MACE-ICH TRIAL SITE FILE INDEX

ISF Trial identifiers front sheet V1.0 20231010
Trial Office contact sheet V1.0 20231010
Investigator Site File Index V1.0 20231115

Section A: Pre-trial opening

A.1	**Trial Development Documentation** Minutes of initial meeting with the Sponsor and confirmation of Sponsor support Evidence of investigator selection Evidence of site selection Evidence of vendor selection Risk assessment Peer review reports Funding application All contracts with the funder and vendors *File Note A1 - Trial Development Documents
A.2	**Study Protocol and associated documents (current versions)** Current signed protocol Information Sheets Consent Forms GP Letter – approved versions printed on local headed paper (current versions can be found on the MACE-ICH website) Case Report Forms Superseded protocols/trial documentation
A.3	**Approval and Agreements** National ethical, Health Research Authority and competent authority (where applicable) approval EudraCT email Local Site Specific Assessment (where applicable) Local NHS Trust R&D or host organisation approval and confirmation of capability and capacity Sponsor / Chief Investigator agreement – File note A3 – Sponsorship letter Sponsor / participating site non-commercial agreement Funding letter - File Note A3 – Funding letter Trial insurance
A4	**Staff Participation** Site Responsibility (Delegation) Log (File Note A4 Site File Delegation Log) Curriculum Vitae and Training Records Attendance at Investigator Training, TAFR01204 Evidence of site initiation Regulatory green light email from the Sponsor
A.5	**Medical Testing and Pharmacy (where applicable)** Accreditation / certification of supporting Laboratories and pharmacies 'Normal ranges' issued by local laboratories Investigational product handling (where applicable) – local procedures where not in the study protocol Investigational product control (where applicable) – local procedures where not in the study protocol Investigational medicinal product records • Appendix 1 - Clinical trials transfer request form • Appendix 2 – IMP site Inventory Log • Appendix 3 – Stroke Unit IMP Accountability Log

	• Appendix 4 - Return of clinical trial supplies • Appendix 5 - Record of IMP destruction • Summary of Product Characteristics (SmPC)
A.6	**Randomization and Blinding** Randomisation, blinding and un-blinding procedures where not in the study protocol *File Note A6 Randomisation and blinding
A.7	**Database Build** Database specification documentation, user acceptance testing, validation documentation, security and access arrangements, and disaster recovery plan * File Note A7 Database Build

Section B: Ongoing Trial

B.1	**Study Protocol Amendments and Approvals** Ethics committee, Health Research Authority and competent authority approvals of amendments Locked amendment tool for each amendment TAFR02404 Amendment Log
B.2	**Staff Participation** Updated delegation log to include new trial staff (file note confirming electronic records) Updated CVs and training records Updated Attendance at Investigator Training, TAFR01204
B.3	**Informed consent** Signed consent forms and GP letters of all trial participants Participant Screening and Enrolment Logs, TAFR01501 and TAFR01502
B.4	**Medical Testing and Pharmacy** Updated accreditation / certification of supporting laboratories and pharmacies Updated 'normal ranges' issued by local laboratories Documented evidence of any changes and their implementation to Investigational product handling (where applicable) – local procedures where not in the study protocol Documented evidence of any changes and their implementation to investigational product control (where applicable) – local procedures where not in the study protocol Updated investigational medicinal product records – certificate of analyses, shipping records, amended labelling to be used (if any)
B.5	**Case Report Forms, Source Documents and Data Management** Completed CRFs or file note explaining where they are stored Source documents related to the trial or file note explaining where they are stored
B.6	**Serious Adverse Events and Serious GCP Breaches** SAE reporting forms: • Signed SAE reports report forms from the MACE-ICH database signed and dated by PI • Completed TAFR01912 SAE reporting forms • Completed TAFR01911 SAE follow-up forms Evidence of notification of actions to be taken and their implementation following a SUSAR (where applicable) GCP breach report, correspondence with the MHRA and REC and subsequent corrective action documentations and evidence (where applicable)

	Protocol violation report forms: • Protocol violation report forms from the MACE-ICH database signed and dated by PI • Completed NUH Non-Compliance Reporting Form TAFR01705
B.7	**Biological Materials (if relevant to the study)** List and location of retained samples Transfer agreements to other institutions
B.8	**Audit and Reporting** Site visit log Site monitoring reports Sponsor audit reports and corrective action forms (if applicable) Internal monitoring/audit reports Local annual reports e.g. R&D
B.9	**Miscellaneous** Correspondence letters, relevant emails etc Medical notes label File note template WPDs Newsletters Eligibility checklist

Section C: Trial Completion

C.1	**Closure** Notification of study closure to the ethics committee, competent authority, HTA, sponsor Documentation of IMP return and/or destruction and pharmacy records
C.2	**Audit and Publication** Final study report Final close-out document (as applicable)
C.3	**IMP Management** IMP accountability logs Evidence of destruction of surplus stocks