

Leave nothing to chance

Let the PAREXEL® PACE™ group
take you through the next stage



LATE PHASE

PAREXEL®
Right where you need us™



When you are ready to move your product from development into the marketplace, you can't afford to take chances that might risk your product's commercial success.



When you partner with PAREXEL and its Peri-Approval Clinical Excellence (PACE) group, we are as committed as you are to collecting the data that will help to strengthen your product's value to health care providers and patients. We understand the challenges you face as you rigorously invest to protect and grow your brand.

We are right where you need us, with the global presence, technology and dedicated late phase expertise to manage all aspects of the peri/post-approval process, as well as to offer strategies to help you navigate through the increasingly complex commercial and regulatory landscape.

PAREXEL has a premier global clinical research group dedicated to late-phase scientific and commercial solutions. With dedicated service areas supporting late phase clinical trials, observational research and post-marketed safety, supported by our integrated market access and commercialization consultancy, we are able to facilitate a seamless transition from development through commercialization.

For every project, the PAREXEL PACE group assembles a dedicated team of personnel. These experts identify and execute a project blueprint drafted specifically to meet your scientific and business objectives. With extensive late phase experience, our teams provide strategic insight, design and implement flexible solutions, proactively solve operational challenges and fastidiously manage project timelines and budget. At PAREXEL, we pride ourselves on our experts because they pride themselves on your success.

“How can I best determine what data I need to meet all of my stakeholders’ needs?”

We understand that your company has more than one reason to conduct late phase studies. Whether it’s to meet regulatory requirements, enable label expansion to reach patients in need, develop new marketing claims, establish a long-term safety profile, or prove comparative or cost effectiveness, the PAREXEL PACE group has the expertise and global resources to determine, collect, and interpret the right data to meet the needs of your stakeholders. Having worked on more than 600 peri-approval programs within the last five years alone and with clinical research experience that spans over 25 years, we can leverage our knowledge to manage your every need with a custom-developed strategy built to meet your individualized goals.

“I want my product to help the people who really need it.”

The PAREXEL PACE group understands that your company is motivated by compassion as well as solid science. We, too, believe that innovative therapies and products should be available to those who will benefit the most. Our Expanded Access Programs include treatment IND studies, emergency use protocols, compassionate use guidelines, and named patient basis programs. You can trust us to honor your intentions that your drugs reach the people who inspired you to develop them.



Service capabilities

Late Phase Clinical Trials

PAREXEL is a leader in the conduct of Phase IIIb/IV clinical trials. In the past three years alone, the PAREXEL PACE group has conducted more than 220 international Phase IIIb/IV clinical trial programs. Collectively, these studies have involved the enrollment of over 330,000 patients at approximately 29,000 sites located across the globe. We provide reliable study feasibility assessments based on a broad and established network of physicians. You can have confidence in us because no matter what your goal, we’ve most likely seen it and done it.

Observational Research

The PAREXEL PACE group has dedicated expertise and significant experience in the conduct of observational research programs, including retrospective studies (e.g. chart reviews) and prospective studies, like patient registries. With a global multi-disciplinary team comprising research specialists, pharmacoepidemiologists, health economics and outcomes researchers, and specialized operational teams, we are able to help you design and execute a study that will best achieve your defined study objectives and meet the needs of your target audiences.





Strategic development & operational services	Unrivalled experience
Phase IIIb	<ul style="list-style-type: none"> • Studies of all sizes to meet various objectives including: <ul style="list-style-type: none"> – New indications – New formulations – Medical outcomes – Direct comparison • Many therapeutic areas • Single country and multinational
Large simple trials/ large phase IV studies	<ul style="list-style-type: none"> • Success with some of the largest trials conducted • Development of simple study designs in this area with scientifically relevant endpoints • Scalable operational infrastructure
Observational studies/registries	<ul style="list-style-type: none"> • Product safety & outcome registry experience • Cohort studies • Non-interventional studies • Cross-sectional studies
Expanded access programs	<ul style="list-style-type: none"> • Treatment IND • Emergency use protocols • Compassionate use • Named patient basis programs
Post-marketing risk management and safety surveillance	<ul style="list-style-type: none"> • Leader in new standard risk management plans • Comprehensive pharmacovigilance • Post authorization safety studies
Health economics and outcomes research	<ul style="list-style-type: none"> • Burden of disease study • Cost minimization assessments • Cost benefit evaluations • Patient reported outcomes research • Clinical outcome studies
Comparative effectiveness research	<ul style="list-style-type: none"> • Design CER programs • Identify appropriate data points to measure effectiveness • Generate maximum value of the product

Patient Safety

The PAREXEL PACE group provides a wealth of patient safety services to also support you across the lifecycle of your products. We are able to help you develop risk management plans (RMPs) and risk evaluation and mitigation strategies (REMS) for your marketing authorization application or new drug application. When your product is marketed, the PAREXEL PACE group can support you with ongoing signal detection and safety surveillance. We provide effective pharmacovigilance processes and systems – handling case processing, follow-up, reporting, and medical assessment. We have a global safety team with a safety support presence in 55 countries and safety operations access to over 70 countries. Our specialized team provides dedicated knowledge of country-specific legislation, with global processes for improved efficiency including off-shoring options for case processing while leveraging our centralized safety hubs in the US, EU and Japan as quality gates. Our safety consultancy services include pharmacovigilance strategy development, process optimization, training, and risk management planning. We can provide full EU QPPV and deputy QPPV services with 24/7 availability.

Case study:

Observational study in a metabolic disease

Project Summary

One of the largest ever observational studies undertaken in this therapeutic area, encompassing approximately 5,000 sites and nearly 60,000 patients in multiple countries across the world

Challenges

- Understanding the challenges of executing research programs in a real world setting
- Identification and qualification of thousands of sites within a short time frame
- Timely submission of patient data and managing very high volume data throughput
- Maintaining data quality across the whole study
- Maintaining operational flexibility across a diverse population of sites while efficiently applying the program budget

PAREXEL Solutions

- Leveraged established global infrastructure and proprietary e-technologies, combining local site support with robust centralized management
- PAREXEL PACE Web Platform™ deployed for global outreach to sites and critical acceleration of start-up
- Intuitive guidance and practical support provided to sites through electronic system and helpdesk to expedite timely data entry into EDC
- Immediate feedback to sites on data discrepancies and missing information using on-line, real-time data validation to drive high quality data

Benefits to Sponsor

- Site activation period reduced to 24 hours
- Recruitment goal completed several months early
- Sponsor site management costs reduced by 150%
- Real-time tracking and metrics through the PAREXEL PACE Web Platform allowed the sponsor to monitor site and data status on a continuous basis throughout the study
- Demonstration of the safety profile of therapy across a very broad population within a short time period





Integration of proprietary technology

With PAREXEL eClinical technologies, we are able to leverage our investment in technology with our wealth of hands-on clinical expertise. The PAREXEL PACE Web Platform is a comprehensive e-clinical platform for late phase research that provides a smooth experience for investigators, eliminating the need for them to access several disparate systems. The web platform provides intuitive, simple access to a number of integrated late phase technologies and facilitates centralized account management.

Users of the PACE Web Platform experience many benefits including:

- Accelerated study start up cycle times and implementation
- Improved process management and workflow
- Simplified access through integration of multiple technologies
- High visibility of program data provided by detailed reporting tools
- Round-the-clock support for users via online user guides and other support functions
- Supports global research programs through inclusion of language and regulatory tools

“I want my late phase service providers to proactively offer ideas, concerns, and insight from the beginning of our engagement.”

PAREXEL doesn't just collect the data you need. We can manage all aspects of your late phase project, strategize with you, and conduct data analyses to maximize your product's long-term positioning in the marketplace. Through collaboration with our clinical operations and commercialization groups, we can conduct health economics research that helps you achieve an optimal price, obtain reimbursement, secure a formulary place, and support product positioning within its target market. The PAREXEL PACE group is your strategic partner in every aspect of late phase and beyond.

“At the end of the day, I need people I can trust.”

We know that you have too much invested in your product – time, money, and reputation – to risk failure in the last home stretch. PAREXEL will not let you fail. We have significant expertise in-house dedicated to peri- and post-approval research, with decades of experience in implementation and management across all areas. As your partners, our own success depends on yours, so we are invested with you.

For more information or to arrange
a customized briefing, please contact
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or email georgina.cattaway@PAREXEL.com

The PAREXEL PACE group is the only resource you need to seamlessly transition from development to market

We offer a comprehensive suite of strategy, data collection and analysis services, as well as direct service capabilities to conduct the crucial studies, to best position your product in a competitive marketplace. We provide:

- Dedicated peri- and post-approval expertise
- Industry leading patient recruitment forecasting tools
- An established global infrastructure
- Specialized expertise for interventional and non-interventional studies
- Proprietary technologies including dedicated web platform
- Post-marketed pharmacovigilance, case processing, and safety services
- Integrated commercialization consultancy services



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