Driving Efficiency in Post-marketing Safety

PAREXEL®

Right where you need us®

The PAREXEL PACE (Peri-approval Clinical Excellence) group is a dedicated unit of late phase specialists providing a full scope of peri/post-approval services that help our biopharmaceutical client's collect the data needed to successfully prove the value, safety and effectiveness of their products.

PAREXEL's PACE group provide a range of tailored pharmacovigilance (PV) services that can effectively address the needs of biopharmaceutical companies of all sizes. With over 30 years of compliance, medical and technology expertise in addition to our unparalleled knowledge of each unique regulatory landscape across the globe, we are able to provide diligently managed, flexible and cost-effective solutions. Our service packages are designed on a case-by-case basis to meet the specific requirements of your organization. This ensures that you have all the support that you need, delivered through a lean operational model, whether it is to manage a specific program, product or even if you are looking to engage with us for a complete pharmacovigilance capability for your organization.

The PAREXEL advantage

After a new therapy succeeds in clinical trials and enters the market, its life becomes even more complex. Safety profiles, real-world performance, and ever-shifting regulations guarantee post-marketing surveillance will be critical to its long-term success. Nevertheless, the wide array of pharmacovigilance services facing sponsors can be daunting. No solution is fit for all products; solutions that fit early in the post-marketing phase might not be appropriate when a product is approved for new indications, for example.

That's why PAREXEL's PACE group, a pioneer in pharmacovigilance services since its earliest days, offers sponsors not only a comprehensive portfolio of Pharmacovigilance capabilities, but also the expertise and wisdom to help sponsors find the right-fit solutions for their products and organizations. With a full suite of scalable and flexible solutions, we can provide the tools and techniques to achieve patient safety, regulatory compliance, and long-term strategic advantage.

Tailored or turnkey pharmacovigilance services

Strategy

Assess pharmacovigilance requirements develop right-sized vision, strategy and approach for client

- Lifecycle PV strategy
- Risk profile definition
- Risk management planning
- Due diligence
- Regulatory compliance
- Cost effectiveness

Implementation

Develop and implement integrated pharmacovigilance system focused on process, people, technology, compliance, science

- Communications & change management
- Process mapping & integration
- SOP development
- Document hierarchy design
- Organizational design
- Metrics that matter
- Technology selection & adoption
- Regulatory documentation of pharmacovigilance system

Operations

Set up and operate outsourced PV projects/functions or entire departments on behalf of client

- Clinical trial AE handling and reporting
- Post-marketing ADR handling and reporting
- Medical reviews, medical writing
- Expert statements, investigator notifications
- Aggregate reporting
- Medical writing services
- Call center and helpline
- EU Qualified person for Pharmacovigilance (QPPV)
- Medical information
- Best practices

Continuous Improvement

- Business process-engineering
- Technology adoption
- Pharmacovigilance training and education
- Comprehensive safety organizational and process training
- Safety governance models
- Customized in-person and online training
- Safety and quality systems
- Qualified person certification training

A single point of contact covering the world

Globally, PAREXEL employs more than 350 safety experts across eleven operational safety hubs. This allows clients to immediately benefit from access to a large, truly global pharmacovigilance organization without the administrative burden of managing the day-to-day operation of the system.

PAREXEL's existing global presence reaches across 71 office locations in 50 countries, with 12,000+ employees located around the world. Our global footprint encompasses not only a strong presence in North America and Western Europe but also leading capabilities in emerging geographies such as Central/Eastern Europe, Latin America, Africa, India, and the Asia-Pacific region. This allows for the accurate gathering of detailed regulatory intelligence, around the clock case processing, cost-effective infrastructure, reporting, and, for most engagements, a single point of contact in our sponsor's time-zone and language.

Your advantages with PAREXEL's PACE group

- Quality systems approach ensures compliance, leading to a reduction in business risk due to favorable inspections outcomes and faster time to market
- Single point of contact in your time-zone
- Access to world-leading technical expertise and operational excellence
- Lower recruitment and headcount expenses
- In-house, dedicated PV regulatory intelligence services
- Scientific developments and new regulatory requirements automatically integrated in process
- "Round-the-clock" availability and geographic reach
- Short lead-in times, clear processes and effective client management
- Seamless integration and implementation
- Lower overall cost base for drug safety activities allowing re-allocation of resources

Best in class technology for patient safety insights

PAREXEL is a technology-oriented CRO that is proud of its strong technical expertise. We have the technical depth to maximize interoperability with our partners' systems and the expertise to integrate them with the latest technology solutions. Highly experienced experts in safety and pharmacovigilance deliver the next generation of contract pharmacovigilance services to our clients today.

Vigilant regulatory expertise

Increasing and evolving safety and pharmacovigilance obligations around the globe require vigilance and expertise. PAREXEL's PACE group operate a dedicated pharmacovigilance Intelligence Collection Centre whose function is to keep abreast of changing global pharmacovigilance legislation. Clients are secure in the knowledge that all our services are conducted in compliance with current regulations and responsive to forecast changes.

Seamless transitions, agile engagements

From individual pharmacovigilance activities to complete partnerships of end-to-end pharmacovigilance processes, the PAREXEL PACE group has the breadth of experience to integrate seamlessly into your business processes. Our pharmacovigilance operations are designed to ensure that each aspect is tailored to your specific requirements in such manner that they are also scalable and flexible while remaining fully compliant with all applicable legislation and guidelines. Modular service offerings and cost structures allow for the integration of additional products and countries into the system with minimal impact to our sponsors. Pro-active project management ensures that all engagements remain on target, highly efficient, and compliant over time. When operational efficiencies or improvements are identified, or if requirements change, the scope of services can easily be adjusted.

PAREXEL pharmacovigilance services provides

- Seasoned regulatory and industry experts who have designed and managed safety systems
- Flexible and scalable solutions customized to your business and technical requirements
- Help in reducing the risks of delayed development, product recalls and harm to patients
- A quality systems approach that ensures compliance, leading to a reduction in business risk due to favorable inspections outcomes and faster time to market
- Lower expenses for recruitment and head count
- Automatic integration of scientific developments and new regulatory requirements into the process
- Global operations 24/7/365 and state of the art technology solutions
- Fast track implementation methodologies with clear processes and effective project management and communications

Highest levels of quality and compliance

Service offerings include the full complement of pharmacovigilance activities.

- Case intake through adverse event management
- Processing and reporting
- Global safety database hosting
- MedDRA coding convention strategies
- Signal detection/trend analysis
- Risk management / risk management planning (e.g. RMP's, Implementation of risk minimization measures)

We can recommend and implement appropriate strategies to manage and measure required post-approval commitments effectively and efficiently. Whether there is a requirement for intensive monitoring in the post marketing phase, the establishment of registries or additional post-approval studies, PAREXEL can support your needs.

With the PAREXEL PACE group, bio/pharmaceutical companies can maintain compliance, avoiding costly setbacks that can threaten both product revenues and reputation while enjoying the quality and efficiencies realized by partnering with a dedicated CRO.

Proactive benefit and risk management is a prerequisite for business success as well as getting and keeping medical products on the market. PAREXEL can be your trusted partner for cost-effective pharmacovigilance services of the highest level of quality and compliance with regulations.

“We work closely with our clients to look around the curve, ahead of today’s conditions toward tomorrow’s strategic opportunities. By partnering with PAREXEL’s PACE group, our clients can focus on their core businesses while getting the best patient safety expertise and capabilities available.”

Gary Coward, Global Head Patient Safety Services

For more information or to arrange a customized briefing, please contact:

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WP-PXLPV-JUL12