Insight Paper

De-risking Medical Imaging in Solid Tumor Trials

Successful medical imaging in solid tumor trials requires the insight and expertise of professionals who are dedicated to providing imaging core lab services and have therapeutic experience, expertise in the modalities required to demonstrate safety and efficacy, and first-hand insight as to what global regulators will look for in your submissions.

Modalities, criteria, and regulators' expectations change frequently. Without the direction of imaging scientists who work day-in and day-out in clinical trial imaging, it would be difficult, if not impossible to keep track of and react to changes prior to study start and First Patient In.

A Look at Changing Regulations in Solid Tumor Research

Your imaging partner needs to be immersed in the scientific advances and regulatory changes that may impact the outcome of your anti-tumor treatment development program, as outlined in the following examples:

Example 1: Antibody Drug Conjugates (ADCs)

Advances in oncology precision medicine and therapy have increased the number of immune therapies and molecular-targeted agents for the treatment of most solid tumors. Although ADCs are one of the fastest-growing classes of cancer drugs in clinical development, they have been associated with the risk of pulmonary abnormalities, the most concerning of which is Drug-induced Interstitial Lung Disease (DI-ILD).

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As a result, regulatory agencies around the world are asking trial sponsors to monitor for ILD toxicity in clinical trials investigating ADCs for the treatment of cancers. High-resolution Computed Tomography (HRCT) is the gold standard for the detection and characterization of ILD and, when combined with clinical and laboratory data, provides a powerful method for accurate diagnosis.

Integration of radiology data with clinical and laboratory tests such as pulmonary function tests and review of this information by a centralized independent joint events committee consisting of expert clinicians provides a consistent and standardized way to adjudicate DIILD cases.

Example 2: Tumor-Infiltrating Lymphocyte (TIL) and CAR-T Therapies

Perceptive has experience supporting imaging trials in cell therapy and understands the evolution of imaging findings in patients undergoing such therapeutic intervention. This allows us to ensure appropriate guidance is documented in the imaging charter and independent readers are trained to provide an assessment in consideration of such novel therapeutic intervention.

Perceptive's Dr. Oliver Bohnsack leverages his knowledge from having co-authored the immune-related response criteria (irRC, 2009), served as first author of irRECIST (2014), and co-authored *Comparison of Assessments using RECIST and irRECIST* by Manitz J. et al. (2020) as he designs and implements optimal imaging strategies for Perceptive's customers developing new oncology treatments.

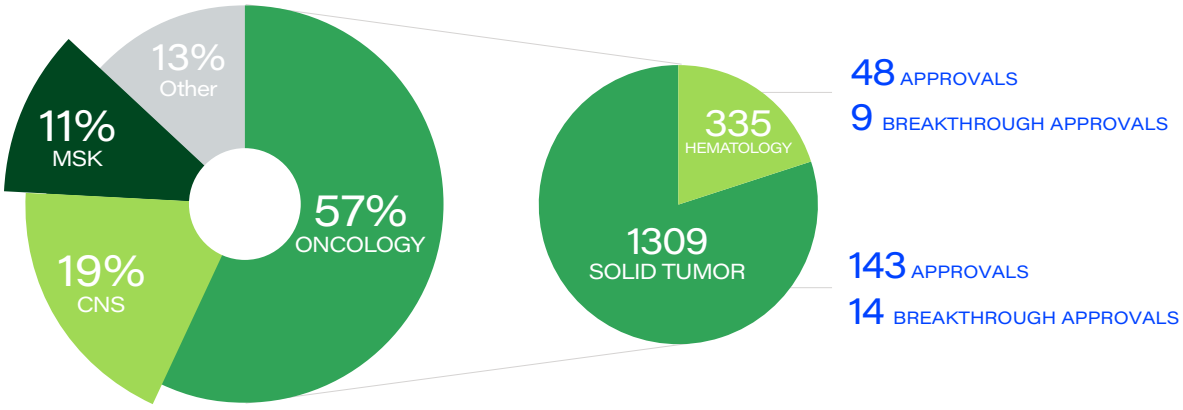
Example 3: Immuno-Oncology Research

Another example is related to the advances we're seeing in the field of immuno-oncology research. Recent findings are driving modifications to established imaging criteria, as evidenced in a Journal for ImmunoTherapy of Cancer paper (2022) marking the first time immune-related criteria show a correlation with overall survival as the most meaningful endpoint in the treatment of cancer patients. As a result, Dr. Oliver Bonshack (see sidebar) suggests that irRECIST can and should replace outdated RECIST 1.1 on all solid tumor trials going forward.

In Solid Tumor Imaging, Experience Matters

Perceptive Imaging scientists have the industry's most extensive experience in oncology clinical trial imaging and are immersed in their therapeutic areas of expertise and modality specialties. The team of over 300 internal scientific and medical experts has successfully managed the imaging components of nearly 3,300 clinical trials across 90 unique oncology indications and has supported over 150 solid tumor regulatory approvals involving the entire span of imaging modalities utilized in tumor patient care.

Perceptive Medical Imaging Experience



Perceptive's scientists are committed to the success of your clinical trial, maintaining regular contact with your team throughout its duration and overseeing the important independent imaging reads that can make or break your trial. This becomes even more critical when your study-specific needs change, like when regulators question the initial data submitted or request additional information on how reads

were conducted. Or, if early results demonstrate superior efficacy and earn your compound fast-track designation, significantly growing and accelerating your imaging needs, most times overnight.

The Value of a Scalable Reviewer Network and Operational Infrastructure

A key component of Perceptive's Medical Imaging offering is the delivery of accurate and precise imaging assessments performed by board-certified experts from a network of over 1,600 independent readers who are well-recognized in their fields. Perceptive's network of readers is active in the clinic and works with patients regularly, ensuring they have a comprehensive and up-to-date understanding of your patients, the disease, and the role of imaging in their assessment.

And, Perceptive's operational model enables our client delivery teams to anticipate your study needs and scale our services to deliver quick and reliable continuity of service with efficient setup of sites and reduced imaging queries to meet your trial timelines, even during mid-study changes (See sidebar).

Having access to so many retained, experienced radiologists – the majority of whom have worked with Perceptive for over a decade – and deep operational expertise delivered through seven global locations centered in key life science hubs, Perceptive Imaging delivers the flexibility and scalability trial sponsors need during all stages of solid tumor treatment development, helping them to overcome challenges and tackle unexpected trial changes as evidenced in the following case studies.

Perceptive Medical Imaging: By the Numbers

450,000+
Annual reads from global sites

4.7M
Total images processed

<24-HR
Case resolution (80K annual cases)

70+
Studies with >10K timepoints

150+
Studies with >1K patients

Case Study 1: Scaling to Support Melanoma PD1/PDL1 Breakthrough Trial

A client approached Perceptive Imaging for support with a PD1/PDL1 trial aimed to treat patients with advanced or unresectable melanoma who were no longer responding to other drugs. The FDA granted breakthrough therapy designation based on data supported by Perceptive's central reviews which demonstrated preliminary clinical evidence that the drug potentially offered a substantial improvement over available therapies on the market.

The phase I study quickly became an advanced phase III study. Perceptive supported a quick ramp-up, providing senior project management and industry-leading scientific guidance to help meet the demands of breakthrough therapy designation. This involved rapid modifications to the imaging charter and read design, adjusting from single review to double review with adjudication and clinical data evaluation by a central oncologist. Perceptive immediately expanded its reader pool and contracted nine additional radiologists and oncologists with expertise in melanoma imaging to meet the sponsor's expedited review timelines and increase in read volume.

Perceptive's medical imaging expertise and access to a deep network of experienced independent readers proved to be a key contributor to the success of the trial and to the FDA's accelerated approval of the novel melanoma treatment.

Case Study 2: Meeting FDA Request for Expanded Imaging during RCC Compound Development

Perceptive supported a phase III Renal Cell Carcinoma adjuvant therapy trial with approximately 1,000 enrolled patients. The trial began with an audit methodology reading only 20% of subjects and later, after receiving FDA feedback, expanded to a full review of all subjects.

The sponsor was interested in obtaining the full set of data as quickly as possible. Perceptive responded by adding eight experienced readers to the study's reviewer pool and managed expedited review for all cases. The Perceptive study team closely monitored reader performance as data was reviewed, ensuring alignment and consistency across a large reader pool to deliver data that demonstrated the compound's efficacy.

The study was a success and based on the imaging data delivered by Perceptive Imaging, the compound became the first FDA-approved immunotherapy for the adjuvant treatment of this RCC patient population.

Contact hello@perceptive.com to learn how the scientific, medical, and operational expertise behind Perceptive Imaging can drive the success of your solid tumor treatment development programs.

perceptive imaging

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