MONITORING VISIT REPORT

TRIAL TITLE:				
TRIAL CODE				
SPONSOR				
CRA				
SITE Nr.				
PRINCIPAL INVESTIGATOR				
INSTITUTION NAME				
DEPARTMENT / UNIT				
VISIT DATE dd/mmm/yyyy		TYPE OF CONTACT	VISIT ☐	CALL ☐
PREVIOUS VISIT DATE dd/mmm/yyyy		TYPE OF CONTACT	VISIT ☐	CALL ☐

Attendees

NAME	ROLE

A - Patient enrollment

NOTE: in general a patient is *ENROLLED* when he/she has been screened, found to fulfill all selection criteria and registered. If the trial design includes different phases (e.g., run-in, randomization, etc) add as many rows as appropriate to document patients entered in each phase.

Planned FPI (dd/mmm/yyyy):	Planned LPI (dd/mmm/yyyy):	Planned LPO (dd/mmm/yyyy):
Actual FPI (dd/mmm/yyyy):	Actual LPI (dd/mmm/yyyy):	

N°		Planned No. pts	Current No. pts	If patient enrolment is unsatisfactory, please comment
1	Screened			
2	Registered			
3	Randomized			
4	On treatment			
5	On follow-up			
6	Off study			

MONITORING VISIT REPORT

B - *Informed Consent*   Verified ☐ Yes ☐ No

(check only previously unchecked ICF; please indicate if more than one IC is used)

Patient Screening No.	IC Version / Date	Date of Signature	Comments (Please State Any Deviation)

C - *Patients*   Verified ☐ Yes ☐ No

Patient No.	Patient status*	Visits reviewed (record only CRFs reviewed at this visit)	Open Queries Y / N	Comments

* 1 Baseline only, not yet treated; 2 On treatment; 3 On follow-up; 4 Off study

D – *Patient eligibility*   Verified ☐ Yes ☐ No

Patient No.	Source Docs Available (Y/N)	Violations Y/N (If Any)	Violations Description	Discussed with trial team (Y/N) / Comment

E - *Protocol violations*   Verified ☐ Yes ☐ No

(deviations from protocol/GCP/regulations which impact on subjects' rights, safety, or welfare and/or the data's integrity)

NONE ☐			
Patient No.	Brief description	Notified by PI to Sponsor (Y/N) /Comment	Discussed with trial team (Y/N) / Comment

MONITORING VISIT REPORT

F - Trial Conduct   Verified ☐ Yes ☐ No

N°		Yes	No	N/A	COMMENTS
1	Are patient identification, screening and registration/randomization logs up to date?				
2	Is PI suitably involved in the conduct of the trial?				
3	Was appropriate staff available during MOV?				
4	Was an Investigator available during the visit?				
5	Are staff dedicating enough time to trial?				
6	Are source documents available?				
7	Are documents accurate and legible?				
8	Is data being entered in a timely manner?				
9	Is there a significant lack of consistency between source documents and CRF data?				
10	Have any unreported SAEs been detected?				
11	Have unreported SAEs immediately been notified to Sponsor?				
12	Has the site staff duly been informed of any protocol/ICF/CRF changes?				
13	Has training for new staff been performed? *Please provide details*				

G - Investigational Medicinal Products   Verified ☐ Yes ☐ No ☐ Not applicable

N°	ISSUE DISCUSSED	Y	N	N/A	COMMENTS
14	Are the IMPs correctly stored?				
15	IMPs temperature log checked?				
16	Are accountability logs up to date				

N°		YES	NO	N/A	COMMENTS
	and consistent? (collect copy of the IMP accountability form)				
17	Has shipping and receipt documentation been filed correctly in ISF?				
18	IMPs returned/destroyed since last visit?				
19	Is IMP stock adequate?				
20	Are IMPs being used according to instructions?				
21	For blinded trials: any code break since last visit?				
22	Are reasons for un-blinding properly documented?				
23	Have there been changes in the Pharmacy? *(location/ equipment /storage/ Referent)*				

H – ISF

Verified ☐ Yes ☐ No

N°	ISF STATUS/ACTIONS	YES	NO	N/A	COMMENTS
24	Are all regulatory approval documents on file?				
25	Are the most updated versions of the IB(s) and/or SPC(s) on file?				
26	Are the most updated version of the protocol and informed consent forms on file?				
27	Is a blank copy of the most updated version of the CRF and SAE form on file?				
28	Is a blank copy of all other forms for patient-reported outcomes collection on file? *(e.g., patient diaries and questionnaires)*				
29	Is a valid insurance certificate on file?				
30	Has the Trial-Specific Training Record been updated?				
31	Have any changes in staff been documented in the Signature and Delegation List?				

32	Are all new staff CVs filed?				
33	Are financial disclosure for new staff filed?				
34	In case of changes, have updated laboratory normal ranges and/or certificates been collected?				
35	Biological sample handling – documentation of collection, storage and shipment on file?				
36	Monitoring Visit Log updated and filed?				
37	Any missing documents? *(Please specify)*				

I - Documents collected at this visit:

Document	Version or Date	Original /copy

Please always collect:

- copy of screening and enrollment log if not regularly sent by Site
- copy of monitoring visit log
- copy of delegation log IF new staff has joined the team
- any new CV /financial disclosure for new Investigators
- training log if new training has been performed
- IMP accountability log if not otherwise documented in this report

J – Other   Verified ☐ Yes   ☐ No   ☐ Not applicable

N°	ISSUE DISCUSSED	YES	NO	N/A	COMMENTS
38	Are supplies of Central Lab. materials adequate (expiry date, No. of kits)?				
39	Are biological samples being managed according to instructions?				
40	Are radiological images being transmitted for central reading as required?				

41	Are patient questionnaires and diaries properly being managed?				
42	Have any other departments involved in the trial been visited? Please specify under Comments the departments and if facilities are still adequate and study procedures adequately followed				
43	Other: Specify				

Pending Actions

The following is a cumulative list. Please don't remove the actions already taken.

ACTION ITEMS PENDING SINCE PREVIOUS VISIT(S)	RESPONSIBLE FOR ACTION	RESOLVED (Y/N)

NEW PENDING ACTION ITEMS	RESPONSIBLE FOR ACTION	BY WHEN

MONITORING VISIT REPORT

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.*

Next visit planned date		Type of contact	visit ☐	call ☐

Report prepared by CRA Print name:	Signature:	dd/mmm/yyyy
Report reviewed and approved by the COC Print name:	Signature:	dd/mmm/yyyy