

## Site Initiation Checklist

### 1. Site Information

Site Number:	
Site Name:	
Principal Investigator:	
Date of Site Initiation Visit:	
Sponsor Reference Number:	
Study Title:	
Short Study Title:	
EudraCT Number:	
IRAS Number:	
Chief Investigator:	
Conducted by:	
Initiation Visit Method:	On site <input type="checkbox"/> Remote <input type="checkbox"/>

### 2. Personnel in Attendance/Completing Report

Name	Title

### 3. Study Overview/Protocol Overview

Items discussed/verified	Comments
Background and purpose of study	

### 4. GCP and Regulatory Compliance

Items Discussed/verified	Yes	No	Comments
Investigator obligations	<input type="checkbox"/>	<input type="checkbox"/>	
Sponsor obligations	<input type="checkbox"/>	<input type="checkbox"/>	
Standard Operating Procedures	<input type="checkbox"/>	<input type="checkbox"/>	
Sponsor reporting requirements	<input type="checkbox"/>	<input type="checkbox"/>	
Amendments	<input type="checkbox"/>	<input type="checkbox"/>	
Annual reports	<input type="checkbox"/>	<input type="checkbox"/>	
Data Protection	<input type="checkbox"/>	<input type="checkbox"/>	
Study record storage requirements	<input type="checkbox"/>	<input type="checkbox"/>	
Archiving arrangements	<input type="checkbox"/>	<input type="checkbox"/>	

### 5. Trial Master File/Investigator Site File

Items Discussed/verified	Yes	No	Comments
TMF/ISF created and complete	<input type="checkbox"/>	<input type="checkbox"/>	

Delegated Individual for TMF/ISF maintenance	<input type="checkbox"/>	<input type="checkbox"/>	
Secure Location/limited Access	<input type="checkbox"/>	<input type="checkbox"/>	

### 6. Study Approval Status/Essential Documents

Items Discussed/verified	Yes	No	N/A	Version/ Comments
EC Favourable opinion/HRA approval	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
R&D/R&I/Host organisation approval/authorisation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Signed Sponsor/CI Agreement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Signed Financial Agreement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol - Confirm protocol signed and dated by the PI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol deviation/Serious Breach reporting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Patient Information Leaflet (document version no and date)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Consent (document version no and date)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Patient Invitation (document version and date)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
GP Letter (document version and date)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Advertisement (document version and date)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CRF (document version and date)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other: Are the contact numbers on the PIS correct/ been checked?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

### 7. Investigator Site Personnel

Items Discussed/verified	Yes	No	Comments
Adequate site staff to conduct the study	<input type="checkbox"/>	<input type="checkbox"/>	
All study team members listed on Delegation of duties log/ all entries signed and dated by PI	<input type="checkbox"/>	<input type="checkbox"/>	
Signed and dated CVs for all study team members	<input type="checkbox"/>	<input type="checkbox"/>	
Documented evidence of GCP / consent/study specific training	<input type="checkbox"/>	<input type="checkbox"/>	

### 8. Recruitment

Items discussed/verified	Yes	No	N/A	Comments
Planned Number of Trial subjects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Methods for identifying Subjects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Research team aware of inclusion/exclusion criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Requirement to complete Subject Screening and Enrolment logs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Procedure for withdrawn Subjects/Lost to follow-up	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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### 9. Informed Consent/Enrolment

Items Discussed/verified	Yes	No	Comments
Informed consent procedures/documentation requirements	<input type="checkbox"/>	<input type="checkbox"/>	
Eligibility criteria confirmed	<input type="checkbox"/>	<input type="checkbox"/>	

### 10. Randomisation/Blinding (check box if N/A )

Items discussed/verified	Yes	No	Comments
Unblinding procedure/code break envelopes	<input type="checkbox"/>	<input type="checkbox"/>	
Randomisation procedures	<input type="checkbox"/>	<input type="checkbox"/>	

### 11. Safety Reporting/Pharmacovigilance (Check box if N/A )

Items Discussed/verified	Yes	No	Comments
AE / SAE reporting procedures	<input type="checkbox"/>	<input type="checkbox"/>	
Notification process	<input type="checkbox"/>	<input type="checkbox"/>	

### 12. Data Collection

Items Discussed/verified	Yes	No	Comments
Format and timelines	<input type="checkbox"/>	<input type="checkbox"/>	
CRF completion guidelines	<input type="checkbox"/>	<input type="checkbox"/>	
Queries and corrections	<input type="checkbox"/>	<input type="checkbox"/>	
eDC training (for electronic case report forms)	<input type="checkbox"/>	<input type="checkbox"/>	
File notes	<input type="checkbox"/>	<input type="checkbox"/>	
Statistical Analysis Plan	<input type="checkbox"/>	<input type="checkbox"/>	

### 13. Source Documentation

Items Discussed/verified	Yes	No	Comments
Source Data agreement in place?	<input type="checkbox"/>	<input type="checkbox"/>	
CRFs as source	<input type="checkbox"/>	<input type="checkbox"/>	
Document retention	<input type="checkbox"/>	<input type="checkbox"/>	

### 14. Equipment List (Check box if N/A )

Items Discussed/verified	Yes	No	Comments
Equipment list	<input type="checkbox"/>	<input type="checkbox"/>	
Calibration of equipment	<input type="checkbox"/>	<input type="checkbox"/>	
Maintenance/service record requirements	<input type="checkbox"/>	<input type="checkbox"/>	

### 15. Specimen collection (Check box if N/A )

Items Discussed/verified	Yes	No	Comments
Specimen Collection	<input type="checkbox"/>	<input type="checkbox"/>	
Sample result verification/CS/NCS status and	<input type="checkbox"/>	<input type="checkbox"/>	

required actions			
Specimens to be obtained	<input type="checkbox"/>	<input type="checkbox"/>	
Specimen Storage	<input type="checkbox"/>	<input type="checkbox"/>	
Specimen storage and tracking logs	<input type="checkbox"/>	<input type="checkbox"/>	
Temperature monitoring	<input type="checkbox"/>	<input type="checkbox"/>	
Sample shipment	<input type="checkbox"/>	<input type="checkbox"/>	
Laboratory training/manual/SOPs	<input type="checkbox"/>	<input type="checkbox"/>	
Lab kits	<input type="checkbox"/>	<input type="checkbox"/>	
Lab Accreditation	<input type="checkbox"/>	<input type="checkbox"/>	
Lab Normal Values	<input type="checkbox"/>	<input type="checkbox"/>	

### 16. Communications

Items discussed/verified	Yes	No	Comments
Format and frequency	<input type="checkbox"/>	<input type="checkbox"/>	
Site contacts	<input type="checkbox"/>	<input type="checkbox"/>	
Recruitment updates to Sponsor	<input type="checkbox"/>	<input type="checkbox"/>	

### 17. Monitoring

Items discussed/verified	Yes	No	Comments
Site Monitoring response requirements	<input type="checkbox"/>	<input type="checkbox"/>	

### 18. SOPs

Items discussed/verified	Yes	No	Comments
Do all members of the study team know how to access the Sponsor SOPs via the webpages?	<input type="checkbox"/>	<input type="checkbox"/>	
CI/PI confirmation of review and compliance with all Sponsor Standard Operating Procedures.	<input type="checkbox"/>	<input type="checkbox"/>	

### 19. Archiving

Items discussed/verified	Yes	No	Comments
Archiving at end of study discussed?	<input type="checkbox"/>	<input type="checkbox"/>	

### Additional Comments/Visit Overview

**The study must not start until Sponsor Green Light has been issued**

**Site Initiation Outstanding Issues Report**

Site Name:	
Site Number (if applicable):	
Sponsor Reference Number:	
Short Study Title:	
Date of Visit:	
Date of Report:	
Date Responses Due Back:	

**The study must not start until Sponsor Green Light has been issued**

No.	Outstanding Issue	Action required	Action Taken	Signature & Date	Reviewer Initials & Date

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: