arriello

From development to market.
Faster. Better. Smarter.

Delivering enhanced Clinical Safety services.

Supporting an American pharmaceutical company with safety and efficacy in clinical trials.

Client type:
Originator.

Geography:
USA.

Lifecycle stage:
Development.

Service area:
Clinical Safety.

Summary.

- Clinical safety project covering several Phase II and Phase III clinical trials, with the indication of Hereditary Angioedema.
- Providing full-scope clinical safety services for three clinical trials.
- Cross-party collaboration involving three clinical trials in multiple countries.

Challenges.

An American pharmaceutical company faced a number of imminent challenges when setting up three Phase II and Phase III clinical trials. Before the company could start the trials, each clinical trial needed a SMP technical document governing clinical safety. Yet multiple, overlapping go-live dates for the trials were coming up fast.

Due to a large number of stakeholders, there was an urgent need for clear lines of communication and effective collaboration, to achieve the best possible efficiency and also for good governance around safety reporting in clinical trials.

The trials were planned to take place across a number of countries. It was important to maintain a good up-to-date understanding of regulatory requirements. This client needed efficient, high-quality regulatory intelligence monitoring for all countries.

Solution.

The Arriello team started by preparing clinical trial-specific SMP documentation to overcome immediate time constraints. Creating a Master SMP document and gaining approval for that across multiple stakeholders and countries massively sped up the preparation and review process for individual trial SMPs. We also implemented a more structured and efficient ways of reporting safety information, by using electronic data capture to retrieve medical history, concomitant medications, and patient demographics.

Our project manager was the single point of contact throughout the project for all clinical trials, countries and services. The PM created a single Project Management Plan covering project governance, communication between all parties, escalation pathways, risk assessment, project KPIs and training.

Additionally, as two of the trials were blinded, our PM's identified the need for a separate reserve budget, 'blinded' from the client team, and coordinated it's set-up.

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The Arriello approach of progressing the project in a proactive manner, and taking responsibility for ensuring safety regulations compliance, delivered an **efficient management of safety data**.

During the set-up phase, we created a **customized regulatory intelligence baseline report** for every country involved in the trials, to ensure our client had all the safety regulations expertise support it needed to get started.

Arriello then provided ongoing intelligence updates on changes to local regulatory requirements which subsequently affected our client's portfolio and business. They gained country-specific insights that **reduced their risk**, allowing them to respond in a timely manner to changes that could impact their clinical trial safety data.

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About us.

Arriello is a leading consultancy and solutions provider of risk management and compliance services to the pharmaceutical industry. We've been making the development-to-market process faster, better, and smarter since 2008.

Our global services span the product life cycle from Clinical to post-submission Regulatory Affairs and Pharmacovigilance, Quality Assurance and Auditing, and innovative automation solutions.

Headquartered in Ireland, with operations across Europe, we consult and create solutions across the EU, North America, LATAM, CIS, MENA, Asia, and South Africa.

With our extensive global network, decades of combined experience and ISO:9001 certification, we are a trusted partner primarily to pharmaceutical and biotech companies.

Our valued clients rely on our ability to deliver, however complex their requirements, through our proven expertise, global coverage, and technology.

ISO 9001 certified

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