

TM112-G

INVESTIGATOR SITE FILE CONTENTS

Not all documents listed below will necessarily be applicable to all studies/trials. Where an entire section is irrelevant for a particular study (e.g. Regulatory Authority for non-CTIMPs), it should be marked as NOT APPLICABLE in this ISF contents list, but the original numbering of the contents page retained, to provide a consistent ISF across all Oxford PC-CTU studies. Where specific documents are deliberately absent, a file note should be included to record the justification for the absence. If a listed document is stored elsewhere, a file note should be included to record its location. Logs should be kept either at the front of the TMF/at the top level folder or at the front of respective sections. For version control logs (TM106-A), a combination of central and/or document/area-specific logs (e.g. one for PIS only or one for all participant-facing information) is acceptable.

Include a Study Flowchart	
Include a Study Information and Contact Page for PI, Site Staff, and Regional Teams (TM112-I)	
Include a File Note Sample (TM112-D) and Log (TM112-E)	
Include a Green Light Letter from CTU (TM110-I)	
Section 1	Sponsorship and Indemnity 1.1 Sponsorship letter and/or agreement (division of Sponsor's responsibilities) 1.2 Indemnity /Insurance arrangements
Section 2	Trial Registration and Portfolio Adoption 2.1 Adoption confirmation 2.2 Trial Registration number (ISRCTN or clinicaltrials.gov) 2.3 CPMS / SiteLine uploads (<i>if applicable</i>) 2.4 Significant correspondence with the CPMS / SiteLine (<i>if applicable</i>)
Section 3	Protocol 3.1 Protocol/clinical investigation plan version control log (TM106-A) if kept here, protocol/clinical investigation plan, version controlled (i.e. with superseded paper documents labelled as such and electronic superseded documents in a separate folder), signed & dated by the CI
Section 4	Patient Information 4.1 Informed Consent Form (ICF) version control log if kept here (TM106-A), ICF, version controlled (i.e. with superseded paper documents labelled as such and electronic superseded documents in a separate folder) Patient Information Sheet(s) (PIS) version control log if kept here (TM106-A), PIS, version controlled (i.e. with superseded paper documents labelled as such and electronic superseded documents in a separate folder) 4.2 Any other written information provided to participants version control log if kept here (TM106-A), any other written information provided to participants, version controlled (i.e. with superseded paper documents labelled as such and electronic superseded documents in a separate folder) 4.3 GP letter version control log if kept here (TM106-A), GP Letter, version controlled (i.e. with superseded paper documents labelled as such and electronic superseded documents in a separate folder) 4.4 Patient recruitment advertisements, version control log if kept here (TM106-A), patient recruitment advertisements, version controlled (i.e. with superseded paper documents labelled as such and electronic superseded documents in a separate folder)
Section 5	Research Ethics Committee (REC) 5.1 REC (initial) favourable opinion letter and email, with approved documents, committee composition list

Section 6	<p>HRA approval and Local approval</p> <p>6.1 HRA (initial) Approval letter and email</p> <p>6.2 Confirmation of Capacity and Capability letter/ email</p>
Section 7	<p>Competent/Regulatory Authority</p> <p>7.1 Clinical Trial (initial) Authorisation (CTA) letter</p> <p>7.2 Development Safety Update Reports (DSURs) and other relevant safety reports</p>
Section 8	<p>Amendments (<i>repeat for each amendment and file in series</i>) <i>Include only approval letters. Approved versions of new documents should be filed in their relevant sections, i.e., an amended approved protocol should be filed in section 3.1.</i></p> <p>8.1 Amendment 1 letters of approval</p> <p>8.2 Amendment 2 letters of approval</p> <p>8.3 Amendment 3 letters of approval</p> <p>8.4 Amendment 4 letters of approval</p> <p>8.5 Amendment 5 letters of approval</p> <p>8.6 Amendment 6 letters of approval</p> <p>8.7 Amendment 7 letters of approval</p> <p>8.8 Amendment 8 letters of approval</p> <p>8.9 Amendment 9 letters of approval</p> <p>8.10 Amendment 10 letters of approval</p> <p>8.11 Amendment 11 letters of approval</p> <p>8.12 Amendment 12 letters of approval</p> <p>8.13 Amendment 13 letters of approval</p> <p>8.14 Amendment 15 letters of approval</p> <p>8.15 Amendment 16 letters of approval</p> <p>8.16 Amendment 17 letters of approval</p> <p>8.17 Amendment 18 letters of approval</p> <p>8.18 Amendment 19 letters of approval</p> <p>8.19 Amendment 20 letters of approval</p> <p>8.20 Amendment 21 letters of approval</p> <p>8.21 Amendment 22 letters of approval</p>
Section 9	<p>CRFs and Data Collection</p> <p>9.1 CRF version control log (TM106-A), copies of template CRFs, version controlled (i.e. with superseded paper documents labelled as such and electronic superseded documents in a separate folder)</p> <p>9.2 Self-evident corrections agreement(DM106-B)</p> <p>9.3 Critical Data Items list</p> <p>9.4 Version control log if kept here, copies of blank questionnaires and diaries, version controlled (i.e. with superseded paper documents labelled as such and electronic superseded documents in a separate folder)</p>
Section 10	<p>Personnel - Trial Site Team</p> <p>10.1 Delegation log and signature form <i>Repeat for each Trial Team member:</i></p> <p>10.2 Signed and dated original CV and GCP - or file note stating location</p> <p>10.3 Evidence of training in protocol, trial related procedures, PC-CTU SOPs and pharmacovigilance e.g. signature confirmation of having read protocol, SIV / training day attendance</p>

Section 11	Working Instructions 11.1 Working instructions version log (TM130-B if kept here), Working Instructions (initial and amended), version controlled (i.e. with superseded paper documents labelled as such and electronic superseded documents in a separate folder)
Section 12	Patient Recruitment 12.1 Screening and recruitment metrics (screening log template, participant ID forms) 12.2 Completed Informed Consent Forms (<i>or File note stating their location</i>) 12.3 Completed CRFs/questionnaires (signed and dated) including documentation of CRF corrections (<i>or file note stating their location</i>)
Section 13	Safety 13.1 Copies of broken blinds (<i>at the end of the trial</i>) 13.2 Copies of completed SAE/SUSAR forms (TM122-A & TM122-B for non-CTIMPs / TM119-B & TM119-G for CTIMPs) 13.3 SAE/SUSAR related correspondence
Section 14	Investigational Medicinal Product (IMP) information / Pharmacy – if relevant 14.1 Investigator's Brochure (IB) and/or Summary of Product Characteristics (SmPC) log of changes if kept here, IB and/or SmPC version controlled (i.e. with superseded paper documents labelled as such and electronic documents kept in a separate folder) 14.2 IB and/or SmPC evidence of receipt (e.g. communication received from CTU, IB/SmPC receipt form TM135-A) 14.3 Safety alert updates 14.4 IMP packaging (label specification, copies of labels) 14.5 Template accountability forms (TM118-A) / inventory forms (Pharmacy)/ dispensing logs / temperature logs (TM110-L) version controlled (i.e. with superseded paper documents labelled as such and electronic documents kept in a separate folder) 14.6 Completed accountability documents (supply, shipping records etc.) 14.7 Certification of IMP analysis and placebo if relevant 14.8 Documentation of IMP destruction (TM118-B) 14.9 Agreement with pharmaceutical company / IMP supplier
Section 15	Clinical Laboratory – if relevant 15.1 Certificates of accreditation for both central and local labs where relevant 15.2 Normal reference ranges, including revisions, for both central and local labs where relevant 15.3 Sample labels 15.4 Lab manual version controlled (i.e. with superseded paper documents labelled as such and electronic documents kept in a separate folder) 15.5 Sample shipment receipt / tracking
Section 16	Equipment – if relevant - NOT APPLICABLE 16.1 Suppliers 16.2 Certification 16.3 Site Equipment Tracking Log (TM132-C) 16.4 Equipment instructions
Section 17	Monitoring 17.1 Incident log (TM125-C), Incident Reporting Forms (TM125-A) 17.2 Monitoring log (QA102-D), Monitoring reports (including communication on monitoring visits/remote checks) 17.3 Monitoring correspondence (including phone, follow-up letters etc.)

Section 18	Newsletters and Promotional Material 18.1 Newsletters 18.2 Flyers 18.3 Presentations
Section 19	Training Materials (for Sites) 19.1 Training meeting agendas 19.2 Training report Sign off form 19.3 Training slides 19.4 Any other relevant training documents/slides (e.g., OpenClinica, RedCap)
Section 20	Device Documentation – NOT APPLICABLE 20.1 Investigator’s Brochure, version controlled (i.e. with superseded paper documents labelled as such and electronic documents kept in a separate folder) 20.2 Device Labels 20.3 Device Accountability
Section 21	General correspondence 21.1 Records of all significant correspondence e.g. relevant telephone conversations and emails relating to the study