

parexel®

Keeping patients at the heart  
of the clinical, regulatory,  
and market access process

Patient Innovation Center



»»» Our philosophy:  
the best-designed studies  
start with the patient

When it comes to recruiting and retaining patients, much depends on the design of your clinical development program. At Parexel, we believe in making it as easy as possible for patients to learn about and participate in clinical trials. For example, using Patient Centric Protocol Optimization (PCPO) to incorporate patient and caregiver needs, views and experiences into trial planning helps create a more patient-friendly study design. And, as well as supporting development of a protocol that is more practical for patients, it also identifies other areas where we can ease patient burden.

To do so may include using tools like patient transportation support, deploying clear and simple education materials so that patients understand their options, or delivering the study as a virtual trial by taking all or part of the study to patients in their homes via a combination of technology, such as sensors, and in-home healthcare support. This can reduce the practical, geographical and financial barriers to participation, opening up trial opportunities to a great number of patients. It also makes their trial experiences more positive and keeps them motivated and engaged.

*With Heart*

»»» A patient-centric approach  
can improve the likelihood  
of launch in oncology, rare  
diseases and beyond

With the steady growth of new medical therapies in development for oncology, neurology and rare diseases, it's more critical than ever that these medications make it to market to help patients. Yet studies in these disease areas often have some of the lowest recruitment and retention rates. This is often due to the additional complexities and health issues that these diseases can present to patients.

*The Innovation Imperative: The Future of Drug Development*, a report by the Economist Intelligence Unit and commissioned by Parexel found that using a patient-centric approach can almost halve the time it takes to recruit 100 patients into neurology and oncology trials, while recruitment into rare disease trials was even faster, taking one fifth the time taken by non-patient-centric trials.<sup>1</sup> We are proud innovators in recruitment and retention in these areas, in particular oncology, where we are 29% faster than the industry average from first to last patient randomized.<sup>2</sup>

Drugs utilizing  
a patient-centric  
design are

**19%**

more likely to launch<sup>3</sup>

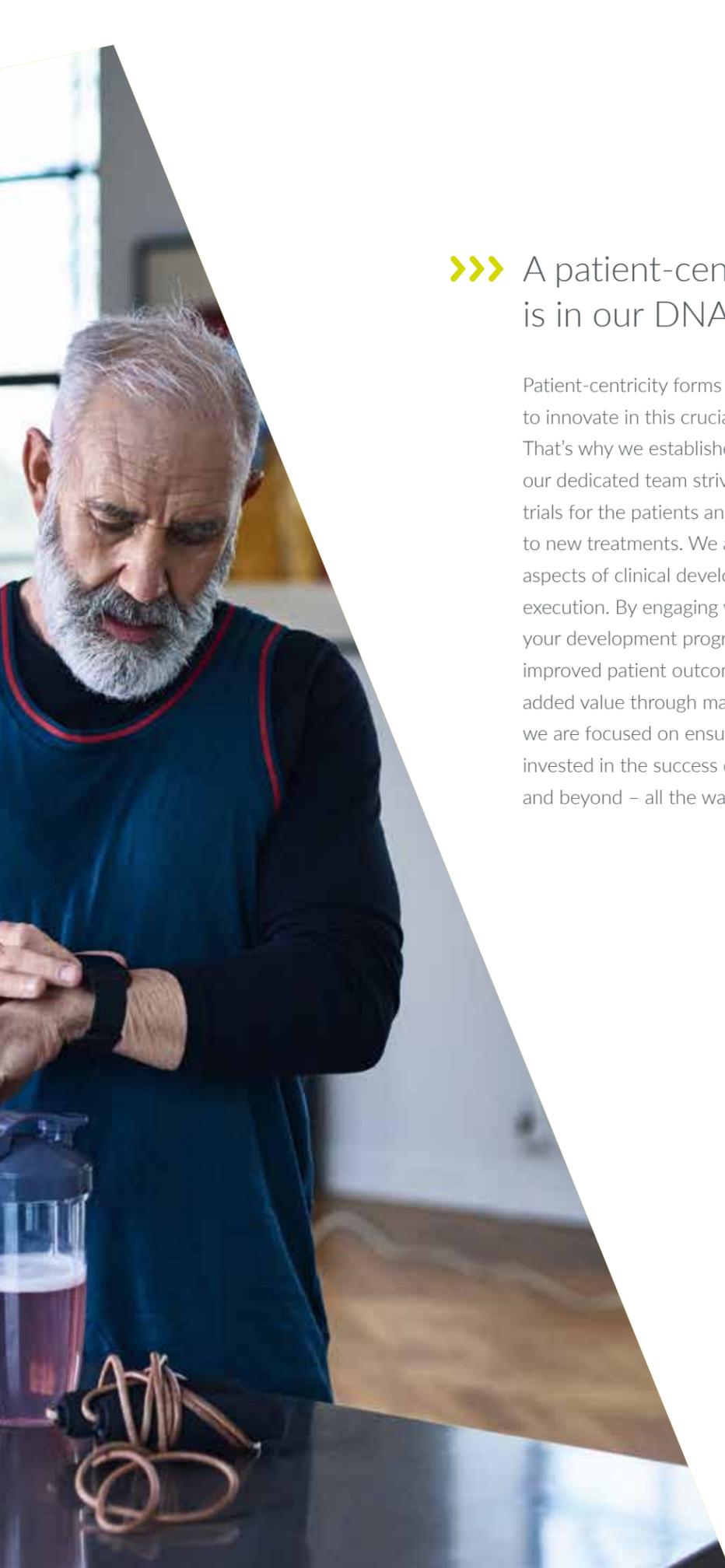


1. *The Innovation Imperative: The Future of Drug Development, Part I: Research Methods and Findings*, The Economist Intelligence Unit, 2018.

2. KMR Group Clinical Program, 2015.

3. *The Innovation Imperative: The Future of Drug Development*, The Economist Intelligence Unit, 2018.





## »»» A patient-centric approach is in our DNA

Patient-centricity forms part of our heritage, and we continue to innovate in this crucial area of clinical development. That's why we established our Patient Innovation Center; our dedicated team strives to reduce the burden of clinical trials for the patients and simplify and accelerate their journey to new treatments. We actively seek patient input into all aspects of clinical development: trial design, recruitment and execution. By engaging with patients we help you design your development program in a way that will demonstrate improved patient outcomes and we help to communicate this added value through market access. Throughout our work, we are focused on ensuring patients are fully engaged and invested in the success of your clinical development and beyond – all the way to market.

## »»» Incorporating patient input at every stage:

### Before the study begins

- › Consider the patient and caregiver needs
- › Provide additional information or training about any study tests or procedures that necessitate it
- › Overcome any practical challenges in the proposed study design
- › Minimize the impact on the patient's and caregiver's quality of life and supporting their experience in the trial

### During the study

- › Reduce the number of study visits
- › Provide study-related technology to simplify the process for patient's and caregiver's
- › Offer help with travel to the study site
- › Ease study burden
- › Provide the right information in the preferred format for patients to stay motivated and engaged

### After the study ends

- › Identify the right channels to thank patients for their important contribution to the study
- › Provide study results
- › Price the treatment well
- › Support a continuous relationship with the clinician if required
- › Consider how the treatment is maintained and transitioned after the trial





»»» We're focused on engaging and supporting patients throughout the development cycle

Through our Patient Innovation Center, we are constantly looking for new ways to empower patients to become active participants in the drug development process. We aim to simplify the patient journey to enhance patient satisfaction and compliance with study requirements. Here are just a few of the ways we have used patient feedback to reduce patient burden:

**Study planning**

Our innovative Patient-Centric Protocol Optimization service proactively involves patients and caregivers and Parexel Site Alliance expert nurses in the protocol design process to identify and address potential practical challenges to study participation.

» We augment the feasibility process by incorporating patient feedback, enabling us to enhance patient access and optimize the patient experience

- » We use a combination of patient, caregiver, and site nurse input to get a clear picture of a study's patient burden to help sponsors positively impact study recruitment and retention
- » Parexel proactively seeks opportunities to address the needs of commercial stakeholders early and build a better value story
- » Our regulatory experts incorporate guidance to address agency requirements from a patient-centric perspective



»»» Here's a snapshot of our Patient Innovation Center services



 <p>Pre-study</p>	<p><b>Study design</b></p> <ul style="list-style-type: none"> <li>› Patient-Centric Protocol Optimization (PCPO)</li> <li>› Regulatory guidance</li> </ul>	<p><b>Comprehensive information</b></p> <ul style="list-style-type: none"> <li>› Patient education around trial designs and participation</li> <li>› Social media communication and online presence across all phases</li> <li>› Animated consent support</li> <li>› Clinical Nurse Educator (CNE) team</li> </ul>
 <p>During study</p>	<p><b>Visit burden</b></p> <ul style="list-style-type: none"> <li>› Virtual trials/decentralized trials</li> <li>› Patient-Centric Protocol Optimization (PCPO)</li> <li>› Home nursing</li> <li>› Sensor integration (remote data collection)</li> <li>› Managing direct-to-patient shipments of drugs, sample kits, and medical devices</li> <li>› Patient Advocacy Group engagement</li> </ul>	<p><b>Ongoing trial engagement</b></p> <ul style="list-style-type: none"> <li>› Patient-reported outcomes</li> <li>› Clinical Nurse Educator teams</li> <li>› Virtual trials/decentralized trials</li> <li>› Virtual trials/direct-to-patient studies</li> <li>› Patient transportation support</li> <li>› Development of trial participant appreciation programs</li> </ul>
 <p>Market access and beyond</p>	<p><b>Evidence generation</b></p> <ul style="list-style-type: none"> <li>› Managed access programs</li> <li>› Patient-centric research methodology such as registries</li> <li>› Leverage real world data to reduce patient burden</li> <li>› Patient-reported outcomes</li> <li>› Patient advisory boards</li> <li>› Payer communications</li> </ul>	<p><b>Patient access and support</b></p> <ul style="list-style-type: none"> <li>› Patient advisory boards</li> <li>› Managed access programs</li> <li>› Clinical Nurse Educator teams</li> <li>› Medical Information Call Center (MICC)</li> <li>› Patient thank you cards and lay study results summaries</li> <li>› Integration of health economic endpoints to understand impact on patients</li> <li>› Bridging program strategies for trial participants prior to marketing authorization/availability</li> <li>› Sharing genetic information back with trial participants</li> </ul>

**Study implementation**

Our patient-centric focus ensures a pragmatic approach to study implementation to reduce patient burden.

We offer a range of services, from the very simple, like supporting patients with clear and simple consent support materials, all the way through to fully virtual trials, where every aspect of the study is delivered to patients in their own homes. Each solution is bespoke to the needs of the particular patient population, the aims of the study, and the geographical nuances. Experts from the Patient Innovation Center and key functions across the organization collaborate to achieve a balance between simplifying the patient journey and maintaining the scientific integrity of the study to ensure the most appropriate strategy is deployed.

**Patient Access**

As the patient's study involvement comes to an end, we deploy a closure plan to help them feel valued and to understand next steps. This includes the provision of lay trial results summaries, as well as a thank you card to show appreciation for their efforts. It can also include ways to transition them to a post-study treatment plan.

Throughout development and beyond, we support the identification, development and communication of evidence to demonstrate improved patient outcomes and product value. These services help to accelerate market access so that patients in need can benefit from innovative new products sooner.

Through our Managed Access Programs, we also facilitate early access to promising new medicines for patients with unmet needs.





»»» We take an end-to-end view to make it easier for patients to participate in your clinical development program

By supporting patient access to and experiences in clinical trials, the Patient Innovation Center sees benefits including:

- » Increased likelihood of launch
- » Enhanced patient experience
- » Positive perception of your company and the wider industry
- » Improved trial performance
  - Faster enrolment
  - Better retention
  - Fewer protocol amendments
- » Smarter development
  - Accelerated regulatory approvals and access
- » A better product value story for Payers
- » Patients who are more likely to speak positively about their experience, recommend clinical trials to others, and even participate again



# Your Journey. Our Mission.®

»»» We're always available  
for a conversation

To learn more about our Patient Innovation Center,  
please contact:

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