

SITE INITIATION VISIT REPORT

TRIAL TITLE:			
TRIAL CODE			
SPONSOR			
CRA			
SITE Nr.			
PRINCIPAL INVESTIGATOR			
INSTITUTION NAME			
DEPARTMENT / UNIT			
VISIT DATE dd/mm/yyyy		TYPE OF CONTACT	VISIT <input type="checkbox"/> CALL <input type="checkbox"/>

Attendees

NAME	ROLE

A - Study enrollment

N°		No.	COMMENTS
1	Total number of patients planned for this Site		
2	Expected monthly enrollment		

B - Confirmation of Investigator's responsibilities

N°		Y	N	N/A	COMMENTS
3	<u>GCP</u> and local regulations				
4	Personal data <u>confidentiality</u>				
5	Adherence to the study <u>protocol</u> and prompt reporting of any <u>deviations</u>				

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N°		Y	N	N/A	COMMENTS
6	Informed consent signature before any study related procedure can start				
7	AE/SAE reporting				
8	Compliance with EC reporting requirements				
9	Accurate and complete source documents				
10	Access to the study documents to CRA/auditors/inspectors				
11	Retention of all study records for the required time				
12	ISF updated and safely stored				
13	Training and prompt communication of any new study information to the site staff				
14	Notification to the Sponsor in case of any changes in the PI's position				

C - Investigators and Site adequacy overview

N°		Y	N	N/A	COMMENTS
15	Completed Site Staff Responsibility Log available?				
16	Have the medical specialists from other departments required by protocol included in the Site Staff Responsibility Log?				

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D - Clinical Protocol Review – Specify version and date: _____

N°		Y	N	N/A	COMMENTS
17	Trial objectives /endpoints				
18	Informed Consent (who will be consenting patients? Document procedure in <i>narrative</i> box)				Version in use: Who will obtain IC?
19	Eligibility criteria				
20	Screening and enrollment procedure				
21	Randomization				
22	Procedure for collection and shipment of biological materials to central laboratory(ies)				
23	Study timelines / visits schedule				
24	Required imaging procedures				
25	Other tests/visits				
26	Discontinuation of Subjects				
27	Unblinding procedures				
28	AE and SAE reporting procedures				
29	Other: <i><specify></i>				

E - Study Procedures Review

N°		Y	N	N/A	COMMENTS
30	Protocol deviations and violations notification to Sponsor				
31	ISF contents and documents management				

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32	Specific study forms and logs to be completed				
33	Training on CRF completion				
34	e-CRF access/ ID/PW /training on remote data capture				
35	Queries resolution				
36	Source documents completion and maintenance				
37	Monitoring visits, frequency, availability of staff during the monitoring visits and follow-up letters				
38	Other: <i><specify></i>				

F – Investigational Medicinal Product(s) (only products under investigation)

Not applicable ☐

N°	ITEM DISCUSSED	Y	N	N/A	COMMENTS
39	Are the IMPs on site? If not please give details in comment box				
40	For marketed IMPs has a study-specific stock been labelled?				
41	Does inventory match delivery documents?				
42	Were the IMPs supplied by the Sponsor in adequate conditions upon receipt? (temperature, packaging, etc.) If not please give details in comment box				
43	Where are the IMPs stored?				
44	Are storage temperature requirements fulfilled?				
45	Were the shipment and storage conditions appropriate?				
46	IMPs prepared by pharmacy?				

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47	Does Pharmacy need a Pharmacy File?				
48	Instructions for IMPs handling, preparation, storage and dispensing available?				
49	IMPs Shipping/receipt records accurate				
50	Were IMP reordering, return/destruction procedures discussed?				
51	Were IMP accountability forms reviewed?				

G – Other Supplies

Not applicable ☐

N°	ISSUE DISCUSSED	Y	N	N/A	COMMENTS
52	Laboratory kits				
53	Blank paper CRFs				
54	Blank questionnaires				
55	Patient diaries				
56	Other: <specify>				

H – Investigator's Study File documents review

N°	ISSUE DISCUSSED	Y	N	N/A	Copy collected	COMMENTS
57	Clinical Trial Agreement					
58	Protocol and Signatures page					
59	Investigator's Brochure / Summary					

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N°	ISSUE DISCUSSED	Y	N	N/A	Copy collected	COMMENTS
	of Product Characteristics					
60	Blank CRF copy					
61	Regulatory and E.C submission and approval documents (including EC members list)					
62	Blank local Patient Information Sheet / ICF					
63	Blank patient diary /questionnaires					
64	Letter to family doctor					
65	Site Staff Responsibility Log					
66	Signed and dated CV for PI and Sub-Investigators					
67	Financial Disclosure Statement for PI and Sub-Investigators					
68	Insurance Certificate					
69	Code breaking procedures for blinded trials					
70	Local laboratory normal ranges and quality certificates/accreditation					
71	Patients screening & enrolment/randomization Log					
72	Patient Identification Log					
73	Source Documents Location List					
74	IMP order forms					
75	IMP Accountability forms					

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N°	ISSUE DISCUSSED	Y	N	N/A	Copy collected	COMMENTS
76	Biological samples tracking form					
77	SAE form					
78	Pregnancy Form					
79	Training log					
80	Monitoring Visit log					

Pending Actions

ID	ACTION ITEM	BY WHEN	WHO
A1			
A2			
A3			
A4			

This Site is now open and recruitment can start immediately: YES ☐ NO ☐

If not, please specify reasons in the narrative section below and specify required actions in the section above.

Remark on Item No.	Expanded Comments
	Please use this section to expand on the previous comments or to add any further useful information. If the comment refers to a specific item, please enter the number of the item the comment is referred to.

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Next visit planned date		Type of contact	visit <input type="checkbox"/>	call <input type="checkbox"/>
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Report prepared by CRA Print name:	Signature:	dd/mm/yyyy
Report reviewed and approved by COC Print name:	Signature:	dd/mm/yyyy