# TRIAL SITE FILE INDEX

## Section A: Pre-trial opening

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| **A.1** | **Trial Development Documentation**<br>Minutes of initial meeting with the Sponsor and confirmation of Sponsor support<br>Evidence of investigator selection,<br>Evidence of site selection,<br>Evidence of vendor selection and RF1 TD002,<br>Risk assessment,<br>Peer review reports,<br>Funding application<br>All contracts with the funder and vendors. |
| **A.2** | **Study Protocol and associated documents (final versions)**<br>Protocol,<br>Information sheet,<br>Consent form and investigator brochure/IMP-D (where applicable) final versions.<br>Protocol to be fully signed<br>Case Report Forms and any other data collection documents, final versions. |
| **A.3** | **Approval and Agreements**<br>National ethical, Health Research Authority and competent authority (where applicable) approval<br>EudraCT email (where applicable)<br>Local Site Specific Assessment (where applicable)<br>Local NHS Trust R&D or host organisation approval and confirmation of capability and capacity<br>Sponsor / Chief Investigator agreement - TMF only<br>Sponsor / participating site non-commercial agreement |
| **A4** | **Staff Participation**<br>Site Responsibility (Delegation) Log, TA008<br>Curriculum Vitae and Training Records<br>Attendance at Investigator Training, RF1 TA008<br>SOP Compliance Form RF3 TA008<br>Evidence of site initiation<br>Regulatory green light email from the Sponsor |
| **A.5** | **Medical Testing and Pharmacy (where applicable)** |
| | Accreditation / certification of supporting Laboratories and pharmacies<br>'Normal ranges' issued by local laboratories<br>Investigational product handling (where applicable) – local procedures where not in the study protocol<br>Investigational product control (where applicable) – local procedures where not in the<br>study protocol<br>Investigational medicinal product records – certificate of analyses, shipping records,<br>labelling to be used<br>QP certification |
| **A.6** | **Randomization and Blinding**<br>Randomization, blinding and un-blinding procedures where not in the study protocol |
| **A.7** | **Database Build**<br>Database specification documentation, user acceptance testing, validation |

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| | documentation, security and access arrangements, and disaster recovery plan |

## Section B: Ongoing Trial

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| **B.1** | **Study Protocol Amendments and Approvals**<br>Log of study documentation amendments, RF1 TA013<br>Current versions of trial documentation: protocol to be fully signed<br>Previous versions of trial documents when superseded, clearly marked as such<br>Sponsor confirmation of amendment categorisation<br>Ethics committee, Health Research Authority and competent authority approvals of amendments |
| **B.2** | **Staff Participation**<br>Updated RF1TA008 to include new trial staff<br>Updated CVs and training records<br>Updated Attendance at Investigator Training, RF1 TA008 |
| **B.3** | **Informed consent**<br>Signed consent forms of all trial participants<br>Participant Screening and Enrolment Log,RF1 TA011 |
| **B.4** | **Medical Testing and Pharmacy**<br>Updated accreditation / certification of supporting laboratories and pharmacies<br>Updated 'normal ranges' issued by local laboratories<br>Documented evidence of any changes and their implementation to Investigational product handling (where applicable) – local procedures where not in the study protocol<br>Documented evidence of any changes and their implementation to investigational product control (where applicable) – local procedures where not in the study protocol<br>Updated investigational medicinal product records – certificate of analyses, shipping<br>records, amended labelling to be used 9if any) |
| **B.5** | **Case Report Forms, Source Documents and Data Management**<br>Completed CRFs (copy where originals are sent to a central collection repository) and<br>amended CRFs<br>Source documents related to the trial<br>Ongoing database amendments, alterations and revision documentation and evidence<br>Data management plan, database lock plan and procedures<br>Monitoring plan |
| **B.6** | **Serious Adverse Events and Serious GCP Breaches**<br>SAE reporting forms, RF1 TA014.<br>eSUSAR / CIOMs form (IMP trials only)<br>SAE reporting forms to the ethics committee<br>Annual safety reports and Development Safety Update Reports (DSUR) to ethics committee and regulatory authority (where applicable)<br>Evidence of notification of actions to be taken and their implementation following a SUSAR (where applicable).<br>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**<br>List and location of retained samples and Tumour Banking |

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| | Transfer agreements to other institutions |
| **B.8** | **Audit and Reporting**<br>Annual progress report(s) to host institution, the ethics committee and competent authority (where applicable)<br>Monitoring reports<br>Sponsor audit reports and corrective action forms<br>Data Monitoring Committee reports (as applicable)<br>Trial Steering Committee reports (as applicable)<br>Statistical analyses reports<br>Funder reports |
| **B.9** | **Vendor Management**<br>Correspondence with and evidence of vendor performance oversight.<br>Contracts for new vendors and correspondence with and evidence of performance management and oversight |
| **B.10** | **Miscellaneous**<br>Correspondence letters, relevant emails etc |

## Section C: Trial Completion

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| **C.1** | **Closure**<br>Notification of study closure to the ethics committee<br>Notification of study closure to the competent authority (where applicable): CESP emails<br>Notification of study closure to the host organisation<br>Notification of study closure to the Sponsor<br>Treatment allocation and decoding documentation<br>Documentation of IMP return and/or destruction and pharmacy records |
| **C.2** | **Audit and Publication**<br>Final study report to REC and funder<br>Evidence of upload of trial results to EudraCT<br>Final close-out audit report (as applicable)<br>Publication |
| **C.3** | **IMP Management**<br>IMP and placebo accountability logs<br>Evidence of destruction of surplus stocks |