Electronic Trial Master File (eTMF) Filing Index for MCRI sponsored clinical trials

General Guidance

- Refer to MCTC069 Guidance Trial Master File (TMF) Table of Contents Document Filing
- Sections can be added as appropriate according to design of the trial, but ensure the numbering remains in sequential order;
- Should a document or section be filed separate from the main TMF or in another section from what is stipulated in the index, the location of the document (e.g. Clinical Trial Pharmacy, participant binder – hard copy) should be entered in the 'Notes' column.
- If a document is not applicable to the trial, please enter 'NA' in the notes column.
- Superseded versions should be clearly indicated e.g. by marking a single line through the front page, noting "Superseded", initialled and dated.
- Some sections should be sub-divided to ease filing.
- Documents relating to an amendment should be filed together. Each amendment should be clearly labelled.
- Correspondence and version-controlled documents must be filed in chronological order with the most recent on top.
- Completed participants' CRFs are considered part of the TMF but must be filed separately from the TMF.

For Single-centre trials carried out at Royal Children's Hospital only

- It is acceptable to only have TMF set up without the need of a separate site file; local essential documents will be included for conducting the trial. In this case, the ISF index should be merged with the TMF index to ensure all documentation is retained correctly with minimal duplication.

Sponsor-Investigator/CPI Name:	
Protocol Name/Acronym:	
Protocol Number: *(If applicable)*	

Section	Folder/Sub-Folder Name	Contents	Notes
1.0	**Central Trial Coordination Team**		
1.1	Contact List	**Documents to be filed in this section include:** • **Participating Site Contact List**	
1.2	Signature and Delegation of Duties Log	**Documents to be filed in this section include:** • **Signature and Delegation of Duties Log -** Include all site staff involved with the trial.	
1.3	CVs	**Documents to be filed in this section include:** • **CV Site Principal Investigator** • **CV Study Coordinator / Research Nurse** • **Original Curriculum Vitae** • **Copies of Medical Licenses, if applicable**	
1.3.1	Other CVs	**Documents to be filed in this section include:** • **Original Curriculum Vitae** from all Site staff involved in the Trial • **Copies of Medical / AHPRA Licenses, if applicable**	
1.4	GCP Training Certificates	**Documents to be filed in this Section include:** • **GCP Certificates**	
1.5	Other Training Certificates	**Documents to be filed inthis section include:** • **Other training certificates**	
1.56	Wet-Ink Signature Page	**Documents to be filed inthis section include:** • **Wet-Ink Signature pages/logs**	
2.0	**Project Management**		
2.1	Trial Start-Up Checklist	**Documents to be filed in this Section include:** • **MCTC CRDO Trial Start-Up Checklist**	

Section	Folder/Sub-Folder Name	Contents	Notes
2.2	Site Selection Documentation	**Documents to be filed in this Section include:** • **CRO/Vendor Selection Criteria Form** • **Drug Distribution and Storage Facility Questionnaire** • **Pre-Trial Site Visit Agenda** • **Pre-Trial Site Visit Checklist** • **Pre-Trial Site Selection Visit Report** • **Site Feasibility Questionnaire Template** • **Site Feasibility Questionnaire** • **Site Feasibility Assessments** • **Clinical CRO/ Vendor Assessment Form** • **Vendor Assessment Form** • **CRO Vendor Assessment Report** • **Vendor Acceptance/Rejection Letter** • **Study Vendor Logs** • **Any significant correspondence relating to SiteFeasibility and Site Selection** • **Site Feasibility Tracker**	
2.3	Administration	**Documents to be filed in this Section include:** • **Roles and Responsibilities Matrix** • **Any significant correspondence**	
2.4	Trial Meeting Agenda/Minutes, Notes, etc.	**Documents to be filed in this Section include:** • **Trial meeting agenda's and minutes of every meeting with the Sponsor-Investigator and/or research team i.e. internal team meetings**	
2.5	Significant Team Correspondence & Communication including Emails, etc.	**Documents to be filed in this Section include:** • **All other significant correspondence**	

Section	Folder/Sub-Folder Name	Contents	Notes
3.0	**Protocol/Protocol Amendments**		
3.1	Protocol Version Tracker	**Documents to be filed in this Section include:** • **Protocol Version Tracker**	
3.2	Current HREC Approved Study Protocol - Signed Protocol Signature Page / Investigator Agreement Page	**Documents to be filed in this Section include:** • **Study Protocol** • **Signed Protocol Signature Pages** • **Previous protocol versions Signed Protocol Signature Pages**	
3.3	Protocol – Evidence of review and approval by Sponsor	**Documents to be filed in this Section include:** • **Protocol Review Checklist – Study Coordinator** • **Protocol Review Checklist – Statistician** • **Protocol Approval and Sign-Off Form**	
3.4	Peer Review – Evidence of Review	**Documents to be filed in this Section include:** • **Evidence of Peer Review**	
3.5	Non-Compliance Reports and Central Non-Compliance Log	**Documents to be filed in this Section include:** • **Non-Compliance Report Form** • **Non-Compliance Review Form** • **Non-Compliance Log**	
3.6	Sponsor-level Serious Breaches and CAPAs	**Documents to be filed in this Section include:** • **Sponsor-level Corrective and Preventive Action Plans** • **Sponsor-level Corrective and Preventive Action Plan Reviews**	
3.7	Copy of all Serious Breach reports to Sponsor-Investigator/HREC or Regulatory Authorities, if applicable	**Documents to be filed in this Section include:** • **Copies of all Serious Breach Reports submitted to Ethics, including supporting ERM documentation and any return acknowledgment** • **Copies of all Serious Breach Reports submitted to Regulatory Authorities any return acknowledgment**	

Section	Folder/Sub-Folder Name	Contents	Notes
3.8	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to protocol development, protocol amendments, sponsor-level serious breaches and CAPAs**	
4.0	**Participant Information & Consent Forms** (Generic / Master templates)		
4.1	PGICF & PICF Version Tracker	**Documents to be filed in this Section include:** • **PGICF & PICF Version Tracker**	
4.2	Master PGICF & PICF – Current HREC Approved Version(s)	**Documents to be filed in this Section include:** • **Template Master PGICF & PICF**	
4.3	Other Approved ParticipantInformation	**Documents to be filed in this Section include:** • **Master copies of advertisements, participant diaries, telephone scripts, GP letters, templates, participant newsletters, cards and questionnaires (eg, QoL) as applicable to study.**	
4.5	PGICF & PICF – Evidence of Review and Approval by Sponsor	**Documents to be filed in this Section include:** • **PGICF / PICF Review Checklist – Study Coordinator** • **PGICF / PICF Approval and Sign-Off Form**	
5.0	**Regulatory Documents**		
5.1	Site Green Light Approval form(s)	**Documents to be filed in this Section include:** • **Site Green Light Approval Form Template**	

Section	Folder/Sub-Folder Name	Contents	Notes
5.2	TGA Acknowledgement Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX)	**Documents to be filed in this Section include:** • **Copy of the CTN Acknowledgement listing all participating sites** • **Copy of the CTX Acknowledgement listing all participating sites**	
5.3	CTN/CTX Submission(s)	**Documents to be filed in this Section include:** • **Copy of the electronic CTN Submission to the TGA listing participating sites** • **Copy of the eBS Submission Document from the TGA, if available** • **Copy of the TGA CTN Invoice, if available** • **Proof of CTN Payment, if available**	
5.4	Other TGA Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence to and from the TGA**	
5.5	International Regulatory Submissions (e.g. MHRA, HPRA, FDA, etc)	**Documents to be filed in this Section include:** • **Relevant International Regulatory Submissions (e.g. IND applications), if available**	
5.6	International Regulatory Approvals	**Documents to be filed in this Section include:** • **Copies of International Regulatory Certificates of Approvals**	
5.7	International Regulatory Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence to and from any Regulatory Agency**	
5.8	Supplementary FDA Documents	**Documents to be filed in this Section include:** • **Financial Disclosure Form (FDA 3454 Form), if applicable** • **Statement of Investigator Form (FDA 1572 Form), if applicable**	

Section	Folder/Sub-Folder Name	Contents	Notes
6.0	**Sponsorship**		
6.1	Sponsor Authorisation Letter	**Documents to be filed in this Section include:** • **A copy of the MCRI Certificate of Sponsorship** • **Subsequent copies of MCRI Certificates of Sponsorship**	
6.2	Completed Risk Assessment/Management Tool	**Documents to be filed in this Section include:** • **A copy of the completed MCRI Sponsorship Application including completed Risk Management Table** • **Copies of any subsequent submissions to the MCRI Sponsorship Committee i.e. in relation to protocol amendments.**	
6.3	Related Correspondence and Meeting Minutes	**Documents to be filed in this Section include:** • **All significant correspondence to and from the Sponsor regarding initial and subsequent submissions.**	
7.0	**Ethics Committee**		
7.1	Ethics Committee Approval Letters, Certificates and Acknowledgements	**Documents to be filed in this Section include:** • **Ethics Committee Aproval Letters/ Acknowledgement relating to the original Protocol/PICF/IB etc** • **Subsequent Amendment approvals/acknowledgement from the Ethics Committee** • **Ethics Aproval Letters/Acknowledgements relating to ALL other project submissions.**	
7.2	Ethics Submission Documentation Initial & Amendments Including responses to HREC queries	**Documents to be filed in this Section include:** • **Complete copy of the initial Ethics Committee application relating to the original Protocol/PICF/IB etc, including a copy of the HREA** • **A copy of the Responses to HREC Queries, if**	

Section	Folder/Sub-Folder Name	Contents	Notes
		applicable • **Complete copy of any Protocol Amendments submitted to Ethics, including supporting ERM documentation** • **Copies of all additional Amendments or Project Notifications submitted to Ethics, including supporting ERM documentation.**	
7.3	Ethics Committee Composition, Constitution & Statement of Compliance	**Documents to be filed in this Section include:** • **Ethics Committee Composition** • **Statement of Compliance of Leading EC**	
7.4	Annual Project Progress Reports and Final Project Report	**Documents to be filed in this Section include:** • **Copies of all Annual Project Progress Reports submitted to Ethics, including supporting ERM documentation** • **Copy of the Final Project Progress Report submitted to Ethics, including supporting ERM documentation.**	
7.5	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence to and from the Ethics Committee regarding initial and subsequent submissions.**	
8.0	**Study-Specific Procedures/SOPs (applicable to either the Central Trial Coordination Team or all sites)**		
8.1	Current MoP / SoP	**Documents to be filed in this Section include:** • **Manual of Procedures Document** • **Any Manual of Procedures associated documents, if applicable** • **Study-Specific SOPs** • **Imaging Manual** • **Imaging Charter** • **Central Review Manual** • **Nuclear Medicine Manual** • **Ophthalmology Manual** • **Radiotherapy Manual** • **Any Study Specific SOP associated documents**	

Section	Folder/Sub-Folder Name	Contents	Notes
9.0	**Site Training**		
9.1	SIV Presentation	**Documents to be filed in this Section include:** • **Site Initiation Visit Presentation slide set** • **Site Initiation Agenda** • **Site Initiation Booking Letter** • **Essential Document Request Letter** • **Site Initiation Attendance Log** • **Site Initiation Follow Up letter** • **Site Activation Letter**	
9.2	Investigator Meeting	**Documents to be filed in this Section include:** • **Investigator Meeting Presentation slide set** • **Investigator Meeting Attendance Log**	
9.3	Other Presentations	**Documents to be filed in thisSection include:** • **File presentations other thanthe generic Master Site Initiation Visit presentation used for site training purposes here.**	
9.4	Training Logs	**Documents to be filed in this Section include:** • **Study-Specific Training Log** • **Other Training Attestation Forms, if applicable**	

Section	Folder/Sub-Folder Name	Contents	Notes
9.5	Other training resources	**Documents to be filed in this Section include:** • **Copies of other site-specific training resources/materials provided to sites.**	
10.0	**Participant Recruitment**		
10.1	Pre-Screening Log Template	**Documents to be filed in this Section include:** • **Pre-Screening Log**	
10.2	Consent, Screening & Enrolment Log Template	**Documents to be filed in this Section include:** • **Consent, Screening & Enrolment Log**	
10.3	Participant ID Log Template	**Documents to be filed in this Section include:** • **Participant ID Log**	
11.0	**Participant Randomisation and Registration Procedures**		
11.1	Randomisation Manual or Participant Registration Procedure	**Documents to be filed in this Section include:** • **Randomisation Manual** • **Participant Registration Procedure**	
11.2	Records of Unblinding (allparticipants)	**Documents to be filed in this Section include:** • **All records of Unblinding during study conductand reasons for unblinding**	
11.3	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence**	
12.0	**Data Management – Forms & Procedures**		
12.1	Blank Sample CRF	**Documents to be filed in this Section include:** • **For eCRFs; annotated CRFs** • **For Paper CRFs; blank CRFs**	

Section	Folder/Sub-Folder Name	Contents	Notes
12.2	CRF Completion Guidelines	**Documents to be filed in this Section include:** • **CRF Completion Guidelines** • **CRF Completion Guidelines**	
12.3	Trial-Specific Data Management Plan	**Documents to be filed in thisSection include:** • **Data Management Plan** • **Data Validation Plan** • **Data Sharing Plan** • **Source Document Plan** • **Medical Review Plan and associated Review Forms** • **Other Data Review Committees and/or Plans**	
12.4	Database Management Documentation • DB Specification • DB Testing • Database Version Tracker	**Documents to be filed in this Section include:** • **Database Specifications** • **Database Review and Testing Log** • **Database Version Tracking Log** • **Transfer of Data Forms**	
12.5	Trial Database Design Approval Form	**Documents to be filed in this Section include:** • **Database Approval Form**	
12.6	Electronic Data Capture (EDC) System Application Form - Template	**Documents to be filed in this Section include:** • **Electronic Data Capture (EDC) System Account Application Form**	
12.7	Completed Electronic Data Capture (EDC) System Application Forms	**Documents to be filed in this Section include:** • **Electronic Data Capture (EDC) System Account Application Form**	
12.8	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to data management.**	

Section	Folder/Sub-Folder Name	Contents	Notes
13.0	**Safety Monitoring & Reporting (all sites)** *Please note that the RSI is filed in section 24.1*		
13.1	Blank Expedited Safety Report Form Template (i.e. SAE Form) and Safety Reporting Guidelines	**Documents to be filed in this Section include:** • **Safety Monitoring Plan** • **Safety Reporting Guidelines for Sites Example** • **Expedited Safety (SAE) Report Coversheet Template** • **Expedited Safety (SAE) Report Form Template** • **Expedited Safety (SAE) Report Completion Instructions** • **Expedited Pregnancy Coversheet** • **Expedited Pregnancy Report Form** • **Expedited Pregnancy Report Completion Instructions** • **Instructions for Medical Monitors** • **Safety Event (SAE) Review Form Template** • **SAE Form for Non-MCRI-Sponsored Studies** • **Review of Safety Events: Instructions for Trial Coordinator**	
13.2	Copy of Completed Expedited Safety Report Forms (all SAEs, suspected SUSARs and USMs) and associated correspondence from all Sites	**Documents to be filed in this Section include:** • **Completed Expedited Safety (SAE) Report Forms** • **Completed Safety Event (SAE) Review Form**	
13.3	Copy of all Safety Reports sent to HREC, TGA, Regulatory Authorities and Participating Sites. i.e. SUSARs, SSIs, USMs, Annual Safety Reports, etc.	**Documents to be filed in this Section include:** • **Copies of Annual Safety Reports submitted to Ethics, including supporting ERM documentation** • **Copies of SUSARs/URSAEs, SSIs and USMs submitted to Ethics, including supporting ERM documentation** • **Copies of trial SUSARs/URSAEs, SSIs and USMs including evidence that they have been appropriately actioned** • **Copies of the submission of SUSARs/URSAEs, SSIs and USMs to appropriate regulatory bodies, as applicable, i.e. TGA**	

Section	Folder/Sub-Folder Name	Contents	Notes
		• **Evidence of notification of all trial SUSARs/URSAEs, SSIs and USMs to participating sites** • **6-monthly SUSAR Line-Listing received from Drug** • **Companies, including evidence they have been actioned accordingly.**	
13.4	Written Procedure for Unblinding in either: The case of a medical emergency For safety reporting purposes	**Documents to be filed in this Section include:** • **Emergency Procedures for Unblinding Manual**	
13.5	Other related correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to safety monitoring and reporting requirements.**	
14.0	**Study Quality Assurance, Monitoring, Audits & Inspections**		
14.1	Clinical Monitoring Plan	**Documents to be filed in this Section include:** • **Clinical Monitoring Plan** • **Risk Assessment and Risk Management Tool forClinical Trials** • **An other monitoring associated documents**	
14.2	Clinical Monitoring Plan – Evidence of Review and Approval by Sponsor-Investigator	**Documents to be filed in this Section include:** • **Clinical Monitoring Plan Approval and Sign-Off Form**	
14.3	Monitoring Log	**Documents to be filed in this Section include:** • **Site Monitoring and Visit Log**	
14.4	Monitoring Visit Reports, including Evidence of Review and Approval by Sponsor/Delegate	**Documents to be filed in this Section include:** • **SIV Report** • **Site Monitoring Visit Report Template**	
14.5	Related Monitoring Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to site monitoring.**	

Section	Folder/Sub-Folder Name	Contents	Notes
14.6	Data Safety Monitoring Board (DSMB)		
14.6.1	DSMB Charter	**Documents to be filed in this Section include:** • **DSMB Charter**	
14.6.2	Charter – Evidence of Review and Approval by Sponsor-Investigator	**Documents to be filed in this Section include:** • **DSMB Charter Approval and Sign-Off Form**	
14.6.3	DSMB Meeting Minutes	**Documents to be filed in this Section include:** • **All minutes from DSMB meetings held throughout trial conduct**	
14.6.4	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence to and from the DSMB** • **All other DSMB related correspondence.**	
14.7	Trial Steering Committee (TSC)/Trial Management Committee (TMC)/Other Committees		
14.7.1	Steering Committee Charter(s)	**Documents to be filed in this Section include:** • **Trial Steering Committee Charter**	
14.7.2	Documentation/Approval by Sponsor-Investigator	**Documents to be filed in this Section include:** • **Charter Approval and Sign-Off Form**	
14.7.3	Committee Meeting Minutes	**Documents to be filed in this Section include:** • **All minutes from Trial Steering Committee/Other Trial Committee meetings held throughout trial conduct**	
14.8	Local Research Governance Office Documentation – all sites: - Copy of all Audit Reports	**Documents to be filed in this Section include:** • **Copies of all Audit Reports sent to Local Research Governance Offices**	
14.9	Regulatory Inspections: - Reports - Related Correspondence	**Documents to be filed in this Section include:** • **Copies of all Regulatory Inspection Reports** • **Any correspondence related to Regulatory Inspections**	

Section	Folder/Sub-Folder Name	Contents	Notes
15.0	**Statistics**		
15.1	Statistical Analysis Plan (SAP)	**Documents to be filed in this Section include:** • **Statistical Analysis Plan (SAP**	
15.2	Statistical Analysis Plan – Evidence of review and approval from Sponsor-Investigator	**Documents to be filed in this Section include:** • **Statistical Analysis Plan (SAP) Approval and Sign-Off Form**	
15.3	Statistical Reports - Reports to DSMB - Other Analyses	**Documents to be filed in this Section include:** • **Copy of the reports to DSMB Committee** • **Copy of any Interim Analyis Statistical Reports** • **Copy of any Other Protocol-Defined Analysis**	
15.4	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating to statistics or the statistical plan for the study**	
16.0	**Centralised Laboratory**		
16.1	Research Sample Lab Manual (If applicable)	**Documents to be filed in this Section include:** **Research Sample Lab Manual** • **Research Sample Lab Manual Approval and Sign-Off Form** • **Biospecimen Collection Forms Template** • **Biospecimen Sample Labels** • **Other Research Sample Related Manuals**	
16.2	Centralised Lab Certification - If applicable	**Documents to be filed in this Section include:** • **Copy of the Central Lab Accreditation**	
16.3	Centralised Lab Reference Ranges - If applicable	**Documents to be filed in this Section include:** • **Copy of the Central Lab Reference Ranges**	
16.4	Biospecimen Log - If applicable	**Documents to be filed in this Section include:** • **Biospecimen Collection Log Template**	

Section	Folder/Sub-Folder Name	Contents	Notes
16.5	Biospecimen Storage Monitoring Documentation - If applicable	**Documents to be filed in this Section include:** • **Any documentation relating to the monitoring of biospecimen storage at the Central Research Laboratory** • **Biospecimen Reconcilation Process**	
16.6	Biospecimen Shipment ReceiptTracking	**Documents to be filed in this Section include:** • **Copies of courier shipping documents, invoices, receipts, custom declarations, consignment notes, import permits etc.**	
16.7	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence to and from the Central Lab or relating to the Biospecimen Research aspects of the study.**	
17.0	**Legal Documentation**		
17.1	Master Clinical Trial Research Agreement (CTRA)	**Documents to be filed in this Section include:** • **Copy ofthe Master Clinical Trial Research Agreement (CTRA)**	
17.2	Other Agreements as applicable: e.g. Material Transfer Agreement (MTA), Confidentiality Agreement (CDA), Pharma Agreements, Data Sharing Agreements	**Documents to be filed in this Section include:** **Copy of other agreements as applicable:** • **Material Transfer Agreements (MTA)** • **Data Sharing/Transfer Agreements** • **Pharma Contract for provision ofDrug and/or Funding** • **Insurance/Indemnity (as applicable)** • **Expressions of Interest (EoI)** • **Other Service/Vendor Agreements**	
17.3	Correspondence with MCRI Legal	**Documents to be filed in this Section include:** • **All significant correspondence to and from the MCRI Legal Team or relating to anyAgreements pertaining to the study.**	
18.0	**Finance Documentation**		

Section	Folder/Sub-Folder Name	Contents	Notes
18.1	Budget Tracking – Forecasts and Actuals	**Documents to be filed in this Section include:** • **A copy of the a trial budget, forecast and actuals**	
18.2	Invoices/Receipts	**Documents to be filed in this Section include:** • **Copies of relevant invoices and receipts pertaining to the study, including per patient payments**	
18.3	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence regarding the study budget, invoice tracking, per patient payments, etc.**	
19.0	**Other Communication**		
19.1	Newsletters to Sites	**Documents to be filed in this Section include:** • **Copies of Newsletters sent to participating sites**	
19.2	Other General Correspondence	**Documents to be filed in this Section include:** • **Other significant general correspondence**	
20.0	**Publications/Abstracts**		
20.1	Publications	**Documents to be filed in this Section include:** • **Copies of accepted publications arising from the study**	
20.2	Abstracts	**Documents to be filed in this Section include:** • **Copies of any accepted abstracts arising from the study**	
21.0	**Clinical Study Report**		
21.1	Clinical Study Report - If applicable	**Documents to be filed in this Section include:** • **Copy of the Final Clinical Study Report**	
21.2	Statistical report	**Documents to be filed in this Section include:** • **Copy of the Statistical Report** • **Copy of the Final Statistical Presentation,** if applicable	

Section	Folder/Sub-Folder Name	Contents	Notes
22.0	**Study Register – Registration and Results Posting**		
22.1	Initial Registration with a Trial Registry Copy of Protocol RegistrationReceipt	**Documents to be filed in this Section include:** • **Copy of the registration release/receipt of the entry from the Registry**	
22.2	Updates to Trial Registry: - Annual updates, updates following change in recruitment status and posting results	**Documents to be filed in this Section include:** • **Copy of any update to the registration record** • **Copy of results posted to the registration record**	
23.0	**Archiving**		
23.1	Archiving Details	**Documents to be filed in this Section include:** • **Investigator Agreement to Archive Template**	
23.2	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence regardingtrial archiving**	

FOR DRUG & DEVICE TRIALS ONLY			
24.0	**Reference Safety Information for each Investigational Product (Drug/Device Trials Only)**		
24.1	Current Reference Safety Information e.g. Current IB or PI	**Documents to be filed in this Section include:** • **Full copy of the Investigator Brochure (IB); or** • **Full copy of the Product Information (PI)** • **Copies of any Associated Documents e.g. IB Addendums etc**	
24.2	IB Version Tracker and PI SignaturePages (if applicable)	**Documents to be filed in this Section include:** • **IB Version Tracker** • **IB Signature Pages signed by Sponsor-Investigator**	
24.3	Superseded Reference Safety Information e.g. IB or PI	**Documents to be filed in this Section include:** • **Superseded copies of the Investigator Brochure (IB)** • **Superseded copies of the Product Information (PI)** • **Superseded Copies of any Associated Documents** • **e.g. IB Addendums etc**	
25.0	**Investigational Product**		
25.1	Product Manufacturing Records: (if using an unregistered (new) IP) - Related Correspondence with IP Manufacturer/Importer - Certificates of Analysis (CoA) - Quality Control Release	**Documents to be filed in this Section include:** • **Any correspondence with Drug Company relating to IP manufacturing or importation, if applicable** • **IP Quality Control Release Documentation relating to the batch of IP supplied for the trial**	
25.2	IP Ordering Information / Drug OrderForm	**Documents to be filed in this Section include:** • **Instructions/Process for ordering IP i.e. via IWRS, if applicable** • **Copy of the Drug Order form used by participating sites to order IP, if applicable**	

25.3	IP Packaging and Labelling	**Documents to be filed in this Section include:** • **Copy of the Primary Label, if applicable** • **Copy of the Secondary Label** • **Secondary Label Approval Form – signed by Sponsor-Investigator, Pharmacy Representative and Sponsor Representative**	
25.4	Instructions for Handling IP and Trial Related Materials - Pharmacy Manual	**Documents to be filed in this Section include:** • **Copy of the Pharmacy Manual** • **Copies of any other IP handling information**	
25.5	Documentation of Central IP Shipment	**Documents to be filed in this Section include:** • **Import Permits e.g. AQIS Import Permit, if applicable** • **Shipping Records – usually located in Pharmacy Folder** • **Import Letter – study specific, signed by Sponsor/ Sponsor-Investigator**	
25.6	Documentation of Central IP: - Quarantines - Returns - Destructions/Drug Destruction Form	**Documents to be filed in this Section include:** • **Process for the reporting of any IP Deviations (i.e. temperature excursions, IP complaints, IP quarantines) and associated forms** • **Process for the Return/Destruction of any unused IP at the end of the study** • **Drug Destruction Form Template**	
25.7	Documentation of IP Dispensing: - Accountability and Reconciliation (used/unused/destroyed) - Drug Accountability Log Templates	**Documents to be filed in this Section include:** • **Bulk Drug Accountability Log Template** • **Individual Drug Accountability Log Template**	
25.8	Copies of Material Safety Data Sheets (MSDS)	**Documents to be filed in this Section include:** • **Copy of the Material Safety Data Sheet (MSDS) for each drug/IP used in the study**	

25.9	Related Correspondence	**Documents to be filed in this Section include:** • **All significant correspondence relating tothe Investigational Product/s.**	