LEAVE NOTHING TO CHANCE

Guiding you from development to market
When you are ready to transition your product from development into the marketplace, you can’t afford to take chances that might risk your product’s commercial success.
Let PAREXEL guide you from development to market, 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 latephase 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, PAREXEL 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.

When you partner with PAREXEL, we are as committed as you are to collecting the data that will help you to strengthen your product’s value to healthcare providers and patients. We understand the challenges you face as you rigorously invest to protect and grow your brand.

SERVICE CAPABILITIES

Driven by our innovation, operational excellence and the best minds

LATE PHASE CLINICAL TRIALS

PAREXEL is a leader in the conduct of Phase IIIb/IV clinical trials. In the past three years alone, our Peri/Post-Approval Services 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

PAREXEL has dedicated expertise and significant experience in the conduct of observational research programs, including retrospective studies (e.g., chart reviews) and prospective studies, such as 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.

PATIENT SAFETY

PAREXEL 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, our Peri/Post-Approval Services group can support you with ongoing signal detection and safety surveillance. We provide effective pharmacovigilance processes and system-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.
PAREXEL 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.

“"I WANT MY PRODUCT TO HELP THE PEOPLE WHO REALLY NEED IT."
<table>
<thead>
<tr>
<th>STRATEGIC DEVELOPMENT &amp; OPERATIONAL SERVICES</th>
<th>UNRIVALED EXPERIENCE</th>
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| **Phase IIIb** | • Studies of all sizes to meet various objectives including:  
  • New indications  
  • New formulations  
  • Medical outcomes  
  • Direct comparison  
  • Many therapeutic areas  
  • Single country and multinational |
| **Large simple trials/ large Phase IV studies** | • 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** | • Product safety & outcome registry experience  
  • Cohort studies  
  • Non-interventional studies  
  • Cross-sectional studies |
| **Expanded access programs** | • Treatment IND  
  • Emergency use protocols  
  • Compassionate use  
  • Named patient basis programs |
| **Post-marketing risk management and safety surveillance** | • Leader in new standard risk management plans  
  • Comprehensive pharmacovigilance  
  • Post-authorization safety studies |
| **Health economics and outcomes research** | • Burden of disease study  
  • Cost minimization assessments  
  • Cost benefit evaluations  
  • Patient reported outcomes research  
  • Clinical outcome studies |
| **Comparative effectiveness research** | • Design CER programs  
  • Identify appropriate data points to measure effectiveness  
  • Generate maximum value of the product |
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, our dedicated Peri/Post-Approval Services 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.

“HOW CAN I BEST DETERMINE WHAT DATA I NEED TO MEET ALL OF MY STAKEHOLDERS’ NEEDS?”
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
- Our proprietary Peri/Post-Approval Technology Solution 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 online, 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 Peri/Post-Approval Technology Solution 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 Peri/Post-Approval Technology Solution is a comprehensive eClinical 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 Peri/Post-Approval Technology Solution 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
PAREXEL IS THE ONLY PARTNERSHIP YOU NEED FOR A SEAMLESS 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/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

Our regional leads are always available for a conversation.

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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/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.

“AT THE END OF THE DAY, I NEED PEOPLE I CAN TRUST.”