PPD Functional Service Partnership (FSP) Pharmacovigilance solutions

Proven quality and experience driven by the utmost commitment to patient safety

Today's pharmacovigilance (PV) systems face complex and evolving global regulations driven by growing adverse event (AE) volumes and constant new streams of data.[1] Whether you need a full global PV solution or discrete PV services to complement your existing infrastructure, we have the experience, talent, and tools to help maintain your regulatory compliance as a sponsor or marketing authorization holder.

We partner with biopharmaceutical, biotech, and medical device companies to monitor patient safety with end-to-end global PV solutions available in a flexible FSP model. With a proven track record built upon decades of experience, PPD™ PV FSP solutions provide robust functional support from early development through regulatory approval and beyond with an uncompromising commitment to quality — while providing much-needed resource flexibility, reliability, and continuity.

30+ years of PV experience

Support based in **35+** countries

1,100+ biopharmaceutical, biotech and medical device companies supported since 1997

1 Deloitte US. Transforming pharmacovigilance systems: Automation, Tech, Analytics. https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/transforming-pharmacovigilance-systems-automation-technology-analytics-for-patient-safety.html

Breadth and depth of our pharmacovigilance services provide the ease of a single flexible partner worldwide

Through nearly 30 years of PV and FSP expertise, we've established a proven track record of stable, high-quality services with the convenience and ease of working with a single global partner. Our PV solutions support all clinical trial and post-marketing needs and bring robust therapeutic area experience and global expertise.

Case processing

End-to-end case processing in English, Japanese and Mandarin – with or without medical review – for all case types from clinical to post marketed

AI driven automated case intake

Proprietary tool uses large language models (LLMs) for versatile data extraction, supplemented by a 3rd party specialized tool for high-volume clients

Safety reporting

Global capabilities backed by robust regulatory intelligence for both Individual Case Safety Report (ICSR) and aggregate safety report submissions

Global literature services

Clinical trial and post-marketed surveillance activities, including ICSR detection and review for aggregate report inclusion and signal detection purposes

Safety science, including signal management

Activities to detect, validate, assess, and track potential signals, as well as support of wider safety science activities (e.g., safety committee coordination, safety labelling support, benefit-risk analysis, responses to regulatory authority safety queries)

Safety writing

Full range of aggregate safety report and risk management plan writing capabilities in English, Japanese and Mandarin to meet product life cycle needs

EU/UK specialty services

EudraVigilance profile management, EU/UK Qualified Person Responsible for Pharmacovigilance (QPPV), and pharmacovigilance system master file (PSMF) development and maintenance

Local PV services

provision of PV services typically performed at a country-level (e.g., local safety officer / national PV contact / local QPPV, local case management, local literature surveillance, local safety reporting, local employee training etc.)

PV agreement (PVA) management

drafting initial and updated PVAs and PV contractual clauses; associated tracking and management

Medical safety evaluation and risk mitigation (M-SERM) physicians

Our team of physicians strategically distributed in global hubs to provide services around the clock

PV consulting

Guidance to establish a new PV system, evolve an existing system, or meet regulations in a new region

PV technology consulting

With an in-depth knowledge of industry best practices, requirements, and the latest technology innovations, our team of dedicated PV programmers, validation experts, and safety database analysts tailor solutions to optimize your PV tech strategy, ensuring compliance and efficiency, using either our propriety solutions, yours, or a combination

Medical GCP services:

- Medical monitoring
- Endpoint Adjudication Committee (EAC)
- Data Safety Monitoring Board (DSMB)
- Medical data review
- Health Canada Safety Medical Officer (SMO)

Top-tier professionals and training deliver the right experience, knowledge, and expertise

Our PV solutions are supported by more than 1,400 experienced PV experts (e.g., physicians, pharmacists, nurses, medical scientists). To keep employees on top of ever-evolving regulations and technology changes, we offer award-winning employee development programs.[1] Trainings include: our corporate and departmental training, mentoring and shadowing, as well as training developed specifically for PV client programs. Our professional development and learning culture also help make ours a great company to work for, thereby increasing PV employee engagement and retention. Our industry-leading retention, in turn, delivers business continuity and the confidence of knowing that your PV system is supported by quality professionals who apply the right experience, knowledge, and expertise.

Industry-leading PV staff retention

- 6 years
  Average tenure for senior and principal level staff
- 8.5 years
  Average tenure for manager level and above level staff

Demonstrated results

Over **400,000** Individual Case Safety Report (ICSR) cycles processed each year for clinical trials and marketed products

ICSRs submitted to **over 3 million** regulatory authorities, ethics committees, and investigator recipients each year

RegView, our proprietary regulatory and PV intelligence platform, provides comprehensive PV regulations and procedural guidance across more than **100 countries**

300+ aggregate safety reports and risk management plans prepared each year

50+ products supported with comprehensive signal detection over the past three years

~99% on-time submission compliance rates over the last year

- ICSR completion – **99.95%**
- ICSR submission compliance – **99.5%**
- Aggregate safety report timeline compliance – **100%**
- Aggregate safety report submission compliance – **98.5%**
- Aggregate safety report quality compliance – **99.1%**

1 *Training magazine*. Training magazine Ranks the Winners of the 2023 Training APEX Awards. https://trainingmag.com/training-magazine-ranks-the-winners-of-the-2023-training-apex-awards/

Advanced systems enhance patient safety monitoring

Our PV solutions leverage new technologies, analytics, process improvements, and automations to gain efficiencies, improve quality, increase consistency, accuracy, and reliability, and reduce the PV cost burden. We are committed to continuously advancing our systems, processes, and technologies, and with our expertise in industry best practices, requirements, and the latest innovations, we also help tailor solutions to optimize your PV tech strategy using our solutions, yours, or a combination.

Across the AE life cycle, we offer a range of bespoke PV technology capabilities to unlock efficiencies:

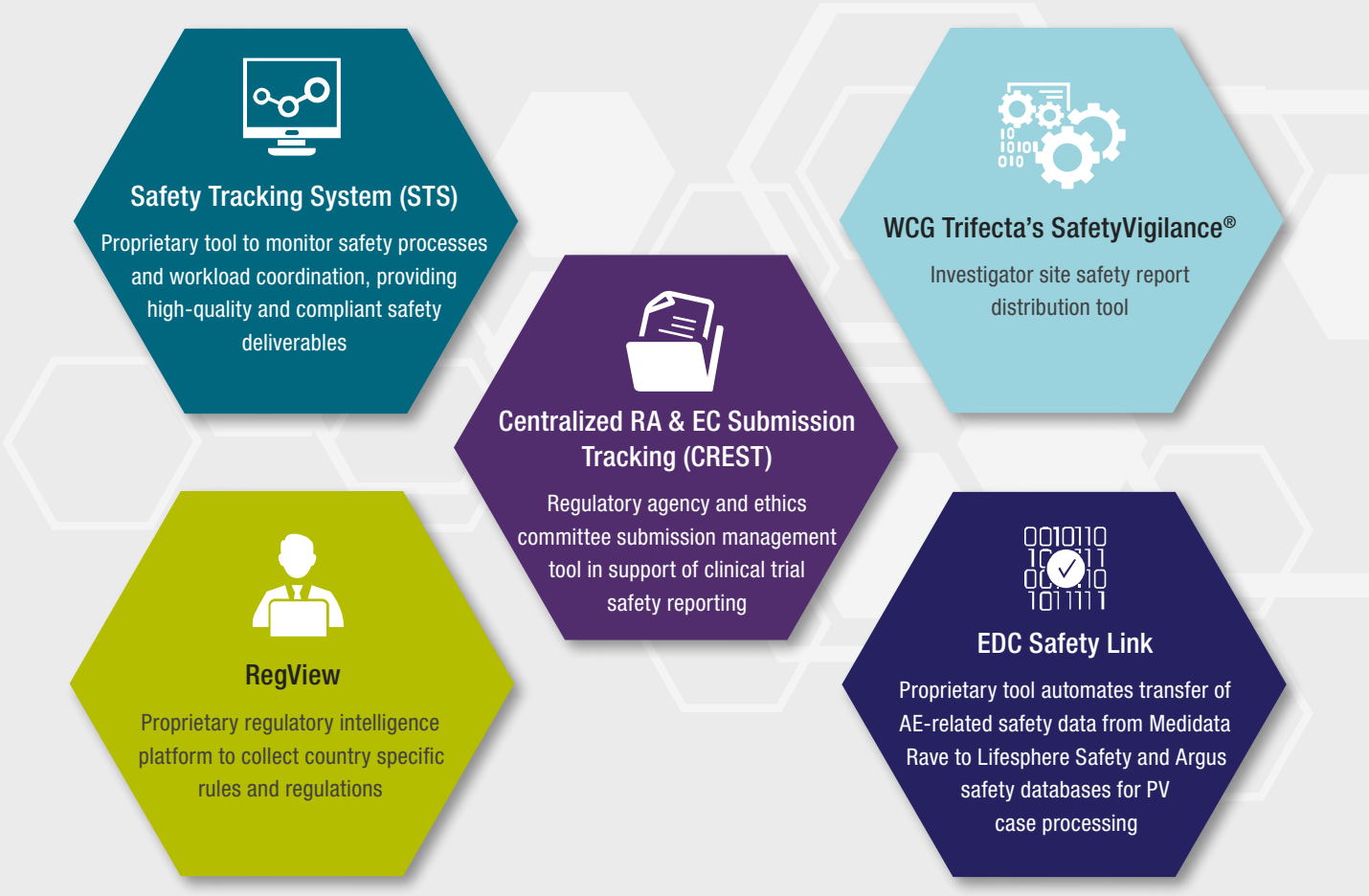
- **Safety Database:** we can either work within and support client safety databases or provide our own safety database solution which also integrates with other systems, including case intake and safety reporting platforms

- **AI Driven Automated Case Intake Solution:** our automated case intake solution improves case intake accuracy, timeliness and cost efficiency by eliminating much of the manual data entry needed to create AE cases in a safety database. The solution uses advanced large language models (LLMs) to automatically extract essential information from emails—including images containing handwritten content—to create AE cases. Integrated into our proprietary Safety Tracking System, it ensures swift and efficient processing within existing PV workflows. To make the review and editing of extracted data as efficient as possible, the interface identifies confidence levels to prioritize reviews. It then allows users to review the extracted data side by side with the original document. When a user clicks on an extracted data element, the system automatically highlights the text in the document from which the data was extracted. Conversely, it allows the user to highlight text in the document and automatically populate a needed data element. Time savings is estimated at 20-30%

- **Integrated Med Comm / PV solution:** We can help optimize your tech-enabled PV delivery through a seamless integration of proprietary technology and best-in-class PV solutions. This approach facilitates interoperability and electronic data exchange between medical information contact centers and PV teams across the AE life cycle, eliminating duplicate data entry efforts and achieving an estimated time savings of 30-40%

- **Rules-based Automation and Generative AI:** our Robotic Process Automation (RPA) Center of Excellence and proprietary Gene.AI platform deliver value across proven use-cases. By automating tasks such as robotic workflow intake, auto-preliminary expectedness assessment, and rule-based decision-making for safety reporting, we streamline processes to enhance efficiency and accuracy and achieving an estimated time savings of 15-20%

Other PV tools and systems include:



Learn more at **ppd.com/fsp-pharmacovigilance**