Imaging-based endpoints play a valuable role in oncology clinical trials. Quantifying the size and number of tumors visualized by imaging provides insights into drug efficacy much faster than relying on traditional clinical endpoints such as patient survival.

Use of imaging as a surrogate endpoint can therefore be a powerful means of demonstrating unmet clinical needs and ultimately accelerating approval of a new drug.

Imaging endpoint assessments are highly dependent on measurement techniques, assessment guidelines, available technology tools and image reviewer expertise. It is critical to avoid introducing bias or variability, which can jeopardize the identification of true safety and efficacy differences among treatment groups.

**Key Benefits**

- Leveraging extensive, cumulative oncology experience:
  - Over 550 oncology global trials including 225 Phase III trials
  - 47 regulatory approvals
- Support and guidance from highly experienced team with intimate understanding of oncology-specific best practices and risk mitigations, ensuring regulatory buy-in prior to starting image analysis
- Holistic one-stop provision of oncology imaging, offering optimal value, convenience and efficiency
- Accelerated study start-up and efficient investigator selection process through utilizing proprietary oncology investigator database
- Reduced variability in acquired images and prevention of analysis discordance between investigative sites and centralized read

**Key Features**

- Full-service oncology model for entire spectrum of modalities from traditional CT/MRI all the way to cutting-edge photography
- Study design consulting, protocol development and assessment criteria guidance
- Integrated suite of advanced technologies to enable imaging visualization, analysis, tracking, reporting and export
- Comprehensive database of oncology investigators complete with historical performance data and trend reporting
- Site qualification and training including customized training programs targeting on-site, radiology and other trial staff
- Flexible read deployment model combining on-staff and subcontracted reviewers
- End-to-end support from a dedicated project team possessing in-depth oncology experience
- Specialist medical writing team for development of detailed image acquisition guidelines, charters and reviewer manuals
• Flexibility of choice between on-staff and subcontracted reviewers to offer combined benefits of rapid turnaround, reduced variability and sub-specialist focus

• Unique and sophisticated technology features that facilitate intelligent workflows and ensure quality data

• Total quality assurance for reliable and reproducible results through fully validated tools and processes

• Ongoing data reconciliation and medical oversight of analysis data to enable early detection of data integrity issues and proactive alerts of outliers

• Global footprint to enable around-the-clock image processing

Oncology Expertise

As a leading imaging provider for clinical trials, PAREXEL Informatics offers multiple solutions to standardize oncology imaging endpoint assessments. With PAREXEL, you get the knowledge and expertise accumulated from our experience of supporting over 550 oncology imaging studies. Representing over 50 percent of our engagements, oncology represents the largest component of our imaging business. When you work with us, you can be confident that you are working with a world leader in oncology imaging.

The structure and expertise of our global organization is aligned to adjust and scale imaging services to your needs. We have the specific expertise and flexibility that you should expect from your imaging partner for early phase, adaptive or exploratory imaging studies. In addition, we have the know-how to implement large late phase submission trials effectively and efficiently with rigor.

Another area of importance and prevalence is the evaluation of cardiac safety in oncology trials. We are able to facilitate your oncology and cardiac safety components in tandem to ensure efficiencies and convenience for you and your sites.

Experts

PAREXEL brings the world’s leading experts to your oncology imaging studies. Our in-house oncology imaging experts draw from their impressive clinical experience and imaging know-how to provide optimal medical support for your studies. Our team possesses intimate understanding of the regulatory requirements and includes George Mills, M.D.—Vice President of Early Phase Consulting.

Complementing the internal oncology imaging experts is a panel of renowned, independent scientific advisors including:

• Bruce D. Cheson, M.D.
• Matthew A. Barish, M.D.
• Mark Huberman, M.D.
• Gregory S. Karczmar, Ph.D.
• Max P. Rosen, M.D., M.P.H.
• Barry A. Siegel, M.D.
• Cheng Yang, Ph.D.

Criteria

The correct interpretation and application of published assessment criteria is essential to providing reliable response outcomes that will accurately reflect efficacy and will stand up to scrutiny by regulators. We have extensive experience supporting a wide range of standardized assessment criteria and can guide you to the right response assessment.
**Indication:** Solid Tumors

**Criteria:**
- RECIST 1.0 (2000)
- RECIST 1.1 (2009)
- Modified RECIST for HCC (2008)
- WHO criteria (1979)
- Modified WHO criteria (2005)
- PCWG2 criteria (2008) – Prostate Cancer
- Macdonald criteria (1990) – Glioma
- PET SUV and Metabolic Response criteria (EORTC 1999)
- Adjuvant setting criteria [study specific]
- Choi criteria (2004)
- DCE-MRI analysis

**Indication:** Lymphoma/Leukemia

**Criteria:**
- IWRC for NHL [Cheson et al. 1999 and 2007]
- NCI-WG for CLL [Cheson et al. 1996]
- Cheson Hallek (iwCLL 2008)

**Modalities**

PAREXEL Informatics has proven capabilities for supporting all of the standard modalities used by investigative sites for routine imaging of oncology patients. With a team of experienced in-house medical imaging experts, including several radiologists, an imaging physicist and a dedicated Exploratory Imaging Group, we are fully equipped and optimally positioned to support new and novel imaging methods.

**Standard Imaging Modalities for Oncology Trials**
- CT
- MRI
- X-ray
- DCE-MRI
- FDG and FLT-PET
- PET-CT
- Laparoscopic video
- Photography
- Bone scan

**Operational Excellence**

Guiding your project through every step of the process is a dedicated team of experts focused on meeting the specific requirements of your protocol. Consisting of a program director, project manager, medical director, medical writer and imaging research associates, and where needed external scientific advisors, the team is focused on delivering the highest levels of project rigor and quality service.

Our in-house medical imaging experts provide consultation on developing the imaging component of your protocol and the analysis design. We ensure a standardization of image acquisition, as well as collection and processing of all images in a central digital repository. Rigorous training and testing of reviewers is performed prior to the independent review. Independent reviewers will complete our training academy, a comprehensive three-step program that ensures effective medical quality control for the selection and management of reviewers for the independent review process. Our medical experts will also conduct ongoing quality checks of the reviewers’ case assessments and reports. These practices enable the independent and unbiased evaluation of images and ensure high-quality image analysis data.
Partnering with PAREXEL means access to our worldwide network of reviewers. Our Global Reviewer Operations group is focused on the management of both our on-staff and subcontracted reviewers. Our flexible reviewer model allows the freedom to choose between our in-house staff and independent reviewer network as well as experts identified by the sponsor.

To supplement training provided at investigator meetings, our seasoned experts can provide advanced on-site training customized to individual customer requirements. We also offer international training via webcasts for radiology and trial staff. Training materials such as CD-ROMs with content required for your investigator sites can also be produced. We can qualify the radiology departments of your investigator sites and confirm that all sites are able to acquire the images according to mutually developed standardized image acquisition guidelines.

Advanced Technology Tools
Our oncology solution is underpinned by an integrated suite of proprietary technology tools specifically designed to provide built-in expertise and rigor and are configurable to support the specific requirements of your protocol. With embedded analysis workflows and criteria rules to streamline the entire process, the combined applications provide superior, intuitive user experiences while ensuring total data quality:

• Advanced technologies to enable imaging visualization, analysis, tracking, reporting and export
• Tight integration of electronic case forms and image analysis application to simplify review workflow
• Unique analysis technology with embedded criteria rules to facilitate intelligent workflows and deliver error-free final product
• Advanced reporting solution for real-time access to imaging and trial data including Metrics Consortium Champion (MCC) “report card” metrics
• Measurement recording and updating to allow automatic calculations for the reviewer, as well as unidimensional, bidimensional and volumetric measurements
• Multiple review platforms including single radiology review, double reads with adjudication, global radiology review and combined radiology-oncology review
• Qualitative and quantitative analysis of PET images with SUV computations
• Integration with ClinPhone® RTSM (Randomization and Trial Supply Management) to facilitate real-time queries on patient statuses, enabling proactive site and patient management

Part of the Perceptive MyTrials® framework, enabling integration with clinical trial software applications to help users plan, design and conduct clinical trial programs in a single place.