MEDPACE

EXPERTS

Medpace Imaging Core Lab

Medpace Imaging Core Lab: Full Service Imaging for Clinical Studies

Medpace Imaging Core Lab (ICL) combines state of the art imaging services with Medpace clinical teams to provide a unique partnering philosophy. Medpace delivers effective, end-to-end collaboration, training, and resource planning around the globe. Working closely with the industry's top therapeutic experts, our proficient and experienced team members engage quickly and provide strategic thinking ensuring quicker start-up times, superior quality, and the most efficient delivery at every phase of your trial.

Medpace ICL provides an end-to-end suite of global imaging services to enhance and expedite biopharmaceutical and medical device development across therapeutic areas utilizing appropriate imaging modalities. ICL partners with imaging experts from major academic and clinical institutions involved in research. These experts have worked on numerous pharma- and device-sponsored studies for many years and have integrated these activities into their daily work-flow to provide timely, expert readings. In addition to readers, the majority of our imaging trial medical experts are drawn from these institutions, which allows us to provide a customized experienced reader network for your study.

The Medpace ICL team brings a robust combination of imaging expertise and clinical trial experience to ensure that imaging components are seamlessly integrated into the complex structure of the overall clinical trial. Medpace ICL is located on a new Medpace campus in Cincinnati US and is adjacent to Medpace Clinical Pharmacology Unit (CPU) and clinics for Phase I-IIb studies requiring an imaging component. ICL is a global core imaging laboratory with additional offices in Leuven and Beijing.

Medpace ICL Services

- Consultation on imaging biomarker strategy for clinical development plans across therapeutic areas
- Preparation of and recommendations for the imaging-related components of the clinical trial protocol, ICFs, and CRFs
- Coordination with Sponsor/clinical CRO on global site selection to ensure that sites have access to imaging capabilities eeded for the trial
    - Evaluation of on-site equipment
    - Identification of qualified on-site imaging staff
- Site qualification to confirm imaging quality prior to trial subject scanning
- Imaging Review Charter to define imaging acquisition, data management, and image analysis procedures
- Standardization of image acquisition protocol across global sites
- Study-specific training of site staff
    - Site imaging technical manual
    - On-site or web-based training (multilingual)
- Training of clinical trial CRAs in imaging components of trial
- Centralized collection and archival of images from sites globally via web to ICL servers or courier to office
- Tracking and quality control/assessment of image data
    - Information available to Sponsor in real time by secure web access using our ClinTrak® Imaging system
    - Images processed and archived by Image Analysts and Project Assistants trained in a uniform manner, following ICL SOPs
    - QC/QA checks
- Proper image de-identification and adherence to imaging protocol
- Real-time feedback to sites on quality issues
    - Utilizes ClinTrak Imaging
- Proprietary 21 CFR Part 11 compliant software
- Complete audit trail
    - Secure server back-up for all images and image analysis data

Full Service Study Design and Management

- Design and implementation of centralized independent review/analysis of images
  - Defined in the Imaging Review Charter
  - Design of imaging related eCRFs for the central image QA/read/analysis results
  - Creation of database for image analysis results
- Data management of imaging results (ClinTrak Imaging)
- Efficient transmittal and analysis of images allows rapid turn-–around for time-sensitive imaging components, such as those for eligibility safety
- Data transfer specification document, and data transfers
- Statistical analysis of imaging results
- Generation of report for imaging component of study
- Seamless integration with other study-related services such as IVRS, web-based reporting, and study management
- Seamless database integration with clinical database
- Regulatory submission preparation

Independent Centralized Image Readers

Medpace ICL can provide blinded central readings from a defined pool of over 200 board certified, subspecialty trained radiologists, cardiologists, and other specialists working in a secure environment utilizing identical software and workstations integrated into ClinTrak Imaging, allowing for prompt turnaround and continuous oversight.

0ur Readers have extensive clinical trial experience with cardiovascular, central nervous system, musculoskeletal, oncological , endocrine, gastrointestinal, and pulmonary diseases, as well as interventional and medical device studies, utilizing imaging modalities such as CT, MRI, PET/CT, 3 D volumetric analysis, ultrasound, DEXA, angiography, endoscopy and photography.

Close Proximity to the Medpace Clinical Pharmacology Unit for Phase I-IIb study needs

The Medpace campus houses the Medpace CRO, Bioanalytical Laboratories, Central Laboratories and the CPU. The outpatient radiology facility containing MRI, CT, ultrasound and other imaging modalities is located adjacent to the 100 bed Medpace Clinical Pharmaceutical Unit providing convenient imaging support for Phase I-IIb studies.

ClinTrak Imaging Integration

Integrated with ClinTrak, the Medpace proprietary study management system, ClinTrak Imaging consists of leading edge technologies to track, interpret, and communicate critical project information in the most timely and secure manner possible. Featuring an intuitive, web-based interface, ClinTrak is designed to integrate all components of the trial and provide access to study data and metrics.

ClinTrak Imaging is an ICL developed proprietary application with web–based front–end and robust SQL–server back-end. Run on Medpace owned and operated redundant services, ClinTrak Imaging provides real-time central tracking, data management, quantitative and qualitative analysis, and image-related reporting information.

Features include:

- Secure username/password access
- Image/scan tracking and archiving
- De–identification
- Data management/query resolution and tracking
- Customized eCRF for entry of image analysis data
- Image analysis results database
- Real–time web–based status reporting
- Audit trail
- 21 CFR Part 11 compliant

About Medpace

Medpace is a leading global full-service clinical research organization providing Phase I-IV core development services for drug, biologic, and device programs. With medical and regulatory expertise in multiple therapeutic specialties, Medpace has assembled the industry's most experienced and therapeutically focused teams to execute at every level of the company's operations, providing complete and seamless drug development services. Medpace creates strategic partnerships with pharmaceutical and biotechnology companies to provide the most efficient and cost effective path to drug development – from program planning and execution to product approval.

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