Arriello

Listen. Advise. Implement.

An ATMP Clinical Trial Application. In the EU, UK, and US.

Client type:
Pharmaceutical.

Geography:
UK/US/EU.

Lifecycle stage:
Clinical Trial.

Summary.

A small US-based biotech startup engaged Arriello to support early-phase regulatory clinical trial submissions for a gene therapy ATMP in the UK, EU and US, as well as regulatory maintenance and local representation for all the clinical trials. The client requested support with:

- Full strategy for early phase clinical trial within the UK, EU and US.
- Submission and maintenance of Phase I/II Proof-of-Concept Study Clinical trial application.
- Expert guidance on ATMP-specific regulatory requirements, lifecycle maintenance, submission, safety and pharmacovigilance reporting, medical writing for IMPD and IB writing, local legal representation, and Pre-IND meeting preparation and attendance.

Challenges.

Global regulatory expertise: The client required regulatory experience and expertise to determine the best strategy for submitting their early phase clinical trial in the UK, EU and US, along with maintenance of the submission when approval was received.

Early Health Authority Interactions: The client wanted to participate in Pre-IND meetings with the FDA and needed support making these submissions and preparing the briefing documents.

ATMP Experience: Due to the nature of the client's product, ATMPs in all three regions are required to submit additional documentation and information, such as environmental impact assessments, additional training requirements for site and so on.

Combined solutions: The client needed support with both Regulatory and Pharmacovigilance submissions and needed this to be as seamless and harmonious as possible.

Local Legal Representatives: For the UK and EU submissions, a local legal representative needed to be identified who was able to complete activities for both regions from the EU, and in the case of the US, a US-based representative supported with submissions for central/local IRB submissions.

Solution.

Arriello assembled a dedicated global regulatory team with strong ATMP and regional expertise to manage submissions across the UK, EU and US.

We were able to apply our extensive regulatory expertise:

- Providing a tailored briefing document outlined key regional differences in processes, documentation, timelines and RFIs, enabling early preparation and mitigating submission risk.
- Supporting with medical writing and regulatory experts, preparing high-quality IMPD, IB and submission dossiers, aligned to ATMP requirements.
- Acting as a single point of contact ensuring close timeline management, regulatory compliance and transparent communication between all parties.
- Providing qualified local representatives in each region to support ongoing compliance and Health Authority interactions.
- As per the client's request, Pre-IND meeting requests were submitted, along with clinical trials submissions for all regions, these were all approved with minimal RFIs and are currently ongoing.

Integrated regulatory and pharmacovigilance services streamlined authority interactions and safety reporting under a single, trusted provider.

Our Holistic Approach.

Arriello's approach involved assembling a team of regulatory experts and experienced project managers, to utilize project management tools to oversee key milestones. This ensured adherence to timelines and regulatory requirements. By providing a clear communication path, efficiency was achieved, exceeding the client's expectations and timelines.

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Integrated Regulatory, Pharmacovigilance, Quality & Compliance.

Why choose Arriello for Regulatory, PV and Quality Compliance?

At Arriello our ethos is simple: to be more than just a service provider – to act as an extension of the client, providing expertise and tailored solutions to improve compliance while also improving efficiency. We believe in supporting our clients at every stage of a project, starting with strategic support and advice and then transitioning to providing any support necessary to help clients meet their goals.

We believe that project delivery should go beyond the provision of services, but bring with it our extensive knowledge, experience, and expertise to not only support immediate needs, but also anticipate future requirements and opportunities.

Our team has a global footprint. Our regulatory, pharmacovigilance and quality compliance services are underpinned by a robust regulatory intelligence framework and broad industry experience enabling us to anticipate and proactively manage changes in regulation or industry best practice throughout your project.

About us.

Arriello is a leading life sciences consultancy, offering expert guidance in regulatory affairs, pharmacovigilance and quality compliance.

Our global services span the product lifecycle from clinical to post-submission regulatory affairs, pharmacovigilance, and quality & compliance.

Headquartered in Ireland and with operations across Europe, we provide services and solutions globally.

With decades of experience, ISO:9001 and ISO/IEC 27001 certification, and a friendly, diverse team, we've been a trusted partner to the life sciences industry, primarily with pharmaceutical and biotech companies since 2008.

ISO 9001 certified

ISO 27001 certified

Global headquarters
Arriello Ireland
Dublin, Ireland

European locations
Arriello
Prague, Czech Republic

Arriello
Lisbon, Portugal

US locations
Arriello USA (East Coast),
Boston, USA

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