

A woman with curly hair is sitting on a brown couch, smiling. She is wearing a green button-down shirt. In the foreground, a white dog is lying on the couch. The background shows a window with red curtains. The image is part of a collage with white geometric shapes.

parexel®

The future of
clinical trials is now

Decentralized Clinical Trials

»»» Changing what's possible today for tomorrow

Whatever challenges the world may throw at us – now, and tomorrow, Parexel's Decentralized Clinical Trials represent an opportunity to rethink and refresh how research studies are conducted, while keeping the patient at the heart of this emerging paradigm. Developed within our Patient Engagement team our flexible Decentralized Clinical Trial solutions provide both fully virtual and hybrid options.

With more than 160 Decentralized Clinical Trials already underway or complete and experience in excess of 200 remote patient engagements strategies, Parexel leads the way as a prepared partner to the industry. Our Decentralized Clinical Trials combine in-house expertise and patient/caregiver insights with the latest technologies to create bespoke strategies that can help you meet your goals. From study design through execution, we'll help you identify and manage all technology requirements. Together, we can help ensure treatments get to the patients who need them most by making it easier for diverse populations and geographies to access research.

*With Heart*TM





»»» Leading the industry by engaging patients in Decentralized Clinical Trials

160+

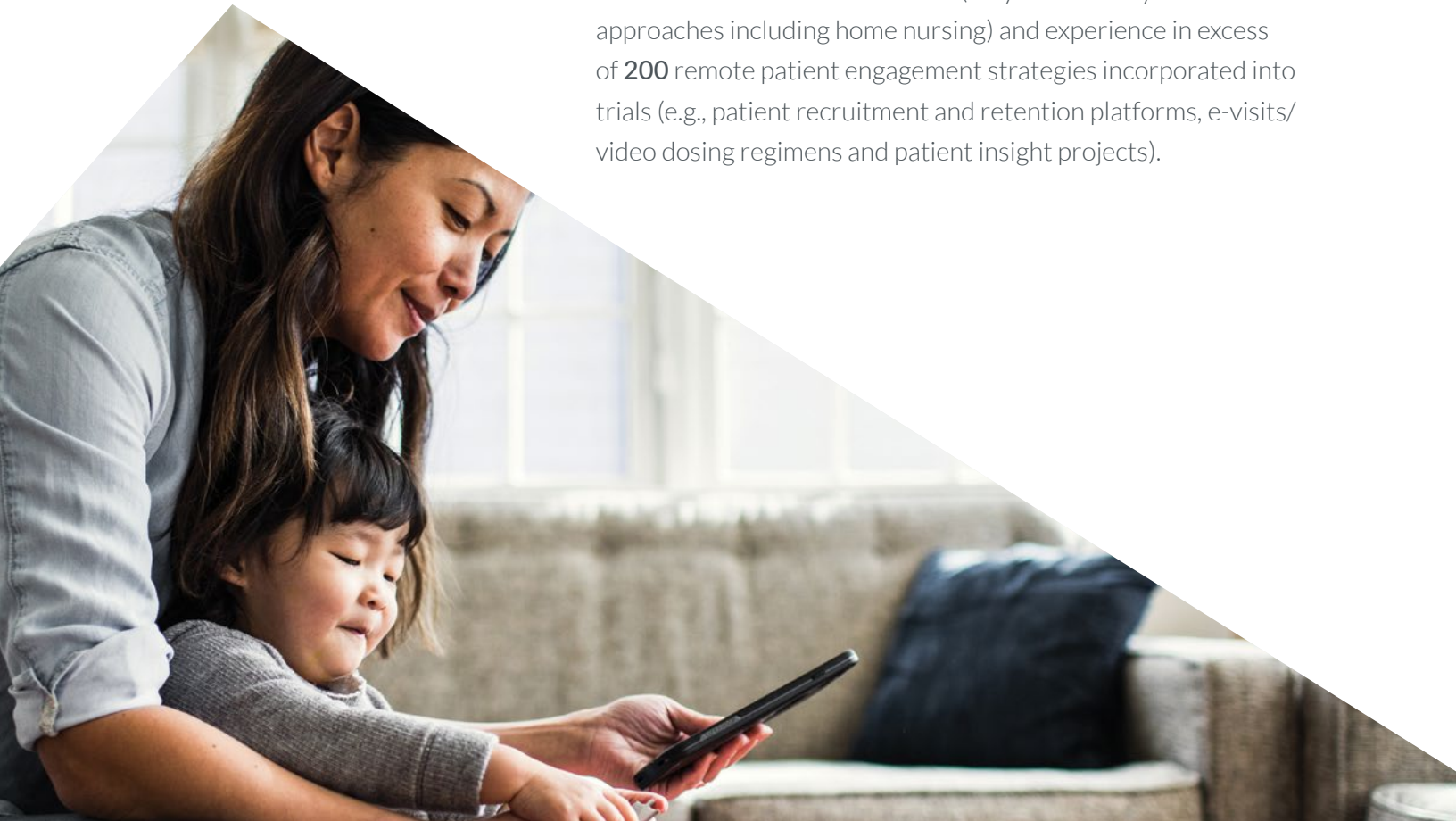
Decentralized
Clinical Trials

200+

Remote Patient
Engagement Strategies

Central to navigating a dynamic research landscape is the ability to harness and apply patient insights. This approach, along with global expertise in understanding the ever-changing regulatory environment and the skills necessary to access and apply fit-for-purpose data, makes Parexel a leader in Decentralized Clinical Trials. All these elements, combined with the expertise of our Patient Engagement team and “best-in-breed” technologies, are essential to creating Decentralized Clinical Trial designs that work for you and can be practically deployed as part of your overall clinical development and market access strategy.

By bringing the trial to the patient’s home – with the help of home trial support, telemedicine capabilities, direct-to-patient drug shipments and more – we are minimizing recruitment and retention barriers. Our experience includes more than **160** Decentralized Clinical Trials (fully virtual or hybrid approaches including home nursing) and experience in excess of **200** remote patient engagement strategies incorporated into trials (e.g., patient recruitment and retention platforms, e-visits/ video dosing regimens and patient insight projects).



This allows us to manage and deliver a wide range of fully virtual and hybrid approaches to Decentralized Clinical Trials while also offering important supporting capabilities:

 **250+**
direct-to-patient shipments

 **300+**
patient apps/eCOA platforms

Increasing the likelihood of launch with patient-centric trials

Drugs developed using patient-centric designs are 19% more likely to launch – 87% versus 68% for drugs developed without this approach. And, they take less time to recruit the first 100 participants, too – 4 months versus the all-trials average of 7 months.¹




19%
more likely
to launch



3 months
faster to recruit
first 100 participants



1. The Economist Intelligence Unit. The Innovation Imperative.
Available at: <https://druginnovation.eiu.com/> Accessed January 2020.



››› Combining expertise, and the latest technology, for real-time data delivery and vital patient insights

Connected devices, like wearables and sensors, can make it easier to collect real-time clinical data readings while enabling patients to communicate with study personnel from home. Parexel has focused on integrating the latest technological advancements and establishing key partnerships with expert providers to be able to identify the right devices and applications for integration into your study.

Working with your team, Parexel is ready to manage the following:

- › Identifying and recommending the right connected devices
- › Engaging and coordinating vendor relationships
- › Evaluating technology for integration to make sure clinical trial objectives, endpoints, and associated measurements or assessments can be done correctly
- › Validating data
- › Integrating data
- › Operationalizing day-to-day activity and oversight
- › Decommissioning upon study completion

»»» Minimizing the patient burden while collecting accurate, real-time data



Case Study

A Decentralized Clinical Trial to evaluate the efficacy of a drug intended to improve nighttime sleep in pediatric and adolescent patients with a rare disorder.

The challenges:

- › Minimizing the burden of study participation for patients and their families
- › Long-term collection of sleep data in a manner that was not intrusive for patients and their families

The solution:

A hybrid approach, combining:

- › Just three in-clinic visits
- › Virtual visits
 - at-home nursing
 - sensors: child-friendly actigraphy watches to collect quality sleep data in a non-invasive way
 - direct-to-patient drug shipments
 - e-diaries

Outcomes / findings:

- › Successful recruitment, pre-screening, and enrollment of patients from different regions—some living >150 miles from the investigative site
- › Implementing patient-centric approaches resulting in improved participation, retention, and compliance
- › Feedback from patients and their families that they truly enjoyed the hybrid approach; as the trial lasted 2 years, they would not have been able to participate if they had to travel to the clinic more frequently
- › Actigraphy watches and e-diaries gave the investigator real-time insight into patients and the ability to identify immediately if data were missed or there were any issues
- › Families enjoyed working with the at-home nursing vendor, who offered flexible visit dates and times so as not to interrupt the families' daily schedules
- › Effective coordination of multiple site visits, at-home visits, external vendors, and new technology solutions to provide an innovative approach that was well-received by patients and their families





»»» Optimizing protocols around patient insights

Our Patient Engagement team helps to put patients first through the use of global patient advisory boards and our Patient Insights methodology. We study the way patients talk about their disease and treatment options, elicit direct feedback from patients and caregivers, and consult with site staff to understand what is important to them and the challenges they face. This enables us to design targeted decentralized trial strategies based on the needs and preferences of patients that reduce the burden of participation, thereby speeding up patient enrollment and supporting retention.

»»» Reducing the patient burden can drive more engaged patients and higher study retention

Parexel's Decentralized Clinical Trials take all or part of the trial to patients in their home, while working in partnership with investigative sites. By doing this, we reduce the geographical, practical, and financial barriers that can prevent patients from participating or staying in a study. This leads to more engaged study participants and higher retention rates.



Geographical

bringing more of the trial to the patient through at-home nursing and technologies



Practical

reducing the demands on patients'/families' time that can prevent study participation



Financial

minimizing travel, accommodation and subsistence requirements



››› Moving to another level of site collaboration

Parexel was recently recognized for its high-quality service by CenterWatch in its Global Clinical Trial Site Relationship Benchmark Survey. Parexel ranked one of the top three CROs among attributes most valued by sites and received “Excellent” ratings on many key performance attributes, including:

- › Well-trained monitors/clinical research associates (CRAs)
- › Organization and preparedness
- › Easily accessible staff maintaining open communication

As sponsors continue bringing many components of studies directly to patients in their homes and in their communities, Parexel seamlessly collaborates with sites to make the process as efficient as possible. As the pioneer in designing and delivering Decentralized Clinical Trials, Parexel may offer sites more study opportunities, wider access to diverse patient populations in their region and reduced dropout rates due to remote patient engagement options. In turn, Parexel can design more effective protocols based on valuable site input about their patients. And, together, Parexel and its site partners are even better poised to improve the overall study experience for patients and sponsors.

We ask:



Which elements of participation may patients/families find challenging?



Does the patient need to attend a site visit for this part of the trial?



Can we reduce the length of time site visits last?



How can we best communicate with patients/families?



Which elements of the trial could work at home?



Case study

A Decentralized Clinical Trial geared to collecting and transmitting clinical trial data with mobile technologies – an exploration of six sensing devices (for monitoring blood pressure, activity levels, asthma, oxygen, blood glucose, and weight) as study endpoints.

The challenge:

- › The need to
 - compare remote sensor device data with standard clinical assessments
 - test medical devices simultaneously
 - have an end-to-end solution to collect, transmit and visualize data

Results:

- › Transmission with minimal/no data loss
- › Lessons learned converted into standard practice
- › Devices used in-clinic with minimal help
- › Some devices can be applied beyond exploratory phase



››› The future of clinical trials is now

By changing what's possible today, Parexel's Decentralized Clinical Trials are providing a future for patients tomorrow.



With Heart™

>>> We're always available for a conversation

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