

Bringing clinical trials to patients with the decentralized model

Rosamund Round, Vice President, Patient Innovation Center
Parexel®

Before the pandemic, Parexel was experienced at executing decentralized clinical trials to improve patient access and experiences. Since, COVID-19, which has had a huge impact on global clinical trials, sponsors, CROs, sites, and patients have pivoted to adapt to a more home- or community-based approach. More than 100 DCTs later, Parexel is at the forefront of industry change.

“Everything we do is built around the patient and caregiver to make participation as easy as possible.” says Rosamund Round, Vice President of Parexel’s Patient Innovation Center. Central to navigating the dynamic research landscape is Parexel’s ability to harness and apply patient insights during DCT planning to ensure that every part of the strategy is formulated with the patient in mind. This approach, along with expertise in global regulatory requirements, technology implementation, and operational deployment, makes the company a leader in decentralized clinical trials.

Rosamund and her team address every aspect of the clinical trial experience keeping the patient’s perspective top of mind – from financial considerations to geography. How far does a patient live from a site? Can the patient afford to take time off of work or afford the transportation? Are there childcare issues?

“These are the everyday life considerations that people think about when they join a trial, aside from purely the medical aspect,” Rosamund says. “We talk to patients and caregivers from the start to ensure we truly understand what the biggest issues are for them and how we can help. The rest of the strategy is built from there. Working this way can also positively impact research access for those who may otherwise find it challenging to participate in research. And, with thoughtful and collaborative planning, a positive experience can also improve compliance and reduce dropout.”

According to Rosamund, by bringing a trial to a patient’s home – with the help of home healthcare

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support, telemedicine and sensors, direct-to-patient drug shipments, and more – she and her team are minimizing recruitment and retention barriers. “All of these elements, combined with the expertise of our Patient Innovation Center and best-in-breed technologies, are essential to creating DCTs that work for patients and can be practically deployed as part of a sponsor’s overall clinical development and market access strategy.”

Rosamund and her team work through the minutiae of every element of the patient experience from start to finish, even down to which charger goes with what device. “In decentralized trials, it’s important to consider the varying comfort levels of participants when it comes to technology and having healthcare staff in their home,” she says. “We want to support patients and their caregivers to ensure they understand how the technology or wearable works, what happens when the home nurse comes to visit, and how to manage the delivery of their medications. If need be, through our Patient Navigator Service, they can speak to a real person on the end of the phone who can help them with anything they need, from simple things like organizing a taxi or rescheduling an appointment, support for their first home-based visit all the way through to counselling for the participant and caregiver if they are struggling with their mental health.”

This intense attention to detail will no doubt come into play with increasing frequency as the industry continues to move toward a hybrid or fully decentralized model. A new report from the

DCTs & digital working hand in hand

With sponsors sitting anywhere on the spectrum from being new to the world of DCTs through to adopting at scale, Parexel’s DCT Consultancy service provides guidance and partnership for success. They are ready to advise on the following:

- › Pipeline review for DCT target identification
- › DCT study design
- › Service identification e.g. home nursing, patient recruitment, technology solutions
- › Budget planning
- › Regulatory acceptance of DCT services
- › Training
- › Patient insights
- › Pandemic risk mitigation

life-science data analytics company GlobalData has found that 67% of the 150 healthcare experts surveyed during the summer of 2020 plan to work in the DCT model. This is a direct result of

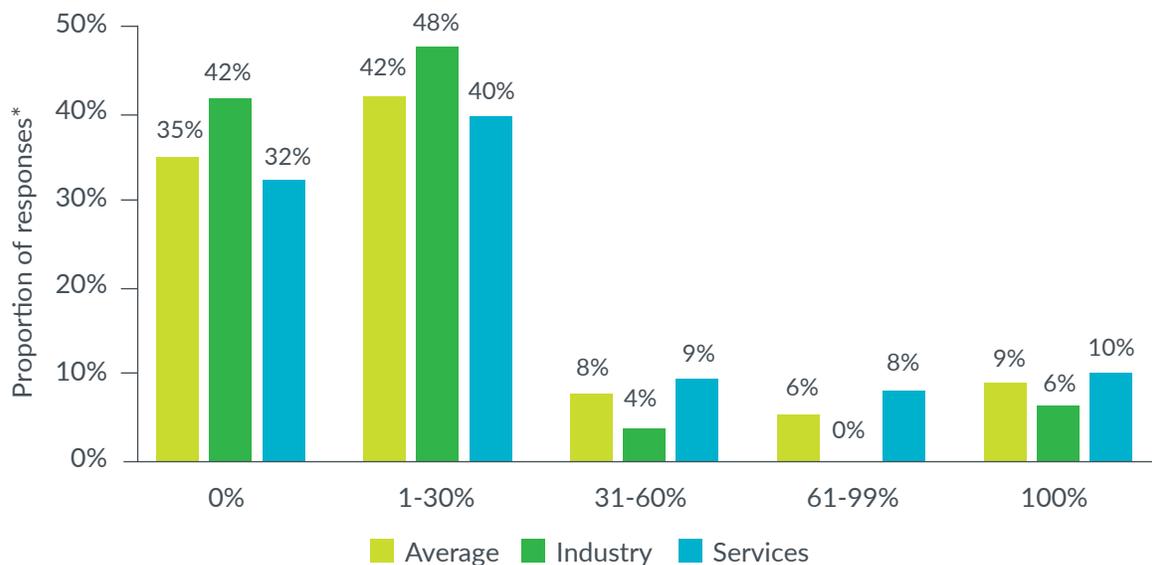
COVID-19, during which many utilized home visits, medication deliveries, and telehealth, which was actively encouraged by the FDA and to ensure patient safety, trial continuity, and data quality of trials during the pandemic lockdown.

Through Parexel's discussions with physicians Rosamund says they have heard that, contrary to what many thought of telehealth pre-pandemic, have actually had a very positive experience. Compliance has increased due to reduced patient burden, real human connections have still been possible and they report having unique insights into patients' lives outside of the traditional site model.

"My vision is that patients have choices so that research participation is as easy as we can possibly make it for them," she says. "In recent months, people have seen what's possible and we need to meet their expectations in the long term beyond the pandemic to enable clinical trial access for those who need it the most."

Rosamund is confident that whatever challenges the world may throw at them – now, and in the future – 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 exciting paradigm.

Current trials featuring decentralized/virtual features



*Respondents indicating not applicable are removed from the analysis

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