The impact of COVID-19 on drug development for rare disease and oncology

REGULATORY & ACCESS

The full effect of the COVID-19 pandemic, particularly on the search for rare disease and oncology treatments, is still uncertain. What we do know is that patients diagnosed with these conditions simply cannot afford delays. With a patient-centric approach and guided by the best minds in the industry, Parexel has a broad perspective to help sponsors, regulators, and patients during this difficult time. We have learned a great deal over the past few months about trial conduct, patient recruitment, risk mitigation, the pace of regulatory approvals, and how patients are faring. And now we want to share this information with you.

Has there been a pause in clinical trials?

Overall, rare disease and oncology studies that had started prior to the pandemic have been largely uninterrupted. At the start of the pandemic, some sponsors did delay new trials and limit patient recruitment to protect patient safety and understand how to effectively mitigate risks. Today, sponsors have mostly restarted enrollment and begun new studies, usually in locations where there is less transmission of the virus.

What adjustments have sponsors made in trial conduct?

They have reduced in-person participation as much as possible. Physician consultations are mostly being done virtually or over the phone. Patients are traveling to sites only when necessary, and instead doing whatever they can at home or at a nearby facility that offers, for example, drive-by blood draws. Family members are generally restricted from accompanying the patient for in-person visits.

The biggest challenge for sponsors is to determine where they can safely open trials and where patients will be willing to attend. Relocating sites to areas where there are lower rates of virus infection is essential to mitigate risk, but these locations may not be as accessible for trial patients.

Have regulators issued guidance regarding trial conduct and evidence?

Sponsors and site personnel have had countless questions about modifying trial conduct and gathering evidence in ways that are acceptable for regulatory submissions. The Food and Drug Administration (FDA) and its global counterparts understand the immense challenges that sponsors and patients are grappling with and have issued guidance throughout the pandemic. The FDA's Oncology Center of Excellence (OCE) published "A Message to Patients With Cancer and Health Care Providers About COVID-19," which emphasizes that the agency is working diligently to address critical issues and identify priorities.

Are regulatory submissions and drug approvals continuing?

Yes. In its work supporting sponsors in regulatory submissions, Parexel has seen that regulators are as engaged as ever, reaching out proactively to help sponsors minimize risks and keep trials running. They are having discussions with colleagues globally to craft a unified approach to mitigating the challenges. They are fielding calls from patients about expanding access to investigational drugs. They are researching use of real-world evidence to help reduce the burden on sponsors, patients, and sites. Finally, regulators have not stopped. For example, the FDA has approved 40 NME/NBEs through September 4, of this year. They appear to be on a pace to easily surpass the 48 NME/NBEs approved in 2019.[1]

1 www.fda.gov

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How are patients coping with these trying circumstances? Are they still participating?

Patients' experience in navigating the healthcare system during the pandemic has been difficult. Some examples include travel complications, the emotional strain of isolation, and uncertainty about continuity of treatment. Newly diagnosed patients in particular have difficulty determining which centers are open and have more challenges to get specialist referrals.

Yet, in our observation, trial participants are generally adapting to these circumstances. Most understand that there is a critical need for better understanding of their condition and want to contribute to research that will help them and others that are in a similar position. They tend to consider these challenges as hurdles that must be overcome, and there is little hesitation to continue in the trial.

Does Parexel have any specific recommendations for sponsors to make life easier for patients?

Our best advice is to reach out to the patients themselves. Partner with them to understand their needs and concerns. Listening can also lead to valuable insight into what is important to them. This can help determine how to adapt clinical trial procedures to encourage patient engagement and protect patient safety during the pandemic, which might include home visits, telemedicine, remote blood draws etc.

Also, work with the patient advocacy groups. These groups tend to be underutilized and can be a tremendous resource. Many of these groups maintain registries to chart the history of the disease and document patients' response to existing therapies. In fact, both the FDA and the European Medicines Agency have used registry data to better understand the history of treatment when a randomized trial is not feasible, as long as the data has been collected in a way they can accept.

How Parexel can help

Parexel's Regulatory & Access consulting organization brings together regulatory and market access consulting expertise to help our clients address the requirements of regulators, providers, payers, and patients holistically. This accelerates timelines, reduces the risk of delays, and improves efficiency. Our staff includes more than 1,000 consultants, including ~100 former regulators / HTA assessors, with localized knowledge covering 110 countries. This is how we make a difference—With Heart.

Parexel International Corporation
275 Grove St., Suite 101C, Newton, MA 02466
+1 978 313 3900
info@parexel.com

Offices across Europe, Asia, and the Americas
www.parexel.com