



HELPING DELIVER LIFE-CHANGING THERAPIES



PHARMACOVIGILANCE

# SERVICES AND EXPERTISE YOU NEED, QUALITY AND DEDICATION YOUR PROGRAM DEMANDS

**575+**   
biopharmaceutical and  
medical device companies

Each year, we process  
**400,000+**

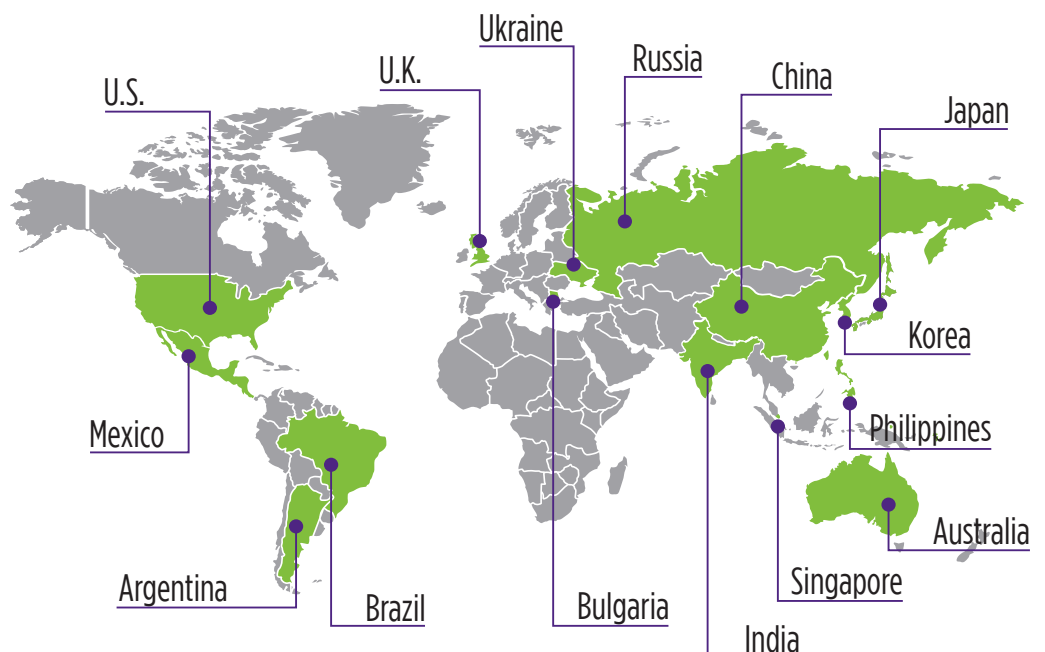
 **ICSRs**  
from clinical trials and  
commercial products

Deliver safety reports to  
**3,000,000+**  
recipients  
per year 

**>99%** on-time  
submission  
compliance 

Since 1997, PPD has delivered comprehensive, end-to-end pharmacovigilance services to more than 575 biopharmaceutical companies and medical device organizations. We offer proven solutions and exceptional quality, ensuring successful delivery of pharmacovigilance services from safety locations around the world. Whether you require a complete global pharmacovigilance and risk management solution or individual services to complement your existing infrastructure, PPD has the experience.

STRATEGIC LOCATIONS IN **28 COUNTRIES**  
WITH **1,400+ STAFF**



# PROVEN QUALITY AND COMPLIANCE

Our global pharmacovigilance team comprised of physicians, pharmacists and other medically trained professionals collaborates with various groups, such as clinical development, regulatory affairs and others, to ensure maximum success for your program.



More than

**55,500+**

**endpoint dossiers**

adjudicated

More than

**1,300**



**safety writing deliverables**

Experienced **signal  
detection team** with more than



**25 years**

of combined experience

**18**



**European Union Qualified Person  
Responsible for Pharmacovigilance  
(QPPV)**

services provided for 18 marketing authorisation holders  
(MAH) and applicants (MAA)

# SOLUTIONS FOR YOUR NEEDS

<b>SAFETY DATABASE MANAGEMENT/HOSTING</b> ARISg/ARISj/ARISc Argus	<b>AE/SAE MANAGEMENT</b>	<b>GLOBAL LITERATURE SURVEILLANCE</b>
<b>GLOBAL SAFETY REPORT SUBMISSIONS</b>	<b>GLOBAL SERVICES FOR CLINICAL TRIALS AND PERI/POST-MARKETING</b>	<b>SAFETY WRITING</b> Aggregate safety reports Risk management plans Regulatory responses
<b>MEDICAL SAFETY DATA REVIEW</b>	<b>SIGNAL MANAGEMENT</b>	<b>IN-COUNTRY PHARMACOVIGILANCE SERVICES</b>
<b>SAFETY DATA EXCHANGE AGREEMENT MANAGEMENT SUPPORT</b>	<b>LABELING (CORE SAFETY INFORMATION) SUPPORT</b>	<b>PHARMACOVIGILANCE CONSULTANCY</b> Standard operating procedure (SOP) development Regulations Strategic medical consulting

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## Clinical Trial Specialty Services:

- Endpoint adjudication coordination, including WebEAS (Cysis)
- Data safety monitoring board (DSMB) coordination

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## EU/UK Specialty Services:

- EudraVigilance profile management, including XEVMPD
- Qualified person responsible for pharmacovigilance (QPPV)
- Pharmacovigilance system master file (PSMF) creation and management

# PROCESS OPTIMIZATION, TECHNOLOGY SYSTEMS

## AUTOMATION

### Centralized Regulatory Authority and Ethics Committee Submission Tracking (CREST)

Automates the generation, delivery and tracking of ICSR submissions to regulatory authorities and ethics committees

### ArisGlobal AgNotify

Efficient delivery of safety reports to clinical trial investigators

### Literature Import Tool

Automatically imports Ovid outputs and performs duplicate checks, thereby enhancing the efficiency of literature surveillance

### Safety Tracking System (STS)

Multifunctional system providing end-to-end workload management and metrics reporting with ability to auto-file into our electronic document management system or electronic trial master file (eTMF)

## BUSINESS PROCESS MANAGEMENT SYSTEMS

### Protocol Inquiry Platform (ePIP)

A web-based platform utilized by our physicians that provides a pathway for clinical trial investigational sites to submit protocol inquiries to PPD

Our technology systems enable you to maintain safety and compliance requirements. Through the Lean Six Sigma approach we improve business processes and control cost.



For more information, please contact us at  
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