INVESTIGATOR SITE FILE INDEX

	Contacts/Investigator Site Personnel Contact details of trial staff **Section A: Pre-trial opening**
A.1	**Trial Development Documentation (Co-ordinating Centre TMF only)** • Minutes of initial meeting with Sponsor • Sponsor confirmation of support • Site selection • Vendor selection • Risk assessment • Peer review reports • Funding application • Contracts with the funder and vendors
A.2	**Study Protocol and associated documents (final versions)** • Current protocol signed by the CI • Information sheets, consent forms, GP letter • Case Report Forms and any other data collection documents.
A.3	**Approval and Agreements** • National ethical, Health Research Authority and competent authority approval. MHRA approval if applicable. • EudraCT email (not applicable for RECAST-3) • Local Site-Specific Assessment (where applicable) • Local NHS Trust R&D or host organisation approval, capability and capacity • Sponsor / Chief Investigator agreement (Co-ordinating Centre TMF only) • Sponsor / participating site non-commercial agreement • Organisational Information Document • Insurance letter (including superseded letters) • UKCRN adoption confirmation

A4	**Staff Participation**
	• Site Responsibility (Delegation) Log, TA008
	  ○ File note confirming use of electronic delegation log for the research team
	  ○ TA008 paper delegation log for ward staff (if applicable)
	• Curriculum Vitae and GCP certificate and relevant training records (i.e. consent)
	• Attendance at Investigator Training, RF1 TA008
	• Ward staff training log (if applicable)
	• SOP Compliance Form RF3 TA008 (Co-ordinating Centre TMF only)
	• Evidence of site initiation
	• Regulatory green light email from the Sponsor

A.5	**Medical Testing and Pharmacy (not applicable for RECAST-3)** • 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 – certificate of analyses, shipping records, labelling to be used • QP certification
A.6	**Randomisation and Blinding** • Randomisation, blinding and un-blinding procedures where not in the study protocol (File note in the Co-ordinating Centre TMF only)
A.7	**Database Build (Co-ordinating Centre TMF only)** • Database specification documentation • User acceptance testing • Validation documentation • Security and access arrangements • Disaster recovery plan

	• **Section B: Ongoing Trial**
B.1	• **Study Protocol Amendments and Approvals** • Log of study documentation amendments, RF1 TA013 (Co-ordinating Centre TMF only) • Current versions of trial documentation: protocol to be fully signed CI, statistician (lead pharmacist where applicable) • Previous versions of trial documents when superseded, clearly marked as superseded including date • Sponsor confirmation of amendment categorisation • Ethics committee, Health Research Authority and competent authority approvals of amendments. MHRA approvals if applicable.
B.2	**Staff Participation** • Updated RF1 TA008 to include new trial staff • Updated CVs, GCP certificates and relevant training records (i.e. Consent) • Updated Attendance at Investigator Training, RF1 TA008
B.3	**Informed consent** • Signed consent forms of all trial participants or file note to say where they are stored if not in the ISF • Participant Screening and Enrolment Log, RF1 TA011
B.4	**Medical Testing and Pharmacy (not applicable for RECAST-3)** • 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 and amended CRFs or a file note to say where they are stored if not in the ISF • Source documents related to the trial • Ongoing database amendments, alterations and revision documentation and evidence (Co-ordinating Centre TMF only) • Data management plan, database lock plan and procedures (Co-ordinating Centre TMF only) • Monitoring plan
B.6	**Serious Adverse Events and Serious GCP Breaches** • SAE reporting forms, RF1 TA014. • eSUSAR / CIOMs form (IMP trials only) • SAE reporting forms to the ethics committee • Annual safety reports and Development Safety Update Reports (DSUR) to ethics committee and regulatory authority MHRA (where applicable) (Co-ordinating Centre TMF only) • Evidence of notification of actions to be taken and their implementation following a SUSADE (where applicable). • GCP breach report, correspondence with the MHRA and REC and subsequent corrective action documentations and evidence
B.7	**Biological Materials (if relevant to the study) (not applicable for RECAST-3)** • List and location of retained samples and Tumour Banking • Transfer agreements to other institutions
B.8	**Audit and Reporting** • Annual progress report(s) to host institution, the ethics committee and competent authority MHRA (where applicable) • Monitoring reports • Sponsor audit reports and corrective action forms • Data Monitoring Committee reports (as applicable) (Co-ordinating Centre TMF only) • Trial Steering Committee reports (as applicable) (Co-ordinating Centre TMF only) • Statistical analyses reports (Co-ordinating Centre TMF only) • Funder reports (Co-ordinating Centre TMF only)
B.9	**Vendor Management (Co-ordinating Centre TMF only)** • Correspondence with and evidence of vendor performance oversight • Contracts for new vendors and correspondence with and evidence of performance management and oversight

B.10	**Miscellaneous**
	• Correspondence letters, relevant emails etc
	• Working practice documents
	• AT4 electronic tourniquet device documents
	  ○ Completed device supplies log and/or delivery note
	  ○ Confirmation of local MPE approval
	  ○ Anetic Aid test report
	  ○ Anetic Aid AT4 device service reports (if applicable)
	  ○ Product Training Guidance - AT4 Electronic Tourniquet (current and superseded versions where applicable)

	Section C: Trial Completion
C.1	**Closure** • Notification of study closure to the ethics committee • Notification of study closure to the competent authority MHRA (where applicable): CESP emails (if applicable) • Notification of study closure to the host organisation • Notification of study closure to the Sponsor • Treatment allocation and decoding documentation • Documentation of IMP return and/or destruction and pharmacy records (as applicable)
C.2	**Audit and Publication** • Final study report to REC and funder • Evidence of upload of trial results to EudraCT (as applicable) • Final close-out audit report (as applicable) • Publication
C.3	**IMP Management (not applicable for RECAST-3)** • IMP and placebo accountability logs • Evidence of destruction of surplus stocks

This file must be kept for 7 years from the date of issue of the final study report

It is acceptable for any superseded documents to be kept in a separate archive file with appropriate file note explaining location