MEDPACE

NEUROSCIENCE IMAGING

Medpace imaging core lab has over a decade of experience in global neuroscience trial management. We're equipped with an experienced team of scientists, clinicians, technologists, project managers, coordinators, and engineers.

Team members include:

- **Clinicians:** Board-certified radiologists and neurologists with extensive clinical trial experience
- **Scientists:** Physicist and engineers with PhD and MS level training covering all neuroimaging modalities and analysis methods
- **Imaging Technologists:** Clinically trained and certified with clinical trial experience across modalities
- **Project Managers:** Specialized training and skills for managing neurodegenerative and neuromuscular disorder trials
- **Project Coordinators:** Experienced in Medpace processes for clinical trial operations, documentation, and quality assurance
- **Software Engineers:** Scientific programmers with expertise in quantitative image analysis and experience developing specialized applications for computing quantitative imaging biomarkers from medical imaging data from various imaging modalities

Medpace imaging core lab will coordinate with your systems and processes to accelerate your program. We have a streamlined process for initiation and management of neuroimaging trials with global and local sites. We abide by imaging Metrics Champion Consortium and are CFR Part 11 compliant and offer a fully-validated image management system for clinical trials that integrates seamlessly with the Medpace clinical trial management system: ClinTrak®. Medpace imaging core lab can successfully integrate standard and novel imaging biomarkers (structural/functional/molecular) into Phase I-III studies from concept through design and execution.

MAKING THE COMPLEX

SEAMLESS™

EXPERTS

- Board-certified readers for neuro-oncology, neurological and neurodegenerative disorders
- Experienced in-house radiologist, neurologist, medical physicists, imaging technologists, and program managers
- In-house database programmers and software developers with knowledge of imaging in clinical trials and agility to quickly configure all the computational resources needed for your trial
- Scientific and medical experts in all neuroimaging modalities including MRI, CT, PET, SPECT, nuclear medicine, and radiation dosimetry

EXPERIENCE

- Team with a broad spectrum of CNS-based imaging biomarker experience
- Training and practice with response assessments for neuro-oncology trials including RANO, RANO-BM, and iRANO
- Experience with advanced MR neuroimaging acquisition and analysis strategies for fMRI, DTI, ASL, DCE
- Neuroradiology review of advanced, quantitative neuroimaging biomarker data

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 trial

NEUROSCIENCE IMAGING EXPERIENCE

Medpace imaging core lab has experience in a range of CNS clinical trials, including Stroke, Neurodegenerative Disorders, Multiple Sclerosis, Psychiatric Disorders, and Neuro-oncology. Medpace has experience across imaging modalities such as X-Ray, Computed Tomography (CT), Single-Photon Emission Computed Tomography (SPECT), Positron Emission Tomography (PET), and Magnetic Resonance Imaging (MRI). We also have extensive experience with advanced MR methods for neuroimaging including:

Advanced Neuro-MRI Methods:

- DTI – Diffusion Tensor Imaging
- fMRI – functional MRI
- fcMRI – functional connectivity of resting state fMRI
- PET – Positron Emmision Tomography
  - FDG-PET with ^{18}F
  - Short-lived isotopes: ^{15}O, ^{11}C, ^{13}N
  - Long-lived isotopes (^{64}Cu, ^{89}Zr, ^{68}Ga) for tumor-binding and monitoring drug delivery
- vMRI – volumetric MRI
  - Structural segmentation
  - Volume measurement
  - WM/GM segmentation and quantitation
  - Cortical thickness measurement
- ASL – Arterial Spin Labeling for quantitative perfusion imaging

INTEGRATED ENVIRONMENT FOR NEUROIMAGING TRIAL MANAGEMENT

Medpace imaging core lab offers centralized global site management for clinical trials. We utilize validated systems and platforms to streamline set up and management. Our dedicated and integrated project team customizes each trial according to the project specific requirements and integrates all aspects of the start up with the sponsor and the CRO efforts. Medpace imaging core lab can work with Medpace or other CROs to provide the same high quality imaging biomarkers for your trial. From start to finish, Medpace imaging core lab creates documentation of imaging related processes and lays down a complete audit trail for each study.

ClinTrak® IMAGING INTEGRATION

Our cloud-based image transmission, review, and analysis system, ClinTrak Imaging, allows real time visualization of all imaging results online for readers, sponsors, auditors and regulators. Advanced quantitative image analysis and automated population of results in a study specific ClinTrak Imaging database are customized for each trial.

ClinTrak Imaging offers:

- Cloud-based image transmission system with zero local IT footprint
- Integrated quantitative image analysis capabilities
- Continuous image data extraction, presentation, independent reader and sponsor access
- Seamless integration with the overall clinical management system (ClinTrak)

ClinTrak Imaging is capable of uploading and managing DICOM images as well as digital video, photography and a variety of other image formats (JPEG, MPEG, AVI, PNG). All analyses can be performed in a blinded fashion according to study-specific requirements. Independent image review can be performed for inclusion/exclusion criteria assessment, on an ongoing basis throughout the study, or in batch analysis when all subjects complete the study. ClinTrak Imaging meets modern international data security requirements and is HIPAA, GDPR and SHEILD 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.

MAKING THE COMPLEX SEAMLESS™