PAREXEL® ACCESS

Positioning your products for market success

PAREXEL®
YOUR JOURNEY. OUR MISSION.™

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Proving value has never been so valuable

On the journey to cure disease, the destination to deliver an effective and profitable product that meets the requirements of many stakeholders, must always remain in sight. Planning for commercialization throughout the development process, and demonstrating safety, effectiveness and value to regulators, payers, healthcare providers and patients alike, is intrinsic to reaching that goal.

Commercial considerations are often overlooked too late in the planning process, potentially leading to the failure of new products. Establishing market-access strategies too late can also delay product launches and slow down time to market, risking competitive vulnerability.

The PAREXEL® Access unit provides a complete and simplified solution encompassing a full spectrum of evidence-based services throughout the product lifecycle, comprising commercial strategy, late-stage clinical operations, medical communications and drug safety services. As a leading provider to the biopharmaceutical industry for more than 30 years, PAREXEL has combined a full scope of evidence-based services into a single integrated group to offer our clients a greater strategic advantage:

- Market access consulting services that align evidence generation and economic evaluation with pricing, reimbursement, and market-access strategy for improved decision making
- Clinical research services that generate the data needed for multiple stakeholders through real-world observational studies, interventional trials, managed access programs, or patient reported outcomes
- Communications services that integrate evidence of product value into comprehensive industry-compliant communications programs

An important corollary of our business is an end-to-end pharmacovigilance solution that routinely monitors the ongoing safety of marketed products, ensuring the scientific rigor of data collected.

By combining our deep experience, innovative strategies and the industry's best minds, we provide a unique, simplified and complete solution that bridges the needs of Medical Affairs, HEOR and Market Access groups. PAREXEL can help identify, generate, evaluate and communicate the evidence of product value that helps to accelerate time to market, de-risk the reimbursement/market access process and improve commercial success opportunity.

EVIDENCE IDENTIFICATION AND EVALUATION

PAREXEL offers a resourceful solution for commercialization by aligning evidence generation and economic evaluation with pricing, reimbursement, and market-access strategy.

These strategic consulting services help you identify and evaluate evidence of product value. This approach encompasses market-access planning, systematic review for evidence development, economic modeling and evaluation, pricing, reimbursement strategies, global value dossier writing, and engagement with Health Technology Assessment (HTA) authorities.

COMMERCIAL DECISION PATHWAYS

Pricing, reimbursement, and market access are important indicators of return on investment after lengthy and costly development programs. PAREXEL's Commercial Decision Pathways solution informs decision-making at key points in the development process, effectively securing the strongest possible foundation to provide value and effectiveness.

These services comprise:

- Due-diligence review for assets evaluation
- Evidence-based portfolio prioritization
- Clinical trial protocols, Target Product Profile (TPP) and label claims
- Evidence and economic needs assessment and evaluation
- Market-access, pricing, reimbursement strategies

ACCESS REALIZATION

The numerous biopharmaceutical clients that we have supported acknowledge that pivotal pricing, reimbursement and market-access work streams are often delayed until the start of Phase III clinical trials. PAREXEL advocates for early understanding of market-access implications that inform trial design, target product profile and label optimization via:

- Astute landscape assessments and strategy determinations leading clients to reimbursement solutions that creatively address payer needs
- Market-access strategy development and execution to achieve optimal conditions based on local, regional and global policies, dynamics and drivers
- Pricing strategies that ensure the full benefit of opportunity in price sensitivity and receptivity

Capturing the information and data necessary to facilitate reimbursement and market access requires manufacturers to move away from blockbuster-era thinking. From a clinical development perspective, regulatory stages are predictable and information requirements are fairly well defined. Achieving commercial success however, requires specialized insight and evidence.

PAREXEL provides strategy direction and evidence generation throughout the development lifecycle, addressing the needs of internal and external stakeholders while shaping, substantiating and articulating product value.

AT PAREXEL, WE PRIDE OURSELVES ON OUR EXPERTS BECAUSE THEY PRIDE THEMSELVES ON YOUR SUCCESS.

EVIDENCE GENERATION

The scientific rigor and innovation applied to evidence generation, both within and outside the clinical development plan, is a leading indicator of commercial viability. We have one of the largest and most globally experienced teams in the industry, comprising research specialists, epidemiologists, health economics and outcomes researchers as well as specialized operational teams, offering best-practice in:

- Phase IIIb/IV Interventional trials
  - More than 600 late phase clinical trials conducted across a broad range of therapeutic areas
- Observational research (prospective and retrospective programs)
  - Approximately 150 observational real-world treatment studies have been conducted recruiting >400,000 patients worldwide
- Managed access programs including treatment IND studies, emergency use protocols, compassionate-use guidelines, and named patient basis programs
- Evidence reviews, meta-analyses, synthesis and reporting
- Data analytics and real-world evidence
- Value messaging and dossier development

To support evidence generation activities, PAREXEL have interacted with more than 200 secondary data sources globally (databases, registries, EMR, Claims) – either through collaboration with the data providers or via third-party directly accessible sources.

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 experience, our teams provide strategic insight, design and implement flexible solutions, proactively solve operational challenges, and fastidiously manage product timelines and budget.

DRUG SAFETY SERVICES

The moment a new therapy succeeds in clinical trials and enters the marketplace, its life becomes more complex. This complexity, combined with the ever-changing landscape of regulatory requirements, means that the pressure on biopharmaceutical companies is ever-increasing.
Despite this pressure, PAREXEL understands that patient safety is at the heart of every company's focus. This is why we are committed to delivering quality integrated services across the full spectrum of the post-approval lifecycle. Our seamless execution, breadth of services, availability of insourcing and outsourcing models, deep expertise, integrated regulatory affairs capability and a highly scalable global capacity enable us to support your team with an innovative offering for pharmacovigilance. Whether you are looking for support with case-handling or managing an entire portfolio of products, PAREXEL can customize a solution tailored to your specific goals and objectives.

EVIDENCE COMMUNICATION

ACCELERATING TIME TO MARKET WITH INTELLIGENCE, DATA AND STRATEGIC INSIGHTS

With three decades of experience, PAREXEL's medical communications services help ensure that your products benefit from insightfully conveyed data and communications excellence. Our highly qualified medical writers and communications experts, supported by creative and production teams, brand strategists, social media experts and medical events specialists, work seamlessly to simplify the complexity involved in creating motivating communications.

Unrivaled in our understanding of today's highly regulated clinical development environment, PAREXEL's team has expertise spanning therapeutic and geographic areas, providing a truly international partnership. Specialists in data analysis, market scoping and strategic communications planning, we integrate your evidence into an insightful, comprehensive and industry-compliant communications program. Examples of where we can support you include:

- Effective expert identification and engagement programs
- Creative medical communications solutions
- Publication planning and scientific writing
- Global meetings and event management
- Exhibit strategy services
- Innovative technology solutions
- Branding strategy and design

A PARTNER YOU CAN TRUST

EVERY STEP OF THE WAY

PAREXEL is one of the few CROs that can provide expert services around the globe to design, execute and communicate successful research under a single roof, not only providing more robust solutions but also eliminating the need for our clients to maintain three, five or more vendor relationships to meet their overall needs.

By working with PAREXEL to align commercial strategy with clinical and regulatory planning throughout the development process, you can improve the likelihood of achieving optimal uptake and profitability—and turn your commitments into competitive advantage.

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

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