

FSP solutions

# 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 volume and constant new streams of data.<sup>1</sup>

Whether you need a full global PV solution or discrete PV functions to complement your existing infrastructure, you need a partner with the experience, talent, and tools to navigate this ever-changing environment and keep your studies on schedule.

Through end-to-end global PV solutions available in a flexible functional service partnership (FSP) model, **PPD™ Functional Service Partnership (FSP) Pharmacovigilance solutions** helps biopharmaceutical, biotech, and medical device organizations monitor patient safety and generate evidence that demonstrates effectiveness, safety, and value. With a proven track record built from decades of experience, we provide the right talent and expertise to help our clients meet their timelines — while providing much-needed resource flexibility, reliability, and continuity.



**25+** years of PV experience



Support based in **35+** countries



**900+** companies supported since 1997

<sup>1</sup>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 pharmacovigilance services provide end-to-end solutions to monitor patient safety

Through 25 years of PV and FSP expertise, the PPD™ clinical research business of Thermo Fisher Scientific has 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 service needs and bring robust therapeutic area experience and global expertise from more than 35 countries. With our exceptional track record of on-time delivery, and the flexibility to choose full PV solutions or discrete functions to complement existing infrastructure, you can rest assured that your PV programs will generate the evidence you need to demonstrate effectiveness, safety, and value.



## Case processing

End-to-end case processing — with or without medical review — for all case types from clinical to post marketing



## Safety reporting

Global capabilities backed by robust regulatory intelligence for both ICSRs and aggregate report submissions



## Global literature services

Clinical and post-marketing surveillance activities, including ICSR detection and review for signal detection purposes



## Signal management

Activities to detect, validate, assess, and track potential signals



## Safety writing

Full range of aggregate safety report and risk management plan writing capabilities to meet life cycle needs



## EU/UK specialty services

Setup and maintenance of complex global PV systems and participation in PV activities per this region's requirements



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

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



## Safety committee management

Fulfills adjudication/clinical endpoint committee (CEC) and data safety monitoring board (DSMB) requirements



## PV consulting

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

# Top-tier pharmacovigilance professionals deliver proven expertise, quality, and compliance

Our deep bench of more than 1,500 well-trained physicians, pharmacists, scientists, and health care professionals supports our PV solutions. To keep these experts on top of ever-evolving regulations and technology changes, we offer award-winning employee development programs.<sup>2</sup> Our industry-topping levels of PV staff retention also drive high stability and business continuity and grant you confidence that your programs are supported by experienced, knowledgeable professionals.



## Experienced and engaged teams

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



## Demonstrated Results

**4 million+ recipients** sent individual case safety reports (ICSRs) each year

Around **400,000 ICSR** cycles processed each year for clinical trials and commercial products

**60,000+ endpoint dossiers** adjudicated since 2000

**400+ aggregate safety reports** and risk management plans prepared each year

**30+ products supported** with comprehensive signal detection since 2013

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

<sup>2</sup>Business Wire, February 2021. "PPD Honored for Employee Development Programs that Deliver Results for Customers." <https://www.businesswire.com/news/home/20210217005667/en/PPD-Honored-for-Employee-Development-Programs-that-Deliver-Results-for-Customers>

# Advanced systems enhance patient safety monitoring



Our PV solutions leverage new technologies, analytics, process improvements, and automation to gain efficiencies, improve quality, increase consistency, accuracy, and reliability, and reduce the PV cost burden. And because today's PV systems face complex and evolving global regulations driven by growing adverse event volume and constant new streams of data, we continuously advance our systems and technologies in areas including the following:



## WCG Trifecta's SafetyVigilance®

Investigator site safety report distribution and clinical monitoring tool



## Safety Tracking System (STS)

Proprietary tool to monitor safety processes and workload coordination



## RegView

Proprietary regulatory intelligence platform to collect country specific rules and regulations



## Safety Databases

Adverse event management through ArisGlobal, Argus, and client systems



## Centralized RA & EC Submission Tracking (CREST)

Regulatory agency and ethics committee submission management tool



## Protocol Inquiry Platform (ePIP)

Provides sites with a 21 CFR Par 11 compliant pathway to submit inquiries to us and client physician teams

Talk with your account representative or visit  
[ppd.com/fsp-pharmacovigilance](https://ppd.com/fsp-pharmacovigilance)  
to learn more about how  
PPD FSP Pharmacovigilance solutions  
helps you generate evidence that demonstrates  
effectiveness, safety, and value so you  
can meet your timelines.

 Learn more at [ppd.com/fsp-pharmacovigilance](https://ppd.com/fsp-pharmacovigilance)

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