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| **RDT010 TRIAL MASTER FILE CHECKLIST**  **Study title:** Click here to enter text.**.**  **Protocol number:** Click here to enter text.  **CI:** Click here to enter text.  **PI:** Click here to enter text.  **Study Co-ordinator:** Click here to enter text.   |  | | --- | | ***General Guidance:***  \* All documents must be version controlled. Superseded versions can be marked by a line through the front cover, noting “SUPERSEDED”, initialled and dated.  \* Correspondence and version-controlled documents must be filed in chronological order with the most recent on top.  \* Some sections can be sub-divided to ease filing.  \* Local versions must be on Institution letter headed paper. | | | | | | | |
| Administrative | | | | | | |
| Contact List *(Contact details for CI, PM, CTC, CTM, Medical Advisor, Statistician, Pharmacist, IMP Manufacturer, Laboratories)* |  |  |  | | | |
| Version Control Log |  |  |  | | | |
| Study Protocol | | | | | | |
| Current Approved Version (Signed by CI) |  |  | |  | | |
| Superseded Approved Protocol(s) |  |  | |  | | |
| Participant Information Sheet And Consent Form | | | | | | |
| Patient Information Sheet (PIS) | | | | | | |
| Current Approved PIS Template |  |  | | | |  |
| Superseded Approved PIS(s) Templates |  |  | | | |  |
| Informed Consent Form (ICF) | | | | | | |
| Current Approved ICF Template |  |  | | | |  |
| Superseded Approved ICF Template |  |  | | | |  |
| GP Letter | | | | | | |
| Current Approved Letter/Information for Patient’s GP |  |  | | | |  |
| Superseded Approved GP Letter/Information for Patient’s GP |  |  | | | |  |
| Sample Diary Cards *(if applicable)* | | | | | | |
| Current Approved Sample Diary Cards |  |  | | | |  |
| Superseded Approved Sample Diary Cards |  |  | | | |  |
| Other Ethics Approved Data collection tools | | | | | | |
| Current Approved Recruitment Advertisement(s) |  |  | | | |  |
| Superseded Approved Recruitment Advertisement(s) |  |  | | | |  |
| REC (Ethics) | | | | | | |
| Ethics Application | | | | | | |
| Amendment submission packages and approval by Ethics |  |  | | | |  |
| Amendment logs |  |  | | | |  |
| Original Ethics Application (Full submission package and approval) |  |  | | | |  |
| Ethics Annual Progress Report(s) & Cover Letter |  |  | | | |  |
| Ethics Study Closure notification and acknowledgment including submitted Clinical Study Report |  |  | | | |  |
| Any Ethics Correspondence |  |  | | | |  |
| Regulatory INCLUDING LOCAL R&D | | | | | | |
| Competent Authority (MHRA) | | | | | | |
| (MHRA) Amendment submission packages and approval by Competent Authority |  |  | | | |  |
| Original Competent Authority application (Full submission package and approval) |  |  | | | |  |
| EudraCT Number |  |  | | | |  |
| * 1. **Data Safety Update Report (DSUR) & Cover letter** |  |  | | | |  |
| Competent authority study closure notification and acknowledgment including submitted clinical study report |  |  | | | |  |
| UHB R&D Acknowledgement Letters |  |  | | | |  |
| * 1. **UHB Trust Authorisation** |  |  | | | |  |
| * 1. **R&D Approvals for substantial amendments** |  |  | | | |  |
| R&D Reports |  |  | | | |  |
| Any Regulatory Correspondence including cover letter for any breach notifications |  |  | | | |  |
| SponsorHIP | | | | | | |
| Sponsor | | | | | | |
| Authorised Sponsorship Form/ Sponsorship Letter/ Sponsorship Agreement |  |  | | | |  |
| Submission cover letter and Sponsor approval of all amendments |  |  | | | |  |
| Insurance or Indemnity Certificate(s) |  |  | | | |  |
| Risk Assessment |  |  | | | |  |
| Related Correspondence |  |  | | | |  |
| Trial Closure Notification and archiving documentation |  |  | | | |  |
| Contracts & Agreements/ Finance/Costings | | | | | | |
| Local Agreements | | | | | | |
| CI/PI Agreement |  |  | | | |  |
| Clinical Service Lead/ Clinical Directors Form |  |  | | | |  |
| Finance |  |  | | | |  |
| Clinical Service Lead/ Clinical Directors Form |  |  | | | |  |
| Grant Application |  |  | | | |  |
| Funding Letter |  |  | | | |  |
| Sign Site Agreements |  |  | | | |  |
| Contracts |  |  | | | |  |
| Contracts (+ amendments) between Third Party Vendors and Sponsor(s) e.g. Central Labs, Technical agreements |  |  | | | |  |
| Confidentiality Agreement(s) |  |  | | | |  |
| Research Team – Staff and Training | | | | | | |
| Delegation of Duties Log for Coordinating Team |  |  | | | |  |
| Signed & Dated CVs & GCP Certificates for Research Team |  |  | | | |  |
| Staff Training Presentations/ Records |  |  | | | |  |
| IMP Section | | | | | | |
| Investigator Brochure and / or SmPC(s) and updates |  |  | | |  | |
| Imp management plan |  |  | | |  | |
| Signed IMP Supply Agreement |  |  | | |  | |
| Pharmacy Manual |  |  | | |  | |
| IMP Accountability/Dispensing log Template |  |  | | |  | |
| Prescription Template(s) |  |  | | |  | |
| Return to Sponsor Form/ Destruction Log Template |  |  | | |  | |
| Decoding/Unblinding procedures (where applicable) |  |  | | |  | |
| IMP documentation for handling, shipping, ordering, including study-specific IMP SOPs. |  |  | | |  | |
| QP release certificates for all IMP batches |  |  | | |  | |
| Certificates of Analysis for all IMP batches |  |  | | |  | |
| Overall study IMP accountability |  |  | | |  | |
| IMP label (as approved by the competent authority) |  |  | | |  | |
| Manufacturing Authorisation – IMP (MIA-IMP) for IMP manufacturer +/- third party (if applicable) and Certificate of GMP compliance of a manufacturer |  |  | | |  | |
| QP Third Party Declaration / Statement of GMP equivalence (for facilities where IMP is manufactured outside of the EU) |  |  | | |  | |
| Investigational Medicinal Product Dossier |  |  | | |  | |
| IMP storage Temperature logs |  |  | | |  | |
| IMP Destruction log |  |  | | |  | |
| Devices (if more than one device is involved, all following sections should be replicated for each device) | | | | | | |
| 10.1 Supply agreements including contact details (if applicable) |  |  | | |  | |
| 10.2 Product characteristics and information leaflets |  |  | | |  | |
| 10.3 Calibration/servicing, procurement arrangements |  |  | | |  | |
| 10.4 Sample label(s)/ superseded versions of labels where applicable |  |  | | |  | |
| 10.5 Device transfer |  |  | | |  | |
| 10.6 Confirmation of return to supplier or decommission of device |  |  | | |  | |
| Pharmacovigilance | | | | | | |
| Template SAE Form & Reporting Procedures including superseded version(s) |  |  | | | |  |
| Safety Reporting Log and Completed SAE forms (including letters to Sponsor, Pharmaceutical Company and SUSARs) |  |  | | | |  |
| Details of any pregnancies occurring in the study, including follow up reports to outcome |  |  | | | |  |
| Details of SAE reports |  |  | | | |  |
| Details of SUSARs reported including follow up reports up to resolution |  |  | | | |  |
| Lists of SAEs and/or SUSARs occurring at Multiple Sites |  |  | | | |  |
| Development Safety Update Reports (DSURs) |  |  | | | |  |
| Patient data | | | | | | |
| Patient recruitment | | | | | | |
| Randomisation or enrolment procedure/instructions |  |  | | | |  |
| Screening Log |  |  | | | |  |
| Master Recruitment/enrolment Log |  |  | | | |  |
| Completed ICFs |  |  | | | |  |
| Study Data | | | | | | |
| Completed CRFs /eCRFs |  |  | | | |  |
| Documentation of CRF corrections and data queries |  |  | | | |  |
| Source data capture tools |  |  | | | |  |
| *<Other completed data collection forms e.g. QoL questionnaires as applicable>* |  |  | | | |  |
| Clinical Trial Samples | | | | | | |
| Sample transfer form template and guidance documents |  |  | | | |  |
| Completed transfer forms |  |  | | | |  |
| Sample Log |  |  | | | |  |
| Biological sample analyses results |  |  | | | |  |
| <Other study specific data collection forms and procedures e.g. imaging> | | | | | | |
| <insert details> |  |  | | | |  |
| Data management and Statistical analysis | | | | | | |
| Case Report Forms | | | | | | |
| Sample Case Report Form(s) / eCRFs (including approval form) |  |  | | | |  |
| Superseded Case Report Form(s) /eCRFs |  |  | | | |  |
| CRF completion guidelines |  |  | | | |  |
| *<Other data collection form templates e.g. QoL questionnaires as applicable>* |  |  | | | |  |
| Data Management Plan |  |  | | | |  |
| Data Query Forms including responses |  |  | | | |  |
| Database system specification (i.e. IWRS, eCRF) |  |  | | | |  |
| Database Validation / release report (i.e. IWRS, eCRF) |  |  | | | |  |
| Statistical Analysis Plan and Updates (if not in Protocol) |  |  | | | |  |
| Statistical reports (interim analyses, final analyses) |  |  | | | |  |
| Deviations and Potential Serious Breaches |  |  | | | |  |
| Central Clinical facilities | | | | | | |
| <Laboratory Name> | | | | | | |
| Certificate of accreditation or established QC/validation and updates |  |  | | | |  |
| Central Laboratories Normal Reference Ranges *(if applicable)* and trial analysis specific SOPs |  |  | | | |  |
| Copies of Calibration certificates for technical equipment |  |  | | | |  |
| Related Correspondence |  |  | | | |  |
| Monitoring and Audits |  | | | | | |
| Risk Assessment |  |  | | | |  |
| Monitoring | | | | | | |
| Monitoring Plan |  |  | | | |  |
| SIVdocumentationincluding presentation, letter, report, attendance log and updates |  |  | | | |  |
| Monitoringdocumentationincluding letter, report, attendance log and updates |  |  | | | |  |
| Site Visits Report |  |  | | | |  |
| Close out visit documentation including letter, report, attendance log and updates |  |  | | | |  |
| **15.3 Audit /Inspection** | | | | | | |
| Audit /Inspection Certificates |  |  | | | |  |
| Audit Reports |  |  | | | |  |
| Feasibility visits conducted and outcomes |  |  | | | |  |
| Committees and Meetings | | | | | | |
| Trial Management Group (TMG) | | | | | | |
| TMG Membership and Terms of Reference |  |  | | | |  |
| TMG Meetings – Agendas and Minutes |  |  | | | |  |
| Confidentiality Agreements for TMG members (if applicable) |  |  | | | |  |
| Trial Steering Committee (TSC) | | | | | | |
| TSC Membership and Terms of Reference |  |  | | | |  |
| TSC Meetings – Agendas and Minutes |  |  | | | |  |
| Confidentiality Agreements for TSC members (if applicable) |  |  | | | |  |
| Independent Data Monitoring Committee (IDMC) | | | | | | |
| IDMC Membership and Charter |  |  | | | |  |
| IDMC Meetings – Agendas and Minutes |  |  | | | |  |
| Confidentiality Agreements for IDMC members (if applicable) |  |  | | | |  |
| Other Committees as Appropriate | | | | | | |
| Membership and Charter |  |  | | | |  |
| Meetings – Agendas and Minutes |  |  | | | |  |
| Investigator Meetings or other meetings as appropriate | | | | | | |
| Agenda, Presentations, Minutes |  |  | | | |  |
| Archiving Arrangements | | | | | | |
| 17.1 Archive Agreements |  |  | | | |  |
| Appointed archivist details |  |  | | | |  |
| Details of Archiving Company (if Applicable) |  |  | | | |  |
| CORRESPONDENCE | | | | | | |