|  |  |  |  |
| --- | --- | --- | --- |
| **JRESDOC0076a**  **International Only Studies Trial Master File (TMF) Index** | | | |
| **Version number:** | Version 2.0 | **Effective Date:** | 13/08/2024 |

|  |  |  |
| --- | --- | --- |
| **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) |  |  |
|  | **Agreements** | | |
| 2.1 | Delegation of Duties Signed Agreement (DDSA) |  |  |
| 2.2 | IMP or Device supply agreement |  |  |
| 2.3 | Pharmacy Agreement *(if applicable)* |  |  |
| 2.4 | Technical Agreement *(if applicable)* |  |  |
| 2.5 | Laboratory Service Agreement *(if applicable)* |  |  |
| 2.6 | CRO agreement *(if applicable)* |  |  |
| 2.7 | Memorandum of Understanding (MoU) *(if applicable)* |  |  |
| 2.8 | Funding agreements |  |  |
| 2.9 | Site Agreements |  |  |
| 2.10 | Annual Report to Funding organisation *(if applicable)* |  |  |
| 2.11 | Grant application(s)/award(s) |  |  |
| 2.12 | Other agreements *(e.g. PIC agreements)* |  |  |
| 2.13 | Vendor Assessments  *(e.g. Central Laboratories assessment)* |  |  |
| 2.14 | 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| 3.2 | Superseded Protocols |  |  |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 *(all sites)* |  |  |
| 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| 5.1 | Participant Information Sheet (PIS)  (*final and superseded)* |  |  |
| 5.2 | Informed Consent Form (ICF) Template  (*final and superseded)* |  |  |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)* |  |  |
|  | **UK Research Ethics Committee (REC)** | | |
| 6.1 | REC Application |  |  |
| 6.2 | Provisional REC approval *(if applicable)* |  |  |
| 6.3 | Queries and Response to conditions of approval  *(if applicable)* |  |  |
| 6.4 | REC Favourable Opinion Letter |  |  |
| 6.5 | Annual Progress Reports (APRs) *(one for each year)* |  |  |
| 6.6 | End of Trial Notification *(inc. supporting documents)* |  |  |
| 6.7 | Related Correspondence |  |  |
| **7.** | **Study Amendments** | | |
| 7.1 | Study Amendment Log |  |  |
| 7.2 | Amendment Submissions and Approvals *(each amendment should be filed separately) - UK REC Approval (if applicable)*  *- Site REC Approval (if applicable)* |  |  |
| **8** | **Investigational Medicinal Product (IMP) (if applicable)**  **(File note 10.6-10.17 to be kept in PSF whilst study open)** | | |
| 8.1 | Investigational Medicinal Product Dossier (IMPD) (*final and superseded)* |  |  |
| 8.2 | Investigator Brochure (IB) (*final and superseded)* |  |  |
| 8.3 | Summary of Product Characteristics (SmPC)  *- SmPC Checking log*  (*final and superseded)* |  |  |
| 8.4 | Manufacturing Authorisation License (MA(IMP))  *(if applicable)* |  |  |
| 8.5 | Quality Product Certificate *(if applicable)* |  |  |
| 8.6 | IMP Handling Instructions / Pharmacy Manual  *(if applicable)* |  |  |
| 8.7 | IMP Label Template and related paperwork  *(sample label approved by MHRA)* |  |  |
| 8.8 | IMP Shipping Records *(all sites)* |  |  |
| 8.9 | IMP Prescription Template |  |  |
| 8.10 | IMP Accountability Log *(all sites)* |  |  |
| 8.11 | IMP Destruction Log *(all sites)* |  |  |
| 8.12 | Temperature readings and temperature deviation log *(if applicable)* |  |  |
| 8.13 | Master Randomisation List |  |  |
| 8.14 | Treatment allocation *(all sites)* |  |  |
| 8.15 | Decoding Procedure for Blinded Trials signed/agreed by pharmacy *(if applicable)* |  |  |
| 8.16 | Related Correspondence |  |  |
| **9.** | **Investigational Medical Device (IMD) (if applicable)** | | |
| 9.1 | Investigational Device Brochure (IDB)  (*final and superseded)* |  |  |
| 9.2 | Manufacturing Device Authorisation License |  |  |
| 9.3 | CE certification |  |  |
| 9.4 | IMD Handling Instructions *(if applicable)* |  |  |
| 9.5 | IMD Label Template *(sample approved by MHRA)* |  |  |
| 9.6 | Certified QP release statement *(if applicable)* |  |  |
| 9.7 | Certificate of Analysis (CoA) *(if applicable)* |  |  |
| 9.8 | IMD Shipping Records *(all sites)* |  |  |
| 9.9 | IMD Prescription Template |  |  |
| 9.10 | IMD Accountability Log *(all sites)* |  |  |
| 9.11 | IMD Destruction Log *(all sites)* |  |  |
| 9.12 | Treatment allocation *(all sites)* |  |  |
| 9.13 | Related Correspondence |  |  |
| **10.** | **Pharmacovigilance** | | |
| 10.1 | Adverse Events (AE) Logs *(all sites)* |  |  |
| 10.2 | SAE report(s) and follow-up information *(all sites)* |  |  |
| 10.3 | SUSAR reports and follow-up information *(all sites)* |  |  |
| 10.4 | Urgent Safety Measures *(if applicable)* |  |  |
| 10.5 | Participant 24hr contact cards |  |  |
| 10.6 | Related Correspondence |  |  |
| **11.** | **Data Management and Statistical analysis/output**  *Should include: statistical analysis plan, data management plan, sample size calculations* | | |
| 11.1 | 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)* |  |  |
| 11.2 | Instructions for completion *(if applicable)* |  |  |
| 11.3 | Data queries |  |  |
| 11.4 | Computerised systems / Database assessment and validation documentation |  |  |
| 11.5 | Statistical Review |  |  |
| 11.6 | Interim Data Analysis *(if applicable)* |  |  |
| 11.7 | Randomisation Vendor and Process *(if applicable)* |  |  |
| 11.8 | Related Correspondence |  |  |
| **12.** | **Monitoring** | | |
| 12.1 | Study Monitoring Plan |  |  |
| 12.2 | Monitoring Visit Logs *(all sites)* |  |  |
| 12.3 | Site Initiation Documentation *(all sites)*  *- Site Initiation Visit Report*  *- Site Initiation Presentation and supporting documents* |  |  |
| 12.4 | Pharmacy Initiation Letter/Report  *(if applicable, may be included in SIV report)* |  |  |
| 12.5 | Monitoring Reports for each visit *(all sites)* *(inc. intent to monitor correspondence)* |  |  |
| 12.6 | Monitoring Close Out reports *(all sites)* |  |  |
| **13.** | **Audits and Inspections** | | |
| 13.1 | Correspondence of Intent to Audit |  |  |
| 13.2 | Audit Follow up |  |  |
| 13.3 | Regulatory Inspections |  |  |
| **14.** | **Central Laboratories *(if applicable)*** | | |
| 14.1 | Contact List |  |  |
| 14.2 | St George’s Evaluation/Assessment |  |  |
| 14.3 | Laboratory Accreditation Certificate *(all sites)* |  |  |
| 14.4 | Laboratory Normal Reference Ranges *(all sites)* |  |  |
| 14.5 | Sample Shipment Record and correspondence *(all sites)* |  |  |
| 14.6 | Sample Collection Log *(all sites)* |  |  |
| 14.7 | HTA Risk Assessment and Registration Form *(if applicable)* |  |  |
| 14.8 | SOPs/Instruction manuals for trial specific procedure(s) |  |  |
| **15.** | **Public Database/Publications** | | |
| 15.1 | Public Database Registration *(e.g. clinicaltrials.gov)* |  |  |
| 15.2 | Presentation(s) related to current results |  |  |
| 15.3 | Publication(s) related to current results |  |  |
| **16.** | **Trial Specific Documentation *(if applicable)*** | | |
| 16.1 | Trial Specific SOPs |  |  |
| **17.** | **Trial Committees** | | |
| 17.1 | Trial Management Group (TMG) *(agendas and minutes)* |  |  |
| 17.2 | Data Monitoring Committee (DMC) *(charter, agendas and minutes)* |  |  |
| 17.3 | Trial Steering Committee (TSC) *(charter, agendas and minutes)* |  |  |
| **18.** | **Correspondence** | | |
| 18.1 | Emails/Letters  *(File note to be added if emails are stored electronically)* |  |  |
| 18.2 | Other |  |  |
| **19.** | **Archiving Arrangements** | | |
| 19.1 | Archiving Procedure |  |  |
| 19.2 | Archiving Personnel Details |  |  |
| **20.** | **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:** | | | |
| 20.1 | Site Contact Details |  |  |
| 20.2 | Sponsor Open Recruitment Letter |  |  |
| 20.3 | Local Insurance Policy |  |  |
| 20.4 | Local Ethics Submission |  |  |
| 20.5 | Local Ethics Approval |  |  |
| 20.6 | Local Regulatory Submissions |  |  |
| 20.7 | Local Regulatory Approvals |  |  |
| 20.8 | Other Local Approvals |  |  |
| 20.8 | Annual Progress Reports |  |  |
| 20.9 | Site Pharmacy Arrangements *(if applicable)* |  |  |
| 20.10 | Site Laboratory Arrangements *(if applicable)* |  |  |
| 20.11 | Recruitment Updates |  |  |
| 20.12 | Audit Certificates *(if applicable)* |  |  |
| 20.13 | Correspondence |  |  |