Customer Story

Almirall

Challenge

Rapid growth in the clinical research industry requires innovative approaches to data analysis.

Innovations in clinical research offer opportunities and challenges

How Almirall built a new data management standard that has dramatically streamlined data and medical monitoring and regulatory compliance across a network of study partners in Europe and the US

After years developing innovative products in the respiratory area, Almirall has become a leading skin health-focused pharmaceutical company. Today, Almirall uses its global network of 13 affiliates and strategic partners to bring novel dermatology products to consumers across the world. This innovative collaboration with health care and aesthetics professionals, both public and private, is key to Almirall's strategy; by working with partners, its reach extends far beyond its size. Almirall's innovative streak has served it well as it adapts to the continuous transformation of the pharmaceutical industry. Diego Herrera, Almirall's Head of Global Data Management and Project Information, and Merce de Frias, International Clinical Trial Manager, are on the front lines of this transformation, as they develop new strategies for meeting the needs of high data quality and regulatory bodies alike.

With improvements in technology and clinical research interest in new tools for managing clinical trials, researchers have begun to tap into the wealth of data that continues to become available. A broader picture of each study participant's response to a study's investigational product (IP) is invaluable to determining safety and efficacy, as well as giving study teams more data from which they can detect outliers, see patterns and identify risks. "The good thing is that as you have more data, then you have the possibility to select what you want to get," explains Herrera. "This means that you can obtain more knowledge about the product you are running."

On the other hand, the sheer quantity of data can present challenges for clinical researchers. "Hyperinformation can generate problems in the decision process since more information does not imply better decisions directly," says de Frias. "A large amount of data requires additional advanced technologies and capacities to perform data scrutiny." For a company that reviewed data using PDF listings until 2011, a higher volume of data was not necessarily a boon to study teams or a signifier of better outcomes. For small, early phase clinical trials, this time-consuming data review process was more manageable, but for large, pivotal studies that include hundreds of patients, reviewing data patient-by-patient is a non-starter.

"You need something that aggregates all the data and allows digitalization," de Frias says. As a data management professional, Herrera agrees: "It's very important to have advanced technology solutions and criteria in order to scrutinize what is relevant for this large amount of data. You have to have good tools to analyze this data. Otherwise, you are lost."

Complying with growing regulatory demands

In parallel with increases in data volume, regulatory demands have likewise increased, resulting in growing costs and extended timelines. Already a highly regulated environment from the international to the local level, the pharmaceutical industry must continue to adapt to the need for data quality, transparency, patient data privacy and the integration of new technologies. But how can researchers balance these competing priorities? "More and more, health authorities are asking sponsors to work in risk-based management, identifying where we have the risk and where are the critical steps [so that we] can focus on them instead of supervising and overseeing the whole process," de Frias explains. Following a risk-based monitoring approach lets clinical operations teams concentrate their efforts and resources on variables with the highest potential impact on the study, while maintaining high data quality and ensuring patient safety. To facilitate this process and comply with regulatory requirements, the right tools are key.

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Diego Herrera, Head of Global Data Management and Project Information

Efficient data review with JMP® Clinical

"We felt that JMP Clinical would provide Almirall the data management possibilities [we needed] without requiring additional data transformation from the CROs to deliver integrated patient data access to clinical teams efficiently not only during the study but also when exploring data retrospectively," Herrera says. The bottom line, he adds, is that JMP Clinical would help them "save on cost and time in the data access process and extend patient data re-use along the clinical development life cycle." Since implementing the software, the Almirall team has transformed how they review data, allowing them to explore risk-based monitoring and collaborate effectively. "JMP Clinical allows us to analyze a large volume of data," de Frias says. "In a risk-based approach, where do you have the risk? In the outliers. We see why they are outliers and how you can solve issues and which actions we need to perform."

JMP Clinical's capabilities allow Almirall's clinical and data management teams to thoroughly review the data in early stages of the clinical trials for early detection of patient data issues or deviations from the protocol, enabling them to make decisions where appropriate. They can also set up alerts for parameters of interest, a critical tool that lets them quickly address problems – like adverse events, for example – at the site level. "If you notice one site with a high rate of PDs or outliers, this may trigger an audit, and if results indicate that the quality is not good, you can decide to exclude subjects from the analysis population," says de Frias. This adaptive study design approach can lead to protocol amendments or require regulatory authorities be alerted depending on the particular safety issue, so the alerts and documentation afforded by JMP Clinical's Notes feature have relieved the regulatory burden on Almirall.

Using Notes sharing architecture to facilitate regulatory compliance

While Almirall has dedicated clinical biostatisticians to support study teams, any software they use must be user-friendly enough to allow study teams to conduct reviews, visualize data and share ideas and findings. JMP Clinical not only gives study teams the ability to quickly and easily create custom reports for the needs of each functional area, it provides a sharing architecture that lets reviewers assess data separately and then compile all notes into a single integrated file using the Notes feature.

As a sponsor, Almirall is required to document how they provide oversight of the study; JMP Clinical's Notes feature confirms that the sponsor has appropriately monitored the safety of patients during the trial, supporting any inspections that may occur in the future and justifying the need to set up new risk-based monitoring approaches. For example, if a certain parameter has shown no safety risk, the study team may decide to source data verify a percentage of patients instead of all patients. When regulatory inspectors ask for justification, the study team can show the reports and notes that led to the decision.

As the clinical research landscape evolves, so does Almirall. The company continues to build on lessons learned from its portfolio, and its use of JMP Clinical is no different; having requested a few customizations from JMP to better align JMP Clinical with regulatory body expectations, Almirall has recently set up and is running a new process of bringing pre-clinical (SEND) and clinical (SDTM) data together in one unique and collaborative data governance process. As a result of these projects, global data governance standards will enable them to expand the use of data, allowing the generation of new hypotheses and compliance where regulatory bodies like the US Food and Drug Administration require that data from all phases of research to be integrated and submitted into a standard format. In addition to streamlining the collection and presentation of data, these standards allow Almirall to make the most of what JMP Clinical has to offer, visualizing and evaluating pre-clinical and clinical data throughout the project development process.

Solution

Use JMP® Clinical to implement targeted data review approaches that address regulatory requirements and ensure patient safety.

Results

Global data governance standards have helped Almirall grow efficiency across its study teams while also relieving the regulatory burden of reporting in the face of increasingly stringent requirements. Integrated data management plays a key role in enabling the support of Almirall strategies to expand into other markets.

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