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GUIDANCE DOCUMENT CONTAINING THE COMMON PROVISIONS ON THE CONDUCT OF GCP INSPECTIONS BY COMPETENT AUTHORITIES OF THE DIFFERENT MEMBER STATES

GUIDANCE FOR EXCHANGE OF GCP INSPECTION REPORTS ACCORDING TO ARTICLE 15 (2) OF DIRECTIVE 2001/20/EC

REVISION 1 (13 MAY 2009)

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This document/forms are part of the guidance documents containing the common provisions on the conduct of GCP inspections. Please check for updates in the Volume 10 of the Rules Governing Medicinal Products in the European Union.

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1. PURPOSE

Inspection documentation is confidential and sensitive. Therefore exchange of inspection reports is restricted and only allowed under certain circumstances. This standard operating procedure ("**SOP**") describes the process of request, release and transmission of Good Clinical Practice ("**GCP**") inspection reports between the Competent Authorities of the Member States of the European Union according to Article 15(2) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use[1] (hereinafter "**Directive 2001/20/EC**").

Article 15(2) of Directive 2001/20/EC reads as follows:

"*Following inspection, an inspection report shall be prepared. It must be made available to the sponsor while safeguarding confidential aspects. It may be made available to the other Member States, to the Ethics Committee and to the Agency, at their reasoned request.*"

2. RESPONSIBILITIES

Besides the responsibility to maintain and archive their inspection files, it is also the GCP inspectorates' responsibility to make inspection reports available to other Member States, Ethics Committees and to the Agency at their reasoned request.

3. REQUEST FOR INSPECTION REPORTS

According to Article 15(2) of Directive 2001/20/EC, the inspection report may be requested by another Member State, the Ethics Committee or the EMEA. This shall ensure that all official actors in charge of authorising clinical trials or medicinal products may get access to the inspection reports. In view of this purpose of the provision, the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human ("CMD(h)"), which essentially brings together the individual authorising Member States in order to coordinate their activity, may also request the inspection report.

First step of the exchange process is the request of the inspection report using the signed "Request for Exchange of Inspection Reports" form. If necessary, the blank form should be made available to the requesting party. On this form the requesting party needs to specify the GCP inspectorate who is asked to make the report available, the inspected institution and key data identifying the clinical trial which was inspected. Furthermore the requesting party needs to assign a contact person to whom the inspection report will be transmitted.

The request of exchange of inspection reports needs to be reasonable and the reason(s) need(s) to be specified on the form. Reasons for a request may be:

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[1] OJ L 121, 1.5.2001, p. 34.

– underlying applications for marketing authorisation: MRPs, DCPs or national applications involving inspected facilities;

– ongoing clinical trials involving inspected facilities;

– other significant reasons.

Before sending the form, it needs to be signed and dated by the responsible representative of the requesting party.

4. RELEASE OF INSPECTION REPORTS

After receipt, the request is reviewed and the justification is checked by the GCP inspectorate. After the decision for transmission of the report has been made, an authorised copy of the report marked as confidential is transferred to the contact person of the requesting party in a secure way via mail or e-mail (using Eudralink, as pdf-file).

5. FORMS NEEDED FOR THIS PROCEDURE

See Annex.

6. REFERENCES AND RELATED DOCUMENTS

Article 15 (2) of Directive 2001/20/EC.

7. RECORDS

The process of request and release of inspection reports is documented and filed by the involved inspectorates.

ANNEX

<Place, Date of the Request>

REQUEST FOR EXCHANGE OF INSPECTION REPORTS BETWEEN THE COMPETENT AUTHORITIES OF THE EUROPEAN UNION MEMBER STATES ACCORDING TO ARTICLE 15(2) OF DIRECTIVE 2001/20/EC

1. REQUESTING COMPETENT AUTHORITY

Name/Address/Fax/Phone	
Country	
Contact Person	

2. COMPETENT AUTHORITY WHO IS ASKED TO MAKE THE REPORT AVAILABLE

Name/Address/Fax/Phone	
Country	

3. INSPECTION INFORMATION / CLINICAL TRIAL PROTOCOL

Site Organisation Name, Address, Country	
Date of Inspection	
EudraCT Number of the Clinical Trial (where available)	
Sponsor Protocol Code	
Short Title of the Clinical Trial	
Name of the Sponsor of the Clinical Trial, Address, Country	

4. REASON/S FOR THE REQUEST OF THE INSPECTION REPORT

Reference number of the underlying CAP, MRP, DCP or national procedure for marketing authorization or CTA and brief summary of the reason/s for the request

Reference number: _____ Reason/s:

Other reason/s for the request

Reason/s:

The requesting/recipient NCA affirms that they have the authority to protect non-public information, including commercially confidential information, provided to its officials or representatives by the inspecting authority (owner of the inspection report) and will protect such information from being disclosed. The requesting/recipient NCA understands that the inspecting authority considers it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the relations between the participants in this exchange (requesting/recipient NCA and inspecting NCA (owner of the inspection report)".

	Requesting Competent Authority Representative
Function	
Name	
Signature	
Date	