



PAREXEL® CLINICAL RESEARCH SERVICES

# *CLINICAL DEVELOPMENT OPTIMIZATION™*

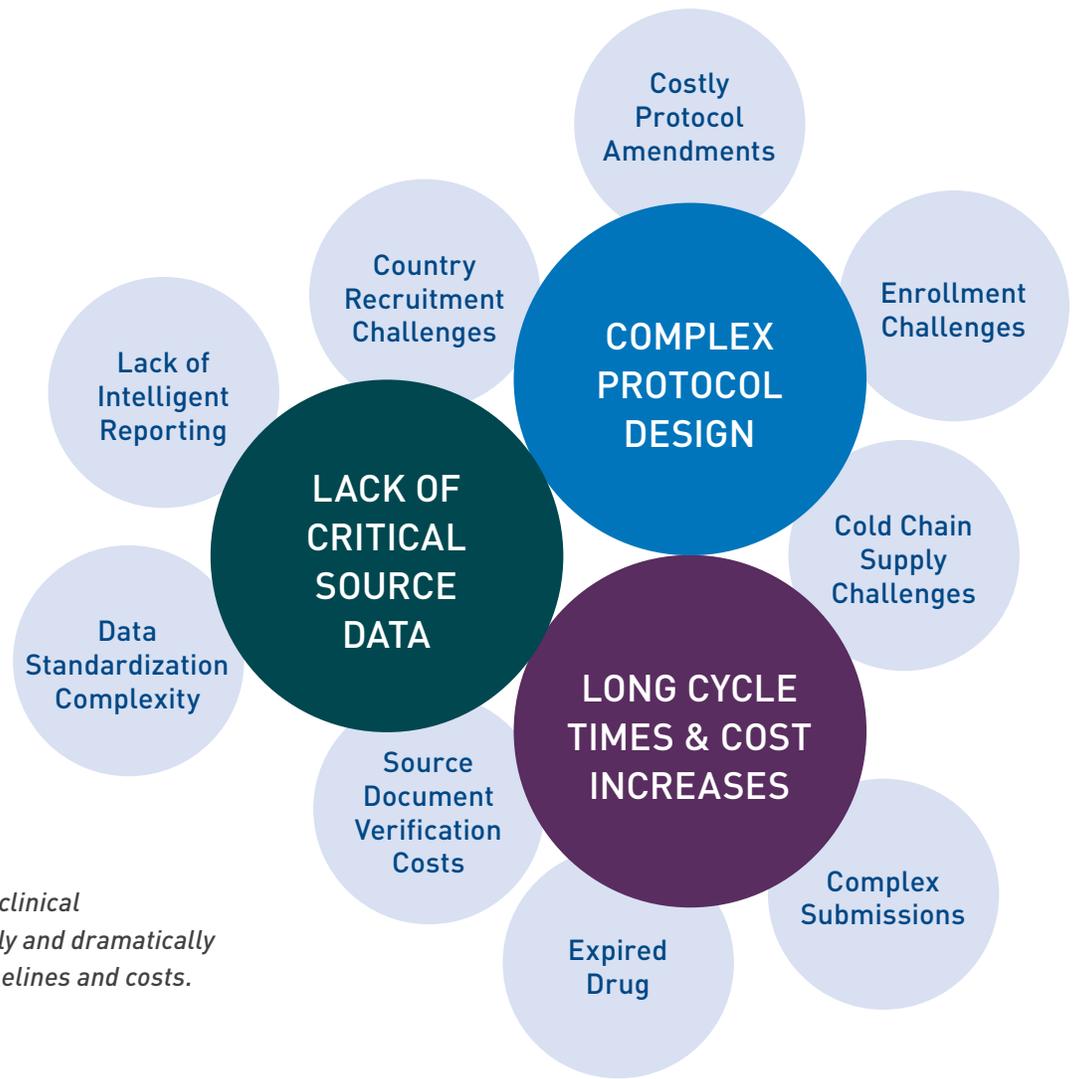
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Enhancing the clinical development process  
to achieve optimal results

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*ADVANCED TECHNOLOGY  
COMBINED WITH INTELLIGENT  
THINKING CAN HELP  
SIMPLIFY THE DRUG  
DEVELOPMENT JOURNEY*





*The challenges associated with clinical development continue to multiply and dramatically impact clinical development timelines and costs.*

Biopharmaceutical companies are focused on efficiency and market approval, yet clinical trials are still too expensive with study cycle times too long to achieve a recoverable time to market.

The biggest challenges faced by biopharmaceutical companies are the escalating cost and duration of clinical development programs.

- Recent estimates have placed the current cost of bringing a new drug to market at \$2.5 billion<sup>1</sup>.
- Protocol amendments can delay a trial by two months, adding an additional \$500,000 per amendment<sup>2</sup>.

PAREXEL® offers end-to-end, technology-enabled, clinical development optimization services to accelerate and simplify study design, start-up, execution and submission. Our unique combination of intelligent thinking and dynamic planning, coupled with social, mobile, analytics and cloud (SMAC) technologies can deliver actionable results sooner to simplify the drug development journey.

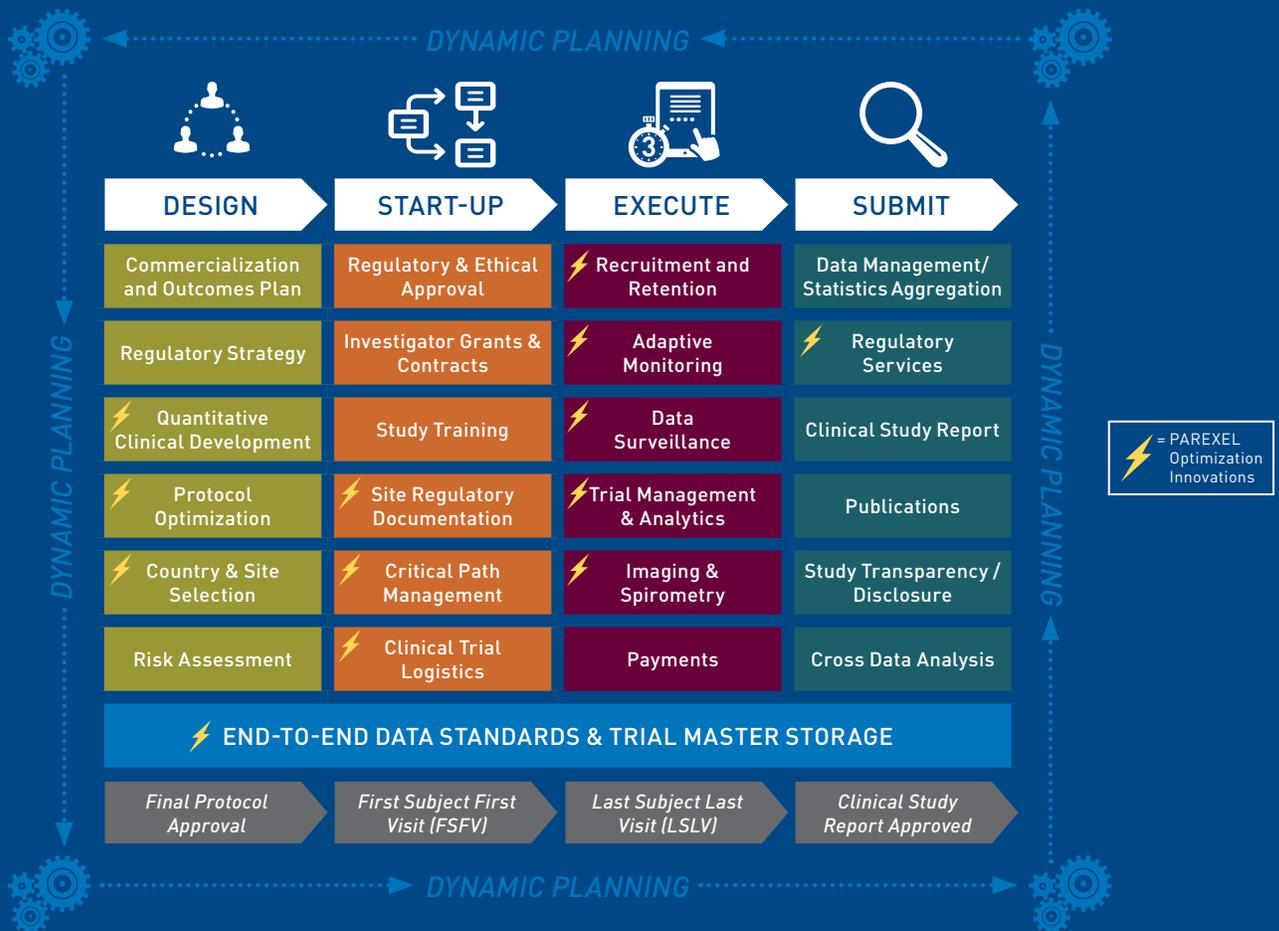
<sup>1</sup> Tuft CSDD Outlook 2015

<sup>2</sup> Tufts May 12, 2014, International Journal of Environmental Research and Public Health.

# ENHANCING 4 CRITICAL STEPS OF THE CLINICAL TRIAL LIFECYCLE

PAREXEL has designed a number of data-driven innovations to deploy during the clinical development process, accelerating time-to-market and containing development costs, while reducing the risk of late-phase failure.

The foundation of PAREXEL® Clinical Development Optimization™ is a broad base of aggregated data and knowledge from study pipelines, the competitive landscape, electronic patient records, site enrollment and quality performance. This broad knowledge base leverages PAREXEL's unique position as leading drug development consultancy, clinical development technology provider, and CRO.





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## *STANDARDIZING DATA FOR DOWNSTREAM DATA CAPTURE AND SUBMISSION*

In today's data-driven environment, application of data standards combined with holistic data collection are essential in generating a bank of knowledge that will inform and guide next step decision making in the drug development process.

PAREXEL's End-to-End Data Standards ecosystem is a comprehensive suite of metadata-driven capabilities based on Clinical Data Interchange Standards Consortium (CDISC) enabling governance and utilization of data standards from the interpretation of the approved protocol, through collection and analysis, to reporting.

Ultimately, PAREXEL treats your data as a knowledge asset and provides data services that are cost effective, seamless, and compliant. PAREXEL Clinical Development Optimization and End-to-End Data Standards enable you to have the right downstream data to enhance the efficiency and success of your regulatory submissions.



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# DESIGN

The design of your clinical protocol impacts every facet of your product lifecycle from study start-up to commercialization, regulatory and risk assessment activities. An intelligent simple protocol that addresses your regulatory and commercial aims whilst being operationally easy to enroll and deliver at sites is a competitive advantage.

PAREXEL's Clinical Development Optimization services deliver:

- **Quantitative Clinical Development** offering Model-based Drug Development where strategic development and investment decisions are enhanced by simulation of clinical trial outcomes or probability of achieving a desired level of efficacy. These simulations are based on a stochastic model of the underlying mechanisms associated with the drug, target, and disease and they predict a drug's benefits and adverse effects in a patient population.
- **Protocol Optimization** which identifies and quantifies the impact of alternate protocol design scenarios on study performance, timelines and costs.
- **Country and Site Selection** combining big data with the voice of the patient, the voice of the investigator, and predictive analytics to optimize the design of your trial, accelerate study start-up, improve execution and deliver data in easy-to-understand, visual formats to facilitate decision-making.



## 2

# START-UP

When the design, optimization and the country and site selection is accelerated, it can help minimize the risk of site delays. To avoid challenges in start-up requires the necessary ethical approval, investigator grants, and study training for sponsors and sites.

PAREXEL's Clinical Development Optimization Start-up services enhance:

- **Site Regulatory Documentation** using PAREXEL's integrated clinical trial management system (CTMS) and electronic trial master file (eTMF), PAREXEL's site start-up process provides collaborative compilation and e-signatures of site-level contracts and regulatory documents to help onboard sites.
- **Critical Path Management** utilizing the predictive analytics to forecast and manage mission critical milestones during start-up processes. This service aggressively removes white space from start-up by better transparency of status data.
- **Clinical Trial Logistics** leveraging the best randomization and trial supply technology with industry-leading supply chain intelligence to deliver integrated, end-to-end logistics management that improves compliance and efficiency, ensuring that drug is available at start-up to help avoid costly delays.

# 3

## EXECUTE

Current data shows that 48% of sites miss enrollment targets, and study timelines are often extended to almost double their original length to meet enrollment levels<sup>3</sup>. Quality of data, standards of monitoring oversight and a failure to account for the unique risks of each protocol also continue to be flagged by Agencies as threats to approvals. PAREXEL Clinical Development Optimization offers services that are tailored to the unique needs of each study, and are targeted at the most impactful areas of study execution.

PAREXEL's Clinical Development Optimization Execution services offers enhanced:

- **Recruitment and Retention** offering the full breadth of services to maximize patient recruitment and ensure retention. Our flexible services support the patient decision to participate in a trial or to help the site complete a patient visit in a busy clinic day. The range includes patient outreach campaigns, social media campaigns, video consent, site support tools, study websites, on-site enrollment managers, patient and investigator apps, digital listening and patient feasibility surveys.
- **Adaptive Monitoring** allowing project teams to define, visualize and respond to protocol risks by reducing errors that matter. It delivers the optimal balance of improved quality by focusing on risk areas, and improves monitoring efficiency.
- **Data Surveillance** to interrogate the study's scientific (clinical) data in order to modify/correct site behaviors or other aspects of study conduct in a way that eliminates or neutralizes risks to a study's data integrity. Use of this service dramatically reduces submission risk as systemic data failures such as endpoint or safety underreporting are avoided. Efficiency benefits are realized through reduced reliance on listings as the primary vehicle for data surveillance reviews.
- **Trial Management and Analytics** utilizing PAREXEL's industry leading IMPACT® CTMS and Analytics technologies, to enable sponsors to use a mobile-enabled, single entry-point to access predictive data analytics for multiple studies simultaneously. Trial management ensures GCP compliance using PAREXEL's standardized system and processes.
- **Medical Imaging** providing data capture and independent review of breakthrough central imaging through scientific expertise, proven processes, and rigorous review.
- **Spirometry** providing review and equipment management within the respiratory therapeutic area





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## SUBMIT

The complexity involved in meeting global regulatory authority requirements continues to increase, with many drugs failing to get approved because the information submitted is insufficient for a determination on safety and efficacy. For example, a review of marketing applications for new molecular entities (NMEs) submitted to the FDA from 2000 to 2012 revealed that about 50% failed to obtain approval during the first-cycle<sup>4</sup>. However, nearly 50% of these failed applications were eventually approved on resubmission after applicants addressed the FDA's concerns related to safety, manufacturing, and labeling. Similar process occurs with authorities globally, requiring expert strategy involving national, regional, and local regulatory expertise.

PAREXEL's Clinical Development Optimization services leverage regulatory experts with industry and authority backgrounds to facilitate regulatory strategy, planning, and relationship management in addition to product detail management, dossier creation and management and to support overall decision-making. Our approach provides visibility into critical submission and content development activities, allowing us to identify and correct potential problem areas early and translate data into clinical, regulatory and commercial insights.

PAREXEL's Clinical Development Optimization services enhance:

- **Regulatory Services** offering end-to-end solutions that support client decision-making through a full complement of customized strategies that minimize risk of product failures, avoid regulatory approval delays, expand into new markets, and achieve effective regulatory partnering to drive efficiencies and pipeline productivity. Led by an extensive team of former healthcare and regulatory professionals from around the world, PAREXEL as the leader in clinical, regulatory and commercial development, is able to provide you with data and insights to accelerate your product or portfolio journey.

<sup>4</sup> Sacks LV, Shamsuddin HH, Yasinskaya YI, et al. Scientific and regulatory reasons for delay and denial of FDA approval of initial applications for new drugs, 2000-2012. JAMA. 2014 Jan 22-29;311(4):378-84.



# *BENEFITS OF CLINICAL DEVELOPMENT OPTIMIZATION*

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## *SPEED*

### **Reach patients faster**

- Enhanced data standardization
- Easier investigators and patient identification
- Shorter timelines for start-up, recruitment and database lock

## *SIMPLICITY*

### **Enhance the customer experience**

- Visualization-based scenario modeling
- Simplified technology integrations that require fewer staff
- Fewer third-party services
- Transparent study controls and collaboration
- A single point of contact 24/7/365

## *SUCCESS*

### **Achieve measurable results**

- Reduction in on-site visits and more efficient collection of core vs non-core data
- Evidence-based effectiveness
- Single, Authoritative Source of Regulatory Information

## ABOUT PAREXEL® CLINICAL RESEARCH SERVICES

Whatever the size or scope of your study, PAREXEL provides the comprehensive clinical research services you need, from First-in-Human through Phase IV and Post-marketing follow-through. We also have the regulatory expertise, clinical trial operations management, payer and market access planning, medical education and communications capabilities to see your journey through efficiently and effectively.

## ABOUT PAREXEL® INFORMATICS

All along your new drug's development path, PAREXEL® Informatics has technological innovations that make the process faster, more precise, more trackable, and more productive. We lead the industry in creating integrated platforms and applications specifically designed to improve how biopharmaceutical companies perform clinical trials, control and share data, track and report patient outcomes, and manage regulatory information worldwide.

We are always available for a conversation.

### UNITED STATES

#### Frederick LeMoine

Vice President,  
Business Development  
+1 919 294 5125  
frederick.lemoine@PAREXEL.com

### EUROPE

#### Andrew Copestake

Vice President, Business Development  
+44 1 895 27 6553  
Andrew.Copestake@PAREXEL.com

### ASIA PACIFIC

#### Brian Yang

Vice President,  
Business Development  
+886 2 21769525  
brian.yang@PAREXEL.com



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

**CORPORATE HEADQUARTERS**

195 West Street  
Waltham, MA 02451  
USA  
+1 781 487 9900

**Offices across Europe, Asia and the Americas**

[www.PAREXEL.com](http://www.PAREXEL.com)

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