KEY FEATURES

- Full-service oncology model for entire spectrum of modalities from ocular imaging to traditional CT/MRI
- Study design consulting, protocol development and assessment criteria guidance
- Integrated suite of advanced technologies to enable image visualization, analysis, tracking, reporting and export
- Comprehensive database of oncology investigators with access to ophthalmology centers complete with historical performance data and trend reporting
- Site qualification and training including customized training programs targeting personnel tasked with oncologic & ophthalmic scanning and other study site staff
- Centralized ophthalmic independent reviews
- End-to-end support from a dedicated project team with solid oncology and ophthalmology experience
- Specialist medical writing team for development of detailed image acquisition guidelines, charters and reviewer manuals centralizing oncology and ophthalmology review

KEY BENEFITS

- Central review of oncologic and ophthalmic imaging occurs through one source providing efficiencies and risk reduction
- Access to experienced and dedicated interdisciplinary teams including Key Opinion Leaders
- A team with significant experience for mitigating logistical challenges associated with connecting an oncology site with scanning facilities (CT/MRI/Bone scan) and ophthalmology centers.
- Deep technological expertise to support multiple OCT scanner vendors for analysis.
Overview

Ocular adverse events are increasingly being reported for molecularly targeted agents (MTAs) that are approved or are under investigation for solid tumors and hematological malignancies. While the mechanism of action is not clear, myriad of anti-cancer therapeutic targets are also expressed in ocular tissues which may result in these severe ocular adverse events.

The ocular toxicity profile with MTAs can be severe and dose limiting and regulatory agencies may request ophthalmic imaging to support approval of these targeted therapies [e.g., MEK inhibitors]. Hence, ophthalmic image acquisition standardization across sites in global multi-site trials is critical. PAREXEL Informatics is a leading imaging core lab with the experience and ability to provide a wide range of services in clinical trials.

Utilizing PAREXEL systems and image export capabilities will reduce the necessary workarounds by the Sponsor. Detailed research into Ophthalmic imaging modalities and partnership with a Key Opinion Leader (KOL) and several well recognized Reading Centers allows us to offer a robust service that, to date is not offered by any other imaging CRO (iCRo).

Experience

PAREXEL Informatics are experts in executing global multi-site ophthalmic imaging clinical trials and can provide appropriate support to ensure standardization across sites, image QC, and storage for eventual submission to the agencies. PAREXEL Informatics can also provide access to independent ophthalmologists to conduct a central read. Figure 1 provides an example of a patient on MEK inhibitors who developed neurosensory detachments which resolved after cessation of the drug or by dose optimization.

PAREXEL Informatics Medical Imaging is equipped with internal full-time ophthalmic imaging experts including PhDs, Certified Retinal Angiographers (CRA) and OCT-Certified (OCT-C) professionals with more than five years of experience in OCT, Fluorescein Angiography, ICG Angiography, Color Fundus Photography, Visual Fields, Microperimetry, and additional photography (FAF, Infrared, Red Free).

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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.

Figure 1.

a: Color fundus photographs (CFP) of the right and left eyes on full dose chemotherapy showed bilateral multifocal neurosensory detachments
b: ...seen on fundus autofluorescence (FAF) as hyperautofluorescent [bright spots] areas
c: Optical coherence tomography (OCT) confirmed multiple neurosensory detachments [*white asterisk] with cystoid macular edema.
d: After stopping chemotherapy, the neurosensory detachments resolved on fundus photographs and (e) OCT

Figure 1.

- a: Color fundus photographs (CFP)
- b: Fundus Autofluorescence (FAF)
- c: Optical Coherence Tomography (OCT)
- d: Fundus Photographs
- e: OCT