

Imaging based eligibility, safety, and efficacy endpoints play a key role in the design of stroke clinical trials. Furthermore, the introduction of quantitative imaging endpoints and automated image processing enables high throughput analysis and adds valuable data in support of faster registrations. Bioclinica also has extensive experience using imaging to achieve regulatory approval of stroke devices.

Bioclinica ensures high quality, reproducible imaging data by minimizing site variability, providing vendor and model specific acquisition parameters, and applying rigorous quality control measures. This standardized framework is also flexible enough to support custom site qualification processes such as integration of standard of care imaging protocols in acute settings.

### Expert Independent Image Review

Board-certified Neuroradiologists assess image data for eligibility criteria, safety findings, and efficacy endpoints. Centralized image review can significantly increase trial efficiency and minimize costs. Data are made available to sponsors in real-time enabling faster patient monitoring and trial decisions.

### Tissue injury: Computed Tomography (CT) / Magnetic Resonance Imaging (MRI)

#### Quantitative Image Analysis

Semi-automated detection of:

- Infarct volume
- White-matter lesion volume
- Edema volume
- Hemorrhage volume

Advanced characterization through

- Diffusion Tensor Imaging (DTI)
- Magnetization Transfer (MT)
- Dynamic Susceptibility Contrast (DSC) perfusion maps (Tmax, CBF, CBV, MTT)
- Functional MRI (fMRI) time shift analysis

#### Qualitative Image Analysis

- Inclusion/exclusion criteria confirmation
- Hemorrhage
- Ischemic changes
- ASPECTS rating
- Swirl sign/spot sign

### Vessel injury: CT Angiography (CTA) / MR Angiography (MRA) / X-ray Angiography

#### Qualitative Image Analysis

- Inclusion/exclusion criteria confirmation
- Clot location, clot properties (length, density)
- Degree of stenosis
- Modified TIC1 scale

