

IMAGING CORE LAB: FULL-SERVICE IMAGING FOR CLINICAL STUDIES

Medpace Imaging Core Labs (MICL) combines state of the art imaging services with Medpace clinical teams to provide efficiency through partnership. Medpace delivers effective collaboration, training, and resource planning around the globe with consultation on imaging biomarker strategy for clinical development plans across therapeutic areas. Working closely with top therapeutic experts, our proficient and experienced team members engage quickly and provide strategic thinking to ensure quicker start-up times, superior quality, and the most efficient delivery at every phase of your trial.

MICL provides an end-to-end suite of global imaging services and modalities to enhance and expedite biopharmaceutical and medical device development across therapeutic areas. MICL partners with imaging experts from major academic and clinical institutions that have experience in clinical trials research and have integrated these activities into their daily work-flow to provide timely, expert readings. Readers and imaging trial medical experts drawn from these institutions enable MICL to provide a customized experienced reader network for your study.

MICL uses registered radiological technologists with experience qualifying sites for novel image acquisition protocols. Medpace has imaging Project Managers who specialize in managing global, imaging-focused trials. This dedicated staff is trained on all imaging components of a clinical trial including site selection. Global site selection is an important part of any study, and MICL has a proven process including evaluation of on-site imaging equipment, identification of qualified on-site imaging staff, and site qualification to confirm imaging.

MAKING THE COMPLEX SEAMLESS™

EXPERTS

- Integrated team of technologists, physicians, and medical physicists with clinical trial experience
- Board certified radiologists with extensive experience as independent readers in clinical trials
- Imaging physicists and computer scientists with advanced knowledge of medical image acquisition and analysis methods.

EXPERIENCE

- Recommendations for imaging- related components of clinical trial protocols, and informed consent
- Cloud-based image and clinical trial management using ClinTrak® Imaging system
 - 21 CFR Part 11 and GDPR compliant
 - Site image transfer and tracking
 - Integrated QC/QA processes
 - Real-time resolution of quality issues
 - Information continuously available to Sponsor
- Images processed and archived following Medpace Core Labs SOP

EXECUTION

- Standardization of image acquisition protocol across global sites
- On-site or web-based training (multilingual)
- Continuous QA/QC to ensure consistent image quality and adherence to imaging protocol
- De-identification of incoming image data
- Study specific manuals for acquisitions at sites and central reviewer procedures
- Imaging Review Charter as recommended by FDA
- Secure GDPR compliant data management
- Complete audit trail



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 ClinTrak Imaging - database for image analysis results
- Data management of imaging results (ClinTrak Imaging)
- Efficient, web-based transmittal and analysis of images allows rapid turn-around for time-sensitive imaging criteria, such as eligibility and safety
- Data transfer specification document, and scheduled data transfers
- Statistical analysis of imaging results
- Generation of report for imaging component of study
- Seamless integration with other study-related services
- Seamless database integration with clinical database regulatory submission preparation

INDEPENDENT IMAGE REVIEW

MICL can provide independent, blinded, central, readings of clinical trial images from a pool of over 200 board certified, subspecialty trained radiologists, cardiologists, and other specialists. MICL central readers work in a secure, online environment using certified software and workstations integrated into ClinTrak Imaging, allowing for prompt turnaround and continuous oversight.

Our readers have extensive clinical trial experience with cardiovascular, central nervous system, musculoskeletal, oncological, metabolic, and pulmonary diseases, as well as interventional and medical device studies. Our imaging expertise includes MRI, PET, CT, angiography, ultrasound, echocardiography, DEXA, endoscopy, photography, ocular CT, and advanced image analysis and rendering.

ClinTrak IMAGING INTEGRATION

Integrated with ClinTrak, the Medpace clinical trial management system, ClinTrak Imaging consists of leading edge technologies to track, interpret, and communicate imaging and related data 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 MICL developed application with web-based front-end and robust SQL-server back-end. ClinTrak software runs on Medpace owned and operated, redundant hardware, 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 and GDPR compliant

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

