Unlocking the value of your product

Access Services
Helping you to reach patients sooner

In your quest to cure disease and improve health and well-being for people across the world, you’re facing an environment that has shifted radically. Gaining regulatory approval used to be the main gateway to market. Now it marks the beginning of another challenging process – reimbursement and market access. The payer landscape is not only complex but fragmented. However, all payers share common goals – the need to ensure that better outcomes for patients can be achieved, and that cost is managed at a sustainable trajectory.
At Parexel, we understand that creating new drugs is increasingly risky, costly and complex. That’s why it’s so important to start with a clear, well-coordinated strategic plan that considers the whole development lifecycle – and beyond. That way you can ensure you satisfy any concerns of all the stakeholders involved – patients, patient advocacy groups, physicians, payers and regulators. With a robust package of safety and effectiveness data, accompanied by real-world evidence, we can help you demonstrate real value and get your drug to the people who need it.
We’re here to help you unlock the value of your product

Commercial risk has become so multifaceted that you need a robust strategy to overcome it. At Parexel, we start by connecting up the whole development process, leveraging our end-to-end clinical development, regulatory, market access and commercialization solutions.

In order to help you maximize the value of your products, we’ll translate our robust market access expertise, research acumen and value communications excellence into strategy, real-world evidence and stakeholder engagement.
We’ll tailor our services to your precise needs

We have a comprehensive range of solutions to support market access right across the development journey. When we partner with you, we will take care to understand exactly what you need and prepare a service package just for you.

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<tbody>
<tr>
<td>Evidence reviews</td>
<td>Health economic models and analysis</td>
<td>RWD database mapping and assessment</td>
<td>Global pricing and market access strategy</td>
<td>Expertise in all types of COAs including PROs, ClinROs, ObsROs PerfOs</td>
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<td>Epidemiology evidence strategy</td>
<td>Cost effectiveness/utilities models</td>
<td>RWD treatment pattern analysis</td>
<td>Local access strategy, plan and submission (UK, Nordics and others*)</td>
<td>Protocol/endpoint review</td>
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<td>HTA/reimbursement evidence strategy</td>
<td>Budget impact models</td>
<td>RWD long-term effectiveness studies</td>
<td>Early HTA and payer engagement</td>
<td>COA instrument reviews/gap analyses</td>
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<td>Post market evidence plan</td>
<td>Field based tools</td>
<td>RWD safety studies</td>
<td>Evidence optimization</td>
<td>COA adaptation/development and validation</td>
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<td>Clinical development plan</td>
<td>Early stage models</td>
<td>RWD cost-of-illness studies</td>
<td>Value communications</td>
<td>Support implementation of COAs in clinical studies</td>
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<td>Early asset prioritization/portfolio review</td>
<td>Country model adaptations</td>
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<td>* submissions in English</td>
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<td>Network metaanalysis/comparative effectiveness</td>
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Our end-to-end services are ready to help you gain market access

**Landscape assessment**
- Identifies:
  - unmet needs
  - potential for differentiation

**Payer engagement**

**Value proposition development**

**Early pricing strategy**
- Payer evidence plan

**Economic SR***
- Establish cost-effectiveness of competitors, understand model drivers and determine which factors influence the cost-effectiveness of a product.
- High value early activity

**1st clinical SR***
- Assess evidence base to identify:
  - benchmark of therapies
  - opportunities
  - challenges

**Phase III trial strategy**

**HTA submission strategy**

**2nd Clinical SR***
- Ensure methodology and:

**Global value dossier**
- HTA agency requirement

**Value**

**Early economic models**
- Gain an early sense of strength of economic case to inform the overall strategy: identify data gaps and key model drivers for end point inclusions in Phase III.

**Suite of economic SR***
- Systematic searches ensure inputs for model parameters are identified using logical, unbiased, and transparent methods, and that the choice of values are justified.
- HTA agency requirement
We’ll help you meet the hopes and expectations of stakeholders for an effective treatment, sooner.

**Start early**

**HTA submission**

**HTA advisory engagement**

Pressure test submission on value messages and model assumptions.

**Early economic models**

Demonstrate the economic value of the new product, via ICERs, ICURs, or cost savings, with settings specific to the country of interest, to the HTA agency’s precise specifications.

Rejections most frequently cite models as reason.

**Pricing strategy**

& 2nd landscape assessment

Scope meet stringent HTA requirements

**Value message testing**

**Value dossier**

End Phase III

Marketing authorization

**Strategy**

**Evidence Evaluation**

**Pricing & Market Access/Value Communications**

**Health Economic Modeling**

*SR = Systematic Review
We’re always available for a conversation

www.parexel.com/access

To learn more about our Adaptive and Flexible Trial designs, please contact:

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