

## CTIMP Monitoring Visit Report

This report is to be used for Sponsor monitoring visits as per SOP S-1007 Sponsor Monitoring.

### Completion of the report:

- Sponsor will complete the report and issue it to the Site along with a list of any findings in the format of a 'Corrective Action Preventative Action' (CAPA) plan within 21 days of the visit.
- Findings from the monitoring visit will be categorised as 'Critical', 'Major' or 'Other' as per SOP S-1016 UoL, 'Procedure in the event of non-compliance in clinical research'.
- Site staff are to read through the report and CAPA, ensuring that they are accurate, noting any actions that are required, and providing additional information/documents where requested.
- Site staff should address all findings, explaining what action(s) they will take in the first instance to correct the issue(s) and in the future to ensure that the issue(s) does not recur.
- Unless specified, site staff must return the completed CAPA to Sponsor within 28 days of issue. Sponsor will follow up the CAPA until completion/closure.
- This report is designed to be adaptable and any report sections that are not relevant to the visit will be marked as not reviewed and the content deleted. Other appropriate adaptations may be made to accommodate the specifics of a trial.
- All sponsor SOPs and associated documents can be accessed via our [website](#).

### Study and Monitoring Visit Information

Question	Answer
Site name/number:	
Principal Investigator:	
Site contact(s):	<insert name, role, contact details (email/phone number)>
Monitoring visit conducted by:	<insert name, role, contact details (email/phone number)>
Monitoring visit number & date:	
Monitoring visit type	<input type="checkbox"/> routine <input type="checkbox"/> triggered
Version and Date report issued:	
Date responses due:	

### List of Site and Monitoring Personnel in Attendance

Name	Position

**Study Status and Details**

Question	Answer	Comments
Current status:	<input type="checkbox"/> open to recruitment <input type="checkbox"/> in follow up	
Current end date:		
Is an extension required:	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unsure	
Planned patient number:		
Planned recruitment timescale:		
Number of patients consented:		
Number of patients on going:		
Number of patients completed:		
Number of patients withdrawn:		
Number of patients ineligible:		
Number of patients lost to follow up:		
Are there any issues with recruitment or retention of participants?	<input type="checkbox"/> yes, <i>provide detail</i> <input type="checkbox"/> no	

**Summary/Purpose of Visit**

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**Outstanding Actions from Last Monitoring Visits**

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**1. Study Team Contacts (  Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Is there a contacts list on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Comments/Findings

**2. Protocol (  Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Is the current approved protocol on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is the Protocol signed and dated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are superseded Protocols on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a protocol deviation log on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Have protocol deviations been reported/reviewed by PI?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Comments/Findings

**3. Ethics (  Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Is the signed and dated IRAS submission form on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Chief Investigator: <b>Date</b> Sponsor: <b>Date</b>
Is the Favourable Opinion Letter/HRA Approval on file / details of Ethics committee constitution?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	REC VA: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	REC PO: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	REC FO: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HRA initial assessment: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HRA approval: <b>Date</b>
Are Substantial Amendments on file?				
<b>SAXX – Date:</b>				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Amendment Tool: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	REC Cover Letter: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	REC VA: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	REC FO: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HRA Initial Assessment: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HRA Approval: <b>Date</b>
<b>SAXX – Date:</b>				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Amendment Tool: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	REC Cover Letter: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	REC VA: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	REC FO: <b>Date</b>

	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HRA Initial Assessment: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HRA Approval: <b>Date</b>
<b>SAXX – Date:</b>				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Amendment Tool: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	REC Cover Letter: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	REC VA: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	REC FO: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HRA Initial Assessment: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HRA Approval: <b>Date</b>
Are Non substantial amendments on file?				
<b>NSAXX – Date:</b>				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Amendment Tool: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HRA Approval/ Acknowledgement: <b>Date</b>
<b>NSAXX – Date:</b>				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Amendment Tool: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HRA Approval/ Acknowledgement: <b>Date</b>
Ethics Correspondence on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Comments/Findings</b>

**4. Competent Authority ( Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Is the CTA Application on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Chief Investigator: <b>Date</b> Sponsor: <b>Date</b>
Is the CTA Acceptance letter?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Acknowledgement of CTA: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	GNA: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	GNA Response: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Acceptance: <b>Date</b>
Are CTA Amendment/submission forms on file?				
<b>SAXX – Date:</b>				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ANNEX 2 form /Amendment tool: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MHRA cover letter: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MHRA VA: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MHRA Approval: <b>Date</b>
<b>SAXX – Date:</b>				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ANNEX 2 form /Amendment tool: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MHRA cover letter: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MHRA VA: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MHRA Approval: <b>Date</b>
<b>SAXX – Date:</b>				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	ANNEX 2 form /Amendment tool: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MHRA cover letter: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MHRA VA: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MHRA Approval: <b>Date</b>
Notice to MHRA of Trial completion on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

MHRA Correspondence on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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<b>Comments/Findings</b>

**5. R&I ( Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Is the Trust Application/Capability Assessment on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Site Feasibility Form: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Validated SoECAT/SoE:
Is the Trust Approval/Authorisation on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Confirmation of Capacity and Capability: <b>Date</b>
Are there Substantial Amendment/s approval on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SAXX: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SAXX: <b>DATE</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SAXX: <b>DATE</b>
Are there Non Substantial Amendment/s approval on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	NSAXX: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	NSAXX: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	NSAXX: <b>DATE</b>
Notification of Trial completion on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Trust Correspondence on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Comments/Findings</b>

**6. Investigator Site Personnel ( Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Is the Delegation of Authority and Signature Log on file and complete?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Any changes in staff since last visit?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are original signed and dated CVs on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there evidence of GCP training for all staff covering the duration of the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there evidence of consent training for all non-medics taking consent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there evidence of protocol training for all staff?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Comments/Findings</b>

**7. Standard Operating Procedures ( Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Are there Current SOPs on File/staff aware of where to access most current SOPs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are Standard Operating Procedures Read Lists completed for all Study team members?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**Comments/Findings**
**8. Study Documentation (  Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Is there a copy of the current approved Patient Information Leaflet on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a copy of the current approved Patient Consent Form on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a copy of the current approved Letter of Invitation on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a copy of the current approved GP Letter on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a copy of the current approved Questionnaires, if applicable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a copy of the current approved Advert if applicable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other study specific documents reviewed and documented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are previous versions of study documentation marked as Superseded?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a copy of the current Case Report Form on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Comments/Findings</b>

**9. Subject Documentation (  Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Is there a current master copy of the screening log template on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is the Subject Screening log complete and up to date?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a current master copy of the Enrolment Log template on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is the Enrolment Log complete and up to date?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Comments/Findings</b>

**10. Randomisation (  Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Is there documentation of the Randomisation Process on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Where is the Master Randomisation List held?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Evidence of correct blinding as per study protocol?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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<b>Comments/Findings</b>

**11. Informed Consent ( Section not reviewed at visit,  Section reviewed at previous visit)**

Items discussed/verified	Yes	No	N/A	Comments
Are study staff aware of the correct ethics approved recruitment and consent process?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all consent forms present and correctly completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Have the correct versions of the PIL and consent form been used according to the timelines of ethics and R&D approval?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Have study participants been re consented on new PIL information if applicable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Has 100% consent audit been undertaken?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are copies of the Patient Information Sheet and Consent present in the medical records and TMF/ISF?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is informed consent process properly documented in the medical/trial records?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Comments/Findings</b>

**12. Safety Reporting/Pharmacovigilance ( Section not reviewed at visit,  Section reviewed at previous visit)**

Items discussed/verified	Yes	No	N/A	Comments
Are SAE reporting Guidelines/SOP and Pharmacovigilance/Governance contact on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a Current SAE form Template on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are SAE reports and associated acknowledgement correspondence from Sponsor on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Have all SAEs been reviewed against the current Reference Safety Information?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are SUSAR reporting guidelines on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are SUSAR reports and associated acknowledgement correspondence from Sponsor/MHRA/R&D on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are there signed and dated annual Development Safety Update Report(s) on	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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<b>Comments/Findings</b>

**13. Reference Safety Information ( Section not reviewed at visit,  Section reviewed at previous visit)**

Items discussed/verified	Yes	No	N/A	Comments
Is there a current Signed and dated Investigator Brochure (IB) on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are superseded IB brochures on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a current signed and dated Summary of Product Characteristics (SMPC) on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are Superseded SMPCs on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are there any Safety alert updates on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Comments/Findings</b>

**14. Monitoring ( Section not reviewed at visit,  Section reviewed at previous visit)**

Items discussed/verified	Yes	No	N/A	Comments
Has an initiation visit taken place?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is the Initiation report on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is the study specific monitoring plan on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is the Monitoring Log template on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a completed monitoring log?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all monitoring visit reports on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all Pharmacy monitoring reports on file if undertaken on separate occasion?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Comments/Findings</b>

**15. Clinical Laboratory/Specimen Collections ( Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Are Central Labs being used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<ul style="list-style-type: none"> <li>Are the current and previous Central Lab accreditations on file?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<ul style="list-style-type: none"> <li>Is Central Lab normal reference ranges on file?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are Local Labs being used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

• Are the Local Laboratory current and previous accreditation certificates on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
• Are Local Lab normal reference ranges on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are sampling and sample handling procedures documented/is there a lab manual on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are specimen results reviewed and signed and dated by PI?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are specimen results that are out of range marked as clinically significant or not clinically significant?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all samples correctly stored in a suitable and secure environment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are sample logs/records held?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are Lab kits available and in date?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are Sample shipment/ receipt tracking available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are storage conditions monitored and recorded?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a contingency plan in place for storage facility failure?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Comments/Findings</b>
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**16. Pharmacy ( Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Are Pharmacy Staff GCP and CVs up to date and on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a complete and updated pharmacy signature log on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are instructions in place with regards to handling trial medication and trial related materials. Dispensing procedure /Randomization/Resupply/Returns and Destruction?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are the current IMP packaging sample labels on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Records of drug dispensing on file and has the drug been correctly dispensed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are drug accountability records being adequately maintained/completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Are their adequate collection, recording and maintenance of temperature monitoring records for all locations storing IMPs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Have any drug excursions been recorded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Has any drug been quarantined?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are expiry/retest dates in accordance with IMP use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is medication compliance checking acceptable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are randomisation codes stored appropriately?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Have any codes been broken?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all required GMP, certificate of analysis and QP release documents on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a Pharmacy approved Prescription template on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all completed prescription on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Comments/Findings</b>

**17. Financial/Legal agreements ( Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Are contracts in place with all Investigators and sub-contractors? Clinical Agreements etc.?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is confirmation of sponsorship on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Letter of Support:
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Initial SGL: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SAXX SGL: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SAXX SGL: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	NSAXX SGL: <b>Date</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	NSAXX SGL: <b>Date</b>
Is funding documentation on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are Insurance/Indemnity statements on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Confirmation of study indemnity: <b>Date(s)</b>
	<b>Arthur Gallagher Professional Indemnity</b>			
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2018-2019
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2019-2020
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2020-2021
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2021-2022	

	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2022-2023
	Arthur Gallagher Clinical Trials Insurance			
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2018-2019
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2019-2020
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2020-2021
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2021-2022
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2022-2023
Is Financial Correspondence on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are there records of subject expenses?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**Comments/Findings**
**18. Study Related Supplies ( Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Are shipment and delivery records on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is collection and return of equipment documented and on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are supply re-order form templates on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are completed supply request forms on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are records kept and retained for maintenance, calibration and validation of all equipment used as part of the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**Comments/Findings**
**19. Annual/Final Reports**

Items Discussed/verified	Yes	No	N/A	Comments
Are annual progress and where applicable safety reports to the Ethics Committee on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are Sponsor confirmations of annual report receipt on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is their evidence of notification of trial completion to Sponsor, REC, Competent Authority and R&D?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**Comments/Findings**
**20. Publication ( Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Are copies of all study analysis publications on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Comments/Findings</b>
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**21. Correspondence (  Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Are meeting agendas and minutes on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are copies of study newsletters on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are copies of all correspondence between the Chief Investigator and collaborating centres on file (multicentre studies only)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is general study related correspondence on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Comments/Findings</b>
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**22. Source Data Verification (  Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Are all source documents available to verify the data in the Case Report Form?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Source Data Agreement: <b>Version, Date</b>
Is the CRF completion timely and accurate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Have all CRF data queries resolved since previous visit?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Has SDV been performed according to the monitoring plan?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Location of source documents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is the Statistical Analysis Plan (SAP) in place? (Required before database lock)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Comments/Findings</b>
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Participant ID Number: XXXXXXXXXXXX	Yes	No	N/A	Comments/Findings
Sticker in medical notes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Consent sticker/annotation in medical notes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Eligibility checked/confirmed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Copy of PIS and CF in the medical notes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Randomisation confirmation (i.e., post-screening) and print out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Blood results signed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Visit dates checked	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
GP letter sent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Re-consented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Source Data Checked	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Participant ID Number: XXXXXXXXXXXXXX	Yes	No	N/A	Comments/Findings
Sticker in medical notes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Consent sticker/annotation in medical notes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Eligibility checked/confirmed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Copy of PIS and CF in the medical notes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Randomisation confirmation (i.e., post-screening) and print out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Blood results signed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Visit dates checked	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
GP letter sent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Re-consented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Source Data Checked	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Participant ID Number: XXXXXXXXXXXXXX	Yes	No	N/A	Comments/Findings
Sticker in medical notes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Consent sticker/annotation in medical notes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Eligibility checked/confirmed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Copy of PIS and CF in the medical notes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Randomisation confirmation (i.e., post-screening) and print out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Blood results signed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Visit dates checked	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
GP letter sent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Re-consented	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Source Data Checked	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**23. Data Protection ( Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
Is all study hard copy documentation stored in a restricted access area?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all study related documentation designed to ensure that they are anonymised by the use of study patient identifier?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are computer records and files containing identifiable data stored on a remote and secure server?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is the emergency recovery procedure for retrieving data available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is access to electronic study records and files password protected?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Are electronic data files for analysis pseudo-anonymised?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Will any documentation be archived off site If yes are details logged with the Sponsor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Where a data access/sharing agreement exists (e.g. with HSCIC), has the data been accessed in accordance with the terms & conditions of the agreement?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Comments/Findings</b>

**24. Other ( Section not reviewed at visit,  Section reviewed at previous visit)**

Items Discussed/verified	Yes	No	N/A	Comments
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Comments/Findings</b>