

# A bespoke cloud based system.

**Pharmacovigilance  
local support.**

**Client type:**  
Biotechnology.

**Geography:**  
USA.

**Lifecycle stage:**  
Post-marketing.

**Service area:**  
Local PV.

## Summary.

- Local PV support in 14 EU countries scaling up to 80 countries.
- Local QP, local literature searching, ICSR processing, local HA, regulatory intelligence.
- This US based Biotechnology company had already chosen Arriello in 2009 to be their partner for outsourcing some of their EU Pharmacovigilance activities, both local and global. The scope covered all local PV needs – local QP contact, local literature searching, case processing, local regulatory intelligence and support with any ad-hoc regulatory submissions.
- Arriello made all these processes faster and better by providing them with one point of contact for vendor management across 14 EU countries.
- The client's objective in 2016 was to expand the number of countries and regions from 14 EU to global coverage, and to harmonize their local Pharmacovigilance support in one place for every country where their product was present.

## Challenges.

Global expansion meant addressing how we could efficiently manage so much information in the most streamlined manner.

14 EU countries had previously been managed by email through one Project Manager, but we knew it would be necessary to use a much more advanced system for so many more countries.

We needed to ensure that system management was simple and effective for both the client and us, and crucially, to ensure uniformity of delivery from 80 vendors at the same time.

## Solution.

We created a provisional proposal for a bespoke SharePoint system for this project and drafted a schematic to show how the system could look and the workflow between the client, us and the 80 vendors. From a structured series of face to face meetings, presenting and discussing options, we built a beta system for testing before launching the final version.

The final system was comprised of modules that allowed vendors to enter information in the same way without being able to see each other's actions, whilst allowing the client and us to have complete oversight and control.

Within each module we built-in a number of specific procedures with approval processes that involved the client and ourselves.

## Faster. Better. Smarter.

Arriello created a cloud-based system that made a complex project extremely manageable, working seamlessly for the client, us and 80 vendors in the minimum of time.

The system has been so successful that it has become **the benchmark for all our projects** of a similar nature.



From development to market.

**Faster. Better. Smarter.**

## 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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