PAREXEL® ACCESS

YOUR COMPLETE PHARMACOVIGILANCE SOLUTION

From commitment to competitive advantage
FROM COMMITMENT TO COMPETITIVE ADVANTAGE. NEXT GENERATION PHARMACOVOGILANCE SOLUTIONS.
Dear Colleague,

The cost of bringing a new product to market continues to increase. The cost of failure after reaching the market is significant. It is therefore critically important to retain a product on the market and ensure that the benefit and risk of the product is routinely evaluated.

The moment a new therapy succeeds in clinical trials and enters the marketplace; its life becomes more complex. Such complexity is unlikely to cease with the introduction of new regulatory requirements governing post-approval pharmacovigilance in the US, EU, Japan and other GCG ICH regions in the past decade. Additionally, the volume of adverse events reported to both agencies and to the Marketing Authorization Holder has been seen to increase significantly every year. In short, an effective post-marketing surveillance strategy is critical for the success of every new therapy.

At PAREXEL, we understand that it is more than about commerce. Patient safety is at the heart of your company’s focus and we share your commitment, ensuring that quality, speed and accuracy are prime concerns to our drug safety teams around the world. For more than 30 years, PAREXEL has helped its clients get their new and innovative drug treatments into the hands that need them most by simplifying their journey to market and throughout the product lifecycle. Among a broad service portfolio, PAREXEL is able to offer an end-to-end post-approval solution that provides seamless execution, deep expertise and a highly scalable global capacity.

We look forward to collaborating with you.

Joshua Schultz
Corporate Vice President
& Worldwide Head
PAREXEL® Access
To help our clients meet increasing regulatory pharmacovigilance obligations, PAREXEL has created a unique offering that better meets the need for scale, global reach and comprehensive product support services.

Through the integration of our industry-leading experts in regulatory, medical affairs and pharmacovigilance, combined with leading technology solutions, we are able to deliver the next generation of end-to-end post-approval services to our clients.
COMPREHENSIVE INTEGRATED SERVICES

PAREXEL provides comprehensive post-approval life cycle management services. We seamlessly integrate services, to give our clients greater value, access to increased efficiencies and a strategic advantage. An example includes the integration of Pharmacovigilance and Regulatory Affairs. We can combine all adverse event management and oversight activities with regulatory activities such as dossier preparation of new filings, dossier maintenance, labelling, RA CMC and affiliate queries. We offer proprietary Regulatory Information Management technology (LIQUENT InSight®). Medical expertise is routinely integrated throughout each engagement.

Our integrated services offer a portfolio planning approach that helps our clients achieve strategic elevation. Significant value and efficiencies can be achieved through strategic portfolio planning, reduced client oversight, offshore cost leverage, single sources of consolidated data and reporting and technology integration.

BROAD, SCALABLE MODELS

Whether you are looking to partner with us for case processing support, aggregate reporting, literature searching, medical assessment, or for an end-to-end
product portfolio maintenance program, PAREXEL can tailor a solution to meet your unique needs.

GLOBAL REACH

At PAREXEL, we don’t just have more locations worldwide, we have more regulatory experience, clinical expertise, and integrated technologies in exactly the countries you need. Following our 2015 acquisition of Quantum Solutions India (QSI), we have the flexible capability and global reach to support large volumes of cases (currently handling ~600,000 cases each year) and can support affiliate models for many countries. PAREXEL has the capacity to rapidly ramp-up or ramp-down services provided to clients to adequately support changes to operational requirements globally. And because our teams are all connected in real time and harmonized to the same protocols and SOPs, you get truly global thinking and results from PAREXEL every time, in every location.

INDUSTRY-LEADING TALENT

PAREXEL has a large team of global Subject Matter Experts (SME’s) who are able to review systems, processes, documentation and technology in order to conduct a detailed gap analysis to identify process improvements, efficiencies, and adapt to changing regulatory. Furthermore these SMEs regularly audit systems and conduct thorough due diligence, develop Standard Operating Procedures (SOPs) and working processes, and support the on-boarding of new employees. The SMEs also can provide training to the Marketing Authorization Holder (MAH), their local affiliates and commercial partners. Our Pharmacovigilance SMEs are able to develop safety data exchange agreements (SDEAs) and negotiate with commercial partners in order to come to an agreement that not only fulfils requirements for the MAH, but ensures that the system remains efficient and compliant.

INTEGRATED REGULATORY INTELLIGENCE

The sole function of our dedicated Regulatory Intelligence Collection Centre is to gather worldwide pharmacovigilance regulatory intelligence to help clients maintain continued compliance.

MEDICAL COMMUNICATIONS CENTER

Our multi-lingual, scalable call center has the capacity to handle many products and/or countries. The center handles medical information requests and product complaints.
PAREXEL has the expertise and capabilities to provide the full spectrum of post-approval life cycle services that offers expert resources and integrated solutions few companies could match on their own when compared with the size and global scope of the PAREXEL organization.

Seamless execution, breadth of services, deep expertise and a highly scalable global capacity make PAREXEL a leader in Pharmacovigilance outsourcing.

Demand from regulators is to increasingly take a systematic and standardized approach that includes regional and affiliate accountabilities in the post-approval tasks. PAREXEL can help you consolidate and simplify your outsourcing strategy, with end-to-end solutions and highly scalable operations around the world. Why juggle multiple providers and compromise efficiency? Access a simplified solution with a partner who can work closely with you to help you navigate through the complexity and more effectively achieve your goals.

A SIMPLIFIED SOLUTION

HIGHEST QUALITY DRIVEN BY INTENSIVE TRAINING

Compliance: 99.7% ICSRs
100% ARs

Accuracy: 99.6% ICSRs
ACCESS TO THE INDUSTRY’S SMARTEST TALENT

- Medical Directors and Drug Safety Physicians (with board certification or equivalent)
- Drug Safety Associates, Specialists and Senior PV Specialists
- Medical Information Technologists with extensive experience in migrating and establishing safety databases on behalf of clients
- PAREXEL Consultants with extensive PV experience in addition to process excellence, six sigma, quality and compliance and risk management. Many also have Regulatory Authority backgrounds
- Quality Process & Training Specialists
- Medical Writers
- Pharmacoepidemiologists
- EU QPPVs and Deputy EU QPPVs via our QPPV office

HIGHLY EXPERIENCED GLOBAL TEAM OF ~1,500

70% PHARMACOVIGILANCE FTE’S

>5 YEARS experience
Adverse Event Management
• All sources – clinical trial, post marketing, other sources e.g. Named Patient Use programs, Registries etc.
• 24/7 call centre capabilities as required (e.g. for case intake), operable from multiple global locations
• Individual Case Safety Report (ICSR) receipt, triage and processing
• Structured to handle both low and high-volume caseloads
• High flexibility to handled rapid changes in case volume
• Submission of expedited reports to Regulatory Authorities

Global Safety Database
• Set up and maintenance of a customized global safety database or direct access to Client-based safety database
• Transfer of legacy cases (any format) into the global safety database

Safety Surveillance
• Includes signal detection, trend analysis and benefit-risk assessments
• Labelling strategy and updating
• Company Core Data Sheet / Core Safety Information updates
• Labelling reviews
• Responses to Regulatory requests

Pharmacovigilance Systems Documentation
• Standard Operating Procedure (SOP) writing
• Detailed Description of the Pharmacovigilance System / Summary of Pharmacovigilance System
• Safety Data Exchange Agreements

Labelling
• Creation and updates of the Company Core Data Sheet (CCDS), Company Core Safety information (CCSI) and Core Safety Profile (CSP)
• Implementation of changes into local labelling

Literature
• Literature searching and reviews

Aggregate Reports
Includes, but is not limited to:
• Periodic Safety Update Reports (PSURs)
• Development Safety Update Reports (DSURs)
• Periodic Suspected Unexpected Serious Adverse Reaction (SUSAR) summary reports
• Annual Safety Reports / IND Annual Reports

Investigational Brochures (IB)
Review of the safety section of the IB including annual updates to ensure it remains current

*All PAREXEL services are governed by a comprehensive internal Quality Management System and are operated in compliance with all applicable regulations.
Medical Information
• Inbound Calling
• Global Expertise
• Multi-Lingual in over 170 different languages
• Call metric tracking
• 24/7 Live Operator, no matter from where the call originates
• Customized Call triage
  - Pharmacovigilance Services
  - Medical Inquiries
  - Adverse Events
  - Product Complaints

Pharmacovigilance Systems / Strategy
• Full strategy development and Pharmacovigilance system implementation
• Process excellence including Six Sigma
• Process and SOP development
• Auditing

EU QPPV Services
• EU Qualified Person for Pharmacovigilance (QPPV) and deputy
• 24/7 Availability
• Capability to meet local requirements [e.g. local QP requirements]

Training
• Pharmacovigilance training [Pharmacovigilance / non-Pharmacovigilance staff]
• Pharmacovigilance education
• Pharmacovigilance Audit preparation / training

Risk Management (RM)
• RM Planning and Strategies
• RM Plans (RMPs) – writing, implementation and follow-up
• Risk Evaluation and Mitigation Strategy (REMS) – writing, implementing and follow-up [e.g. measurement of success etc.]

Specific Safety Issues
E.g. implementation of:
• Preparation of response to ad hoc questions from Regulatory authorities
• Observational studies
• Phase IV studies [Post Authorization Studies (PAS), Post Authorization Safety Studies (PASS), registries]

Copy Approval
• Promotional review – either via PAREXEL or Client systems [e.g. Zinc]