ASSESSING IMAGING ENDPOINTS FOR CARDIOVASCULAR CLINICAL TRIALS

KEY FEATURES

- Dedicated cardiac leadership team with over 35 years of relevant industry experience
- Best-in-class cardiac imaging analysis and reporting software, coupled and integrated with our core technologies
- Experience in over 126 cardiac trials and over 293,915 timepoints
- Ability and experience to work with all cardiac imaging modalities
- Flexible read deployment model combining on-staff and subcontracted reviewers
- Program level, client-specific approach for similar cardiac imaging protocols

KEY BENEFITS

- Full trial support from consulting through project execution and regulatory submission
- Intelligent analysis form design to increase data quality
- Application of best practices spread across all cardiac studies
- Single vendor solution for all cardiac imaging modalities
- Cost savings by reducing rereads and increasing data integrity through independent reviewer accuracy and reproducibility
- Scalability to tailor cardiac imaging solutions to meet individual study requirements
- Program approach to decrease start-up time and costs while increasing team efficiency

Inclusion of standardized cardiovascular imaging endpoints in clinical trials is becoming increasingly valuable, often resulting in an accelerated understanding of a drug’s effect on cardiovascular safety and efficacy. 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.

Cardiovascular Expertise

As a leading imaging provider for clinical trials, PAREXEL Informatics offers multiple solutions to standardize cardiovascular imaging endpoint assessments. With extensive experience accumulated from supporting over 126 cardiovascular imaging studies, our global organization is able 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 clinical trials of non-cardiac drugs, for example, in oncology therapy. PAREXEL is able to facilitate optimal and consistent assessment of cardiac safety and oncolytic efficacy, ensuring efficiencies and convenience for your investigator sites.

Experts

PAREXEL brings the world's leading experts to your cardiovascular imaging studies. Our cardiovascular 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.

Our panel of renowned cardiovascular imaging experts includes:

- Henri Cuenoud, M.D.
- Peter Gardiner, MB ChB, MRCP, FFPM
- Edwin L. Palmer, M.D.
- Georges El Fakhri, Ph.D.
- Suhny Abbara, M.D.

Modalities

PAREXEL Informatics has proven capabilities for supporting all of the standard modalities used by investigative sites for routine imaging of the cardiovascular system. Imaging can be as simple as the basic evaluation of cardiac safety for a non-cardiac drug using echocardiography with assessment of left ventricular ejection fraction (LVEF) and LV wall motion. Or imaging could be more complex with assessments of cardiac size and function with echocardiography including LV mass and fractional shortening. With a team of experienced medical imaging experts, including cardiologists, radiologists, an imaging physicist and a dedicated Exploratory Imaging group, we are fully equipped and optimally positioned to support existing, as well as new and novel imaging methods.

Standard Imaging Modalities for Cardiovascular Endpoints

- Ultrasound
  - Echocardiography
  - Carotid ultrasound, including IMT assessment
  - Venous ultrasound
  - Intravascular ultrasound (IVUS)

- Nuclear Imaging
  - Single photon emission computed tomography (SPECT)
  - MUGA
  - Positron emission tomography (PET)

- Invasive Angiography
  - Peripheral arteriography, including digital subtraction angiography (DSA)
  - Quantitative coronary angiography (QCA)
  - Venography (phlebography)

- Magnetic Resonance Imaging (MRI)
  - Diffusion/perfusion MRI
  - Cardiac MRI
  - Magnetic resonance angiography (MRA)

- Computed Tomography
  - Perfusion CT
  - Cardiac CT, including coronary calcium scoring
  - High-resolution CT (HRCT)
  - Computed tomographic angiography (CTA)

Operational Excellence

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

Our in-house cardiovascular imaging experts provide consultation on developing the imaging components 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.

Clinical site qualification, including assessment of test images when necessary, is a critical component of study initiation. Rigorous training and testing of reviewers is performed prior to the independent review.

Independent cardiovascular 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 cardiovascular reviewers. Our Global Reviewer Operations group is focused on the management of both our on-staff and independent 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 remote on-site training customized to individual customer requirements. We also offer international training via webcasts for cardiovascular imaging and trial staff. Training materials such as CD-ROMs with content required for your investigator sites can also be produced. We can qualify the cardiovascular imaging 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 cardiovascular solutions utilize best-in-class technology integrated with our sophisticated analysis technology platform to deliver configurable solutions for your protocol. With embedded analysis workflows and rules to streamline the entire process, the combined applications provide superior, intuitive user experiences while ensuring total data quality.

- Advanced technologies to enable cardiovascular image visualization, tracking, processing, analysis, reporting and data export
- Tight integration of electronic case forms and image viewing software to simplify review workflow
- Unique analysis technology with embedded 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
- Automated upload of reviewer assessments from the image review software to the electronic case report form
- Echocardiography processing and analysis software from DigiSonics, with a full range of possible assessments of cardiac structure and function
- Integrated nuclear cardiology processing and analysis software from HERMES Medical, including the ability to handle MUGA or radionuclide angiography, cardiac SPECT and cardiac PET
• Quantitative and qualitative tools for the assessment of peripheral arterial occlusion using angiography

• 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.