On the journey to cure disease, the challenges can be daunting. Regulators are applying higher levels of scrutiny and access to drugs is more consistently dependent on demonstration of value and effectiveness. By aligning commercial strategy with clinical and regulatory planning earlier in the development process, the likelihood of achieving optimal uptake and profitability is significantly increased.

ELIMINATING BARRIERS TO ACCESS AND REIMBURSEMENT

PAREXEL offers a bold solution for market access consulting following our acquisition of HERON Commercialization in 2013. Aligning evidence generation and economic evaluation with pricing, reimbursement, and market access strategy, PAREXEL helps to realize product value and commercial opportunity early and throughout the product development lifecycle.

PAREXEL’S COMMERCIAL DECISION PATHWAYS

Pricing, reimbursement and market access are seminal indicators of return on investment after lengthy and costly development programs. Commercial considerations are often overlooked, however, until too late in the planning process, resulting in clinical data that fails to meet the needs of payers and reimbursement authorities. The consequences of this exclusion can be catastrophic, leading to the failure of many new technologies to achieve their full commercial potential. PAREXEL’s Commercial Decision Pathways inform decision-making at seminal points in the development process, effectively securing the strongest possible foundation to prove value and effectiveness.
PAREXEL’s Commercial Decision Pathways inform decision-making throughout the development process, effectively securing the strongest possible foundation to prove value and effectiveness.

### Asset Decisions

<table>
<thead>
<tr>
<th>Portfolio strategy</th>
<th>Compound acquisition/development</th>
<th>Brand strategy</th>
<th>Brand life extension</th>
</tr>
</thead>
</table>

| Pre-clinical studies | Phase 1 studies | Phase 2 studies | Phase 3 studies | Regulatory submissions | Market access submissions | Late phase |

### Commercial, Reimbursement & Access Support

| Due diligence review for asset acquisition | Evidence-based compound/indication prioritization | Clinical trial protocol development | Market access needs assessment and evidence generation | Market access, pricing and reimbursement strategy |
Due diligence review for asset evaluation. To support informed go/no-go decisions in prioritizing drug, biologic and device acquisition or sale, PAREXEL offers access to the priorities of payers and policy makers through:

- Epidemiological analysis of patient populations
- Systematic review of competitive and comparator treatments
- Economic analysis of market potential
- Indication review (including subpopulations and reimbursement/payer landscape) in major markets

Evidence-based portfolio prioritization. To inform compound development and indication sequencing critical to commercial success, we provide:

- Epidemiological analysis of patient sub-populations
- Clarification of unmet need
- Early health economic modeling
- Critical review of competitive and comparator product(s)

Clinical trial protocols, Target Product Profile (TPP), and label claims. To support market access by demonstrating value, PAREXEL delivers insights based on:

- Systematic review of competitive and comparator treatments
- Payer coverage and data requirements
- Message synthesis based on deep knowledge of variation in market requirements

Evidence and economic needs assessment and evaluation. To develop powerful and rigorous evidence strategies that ensure successful reimbursement and sustainable market access, we provide:

- Claims analysis
- Budget impact and comparative cost effectiveness models
- Value dossiers
- Comparative Effectiveness Research

Market access, pricing and reimbursement strategies. To creatively address payer needs, PAREXEL provides:

- Health Technology Assessment strategies and submissions
- Payer value proposition development and access to a large proprietary payer database
- Geographically relevant market access strategies
- Qualitative and quantitative pricing models to ensure access strategies creatively address payer needs
EVIDENCE TO ACCESS

PAREXEL’S SERVICES

Evidence Generation
The strategic rigor and creativity applied to evidence generation, both within and outside the clinical development plan, is a leading indicator of commercial viability. Our staff is one of the largest and most globally experienced in the industry, offering best practice:

- Evidence reviews, meta-analyses, synthesis, and reporting
- Data analytics and real world evidence
- Health economic modeling and economic evaluation
- Value messaging and dossier development
- Active Evidence – strategically mapped to PAREXEL’s Commercial Decision Pathways, Active Evidence ensures that key internal stakeholders have current data and information for informed decision-making

Access Realization
Biopharmaceutical clients we have supported through the years 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 mastery 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
**DEFINING VALUE DRIVERS**

Planning and delivering evidence required for sustainable value—that’s how PAREXEL helps you maximize return on investment.

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**Delivering Time to Access Delays Time to Peak Sales, Significantly Impacting Lifecycle Return on Investment**

<table>
<thead>
<tr>
<th>Revenues</th>
<th>Investment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Earlier launch and faster uptake</td>
<td>Asset with early commercial development strategy</td>
</tr>
<tr>
<td>Earlier and higher peak revenues</td>
<td>Asset with no early commercial development strategy</td>
</tr>
<tr>
<td>Higher maintenance of revenues over time</td>
<td>Small initial investment</td>
</tr>
</tbody>
</table>

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**Benefits of early asset commercialization development**

- Market entry with optimal strategy for pricing, therapy area and launch
- Faster time to peak sales, resulting in increased lifecycle revenue and profit
- Liberty to make more strategic decisions compared to later stage asset development which can have restrictions
- Better understanding of market landscape and potential post launch scenarios
- Ability to spot potential market access hurdles early and develop strategies to overcome these
- Minimizes delays for approval, access and reimbursement if the correct strategies are identified and followed through

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**THERAPEUTIC AREAS**

- Oncology
- Cardiovascular
- CNS
- Endocrinology/Metabolism
- Infectious Diseases
- Allergy/Immunology
- Pulmonology
- Gastroenterology
- Obstetrics/Gynecology

**PRODUCT AREAS**

- Drugs
- Biologics
- Medical Devices/Diagnostics

**DELIVERY MODELS**

- Strategic Partnerships
- Functional Services
- PAREXEL's Commercial Decision Pathways
- Project-/Program-Focused Consulting
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 strategic direction and evidence generation throughout the development lifecycle, addressing the needs of internal and external stakeholders while shaping, substantiating and articulating product value. Your journey is to cure disease with efficacious, safe, and cost-effective health treatments. Our mission is to support you with commercial talent and experience that result in faster, smarter drug development. We look forward to the opportunity.

We are always available for a conversation.

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

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