Trial Master File (TMF)

	Contents	Notes
1.0	**Central Trial Coordination Team**	
1.1	Contact List	
1.2	Delegation and Signature Log	*Completed Site-Specific Signature & Delegation Logs in Section 1.2 of the SIF.*
1.3	CVs	
1.4	GCP Training Certificates	
1.5	Other Training Certificates	
2.0	**Project Management**	
2.1	Trial Start-Up Checklist	
2.2	Site Selection Documentation	
2.3	Administration	
2.4	Trial Meeting Agenda/Minutes, Notes, etc.	
2.5	Significant Team Correspondence & Communication including Emails, etc.	
3.0	**Protocol/Protocol Amendments**	
3.1	Protocol Version Tracker	
3.2	Current HREC Approved Study Protocol with Signed Protocol Signature Page / Investigator Agreement Page	*Protocol signature pages signed by Site Investigators in Section 3.2 and 3.3 of the SIF.*
3.3	Superseded Study Protocols with signed Protocol Signature Page / Investigator Agreement Page	
3.4	Protocol – Evidence of review and approval by Sponsor	
3.5	Peer Review – Evidence of Review	
3.6	Non-Compliance Reports and Central Non-Compliance Log	*Non-compliance report forms completed by Sites in section 3.5 of the SIF.*
3.7	Sponsor-level Serious Breaches and CAPAs	
3.8	Copy of all Serious Breach reports to Sponsor-Investigator/HREC or Regulatory Authorities	
3.9	Related Correspondence	
4.0	**Participant Information & Consent Forms**	
4.1	PGICF & PICF Version Tracker	
4.2	Template Master PGICF & PICF – Current HREC Approved Version(s)	*Site-specific PGICF & PICF's in section 4.1 of the SIF.*
4.3	Other Approved Participant Information	
4.4	Superseded Template PGICF & PICF	
4.5	PGICF & PICF – Evidence of Review and Approval by Sponsor	
4.6	Other Superseded Participant Information	
5.0	**Regulatory Documents**	
5.1	Site Green Light Approval form(s)	*Site-specific Green Light Approval Forms in section 5.3 of the SIF.*
5.2	TGA Acknowledgement Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX)	
5.3	CTN/CTX Submission(s)	
5.4	Other TGA Correspondence	
5.5	International Regulatory Submissions	
5.6	International Regulatory Approvals	
5.7	International Regulatory Related Correspondence	
5.8	Supplementary FDA Documents	*Completed site-specific 1572 and 3454 forms in*

		section 5.2 of the SIF.
6.0	**Sponsorship**	
6.1	Sponsor Authorisation Letter	
6.2	Completed Risk Assessment/Management Tool	
6.3	Related Correspondence and Meeting Minutes	
7.0	**Ethics Committee**	
7.1	Ethics Approval Letters (current and superseded)	*Country specific approvals filed in section 6.2 of the SIF where applicable.*
7.2	Ethics Submission Documentation (initial and amendments including queries + responses)	
7.3	Ethics Committee Composition, Constitution & Statement of Compliance	
7.4	Annual Project Progress Reports and Final Project Report	
7.5	Related Correspondence	
8.0	**Study-Specific Procedures/SOPs (applicable to either the Central Trial Coordination Team or all sites)**	
8.1	Current MoP / SoP	
8.2	Superseded MoP / SoP	
9.0	**Site Training**	
9.1	SIV Presentation	*Site-Specific SIV presentations, agendas, and attendance logs in section 9.1 of the SIF.*
9.2	Investigator Meeting	
9.3	Other Presentations	
9.4	Training Logs	*Site- Specific Training Logs/Forms filed in section 10.3 of the SIF.*
9.5	Other training resources	
10.0	**Participant Recruitment**	
10.1	Pre-Screening Log Template	
10.2	Consent, Screening & Enrolment Log Template	*Completed participant screening logs in section 11.2 of the SIF during accrual. At the end of accrual, completed screening logs are moved to this section of the TMF.*
10.3	Participant ID Log Template	
11.0	**Participant Randomisation / Registration Procedures**	
11.1	Randomisation Manual or Participant Registration Procedure	
11.2	Records of Unblinding (all participants)	
11.3	Related Correspondence	
12.0	**Data Management – Forms & Procedures**	
12.1	Blank Sample CRF	*Completed paper CRFs are considered part of the TMF, but are filed separately.*
12.2	Superseded CRF	
12.3	CRF Completion Guidelines	
12.4	Trial-Specific Data Management Plan	*Completed Source Document Plans in section 13.4 of the SIF.*
12.5	Database Management Documentation	
12.6	Trial Database Design Approval Form	
12.7	Electronic Data Capture (EDC) System Application Form - Template	
12.8	Completed Electronic Data Capture (EDC) System Application Forms	*Completed site-level EDC Account Application Forms in Section 13.3 of the SIF.*
12.9	Related Correspondence	

13.0	**Safety Monitoring & Reporting (all sites)**	
13.1	Blank Expedited Safety Report Form Template (i.e. SAE Form) and Safety Reporting Guidelines	
13.2	Copy of Completed Expedited Safety Report Forms and associated correspondence from all Sites	*All Expedited Safety Report forms received from Sites, and their corresponding Safety Event Review forms received from Medical Monitors, will be filed separately throughout study, and moved to Section 13.2 of this section at the end of the study.*
13.3	Copy of all Safety Reports sent to HREC, TGA, Regulatory Authorities and Participating Sites.	
13.4	On-Site procedure for unblinding in either the case of medical emergency or for safety reporting purposes	
13.5	Other related correspondence	
14.0	**Study Quality Assurance, Monitoring, Audits & Inspections**	
14.1	Clinical Monitoring Plan	
14.2	Clinical Monitoring Plan – Evidence of Review and Approval by Sponsor-Investigator	
14.3	Monitoring Log	
14.4	Monitoring Visit Reports, including Evidence of Review and Approval by Sponsor/Delegate	*Completed Site-Specific Monitoring Visit Reports are filed in section 15.3 of the SIF.*
14.5	Related Monitoring Correspondence	
14.6	**Data Safety Monitoring Board (DSMB)**	
14.6.1	DSMB Charter	
14.6.2	Charter – Evidence of Review and Approval by Sponsor-Investigator	
14.6.3	DSMB Meeting Minutes	*Minutes from closed DSMB meetings are kept confidential, and not filed in the TMF until the end of the study.*
14.6.4	Related Correspondence	
14.7	Trial Steering Committee (TSC)/Trial Management Committee (TMC)/Other Committees	
14.7.1	Steering Committee Charter(s)	
14.7.2	Documentation/Approval by Sponsor-Investigator	
14.7.3	Committee Meeting Minutes	
14.8	Local Research Governance Office Documentation including audit reports – all sites	*RGO Acknowledgements of submitted Audit reports in Section 7.3 of the SIF.*
14.9	Regulatory Inspection reports and correspondence	
15.0	**Statistics**	
15.1	Statistical Analysis Plan (SAP)	
15.2	Statistical Analysis Plan – Evidence of review and approval from Sponsor-Investigator	
15.3	Statistical Reports, including reports to DSMB and other analyses	
15.4	Related Correspondence	
16.0	**Centralised Laboratory**	
16.1	Research Sample Lab Manual	
16.2	Centralised Lab Certification	*Laboratory Accreditation for Local Laboratories in section 16.2 of the SIF.*
16.3	Centralised Lab Reference Ranges	*Local Lab Reference Ranges for participating sites are filed in section 16.3 of the SIF.*
16.4	Biospecimen Log	*Site-specific Biospecimen Collection Logs are filed in section 16.4 of the SIF.*
16.5	Biospecimen Shipment Receipt Tracking	
16.6	Biospecimen Storage Monitoring Documentation	

16.7	Related Correspondence	
17.0	**Legal Documentation**	
17.1	Master Clinical Trial Research Agreement (CTRA)	
17.2	Other Agreements as applicable:	
17.3	Correspondence with MCRI Legal	
18.0	**Finance Documentation**	
18.1	Budget Tracking – Forecasts and Actuals	
18.2	Invoices/Receipts	
18.3	Related Correspondence	
19.0	**Other Communication**	
19.1	Newsletters to Sites	
19.2	Other General Correspondence	
20.0	**Publications/Abstracts**	
20.1	Publications	
20.2	Abstracts	
21.0	**Clinical Study Report**	
21.1	Clinical Study Report	
21.2	Statistical report	
22.0	**Study Register – Registration and Results Posting**	
22.1	Initial Registration with a Trial Registry	
22.2	Updates to Trial Registry	
22.3	Related Correspondence	
23.0	**Archiving**	
23.1	Archiving Details	
23.2	Related Correspondence	
24.0	**Reference Safety Information for each Investigational Product (Drug/Device Trials Only)**	
24.1	Current Reference Safety Information (IB or PI)	
24.2	IB Version Tracker and PI Signature Pages (if applicable)	
24.3	Superseded Reference Safety Information	
25.0	**Investigational Product**	
25.1	Unregistered Product Manufacturing Records including COA, Quality Control release and correspondence	
25.2	IP Ordering Information / Drug Order Form	
25.3	IP Packaging and Labelling	
25.4	Instructions for Handling IP and Trial Related Materials	
25.5	Documentation of Central IP Shipment	*All IMP related activities have been delegated to Central Pharmacy or Site Pharmacy – documents located in Central or Site Pharmacy folder.*
25.6	Documentation of IP Dispensing, Accountability and Inventory	*Site-specific Drug Destruction Forms filed with the Site Pharmacy, and moved to section 22.3 of the SIF at the end of the study.*
25.7	Documentation of IP Quarantines, Returns, & Destruction	*Site-specific Accountability Forms filed with the Site Pharmacy, and moved to section 22.5 of the SIF at the end of the study.*
25.8	Copies of Material Safety Data Sheets (MSDS)	

25.9	Related Correspondence	