Sponsor Number:		**EudraCT Number:**	
Study Title:		**IRAS Number:**	
Chief Investigator:		**EDGE Number:**	

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Site Initiation Visit

1. Site Information

Site Number:	
Site Name:	
Principal Investigator:	
Date of Site Initiation Visit:	
Conducted by:	
Initiation Visit Method:	Onsite ☐ Remote ☐

2. Key Site Personnel

Key Site Personnel to be listed below. All those in attendance must sign the SIV Attendance Log. Those unable to attend the SIV must ensure they undergo appropriate trial training prior to conducting any trial-related activities.

Name	**Title**

3. Study Overview/Protocol Overview

Items discussed/verified	Comments
Background and purpose of study	
Study IMP/s	

Date of Visit:		**Date & Version of Report:**		**Date Responses Due:**	

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4. GCP and Regulatory Compliance

Items Discussed/verified	Yes	No	N/A	Comments
Investigator obligations	☐	☐	☐	
Sponsor obligations	☐	☐	☐	
Standard Operating Procedures	☐	☐	☐	
Ethics reporting requirements	☐	☐	☐	
MHRA reporting requirements	☐	☐	☐	
Sponsor reporting requirements	☐	☐	☐	
Amendments	☐	☐	☐	
Data Protection	☐	☐	☐	
Study record storage requirements	☐	☐	☐	
Archiving arrangements	☐	☐	☐	

5. Trial Master File/Investigator Site File

Items Discussed/verified	Yes	No	N/A	Comments
Site File = created, sent to site and complete	☐	☐	☐	
Delegated Individual for Site File maintenance	☐	☐	☐	
Secure Location/limited Access	☐	☐	☐	

6. Study Approval Status/Essential Documents

Items Discussed/verified	Yes	No	N/A	Version/ Comments
MHRA Approval	☐	☐	☐	
REC Favourable opinion/HRA approval	☐	☐	☐	
Composite of REC committee	☐	☐	☐	
R&D/R&I Approval	☐	☐	☐	

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Signed Sponsor/CI Agreement	☐	☐	☐	
Signed Financial Agreement	☐	☐	☐	
Indemnity/Insurance	☐	☐	☐	
Approved Reference Safety Information (RSI): Investigator Brochure/SmPC	☐	☐	☐	
Protocol (+ protocol signed by PI?)	☐	☐	☐	
Protocol deviation/Serious Breach reporting	☐	☐	☐	
Patient Information Leaflet	☐	☐	☐	
Consent	☐	☐	☐	
Patient Invitation	☐	☐	☐	
GP Letter	☐	☐	☐	
Advertisement	☐	☐	☐	
Other study documents	☐	☐	☐	
CRF	☐	☐	☐	
Other: Have any contact numbers on PIS been checked?	☐	☐	☐	

7. Investigator Site Personnel

Items Discussed/verified	Yes	No	N/A	Comments
Adequate site staff to conduct the study	☐	☐	☐	
Signed and dated CV for all study team members	☐	☐	☐	
GCP Training	☐	☐	☐	
Process for training new staff	☐	☐	☐	
All study team members listed on Delegation of Authority and Signature Log	☐	☐	☐	

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8. Recruitment

Items discussed/verified	Yes	No	N/A	Comments
Planned Number of Trial subjects	☐	☐	☐	
Methods for identifying Subjects	☐	☐	☐	
Requirement to complete Subject Screening and Enrolment logs	☐	☐	☐	
Procedure for Withdrawn Subjects/Lost to Follow-up	☐	☐	☐	

9. Informed Consent/Enrolment

Items Discussed/verified	Yes	No	N/A	Comments
Informed consent procedures/documentation requirements	☐	☐	☐	
Eligibility criteria	☐	☐	☐	
100% consent audit requirements	☐	☐	☐	
Randomisation procedures	☐	☐	☐	

10. Investigational Medicinal Products

Items discussed/verified	Yes	No	N/A	Comments
QP release document	☐	☐	☐	
Certificate of analysis	☐	☐	☐	
Receipt	☐	☐	☐	
Labelling and packaging	☐	☐	☐	
Storage requirements	☐	☐	☐	
Dispensing procedures	☐	☐	☐	
Drug accountability	☐	☐	☐	

Date of Visit:		**Date & Version of Report:**		**Date Responses Due:**	

Return of IMP procedures	☐	☐	☐	
Reordering procedures	☐	☐	☐	
Drug Destruction	☐	☐	☐	
Unblinding procedure/code break envelopes	☐	☐	☐	

11. Safety Reporting/Pharmacovigilance

Items Discussed/verified	Yes	No	N/A	Comments
AE / SAE reporting procedures	☐	☐	☐	
SUSAR reporting procedures	☐	☐	☐	
Notification process	☐	☐	☐	
Urgent Safety Measures	☐	☐	☐	
Data Safety Monitoring Board meeting and reporting requirements	☐	☐	☐	

12. Data Collection

Items Discussed/verified	Yes	No	N/A	Comments
Format and timelines	☐	☐	☐	
CRF completion guidelines	☐	☐	☐	
Queries and corrections	☐	☐	☐	
MACRO Database training	☐	☐	☐	
File notes	☐	☐	☐	
Statistical Analysis Plan	☐	☐	☐	

13. Source Documentation

Items Discussed/verified	Yes	No	N/A	Comments

Source Data Agreement	☐	☐	☐	
CRFs as source	☐	☐	☐	
Document retention	☐	☐	☐	

14. Equipment List

Items Discussed/verified	Yes	No	N/A	Comments
Equipment list	☐	☐	☐	
Calibration of equipment	☐	☐	☐	
Maintenance/service record requirements	☐	☐	☐	

15. Specimen Collection

Items Discussed/verified	Yes	No	N/A	Comments
Specimen Collection	☐	☐	☐	
Sample result verification/CS/NCS status and required actions	☐	☐	☐	
Specimens to be obtained	☐	☐	☐	
Specimen Storage	☐	☐	☐	
Specimen storage and tracking logs	☐	☐	☐	
Temperature monitoring	☐	☐	☐	
Sample shipment	☐	☐	☐	
Laboratory training/manual/SOPs	☐	☐	☐	
Lab kits	☐	☐	☐	
Lab Accreditation	☐	☐	☐	
Lab Normal Values	☐	☐	☐	

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16. Communications

Items discussed/verified	Yes	No	N/A	Comments
Format and frequency	☐	☐	☐	
Site contacts	☐	☐	☐	
Recruitment updates to sponsor	☐	☐	☐	

17. Monitoring

Items discussed/verified	Yes	No	N/A	Comments
Site monitoring Plan	☐	☐	☐	
Site Monitoring response requirements	☐	☐	☐	

Additional Comments/Visit Overview

Date of Visit:		**Date & Version of Report:**		**Date Responses Due:**	

Sponsor Number:		**EudraCT Number:**	
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Outstanding Actions

Site Number:	
Site Name:	
Sponsor Reference Number:	
Short Study Title:	

No.	Outstanding Issue & Action Required	Action Taken/Response	Signature & Date	Sponsor Sign-off & Date

Date of Visit:		**Date & Version of Report:**		**Date Responses Due:**	

Sponsor Number:		**EudraCT Number:**	
Study Title:		**IRAS Number:**	
Chief Investigator:		**EDGE Number:**	

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Site Initiation Visit and Report Completed by:	Responses Completed by:	Principal Investigator Sign-off:
Name:	Name:	Name:
Role:	Role:	Role: Principal Investigator
Email:	Email:	Email:
Signature:	Signature:	Signature:
Date:	Date:	Date:

Site Initiation Visit and Report Closed by:
Name:
Role:
Email:
Signature:
Date:

Date of Visit:		**Date & Version of Report:**		**Date Responses Due:**	