CE Marked/Proof of Concept Medical Device Trial 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.
- Any report sections marked **NA** do not require completing and can be left blank.
- All sponsor SOPs and associated documents can be accessed via our website.

This report is designed to be adaptable to each study, sections headings can be marked not applicable and content deleted if they are not required to be completed.

1. Visit Information

Details required	Study specific information
Site name:	
Principal investigator:	
Site contact(s):	
Monitoring visit conducted by:	**<insert name, role, contact details (email/phone number)>**
Monitoring visit number & date:	
Monitoring visit type	☐ routine ☐ triggered
Version and Date report issued:	
Date responses due:	

Summary of Visit and Outstanding Actions from Previous Monitoring Visits

List of Site and Monitoring Personnel in Attendance	
Name	**Position**

2. Study Status

Question	Answer	Comments
Current status:	☐ open to recruitment ☐ in follow up	
Current end date:		
Is an extension required:	☐ yes ☐ no ☐ 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Number of patients withdrawn:		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?	☐ yes, *provide detail* ☐ no	

3. Site File Review

3.1 Overview of the Site File

Items Discussed/Verified	Yes	No	N/A	Comments and Findings
Site File is complete, accurate, up-to-date, well-maintained	☐	☐	☐	

3.2 Contacts (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

Items Discussed/Verified		Yes	No	N/A	Comments and Findings
Contact List containing key trial management personnel, Sponsor, 3rd party organisation(s) and Pharmacy contact details	**<insert version and date>**	☐	☐	☐	

4. Trial Approvals and Amendments

4.1 Protocol/Clinical Investigation Plan (CIP) (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

Items Discussed/Verified		Yes	No	N/A	Comments and Findings
Current approved Protocol/Clinical Investigation Plan (CIP)	**<insert version and date>**	☐	☐	☐	
Protocol/CIP Signature Page	Chief Investigator **<insert date>**	☐	☐	☐	
	Sponsor **<insert date>**	☐	☐	☐	
	Principal Investigator **<insert date>**	☐	☐	☐	

Superseded Protocol/CIP(s)	**<insert version and date>**	☐	☐	☐	
	<insert version and date>	☐	☐	☐	
	<insert version and date>	☐	☐	☐	
Protocol/CIP Deviation Tracking Log	*Record Protocol/CIP Deviations/make a copy of the Protocol/CIP Deviation Tracking Log*	☐	☐	☐	
Protocol Deviation/CIP Tracking Log/Site File Note(s) signed by the Principal Investigator	*Verify that the corrective and preventative actions are appropriate*	☐	☐	☐	

4.2 Research Ethics Committee (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

NB. This section can be deleted depending upon the version/structure of the site file index being used

Items Discussed/Verified		**Yes**	**No**	**N/A**	**Comments and Findings**
Signed IRAS Application	Chief Investigator **<insert date>**	☐	☐	☐	
	Sponsor **<insert date>**	☐	☐	☐	
	Supervisor(s) **<insert date>**	☐	☐	☐	
REC Approvals	Valid Application **<insert date>**	☐	☐	☐	
	Provisional Opinion **<insert date>**	☐	☐	☐	

	Response **<insert date>**	☐	☐	☐	
	Favourable Opinion **<insert date>**	☐	☐	☐	
	REC Members/Constitution	☐	☐	☐	
Substantial Amendment **<insert number>**	Amendment Tool **<insert date>**	☐	☐	☐	
	Valid Application **<insert date>**	☐	☐	☐	
	Favourable Opinion **<insert date>**	☐	☐	☐	
Substantial Amendment **<insert number>**	Amendment Tool **<insert date>**	☐	☐	☐	
	Valid Application **<insert date>**	☐	☐	☐	
	Favourable Opinion **<insert date>**	☐	☐	☐	
Non-Substantial Amendment **<insert number>**	Amendment Tool **<insert date>**	☐	☐	☐	
	Valid Application **<insert date>**	☐	☐	☐	
	Favourable Opinion **<insert date>**	☐	☐	☐	
Non-Substantial Amendment **<insert number>**	Amendment Tool **<insert date>**	☐	☐	☐	
	Valid Application **<insert date>**	☐	☐	☐	
	Favourable Opinion **<insert date>**	☐	☐	☐	

Correspondence	☐	☐	☐	

4.3 Health Research Authority (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

NB. This section can be deleted depending upon the version/structure of the site file index being used

Items Discussed/Verified		**Yes**	**No**	**N/A**	**Comments and Findings**
HRA Approvals	Initial Assessment **<insert date>**	☐	☐	☐	
	Response **<insert date>**	☐	☐	☐	
	Approval **<insert date>**	☐	☐	☐	
Substantial Amendment **<insert number>**	Approval **<insert date>**	☐	☐	☐	
Substantial Amendment **<insert number>**	Approval **<insert date>**	☐	☐	☐	
Non-Substantial Amendment **<insert number>**	Approval **<insert date>**	☐	☐	☐	
Non-Substantial Amendment **<insert number>**	Approval **<insert date>**	☐	☐	☐	
Correspondence		☐	☐	☐	

4.4 Other <insert details> (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit, ☐ Section is not applicable)

NB. This section can be deleted depending upon the version/structure of the site file index being used

Items Discussed/Verified	**Yes**	**No**	**N/A**	**Comments and Findings**

Application **(<insert name of Authority i.e., CAG/ARSAC>)**	Valid Application **<insert date>**	☐	☐	☐	
	Response **<insert date>**	☐	☐	☐	
	Approval **<insert date>**	☐	☐	☐	
Substantial Amendment **<insert number>**		☐	☐	☐	
		☐	☐	☐	
		☐	☐	☐	
		☐	☐	☐	
Correspondence		☐	☐	☐	

4.5 Participating NHS Trust (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

NB. This section can be deleted depending upon the version/structure of the site file index being used

Items Discussed/Verified		**Yes**	**No**	**N/A**	**Comments and Findings**
CRN Portfolio	Portfolio Adoption Confirmation **<insert date>**	☐	☐	☐	
	Validated SoECAT **<insert version and date>**	☐	☐	☐	
Site Feasibility Form		☐	☐	☐	
NHS Site Approvals	Confirmation of Capacity and Capability **<insert date>**	☐	☐	☐	

	Signed OID **<insert date>**	☐	☐	☐	
	Signed mNCA **<insert date>**	☐	☐	☐	
	Sponsor Green Light **<insert date>**	☐	☐	☐	
Substantial Amendment **<insert number>**	Confirmation of Capacity and Capability **<insert date>**	☐	☐	☐	
	Sponsor Green Light **<insert date>**	☐	☐	☐	
Substantial Amendment **<insert number>**	Confirmation of Capacity and Capability **<insert date>**	☐	☐	☐	
	Sponsor Green Light **<insert date>**	☐	☐	☐	
Non-Substantial Amendment **<insert number>**	Confirmation of Capacity and Capability **<insert date>**	☐	☐	☐	
	Sponsor Green Light **<insert date>**	☐	☐	☐	
Non-Substantial Amendment **<insert number>**	Confirmation of Capacity and Capability **<insert date>**	☐	☐	☐	
	Sponsor Green Light **<insert date>**	☐	☐	☐	
Non-Substantial No Study-Wide Review Amendments **<insert number>**	Amendment Tool **<insert date>**	☐	☐	☐	
	C&C Approval **<insert date>**	☐	☐	☐	
Non-Substantial No Study-Wide Review Amendments **<insert number>**	Amendment Tool **<insert date>**	☐	☐	☐	
	C&C Approval **<insert date>**	☐	☐	☐	

Correspondence	☐	☐	☐	

4.6 Sponsor Approvals, Financial and Legal (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

NB. This section can be deleted depending upon the version/structure of the site file index being used

Items Discussed/Verified		**Yes**	**No**	**N/A**	**Comments and Findings**
Trial Indemnity Certificate	**<insert date>**	☐	☐	☐	
Trial Insurance **<year>**	Professional Indemnity	☐	☐	☐	
	Clinical Trial	☐	☐	☐	
Contracts, Agreements and Finance	**<insert details>**	☐	☐	☐	
	<insert details>	☐	☐	☐	
	<insert details>	☐	☐	☐	
Sponsor Green Lights	Trial Start **<insert date>**	☐	☐	☐	
	Amendment **XX <insert date>**	☐	☐	☐	
	Amendment **XX <insert date>**	☐	☐	☐	
	Amendment **XX <insert date>**	☐	☐	☐	
	Amendment **XX <insert date>**	☐	☐	☐	

Other **<insert details>**	**<insert details>**	☐	☐	☐	
Correspondence		☐	☐	☐	

4.7 Trial Approvals (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

NB. This section can be deleted depending upon the version/structure of the site file index being used

Items Discussed/Verified		**Yes**	**No**	**N/A**	**Comments and Findings**
Trial Indemnity Certificate	**<insert date>**	☐	☐	☐	
Trial Insurance **<year>**	Professional Indemnity	☐	☐	☐	
	Clinical Trial	☐	☐	☐	
Contracts, Agreements and Finance	**<insert details>**	☐	☐	☐	
	<insert details>	☐	☐	☐	
	<insert details>	☐	☐	☐	
Signed IRAS Application	Chief Investigator **<insert date>**	☐	☐	☐	
	Sponsor **<insert date>**	☐	☐	☐	
	Supervisor(s) **<insert date>**	☐	☐	☐	
REC Approvals	Valid Application **<insert date>**	☐	☐	☐	

	Provisional Opinion **<insert date>**	☐	☐	☐	
	Response **<insert date>**	☐	☐	☐	
	Favourable Opinion **<insert date>**	☐	☐	☐	
	REC Members/Constitution	☐	☐	☐	
HRA Approvals	Initial Assessment **<insert date>**	☐	☐	☐	
	Response **<insert date>**	☐	☐	☐	
	Approval **<insert date>**	☐	☐	☐	
Other Authority Approvals **(<insert name of Authority>)**	Valid Application **<insert date>**	☐	☐	☐	
	Response **<insert date>**	☐	☐	☐	
	Approval **<insert date>**	☐	☐	☐	
CRN Portfolio	Portfolio Adoption Confirmation **<insert date>**	☐	☐	☐	
	Validated SoECAT **<insert version and date>**	☐	☐	☐	
NHS Site Approvals	Site Feasibility Form	☐	☐	☐	
	Confirmation of Capacity and Capability **<insert date>**	☐	☐	☐	
	Signed OID **<insert date>**	☐	☐	☐	

	Signed mNCA **<insert date>**	☐	☐	☐	
Sponsor Green Light	**<insert date>**	☐	☐	☐	
Correspondence		☐	☐	☐	

4.8 Trial Amendments (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

NB. This section can be deleted depending upon the version/structure of the site file index being used

Items Discussed/Verified		**Yes**	**No**	**N/A**	**Comments and Findings**
Substantial Amendment **<insert number>**	Amendment Tool **<insert date>**	☐	☐	☐	
	REC Valid Application **<insert date>**	☐	☐	☐	
	REC Favourable Opinion **<insert date>**	☐	☐	☐	
	MHRA Valid Application **<insert date>**	☐	☐	☐	
	MHRA GNA **<insert date>**	☐	☐	☐	
	MHRA Approval **<insert date>**	☐	☐	☐	
	HRA Approval **<insert date>**	☐	☐	☐	
	Confirmation of Capacity and Capability **<insert date>**	☐	☐	☐	
	Sponsor Green Light **<insert date>**	☐	☐	☐	

Substantial Amendment **<insert number>**	Amendment Tool **<insert date>**	☐	☐	☐	
	REC Valid Application **<insert date>**	☐	☐	☐	
	REC Favourable Opinion **<insert date>**	☐	☐	☐	
	MHRA Valid Application **<insert date>**	☐	☐	☐	
	MHRA GNA **<insert date>**	☐	☐	☐	
	MHRA Approval **<insert date>**	☐	☐	☐	
	HRA Approval **<insert date>**	☐	☐	☐	
	Confirmation of Capacity and Capability **<insert date>**	☐	☐	☐	
	Sponsor Green Light **<insert date>**	☐	☐	☐	
Non-Substantial Amendment **<insert number>**	Amendment Tool **<insert date>**	☐	☐	☐	
	REC Valid Application **<insert date>**	☐	☐	☐	
	REC Favourable Opinion **<insert date>**	☐	☐	☐	
	HRA Approval **<insert date>**	☐	☐	☐	
	Confirmation of Capacity and Capability **<insert date>**	☐	☐	☐	
	Sponsor Green Light **<insert date>**	☐	☐	☐	

Non-Substantial Amendment **<insert number>**	Amendment Tool **<insert date>**	☐	☐	☐	
	REC Valid Application **<insert date>**	☐	☐	☐	
	REC Favourable Opinion **<insert date>**	☐	☐	☐	
	HRA Approval **<insert date>**	☐	☐	☐	
	Confirmation of Capacity and Capability **<insert date>**	☐	☐	☐	
	Sponsor Green Light **<insert date>**	☐	☐	☐	
Non-Substantial No Study-Wide Review Amendments **<insert number>**	Amendment Tool **<insert date>**	☐	☐	☐	
	C&C Approval **<insert date>**	☐	☐	☐	
Non-Substantial No Study-Wide Review Amendments **<insert number>**	Amendment Tool **<insert date>**	☐	☐	☐	
	C&C Approval **<insert date>**	☐	☐	☐	
Correspondence		☐	☐	☐	

5. Site Personnel

5.1 Research Staff and Training (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

Items Discussed/Verified	**Yes**	**No**	**N/A**	**Comments and Findings**

Delegation of Authority and Signature Log	Changes to staff and/or delegated duties since the last visit	☐	☐	☐	
	All staff are listed	☐	☐	☐	
	Pharmacy/Imaging staff listed	☐	☐	☐	
	All staff are signed off	☐	☐	☐	
	Delegated duties are appropriate	☐	☐	☐	
	Consent delegation checked	☐	☐	☐	
	Errors identified with completion	☐	☐	☐	
	Copy of DoA obtained	☐	☐	☐	
Staff Training records must cover the entire duration of time working on the trial, CVs and GCP certificates < 3 years old, Protocol Training (including following Substantial Amendment(s))	Signed and Dated CV	☐	☐	☐	
	CTIMP GCP	☐	☐	☐	
	Consent Training (non-medics)	☐	☐	☐	
	Protocol Training Log	☐	☐	☐	
	Sponsor SOP Read Log	☐	☐	☐	
Study-specific SOPs	**<insert list of SOPs if relevant>**	☐	☐	☐	

5.1.1 Table 1 – Record of Research Staff and Training (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

Name	Role	Delegation Log	CV	GCP	Consent Training	Protocol Training	SOP Read Log	Comments/Findings
					☐	☐	☐	
					☐	☐	☐	
					☐	☐	☐	
					☐	☐	☐	
					☐	☐	☐	
					☐	☐	☐	
					☐	☐	☐	
					☐	☐	☐	
					☐	☐	☐	
					☐	☐	☐	

6. Trial Document and Participant Management

6.1 Trial Documentation (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

Items Discussed/Verified	**Yes**	**No**	**N/A**	**Comments and Findings**

Participant Information Sheet (Long/Short)	Current **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
Consent Form	Current **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
GP Letter	Current **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
Advert	Current **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
Questionnaires	Current **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	

	Superseded **<insert version and date>**	☐	☐	☐	
Diaries	Current **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
Other **<list>**	**<insert version and date>**	☐	☐	☐	
Other **<list>**	**<insert version and date>**	☐	☐	☐	
Other **<list>**	**<insert version and date>**	☐	☐	☐	

6.2 Medical Device Trial Supplies (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit, ☐ Section is not applicable)

Items Discussed/Verified		**Yes**	**No**	**N/A**	**Comments and Findings**
Manufacturer instructions/manual	Current **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
Device Supplies **<insert details>**	Shipment/delivery records	☐	☐	☐	
	Collection/return records	☐	☐	☐	
	Reorder templates	☐	☐	☐	

	Maintenance/calibration/testing records	☐	☐	☐	
Device Labelling	Current Label **<insert version and date>**	☐	☐	☐	
	Labelling is correct	☐	☐	☐	
Device Accountability	Master Accountability Log on file	☐	☐	☐	
	Accountability Log accurate and complete?	☐	☐	☐	
Storage	**<insert details of location and oversight>**	☐	☐	☐	
Other **<list>**	**<insert details>**	☐	☐	☐	

6.3 Participant Documentation (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

Items Discussed/Verified		**Yes**	**No**	**N/A**	**Comments and Findings**
Screening Log	Template on file	☐	☐	☐	
	Complete/up to date	☐	☐	☐	
	Other	☐	☐	☐	
Enrolment Log	Template on file	☐	☐	☐	
	Complete/up to date	☐	☐	☐	

	Participants marked as Complete/Lost to follow up	☐	☐	☐	
Participants Information Sheet and Consent Form Audit **<insert details about the REC approved process for screening and enrolling participants>**	100% Audit Completed	☐	☐	☐	
	PIS Version(s) Audited **<insert version(s) and date(s)>**	☐	☐	☐	
	CF Version(s) Audited **<insert version(s) and date(s)>**	☐	☐	☐	
	Approved process being followed	☐	☐	☐	
	Consent Form errors identified	☐	☐	☐	
	Participants have been re-consented appropriately	☐	☐	☐	
Randomisation (☐ Not Applicable)	Randomisation process/SOP **<insert version(s) and date(s)>**	☐	☐	☐	
	Location of master randomisation list	☐	☐	☐	
	Errors identified with the randomisation procedure	☐	☐	☐	
	Appropriate documentation of errors	☐	☐	☐	
	Blind maintained for staff and/or participants	☐	☐	☐	
	Unblinding appropriately documented	☐	☐	☐	
Other		☐	☐	☐	

6.3.1 *Table 2 – Participant and Consent Audit* (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

Participant ID number	CF version	CF completion checked?	Medical Record Annotation present?	Medical Record Trial sticker present?	CF/PIS in Medical Records?	GP Letter present?	Original CF in the Site File?	Comments/Findings
		☐	☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	☐	

6.4 Data Management and Case Reports Forms (CRFs) (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

Data Management Items Discussed/Verified		**Yes**	**No**	**N/A**	**Comments and Findings**
Method of data collection: ☐ Paper CRF ☐ Electronic CRF ☐ Combination	Data collection is up to date	☐	☐	☐	
Database being used: ☐ Excel ☐ Access ☐ Redcap ☐ Macro ☐ Other:_____	Data entry is up to date	☐	☐	☐	
Data Management Plan (DMP)	**<insert version and date>**	☐	☐	☐	
Is there a robust process in place for reviewing and amending the DMP in response to Protocol amendments (if applicable)?		☐	☐	☐	
Data Handling, Collection, Storage, Management	Concerns Identified	☐	☐	☐	
	Documentation appropriately pseudonymised/anonymised?	☐	☐	☐	
	Restricted access to paper documentation	☐	☐	☐	
	Restricted access to electronic records	☐	☐	☐	
	Restricted access to blinded documentation	☐	☐	☐	

Statistical Analysis Plan (SAP)	**<insert version and date>**	☐	☐	☐	
Is there a robust process in place for reviewing and amending the SAP in response to Protocol amendments (if applicable)?		☐	☐	☐	
Case Report Forms (CRFs) Items Discussed/Verified		**Yes**	**No**	**N/A**	**Comments and Findings**
Is there a robust process in place for reviewing and amending the CRFs in response to Protocol amendments (if applicable)?		☐	☐	☐	
<Title of CRF>	Current **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
<Title of CRF>	Current **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
<Title of CRF>	Current **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
<Title of CRF>	Current **<insert version and date>**	☐	☐	☐	

	Superseded **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
<Title of CRF>	Current **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
<Title of CRF>	Current **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
Other **<list>**	**<insert version and date>**	☐	☐	☐	
Other **<list>**	**<insert version and date>**	☐	☐	☐	
Other **<list>**	**<insert version and date>**	☐	☐	☐	

6.5 Source Data Verification (SDV) (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

Items Discussed/Verified	**Yes**	**No**	**N/A**	**Comments and Findings**
SDV completed in accordance with the monitoring plan? **<list of source documents provided>**	☐	☐	☐	

All source documents available to verify data in the CRF and as per the Source Data Agreement?	☐	☐	☐	
CRF completion is timely and accurate	☐	☐	☐	
Errors identified at previous visits have been resolved	☐	☐	☐	
Are the CRFs complete for each visit?	☐	☐	☐	
Is there evidence of an eligibility check being performed?	☐	☐	☐	
Eligibility confirmed and documented in the notes **prior to randomisation** by a delegated person (clinician)?	☐	☐	☐	
Randomisation results checked for each participant?	☐	☐	☐	
Have all visit dates been checked?	☐	☐	☐	
All visits fully annotated in the medical/study records?	☐	☐	☐	
Specimen results reviewed, signed and dated by PI/delegated clinician **within 7 days**?	☐	☐	☐	
Out of range results marked as clinically significant or not clinically significant?	☐	☐	☐	
AEs/SAEs recorded, reviewed and reported appropriately?	☐	☐	☐	
Concomitant medications checked and recorded appropriately?	☐	☐	☐	
Protocol Compliance checked and adequate?	☐	☐	☐	
Protocol Deviations identified and recorded?	☐	☐	☐	

Primary Endpoint(s) **<insert details>**	Concerns Identified	☐	☐	☐	
Secondary Endpoint(s) **<insert details>**	Concerns Identified	☐	☐	☐	
Other Endpoint(s) **<insert details>**	Concerns Identified	☐	☐	☐	
Missing/Spurious Data	Concerns Identified	☐	☐	☐	
Participant **<insert ID number>** Visit(s) reviewed: **<list>**		Comments/Findings:			
Participant **<insert ID number>** Visit(s) reviewed: **<list>**		Comments/Findings:			
Participant **<insert ID number>** Visit(s) reviewed: **<list>**		Comments/Findings:			
Participant **<insert ID number>** Visit(s) reviewed: **<list>**		Comments/Findings:			

7. Safety and Pharmacovigilance

7.1 Safety Reporting and Management (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

Items Discussed/Verified	**Yes**	**No**	**N/A**	**Comments and Findings**
Have there been any safety concerns or Device Deficiencies?	☐	☐	☐	

Safety Concern/Device Deficiency 1	**<insert details and ensure correspondence filed>**	☐	☐	☐	
Safety Concern/Device Deficiency 2	**<insert details and ensure correspondence filed>**	☐	☐	☐	
Safety Concern/Device Deficiency 3	**<insert details and ensure correspondence filed>**	☐	☐	☐	
Is there a robust process in place for reviewing and amending the Protocol and CRFs in response to safety concerns or Device Deficiencies (if applicable)?		☐	☐	☐	
SAE/SADE/USADE Reporting **<insert details of the approved template to be used i.e., Sponsor template, trial-specific template, company template, other and any relevant details regarding the approved reporting arrangements>**	SAE/SADE/USADE template(s) **<insert version and date>**	☐	☐	☐	
	SAE/SADE/USADE reporting guidelines **<insert version and date>**	☐	☐	☐	
	SAE/SADE/USADEs being reported in accordance with approved arrangements	☐	☐	☐	
	Concerns Identified?	☐	☐	☐	
	SAE/SADE/USADE Log accurate and complete *(see Table 3 below)*	☐	☐	☐	
	Copies of all SAE/SADE/USADEs and correspondence	☐	☐	☐	
Annual Progress Reporting *Ensure that there are copies of the final reports, REC and Sponsor acknowledgements and any relevant correspondence*	Annual Progress Report **<insert year>**	☐	☐	☐	
	Annual Progress Report **<insert year>**	☐	☐	☐	

Other **<list>**	**<insert details>**	☐	☐	☐	

7.1.1 Table 3 – SAE/SADE/USADE Reporting Audit (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit, ☐ Section is not applicable)

Participant ID number	SAE/SADE/USADE Title	Initial	Follow-up 1	Follow-up 2	Follow-up 3	Final	Comments/Findings
		☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	
		☐	☐	☐	☐	☐	

Participant ID number	SAE/SADE/USADE Title	Initial	Follow-up 1	Follow-up 2	Follow-up 3	Final	Comments/Findings
		☐	☐	☐	☐	☐	

7.2 Trial Oversight (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit)

Items Discussed/Verified		**Yes**	**No**	**N/A**	**Comments and Findings**
Monitoring Plan	Current **<insert version and date>**	☐	☐	☐	*High-risk studies only
	Superseded **<insert version and date>**	☐	☐	☐	
	Superseded **<insert version and date>**	☐	☐	☐	
Monitoring and Auditing Visits *Ensure that all closed reports and correspondence are filed, check that actions from previous visit have been completed*	SIV **<insert date>**	☐	☐	☐	*High-risk studies only
	MV01 **<date>**	☐	☐	☐	
	MV02 **<date>**	☐	☐	☐	
Monitoring Visit Log Signed?		☐	☐	☐	
Meetings *Ensure all agendas and minutes are on file*		☐	☐	☐	
		☐	☐	☐	
		☐	☐	☐	

General Correspondence *Ensure there is evidence of trial oversight, decision making and correspondence between sites (if applicable)*		☐	☐	☐	
		☐	☐	☐	
		☐	☐	☐	
Newsletters	**<insert details>**	☐	☐	☐	
	<insert details>	☐	☐	☐	
	<insert details>	☐	☐	☐	
Other **<list>**	**<insert details>**	☐	☐	☐	
Other **<list>**	**<insert details>**	☐	☐	☐	
Other **<list>**	**<insert details>**	☐	☐	☐	

8. Samples, Specimens and Laboratories

8.1 Sample Management (☐ Section not reviewed at visit, ☐ Section reviewed at previous visit, ☐ Section is not applicable)

Items Discussed/Verified		**Yes**	**No**	**N/A**	**Comments and Findings**
Central Labs (☐ Not Applicable)	**<insert details>**	☐	☐	☐	
	Accreditation Certificates **<insert version and date>**	☐	☐	☐	
	Reference Ranges **<insert version and date>**	☐	☐	☐	

	Sample Handling SOP **<insert version and date>**	☐	☐	☐	
	Lab Kits (available and in date)	☐	☐	☐	
Local NHS Pathology Labs	**<insert details>**	☐	☐	☐	
	Accreditation Certificates **<insert version and date>**	☐	☐	☐	
	Reference Ranges **<insert version and date>**	☐	☐	☐	
	Sample Handling SOP **<insert version and date>**	☐	☐	☐	
Departmental Research Labs (☐ Not Applicable)	**<insert details>**	☐	☐	☐	
	Accreditation Certificates **<insert version and date>**	☐	☐	☐	
	Lab Manual **<insert version and date>**	☐	☐	☐	
	Sample Handling SOP **<insert version and date>**	☐	☐	☐	
	Lab Kits (available and in date)	☐	☐	☐	
Storage and Shipment	Storage Location	☐	☐	☐	
	Custodian/Point of Contact	☐	☐	☐	
	Sample Logs	☐	☐	☐	
	Temperature Monitoring	☐	☐	☐	

	Temperature Deviations	☐	☐	☐	
	Sample Shipment Records	☐	☐	☐	
	Contingency Plan	☐	☐	☐	
Other **<list>**	**<insert details>**	☐	☐	☐	
Other **<list>**	**<insert details>**	☐	☐	☐	
Other **<list>**	**<insert details>**	☐	☐	☐	