GCP Integrated Inspection Report

On behalf of the European Medicines Agency

XXX

Inspector in charge of this inspection report

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Integrated inspection report date: DD-MM-YYYY

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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
GCP	good clinical practice
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
IIR	integrated inspection report
ISF	investigator site file/investigator
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
RI	reporting inspector
SI	sub investigator
QA	quality assurance
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	
Number of sites inspected	

Inspection details				
Inspection	**Site inspected**	**Inspection dates**	**Inspection team**	**Issue dates**
Inspection site 1				**Report** DD/MM/YY
				Addendum1 DD/MM/YY
				Addendum 2 DD/MM/YY

** RI= reporting inspector; LI= lead inspector, I= inspector; E= expert; O= observer*

2. Background and general information

2.1. Reason for and scope of the inspection

Type here

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, XX GMP, Annex 13 Manufacture of investigational medicinal products, XX 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. GCP inspection finding grading

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.
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.

3. Description of GCP inspection findings and responses

3.1. Foreword

Inspection reports for the sites inspected are contained in the appendices. These reports contain full details of the inspections, the findings and the responses and the inspector evaluation of the responses. This report is to provide an overview of the findings from the inspections. For more detail refer to the individual inspection report(s).

3.2. Number of inspection findings

At the inspection of there were critical, major and minor findings.

3.3. Summary of inspection findings and evaluation by the inspectors of the response from inspectee(s)

Type here

4. Conclusions from inspection findings

4.1. Assessment of the relevance of the findings for the full study

Type here

4.2. Quality of the data, ethical conduct and GCP compliance

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4.3. Recommendation for the acceptability of the clinical trial data for the submitted application assessment

Type here

4.4. Recommendation for follow up actions (GCP systems)

Type here

5. Date and signatures of inspectors

Date	
Print name	
Functions	Reporting inspector
Signature	

Date	
Print name	
Function	XX
Signature	

Date	
Print name	
Function	XX
Signature	

6. Appendices

Inspection report 1

Inspection report 2