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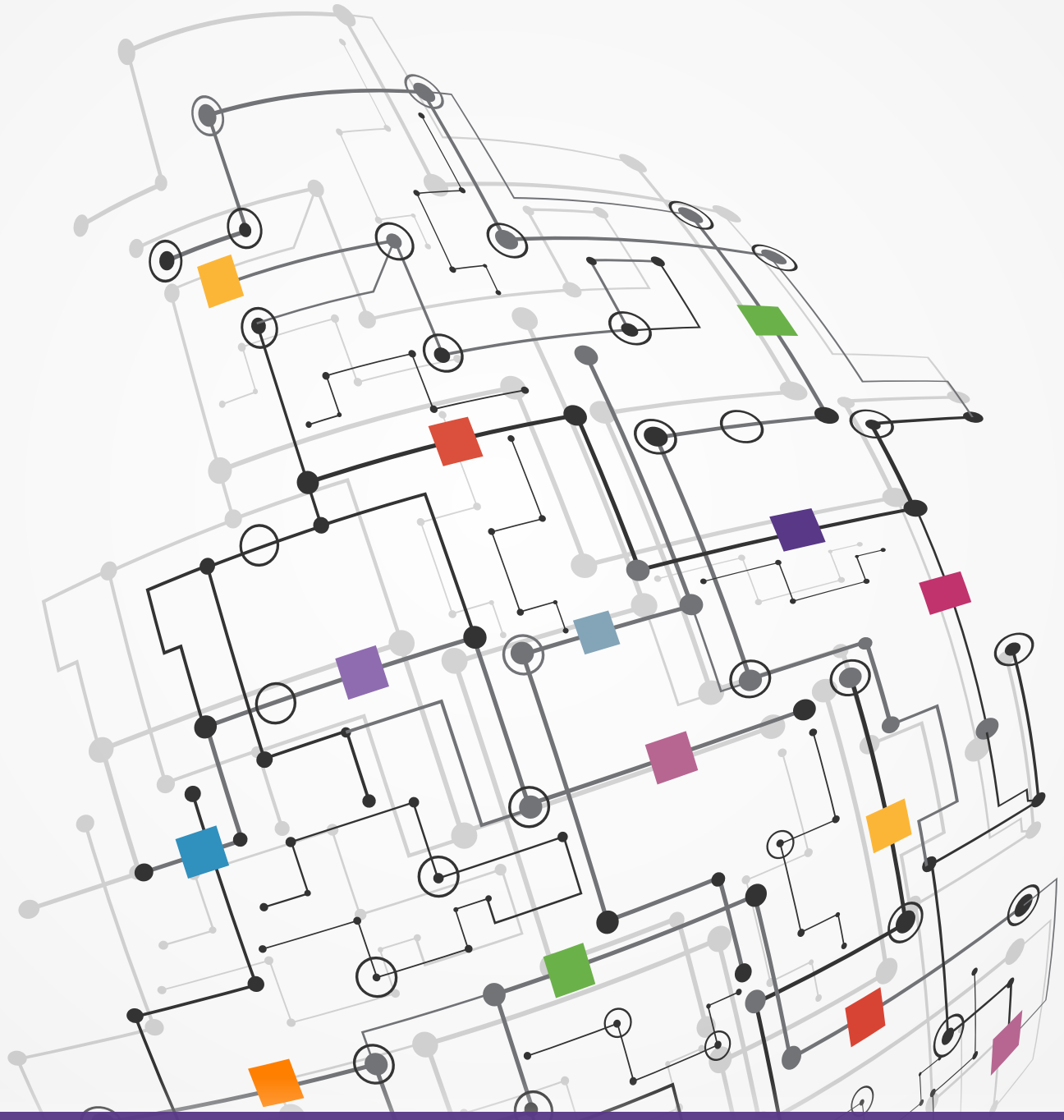

A PHARMACOVIGILANCE SUCCESS STORY

CURRENT LANDSCAPE

Biopharmaceutical companies rely on global contract research organizations to deliver post-marketing pharmacovigilance services and to provide safety surveillance and monitoring to meet regulatory requirements for approved products. Certain products may need formal risk evaluation and mitigation strategies (REMS) or a risk management plan (RMP), creating a need for outsourcing expertise. PPD continues to enhance its services for holistic lifecycle management tasks and pharmacovigilance regulatory reporting. PPD has more than 800 safety professionals with deep understanding of complex regulatory requirements, and has the capability to deliver flexible, scalable technologies and solutions to meet the changing needs of biopharmaceutical companies across the globe.

SEIZING A CLIENT OPPORTUNITY

PPD recognized an opportunity to join with ArisGlobal to provide its clients with an agile solution that would help them remain current with continually evolving regulations.

"After considerable internal review and evaluation, our assessment was that a new cloud-based database was the most appropriate approach to offer our clients a next-generation drug safety solution," says Brian Wellins, Senior Director of Pharmacovigilance at PPD, who manages the Safety Technical Operations (STO) team. "We also concluded that the database we chose must provide functionality that would support continuous Pharmacovigilance regulatory reporting compliance in the most cost-effective manner possible, while providing complete confidence for PPD and its clients."

THE ARISGLOBAL CONNECTION

During the evaluation process, PPD determined that, in addition to ARISg's ease of configuration and cloud access, ArisGlobal was committed to maintaining a strong overall regulatory focus and would keep its software solutions as current as possible with evolving global regulations.

By working with ArisGlobal, PPD can offer its clients the following benefits:

- More efficient and effective pharmacovigilance services, including case processing.
- Strategic, coordinated staffing solutions to support administrative technological needs.
- Quicker, more seamless response to regulatory mandates through the electronic E2B-compliant submission of ICSRs in XML format.
- Rapid configuration to support and quickly scale up new post-marketing pharmacovigilance clients.
- Read-only access to the safety database along with training on the system to enable clients to access the system and see their data in real time. This allows PPD to manage the data in the database and the client to work closely to review data integrity from an aggregate perspective.

"ArisGlobal's core competitive advantage is our more than 30 years of industry experience in building and refining our safety platform," says ArisGlobal Managing Director Sonia Veluchamy. "PPD recognized this, and we couldn't be more proud of our mutually beneficial relationship, and the profound impact it's having for their clients."

DELIVERING CLIENT SUCCESS

Since it began working with ArisGlobal, PPD has been able to use its offering of ARISg in the cloud to accomplish some impressive results. The following three examples highlight these gains:

- After the system went live, a client partnered with PPD to support an influx of legal adverse event cases requiring evaluation, data entry, processing and submission. Less than two months after signing the client contract, PPD submitted 33,000 cases to the U.S. Food and Drug Administration (FDA). This was accomplished by working collaboratively with ArisGlobal to create a programmatic upload of cases (E2B fields), which eliminated much of the manual data entry. In addition, PPD's pharmacovigilance team worked with the client to determine the most efficient method for accurate processing of complex and volume-heavy source documents. The case processing timeline, quality of data entry and medical assessment exceeded the client's expectations.

- ARISg has helped PPD successfully manage ad hoc requests from regulatory agencies more efficiently. For one of PPD's clients, the FDA requested supplemental information to be confirmed by an adjudication panel for an interim study report (ISR) to evaluate a new potential special interest event (SIE). PPD was able to easily extract the data from the ARISg database to identify potential cases and use the system to complete the remaining requested activities. PPD's pharmacovigilance department was able to generate 260 SIE narratives, perform extensive site follow-up, and provide 110 death narratives with source documentation to the adjudication panel. The client submitted the requested ad hoc report on time to the authority.

- A PPD client requested assistance to address a backlog of 55 periodic adverse drug experience reports (PADER) and periodic safety update reports (PSUR) for oncology and anti-infective products within 12 months. Known overlapping data lock and submission timelines were complicating the delivery. ARISg facilitated quick and efficient generation of periodic reports within the system based on industry standard reporting requirements. PPD was able to assign a lead safety specialist for each report, who compiled the data and wrote all sections of the report. A PPD safety physician then provided medical review of the reports. All reports were successfully compiled and submitted to the client on time.

CONCLUSION: MUTUAL BENEFITS

The relationship between PPD and ArisGlobal continues to mature thanks to a shared focus on excellence, patient safety and successful outcomes for clients.

"By collaborating with ArisGlobal, we are better able to provide a cost-effective, pragmatic solution to our clients who are seeking to meet the complex and evolving regulatory requirements in pharmacovigilance and to achieve compliance quickly," says Cindy Elko-Simms, Vice President, Pharmacovigilance at PPD.

"Our relationship with PPD is based on innovation and a commitment to helping their clients – highly regulated life sciences companies – quickly respond to drug safety and risk management requirements in order to bring their products to market," says Dr. Krishna Bahadursingh, ArisGlobal's Senior Vice President of Safety and Risk Management.

About ArisGlobal®

ArisGlobal's cloud-based solutions facilitate global drug development and regulatory compliance within the life sciences and healthcare industries. Its cloud platform supports the entire product life cycle including clinical development, regulatory affairs, safety and pharmacovigilance and medical communications. Hundreds of drug and device manufacturers, CROs and regulatory agencies leverage ArisGlobal's advanced technology solutions spanning regulatory information management, risk evaluation and mitigation strategies, medical information and clinical trial management software to make better and more informed decisions, facilitate compliance, reduce risk, and improve operational efficiency. Headquartered in the United States, ArisGlobal has regional offices in Europe, India and Japan. Visit **arisglobal.com** or follow ArisGlobal on LinkedIn and Twitter.

About PPD

PPD is a leading global contract research organization (CRO) providing comprehensive, integrated drug development, laboratory and lifecycle management services to pharmaceutical, biotechnology, medical device, academic and government organizations. With offices in 46 countries and more than 18,500 professionals worldwide, PPD applies innovative technologies, therapeutic expertise and a firm commitment to quality to help clients and partners bend the cost and time curve of drug development to deliver life-changing therapies that improve health. Visit PPDI.com or follow PPD on LinkedIn and Twitter.