**Trial Master File INDEX**

The filing of essential documents in the TMF should be done in accordance with JRO/INV/S02 SOP for the Preparation and Maintenance of the Trial Master File (TMF) and Investigator Site File (ISF) for CTIMPs Sponsored by UCL.

This index should be printed and placed in the front of the Trial Master File (TMF).

Once a document has been filed, add ‘YES’ in the ‘FILED?’ column. Where the document is not applicable for the trial add ‘N/A’. If a document is filed in another location add details of this location.

| **SECTION NAME** | **DOCUMENT NAME** | **FILED?**  **(YES or N/A)** |
| --- | --- | --- |
| 1. **TRIAL ADMINISTRATION & MANAGEMENT** | | |
| * 1. **Contact Information** | UCL JRO Trial Contact Sheet |  |
| * 1. **Training** | Staff CVs (signed and dated) |  |
| Staff Training Records (e.g., GCP Certificates, Protocol and trial specific training) |  |
| * 1. **Statistician CV** | Statistician CV |  |
| * 1. **Site Contact Information** | Site Contact Information |  |
| * 1. **TMF Review** | TMF Review Checklist |  |
| * 1. **Central Trial Responsibilities Log** | Central Trial Responsibilities Log |  |
| * 1. **Trial Management Plans** | Contract Research Organisation (CRO)/Clinical Trial Unit (CTU)/Sponsor Oversight/ Project Management Plan *(if applicable)* |  |
| * 1. **Newsletters** | Newsletters *(if applicable)* |  |
| * 1. **Trial Close Out & Archiving** | Confirmation of Trial Close & Archiving Email / Letter |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **UCL SPONSORSHIP** | | |
| * 1. **Sponsor Letters** | Sponsorship Letter(s) - In principle/ Final |  |
| Legal Representative Letter of Engagement *(if applicable)* |  |
| Other |  |
| * 1. **Insurance** | Insurance Certificate/ Policy |  |
| * 1. **Peer Review** | Peer Review *(if applicable)* |  |
| * 1. **Conflict of Interest** | Conflict of Interest Management Plan *(if applicable)* |  |
| * 1. **Trial Registry Confirmation** | Trial Registration confirmation (e.g., Clinicaltrials.gov, ISRCTN) |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **AGREEMENTS** | | |
| * 1. **IMP** | Investigational Medicinal Product (IMP) Supply/ Manufacture/ Import Agreement |  |
| Quality and Technical Agreements (i.e., manufacturing/ QP release, packaging, radiolabelling, IMP importation) |  |
| Other |  |
| * 1. **Laboratory** | Central Laboratory Services Agreement/ Material Transfer Agreement if not with the model Non-Commercial Agreement (mNCA) *(if applicable)* |  |
| * 1. **Service Provider** | CTU/ CRO Agreement/ Service Level Agreement *(if applicable)* |  |
| * 1. **Randomisation System** | Randomisation/ Code Break System Agreement *(if applicable)* |  |
| * 1. **Sponsor-CI Agreement** | Sponsor- Chief Investigator (CI) Agreement |  |
| * 1. **Clinical Trial Site Agreement** | Sample model Non-Commercial Agreement (mNCA) |  |
| Signed mNCA (including pharmacy/ laboratory and material transfer agreement *if applicable*) |  |
| * 1. **Other Agreements** | Confidentiality Agreements *(if applicable)* |  |
| Other agreements *(If applicable)* |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **FUNDING AND FINANCE** |  |  |
| * 1. **Grant Award** | Funding – Grant Application |  |
| Funding – Grant Award Letter/ Agreement |  |
| * 1. **Funding Agreement** | Funding Agreement |  |
| * 1. **Other Funding** | Other |  |
| * 1. **Invoices** | Invoices |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **RESEARCH ETHICS COMMITTEE, HEALTH RESEARCH AUTHORITY & NATIONAL INSTITUTE FOR HEALTH RESEARCH (REC, HRA & NIHR)** | | |
| * 1. **REC** | | |
| * + 1. Application | Initial Signed Application, supporting documentation and cover letter to REC |  |
| Response to Conditions of Approval *(if applicable)* |  |
| * + 1. Approvals | REC / Gene Therapy Advisory Committee (GTAC) Validation Letter, Favourable/ Provisional/ with Conditions Letter |  |
| * + 1. Annual Progress Reports | Annual Progress Report to REC and acknowledgement |  |
| * + 1. End of Trial to REC | End of Trial Notification to REC and acknowledgement |  |
| Final Report Notification and supporting documents |  |
| * + 1. Other Notifications | Serious Breach Notifications and acknowledgement *(if applicable)* |  |
| Notification of Urgent Safety Measures *(if applicable)* |  |
| Other |  |
| * + 1. Correspondence | General correspondence |  |
| * 1. **HRA** | | |
| * + 1. Application | Statement of Activities/ Organisation Information Document (OID) |  |
| Schedule of Events/ Schedule of Events Cost Attribution Template (SoECAT) |  |
| * + 1. Assessment & Approval | HRA Initial Assessment Letter |  |
| HRA Final Assessment/ Approval Letter |  |
| * + 1. Correspondence | General correspondence |  |
| * 1. **NIHR** | | |
| * + 1. Portfolio Adoption | Portfolio Adoption Confirmation |  |
| * + 1. Correspondence | General correspondence |  |
| 1. **MEDICINES AND HEALTHCARE REGULATORY AGENCY (MHRA)** | | |
| * 1. **CTA Application** | Clinical Trial Authorisation (CTA) Initial signed application and supporting documentation to MHRA (including Cover Letter, Response to Conditions of Approval/ Non-acceptance) |  |
| * 1. **Approvals** | MHRA Validation Letter/ Acceptance Letter/ with Conditions Letter/ Grounds for Non-acceptance Letter |  |
| * 1. **Other Notifications** | Serious Breach Notifications *(if applicable)* |  |
| Notification of Urgent Safety Measures *(if applicable)* |  |
| * 1. **End of Trial** | End of Trial Notification to MHRA |  |
| Final Report Notification and supporting documents |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **AMENDMENTS** | | |
| * 1. **Amendment #** | | |
| * + 1. Submission | Substantial and Non-Substantial Amendments (including where applicable, completed Amendment Tool, cover letter, supporting documents, response to conditions of approval) |  |
| * + 1. Approvals | Amendment HRA/ REC/ GTAC/ MHRA Approval Letter(s)/ Substantial and Non-substantial Amendments Favourable Opinion Letter/ with Conditions Letter |  |
| Trust R&D NHS Permission Letter / acknowledgement for Trial Amendments |  |
| * + 1. Correspondence | General correspondence |  |
| 1. **PROTOCOL** | | |
| * 1. **Current** | Current approved Protocol & signature page |  |
| * 1. **Superseded** | Superseded Protocol versions |  |
| * 1. **Protocol Development** | Protocol development documentation - draft versions and correspondence |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **PARTICIPANT INFORMATION** | | |
| * 1. **Participant Information Sheet (PIS) & Informed Consent Form (ICF)** | | |
| * + 1. Current | Current approved Template Participant Information Sheet (PIS) / Informed Consent Form (ICF) |  |
| * + 1. Superseded | Superseded Template Participant Information Sheet (PIS) / Informed Consent Form (ICF) |  |
| * 1. **GP Letter** | | |
| * + 1. Current | Current approved Template GP letter |  |
| * + 1. Superseded | Superseded versions of Template GP letters |  |
| * 1. **24hrs Contact Card** | 24 hrs contact card *(if applicable)* |  |
| * 1. **Questionnaires** | | |
| * + 1. Current | Current Template Quality of Life Questionnaires (*validated / trial specific if applicable)* |  |
| * + 1. Superseded | Superseded versions of Template Quality of Life Questionnaires (*validated / trial specific if applicable)* |  |
| * 1. **Patient Diary** | | |
| * + 1. Current | Current Template Patient Diaries (*if applicable*) |  |
| * + 1. Superseded | Superseded versions of Patient Diaries (*if applicable*) |  |
| * 1. **Other** | Other (e.g., posters, leaflets) (*if applicable*) |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **INVESTIGATIONAL MEDICINAL PRODUCT (IMP)** | | |
| * 1. **SODA/ ATIMP Management Plan** | | |
| * + 1. Current | Current Summary of Drug Arrangements (SODA)/ Advanced Therapy Investigational Medicinal Product (ATIMP) Management Plan and associated documents |  |
| * + 1. Superseded | Superseded SODA/ ATIMP Management Plan and associated documents |  |
| * 1. **IMPD** | | |
| * + 1. Current | Current Product Information (Full/ Simplified Investigational Medicinal Product Dossier (IMPD)) |  |
| * + 1. Superseded | Superseded Product Information (Full/ Simplified IMPD) |  |
| * 1. **Safety Document (IB / SmPC)** | | |
| * + 1. Current | Current IMP Safety Information document (Investigator Brochure (IB) or Summary of Product Characteristics (SmPC)) |  |
| * + 1. Superseded | Superseded version of IMP Safety Information document (IB or SmPC) |  |
| * + 1. Review | JRO and CI review of IB/ SmPC updates |  |
| * + 1. nIMP | Safety document for unlicensed non-Investigational Medicinal Product (nIMP) *(if applicable)* |  |
| * 1. **GMS Approval (if applicable)** | Genomic Medicine Service (GMS) Approval *(if applicable)* |  |
| * 1. **IMP Label** | | |
| * + 1. Current Labelling Form | Current IMP Label Regulatory Approval Form |  |
| * + 1. Superseded Labelling Form | Superseded IMP Label Regulatory Approval Form |  |
| * + 1. Current Label Artwork | Current Label Artwork |  |
| * + 1. Superseded Label Artwork | Superseded Label Artwork |  |
| * 1. **QP release** | Certified Qualified Person (QP) Release Statement *(if applicable)* |  |
| QP Statement on EU GMP Compliance *(if applicable)* |  |
| QP Declaration *(if applicable)* |  |
| IMP Certificate of Analysis *(if applicable)* |  |
| TSE Certificate *(if applicable)* |  |
| * 1. **Recalls** | IMP Recalls *(if applicable)* |  |
| * 1. **IMP Accountability Log** | IMP Accountability Log Template *(if applicable)* |  |
| * 1. **IMP Destruction & Transfer** | IMP Destruction Log Template *(if applicable)* |  |
| * 1. **IMP Temperature Deviations** | Temperature Log Template *(if applicable)* |  |
| Temperature Deviation Log Template *(if applicable)* |  |
| * 1. **IMP Shipment & Orders** | IMP Shipment Records |  |
| IMP Orders |  |
| * 1. **IMP Prescription Template** | IMP Prescription Master Template |  |
| * 1. **Other** | Other |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **DATA MANAGEMENT** | | |
| * 1. **Data Protection** | | |
| * + 1. UCL Data Protection Registration | UCL Data Protection Registration Application Form |  |
| Data Protection Impact Assessment (DPIA) *(if applicable)* |  |
| UCL Data Protection Registration Confirmation |  |
| * + 1. Data Protection Breaches | Data Protection Breach Reports *(if applicable)* |  |
| * 1. **CRF** | | |
| * + 1. Current | Current approved CRF |  |
| * + 1. Superseded | Superseded versions of CRF |  |
| * + 1. CRF Approval | CRF Sign-off Form – CI and Statistician approval |  |
| * 1. **Data Management Plan** | | |
| * + 1. Current | Current Data Management Plan/ SOP |  |
| * + 1. Superseded | Superseded Data Management Plan/ SOP |  |
| * 1. **Database / eCRF / Randomisation system** | User manuals |  |
| Database validation documentation *(if applicable)* |  |
| User Acceptance Testing (UAT) *(if applicable)* |  |
| * 1. **Completed CRFs** | Completed CRFs |  |
| Completed Diaries *(if applicable)* |  |
| Completed Quality of Life Questionnaires *(if applicable)* |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **PHARMACOVIGILANCE** | | |
| * 1. **SAE Log/ Listings** | | |
| * + 1. [Trial Site Name] | Completed SAE Recording Logs/ Listings from sites |  |
| * 1. **Unblinding (if applicable)** | Documentation of Emergency Un-blinded cases *(if applicable)* |  |
| * 1. **DSUR** | | |
| * + 1. [DSUR#\_Year] | Development Safety Update Report (DSUR) |  |
| Submission to MHRA and REC |  |
| * 1. **End of trial SAE reconciliation** | Documented reconciliation between JRO SAE list and trial database |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **MONITORING** | | |
| * 1. **Monitoring Plan** | | |
| * + 1. Current | Current Monitoring Plan |  |
| * + 1. Superseded | Superseded Monitoring Plan |  |
| * 1. **Central Coordinating Centre Initiation (if applicable)** | Central Coordinating Centre Initiation Pack |  |
| Central Coordinating Centre Initiation Slides |  |
| Central Coordinating Centre Initiation Report |  |
| Central Coordinating Centre Initiation Attendance Log |  |
| * 1. **Central Coordinating Centre Monitoring Visits (if applicable)** | Letter/ Email of Intent to Monitor Central Coordinating Centre |  |
| Central Coordinating Centre Monitoring Reports |  |
| Central Coordinating Centre Monitoring Visit Log |  |
| * 1. **Central Coordinating Centre Close Out (if applicable)** | Central Coordinating Centre Close Out Report |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **STATISTICS** | | |
| * 1. **Statistical Analysis Plan** | | |
| * + 1. Current | Current Statistical Analysis Plan |  |
| * + 1. Superseded | Superseded Statistical Analysis Plan |  |
| * 1. **Randomisation List** | Master Randomisation List *(if applicable)* |  |
| * 1. **Analysis** | | |
| * + 1. Interim | Interim Data Analysis *(if applicable)* |  |
| * + 1. Final | Final Data Analysis / End of Trial Report |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **PUBLICATIONS** | | |
| * 1. **Conferences** | Conference slides/ abstracts |  |
| * 1. **Publications** | Related publications/ abstracts |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **TRIAL OVERSIGHT COMMITTEES** | | |
| * 1. **TMG** | Trial Management Group (TMG) Terms of Reference/Charters |  |
| TMG reports/minutes |  |
| * 1. **DMC / IDMC** | Data Monitoring Committee/Independent Data Monitoring Committee (DMC)/(IDMC) Terms of Reference/Charters |  |
| DMC/IDMC reports/minutes |  |
| * 1. **TSC** | Trial Steering Committee (TSC) Terms of Reference/Charters |  |
| TSC reports/minutes |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **AUDITS & INSPECTIONS** | | |
| * 1. **Letters** | Letter of Intent to Audit by Sponsor or External Representative / Audit plan |  |
| * 1. **Audit Certificate / Report** | Audit Summary Report |  |
| Audit Summary Report for Site (*where applicable to that site*) |  |
| Audit Certificate |  |
| * 1. **Follow up** | Follow up from Audit |  |
| * 1. **Inspections** | Regulatory Inspections documentation |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **CENTRAL LABORATORIES & SAMPLES** | | |
| * 1. **[Lab Name]** | | |
| * + 1. Accreditation Certificates | Accreditation Certificates/ Conformity Documentation |  |
| * + 1. Sample Analysis Plan | Sample Analysis Plan *(if applicable)* |  |
| * + 1. Deviations | Notification of deviations *(if applicable)* |  |
| * 1. **Laboratory /Sample Processing Manual** | Laboratory/ Sample Processing Manual |  |
| * 1. **Sample Shipment / Receipt** | Sample Shipment / Receipt Documentation |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **PROCEDURAL DOCUMENTS** | | |
| * 1. **Trial SOPs/ Plans** | | |
| * + 1. Current | Current Trial Specific SOPs / Plans (e.g., Randomisation Plan, Unblinding Plan, Sample Management Plan, Dose Decision and Dose Escalation Plan) |  |
| * + 1. Superseded | Superseded Trial Specific SOPs / Plans |  |
| * 1. **JRO SOPs** | JRO SOPs (e.g., SOP for the Recording, Management and Reporting of Adverse Events by Investigators, SOP for the Recording & Reporting of Deviations, Violations, Potential Serious Breaches, Serious Breaches and Urgent Safety Measures) |  |
| * 1. **JRO SOP training logs** | JRO SOP training logs |  |
| * 1. **Correspondence** | General correspondence |  |
| 1. **SITE SPECIFIC DOCUMENTS** | | |
| * 1. **[Add Site Name]** | | |
| * + 1. NHS Permissions | Site R&D Confirmation of Capacity & Capability / NHS Permission Letter |  |
| * + 1. Open to Recruitment | Open to Recruitment Letter |  |
| * + 1. Deviations (Protocol, GCP, SOP) | Completed Log of Deviations, Violations, Potential Serious Breaches, Serious Breaches, Urgent safety measures |  |
| * + 1. Delegation Log | Completed Staff Signature and Delegation of Responsibilities Log |  |
| * + 1. Correspondence | General correspondence |  |