parexel

Building oncology trials for those who need them most

Oncology Center of Excellence

For families facing cancer, new treatments can't wait

Last year alone, there were 17 million new cases of cancer and almost 10 million cancer deaths reported worldwide,[1] not to mention the countless families left in its wake. Each of these people exemplify why we work with urgency – to provide hope to those who need it. Every day, we are united in our drive to develop more effective and better targeted therapies for people with cancer.

Although there have been recent breakthroughs in targeted therapy, immunotherapy, and cellular therapy, only a small portion of these agents make their way through the long and winding evaluation and approval process. And those that do often take a frustratingly long time. Time that patients, and their families, simply don't have. That's why we give it our all to advance research around patients – so we can more quickly develop the treatment they need.

A clear need for a new approach

As medicine advances, it's more important than ever to set cancer breakthroughs up for success. This starts with putting patients at the heart of clinical development planning.

A 2018 study, *The Innovation Imperative: The Future of Drug Development* written by the Economist Intelligence Unit and commissioned by Parexel, found four specific areas of innovation that most impact drug development based on metrics of trial efficiency, likelihood of drug launch from Phase II or III, and formulary or market access. These include adaptive trial designs, patient-centric trials, precision medicine trials, and real-world data (RWD) trials.

In fact, the greatest benefit from these four innovative approaches was seen in cancer research where incorporating even one of these approaches increased the likelihood of launch from 53% to an average of 86%.

Unfortunately, only

6%

of oncology trials are making use of these innovations.

1. Worldwide cancer statistics. Cancer Research UK website. https://www.cancerresearchuk.org/health-professional/cancer-statistics/worldwide-cancer. Accessed May 22, 2019.

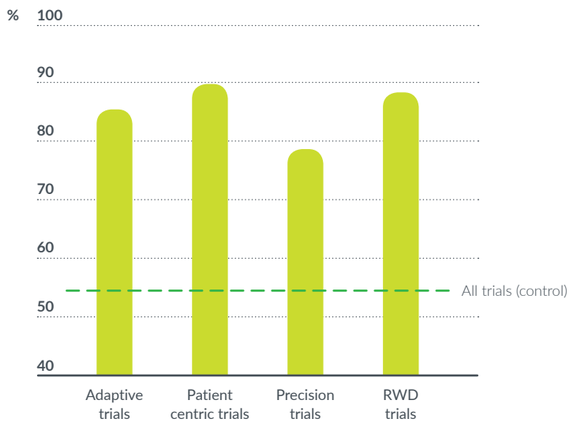
With Heart

The benefits of adopting innovation

The absolute benefits of incorporating innovations, such as adaptive trial designs, patient-centric trials, precision medicine trials, or RWD trials, with respect to the likelihood of oncology drug launch from Phase II or III, ranged from 26% to 37%, depending on the area of innovation.

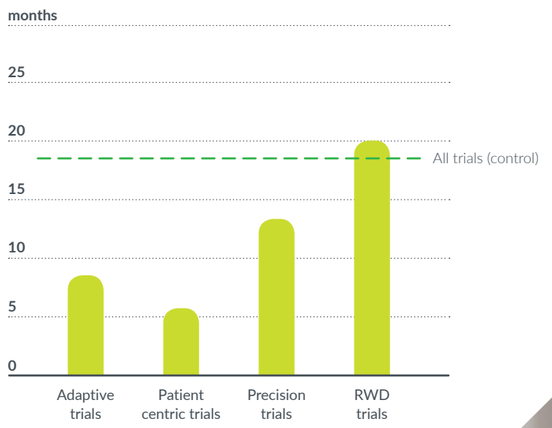
Of course, trials cannot happen without participants. By adopting these approaches, the average time to recruit 100 patients was improved by 37% – down from 19 to 12 months.

Oncology Phase II and III
Likelihood of launch with innovation



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

Oncology trial efficiency with innovation
Time to recruit 100 patients



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

Oncology Center of Excellence – focused on delivering breakthroughs

When it comes to getting promising therapies to those who need them, our dedicated people, proven processes, impactful innovative approaches and culture of caring, all work together to ease the journey for patients, for investigators, and for you. Our Oncology Center of Excellence (CoE) combines our new early advisory service of medical, regulatory, genomics/biomarkers, and biostatistics experts with the support of an experienced multi-disciplinary team and key technology platform partnerships to help bring your breakthrough treatments to market faster, because we know patients are waiting for them.

The Oncology CoE is about more than just sharing our years of experience and global expertise. It is about providing early and ongoing regulatory, scientific, medical, strategic and operational advice throughout the life of a project to help ensure that every aspect of the research process is optimized for success.

Connecting you to the knowledge you need

When you put your trust in our Oncology CoE, you're plugging into a network of industry leaders and capabilities ready to assist you on the varied and nuanced aspects of your oncology program, to optimize and simplify development and design.

Oncology Expertise:

- Recent key medical oncologist/ hematologist and ex-FDA appointments
- 50+ physicians with oncology expertise
- Expertise in Asia-Pac, including China and Japan
- Experts in innovative study designs
- Clinical Pharmacologists and Quantitative Clinical Development (QCD) Scientists
- Virtual Trials – hybrid and fully virtual
- In-house medical imaging
- Integrated medical writing team
- 1,000+ project staff with oncology expertise
- Leader in clinical trial supplies and logistics

Oncology Experience over last five years:

- 425+ clinical projects
- 2,350+ cross-functional projects
- Enrolled over 70,000 patients
- Worked with 23,000+ unique sites
- 200+ clinical projects in Asia-Pac
- 490+ oncology medical imaging projects

Our breadth of expertise in oncology

We put all we've got into clinical development of cancer therapies because for some patients, it's all they've got.

parexel® Oncology Center of Excellence

Early Advisory Service

- Simplified and expedited access to Parexel's global breadth and depth of experience and expertise across all phases and aspects of development
- Core team of regulatory, medical, operations, biostatistics and genomics backed with an experienced cross-functional team

Portfolio Management and Asset Valuation

- Portfolio optimization
- Strategic consulting
- Partnering models
- Mergers and acquisitions
- Asset valuation and indication prioritization
- Asset transfer support
- Early evidence review
- Integrated development strategy and planning

Smart Design and Innovation

- Strategic feasibility
- Adaptive designs
- Medical/Scientific optimization
- Patient centric protocol optimization
- Real World Evidence (RWE)
- Precision medicine trials
- Cell therapy (Car-T, Gene)

Regulatory Support and Consulting

- A team that includes former regulatory officials
- Experience working with the global regulatory authorities including: FDA, EMA, MCC, MHRA, PMDA, NPMA, BfArM, and PEI

Predictable Delivery

- Ranked #1 among global CROs for Phase II/III service provider leadership by 2019 ISR report
- Risk assessments
- First-in-class start-up
- Clinical trial supplies and logistics (CTSL)
- Site alliances
- Integrated medical writing services
- Flexible outsourcing models

Patient Innovation Center

- Virtual trials
- Tailored patient recruitment tactics
- Site engagement portal
- Relationships with patient advocacy groups and professional societies

Robust Medical Expertise/Experience

- Recent key medical oncologist/hematologist and ex-FDA appointments
- Academic clinical experience and ongoing relationships with investigators and KOLs
- Expertise in early phase, targeted therapies, immuno-oncology, and cellular therapies across multiple therapeutic indications
- Expertise in Asia Pac, including China and Japan

Technology and Medical Imaging

- In-house Imaging
  - irRECIST
  - Lugano criteria
- Perceptive® Cloud
- Risk-based monitoring
- Partnerships with best-in-class providers

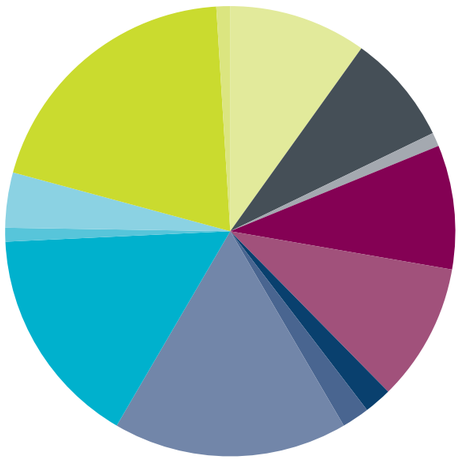
Biotech

- Dedicated teams with deep biotech experience
- Flexible, scalable approach
- Expertise in navigating investment and fundraising options

In-house imaging solutions

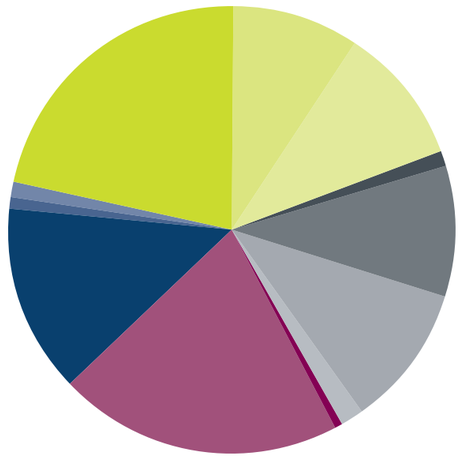
We are the only CRO with in-house medical imaging capabilities and can offer a full range of imaging services appropriately scaled for study phase, from assessment of preliminary efficacy in early phase to blinded independent central review in registrational studies. Our centralized imaging solutions are powered by an integrated suite of advanced technologies which facilitate intelligent workflows and ensure quality data.

Care that spans all cancer types



Parexel oncology/hematology cross-functional projects past 5 years

- Solid tumors, 20%
- Other, 1%
- Benign hematology, 9%
- Breast cancer, 8%
- CNS cancer, 1%
- Gastrointestinal cancer, 9%
- Genitourinary cancer, 10%
- Gynecologic cancer, 2%
- Head and neck cancer, 2%
- Hematologic malignancies, 17%
- Lung cancer, 16%
- Sarcoma, 1%
- Skin cancer, 4%



Parexel oncology/hematology clinical projects past 5 years

- Solid tumors, 22%
- Benign hematology, 9%
- Breast cancer, 10%
- CNS cancer, 1%
- Gastrointestinal cancer, 9%
- Genitourinary cancer, 10%
- Gynecologic cancer, 2%
- Head and neck cancer, 1%
- Hematologic malignancies, 20%
- Lung cancer, 14%
- Sarcoma, 1%
- Skin cancer, 1%

Smart partners for intelligent delivery

We are committed to helping clients bring cutting edge therapies to treat and potentially cure patients with cancer. That's why we develop strong relationships with best-in-class partners pushing the boundaries of what technology can do. With innovations like artificial intelligence and machine learning, we can equip you with the latest tools to drive efficiencies in study design, site selection, recruitment, medical imaging, and more.

Perceptive® Cloud

Created in partnership with Microsoft, Perceptive® Cloud combines our industry expertise with intelligent cloud services invested in global compliance certification and enterprise-grade security to streamline processes, optimize workflows, and promote collaboration.

SHYFT Analytics

By leveraging SHYFT's clinical data analytics platform, we've boosted data-linking and real-world evidence (RWE) capabilities. This allows you to generate real-time insights for everything from strategic consulting and pivotal trial feasibility to late phase health economics and outcomes research with a much higher level of efficiency.

Datavant

Through our partnership with Datavant, we can connect you with secured de-identified healthcare data from a number of real-world and clinical data sources to enhance drug development and commercialization.

Longboat

We use Longboat's technology to enhance patient-centricity by providing an integrated clinical trial support platform for both sites and patients. This helpful platform provides visit reminders and other essential information to support the study team and patients on their journey.

Keeping patients at heart

When you engage with our Oncology Center of Excellence, we can help provide your oncology development with:

- Simplified access to our extensive experience in oncology drug development
- Improved study design and operational plans, which can help increase the likelihood of success
- Acceleration of study start-up timelines achieved through earlier engagement, programmatic asset management, and standardization
- Greater predictability and reduced changes in scope
- Improved interactions with regulatory agencies, which can positively impact your success rate with regulatory submissions
- Development and incorporation of evidence generation to quantify the value of an asset for market access

Your Journey. Our Mission.®

We're always available for a conversation

To learn more about our Oncology Center of Excellence, please contact: OncologyCoE@parexel.com

Parexel International Corporation
195 West Street, Waltham, MA 02451, USA
+1 781 487 9900
info@parexel.com

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

parexel®