|  |
| --- |
| **JRESDOC0003****Trial Master File (TMF) Index** |
| **Version number:** | Version 9.0 | **Effective Date:** | 11/08/2021 |

|  |  |
| --- | --- |
| **Trial Acronym/Short Title** |  |
| **Chief Investigator (CI)** |  |
| **Sponsor Contact** |  |
| **JRES ID:** | **IRAS ID:** | **EudraCT ID:** |

|  |  |  |
| --- | --- | --- |
| **Table of content:** | **Filed** | **N/A** |
|  | **Sponsorship** |
| 1.1 | Risk Assessment Questionnaire and Assessment |  |  |
| 1.2 | Sponsorship in Principle Letter |  |  |
| 1.3 | Final Sponsorship Letter |  |  |
| 1.4 | Insurance/Indemnity Policy |  | SGH studies |
| 1.5 | Peer Review (if applicable) |  |  |
| 1.6 | Care Group Lead Approval  |  |  |
| 1.7 | Capacity and Capability  |  |  |
| 1.8 | Open to Recruitment Letter  |  |  |
| 1.9 | Pharmacy Greenlight  |  |  |
|  | **Agreements** |
| 2.1 | NIHR adoption-rejection *(inc. Portfolio Adoption Form)* |  |  |
| 2.2 | Delegation of Duties Signed Agreement (DDSA) |  |  |
| 2.3 | IMP or Device supply agreement |  |  |
| 2.4 | Pharmacy Agreement *(if applicable)* |  |  |
| 2.5 | Technical Agreement *(if applicable)* |  |  |
| 2.6 | Laboratory Service Agreement *(if applicable)* |  |  |
| 2.7 | CRO agreement *(if applicable)* |  |  |
| 2.8 | Memorandum of Understanding (MoU) *(if applicable)* |  |  |
| 2.9 | Funding agreements |  |  |
| 2.10 | Non-commercial agreement between SGUL and SGH |  |  |
| 2.11 | Annual Report to Funding organisation *(if applicable)* |  |  |
| 2.12 | Grant application(s)/award(s) |  |  |
| 2.13 | Other agreements *(e.g. PIC agreements)* |  |  |
| 2.14 | Vendor Assessments *(e.g. Central Laboratories assessment)* |  |  |
| 2.15 | Related Correspondence |  |  |
|  | **Protocol** |
| 3.1 | Final Approved Protocol  |  |  |
| 3.2 | Superseded Protocols  |  |  |
| 3.3 | Draft / tracked changes protocols |  |  |
| 3.4 | Deviation Forms *(all sites)* |  |  |
| 3.5 | PI Protocol Acknowledgement Signature Page *(all sites)* |  |  |
| 3.6  | Related Correspondence |  |  |
|  | **Study Team Documentation**  |
| 4.1 | Study Training log(s) *(SIV, protocol, amendments etc.)* |  |  |
| 4.2 | Protocol Training Materials *(e.g. study presentations)* |  |  |
| 4.3 | JRES SOP read log *(also for subsequent versions)* |  |  |
| 4.4 | Staff Signature and Delegation Log  |  |  |
| 4.5 | CVs and GCP Log *(all sites)* |  |  |
| 4.6 | CVs and GCP certificates *(included all staff on listed study delegation log)* |  |  |
|  | **Participant Information** |
| 5.1 | Participant Information Sheet (PIS) (*final and superseded)* |  |  |
| 5.2 | Informed Consent Form (ICF) Template (*final and superseded)* |  |  |
| 5.3 | GP Letter Template (*final and superseded)* |  |  |
| 5.4 | Other study related information & documentation*(e.g. Recruitment poster, diary cards, questionnaires)* |  |  |
|  | **Research Ethics Committee (REC)**  |
| 6.1 | REC Application  |  |  |
| 6.2 | Schedule of Events  |  |  |
| 6.3 | REC Validation letter  |  |  |
| 6.4 | Provisional REC approval *(if applicable)* |  |  |
| 6.5 | Queries and Response to conditions of approval *(if applicable)* |  |  |
| 6.6 | REC Favourable Opinion Letter  |  |  |
| 6.7 | Annual Progress Reports (APRs) *(one for each year)* |  |  |
| 6.8 | End of Trial Notification*(inc. supporting documents)* |  |  |
| 6.9 | Related Correspondence |  |  |
| **7.**  | **Medicines and Healthcare Regulatory Agency (MHRA)** |
| 7.1 | CTA application *(inc. IRAS form)* |  |  |
| 7.2 | MHRA Acknowledgement/ Remarks / Response/ Notice of Acceptance  |  |  |
| 7.3 | Declaration of End of Trial (DET) |  |  |
| 7.4 | Final Report to MHRA *(inc. supporting documents)* |  |  |
| 7.5 | Confirmation of EudraCT registration |  |  |
| 7.6 | Related Correspondence |  |  |
| **8.** | **Health Research Authority (HRA)** |
| 8.1 | HRA initial assessment letter |  |  |
| 8.2 | HRA Acknowledgement  |  |  |
| 8.3 | HRA Approval Letter  |  |  |
| **9.** | **Study Amendments** |
| 9.1 | Study Amendment Log |  |  |
| 9.2 | Amendment Submissions and Approvals *(each amendment should be filed separately)- REC Approval (if applicable)- HRA Approval (if applicable)- MHRA Approval (if applicable)**- R&D Capacity and Capability Approvals (if applicable for all sites)*  |  |  |
| **10.** | **Investigational Medicinal Product (IMP) (if applicable)****(File note 10.6-10.17 to be kept in PSF whilst study open)** |
| 10.1 | Investigational Medicinal Product Dossier (IMPD) (*final and superseded)* |  |  |
| 10.2 | Investigator Brochure (IB) (*final and superseded)* |  |  |
| 10.3 | Summary of Product Characteristics (SmPC) *- SmPC Checking log* (*final and superseded)* |  |  |
| 10.4 | Manufacturing Authorisation License (MA(IMP)) *(if applicable)* |  |  |
| 10.5 | Quality Product Certificate *(if applicable)* |  |  |
| 10.6 | IMP Handling Instructions / Pharmacy Manual *(if applicable)* |  |  |
| 10.7 | IMP Label Template and related paperwork *(sample label approved by MHRA)* |  |  |
| 10.8 | IMP Shipping Records *(all sites)* |  |  |
| 10.9 | IMP Prescription Template |  |  |
| 10.10 | IMP Accountability Log *(all sites)* |  |  |
| 10.11 | IMP Destruction Log *(all sites)* |  |  |
| 10.12 | Temperature readings and temperature deviation log *(if applicable)* |  |  |
| 10.13 | Master Randomisation List  |  |  |
| 10.14 | Treatment allocation *(all sites)* |  |  |
| 10.15 | Decoding Procedure for Blinded Trials signed/agreed by pharmacy *(if applicable)* |  |  |
| 10.16 | Related Correspondence  |  |  |
| **11.** | **Investigational Medical Device (IMD) (if applicable)** |
| 11.1 | Investigational Device Brochure (IDB) (*final and superseded)* |  |  |
| 11.2 | Manufacturing Device Authorisation License  |  |  |
| 11.3 | CE certification |  |  |
| 11.4 | IMD Handling Instructions *(if applicable)* |  |  |
| 11.5 | IMD Label Template *(sample approved by MHRA)* |  |  |
| 11.6 | Certified QP release statement *(if applicable)* |  |  |
| 11.7 | Certificate of Analysis (CoA) *(if applicable)* |  |  |
| 11.8 | IMD Shipping Records *(all sites)* |  |  |
| 11.9 | IMD Prescription Template |  |  |
| 11.10 | IMD Accountability Log *(all sites)* |  |  |
| 11.11 | IMD Destruction Log *(all sites)* |  |  |
| 11.12 | Treatment allocation *(all sites)* |  |  |
| 11.13 | Related Correspondence |  |  |
| **12.** | **Pharmacovigilance** |
| 12.1 | Adverse Events (AE) Logs *(all sites)*  |  |  |
| 12.2 | SAE report(s) and follow-up information *(all sites)*  |  |  |
| 12.3 | SUSAR reports and follow-up information *(all sites)* |  |  |
| 12.4 | Urgent Safety Measures *(if applicable)* |  |  |
| 12.5 | Development Update Safety Reports (DSURs) |  |  |
| 12.6 | Participant 24hr contact cards |  |  |
| 12.7 | Related Correspondence |  |  |
| **13.** | **Data Management and Statistical analysis/output***Should include: statistical analysis plan, data management plan, sample size calculations* |
| 13.1 | Current Trial Case Report Forms (CRFs) templates |  |  |
| JRES review and approval for Trial CRF(s) versions |  |  |
| Draft and Superseded Trial CRF(s) versions *(if applicable)* |  |  |
| 13.2 | Instructions for completion *(if applicable)* |  |  |
| 13.3 | Data queries |  |  |
| 13.4 | Computerised systems / Database assessment and validation documentation |  |  |
| 13.5 | Statistical Review  |  |  |
| 13.6 | Interim Data Analysis *(if applicable)* |  |  |
| 13.7 | Randomisation Vendor and Process *(if applicable)*  |  |  |
| 13.8 | Related Correspondence |  |  |
| **14.** | **Monitoring** |
| 14.1 | Study Monitoring Plan  |  |  |
| 14.2 | Monitoring Visit Log  |  |  |
| 14.3 | Site Initiation Documentation*- Site Activation Form**- Site Initiation Meeting Report* *- Site Initiation Presentation and supporting documents* |  |  |
| 14.4 | Pharmacy Initiation Letter/Report *(if applicable, may be included in SIV report)* |  |  |
| 14.5 | Monitoring Reports for each visit *(inc. intent to monitor correspondence)*  |  |  |
| 14.6 | Monitoring Close Out reports |  |  |
| **15.** | **Audits and Inspections** |
| 15.1 | Correspondence of Intent to Audit |  |  |
| 15.2 | Audit Follow up |  |  |
| 15.3 | Regulatory Inspections |  |  |
| **16.** | **Central Laboratories *(if applicable)*** |
| 16.1 | Contact List  |  |  |
| 16.2 | St George’s Evaluation/Assessment |  |  |
| 16.3 | Laboratory Accreditation Certificate |  |  |
| 16.4 | Laboratory Normal Reference Ranges |  |  |
| 16.5 | Sample Shipment Record and correspondence *(all sites)*  |  |  |
| 16.6 | Sample Collection Log *(all sites)* |  |  |
| 16.7 | HTA Risk Assessment and Registration Form *(if applicable)* |  |  |
| 16.8 | SOPs/Instruction manuals for trial specific procedure(s) |  |  |
| **17.** | **Public Database/Publications** |
| 17.1 | Public Database Registration *(e.g. clinicaltrials.gov)* |  |  |
| 17.2 | Presentation(s) related to current results |  |  |
| 17.3 | Publication(s) related to current results |  |  |
| **18.** | **Trial Specific Documentation *(if applicable)*** |
| 18.1 | Trial Specific SOPs |  |  |
| **19.** | **Trial Committees** |
| 19.1 | Trial Management Group (TMG) *(agendas and minutes)* |  |  |
| 19.2 | Data Monitoring Committee (DMC) *(charter, agendas and minutes)* |  |  |
| 19.3 | Trial Steering Committee (TSC) *(charter, agendas and minutes)* |  |  |
| **20.** | **Correspondence**  |
| 20.1 | Emails/Letters *(File note to be added if emails are stored electronically)* |  |  |
| 20.2 | Other |  |  |
| **21.** | **Archiving Arrangements** |
| 21.1 | Archiving Procedure |  |  |
| 21.2 | Archiving Personnel Details |  |  |
| **22.** | **Site Specific Documentation** Please assemble Section 22 for **each site detailed** in section 22.1 participating in the trial (*i.e.* Section 22.2, 22.3 *etc.*) |
| **Participating Trial site Name and Identifier:** |
| 22.1 | Site Feasibility Checklist *(signed off by JRES)* |  |  |
| 22.2 | Site Contact Details |  |  |
| 22.3 | Clinical Trial Site Agreement *(CTSA)* |  |  |
| 22.4 | Sponsor Open Recruitment Letter |  |  |
| 22.5 | Site Pharmacy Arrangements *(if applicable)* |  |  |
| 22.6 | Site Laboratory Arrangements *(if applicable)* |  |  |
| 22.7 | Recruitment Updates  |  |  |
| 22.8 | Audit Certificates *(if applicable)* |  |  |
| 22.9 | Correspondence |  |  |