GCP Inspection Report XXX at XXX site

On behalf of the European Medicines Agency

XXX

Inspector in charge of this inspection report

Name:

Position:

Address:

Tel:

E-mail:

XXX XXX XXX

Inspection report date:	DD-MM-YYYY
Responses to inspection report:	Dated as per Addendum 1
Evaluation of inspection responses:	Dated as per Addendum 2

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Abbreviations

ADR	adverse drug reaction
AE	adverse event
CA	competent authority
CAPA	corrective action preventive action
CHMP	Committee for Medicinal Products for Human Use
CRA	clinical research associate
(e)CRF	(electronic) case report form
CRO	contract research organisation
CSR	clinical study report
CSV	computer system validation
DSUR	development safety update report
e-Pro	electronic patient reported outcome
I	inspector
IB	investigator's brochure
ICF	informed consent form
ICH	International Conference on Harmonisation
(I)EC	(independent) ethics committee
IMP	investigational medicinal product
IR	inspection report
IRT	interactive response technologies
ISF	investigator site file/investigator TMF
ITT	intent-to-treat
IVRS	interactive voice response system
IWRS	interactive web response system
LI	lead inspector
MAA	marketing authorisation application
MVR	monitoring visit report
PI	principal investigator
PIS	patient information sheet
PP	protocol population
RI	reporting inspector
SI	sub investigator
QA	quality assurance
QC	quality control
RA	regulatory authority
SAE	serious adverse event
SAR	serious adverse reaction
SOP	standard operating procedure
SUSAR	suspected unexpected serious adverse reaction
TMF	trial master file

1. Administrative information

Investigational medicinal product(s)	
Product(s)	

Application	
EMA reference number	
Name and full address of the applicant	

Clinical trial(s)	
EudraCT number	
Sponsor	
Trial protocol code	
Trial protocol title	
Total number of investigator sites	
Total number of subjects	
Clinical trial report date and version	

Site details	
Organisation name	
Principal investigator [if applicable]	
Address	

Key data from site inspected	
Number of subjects at this site	
First patient first visit	
Last patient last visit	
Screened	
Randomised	
Withdrawals/drop outs	

Dates of inspection	

Inspection team	Authority	Country
Reporting inspector (RI)		
Lead inspector (LI) XXX		
Inspector (I)		
Expert		
Observer		

2. Background and general information

2.1. Reason and cause for the inspection

Text

2.2. Reference texts

- Regulation (EC) 726/2004
- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001
- Directive 2001/83/EC as amended by Directive 2003/63/EC of 25 June 2003
- Directive 2005/28/EC of the European Commission of 8 April 2005
- CPMP/ICH/135/95 'Note for Guidance on Good Clinical Practice', July 1996
- World Medical Association Declaration of Helsinki, in the version,
- GMP, Annex 13 Manufactur of the investigational medicinal products,
- CPMP/ICH/137/95 "Note for Guidance on Structure and Content of Clinical Study Reports", July 1996
- CPMP/ICH/363/96 "Note for Guidance on Statistical Principles for Clinical Trials", September 1998
- CPMP/EWP/QWP/1401/98, Guideline on the Investigation of Bioequivalence', 1 August 2010
- EMA/CHMP/EWP/192217/2009 'Guideline on Bioanalytical Method Validation', 1 February 2012

2.3. Grading of findings

Critical (CR)	
Definition	Conditions, practices or processes that adversely affect the rights, safety or wellbeing of the subjects and/or the quality and integrity of data. Critical observations are considered totally unacceptable.

Critical (CR)	
Possible consequences	Rejection of data and/or legal action required.
Remark	Observation classified as critical may include a pattern of deviations classified as major, bad quality of the data and/or absence of source documents. Manipulation and intentional misrepresentation of data belong to this group.

Major (MA)	
Definition	Conditions, practices or processes that might adversely affect the rights, safety or wellbeing of the subjects and/or the quality and integrity of data. Major observations are serious deficiencies and are direct violations of GCP principles.
Possible consequences	Data may be rejected and/or legal action required.
Remark	Observations classified as major, may include a pattern of deviations and/or numerous minor observations.

Minor (MI)	
Definition	Conditions, practices or processes that would not be expected to adversely affect the rights, safety or wellbeing of the subjects and/or the quality and integrity of data.
Possible consequences	Observations classified as minor, indicate the need for improvement of conditions, practices and processes.
Remark	Many minor observations might indicate a bad quality and the sum might be equal to a major finding with its consequences.

Comments	The observations might lead to suggestions on how to improve quality or reduce the potential for a deviation to occur in the future.

Responsibility for the finding	The responsibility for addressing the finding will be stated. This could be sponsor/CRO, investigator, IEC etc.

2.4. List of persons involved in the trial and contacted during the inspection

Type here

Full name	Job title	Role in the trial inspected

3. Operational resources

3.1. Organisation

Not applicable.

3.2. Personnel

Not applicable.

3.3. Qualifications and training

Not applicable.

3.4. Facilities

Not applicable.

3.5. Equipment

Not applicable.

3.6. Computer systems

Not applicable.

4. Administrative aspects of the trial

Not applicable.

4.1. National competent authority

Not applicable.

4.2. Independent research ethics committee (IEC)

Not applicable.

4.3. Other committees, any other validation or authorisations required

Not applicable.

4.4. Contract(s) and agreement(s)

Not applicable.

4.5. Insurance

Not applicable.

5. Trial master file

5.1. Production, version control and content of essential documents

Not applicable.

5.2. Completeness, availability, content and structure of TMF/ISF

Not applicable.

6. Clinical conduct of the trial

Not applicable.

7. Management of the trial by sponsor/CRO

Not applicable.

8. Safety reporting

Not applicable.

9. Investigational medicinal product(s) (IMPs)/pharmacy

Not applicable.

10. Clinical data management

Not applicable.

11. Source data review/verification

Not applicable.

12. Clinical trial monitoring

Not applicable.

13. Instrument-based diagnostics/ examinations

Not applicable.

14. Clinical sample management

14.1. Clinical samples (at investigator site)

Not applicable.

14.2. Clinical samples (at laboratory or analytical site)

Not applicable.

15. Laboratory

Not applicable.

16. Bioanalysis (PK) laboratory

16.1. Methods used

Not applicable.

16.2. Method validation and report

Not applicable.

16.3. Results

Not applicable.

17. Pharmacokinetic analysis

Not applicable.

18. Statistical analysis

Not applicable.

19. Reports

19.1. Clinical study report

Not applicable.

19.2. Bioanalytical report

Not applicable.

20. Quality management system

20.1. Standard operating procedures (SOPs)

Not applicable.

20.2. Quality control

Not applicable.

20.3. Quality assurance

Not applicable.

21. Summary, discussion and conclusion

21.1. Summary and discussion

Type here

21.2. Interim conclusion

Type here

22. Signatures

Date	
Print name	
Function	
Signature	

Date	
Print name	
Function	
Signature	

Date	
Print name	
Function	
Signature	

Appendices

A1. Summary of activities inspected

Area [report section]		Reviewed / inspected (tick*)	Comments	Findings (enter number of)			
Operational resources [3]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Organisational structure [3.1]						
	Interviews with key personnel involved in the trial [3.2]						
	Delegation of duties & specimen signatures [3.2]						
	Qualifications, protocol and GCP training of personnel [3.3]						
	Clinical facilities [3.4]						
	Laboratory facilities [3.4]						
	Apparatus, equipment, material, reagents, calibration [3.5]						
	Archiving facilities [3.4]						
	Computer systems [3.6]						
	Other (specify)						

Administrative aspects of the trial [4]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	CA approval (initial & amendments) /communication [4.1]						
	IRB/IEC opinions (initial & amendments) /communication [4.2]						
	Institutional correspondence and approval & other bodies giving approval [4.3]						
	Contract(s) & agreement(s) [4.4]						
	Insurance [4.5]						
	Other (specify)						
Trial master file (sponsor and investigator) [5]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Production, version control and content of essential documents [5.1] for example:- • PIS/ICF • Protocol & amendments • Investigator brochure • Case report form • Trial manuals/plans/guides (sponsor created) • Instructions/proformas etc. (site created) • Subject screening and enrolment log						
	Completeness, availability, content and structure of TMF/ISF [5.2], for example:- • Access and storage of essential documents						
	Other (specify)						

Clinical conduct of the trial [6]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Subject recruitment						
	Subject identification						
	Subject confidentiality						
	Informed consent process and completed documentation						
	Subject screening and eligibility						
	Compliance with trial protocol clinical procedures (examinations/assessments)						
	Other (specify)						
Management of the trial by the sponsor/CRO [7]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Delegation of duties						
	Management of CROs/vendors, if applicable						
	Trial management, communication, escalation						
	Investigator selection						
	Training of investigator sites						
	Protocol deviation management						
	Protocol amendment implementation						
	Serious breaches and issue resolution						
	Data monitoring and other trial committees						
	Other (specify)						

Safety reporting [8]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Collection of AES and review						
	Collection of SAEs						
	Processing of SAE cases & use of PV databases						
	Expedited reporting to IEC/CA						
	Reporting safety information to investigators						
	Aggregate reports (DSURS)						
	Urgent safety measures						
	Other (specify)						
Investigational medicinal product(s)/pharmacy [9]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Manufacturing/assembly/labelling/importation/QP certification/reconstitution						
	IMP expiry and extensions						
	Randomisation implementation						
	Regulatory green light, shipping and transit						
	Storage (and temperature monitoring)						
	IRT system (trial specific build, use)						
	Prescribing, dispensing and administration to subjects						
	Subject compliance						
	Accountability (shipping, site and subject level), returns/destruction						
	Emergency code breaking system						
	Other (specify)						

Clinical data management [10]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	CRF and trial specific eCRF design/build, functionality, source in CRF, (independent copy on site etc.)						
	Diaries and e-PRO						
	Data entry, verification/validation (edit checks), self-evident corrections, audit trails						
	Data handling/transfers, coding						
	Data reconciliation (e.g. with lab data, PV data)						
	Database lock						
	Un-blinding						
	Other (specify)						
Source data review/verification [11]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Safety & efficacy data (reliability of data, protocol compliance) SDV performed for subject numbers (enter details):						
	Other (specify)						
Clinical trial monitoring [12]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Compliance with monitoring plan/procedures						
	Reporting of monitoring visits (assessment/routine/close out)						
	Issue resolution and escalation of issues						
	Central monitoring activities						
	Other (specify)						

Instrument-based diagnostics/examinations [13]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Laboratories, technical departments, other vendors						
	Data transfers						
	Standardisation/validation						
	Committees involved in evaluations						
	Other (specify)						
Clinical sample management [14]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Handling of samples at investigator site (sample taking and management in the clinic) [14.1]						
	Storage of samples (temperature monitoring)						
	Handling of samples at laboratory or analytical site [14.2]						
	Other (specify)						
Laboratory (not PK – i.e. for biochemistry, haematology etc.) [15]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Certification/accreditation						
	Normal ranges						
	Results reporting back to site						
	Other (specify in comments)						

Bioanalysis (PK) laboratory [16]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Methods used [16.1]						
	Method validation and report [16.2]						
	Results [16.3]						
	Other (specify)						
Pharmacokinetic analysis [17]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Statistical/pharmacokinetic software						
	Incurred sample reanalysis (ISR)						
	PK profile parameters						
	Subject populations						
	Other (specify)						
Statistical analysis [18]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Trial design input, sample size calculation						
	Randomisation generation						
	SAP/TFL shells						
	Analysis populations & data review meeting						
	Programming & CSV						
	Analysis						
	Other (specify)						

Reports [19]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Bioanalytical report [19.1] Same as report						
	CSR production [19.2] • Content & structure • Management of protocol non compliance • Statement about GCP compliance • Accuracy and completeness						
	Other (specify)						
Quality management system [20]				**Critical:**		**Major:**	
OPTIONAL TO COMPLETE	Standard operating procedures [20.1]						
	Quality control [20.2]						
	Quality assurance /auditing [20.3]						
	Other (specify)						

A2. Trial documentation and approvals

APPROVAL DATES							DOCUMENT VERSIONS			
SUBMISSON	**Substantial (S)/ Non-substantial (NS)**	**CA**	**IEC/ IRB**	**Sponsor approval (if applicable)**	**Investigator approval (if applicable)**	**Any other required approvals**	**Protocol version**	**Subject information and consent form version/date**	**Other documents**	**INITIATION/ IMPLEMENTATION DATE**
Initial Date:										
#2 Date:										
#3 Date:										
#4 Date:										
#5 Date:										
#6 Date:										
#7 Date:										
#8 Date:										
#9 Date:										

A3. Appendix – landscape format

A4. Title

GCP INSPECTION REPORT XXX at XXX site.

Addendum 1: Response from the sponsor or inspectee

XXX XXX XXX

Date responses received by the inspector: DD/MM/YYYY

The following attached documentation is the response received from the sponsor or inspectee.

GCP INSPECTION REPORT XXX at XXX site.

Addendum 2: Evaluation by the inspectors of the response to the inspection report

XXX XXX XXX

Date of Evaluation*:* DD/MM/YYYY

Final conclusions from inspection findings

Assessment of the relevance of the findings for the full trial

Type here

Quality of the data and GCP compliance

Type here

Recommendation for the acceptability of the clinical trial data

Type here

Recommendations for follow up actions (GCP systems)

Type here

Signatures

Date	
Print name	
Function	
Signature	

Date	
Print name	
Function	
Signature	