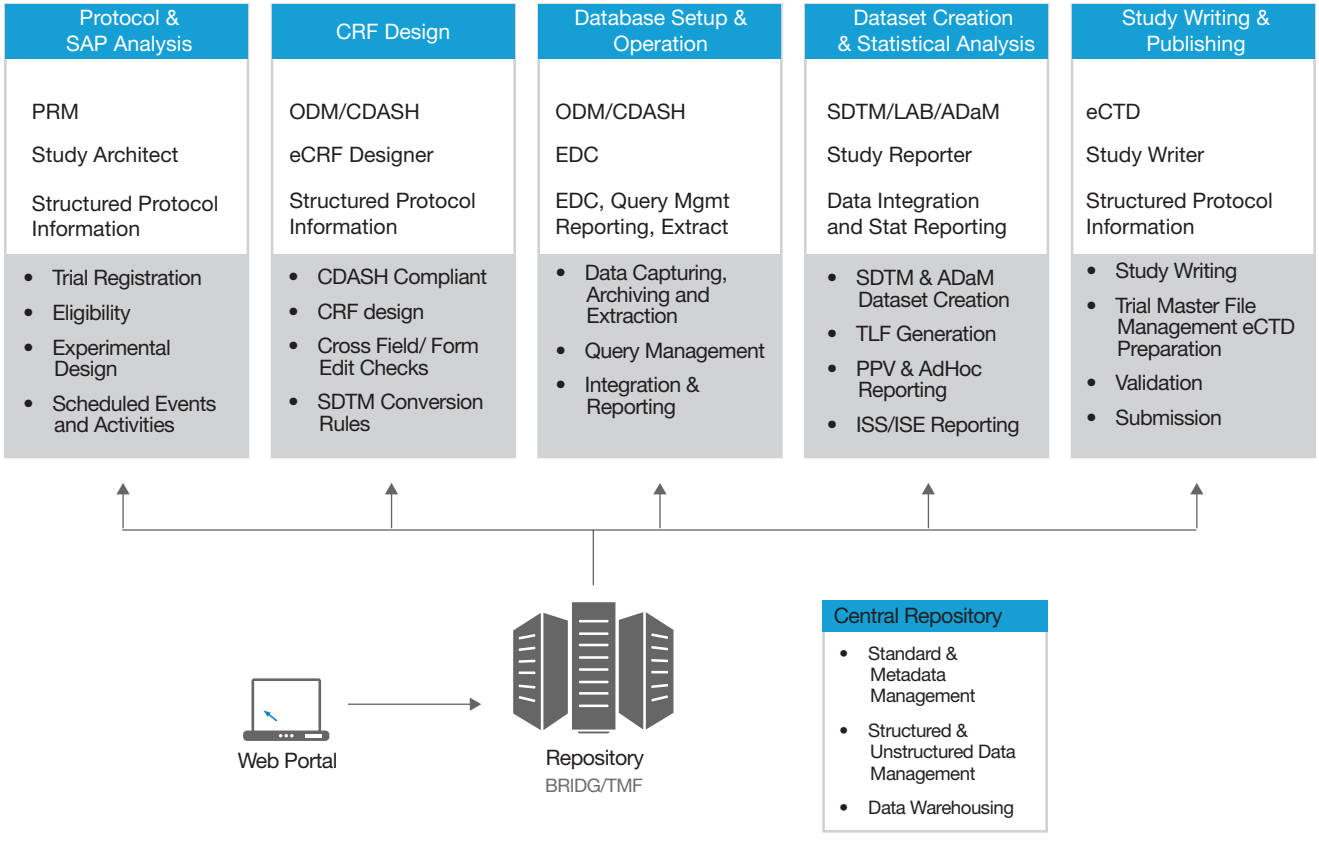
Application Summary Proposition

HCL has developed an innovative metadata driven approach to "Industrialized Clinical Data Standards Management". Our Data Integration as a Service (DIAAS) proposition is a "One Stop Shop" for data transformation from any source to any industry or proprietary target standards. This service is available for conversion to the following formats: CDISC standards (ODM, CDASH, SDTM, LAB, ADaM), or BRIDG model. It will deliver significant business value through the increased automation of key portions of the legacy clinical data conversion process using Business Process Management tools (BPM), including work flow management, business activity monitoring and collaboration.

The system is deployed on HCL's Infrastructure Cloud offering virtually unlimited scalability and complete security for our clients. The system can be used for legacy (archived) studies as well as for the active or live studies with both Data Warehousing and Regulatory submission targets.

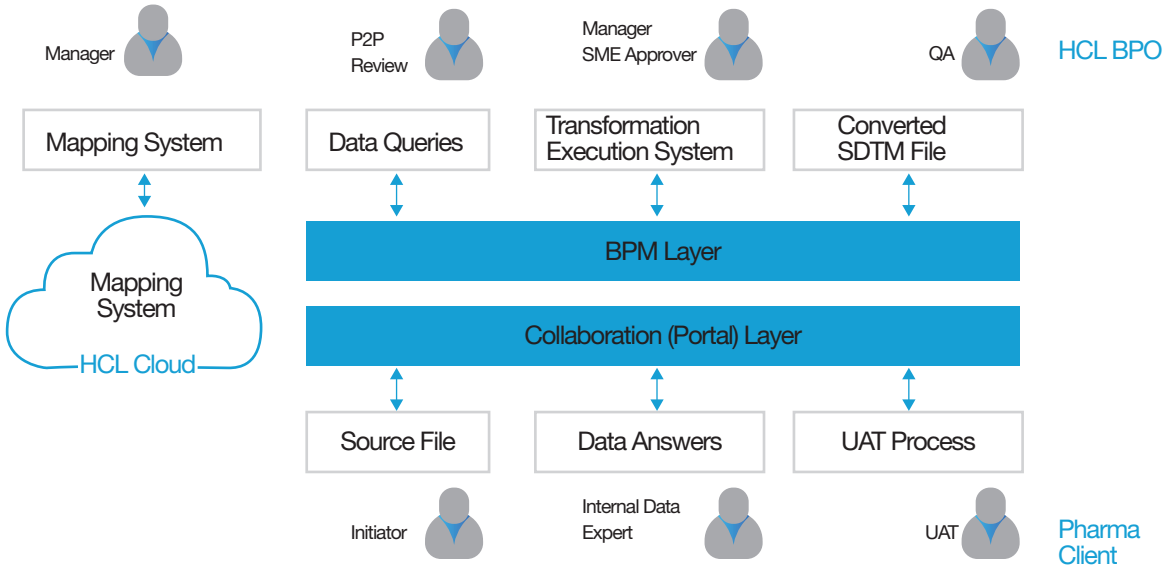
What HCL brings to the table?

HCL offers the DlaaS Platform as "One Stop Shop" solution for data transformation from any source to any industry or proprietary target standards.
Below is a depiction of a typical clinical study lifecycle stages. Stage 4 is when the study conversion occurs.



The system and product features of DIaaS Platform include

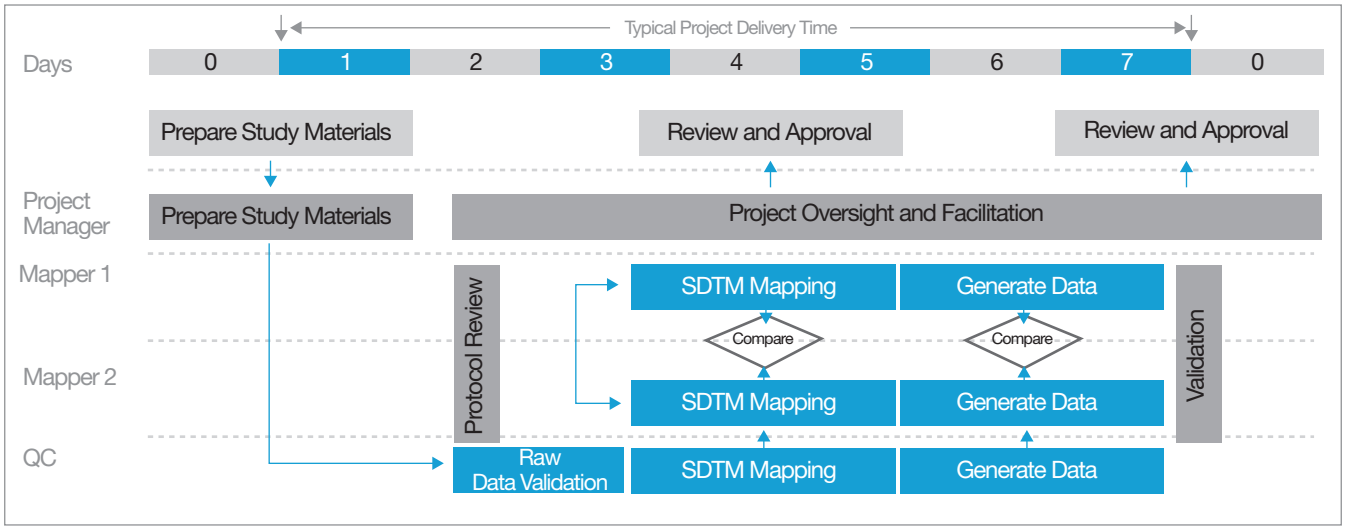
CDISC SDTM 'Assembly Line'



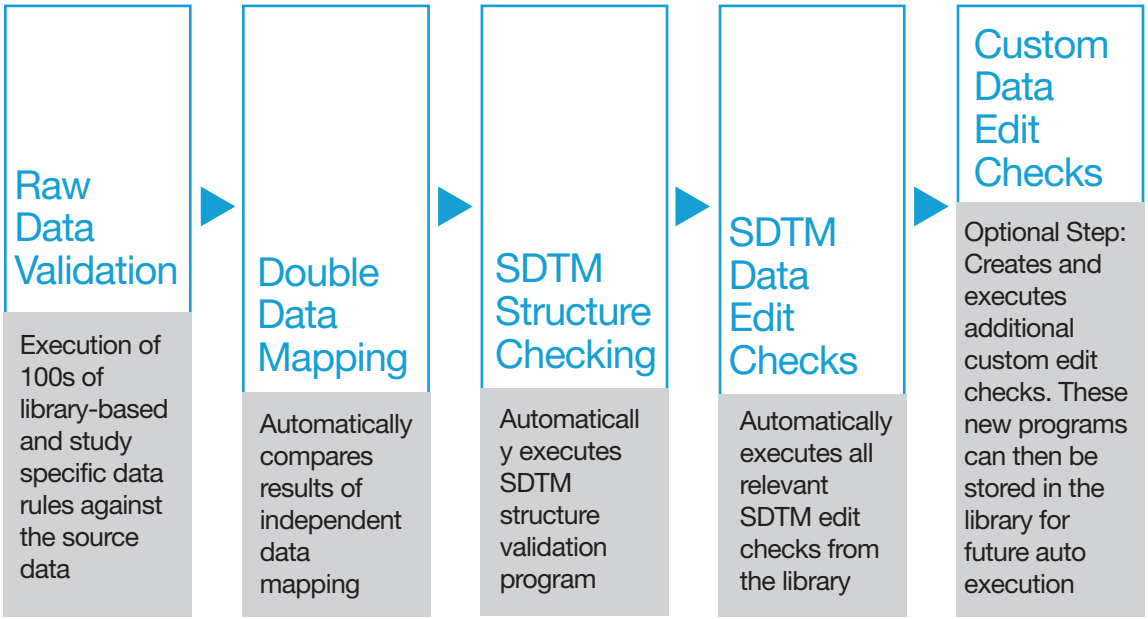
Product features of DIaaS Platform

- Metadata Driven
- 100% Transparency
- 100% Consistency
- 100% Traceability
- Raw Data Profiling
- Define PDF and XML
- Workflow Management
- Built-in Validation Framework
- Library and Knowledge Base
- Unlimited Scalability
- Economies of Scale

High level legacy study conversion approach



Comprehensive multi-step validation minimizes or eliminates UAT



Key principles to the approach

The metadata driven approach gives complete control in successfully performing and managing legacy study data conversions. The benefits of this approach are illustrated below:

Challenges

- Constantly Changing Requirements
- Enterprise View has been a mirage
- Slow turn around
- Organic growth

Solutions

- Govern & Manage requests, Enhance knowledge
- Develop Enterprise Level Semantics
- Improve Analysis, Design & Development
- Adopt Application, Agnostic Data Architecture

Metadata Driven Approach (MDA)

- Manage the Intelligence
- Automate the Mechanics

Business Benefits

DIaaS Platform offers the following business benefits:

Cost

- Reduction in sponsor provided time/resource requirements
- Simplified pricing
- Error reduction

Control

- Standardized & metadata driven
- Elimination of “black box processes”
- Elimination of bottle necks
- Process visibility for sponsors

Performance

- Streamlined processes
- Automated programming

Quality

- Single version of truth
- Enhanced communication
- Reduction in human error
- Built in QA/QC framework

HCL Industrialized Data Standards Management Service Offerings

Data Standardization Consulting Services

- Establish Data standards strategy
- Perform gap-analysis
- Develop implementation roadmap
- Implement solution

End to End Data Submission Package

This standard service includes:

- Migration of source clinical study to an SDTM/ADaM compatible SAS transport file per the FDA regulations
- Creation of documents - Annotated CRFs, Define.xml, Define.pdf, Reviewer Guide, etc.
- Pre-conversion processing (standardization, integration, profiling, and cleansing) of the source file, raw CRF annotation, double data mapping and 3-step SDTM/ADaM data validation

Additional optional services include:

- Validation against existing reports, such as CSR
- Pre conversion additional data checking
- Post conversion additional data checking
- Custom edit checks
- Integrated Summary of Safety and Efficacy (ISS/ISE)

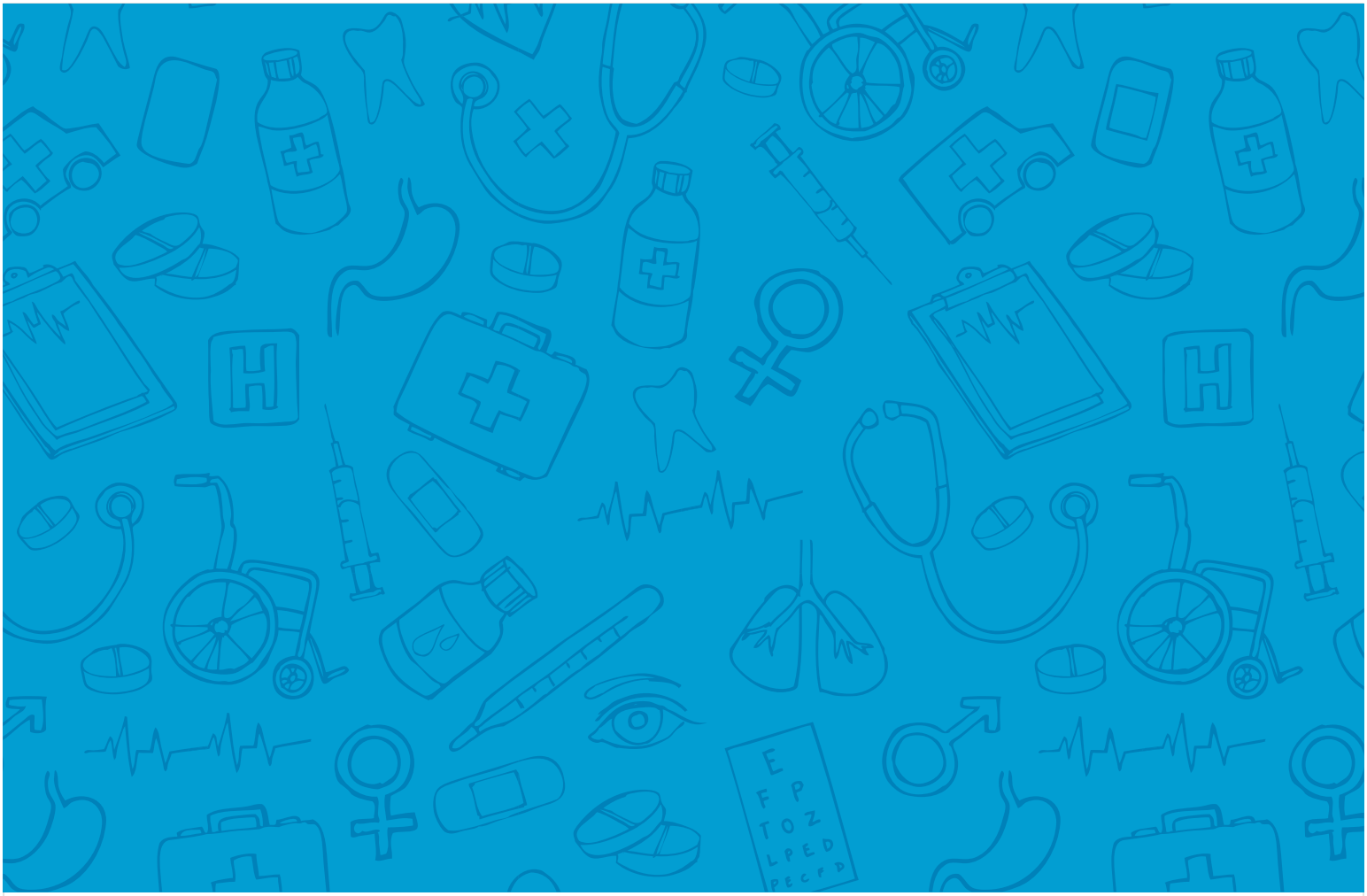
CDISC SDTM conversion for live/legacy studies

This standard service includes:

- Inputs – EDC (e.g. OC-RDC, InForm, Rave, ODM)
- Pre conversion processing
- Metadata-driven conversion into sponsor specific SDTM format
- Single data mapping
- 2-step SDTM data validation
- Real-time data validation
- Data visualization (patient profiles), analysis and reporting

Additional optional services include:

- Pre conversion additional data checking
- Post conversion additional data checking
- Custom edit checks
- Double data mapping and corresponding validation



CDISC ADaM conversion

This standard service includes:

- Migration of source clinical study to an ADaM compatible SAS file per customer's Analysis, Reporting, and Data Warehousing requirements
- Pre conversion source file processing
- Single data mapping
- 2-step ADaM data validation

Additional optional services include:

- Validation against existing reports, such as CSR
- Pre conversion additional data checking
- Post conversion additional data checking
- Custom edit checks
- Double data mapping and corresponding validation

BRIDG model conversion

This standard service includes:

- Migration of source clinical study to BRIDG compatible SAS file per BRIDG and customer's Data Warehousing definitions
- Pre conversion source file processing
- Single data mapping
- 2-step BRIDG data validation
- SDTM dataset creation
- ADaM dataset creation

Additional optional services include:

- Develop enterprise level logical and semantic model
- Pre conversion additional data checking
- Post conversion additional data checking
- Custom edit checks
- Double data mapping and corresponding validation

Note:

These services are available to pharmaceutical and CRO sponsors and can be integrated with any internal systems.

All of the above applications are available on HCL's cloud with customers having access to the environment via web based collaboration tools.

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 global landscape 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 Healthcare & Life Sciences. HCL takes pride in its philosophy of 'Employees First, Customers Second' which empowers its 90,190 transformers to create real value for the customers. HCL Technologies, along with its subsidiaries, had consolidated revenues of US$ 5.2 billion, as on 31st March 2014 (on LTM basis). For more information, please visit www.hcltech.com

HCL – Life Sciences & Healthcare

HCL is one of the market leaders in life sciences & healthcare IT service providers. HCL's clientele includes nine of the top ten global pharmaceutical companies, six of the top ten health insurers, one of the largest payer conglomerates in US and top five service providers in UK. With experienced and certified technology and domain specialists, HCL offers services in the critical areas of drug discovery, clinical development, drug safety, Pharmacovigilance, regulatory compliance, manufacturing and plant automation, sales and marketing, member experience management, fraud, waste and abuse management, ICD-10 transformation and others.

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