PAREXEL® ACCESS

# *MANAGED ACCESS PROGRAMS*

PAREXEL®
*YOUR JOURNEY. OUR MISSION.®*

Demands are increasing on biopharmaceutical companies developing treatments for unmet diseases to make them available to select patients even before the drug is labeled, packaged and fully commercialized. These patients, facing life-threatening or severely debilitating disease, may lack access to the treatment for any number of reasons. They may be ineligible for an ongoing trial, trials may not yet have begun or regulatory or reimbursement processes are still ongoing. In many cases, a treating physician or patient requests access because there is no comparable or satisfactory alternative therapy available, and the risk to the patient is not greater than the probable risk from the disease or condition.

While these demands are not new, they are more frequent today because they are driven by an unprecedented public awareness of the various stages and status of product development. This awareness extends beyond the medical community and patient advocacy groups to patients and their families.

# COMPASSIONATE USE

When possible, decision makers at biopharmaceutical companies are often willing to provide compassionate use of an investigational medical product when patients have run out of options. At the core of this willingness is the desire to accomplish their essential mission: to cure disease and improve the human condition. However, there are sizable challenges involved in the conduct of these programs, for example:

- A fragmented regulatory landscape across countries and regions, and lack of standardization in processes and requirements for managed access
- Identification of suitable patients and treating physicians, and determining what constitutes an unmet medical need
- Rapid start-up requirements for patients with urgent health issues
- Logistics and control in managing initial and ongoing delivery to the patient/physician, especially when product supply is limited, or special handling such as temperature control is required
- Ethical and financial considerations
- Lack of reimbursement mechanisms

For these reasons and more, biopharmaceutical companies reach out for specialized expertise and resources to help manage the complexity inherent in providing access to an investigational treatment. Outsourcing allows them to focus on their core R&D strategy while outside experts assure that these important managed access programs – which are quite different from a conventional clinical trial – are executed in a timely and professional way.

# PAREXEL'S MANAGED ACCESS PROGRAM SERVICE

PAREXEL has long been in the forefront in providing services to support the design, development, and delivery of managed access services. Our staff has many years of experience in the operational and regulatory requirements of managed access programs to enable efficient and cost-effective implementation in each country involved.

To help our clients meet these growing demands, we have combined several of our core services to offer end-to-end design, development, and global delivery of managed access programs. By applying the best minds to the task at hand, PAREXEL simplifies the journey between science and new treatments. New products can reach patients sooner thanks to innovation, problem-solving, and an unparalleled level of support for all key components of a managed access program.

## OPERATIONAL EXPERTISE

Navigating the regulatory maze and understanding country-specific nuances is foundational to a worldwide managed access program. PAREXEL offers local support, knowledge, training and guidance, with a staff of medics to support treating physicians, and experts to help refine the regulatory strategy.

Our team of experts have worked with small, mid-sized and large organizations across the entire clinical development and commercialization continuum and they understand the complex regulatory and logistical issues of running managed access programs worldwide.

## PROPRIETARY TECHNOLOGY

A web-based MyAccessPrograms™ platform supports patient identification and management of requests, as well as physician enrollment, drug supply management, and resource determination (the amount of drug, budget, and staffing). The workflow-enabled platform allows for more predictable and rapid drug supply for patients who need the product urgently.

This access-controlled platform serves as a central hub for all relevant parties associated with the managed access program, providing around-the-clock visibility

into the progress of the program. This encompasses communications with multiple stakeholders, such as sales teams and patient advocacy groups.

Further, the technology can service multiple Access Programs for a client to drive greater efficiency and a centralized resource for all stakeholders.

## GLOBAL CLINICAL TRIAL SUPPLIES & LOGISTICS

PAREXEL is uniquely capable of managing supply and control of the medicinal product which affords our clients the optimal mix of centralized control and practical, country-specific import/export, and regulatory experience. Our dedicated Clinical Trial Supplies and Logistics Unit, comprised of highly qualified and experienced clinical logistics professionals, has operations in over 80 locations in 51 countries around the world, and four strategically placed global hubs. In addition, we maintain relationships with – and continually monitor – all material suppliers involved in the managed access program.

This team coordinates drug supply manufacturing and manages import/export requirements, labeling, distribution, inventory control, and return to destruction of unused medication. The MyAccessPrograms™ platform interfaces directly with the supplies system and patient registration; patient registration triggers requests for supply and resupply. The result is on-time delivery and ongoing availability of the product for each enrolled patient.

The logistics unit optimizes drug supply based on the needs and forecast of the program, based on sophisticated computer simulation. Since the expected volume of patients cannot always be predetermined, we offer proactive drug supply management and a scalable approach.

In addition, this team offers laboratory services, managing and organizing a centralized lab system, supplying forms and kits for patient visits, overseeing transportation logistics for lab samples, and administering lab data. This approach ensures adherence with standard operating procedures (SOPs), as well as oversight of all aspects of pharmacovigilance and reporting requirements of safety events.

## MARKET ACCESS

Any managed access program must include a high-level strategic roadmap to commercialization, transitioning the product from compassionate use to full market access. Toward that end, our services can help you determine the utility of collected data for commercial and medical stakeholders (including real-world value definition, value demonstration, and pricing), and develop evidentiary data for potential reimbursement from payers.

The protocol defines an approach for patients to withdraw from the managed access program and transfer to a patient registry once commercial supply is available in their country. Further, the program generates early "real-world access" experience that can be used to help educate physicians in the most effective use of the drug.

Ultimately, achieving commercial success requires specialized insight and evidence. PAREXEL® Access offers market-access strategy development and execution to achieve optimal consideration based on local, regional and global policies, dynamics, and drivers. We provide strategy direction and evidence generation throughout the development lifecycle, addressing the needs of internal and external stakeholders while shaping, substantiating, and articulating product value. These experts identify and execute a project blueprint drafted specifically to meet your scientific and business objectives.

# *A PARTNER YOU CAN TRUST*

PAREXEL's Managed Access Program service helps biopharmaceutical companies bridge the gap between product development and product launch in delivering life-saving treatments in challenging circumstances. Our unmatched service is provided by experienced global teams with deep expertise, mature services, and integrated proprietary technology and logistics offerings. Equally, well-suited to multinational corporations as well as emerging and midsize organizations, our services are available on a turnkey or as-needed basis.

In any case, we will work closely with you to develop the right strategy. Our leadership approach is collaborative and transparent, involving ongoing communications at a frequency appropriate for each phase of the project. With close attention to the budget, resources and timelines, our project management teams strive for on-schedule decision-making through well-run, highly focused meetings with prompt and thorough communications over the course of the program.

Our Managed Access Program service supports and adheres to our clients' policies and provides significant savings in costs and timelines through built-in efficiencies at both global and local levels. You can count on PAREXEL for a complete end-to-end solution, offering:

- Extensive experience in oncology, infectious disease, rare and orphan diseases, and CNS
- An inclusive library of best practices and dedicated SOPs
- Specialized strategies, skills and resources, different from a conventional clinical trial to deliver compassionate use through managed access
- Support in navigating complex regulatory and logistical issues worldwide
- Cost-effective, centralized management combined with integrated drug supply and logistics with state-of-the-art technology
- Support for participating physicians and pharmacists while achieving program objectives
- Highly efficient, cost-effective systems and procedures to maximize ROI

## We are always available for a conversation.


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


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BR-ACCESSMAPOVW-DEC16