

PAREXEL® CLINICAL RESEARCH SERVICES: EARLY PHASE

# *STARTING STRONGER IN PHASE I THROUGH IIA*

Adding value from first-in-human through proof-of-concept



# YOUR JOURNEY. OUR MISSION.®

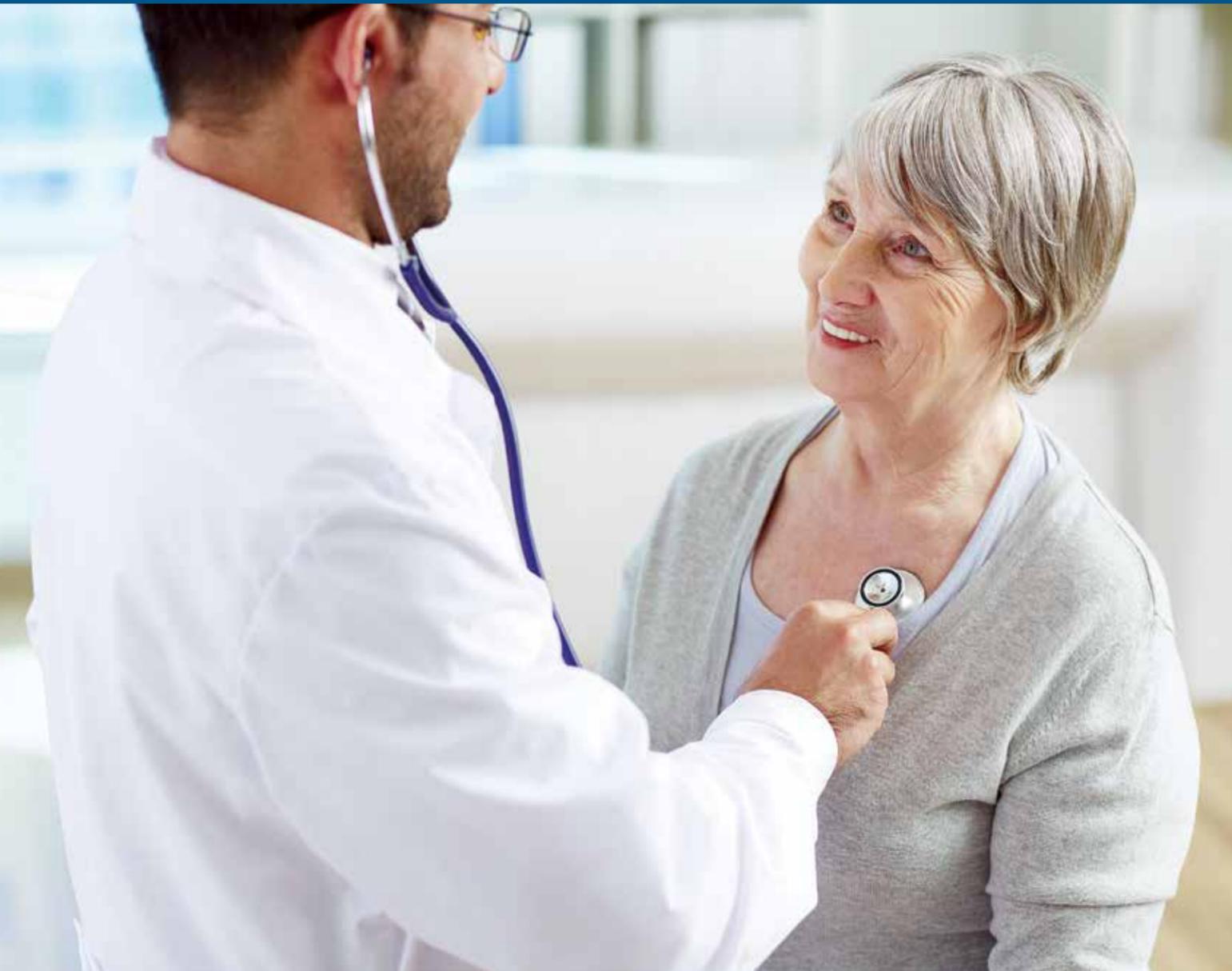
Achieve success through early testing of compounds in patients and healthy volunteers.

As an established partner to the biopharmaceutical industry, PAREXEL knows the complex challenges you face today: accessing target patient populations and healthy volunteers, navigating regulatory issues, and ensuring data quality. There is little—or no—room for error. We anticipate obstacles and offer timely solutions. With a full scope of services from First-in-Human (FiH) through Proof-of-Concept (PoC), our Early Phase Services help you set a solid foundation so that you have a better chance of achieving success. Our consistent delivery of timely results and high-quality data adds value now—and greater value in the long term. We provide expertise and guidance to help you collect the right data and mitigate the risk of Phase III failure.

- Extensive therapeutic expertise
- 125+ healthy volunteer studies performed annually
- 200+ early phase trials in patients within the last 3 years
- 35+ diverse patient populations enrolled each year
- Strategic global locations in 4 unique regulatory environments
- Parallel drug development in multiple clinics
- Global harmonization/seamless multi-center conduct
- Flexible, rapidly mobilized study teams
- Development planning and regulatory support & consulting services

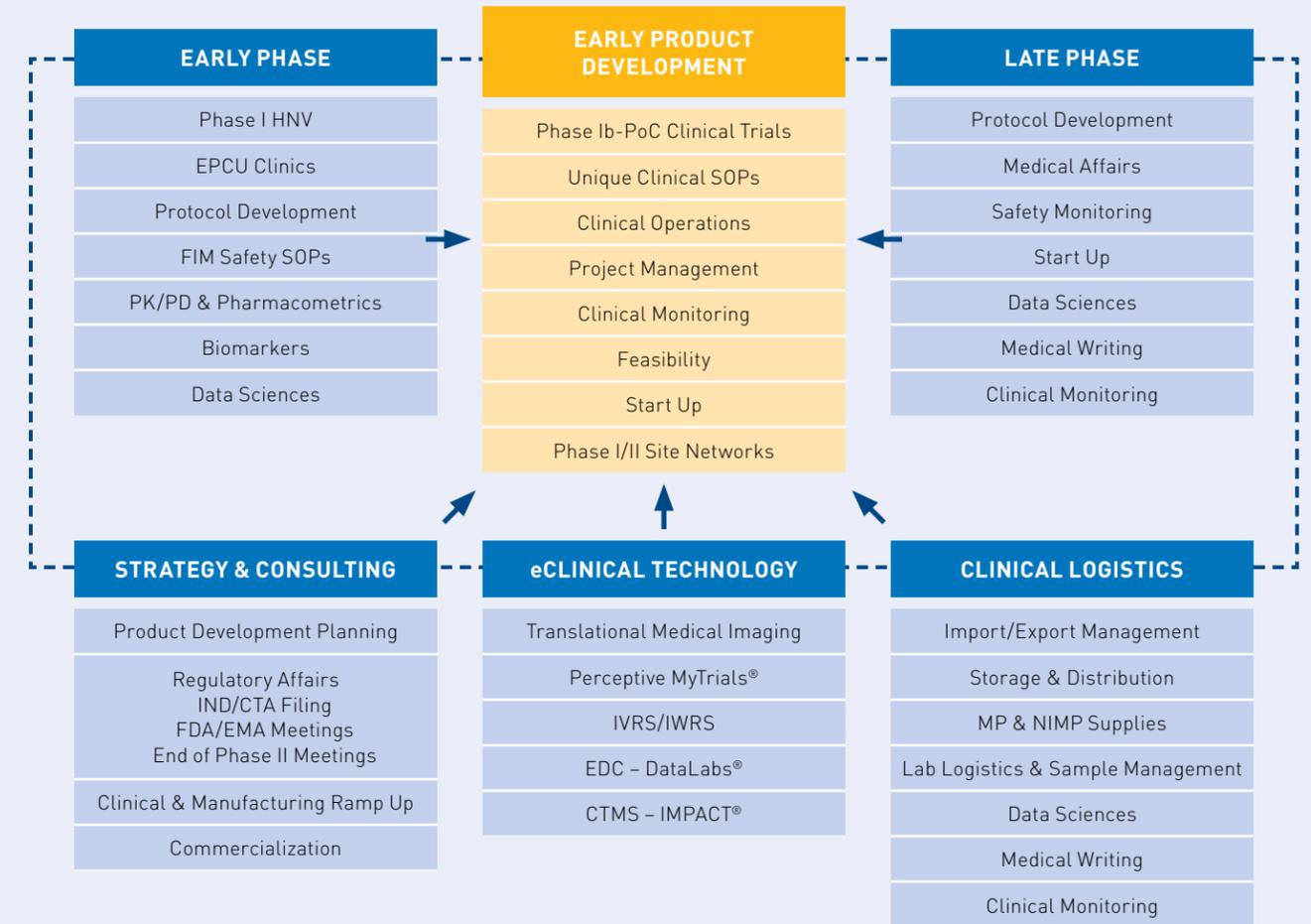
## ENSURING SAFETY FOR YOUR FIRST-IN-HUMAN STUDIES

Your journey from new molecule to new medicine starts with access to diverse patient populations and healthy volunteers, world-class facilities, and more timely results. PAREXEL provides comprehensive early phase testing services through our own hospital-based clinical units on three continents. This ensures the highest patient safety standards, on-site lab facilities, and quick, in-house access to the volunteers you need—delivering the best return on your investment.





# HELPING CLIENTS MAKE CRITICAL GO/NO-GO DECISIONS



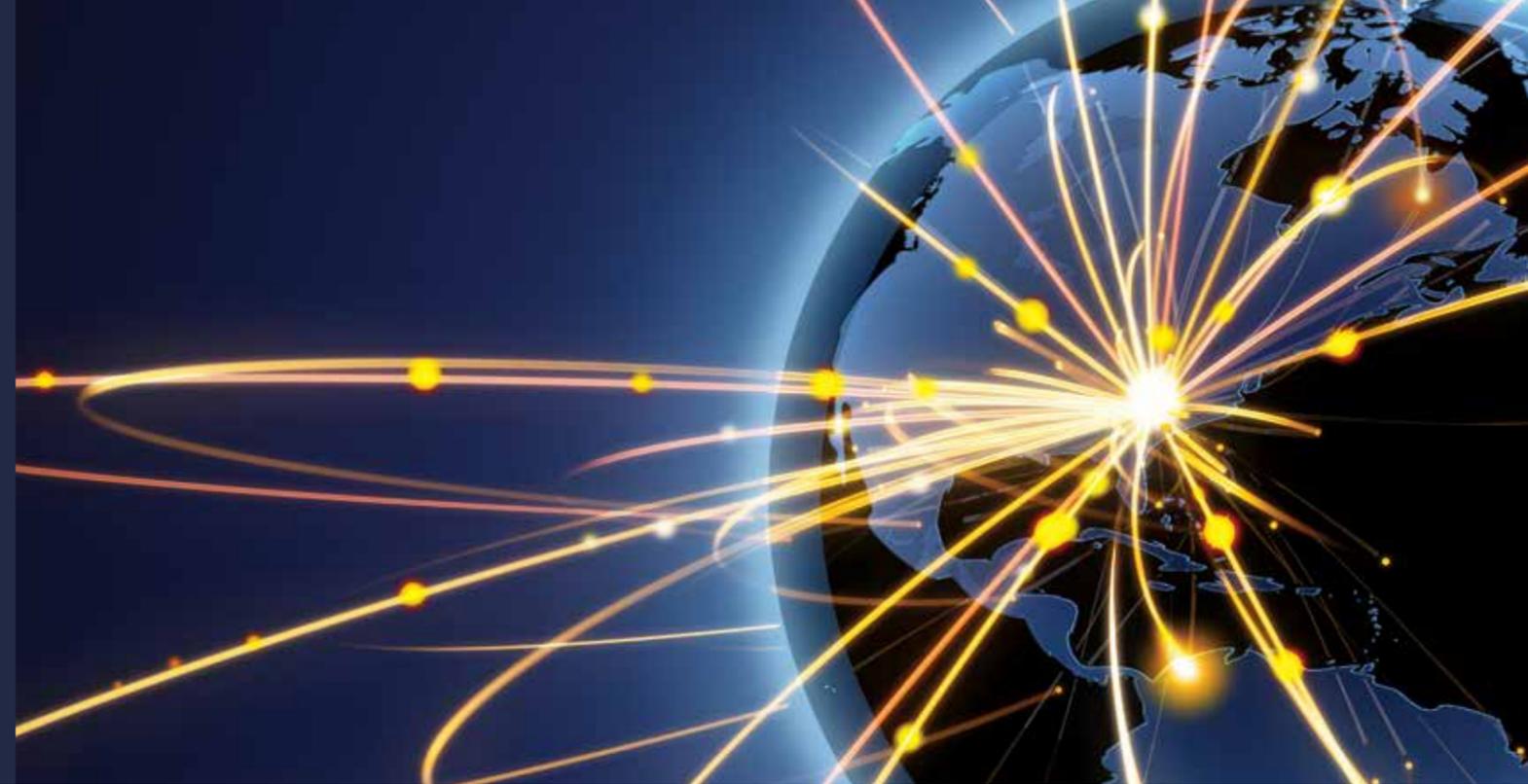
## INTEGRATING ALL FACETS OF TRANSLATIONAL DEVELOPMENT

Our Early Product Development (EPD) team delivers exceptional Phase IIa research by offering the speed and dexterity translational medicine expects, while also being supported by a global scientific, regulatory and clinical organization.

### Solution driven capabilities:

- Dedicated clinical operations teams that are experienced in all aspects of early clinical activity and site management (safety, labs, monitoring, technical training, cohort review, and recruitment screening)
- Operational flexibility that supports uniquely customized solutions such as multi-stage dose escalation protocols and adaptive designs
- Integrated planning and management to take programs from IND through Proof-of-Concept under a single contract
- Unique clinical SOPs that cover, clinical operations, project management, clinical monitoring, feasibility, start up and a Phase I/II site network
- Therapeutically aligned teams with expertise in oncology, CNS, immunology, respiratory/autoimmune, hepatic and renal failure, and pediatrics
- 90 dedicated global employees executing studies in North America, Europe and Asia-Pacific

# THE RIGHT PATIENTS FOR FASTER ENROLLMENT



PAREXEL's vast database of patients and healthy volunteers allows us to quickly recruit and enroll volunteers to meet—and even exceed—study enrollment timelines.

Close collaboration among our early phase clinical units in United States, Europe, and South Africa facilitates expedited parallel recruitment for those occasions when you might challenge us with an unusual patient population, tougher inclusion criteria or tighter timelines. We are ready for these challenges with global SOPs, harmonized processes, and pre-screened patient databases.

**49** DIFFERENT  
PATIENT TYPES

IN **12** KEY  
THERAPEUTIC AREAS

RESULTING IN  
**OVER 6,900** PATIENTS  
ENROLLED

IN **290** DIFFERENT  
PATIENT STUDIES

IN JUST THE  
**LAST 5 YEARS** ALONE!

## WORLD LEADER OF ETHNOBRIDGING TRIALS

Inclusion of Asian countries in global drug development and registration of drugs in the Asia Pacific region has become increasingly important in recent years. Global companies are collecting Japanese, Chinese and Korean Phase I data early in development to fulfill the following goals:

- Fast track Japan development—Chinese and Korean PK data are frequently needed
- Facilitate Asian trials
- Facilitate the inclusion of Asian countries in global trials
- Use data for drug registration in the region

Over the past 12 years, we have successfully conducted over 120 ethnobridging studies, enrolling more than 3,000 subjects. Our unit in Los Angeles is the home to the largest first generation Asian community anywhere in the world. No other city, including Honolulu, comes close.

Over the years, scientists at PAREXEL have worked closely with Asian regulators to design studies done outside of Asia but accepted by the Asian regulators. In fact, we have developed the definition of a Japanese subject, which is now widely used in the industry. Our experts are available to provide consultation and input to regulatory issues, protocol designs and analysis of data.



## *INTEGRATED EXPERTISE FOR A MORE SUCCESSFUL OUTCOME*

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With in-depth scientific and therapeutic expertise, we design and implement early phase studies for new drug entities across a broad range of therapeutic indications. Our team provides customized solutions, including the appropriate use of biomarkers and adaptive trial designs.



## UNPARALLELED EXPERIENCE ACROSS A SPECTRUM OF THERAPEUTIC SPECIALTIES

### ONCOLOGY/HEMATOLOGY

The emergence of targeted oncology and hematology therapies for cancer and blood disorders has created tremendous hope for the millions of patients who suffer from these diseases. Our team of oncologists and hematologists have participated in trials for many different classes of cancer therapeutics, including extensive work in cytotoxics, biologics, targeted therapeutics, immunotherapies, vaccine therapies, and supportive-care products.

### CNS

PAREXEL's Early Phase clinical experts are equipped with the knowledge to deliver a wide range of services and techniques in psychiatric and neurological studies of varying complexity, with emphasis in acute psychiatric and sleep disorders. Our experience conducting studies in Parkinson's and Alzheimer's disease, schizophrenia, and major depressive disorders, among others, is second to none.

### CARDIOVASCULAR

Cardiac safety is a critical factor in clinical trials. Our comprehensive cardiovascular expertise comes with a wide range of related services such as Intensive ECG and Thorough QT/QTc studies to assess cardiac safety of new compounds. Each of our units has a considerable number of beds equipped with telemetric bedside monitoring and ambulatory/holter ECG equipment. A seasoned staff provides top-quality readings of clinical cardiovascular data. Additionally, we collaborate with most ECG core labs and can easily work with your preferred lab. All clinical units have state-of-the-art equipment and perform cardiac studies according to international guidelines.

### RESPIRATORY

We have considerable experience in performing Phase I through Phase IIa clinical trials in respiratory medicine and therapeutics. Our sites are equipped with the latest in sophisticated respiratory monitoring technologies, including whole-body plethysmography and spirometry. We routinely perform exercise testing, bronchial challenges, and additionally, through our hospital-based units, can access more complex measurements such

as bronchoscopy and bronchoalveolar lavage (BAL). Our access to respiratory populations is unrivaled and PAREXEL provides the ultimate benefit for your trial in respiratory patients—the season switch. Our locations in both northern and southern hemispheres allow an uninterrupted flow of patients without seasonal disruption.

### METABOLISM/ENDOCRINE

PAREXEL offers manual glucose clamp studies in a cutting-edge, 10-bed glucose clamp unit. More than 40 studies have been performed in both healthy volunteers and patients with Type I and Type II diabetes since the clamp unit opened in 1995. We are constantly recruiting to expand our extensive database of Type I and Type II diabetes patients. We also have considerable experience in obesity studies.

Other areas of therapeutic expertise include infectious disease, allergy/immunology, dermatology, rheumatology and pain.

## FULL SCOPE OF SERVICES TO HANDLE THE MOST COMPLEX STUDIES

The breadth of our capabilities and harmonization across our global clinical units enable PAREXEL to carry out extremely complex studies.

### EARLY PHASE SERVICES INCLUDE:

- First-in-Human
- Proof-of-Concept
- Ethnobridging
- Dose escalation (including long-stay studies)
- Clinical pharmacology
- Pharmacokinetic/pharmacodynamic characterizations
- Disease modeling
- Polysomnography
- tQTc
- Bioequivalence/bioavailability
- Bioanalytical and biomarker services
- Biomarker development and analysis
- Clinical data services
- Positron-Emitting Tomography (PET)
- Functional Magnetic Resonance Imaging (fMRI)
- Quantitative EEG
- Evoked potential techniques
- Inpatient acute psychiatric therapies



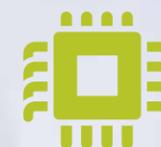
OVER 30 YEARS' EXPERIENCE

KEY INDUSTRY OPINION LEADERS



HIGH QUALITY PROJECT MANAGEMENT

TECHNOLOGY DRIVEN



# MANY OPTIONS, ONE BEST CHOICE

PAREXEL offers a broad range of services, yet this range alone is not the key advantage we offer. Our ability—and commitment—to customize our service offerings to the needs and goals of our clients is what sets us apart.

Our project management is streamlined and processes are harmonized globally. And because we can provide almost every service required without subcontracting, we are able to control the quality, integrity, and accuracy of every aspect of your early phase studies. Working with our early phase team to conduct your early phase trials saves time and yields more valuable results. The operational excellence you need in patient and healthy volunteer studies—therapeutic expertise, extensive hospital-based resources, dependable project management, and specialized trial design expertise—combined with rapid recruitment—returns solid, reproducible outcomes that will help you succeed in later phase trials.

We design and implement an entire scope of early phase studies across a broad range of therapeutic indications. Our services integrate regulatory strategies with drug development and clinical pharmacology capabilities. And recognizing that each trial faces unique challenges and opportunities, our teams provide customized solutions, including the appropriate use of biomarkers and adaptive trial designs.

Working regularly with the FDA, EMEA, MCC, MHRA, and BfArM, and with experience of other regulatory authorities, we can provide a wealth of advice and guidance to support your global regulatory strategies and help you select the optimal regulatory environment for your unique needs.

## INDUSTRY-LEADING TECHNOLOGIES

We continue to provide our partners greater value and efficiency from the best technologies available. Most of our early beds are equipped with ClinBase™, an electronic source data capture and clinical trial management system. ClinBase™ is fully validated and compliant with industry standards including 21CFR11 and gives you the option of secure online access to allow visibility to emerging data from anywhere in the world. We can also support EDC systems that you may specifically request and can provide flexibility to meet your needs.



## PAREXEL'S GLOBAL NETWORK OF EARLY PHASE UNITS

**We are always available for a conversation.**

**Yves Grenon**

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Business Development Early Phase

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

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