		Guidance from the MHRA on gaining authorisation in the UK		
	Essential documents required for Trial Master File	**Templates**	**Templates**	**Relevant SOPs**
1	**Trial Summary**	Insert Executive summary and flow diagram from the protocol.	Clinical Trials Toolkit - Routemap web link	Generic: SOP009; SOP013; SOP011; SOP052; SOP055; SOP064
2	**Version control log**	Version control template		SOP043
3	**Contact details sheet**	Insert contact details from protocol		
4		File note form		SOP041
Trial Specific Documentation				
5	Current approved protocol with signatures	Protocol Template CTIMP		SOP019
6	Approved Patient Information Sheet (PIS), Informed Consent Form, GP Letter	Patient Information Sheet and Consent Form Template	GP Letter template	SOP020; SOP003; SOP060
7	Previous versions of protocol(s), PIS, Informed Consent Form, GP Letter			
8	Study specific Standard Operating Procedures			
Sponsorship and NHS permission				
9	Trust Approval Letter			SOP034
10	Letter of acceptance of sponsorship			SOP048
11	Peer Review			
12	Sponsorship delegation log	Delegation of sponsor responsibilities form		
13	Project Management Delegation Log		MHRA Project Management Considerations Table	SOP055
14	Risk Assessment and superseded versions	CTIMP Risk Assessment form		SOP065
Site Personnel				

15	Up-to-date, signed and dated CVs and GCP training records			SOP049
16	Delegation Log	Delegation log template		SOP030
Finance				
17	Grant Application			
18	Clinical Trial Agreement / Funding agreement letters			SOP023; SOP024; SOP066
19	Finance correspondence: funder / contracts			
20	Indemnity certificates / policy			
21	Site Agreements	Model clinical trial agreements web link		
22	Research Account statements			
23	Invoices			
24	Finance correspondance with sites			
25	Other finance correspondence other than contracts			
Ethics & MHRA				
26	EUDRACT number	EudraCT website		
27	HRA correspondence	weblink to HRA Approval info page		
28	Adoption onto the NIHR portfolio			
29	Ethics application including correspondence	web link to REC approval information		SOP005
30	Favourable Ethical Approval letter			
31	MHRA application including correspondence	web link for gaining MHRA approval information		SOP014
32	Clinical Trial Authorisation letter			
33	Copy of the Annual Progress Report(s) to Ethics	HRA website link giving up-to-date information		
34	Copy of the end of trial notification form and report sent to Ethics & MHRA			
Amendments				

35	Amendments to ethical approval a separate bundle of documents filed in chronological order for each amendment comprising copies of: 1) all the amended documentation 2) approval – Ethics; MHRA; HRA; R&D (as required)	web link to MHRA amendment process	web link to which bodies need to approve an amendment	SOP037
36	Correspondence regarding the amendment			
Pharmacovigilence				
37	Investigators Brochure (IB) and/or Summary of Product Characteristics (SmPC) and updates	SmPC / IB Checklist	Link to website to check for updates to SmPC	
		Links to example IMPDs on MHRA website		
38	Pharmacovigilence SOP inc blank SAE forms	Template AE reporting form	Safety Reporting - Sponsor responsibilities	SOP012
		Template SAE / SAR Reporting Form	Safety Reporting - Investigator Responsibilities	
39	SAE reports			
40	SUSAR reports			
41	DSUR reports	DSUR Template	Include covering letters to both MHRA and REC	SOP063
42	Procedure for randomisation, unblinding and code break (if applicable)		Template code break request form	SOP069
43	Details of testing	Test code break form		
44	Details of any codebreaks			
45	Details of any Protocol non-compliance or Serious Breach of protocol			SOP050; SOP051
46	Details of any Urgent Safety Measures			SOP071
47	Notification of sponsors to Investigators of safety information			

48	Copies of any adverse event reports made under the normal reporting procedures used by the Trust			
Pharmacy				SOP022; SOP073; SOP074; SOP075; SOP076
49	Quality Agreement			
50	Instructions for handling IMP (if not included in protocol)			
51	Sample of label/ superseded versions of label (if applicable)			
52	Shipping records, inc. ordering forms (if applicable)			
53	IMP accountability	Template IMP accountability log		SOP072
54	Termination: Documentation of IMP destruction			
Data collection, analysis and publication				
55	Data Management Plan			
56	Database management -			SOP057; SOP058; SOP059; SOP068
57	Sample case report forms (CRFs) + Copy of other approved data collection instruments (eg questionnaires)			SOP047; SOP053; SOP054
58	Completed CRFs + data collection instruments			
59	Data queries			
60	Statistical Analysis Plan	template statistical analysis plan		SOP017; SOP018
61	Interim reports			
62	Publication(s)			
Monitoring				
63	Monitoring Plan	Template Monitoring Plan	Template Monitoring Schedule	SOP016
64	Audit Plan			SOP063
65	Trial initiation Report	Initiation report form		SOP015

66	Monitoring Reports			
67	Audit Reports			
68	Close Down Report			SOP021
69	Correspondence regarding monitoring and/or audit			
Meeting				
70	Project team meetings			
71	Project team correspondence			
72	Trial Steering Committee meeting Terms of Reference	ToR for Trial Steering Committee	TMG with independant Chair Charter (if no DMC)	
73	Trial Steering Committee meeting minutes			
74	Trial Steering Committee correspondence			
75	Data Monitoring Committee Charter / Terms of Reference	DMC Charter template		
76	Data Monitoring Committee meeting			
77	Data Monitoring Committee correspondence			
Laboratory				
78	Lab accreditation certificates			
79	Normal values/ ranges			
80	Record of retained tissue/ body samples (if any)			
81	Material Transfer Agreements	Material Transfer Agreement template		
Participant logs and consent forms				
82	Screening/enrolment log (including subject identification list)			SOP031
83	Signed Consent Forms			
Other				

84	Copies of all other correspondence relating to the trial (excluding REC, MHRA and R&D) records of all significant phone conversations relating to trial			