PPD®

HELPING DELIVER LIFE-CHANGING THERAPIES

PHARMACOVIGILANCE

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

575+
biopharmaceutical and medical device companies

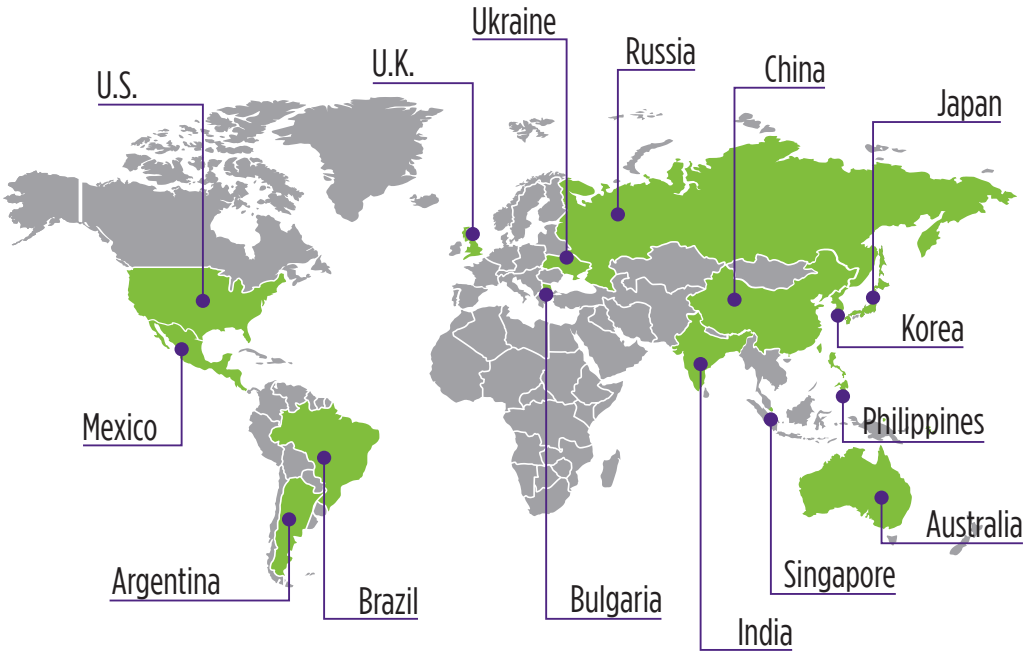
Each year, we process
400,000+
ICSRs
from clinical trials and commercial products

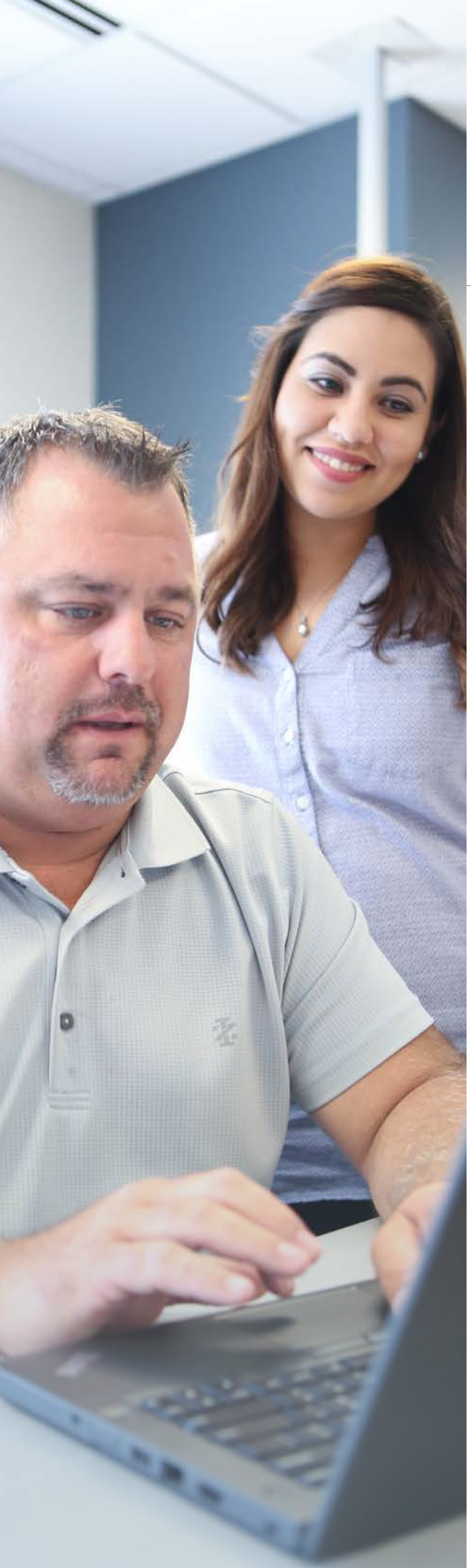
Deliver safety reports to
3,000,000+
recipients
per year

>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

SAFETY DATABASE MANAGEMENT/HOSTING ARISg/ARISj/ARISc Argus	**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**	**IN-COUNTRY PHARMACOVIGILANCE SERVICES**
SAFETY DATA EXCHANGE AGREEMENT MANAGEMENT SUPPORT	**LABELING (CORE SAFETY INFORMATION) SUPPORT**	**PHARMACOVIGILANCE CONSULTANCY** Standard operating procedure (SOP) development Regulations Strategic medical consulting

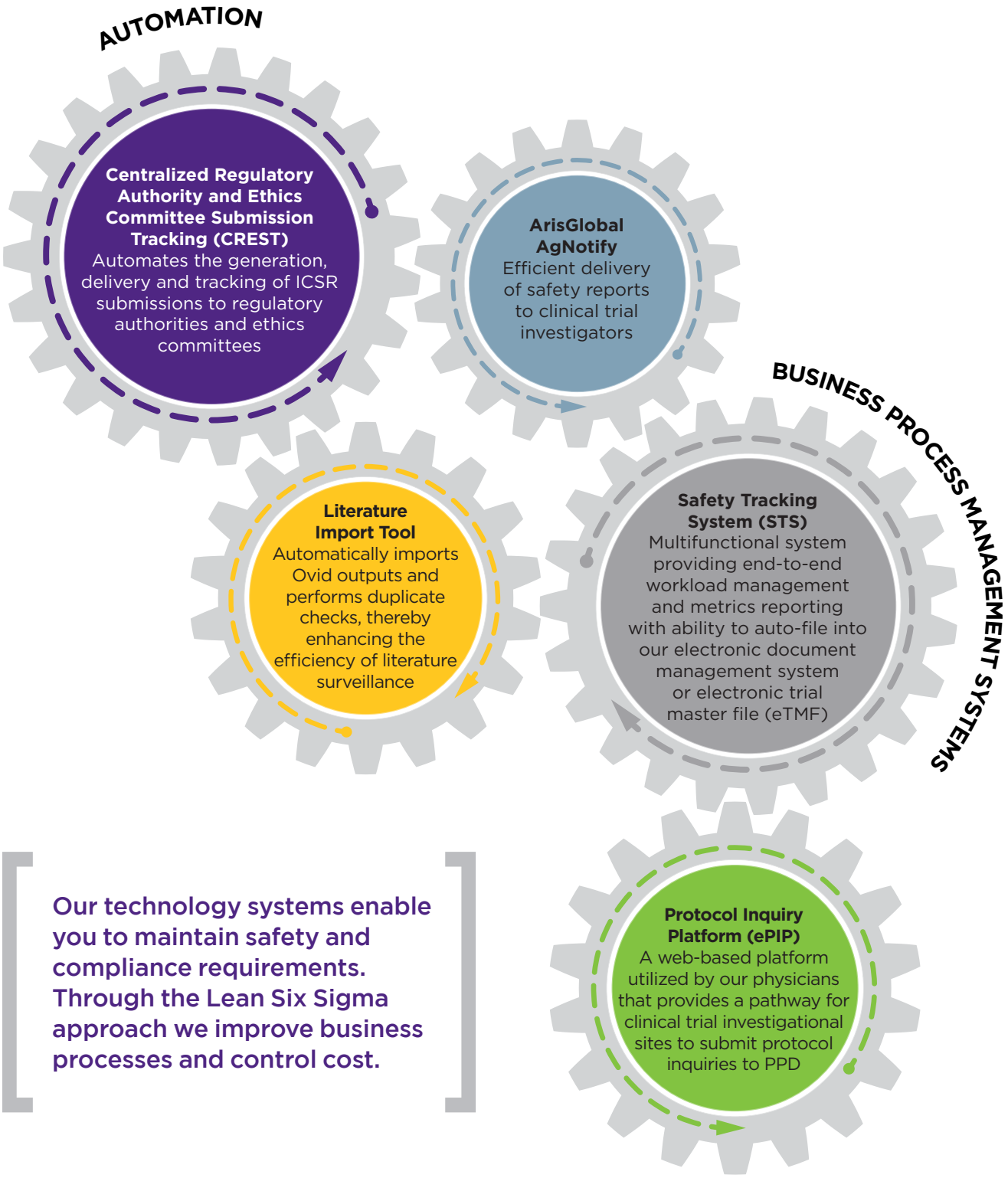
Clinical Trial Specialty Services:

- 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

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