

PAREXEL® CLINICAL RESEARCH SERVICES: PHASE II-III

THE ROUTE TO APPROVAL AND MARKET

Accelerating Access to Study Investigators, Patients and Efficacy Data



YOUR JOURNEY. OUR MISSION.®

Driving your study to success with intelligent planning, focused execution, state-of-the-art technology and a commitment to excellence.

The modern early phase of the clinical development journey requires you demonstrate Proof-of-Concept earlier, develop a commercialization strategy sooner, recruit sites, investigators and patients faster, and use data to make decisions smarter. PAREXEL's Early Product Development and Phase II-III teams have developed an integrated and adaptive approach to make your journey easier. From Proof-of-Concept studies through product launch, PAREXEL can serve as your total development partner, delivering any phase of clinical research.

For more than 30 years, PAREXEL has been a trusted partner for the complex development journey required of biopharmaceutical and medical device companies. We simplify the journey for our clients, so that their new products can reach patients rapidly.

SCALING UP / SCALING DOWN

Your progress to Phases IIb and III will have twists and turns. PAREXEL's worldwide infrastructure and end-to-end expertise can help you optimize your studies and implement pivotal trials expeditiously.

Now, more than ever, early product development serves a critical phase of drug development. Biopharmaceutical companies must not only make smarter go/no-go decisions to sharpen the focus of their portfolios, they also must begin developing a commercialization strategy earlier to assure new treatments will be reimbursable.

PAREXEL's Early Product Development (EPD) team takes a collaborative, multi-disciplinary approach to designing studies that accelerate the capture of data points that matter most in the all-important "learn" translational space.

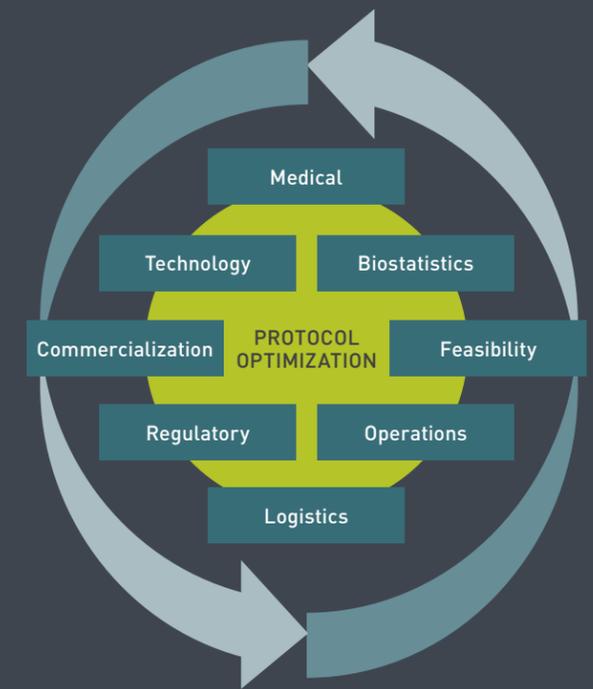
PAREXEL's EPD taps into a pool of experts in bioanalytics, biomarkers, clinical pharmacology, population pharmacokinetics, protocol design, statistics, translational medicine and operations to create lean teams that will assess your plan rapidly, then design and conduct the right trial efficiently.

Our EPD team benefits from:

- Relationships with preferred translational medicine/early phase research centers around the world
- PAREXEL's Phase I unit and extensive network of early phase and commercialization experts
- Site management experts that know how to meet enrollment goals
- PAREXEL Informatics' technological innovations to make the clinical development process faster, more precise, trackable, productive and compliant with local regulatory guidelines
- World-class regulatory leadership and more than 625 regulatory professionals who will identify the most expedient development path for your product

With broad expertise and global coverage, PAREXEL's EPD has the capabilities to accelerate Proof-of-Concept and successfully deliver the early phases of your clinical research.

OPTIMIZING STUDIES WITH MARKET INTELLIGENCE



“HOW CAN I PLAN THE BEST CLINICAL TRIAL TO GET MY PRODUCT TO THE PEOPLE WHO REALLY NEED IT MOST?”

Failed planning is the single biggest reason for study delays. Failed plans lead to overloaded or unrealistic protocols that contain nice-to-have elements or disregard the state of medicine in a country or site.

PAREXEL's Feasibility and Enrollment Solutions team and exclusive Study Optimization Services use market data and historical study performance to improve go/no-go decisions, accelerate patient recruiting and plan for success.

Feasibility planning at PAREXEL includes:

- Global trial placement strategies to find the right countries
- Healthcare alliances and site intelligence to identify the right sites
- Electronic health data to recruit the right patients quickly
- Digital media and site support to enroll and retain your patients
- Clinical logistics services to run the study smoothly

Understanding investigators' perceptions before your study begins can help recruit investigators and patients. PAREXEL conducts online surveys to determine what your study community thinks about your product. These surveys help us identify thought leaders and influencers that will help with patient recruitment and that we must keep engaged throughout the study.

PAREXEL also maintains relationships with 11 site management organizations (SMOs) in 25 countries. These 11 SMOs are focused exclusively on clinical research and offer our clients full control over sites as commercial sites and local relationships to accelerate patient recruitment. The SMOs can apply different relationship and commercial models to your study.

To further reduce the overall time and cost to execute your study, PAREXEL's exclusive Study Optimization Services incorporates insights from feasibility, subject matter experts (SMEs) from other key functions and historical data to identify opportunities to reduce the overall time and cost to execute your studies.

PAREXEL's Study Optimization Services can identify opportunities to:

- Streamline visits/procedures to reduce costs
 - Adjust sample sizes to increase trial speed
 - Modify inclusion/exclusion criteria to speed enrollment
 - Optimize site/country mix to reduce overall costs.
- In the past five years, PAREXEL has completed more than 3,500 studies in 110+ countries. Of these, 2,447 were early phase and Phase II-III trials.

ENHANCING DECISION-MAKING WITH DATA-DRIVEN MONITORING



“HOW CAN I BEST USE DATA TO MAKE SMARTER DECISIONS?”

Data-driven monitoring can help biopharmaceutical and medical device companies make smarter decisions around risk and workloads at trial sites.

PAREXEL is an industry pioneer in data-driven monitoring and has developed the tools and technologies to support risk-based monitoring plans. We were an early adopter of electronic data capture (EDC), and data-driven monitoring is part of our standard site management process.

Our data-driven monitoring strategy uses EDC systems to replace routine periodic monitoring visits and 100% source data verification (SDV) with data-triggered visits and risk-based SDV strategies.

OUR ALGORITHMS FOR DATA-DRIVEN MONITORING MEASURE:

- Risk factors, such as patient safety and data integrity
- Workload, including SDV, drug accountability and site regulatory document review, among others
- Study-specific factors, such as interim database lock or maximum interval between site visits
- Site relationships

In all cases, our data-driven monitoring algorithms are customized based on the protocol.

PAREXEL's approach to data-driven monitoring uses both centralized and targeted on-site monitoring to provide high-quality and timely clinical study reporting.

Because clinical research is about people studying people, PAREXEL puts an emphasis on the human factor in site monitoring. We have developed internal change management protocols and a new site management approach that allows our team to leverage the new way of monitoring sites. PAREXEL acknowledges the fact that technical solutions are driving this new approach, but what really makes it efficient is the staff being empowered and trained to use this new approach.

DELIVERING THE EXPERTISE TO SHORTEN TIMELINES



“WHAT IF WE HAVE QUESTIONS OUTSIDE OUR AREAS OF EXPERTISE?”

Clinical development is complex. It requires knowledge of complicated processes and systems, and the ability to make timely decisions in the face of constant change.

PAREXEL has assembled a team of subject matter experts (SMEs) from academia, drug and medical device development and clinical research. These experts understand all aspects of clinical development, can anticipate challenges and will provide solutions. As a partner, you have access to our Expert Office and our in-house SMEs for many aspects including drug development planning, medical imaging, regulatory affairs, production, and commercialization.

Our mission is to provide you with access to best-in-class expertise and leadership and serve as your complete study solution.

PAREXEL has assembled a team of experts in all scientific, medical, clinical and regulatory areas related to drug and medical device development. They have extensive experience in:

- Protocol and clinical development plan design
- Feasibility assessments
- Eligibility criteria, safety reporting and recruitment strategies
- Endpoint event review management
- Internal/external study team training
- Consistent standards of care worldwide
- Commercialization strategies

THE BEST GUIDES FOR YOUR JOURNEY AND THE BEST PATH FORWARD



“AT THE END OF THE DAY, I NEED PEOPLE WHO I TRUST WILL KNOW THE BEST WAY FORWARD.”

You need the best project team to make your development journey easier. At PAREXEL, our people have an industry-wide reputation for solving problems, improving process efficiencies and delivering projects on schedule and on budget.

All of our project leaders undergo rigorous training and at the start of every project, they create and deliver a project plan that includes the details for completing the study and for communicating with you. We know there may be bumps along the way, so regular and constant communication is key. Our project leaders are trained to use the best software in the clinical development business. These include:

- The Perceptive MyTrials® platform, which consolidates all aspects of a study in one place
- IMPACT® CTMS (Clinical Trials Management System), a leading solution for biopharmaceutical companies of all sizes with more than 26,000 users in studies covering more than 80,000 study subjects
- eTMF (Electronic Trial Master File), solutions and strategies for organizing and storing documents, images and other digital content for your trial in compliance with regulatory agencies

When used by PAREXEL’s people, these tools lead to increased performance.

No matter where you are in clinical development and what services you need, PAREXEL has the expertise to complete your Early Phase and Phase II-III studies successfully.

PAREXEL’s full line of clinical development and commercialization services have been evolving over the past 30 years. We have a reputation for providing the highest-quality service to our biopharmaceutical and medical-device partners and are often called upon to deliver studies that face specific challenges.

We look forward to helping you complete your drug development journey.

Our regional leads are always available for a conversation.

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*WHEREVER YOUR
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