PAREXEL® INFORMATICS AND ALMIRALL

TRANSFORMING DATA MANAGEMENT WITH THE USE OF AN INTEGRATED TECHNOLOGY SUITE

Situation

Almirall R&D Sant Feliu top priorities are safeguarding the health of patients enrolled in clinical trials and obtaining reliable data. Capturing, validating and analyzing patient data and intervening swiftly is crucial.

Challenge

Trials were becoming more complex, and projects were becoming more complicated and ambitious, with multiple players involved. The volume of patient data and the number of information sources were increasing dramatically.

"It was becoming more and more difficult to capture and rationalize clinical data and present it so that researchers could visualize it and make sound decisions quickly," recalls Diego Herrera, Head of Global Data Management and Project Information. "We needed to replace our obsolete technology, but new technology wouldn't be enough. We needed to transform the way we approached data management."

Solution

Almirall partnered with PAREXEL® Informatics to develop and pilot a new data management model. The effort involved reviewing business processes, implementing Clinical Data Interchange Standards Consortium (CDISC) standards, enabling near real-time data visualization of operational and scientific data, and investing in new technology.

Almirall chose Perceptive MyTrials® from PAREXEL as the technology foundation for the new model. With this hosted suite of integrated applications, the data management team has become an effective partner to scientific teams. The team now enables seamless access to comprehensive data collected from and across clinical research organizations (CROs).

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The Need for a Transformational Change

In the pharmaceutical industry, data management teams have traditionally been perceived as data providers in support of clinical study teams. This was the case at Almirall. Data management was responsible primarily for these traditional tasks prior to database lock and data loading. Almirall data managers, however, were convinced that they had much more to offer. Using input obtained from clinical personnel in operations, safety and analytics, the team identified several key areas in which they could add strategic value.

Because they were using obsolete technology, data managers were receiving data transfers from the CROs only every four to five weeks. As a result, clinical personnel had to wait for long time to have to access patient data. The team wanted to make data available much more quickly as well as to improve medical and monitoring control over the safety and study data.

Ensuring data quality was driving up costs because, in addition to day-to-day data management activities at Almirall, the team was duplicating activities contracted out to CROs. The CROs were using their own standards and processes to collect and transfer data to Almirall in accordance with study specifications. As a result, the data lacked consistency. Consequently, internal resources spent a considerable amount of time running data checks and ensuring that data collected by each CRO complied with criteria that Almirall had established.

"What we envisioned was an environment that would integrate the management of all clinical trials data into a single eClinical platform," Herrera explains. "The environment would combine operational data such as trial planning, start-up and monitoring, which resides in IMPACT CTMS, with patient data such as vital signs, demographics, adverse events, results of electro-cardiograms, lab and pulmonary function testing, and patient quality-of-life and diary data, which comes from many different data collection instruments."

An important aspect of the vision was the adoption of pure CDISC standards. CDISC compliance would reduce data risks by addressing three data quality concerns: CRO conformance to support standards, CDISC validation rules and data traceability.

The Transformation Strategy

To make its vision a reality, data managers developed a three-year strategy that transformed the team from an isolated provider of data to a key player in successful clinical trials that comply with relevant standards and enhance the safety of subjects participating in the trial. The strategy encompassed:

- A comprehensive review of data quality and data exchange standards
- Implementation of CDISC standards
- Establishment of data quality checks that ensure compliance with CDISC and maintain completeness and quality of data in line with Almirall internal policies
- Near real-time data visualization of operational and scientific data through graphical reports and metrics
- Technology and data integration

Almirall had been using PAREXEL Informatics IMPACT® CTMS to handle clinical trial management since the late 1990s. The team determined that this area of its clinical trial operations was functioning efficiently. To test out the viability of its vision for an integrated environment, the team conducted a pilot hosted by PAREXEL Informatics and co-developed with Almirall. The technology platform included DataLabs® EDC, ClinPhone® RTSM, IMPACT CTMS, a pilot metadata repository, Clinical Data Exchange Services (to support weekly transfer of data between PAREXEL and Almirall), Clinical Metrics Data Mart (to manage operational metrics, expanded with capacity to store integrated SDTM data), and the Data Consistency Checker (to check patient data consistency and conformance to Almirall study data standards).

To facilitate medical and data review, the team created a new role — the Data Visualization Manager. This manager is responsible for defining a more robust understanding of study data structures while more effectively answering ongoing questions raised by clinical teams. The person assigned to this role has become an expert in data visualization.

The team compared the results of the pilot with an earlier study of similar complexity. According to Herrera, the pilot study was actually more complex. However, the similarities enabled the team to measure the impact of the new model.

Tangible Results

"The pilot clearly demonstrated that by combining new data standards and revamped processes with the PAREXEL Informatics solutions, we could achieve substantial gains over our previous approach," Herrera says. "Our new approach transformed the role of data management to encompass new organizational activities such as standard governance, compliance with CDISC standards, management of visualization reports, strengthening of CRO partnerships and clinical data management openness."

With the new processes and technologies, medical reviewers now access fewer files, which increases their productivity. More important, they no longer have to wait five weeks to gain access to patient data. Faster access is particularly critical for studies related to life-threatening diseases as well as when there are large volumes of safety data to be reviewed.

The highly visual presentation of data speeds analysis and enables clinical teams to respond quickly to issues that could affect patient safety or interfere with trial progress. Visual presentation of patient distribution and baseline characteristics, for example, provides visibility in advance as to the type of population participating in any given study. Additional examples include the most frequently reported adverse effects by term and by MedDRA categories, the number of protocol deviations by country, site and category, and the most frequently reported prior and concomitant medications by term and by grouping. Visualization enables data managers and other scientific roles within the company to quickly identify patterns such as common data element errors and outliers.

By improving the quality of the data received from CROs and automating data checking and validation, the data management team has minimized data quality control efforts and eliminated redundant tasks. Today, data managers focus their attention on

- **Time to data visualization slashed from 5 weeks to 1 week**

- **65%+ reduction in data transfer time**

- **Time between recruitment data capture and availability of metrics reduced to 15 minutes**

- **58% reduction in time between last patient last visit to database lock**

"Our new approach transformed the role of data management to encompass new organizational activities such as standard governance, compliance with CDISC standards, management of visualization reports, strengthening of CRO partnerships and clinical trials transparency."

Diego Herrera

Head of Global Data Management and Project Information

oversight, consistency of study data structure and ensuring that data management deliverables comply with the defined quality criteria.

The team is now driving just-in-time reporting of trial conduct progress, weekly access and visualization of patient data by clinicians and enforcement of study standards. As such, the team has become responsible for ensuring consistent study data surveillance.

Closing Comments

According to Herrera, the partnership with PAREXEL Informatics played an important role in empowering the data management team to transform itself and, as a result, deliver exceptional value to Almirall clinical teams. "We've collaborated successfully with PAREXEL since the late 1990s and we have a lot of confidence in their knowledge and experience," he concludes. "When we approached PAREXEL with our vision for data management transformation, everyone understood what we wanted to accomplish. Their commitment and expertise combined with the dedication and efforts of my team helped us become strategic players in Almirall's clinical trial process."

Herrera says that the story is not yet over. The data management transformation continues as the team works to evolve its processes and technologies, with a constant focus on optimization. The next generation of technologies, especially in data governance, will open up new opportunities that will further facilitate data access and data integration, enabling more changes that enable the modernization of data management.

ABOUT ALMIRALL, S.A.

Founded in 1943, Almirall has become a source of value creation for society due to its vision and the commitment of its long-standing major shareholders. Based in Barcelona, this global company is dedicated to providing valuable medicines through its research and development, agreements and alliances. The company's work covers the whole of the drug value chain. A consolidated profitable growth allows Almirall to devote its talent and efforts in the dermatology area, with an additional interest in other specialist-driven areas. The company has built a trusted presence across Europe, as well as in the U.S., Canada and Mexico. For more information please visit www.almirall.com.

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