A Clinical Data Warehouse Solution to Improve Operational Efficiencies

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The changing trends in the life sciences industry in terms of outsourcing, partnering and globalization have created the need to improve overall working efficiency and communication between partners and service providers. Contract research organizations (CROs), such as ICON, understand the intense pressure to reduce cost and timelines for drug development while ensuring data quality. Accordingly, ICON is among the “eCROs” to have emerged that have the informatics capabilities to re-aggregate clinical trial data in a time and cost-effective manner.

Increasingly, CROs now have a stake in clinical drug development through risk sharing with pharmaceutical companies and involvement at every step of the process. Clearly, this new model involves handling larger volumes of data from a vast number of different sponsors and in different formats. For ICON, the implementation of a clinical data warehouse was an obvious solution to manage these large volumes of disparate data. Through the identification of a specific business case and definition of precise project parameters, the company has succeeded in implementing a clinical data warehouse that delivers operational efficiency and, consequently, competitive advantage.
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Business challenges/unmet needs leading to a clinical data warehouse

The CRO’s main business challenge, in terms of data, is the increasing volume and variety of sponsors/clients that it typically engages with. CROs typically handle large volumes of disparate data from different sources presented in various formats. One challenge is how to effectively and efficiently access and manage disparate data while maximizing value, increasing usability and maintaining data integrity. ICON realized the limitations of previous approaches to data handling which were unworkable and unsustainable over the long term. It identified an urgent need to move away from traditional and ad hoc practices, to a more harmonized approach to clinical trial data handling. ICON also realized the need to convert data, which may have been overly technically or scientifically focused, to a more accessible and usable form for operations teams. This would enable CRO clinical trial study teams and sponsors to more effectively access, analyze and use data on a real-time basis (compared to previous batch-centric approaches). Thus, a plan was defined to implement and establish a clinical data warehouse.

“We [ICON] knew what we needed to do and we went about doing that in a very focused and directed way.”

A CRO approach for implementing a clinical data warehouse

ICON’s approach to implementing a clinical data warehouse was specifically directed and purposed to meet the need as identified by its business case; to make large volumes of data usable and empower study teams to proactively manage their studies based on more insightful data. The solution had to be scalable, thus handle increasing volumes of data, and implementation and deployment had to be rapid in a specified time frame in keeping with typical CRO project turnarounds.

In addition, to ensure these targets were met, the clinical data warehouse would include only new clinical trial study data. Legacy data and associated legacy data conversions were not incorporated in the clinical data warehouse – an approach that is suited to CROs typically contracted scope of services within the trial execution phase.

“We [ICON] took a very purposeful and directed approach. We wanted to do something quick; we wanted to do something manageable.”

A general approach when implementing a clinical data warehouse is to deploy a range of technologies targeting various layers of data management from data input and governance to data output and reporting, publication, visualization and collaboration. ICON contracted with Oracle to supply key enabling products/technologies to form the basis of the clinical data warehouse platform for data custody, governance, and export to sponsors. In addition, third-party providers were contracted to supply supplementary tools for data access and visualization. Together all of the interlinked technologies ultimately allow clinical study teams to gain access to and insights on trial data.

Finally, and most importantly, implementation of a clinical data warehouse requires support and buy-in from key stakeholders,
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particularly executive personnel, who can catalyze the speed of the overall project. For ICON, there was both executive and board support from the project outset as one of the company’s strategic goals was to improve its information and informatics capability. A clinical data warehouse is directly associated with this goal, hence implementation was unanimously supported and deployment was successful.

Implementation challenges, solutions and standardization

ICON’s clinical data warehouse implementation was divided into a number of manageable phases, to acquire, centralize, standardize and visualize data and subsequently, to address associated operational deployment and change management challenges. The challenges of rapid deployment were overcome by defining simplified, achievable use cases and having appropriate milestones by which to assess progress.

There have been technical challenges, particularly during early implementation. ICON was one of the first to adopt this clinical data warehouse strategy and consequently experienced pain points associated with being pioneers. These have lessened over the years as other organizations have adopted the strategy and product solutions have been identified to address these early challenges.

Data standardization has been a corner stone to the success of ICON’s clinical data warehouse and was an important consideration even before use case identification and project initiation. The CRO approach to standardization is different from a pharmaceutical company based on the nature of CRO activities. CROs typically engage with numerous, diverse sponsors, each with their pre-defined set of requirements in terms of a clinical trial, thus a CRO must set its own internal standards. ICON has achieved this through the development of a comprehensive clinical data standards hub, built off Clinical Data Interchange Standards Consortium (CDISC) standards and the study data tabulation model (SDTM), which drives operational data review, data visualization and data delivery.

A clinical data warehouse as part of an overall integrated information platform – ICONIK™

In July 2010, a year after signing the initial contract with their selected clinical data warehouse provider (Oracle), ICON launched its clinical data warehouse platform. The clinical data warehouse is a key part of ICON’s overall integrated information platform – ICONIK™.

“For us [ICON] ICONIK™ is about trying to be very transparent with our client in terms of how we are running their studies, trying to drive operational efficiencies and improve quality, and being proactive in terms of what we do in the conduct of our studies.”

ICONIK™ is a powerful integrated information platform that consolidates, standardizes and visualizes both operational and clinical data, to provide a single holistic view of all study information to both sponsor and CRO teams. It offers near real-time access to clinical trial performance metrics, critical safety and efficacy data, and the ability to analyze these data in novel ways. The ICONIK™ information platform and associated operational processes improve data quality and
subject safety while yielding significant operational efficiency gains (Figure 1).

Oracle Life Sciences Data Hub powers the clinical data warehouse and alongside an operational metrics data warehouse, ICON has the key components in place to drive operational activities such as assessing study feasibility, trial start-up, subject enrolment, subject retention, and safety.

ICONIK™’s integrated information platform provides four levels of knowledge to the sponsor and study teams:

- Operational efficiency – automated processes to gather and surface information
- Transparency – increased transparency to clients throughout the development process
- Visibility – accurate and detailed information on site performance and risk
- Quality – increased focus on data integrity and control of clinical data

The ICONIK™ integrated information platform and associated operational processes has enabled the company to revolutionize management of clinical trials, such as improving study planning and design by access to historical and operational clinical data to guide protocol development and provide quicker evaluation of site feasibility, faster identification of delays or potential difficulties in site start-up, and the ability to obtain insights into patient eligibility and screening failures to improve retention rates, among others.

Today, ICON’s enhanced Sponsor Reporting Services offers a number of key benefits for the optimized visualization of data from the clinical data warehouse. The enhanced Sponsor Reporting Services provide a single source for study team members to access study information in a consistent manner across the lifecycle of a study. Using clinical data from electronic data capture (EDC), interactive voice response (IVR), eDiary or Central Laboratory, a study or a program of studies can be instantly evaluated from a scientific, safety and quality perspective. Any operation, from the detection of a safety signal to the data quality analysis of a solitary site, can be performed in a few clicks.
Main users of the clinical data warehouse, benefits and impact

The main users of the clinical data warehouse are the ‘end consumers’ (i.e. the clinical trial study teams, clinical data teams, the medical monitors, study start-up teams, quality assurance teams, who are the main beneficiaries of the clinical data warehouse) rather than data programmers. Such endusers may not necessarily log on, but do consume all data, insights and analyses of study performance and status and use these to inform operational decisions.

One of the best examples to illustrate this is the ICONIK™ Monitoring service, where the centralized monitoring team routinely uses holistic scientific data analysis, together with clinical research associate site knowledge to direct central and site monitoring activities. The centralized monitoring team has access to and continually reviews real-time investigator performance and risk metrics, all of which are predictive of overall investigator performance and compliance. Investigators with abnormal behavior patterns are tracked and analyzed centrally in order to evaluate the need for site-specific action and ensure a focused approach to monitoring. Study teams are managing monitoring resources in a flexible and intelligent way, employing resources as and when they are required based on the demands of the study.

“We [ICON] have 8,500 employees in the company and our view is that the clinical data warehouse is the foundation from which we get the data that all of the teams consume; without the clinical data warehouse and operational data warehouse they would not have access to this.”

Conclusion

A clinical data warehouse offers a data-handling solution for CROs as it enables the centralization and governance of clinical data which ultimately facilitates the publication of data in a usable format. For ICON, the main focus of the clinical data warehouse was to convert previously technical data to a more usable and understandable form for clinical trial study teams and sponsors, which could then drive operational decisions. In other words, operational efficiency was at the heart of the decision-making process.

ICON believes that its implementation of a clinical data warehouse has differentiated it from other CRO competitors. The company’s pioneering efforts to implement ICONIK™ has facilitated access to useful, comprehensive real-time data for its study teams and sponsors, giving the company a competitive advantage over other CROs.

As the company looks to the future, the aim is to continue to focus on operational activity and identify niche areas within this space on which to deliver added value to its sponsors/clients. ICON has successfully implemented and deployed its clinical data warehousing solution and 3 years from initial deployment of ICONIK™, the company has already realized its main aim, which was to ensure accessibility to operationally useful data. The clinical data warehouse will continue to evolve and deliver benefits and efficiencies.