



# Clinical Data Transformation

## Boost R&D Efficiency with Standardized Clinical Data

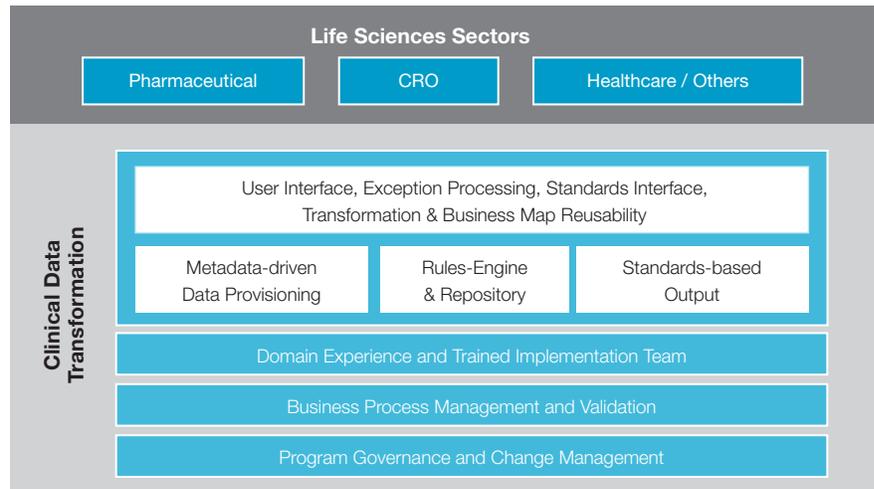
HP and Capgemini work with Life Sciences organizations to design and deploy solutions and strategies to help achieve outcomes that matter to our clients. Capgemini's Collaborative Business Experience® and Life Sciences domain experience is complementary to HP's powerful technology portfolio and industry-specific capabilities. Together, we provide the optimal combination of business and technical knowledge to help companies align their business and IT functions to generate profit and accelerate growth. We are dedicated to our clients' needs with an emphasis on customer satisfaction and intimacy, which drives us to deliver deeper insights and tangible business outcomes.

Life Sciences companies are grappling with lengthy R&D cycles, which contribute to added cost and prolonged time-to-market. Even as companies explore ways to make their clinical R&D development models more efficient, improving the flow of clinical data across the R&D value chain is often left untouched.

Clinical Data Transformation (CDT) encompasses the flow of data across the R&D value chain—from the point of origination to a state of enrichment—ready for consumption by business-critical, upstream activities such as



**Figure 1: Capgemini Clinical Data Transformation Solution**



**Transform data from disparate sources to industry-accepted CDISC standards for more effective cross-trial analysis and efficient regulatory submissions**

analysis, modeling, simulation and submission. A comprehensive CDT program includes standardized, repeatable processes, integrated technology and 21 CFR Part 11 compliant systems. It conforms to emerging industry standards (e.g., SDTM, SEND) or client-specified standards. Such a program is designed to comply with established privacy rules and managed security rights, and enable access to data, for both legacy and active trials.

With regulatory agencies on the path to mandating standards, companies across the industry are at various stages of maturity in their CDT programs. Organizations understand that adopting emerging standards is critical for success, and still they are challenged on how to implement these new standards while managing the impact they may have to technology, infrastructure and processes—all while maintaining business as usual.

### **CDT: Helping to Accelerate the R&D Cycle**

Capgemini's broad CDT offering consists of an innovative technology solution that can be readily integrated into your organization. It combines leading processes, program governance, quality control and an industrialization capability (see Figure 1).

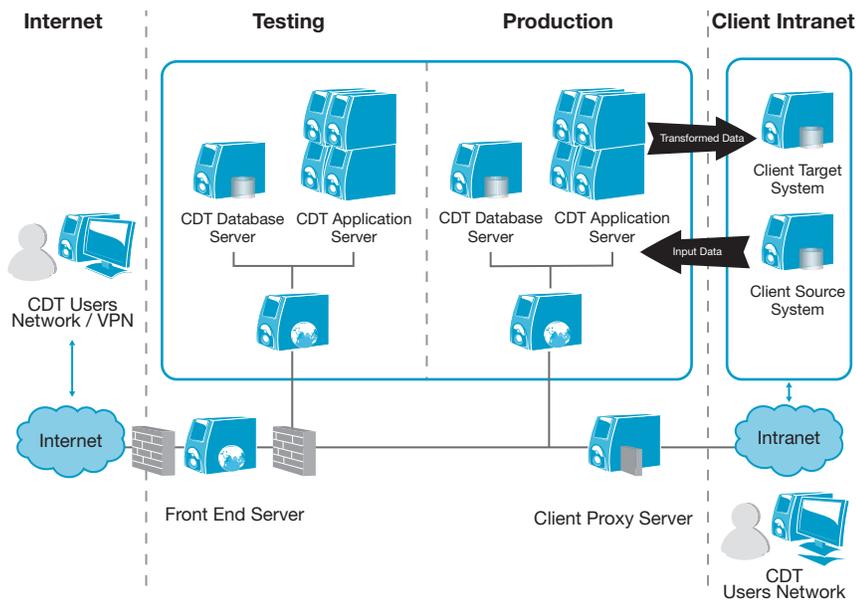
Capgemini helps companies transform disparate data from multiple sources and systems to industry-accepted standards (e.g., CDISC) more quickly and cost effectively. This robust CDT solution enables efficient electronic acquisition, exchange, submission and archiving of clinical data. The offering helps improve the data management value chain, specifically around migration, conversion, and storage of clinical trial data (both structured and unstructured). Decision-making is enhanced with effective statistical analysis of trial-specific and cross-trial data

The result helps companies to improve time-to-market, shorten data management and analysis timelines, and ultimately reduce clinical trial costs. As an early adopter of data standards and CDT, your organization can gain a competitive edge over those that have yet to embrace such a program.

**Key Features and Benefits of the CDT Solution**

- Improve R&D efficiency and help reduce clinical trial costs
  - Reusable business maps and transformation logic
  - Pre-built testing templates and data verification service
  - Automated verification process and graphical reports
  - Business process management, standards management
- Speed the adoption of emerging standards
  - Support for different source data types (SAS datasets, RDBMS tables/views, flat files)
  - Validated, 21 CFR Part 11 compliant solutions
  - Options for different output data types (SAS datasets)
  - Program governance and change management
- Provide easy access to clinical data
  - Easy-to-use, metadata-driven user interface
  - Multi-user, multi-threaded architecture powered by HP
  - Study prioritization capability
  - Flexible service model (captive, shared or hosted) at Capgemini's data center or client-owned data center

**Figure 2: Clinical Data Transformation Physical Architecture**



Capgemini has managed transformations across all four phases of clinical trials and various therapeutic areas, including Cardiovascular, Infectious Diseases, CNS, Oncology and Endocrinology. Our highly industrialized, scalable, user-friendly and flexible CDT solution can handle the variability, complexity and increasing demands of clinical data. We execute CDT programs with low defect rates in only a few weeks, depending on complexity.

### The HP Difference

Capgemini, in collaboration with HP, has developed a reference architecture for CDT based on the market-leading HP BladeSystem c-Class and proven enterprise-class HP Integrity servers and storage. This reference architecture provides recommended hardware configuration templates based upon predefined user counts/workloads (see Figure 2). The offerings have been designed and documented to reduce the time, complexity and risks of procuring and deploying new

technology in the enterprise. They are based upon the real-world experience of Capgemini architects and HP engineering experts, deploying CDT solutions to our valued clients.

The CDT reference architecture features a multi-tiered server architecture with granular sizing points based on workload and user counts. In addition, the reference architecture provides a starting point in the infrastructure planning and design process by documenting approved landscape configurations. This not only helps with budget estimates for hardware during project planning phases, but also helps to reduce solution deployment time and achieve faster time to production.

Capgemini and HP offer this validated CDT solution to help organizations achieve continuous improvements in the management of clinical data, resulting in cost savings, mitigated risks, and ultimately reduced time-to-market of new products.

### A Vision for the Life Sciences Industry

Capgemini is further developing innovative solutions for the Life Sciences industry by working with partners, key clients and industry-leading stakeholders. Our investments span across Life Sciences and include R&D Portfolio and Project Management to assist our clients with the entire R&D value chain. Our technology and business consultants work with leading Life Sciences companies to drive CDT initiatives in an efficient, cost-effective manner.

If you are interested in learning more about how Clinical Data Transformation or our other Life Sciences solutions can help your company adapt to industry standards and FDA guidelines, please contact us.



### About Capgemini

Capgemini, one of the world's foremost providers of consulting, technology and outsourcing services, enables its clients to transform and perform through technologies. Capgemini provides its clients with insights and capabilities that boost their freedom to achieve superior results through a unique way of working, the Collaborative Business Experience.™ The Group relies on its global delivery model called Rightshore®, which

aims to get the right balance of the best talent from multiple locations, working as one team to create and deliver the optimum solution for clients. Present in more than 30 countries, Capgemini reported 2009 global revenues of EUR 8.4 billion (approximately USD \$11.6 billion) and employs 90,000 people worldwide.

More information is available at [www.us.capgemini.com](http://www.us.capgemini.com)

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