#### porexel.

# Unlocking the value of your product

Access Services

Regulatory and Acce

### >>> 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.

With Heart



#### >>> One drug, many stakeholders. We're here to help you satisfy them all

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, wellcoordinated 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.

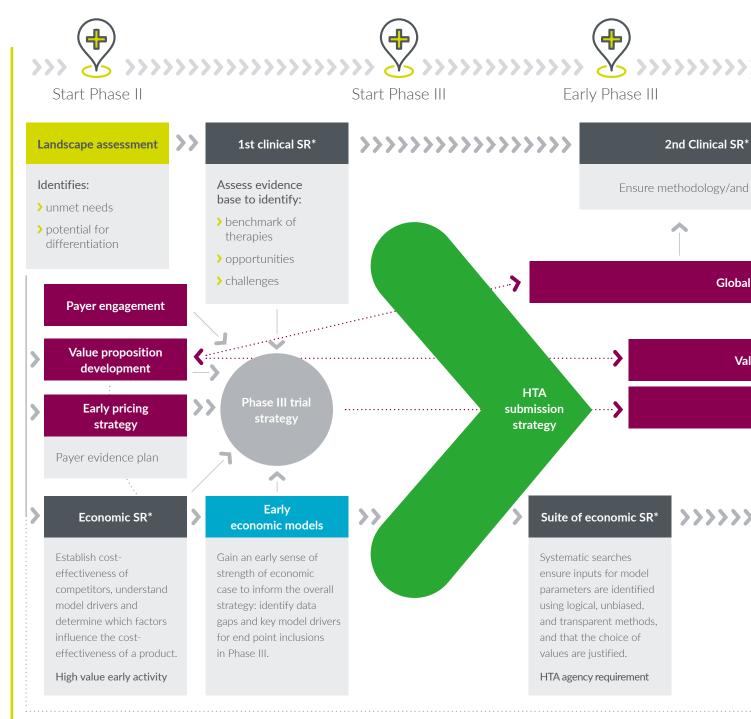
## >>> We'll tailor our services to your precise needs

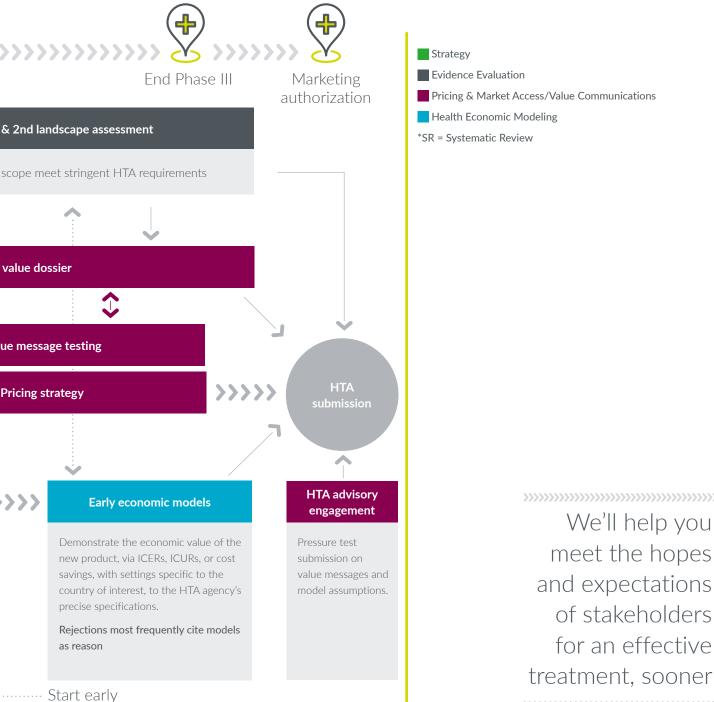
We have a comprehensive range of solutions to support market access right across the development journey. When we partner with you, we will take care to understand exactly what you need and prepare a service package just for you.

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Evidence	Health Economic	Real-World	\$\$\$         Image: Constraint of the second	Clinical Outcomes
Evaluation (EE)	Modeling (HEMU)	Data (RWD)		Assessment (COA)
<ul> <li>&gt; Evidence reviews</li> <li>&gt; Epidemiology evidence strategy</li> <li>&gt; HTA/ reimbursement evidence strategy</li> <li>&gt; Post market evidence plan</li> <li>&gt; Clinical development plan</li> <li>&gt; Early asset prioritization/ portfolio review</li> <li>&gt; Network metaanalysis/ comparative effectiveness</li> </ul>	<ul> <li>&gt; Health economic models and analysis</li> <li>&gt; Cost effectiveness/ utilities models</li> <li>&gt; Budget impact models</li> <li>&gt; Field based tools</li> <li>&gt; Early stage models</li> <li>&gt; Country model adaptations</li> </ul>	<ul> <li>&gt; RWD database mapping and assessment</li> <li>&gt; RWD treatment pattern analysis</li> <li>&gt; RWD long-term effectiveness studies</li> <li>&gt; RWD safety studies</li> <li>&gt; RWD cost-of- illness studies</li> </ul>	<ul> <li>&gt; Global pricing and market access strategy</li> <li>&gt; Local access strategy, plan and submission (UK, Nordics and others*)</li> <li>&gt; Early HTA and payer engagement</li> <li>&gt; Evidence optimization</li> <li>&gt; Value communications</li> <li>* submissions in English</li> </ul>	<ul> <li>&gt; Expertise in all types of COAs including PROs, ClinROs, ObsROs PerfOs</li> <li>&gt; Protocol/endpoint review</li> <li>&gt; COA instrument reviews/gap analyses</li> <li>&gt; COA adaptation/ development and validation</li> <li>&gt; Support implementation of COAs in clinical studies</li> </ul>

>>> Our end-to-end services are ready to help you gain market access





#### Your Journey. Our Mission.®

>>> 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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