PPD®

HELPING DELIVER LIFE-CHANGING THERAPIES

PHARMACOVIGILANCE

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

695+
biopharmaceutical and medical device companies

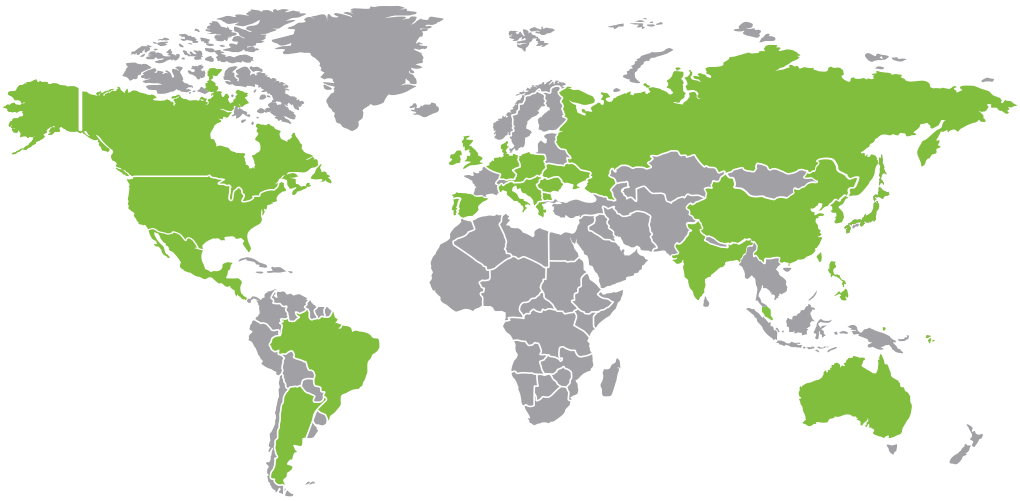
Each year, we process
500,000+
ICSRs
from clinical trials and commercial products

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

SAFETY DATABASE MANAGEMENT/HOSTING
Aris Global's LSSg/LSSj/LSSc

AE/SAE MANAGEMENT

GLOBAL LITERATURE SURVEILLANCE

GLOBAL SAFETY REPORT SUBMISSIONS

GLOBAL SERVICES FOR CLINICAL TRIALS AND PERI/POST-MARKETING

SAFETY WRITING
Aggregate safety reports
Risk management plans
Regulatory responses

MEDICAL SAFETY DATA REVIEW

SIGNAL MANAGEMENT AND SAFETY SCIENCE

IN-COUNTRY PHARMACOVIGILANCE SERVICES

SAFETY DATA EXCHANGE AGREEMENT MANAGEMENT

LABELING (CORE SAFETY INFORMATION) SUPPORT

PHARMACOVIGILANCE CONSULTANCY
Standard operating procedure (SOP) development
Regulations
Strategic medical consulting

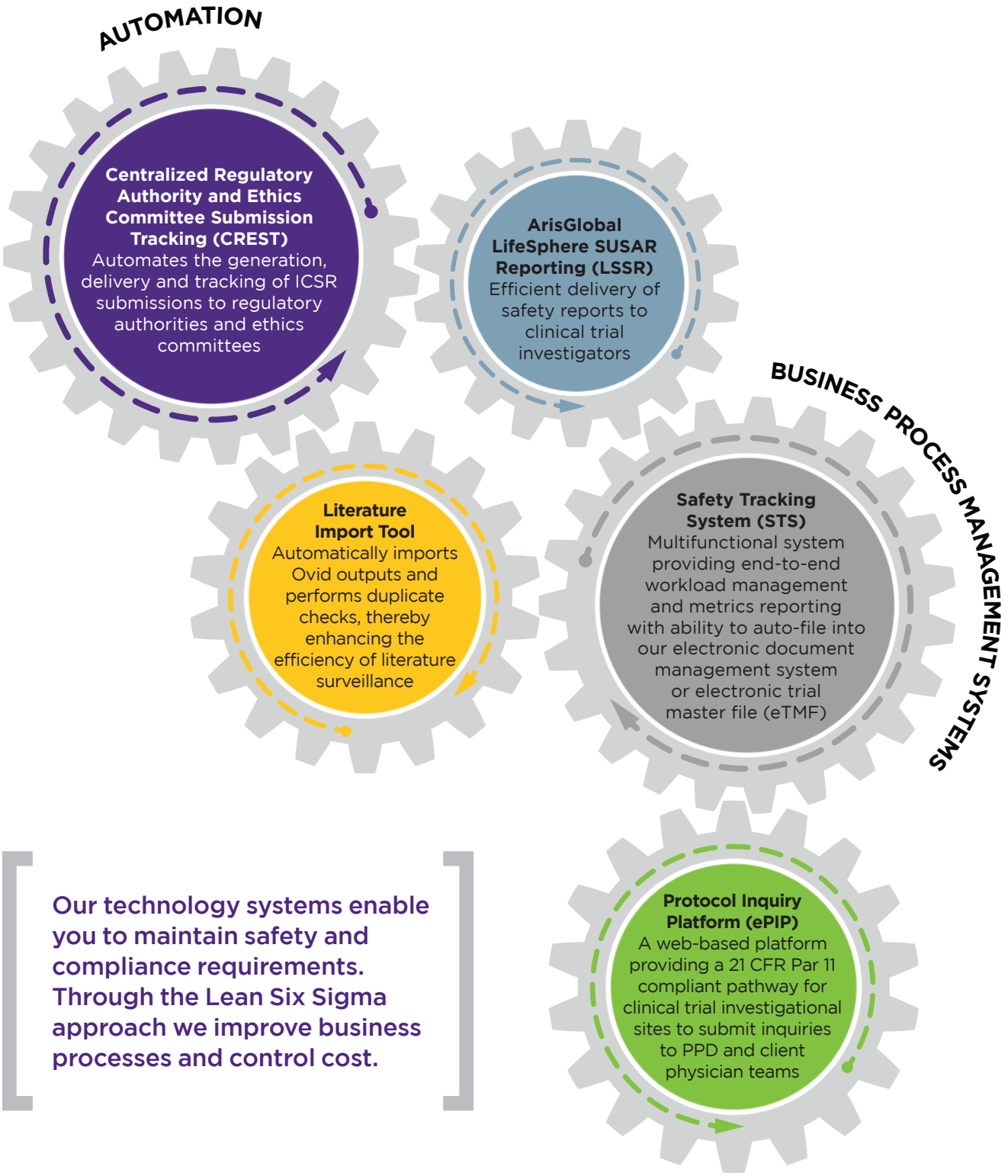
Clinical Trial Specialty Services:

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

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



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

PPD®

For more information, please contact us at
+1 877 643 8773 or +1 919 456 5600

ppd.com

twitter.com/PPDCRO

facebook.com/PPDCRO

youtube.com/PPDCRO

linkedin.com/company/ppd