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Clinical Data Transformation:
Transforming Information into Knowledge and Competitive Advantage

The Current Situation

We are all painfully aware of the current trends that are impacting our business:

- Weak to moderate pipelines
- Increased time and cost of research trials
- Payors moving swiftly toward requiring 'evidence-based medicine'
- Health regulators increasing their focus on patient safety as well as supporting the implementation of novel, new technologies to facilitate adaptive trials and a future 'bench to bedside' model.

Internally, we struggle to 'kill early and cheap,' commercialize early and transform our business model to deliver successful products and receive faster approvals. Many internal challenges prohibit this transformation (Figure 1).

Although this paints what some might call a 'bleak picture,' it does not take into account the gold mine of retrievable historical knowledge (data) each biopharmaceutical company currently possesses.

The ability to tap into and leverage these assets can transform the business in significant and important ways.

Figure 1: Internal Challenges for Biopharmaceutical Companies

Internal Challenge	Consequences
Lack of data/metadata standardization and interoperability	■ Silos of data across and within business functions ■ Data duplication (version of the truth is questionable) ■ Data are not equal to knowledge ■ Data sharing not enabled (researchers must juggle multiple organizations, activities, data and hand-offs) ■ Limited re-use (reinvention required for each trial build, execution and reporting) ■ Inconsistent protocol development (prior experiences not always known)
Non-interoperable legacy systems and application architecture	■ Integration performed within application code (de-coupling issues, long term turn around for changes, testing, validation and additional integration) ■ Prohibitive data sharing ■ Compliance issues ■ No real-time data collection and limited collaboration capability (with external partners) ■ High degree of manual intervention for submissions, audit support, and response to regulatory inquiries ■ Prohibition of the introduction of novel, new technologies (e.g., genomics, genetics, proteomics) ■ Difficult communications (many single point interactions) ■ Systems processing at functional orientation (not concentric)
"Me too" product development paradigm	■ Regulators/payors requiring greater proof of safety and efficacy for approval and for payment (formulary placement) ■ Strong revenue streams no longer assured ■ Strong threat by generics
Investment challenges	■ Minimum disease understanding ■ Limited skill sets to adopt novel new technologies outside of Discovery (targeted treatments, early commercialization and lucrative diagnostics) ■ Project portfolio and roadmap not clearly defined, prioritized and/or funded

The Way We See It - A Need for Change

Why focus on data transformation, and why now? Why is this so important? How can this type of transformation not only impact the bottom line, but also unleash productivity and innovation?

Today, we see data transformation as a key lever for addressing many of the core issues faced by our clients (Figure 2).

We are working with several clients to leverage this underutilized asset. Data transformation is helping clients realize their goals of data integration, interoperability, re-use, and in the end, creating a proprietary advantage. This transformation is resulting in a significant competitive advantage by leaping ahead in their pipeline productivity.

Figure 2: Data Challenges the Industry Faces

Data Challenges	Impact
Unrealized return on data investment	■ Expensive to collect, integrate, interpret and report out ■ Massive, multiple data stores - too expensive to address *en-masse* or on an *ad hoc* basis ■ Data are underutilized after product registration
Regulatory pressures	■ A higher level of understanding and proof of product safety profile early in the process ■ New skill sets for e-submission (eCTD), xml authoring ■ Adopt new strategies and collaboration to improve and accelerate product development (e.g., adaptive trials, increased use of biomarkers and 'omics' technologies for delivering targeted treatment group products, translational medicine) ■ Publicly report negative studies promptly
Evidence requirements	■ Requires improved product understanding throughout its lifecycle (benefits at registration and beyond) for both safety and efficacy ■ "Me too" products require more evidence of efficacy to achieve approval ■ In-licensing deals too often are not able to reproduce claimed findings
Integration and collaboration	■ Unable to cost-effectively integrate and share data, in standard format, with alliance partners and CROs ■ Lack of internal bi-directional data and information flow capability (e.g., two-way flow between preclinical and clinical to support M&S in full development) ■ Inability to mine data (across a compound, class of drugs, conduct signal detection, integrate with genetics and genomics)

"Voice of the Customer" pressures	■ Patient Advocacy Group's dissatisfaction that:
	  ■ Centralized trial information is not easily accessible to clinicians
	  ■ Product contraindications, side effects and efficacy data are aggregations of statistical information and not meaningful to individuals
	■ PBM requires more evidence of efficacy and safety for reimbursement rates and in some cases to achieve formulary status

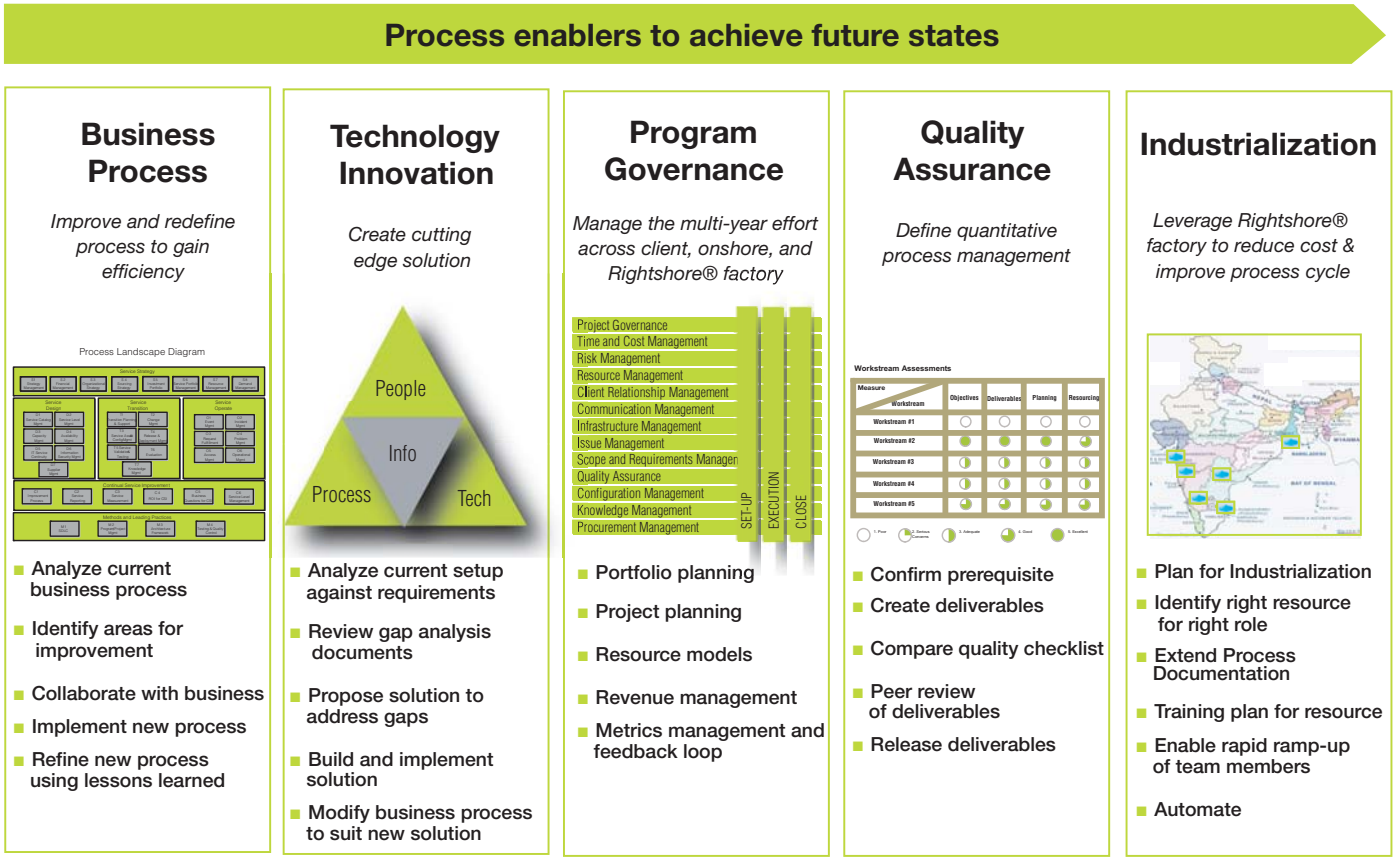
The Solution: Clinical Data Transformation

Capgemini's solution for transforming data into information and finally, into knowledge is driven by the critical needs of the business and based on the outcome of our collaborative approach. We then 'industrialized the solution' - transforming both business processes and IT delivering tools to automate the solution (removing multiple hand-offs and manual processing) and eliminating data redundancies and risk. The results include:

- Automation that is clearly driven by the needs of the business and in line with the strategy
- Optimized business processes, clearly defined roles and responsibilities and governance
- Decreased transformation costs by providing functional and technical resources with our Rightshore® approach

Unlike failed, traditional approaches for just automating business processes, we designed and implemented a clear relationship of the business strategy through the architecture. Subject-matter-experts, with full functional expertise and experience within each business function, provide in-depth working knowledge of the data, metadata requirements, and industry standards for interoperability (both syntactic and semantic). We built a framework that optimized the business processes, and developed standard

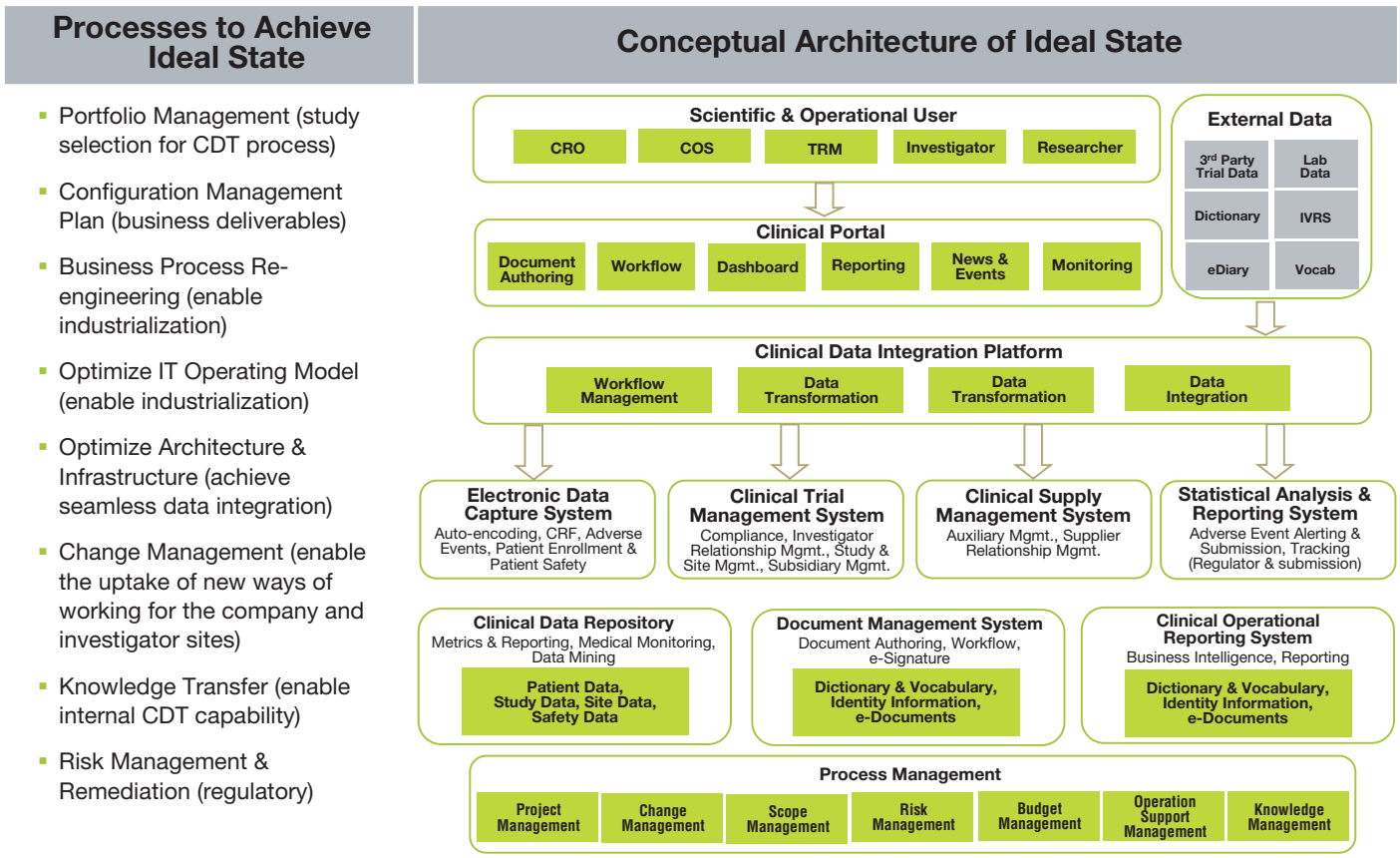
Figure 3: Clinical Data Transformation Approach



processes and templates for transforming clinical data - thus reducing compliance risks for data veracity and authenticity. Our solution enables data flow from collection through analysis to reporting, eliminating re-format or re-work from the point of data collection through to analysis and electronic submission.

To drive down the cost of data transformation, we then industrialized the approach with a factory model - using onshore and offshore resources to not only capitalize on reducing our clients' financial and human resource costs, but also to support a continued and efficient data flow to meet regulatory requirements for e-records. Data are extracted from multiple legacy systems in standard format and loaded into a data repository enabling both syntactic and semantic interoperability throughout the product lifecycle. Our solution supports full audit trail functionality as well as a data validation utility that automates the task of verifying data were not transformed (changed or modified) during data flow. Early on, we worked with the business to identify and establish a check point as well as business and technical processes to eliminate data inconsistency issues.

Figure 4: Components of Clinical Data Transformation



A data repository houses pre-clinical, clinical and other reportable data (e.g., genomics, microarrays, etc.) in submission-ready format and enables import of external data from co-development partners. Data mining capability is enabled with standard connection APIs. Extracting data from disparate sources in standard format eliminates the intensive and time-consuming work of data interpretation and re-formatting for ready use.

Benefits of the Model

Being able to access interoperable data (transforming data into information and into knowledge) in a standard format with standardized accessibility removes the hurdles previously in place. Clients are now able to:

- Access bi-directional knowledge flow to enable M&S activities in full development (to support adaptive trials and translational medicine)
- Conduct data mining to optimize pharmacovigilance capabilities
  - Kill early and cheap
  - ID safety issues early and during post-approval
  - Evaluate old compounds with new technologies (for additional indications as well as combinational product development)
- Optimize the exchange of knowledge to/from health authorities, CROs and/or co-development partners
- Optimize dossier compilation and enable e-filing faster
- Reduce the regulatory risks posed by legacy systems
- Reduce the cost of conducting business with an industrialized solution
- Reduce the cost of maintaining legacy systems

Industrialization also supports the publishing of research trial data (from on-going or 'live' studies) from legacy systems to new platforms (any EDC application) on through to the data repository in a standard format. At a high level, our factory solution delivers:

1 Transformation of R&D and the product trial lifecycle.

2 Adoption of standards and implementation of a platform that enables EDC and rapid e-submission.

3 A platform that enables collaboration with regulatory authorities and co-development partners. This allows for quick response to agency questions before moving forward on INDs, NDAs, and BLAs.

4 A platform with established validated environments and audit trail functionality.

5 The edge to out perform the competition.

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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 2008 global revenues of EUR 8.7 billion (approximately $12.7 billion) and employs over 92,000 people worldwide.

More information about our services, offices, and research is available at www.us.capgemini.com.

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