Pharmacovigilance.

Global and Local Services.

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Arriello's Global and Local Pharmacovigilance Services.

Failing to properly monitor, assess and report safety concerns puts patients as well as your investment in your Marketing Authorization at risk.

A poor translation can lead to a misunderstood critical report. An article on an adverse reaction buried in a local scientific journal can go undetected. A follow-up on a case isn't carried out. All these errors can lead to a significant level of risk with non-compliance of regulatory requirements, major or critical inspection findings, and patient safety.

And that's why the quality and efficiency of the processes and management of your PV System are critical.

Arriello has been a leading supplier of Global and Local Pharmacovigilance Services, since 2008. Our team has a combined experience of over **100 years** across the **EU, US, LATAM, MENA, CIS, APAC** regions and **South Africa**.

We are constantly expanding our global coverage and currently operate in **143 countries** with the ability to expand this as required.

Whatever your Pharmacovigilance needs, our experts can advise, implement and continue to minimize your risks and keep you fully compliant.

> *"Throughout the project you have approached the ICON-Arriello relationship with a friendly, constructive and collaborative attitude. I personally appreciated your valuable support, professionalism and conscientiousness. In the face of conflicting priorities and multiple customer demands you remained composed and professional."*

Donna Hartley
Drug Safety Manager, Pharmacovigilance and Safety Services, ICON plc, Ireland

Global Pharmacovigilance Services.

Our Global Pharmacovigilance System and Services have been developed and refined over several years and are maintained by our in-house European Union Qualified Persons Responsible for Pharmacovigilance (EU QPPVs) and Deputy QPPVs, backed up with the support of a range of Medical specialists.

Our comprehensive range of services includes:

PV System setup, maintenance and EU QPPV Services.

We are fully responsible for the creation and maintenance of your Pharmacovigilance System Master File (PSMF) and ensuring your PV System is fully compliant with European and International regulations and guidelines through our team of experienced EU QPPV's and Deputy EU QPPV's.

We constantly monitor the EMA (European Medicines Agency), HMA, Official Journal of the EU, CIOMS and ICH websites for global PV Regulatory Intelligence updates and advise on the impact to your procedures and medicinal products.

Comprehensive ICSR Management.

Managing your Individual Case Safety Reports (ICSR's) accurately and efficiently is critical to an effective PV System and Arriello provides full support for each step of the ICSR handling process.

From collection and translations to data entry, quality check, medical review and submission, we'll manage your safety data and meet all your ICSR requirements. Our capabilities include MedDRA coding, case assessment, and electronic reporting through EudraVigilance.

Pharmacovigilance Signal Management.

Rely on Arriello for Signal Management, and gain peace of mind knowing our experts have the in-depth knowledge you need to stay compliant.

From keeping tabs on adverse events in EudraVigilance to helping your organization follow Good Pharmacovigilance Practices (GVP), our team members will help you follow the right regulatory guidelines.

Global Literature Monitoring.

Global Literature Monitoring is a key part of a full Good Vigilance Practice (GVP) based on Pharmacovigilance System and at Arriello, we screen using Embase with Medline database.

Using broad and narrow literature queries, we search for ICSRs, published studies and information relevant for the safety of your products. We make sure we've fully assessed any available information that may impact on patient safety or require further investigation.

Choosing the right service and people is critical.

Your choice of pharmacovigilance provider can have profound impacts on the success of your products in the marketplace through their life cycles. Ensuring compliance and safety, whilst being able to manage risk and plan around change, requires experience and depth of knowledge.

Director of Drug Safety and EU QPPV Peter Kohut, talks about what he sees as important to provide an excellent pharmacovigilance service for clients.

> ***"To be effective, you have to be supported by the right company infrastructure, with in depth knowledge and a great Quality Management system. And that's exactly what we have built at Arriello, because these are our foundations of an efficient PV system and an excellent service."***

Peter Kohut
Director of Drug Safety | EU QPPV

Aggregate Safety Reports.

We can handle all your Aggregate Safety Reporting obligations throughout the life-cycle of your product with the creation of Development Safety Update Reports (DSURs) and Periodic Safety Update Reports (PSURs).

From compiling your DSUR information to preparing your PSUR for the European Medicines Agency (EMA), we have the knowledge and expertise you need to stay compliant with requirements.

Risk Management.

An effective Risk Management System and the development and update of Risk Management Plans, mandatory in the EU, are a critical part of Pharmacovigilance and patient safety. If you don't effectively monitor for important identified and potential risks or missing information your Marketing Authorization or Application is itself at risk.

Arriello's in-house Risk Management expertise can identify new safety concerns and propose appropriate risk minimization measures, keeping you compliant and improving patient safety.

> *"Arriello has highly knowledgeable staff in all countries with a very professional attitude. They are very fast in responding when needed."*

Berit Lindholm
CEO, Bluefish Pharmaceuticals, Sweden

Local Pharmacovigilance Services.

We can create an efficient, high quality and completely tailored Local PV Service solution to all your requirements around the world. Our global coverage is extensive and we currently operate in **143 countries** with the ability to expand this as required.

Our comprehensive range of services includes:

LPPV – Local Person Responsible for Pharmacovigilance.

Through consultation and our extensive experience and knowledge of Local PV requirements, we know what is required in each market and how that matches your requirements. We can then provide either a Local Qualified Person for Pharmacovigilance Service (LQPPV), or a Local Contact Person for Pharmacovigilance Service (LCPPV) where this is legally required.

We can do this in all your markets through our comprehensive international vendor network which is qualified and audited by our dedicated vendor management department.

Local Literature Monitoring.

Literature Monitoring specifically at the individual country level is a key part of our Local Pharmacovigilance System at Arriello. Using broad and narrow search strategies and keywords, we search local medical and scientific journals including published study results, literature reviews, meta-analysis, etc.

We can also fully assess all screened information to identify any impacts on patient safety, or anything that may require further investigation or changes in specific markets.

Drug Safety Officer.

Where an LPPV is not legally required we can provide the services of a Drug Safety Officer (DSO), a growing role in Pharmacovigilance. This role is often connected/interchangeable with the title Local Safety Officer (LSO) and others which can differ country by country and client by client.

The DSO role objective is primarily the same regardless of title; to have a dedicated knowledgeable and efficient technical service at the individual country/territory level.

At Arriello we offer a unique blend of in-house resource and expertise, combined with local in-country staff who fully understand local regulations.

This includes but not limited to Individual Case Safety Reports (ICSR) intake and local level processing, local submissions (aggregate reports, RMPs, ICSRs, etc.), compliance monitoring, the implementation of local PV requirements in relevant procedures and systems, providing PV/product-specific training, Health Authority inspections and many more! As the role is flexible depending on individual client needs and local PV regulations, the exact mix of capabilities and requirements varies.

Whatever your Drug Safety Officer requirements, we can propose and deliver a **faster, better, smarter** solution to meet them.

Regulatory Intelligence.

Our **faster, better, smarter** approach extends right down to the requirements from our local vendors. They provide us with regular updates on changes to local regulatory requirements and legislation by monitoring official sources such as their National Competent Authority, Health Ministry websites and others. Then, all this information is double-checked by another vendor to ensure it is all correct.

This depth of research and monitoring, with a double-verification process, means you can be confident that you're fully compliant in that market. Plus, you'll gain country-specific insights that could reduce your risk and allow ample forward planning of changes and implementation that can impact your PV System or your product.

Pharmacovigilance Translations to/from Local Languages.

Clear communication is critical for maintaining your MA and protecting lives. We provide translations specifically for Life Sciences materials across all therapeutic areas.
From ICSRs to abstracts and articles from local Literature Screening, translations are available in virtually any language and at any scale. Our network is based on a mix of certified translators, or local translators that meet a minimum three criteria of medical background, local language plus English knowledge.

Local ICSR Management.

We offer complete support for the management of local ICSRs, including but not limited to:

Safety mailbox management.
We can monitor, assess, track, process and forward any correspondence and information received in the local safety mailbox.

Local case submission.
We can process all local submissions to the National Competent Authorities according to the country specific requirements (e.g. on format, timelines, route of submission, etc.).

Case follow-up.
We ensure that all cases that require additional information after initial review are rigorously followed-up back to their sources.

Safety Reports.

Whatever the specific requirement is for writing and developing Safety Reports, you can trust Arriello's Pharmacovigilance experts to gather the right data, use the right formats, and follow the right processes to comply with local regulatory requirements.

Vendor Vetting and Management.

Our large vendor network includes **128 companies** in **92 countries** but that doesn't mean they aren't subject to the demands of our **faster, better, smarter** culture.

When you partner with Arriello you can be sure quality extends right through to our vendors thanks to the robust processes our vendor management department has in place for vetting and management including:

Qualification for selection.
Using a balanced scorecard, our department assesses and monitors potential vendors based on predefined criteria.

Reporting.
We regularly require our vendors to provide reports on their performance, which are then checked internally by our PV project managers and specialists. We also monitor all reporting timelines are adhered to for compliance too.

Compliance monitoring.
To ensure our vendors are fully compliant, we conduct on-site and off-site audits based on the frequency identified in the approach to risk planning or Risk Management Plan.

Training.
With training, we use education to empower our vendors to follow Arriello's best practices and our **faster, better, smarter** approach.

Audit and Training.

Audit/Inspection Readiness – AIR.

If you'll soon undergo an audit, you don't have to face it alone. At Arriello, our experienced team has a deep understanding of the auditing process.

We are audited numerous times each year as part of the auditing process of our clients as they themselves either prepare to be audited or, as part of a health agency inspection, where we are part of the system they maintain. True to our **faster, better, smarter** ethos, we are fully ISO 9001 Certified for Quality Management and we are able to offer this expertise as a service.

With our team, you can:

Have Arriello audit your organization for best practices through a detailed gap analysis and report.

Prepare for a Good Pharmacovigilance Practice (GVP) Audit.

Ready your team for a Health Inspection Audit.

Learn how to audit internal teams and vendors.

Pharmacovigilance Training.

In addition to our in-house Pharmacovigilance Services, we can also provide Pharmacovigilance Training for your specific project or as a standalone service.

Intelligent Automation.

IntelliCASE.
Speech enabled case reporting in your pocket!

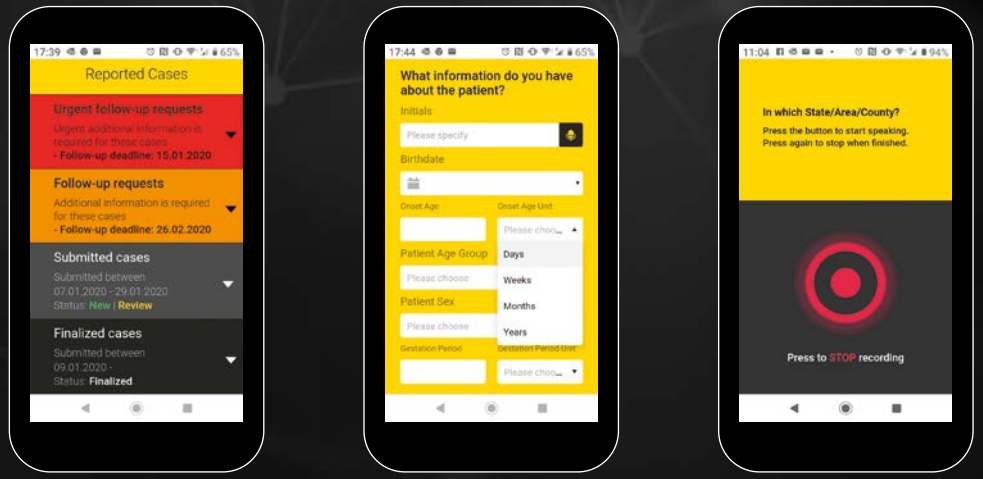
IntelliCASE is the world's first mobile, customizable, ICSR solution that allows you to use speech to text in multiple languages.

IntelliCASE provides a simple, intuitive and easy way to complete a structured case report form on your mobile device. It indicates the fields required for a valid case, allows you to attach photos or other files, save the report as a draft if required and preview/edit it before submission.

IntelliCASE is E2B R3 compliant, fully validated to GAMP 5 GxP standards and recommendations, and all data handling and storage is GDPR compliant too. Our testing shows we can reduce the average processing time compared with a 'traditionally processed' case (reported by email, fax or call), from **1.5 hours down to 30 minutes including QC check with IntelliCASE, a massive 66% time saving!**

Creating a case report, on the move, when you want, just became a whole lot easier.

https://www.arriello.com/automation/intellicase/



from development to market.
faster. better. smarter.

arriello

About us.

Arriello has been a leading provider of risk management and compliance services to the Life Sciences sector since 2008.

These include Market Consultancy, Global Regulatory Affairs strategy and implementation, Full and Local Pharmacovigilance solutions, Clinical Drug Safety, and Quality and Compliance auditing and systems.

Our brief is simple; to make the process from development to market faster, better and smarter.

Headquartered in Ireland, with European operations in Central Europe, we provide expert Market Access guidance across the EU, US, LATAM, CIS, MENA, Asia and South Africa.

With our extensive global vendor network, ISO 9001 certification, years of experience and satisfied clients, including Global Originators, Biotechs, Generics and CROs, you can be confident in our ability to deliver.

However complex or simple your requirements, you can rely on us as a trusted partner.

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