# Study Protocol

## LVO detection on CTA in stroke

as part of Project AIR

1. **Objective**
   Validate and compare the stand-alone diagnostic performance of commercial artificial intelligence (AI) based software for the automated detection of large vessel occlusions (LVO) on computer tomography angiography (CTA) in patients with a suspicion of acute ischemic stroke.

2. **Study design**
   An ongoing retrospective study in which commercial AI software is being validated on a dataset from multiple centers. Vendors make their algorithm temporarily available to the researchers to generate the results. The data will not be shared with the vendors. Reader studies on the same dataset are performed by radiologists to provide context to the stand-alone software performance.

3. **Study population**
   3.1. **Inclusion criteria**
   - Centers: Academic, non-academic
   - Patient age: >18 years old
   - Patients with a suspicion of acute ischemic stroke
   - Maximum one study per subject
   - CTA available within 24 hours after onset or last seen well
   - Non contrast CT available
   - Occlusions:
     - Occlusion in middle cerebral artery (M1, M2 stop) and intracranial internal carotid artery

   3.2. **Exclusion criteria**
   - CTA trauma
   - Intracranial hemorrhage
   - Occlusion types other than middle cerebral artery (M1, M2 stop) and intracranial internal carotid artery
   - Technically inadequate CTA (poor contrast bolus, substantial motion, metal artifact that precludes accurate assessment of the intracranial arteries to the level of the distal M2 segments of the middle cerebral arteries)

   3.3. **Sample size**

- Data will be collected from at least three centers in Europe, with a minimum of 60 samples per center.
- Initial target: 200
- Positive/negative ratio: 1/1
- Enriched series

## 4. Possible investigational products

Preliminary selection of products that are potentially eligible for this study. We welcome feedback about additional products.

- Aidoc - Large Vessel Occlusion
- Arterys - Neuro AI
- Avicenna - CINA LVO
- Brainomix - e-CTA
- iSchemaView - Rapid CTA/LVO
- NICO.LAB - StrokeViewer
- Viz.ai - Viz LVO

## 5. Methods

### 5.1. Study parameters

#### 5.1.1. Metrics

- Sensitivity
- Specificity
- F1-score

#### 5.1.2. Subgroup analysis

Vendors can notify us about subgroups that are outside the intended use of their product. Results regarding these products and subgroups will not be published.

- LVO location type: M1/M2/ICA
- CT manufacturer: GE, Philips Healthcare, Siemens Healthineers, Canon, Toshiba.

#### 5.1.3. Not-processed-rate

### 5.2. Data collection

#### 5.2.1. Imaging data

- DICOM file of NCCT
- DICOM file of CT angiography
- DICOM file of CT perfusion (if available)

#### 5.2.2. Clinical data

- Center: coded
- Patient age: years
- Gender: M/F
- Acquisition machine brand: coded
- CTA slice thickness: mm
- Acquisition date: years
- LVO present: 0/1 (clinical diagnosis)
- Location of LVO: M1/M2/ICA

- If available:
  - Baseline ASPECTS
  - Baseline NIHSS
  - Time of onset to imaging
  - Therapy
  - Sidedness of the neurological deficit

### 5.3. Reference standard

The reference standard for the presence or absence of an intracranial vessel occlusion was set based on the evaluation by three experienced observers and the judgment of an independent neuroradiologist serving as referee in case of discrepancy between the observers. Anonymized clinical data, NCCT and CTP imaging, as well as the evaluation results of all observers were available to the referee.

### 5.4. Software prediction outcome

5.4.1. LVO presence (M1/M2/ICA): Yes/No

### 5.5. Reader study questions

5.5.1. Is a large vessel occlusion present?

- Yes/No

5.5.2. Location of the large vessel occlusion

- Sidedness: Left/Right
- Vessel: M1/M2/ICA

## 6. Statistical analysis

### 6.1. Comparing with average readers

- Sensitivity, specificity: confidence intervals with the Adjusted Wald Method, Bonferroni-corrected.