

TERMS OF REFERENCE



Pilot III Bench-top Simulation for Stroke Devices

Introduction

This pilot project aims to develop standardized procedures for validating clinically relevant bench top simulation systems for testing of mechanical neuro-thrombectomy technologies for the treatment of acute ischemic stroke (AIS). By engaging with SME's developing medical devices, this study seeks to support stakeholders optimise technologies design efficacy reducing the requirement for extensive animal trials, enhancing cost effectiveness and reducing R&D timelines.

Purpose and scope

Aligned to the objectives of the STEP4NAMs project, this pilot study intends to enable SME's to conduct more effective design verification testing and gain a far greater insight into the challenges faced in treating the target disease:

- Improve clinical relevance over animal models
- Reduce the number of animals used in pre-clinical studies
- Product Development: Accelerate the design process
- Allow companies to reiterate standardised bench top tests

The study seeks to develop knowledge on replicating clot-blood vessel wall adhesions using 3D-bio-printed materials. The goal is to establish best practices for the validation of bench-top simulation for the testing of neuro-thrombectomy technologies through tailored training activities and the NAM validation manual.

Approach and methodology

The planned activities of the pilot study include:

- Translate neurovascular medical data.
- Manufacture models using a range of 3D bioprinting.
- Protocols to validate geometrical and mechanical compliance.
- Develop industry guidelines for the fabrication of clot analogues and the necessary steps to characterise each clot type.
- Incorporate thin-walled models into a simulation system replicating blood flow rate/pressure/temperature.
- AIS will be created by releasing various clot analogues within the cerebral flow simulator.

The proposed pilot will allow for the collaboration with 2-4 medtech partners who will play a role in:

- Informing the design and user requirement specification of the bench-top testing system.
- Review and approve the final design of the bench-top system in advance of fabrication.
- Review and approve validation protocols.
- Conduct device performance tests and provide feedback.

Pre-requisite for participation

Participating companies must be operating in the MedTech space and actively involved in the development of vascular or thrombectomy technologies. Partnering company's must be willing to engage in activities outlined above.