



HELPING DELIVER LIFE-CHANGING THERAPIES



PHARMACOVIGILANCE

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

**695+**   
**biopharmaceutical and  
medical device companies**

Each year, we process

**500,000+**

 **ICSRs**  
from clinical trials and  
commercial products

Deliver safety reports to

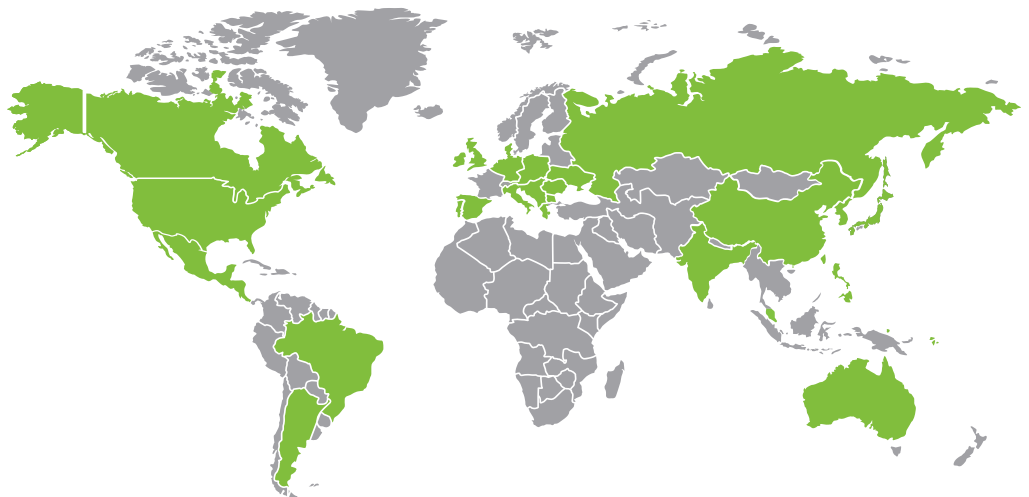
**3,000,000+**

**recipients**   
per year

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

Since 1997, PPD has delivered comprehensive, end-to-end pharmacovigilance services to more than 695 biopharmaceutical and medical device companies. 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+ EMPLOYEES**



# PROVEN QUALITY AND COMPLIANCE

Our global pharmacovigilance team comprised of physicians, pharmacists, scientists, and health care 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

**1,500**



**aggregate report and  
RMP deliverables**

providing **signal detection  
services since 2013** via a team  
of experienced scientists with more than



**30 years**

of combined experience

**21**



**Qualified Persons Responsible  
for Pharmacovigilance (QPPV)**

services provided for 21 marketing authorisation  
holders (MAH) and applicants (MAA)

# SOLUTIONS FOR YOUR NEEDS

|   |  |   |
|---|--|---|
| <b>SAFETY DATABASE MANAGEMENT/HOSTING</b><br>Aris Global's LSSg/LSSj/LSSc | <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><br>Aggregate safety reports<br>Risk management plans<br>Regulatory responses                                    |
| <b>MEDICAL SAFETY DATA REVIEW</b>   | <b>SIGNAL MANAGEMENT AND SAFETY SCIENCE</b>                        | <b>IN-COUNTRY PHARMACOVIGILANCE SERVICES</b>  |
| <b>SAFETY DATA EXCHANGE AGREEMENT MANAGEMENT</b>                          | <b>LABELING (CORE SAFETY INFORMATION) SUPPORT</b>                  | <b>PHARMACOVIGILANCE CONSULTANCY</b><br>Standard operating procedure (SOP) development<br>Regulations<br>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 LifeSphere SUSAR Reporting (LSSR)

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 providing a 21 CFR Par 11 compliant pathway for clinical trial investigational sites to submit inquiries to PPD and client physician teams

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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