How to accelerate oncology clinical trials through site relationships and patient insights

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All stakeholders benefit when patients and their insights are at the heart of every aspect of clinical development. However, putting that approach into practice requires knowledge of the unique needs of cancer patients. Parexel has accrued that knowledge through ongoing initiatives that have strengthened its relationships with the sites, investigators and research nurses who know patients best.

Scientific breakthroughs mean there are a growing number of innovative investigational oncology agents with the potential to improve outcomes. Yet, while progress is a boon for patients, it also creates competition for trial subjects and high quality, high enrolling sites. In managing the situation, Parexel evaluates clinical trials through the lens of the patient.

As the disease is often aggressive, frequently associated with symptoms resulting from progression, the window in which to choose and initiate treatment is short for many oncology patients. For almost all patients with advanced stage cancer, investigational therapies remain the best option due to the limited efficacy of approved treatments. Many oncology patients have symptoms that impact their performance status and need effective therapies to feel better.

Oncology patients share unique relationships with their doctors that develop over years. The stakes are high. Managing patient care is a team effort and the bonds are intense, leading patients to have a strong desire to remain under the care of their local oncologist and a willingness to be guided by their recommendations. Patients, as well as family members, caregivers and others who are indirectly affected by the disease, trust their oncologists. When it is necessary for a patient to be referred to an academic medical center for a clinical trial that is not available at their local site, an important new relationship is established with the academic site investigator. The patient's trust in this investigator's recommendations remains a critical part of the decision-making process regarding clinical trial participation.

Forging site relationships

The importance of the oncologist-patient relationship makes it critical for CROs to forge strong ties to sites, including both community-based and academic centers. Those ties enable CROs to get early feedback on study design, improve recruitment strategies, understand what sites need to implement solutions and technology, and to learn how to make studies less burdensome for patients.

Patients and oncologists are joined in a battle against a serious illness. CROs have the privileged ability to join that fight, providing the needed tools to make the journey easier for all stakeholders, not more complicated. CROs can facilitate research as a treatment option for all patients, regardless of their proximity to an academic research institution.

Those considerations led Parexel to launch the Site Alliance program more than eight years ago. The program builds upon long-standing relationships with the most active research institutions, enabling Parexel to work consistently with leading sites and, in doing so, realize benefits for all stakeholders.

Through the Alliance program, Parexel has worked to understand site needs, processes and capabilities before selection and activation of a specific project. Parexel offers guidance on how to accelerate start-up and rapidly access the right patients. In collaboration with oncologists, Parexel works to bring trials closer to patients and identify ways to successfully partner in clinical research.

This initiative has led Parexel to establish master confidentiality and services agreements with sites. Such agreements enable Parexel medical directors to get early feedback on study design from investigators, many of whom are former colleagues and key opinion leaders, and share information about upcoming, cutting-edge trials that oncologists want for their patients.

Parexel regularly engages with sites to provide access to innovative umbrella, basket, platform, and adaptive design trials, facilitating discussions about investigative team structures and ensuring appropriate processes and resources are in place. This communication with sites and investigators frequently leads to prioritization of the trial of interest, often from a broad menu of early-phase studies available at the site.

Overall, these relationships have allowed Parexel to drive its patient and site-centric strategy, facilitate access to investigator insights and identify ways to be better partners in clinical research for the benefit of patients. By developing strong ties, Parexel and its partners can anticipate and proactively manage issues before they arise and remove roadblocks to make trials less burdensome to sites and patients.

Accessing patient insights

The Site Alliance is part of a broader effort at Parexel to collect and utilize patient insights. Parexel has created dedicated patient advisory groups in each geographic region. During the COVID-19 pandemic, these groups discussed ways to ensure patient safety, support trial continuity and overcome logistical challenges. Parexel was the first top-tier CRO to hire a Chief Patient Officer.

Parexel also performs patient burden analyses for almost every project. The analyses evaluate the care pathways, barriers to participation and other factors critical to the patient experience. Burdens can vary by geography and culture, making local insights key to successful study operationalization.

Nurses often have unique insights into patients and their burdens. Recognizing that, Parexel formed a nurse advisory panel in the U.S. to gather the views of these patient advocates. The success of the panel, and recognition of the need for local insights, spurred work to create similar bodies in Europe and Asia Pacific.

Patient insights directly benefit all stakeholders. Such insights have shown sponsors how an investigational drug will be received and used in the real world. Other components of feedback have, for instance, driven changes to the frequency of in-person office visits, pharmacokinetic blood draws and on-treatment biopsies, enabling sponsors to obtain the essential data while minimizing patient burden.

By putting patients at the heart of everything we do, Parexel makes trials more appealing to oncology patients, improves recruitment and retention, and thereby delivers benefits to all stakeholders in order to optimize the clinical trial experience.

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