CLOSE-OUT 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 ☐

Attendees

NAME	ROLE

A - Trial enrollment final status

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

N°		No. pts	Comments
1	Registered		
2	Randomized		
3	Treated		
4	Off study		

5	Was the site prematurely closed? ☐ No ☐ Yes	If yes, provide reasons:
6	Are all patients off study? ☐ No ☐ Yes	If no, specify - No. of patients still on treatment: - No. of patients still on follow-up: - Patient handling after site closure visit agreed with Sponsor? (Y/N)

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B - Trial Conduct:

N°	Check item	YES	NO	NA	COMMENTS
7	Any issue related to the ICF (signature, versioning, archive) solved?				
8	CRFs completed and signed by PI?				
9	All data queries resolved?				
10	All previously unreported SAEs sent to the Sponsor?				
11	All SAE followed-up as required by protocol?				
12	Drug accountability forms verified, signed and any issue solved				
13	Unused IMP(s) checked and returned or destroyed as planned*: please specify*				
14	Was any code breaking duly documented? *if applicable*				
15	All biological samples collected / sent as required				

C – ISF

N°	Check item	YES	NO	N/A	COMMENTS
16	Are all regulatory approval documents and relevant correspondence on file?				
17	Are the most updated versions of the IB(s) and/or SPC(s) on file?				
18	Are the most updated version of the protocol and informed consent forms on file?				
19	Is a blank copy of the most updated version of the CRF and SAE form on file?				
20	Is a blank copy of all other forms for patient-reported outcomes collection on file? *(e.g., patient diaries and questionnaires)*				
21	Is the Trial-Specific Training Record on file?				

22	Is the Signature and Delegation List up-to-date and on file?				
23	Are all site staff CVs filed?				
24	Are financial disclosures of the site staff filed? *(Please collect copy if applicable)*				
25	Are all laboratory normal ranges and certificates on file?				
26	Is all biological sample handling – documentation of collection, storage and shipment on file?				
27	Is a copy of all data generated at the site archived? *(specify if in electronic or paper format)*				
28	Is all IMP-related documentation on file, including drug records maintained at the pharmacy during the trial?				
29	Monitoring Visit Log updated and filed? (the final Monitoring Visit Log including the Close-out Visit is to be sent to the site along with the last follow-up letter)				
30	Any missing documents? *(Please specify)*				

D – Items discussed with Investigator

N°	Discussion item	YES	NO	NA	COMMENTS
31	ISF retention and archiving				Specify - Location: - Reference person: - Agreed retention period:
32	Source Documents retention and archiving				Specify - Location: - Reference person: - Agreed retention period:

33	Obligations of the Investigators concerning reporting of trial completion to the EC				
34	Possible audits and inspections				
35	Publication policy				

E - Documents collected at this visit

Document	O= Original C= Copy	Provide details as needed (e.g., version, date)
Subjects screening and enrollment/randomization logs		
Signature and Delegation List		
CVs (updated or not yet collected at previous visits)		
IMP Accountability forms		
Any equipment on loan to site (centrifuge, freezer, etc.), specify:		
Other, specify:		

F - Pending Actions

Please report only the actions pending since the LAST previous visit.

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

NEW PENDING ACTION ITEMS	RESPONSIBLE FOR ACTION	BY WHEN
Specify how the pending actions will be followed-up:		

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