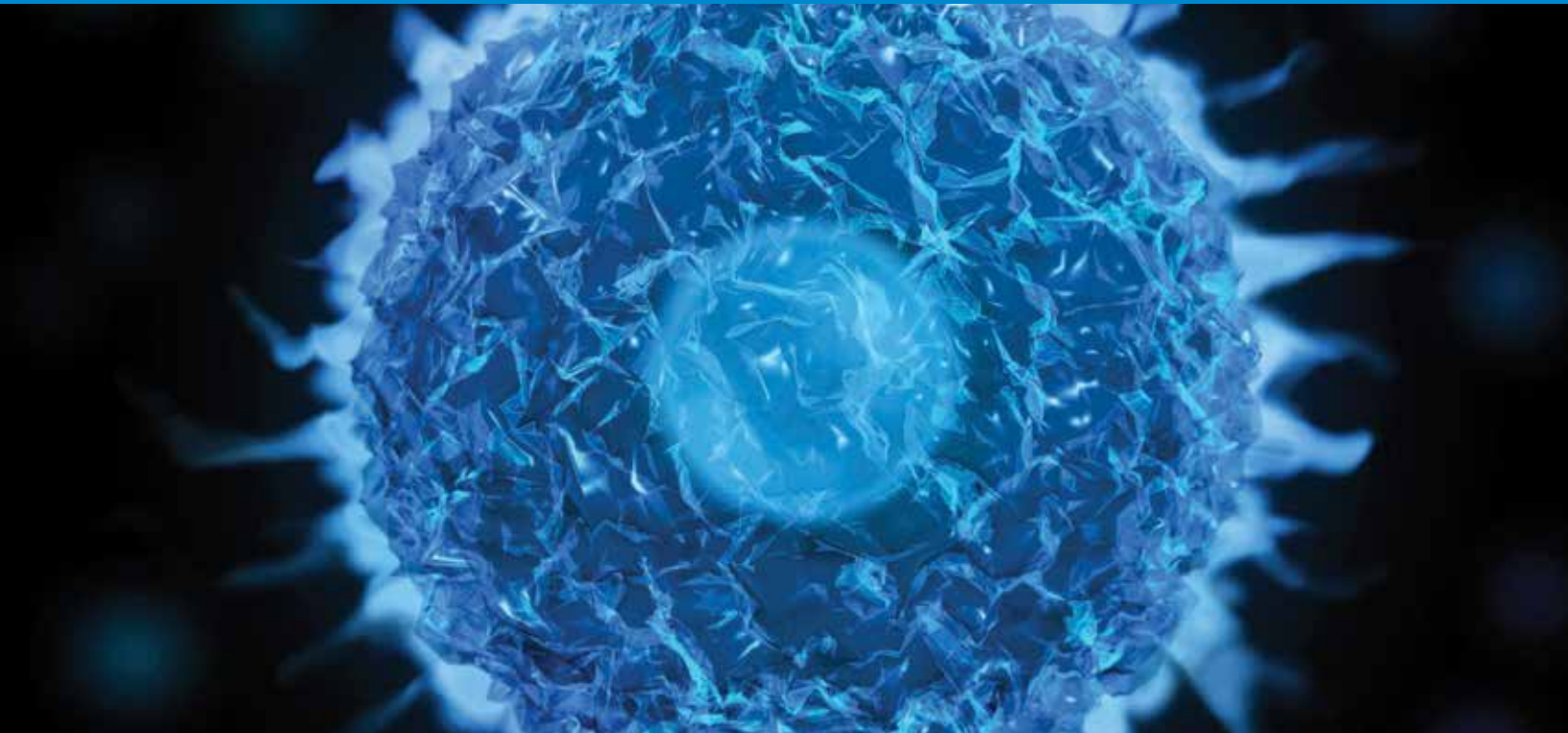


# *PAREXEL<sup>®</sup> BIOPHARM UNIT*

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Defining the path from innovation to patient access



# *YOUR JOURNEY. OUR MISSION.<sup>®</sup>*

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Positioning emerging companies for success with global clinical,  
consulting and technological expertise







**Emerging biopharmaceutical companies face enormous pressures: overcoming financial constraints, demonstrating proof-of-concept, and crafting Common Technical Documents and Target Product Profiles with the necessary endpoints to support regulatory approval. Finding the right partner is critical.**

PAREXEL understands the journey for small to mid-sized companies is different—we have been working with emerging companies since our founding more than 30 years ago. Emerging companies need a partner who understands their challenges and delivers a tailored solution. The right partner knows how to accelerate development and maximize value. They have extensive therapeutic expertise to help simplify the path a compound travels from discovery to patient. As one of the world's leading biopharmaceutical services firms, PAREXEL is that partner. Working with emerging companies is in our DNA.

In 2012, PAREXEL launched its BioPharm Unit to deliver innovative solutions to help emerging companies expand their in-house expertise, support internal decision-making and position themselves among industry leaders.

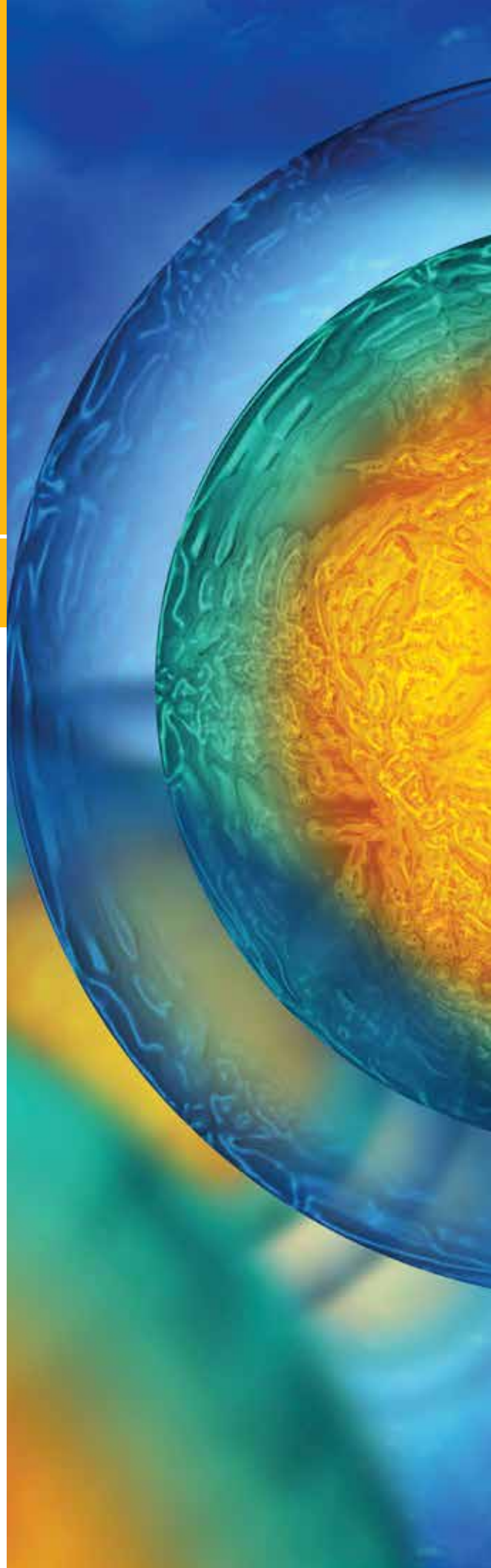
# *SIMPLIFYING YOUR JOURNEY*

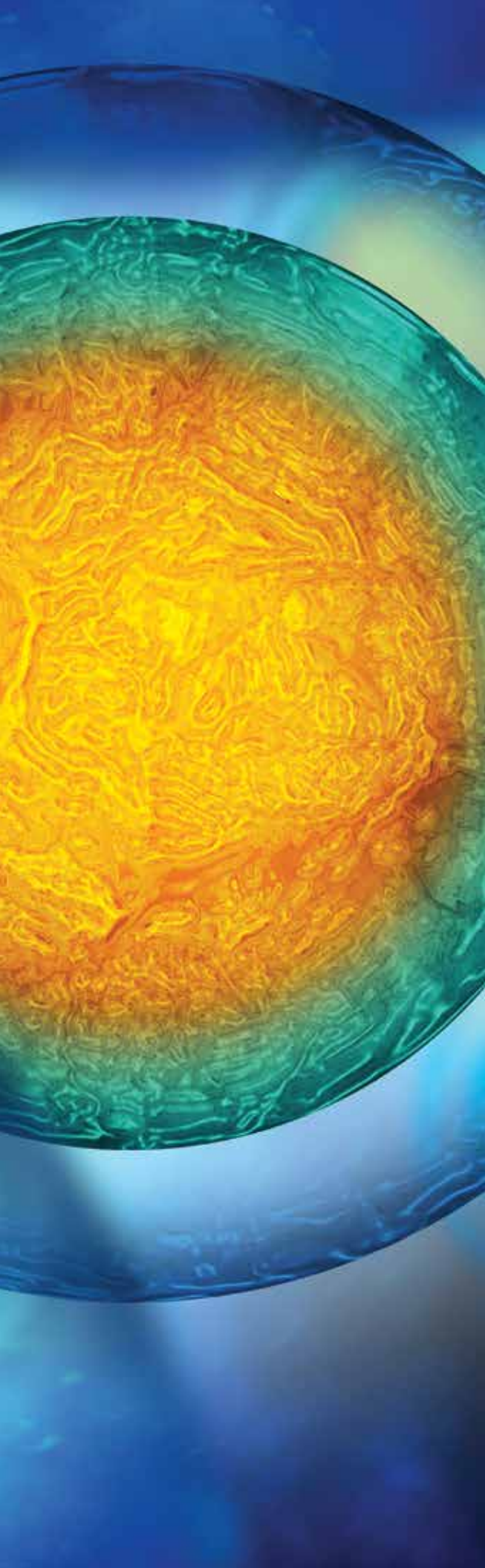
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EMERGING COMPANIES DRIVE THE GENESIS OF INNOVATION FOR THE BIOPHARMACEUTICAL INDUSTRY. RECENT DATA INDICATES

**80%** OF ONGOING  
DEVELOPMENT  
PROGRAMS

ORIGINATED OUTSIDE THE TOP 25  
PHARMACEUTICAL COMPANIES.





PAREXEL knows that no two projects are alike. That's why for every drug, treatment and molecule we work on, we assign a senior PAREXEL executive to lead a team that will work closely with you. We develop a strategy that reduces complexity, accelerates timelines, reduces fixed costs and helps you reach your goals faster. Our solutions are designed to meet your clinical, regulatory and commercialization challenges, differentiate your compound and company in the eyes of potential investors and partners, and help you derive the most value for your product.

**Emerging companies partner with the PAREXEL BioPharm Unit for:**

**Flexible Delivery Model.** Our delivery model allows you to access expertise when you need it. By working side-by-side with you, we become your partners so that our success is yours.

**Strong, Comprehensive Data Packages.** We help develop the data packages that contain clinical, regulatory and reimbursement-related data to increase investor and partner confidence in pre-commercialized compounds and early-stage companies.

**Market Access Expertise.** We provide customized solutions and expertise, aligning evidence development and economic evaluation with pricing, reimbursement and market access strategies. Our approach helps you realize product value and commercial opportunity, early and throughout the product development cycle.

**Real World Assessments.** Our teams help you develop unbiased, real world assessments of your compound and its clinical and commercialization path.

**Deep Knowledge of Investor and Partner Mindsets.**

PAREXEL has worked with companies of all sizes across the entire clinical development and commercialization continuum. Our understanding of investors and partners combined with our expertise in advancing compound development is a reassuring complement to your innovative compound.

**Formal Relationship with a Leading Global CRO.** With 81 locations in 51 countries on five continents, we have the expertise and global facilities to advance your journey through the development process.



# DELIVERING THERAPEUTIC EXPERTISE THAT DRIVES SUCCESS

PAREXEL HAS BEEN INVOLVED  
IN THE DEVELOPMENT OF

 **95%**

**OF THE TOP 200**  
BEST-SELLING DRUGS  
IN THE WORLD.

As a leading global biopharmaceutical services organization, PAREXEL has helped clients develop therapies across all major therapeutic areas, from classic small-molecule medications to the latest biologic and recombinant drug candidates.

Within this broad expertise, the PAREXEL BioPharm Unit can help you design and conduct the most effective proof-of-concept trials to decrease risk, accelerate go/no-go decisions, avoid costly clinical development failures and plan for future clinical development.

We have extensive trial experience in oncology and hematology, central nervous system disorders, cardiovascular, metabolic diseases, infectious diseases and many other therapeutic areas.



**In the past few years, PAREXEL has provided clinical development services covering Phases I-IV for:**

- Almost 1,000 oncology projects in nearly all solid tumor types and hematologic malignancies, and multiple classes of agents, which collectively enrolled more than 288,000 patients around the world
- More than 338 neurology projects, which collectively enrolled more than 73,000 patients
- Over 380 projects in the area of metabolic/endocrine disorders, which collectively enrolled more than 128,000 patients
- Greater than 250 infectious disease projects, which collectively enrolled more than 85,960 patients
- 100 plus psychiatry projects, which collectively enrolled more than 10,000 patients

In addition, PAREXEL's Medical Imaging team performed central review services in 50 percent of all Breakthrough Therapy approvals by the US FDA, including the first-ever Breakthrough Approval.

**PAREXEL's therapeutic expertise includes:**

- Allergy/Immunology
- Anesthesia
- Cardiovascular
- Central Nervous System
- Dentistry
- Dermatology
- Endocrine/Metabolism
- Gastroenterology
- Genitourinary
- Gerontology
- Infectious Diseases
- Obstetrics/Gynecology
- Oncology/Hematology
- Ophthalmology
- Orthopedics
- Otolaryngology
- Pediatrics
- Podiatry
- Psychiatry
- Pulmonology
- Rheumatology
- Veterinary Medicine

# MAXIMIZING PRODUCT VALUE

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Whether you seek to out-license your compound, enter the clinic, reach proof-of-concept or commercialize, the PAREXEL BioPharm Unit can help you optimize protocols and trial design, define the endpoints that matter most, assure investors, and navigate regulatory authorities for approval and payers for reimbursement. Our commercial experts will advise you on accelerated development options and will work with you to align evidence development and economic evaluation with pricing, reimbursement and market access strategies early in and throughout the product development process.

## **We provide industry-leading clinical research practices and technology, from Phase I through Phase IV, including:**

- Comprehensive Clinical Research Services from First-in-Human through Phase IV and Post-marketing follow-through
- Global Medical Services, a single point of contact providing fast access to PAREXEL's comprehensive worldwide therapeutic, regulatory and clinical operations expertise
- Access to more than 225,500 site investigators in more than 91 countries across 20 therapeutic areas
- Innovative patient recruitment techniques, strong relationships with key opinion leaders in academic centers and community settings, and access to Electronic Health Records for additional patient information
- Medical imaging services to efficiently deliver preliminary clinical evidence
- PAREXEL® Access, a full spectrum of evidence-based value demonstration services throughout the product lifecycle comprising: market access consulting, late-stage interventional and observational research, medical communications and drug safety services
- PAREXEL Consulting, scientific, regulatory and operational expertise, applied early and throughout the development process, to maximize product or portfolio value for faster, smarter drug development
- Clinical Development Optimization, providing end-to-end services utilizing advanced technology to accelerate and simplify study design, start-up, execution and submission





- Protocol Optimization Services to assess the competitive landscape, trial sites and patient populations and determine the best pathways to regulatory approval
- Adaptive trial design to facilitate go/no-go decision-making, streamline the drug development process and increase efficiencies and success rates
- Data-Driven Monitoring to help organize your data in new and meaningful ways, identify study risks and facilitate faster, more accurate decision-making while improving quality through a risk-based approach
- IMPACT® Express Clinical Trial Management System (CTMS), provides a quick-to-implement, cost-effective clinical trial management solution to simplify clinical trial management and monitoring for small to mid-sized biopharmaceutical companies
- Unmatched clinical trial supply management technologies, services and logistics team to manage your clinical trial materials, ancillary supplies and laboratory logistics around the world

**Companies that partner with the PAREXEL BioPharm Unit benefit from:**

- A senior PAREXEL executive who provides clear direction and assures that our work links with your objectives
- A flexible relationship model that allows you to access specific expertise, resources and technology when you need it most
- Global drug development, scientific and regulatory expertise to help optimize protocols and trial design and navigate regulatory authorities for approval
- Commercialization strategies to help accelerate development options, substantiate value and vet evidence with payer networks early and throughout development
- Offices across Europe, Asia and the Americas that provide access to sites and patient populations around the world
- Accountability for delivery, quality and alignment of incentives in meeting your clinical development milestones
- Access to venture capital or funding partners

**52%** 

**OF ALL PHASE III FAILURES ARE DUE TO EFFICACY ISSUES.<sup>1,2</sup>**

**30%** 

**ARE DUE TO SAFETY ISSUES. PAREXEL'S BIOPHARM UNIT CAN HELP MITIGATE THESE ISSUES BY IMPROVING PROTOCOLS AND TRIAL DESIGN.**

<sup>1</sup> Tufts Center for the Study of Drug Development Impact Report September/October 2013: Causes of clinical failures vary widely by therapeutic class, phase of study

<sup>2</sup> Pointed View, Windover Information 2013: Why NMEs and Therapeutic Biological Products Fail in the First FDA Review Cycle. PAREXEL Consulting, Mills et al.



# OPTIMIZING YOUR CLINICAL SUCCESS WITH PRECISION

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## GENOMIC MEDICINE

In compound development today, a robust Pharmacogenomics plan cannot be an afterthought. PAREXEL's Genomic Medicine team can help you integrate genomic research into your global drug discovery and development—programs for a smoother journey to market.

**From discovery to post-marketing surveillance, the team applies expertise, innovation and state-of-the-art methodologies to help clients:**

- Develop genomic strategies for selected programs or across portfolios of medicines
- Design and develop biomarker strategies for integration into clinical trials
- Optimize the collection and management of pharmacogenomic (PGx) samples and data
- Maximize the utility of genomic data through our expert analysis, results interpretation, and regulatory reporting
- Improve understanding of drug metabolism and transport

- Stratify or enrich patient populations through clinical trial design
- Differentiate their drugs from competitor medicines
- Develop and support companion diagnostic strategies
- Identify and validate drug targets and make recommendations on the primary indication for use
- Reposition existing drugs for new indications
- Ensure genomic data are collected with an eye toward regulatory requirements

### **Comprehensive Capabilities include:**

- Pharmacogenomics (PGx)
- Data Analytics/Informatics
- Target Validation and Repositioning



## QUANTITATIVE CLINICAL DEVELOPMENT

PAREXEL's Quantitative Clinical Development team, offers unsurpassed expertise in clinical PK/PD, pharmacometrics, and model-based drug development (MBDD) from translational sciences for First-in-Human (FIH) through all phases of drug development including marketed products.

With pharmacometricians in the US and Europe, we offer seamless integration of PK/PD modeling and simulation services across numerous therapeutic indication and all phases of development.

### Our experts provide scientific and regulatory input for:

- Optimizing Phase I and II development programs based on preclinical data and emerging data
- Assimilating non-clinical data to select and justify the first -in-human dose and escalation plan using PK/PD modeling and other techniques

- Identifying the target therapeutic concentration range together with potential Therapeutic Index relative to Cost of Goods estimates
- Continuously utilizing emergent clinical data to refine the PK/PD model to inform evidence-based decision-making
- Supporting NDA/MAA submissions, labeling and regulatory questions/interactions

### Comprehensive Capabilities include:

- Quantitative Clinical Pharmacology
- Pharmacometrics
- Systems Pharmacology
- PK Analysis and Programming



# AN UNMATCHED DEDICATION TO EMERGING BIOPHARMACEUTICAL COMPANIES

As one of the world's leading biopharmaceutical services firms, PAREXEL regularly invests in market research to help emerging companies better position themselves for investors and partners. Our survey of investment professionals, *Positioning Emerging BioPharma for Investors*, showed that investment in pre-commercialized compounds or emerging companies is highly competitive—only 4 percent of deals evaluated in a 12-month period received funding and about 42 percent of initial investments were made with compounds during Phase I/IIa.

## INTEGRATED END-TO-END SOLUTIONS FOR ALL ASPECTS OF DRUG DEVELOPMENT

Emerging companies partner with the PAREXEL BioPharm Unit because our integrated and customized solutions help:

- Enhance internal capabilities and close any gaps in expertise
- Expand capacity to keep pace with time sensitive development activities
- Reach faster go/no-go decisions by demonstrating Proof of Concept
- Increase the value of your compound by defining clinical development and/or understanding regulatory and reimbursement challenges while decreasing risk earlier in the commercialization process
- Accelerate study start-up and site selection
- Ensure that logistical planning and execution is integrated into the entire trial process beginning with study start-up planning through the end of each study's life cycle



PAREXEL'S RESEARCH INDICATES THAT INVESTORS PREFER COMPOUNDS WITH CLEAR PRODUCT CHARACTERISTICS, CLINICAL STUDY RESULTS, A TARGETED PATIENT POPULATION AND WELL-DEFINED DEVELOPMENT TIMELINES.

# THE PATH TO SMARTER DRUG DEVELOPMENT

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The PAREXEL BioPharm Unit partners with clients to navigate the ever-evolving and complex development process, leveraging the collective strength of scientific and clinical research expertise, decision-enabling technologies and global consulting to optimize the commercial potential of your pipeline. Our integrated consulting teams:

- Prioritize portfolios and shape global development strategies
- Advise on accelerated and adaptive development options, mapping optimal clinical and regulatory pathways for speed to market

- Navigate regulatory hurdles, helping you keep pace with the ever-changing global regulatory landscape
- Differentiate product/maximize portfolio value for approval and access
- Provide regulatory expertise and access to established relationships with worldwide regulatory bodies

We welcome the opportunity to design a personalized solution to your critical clinical, regulatory or commercialization challenges and to help simplify your journey to success.

## PAREXEL OPERATES IN 81 LOCATIONS IN 51 COUNTRIES







If you are an emerging biopharmaceutical company, you need the best team to differentiate your product in the marketplace and maximize the value of your product or portfolio.

Our regional leads are always available for a conversation.

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*WHEREVER YOUR  
JOURNEY TAKES YOU,  
WE'RE CLOSE BY.*

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