Alzheimer’s Disease – Imaging Expertise

Magnetic Resonance Imaging (MRI)

MRI-based eligibility, safety, and efficacy endpoints play a key role in the design of AD clinical trials. Furthermore, the introduction of quantitative MRI endpoints and automated image processing enables high throughput analysis and adds valuable data in support of faster registrations.

EXPERTISE IN QUANTITATIVE IMAGE PROCESSING FOR AD TRIALS

- Cross-sectional cortical and subcortical segmentation (Freesurfer based)
- Longitudinal based measurements using Tensor based Morphometry (TBM) and Boundary Shift Integral (BSI)
- Global, regional, and longitudinal changes in cortical thickness
- Quantification of intracranial cavity volume
- Quantification of hyperintense FLAIR/T2 lesions
- Diffusion-Weighted Imaging (DWI) histogram analysis
- Diffusion-Tensor Imaging (DTI) histogram analysis
- Arterial Spin Labeling (ASL) perfusion analysis
- Resting-state and task-based fMRI

Positron Emission Tomography (PET)

Molecular imaging tracers used to visualize amyloid and assess brain function provide key tools for identifying early disease.

MOLECULAR IMAGING TRACERS

- 18F FDG-PET
- Amyloid-PET
  - 11C PIB
  - 18F Florbetapir
  - 18F Flutemetamol
  - 18F Florbetaben
- Tau-PET
  - 18F-T807

AMYLOID PET OUTCOME MEASURES

- Visual reads
- Quantitative SUVr
  - Freesurfer-based
  - SPM-based
- Hybrid visual/quantitative SUVr
- Distribution Volume Ratio (DVR)

FDG PET OUTCOME MEASURES

- MetaROI: Meta-region assessment (Landau & Jagust)
- Freesurfer-based approaches
- PMOD Alzheimer’s Discrimination Analysis (PALZ)

SITE QUALIFICATION AND TRAINING

- Network of 200+ global PET sites
- On site or remote training
- Use of Hoffman phantom scans

ABSOLUTE QUANTIFICATION FOR NOVEL PET TRACERS

- Dynamic PET acquisition
- Blood sampling standardization
- Kinetic analysis and modeling

SITE STANDARDIZATION AND IMAGE QC

BioClinica ensures high quality, reproducible MRI and PET data by minimizing site variability, providing vendor and model specific acquisition parameters, and ongoing quality control.
## Functional MRI (fMRI)

*Initiatives to improve the standardization of fMRI acquisition, processing, and analysis are facilitating its implementation as a primary or exploratory endpoint in large, multi-center clinical trials. BioClinica has expertise with task-based and resting-state fMRI, with a focus on standardized capabilities for clinical trials.*

### ACQUISITION

- Deployment across major vendors (GE, Philips, and Siemens) at both 1.5T and 3T
- Deployment across expert academic centers as well as standalone clinical imaging facilities
- Standardization across sites and optimization at each site
- Experience with many types of cognitive tasks, facilitating standardization of stimulus presentation across sites
- Behavioral responses (for task-based fMRI) and physiological recordings
- fMRI time series and additional sequences for image processing and analysis (high-resolution structural imaging, field mapping)
- Technologist training (remote or on-site)
- Site qualification including phantom scanning (including both static and temporal stability evaluation) and/or *in vivo* testing
- In-depth quality assessment and site feedback with fast turnaround

### PROCESSING, ANALYSIS, AND REPORTING

- 100% automated preprocessing stream including motion correction, distortion correction, registration to anatomical space, segmentation and parcellation
- For resting-state fMRI, the complete connectivity matrix reports functional relationships between all brain regions (seed-based and ICA approaches also possible)
- For task-based fMRI, General Linear Models (containing predictors of interest and nuisance regressors) are estimated to derive the effects of a task

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### ABOUT BIOCLINICA

BioClinica accelerates the development of new medical therapies by delivering expertise and technologies that enhance clinical research, worldwide. Our industry-leading medical imaging services, cardiac safety, and enterprise eClinical platform bring a new level of quality and efficiency to every phase of clinical development. Our experience spans three decades and includes thousands of studies in all therapeutic areas, from design and management, through submission and post-approval. BioClinica serves more than 400 pharmaceutical, biotechnology, and device companies – including all the top 20 – through a network of offices in the U.S., Europe, and Asia.