

TECHNOLOGICAL EXPERTISE

Clinical trials involving disorders of the Central Nervous System present a number of challenges. With a wealth of domain knowledge utilizing validated scoring methods, BioClinica provides proven expertise in centralized image processing and analysis in all necessary modalities and techniques.

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BIOCLINICA[®]
Global clinical trial solutions. Real-world results.

NEUROLOGY

OUR EXPERTISE SUPPORTS:

Expertise

- ⌚ Medical Imaging Consulting
- ⌚ Site Standardization and Technical Support (including phantom acquisitions)
- ⌚ Image Management Services for MRI, CT, PET and Intracranial Doppler
- ⌚ Image Processing Services including 3-D Image Registration, Lesion Detection, Brain and Hippocampal Atrophy Quantification, Perfusion, Diffusion, Diffusion Tensor Imaging, etc.
- ⌚ Eligibility / Safety / Efficacy – Assessment Services
- ⌚ Independent Blinded Reads

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MODALITY EXPERTISE

Modern neuro-imaging techniques like Magnetic Resonance Imaging (MRI) can reveal brain tissue abnormalities resulting from neurodegenerative and vascular diseases such as Alzheimer's Disease (AD), Multiple Sclerosis (MS) and stroke. BioClinica has extensive expertise in the expanding role of quantitative image analysis in the evaluation of drug therapy and devices in this therapeutic area.

BioClinica offers automated MRI analysis technology to assess quantitative parameters such as brain and hippocampal atrophy, focal and diffuse white matter abnormalities, Diffusion-Weighted Imaging (DWI), Diffusion Tensor Imaging (DTI) and Perfusion Imaging. Automated image processing is performed at the Core Lab prior to centralized independent blinded review.

Initial site qualification, ongoing site Quality Assurance (with phantom scans if required) and the quality of image data collected from the sites have a key impact on the overall quality of the imaging component of CNS trials.

We have successfully performed a number of Phase II & III CNS trials including quantitative endpoints.

Site Qualification & QA

- Phantom-based Qualification
- Site Training

Advanced Image Processing & Quantification Services

- Lesion Quantification & Tracking
- Brain, Ventricular & Hippocampal Atrophy
- Atlas-Based Segmentation
- Diffusion / Perfusion / Magnetization Transfer Imaging

Independent Blinded Image Review

- Eligibility / Safety Evaluations
- Efficacy Evaluation (Quantitative Endpoints)

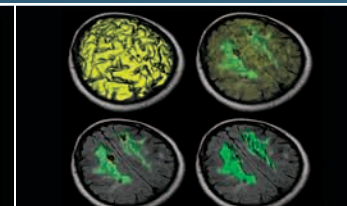
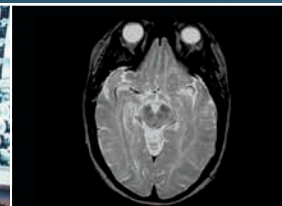
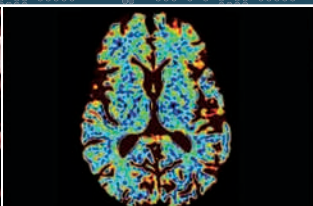
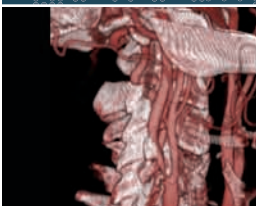
INDEPENDENT REVIEW EXPERTISE

The independent blinded interpretation of the imaging data is of paramount importance in every clinical trial. BioClinica's Bio-READ™ system provides the platform for state-of-the-art radiological evaluation of the clinical trial data. The Bio-READ™ system allows the images to be displayed in a completely blinded fashion, eliminating potential bias associated with the review. The Neuroradiologists selected for these reads are all Board-certified experts in their respective fields. The conduct of remote read sessions can significantly increase the efficiency of central reading activities while minimizing the inherent costs.

REAL-TIME SPONSOR ACCESS TO IMAGE & E-CRF DATA

The image evaluation results are made available at sponsor's site in real-time to facilitate the tracking of operations and allowing fast decision making when it comes to patient monitoring in case of safety findings.

NEUROLOGY EXPERTISE



BioClinica has extensive experience involving the management and analysis of images for Central Nervous System (CNS) clinical trials. We have completed over 60 trials in a number of neurology indications including:

Alzheimer's Disease (AD)

Multiple Sclerosis (MS)

Stroke

Stroke Secondary Prevention

Vascular Dementia (such as CADASIL)

Intracerebral Hemorrhage (ICH)

Traumatic Brain Injury (TBI)

Brain Aneurysm

Depression

Epilepsy

Parkinson's Disease