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Human Medicines Division
Quality and Safety of Medicines

Procedure for coordinating GCP inspections requested by the CHMP

GCP Inspectors' Working Group

Applies to: European Medicines Agency, EU/EEA inspection authorities	
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1. Summary of scope

This procedure describes the coordination process of Good Clinical Practice (GCP) inspections requested by the Committee for Medicinal Products for Human Use (CHMP), with a particular focus on the roles of National Competent Authorities (NCA) of the Member States (MS) and European Medicines Agency (EMA).

2. Introduction

Only GCP inspections requested by the CHMP are detailed in this procedure.

The legal basis for GCP inspections of medicinal products for which a marketing authorisation application (MAA) has been submitted to the Agency, is found in article 57(a)(i) of **Regulation (EC) No. 726/2004**. This provides that the Agency shall, within its Committees, undertake the following tasks:

- coordination of the scientific evaluation of the quality, safety and efficacy of medicinal products which are subject to EU marketing authorisation procedures;
- coordination of the verification of compliance with the principles of good manufacturing practice, good laboratory practice and good clinical practice and the verification of compliance with pharmacovigilance obligations.

One of the criteria for making a decision on an MAA is the assessment of the submitted clinical documentation. According to the introduction and general principles of Annex 1 of **Directive 2001/83/EC**, all clinical trials included in an EU MAA are required to follow principles equivalent to the provisions of the relevant EU legislation on clinical trials. Therefore, the assessment of clinical documentation may lead to a request for a GCP inspection.

Any clinical trial included in the MAA could be subject to inspection. This could be a for-cause or routine inspection. The objective of a GCP inspection requested by the CHMP is to:

- determine whether the trial was conducted in accordance with applicable regulatory requirements, which include local regulations and ethical standards, **ICH E6**, and **Directive 2001/83/EC**;
- provide answers to questions arising from the MAA assessment process where it has been determined that these can best be provided through inspection;
- determine whether the data submitted in the dossier is credible and accurate.

Routine inspections are carried out as a routine surveillance of GCP compliance, in the absence of specific concerns. Applications, trials and sites for routine inspections are, however, selected based on a set of criteria to ensure that a range of different situations are covered, and that inspection resources are used efficiently. Routine inspections are usually requested early (at the beginning of the procedure in case of an accelerated procedure, and, in a standard procedure, on day 30 or at the latest day 60) in the assessment procedure and before the adoption of the List of Questions.

A for-cause inspection is requested when a concern arises during the evaluation of the MAA. For-cause inspections can be triggered at any time during the MAA review. For details on the selection of applications for routine inspections as well as for-cause inspections, refer to the 'Points to consider for assessors, inspectors and European Medicines Agency inspection coordinators on the

identification of triggers for the selection of applications for routine and for-cause inspections, their investigation and scope of such inspections'[1].

3. Applicability of this procedure and definition of terms

3.1. NCAs and inspectors to whom this procedure applies

For the purposes of this procedure, NCAs involved may be:

- from the same country as the CHMP rapporteurs;
- from the EU/EEA countries where the sites to be inspected are located;
- from other EU/EEA countries if needed.

The inspectors performing the tasks and duties described in this procedure are appointed by the NCAs involved.

In accordance with Article 11 of the **Commission Implementing Regulation (EU) 2017/556**, the inspections shall be carried out on behalf of the Community and the results shall be recognised by all the other MSs.

3.2. Definition of terms

3.2.1. Inspection procedure

An inspection procedure is an umbrella term to describe a number of individual inspections that culminate in the delivery of an integrated inspection report (IIR). The IIR summarises the findings across all individual site inspections.

3.2.2. Site inspection

A site inspection is an individual inspection of a distinct component of a clinical trial. This takes place at a distinct location where trial activities are conducted (e.g. hospital, sponsor or service provider) but can also include a dedicated department within a larger facility. The results of each site inspection are documented in a dedicated inspection report (IR).

3.2.3. Reporting inspectorate

The reporting inspectorate is the NCA from an EU/EEA member state, which takes the responsibility for organising, planning and reporting the GCP inspection procedure and for designating the reporting inspector for the requested inspection procedure.

3.2.4. Reporting inspector

The reporting inspector (RI) is designated by the reporting inspectorate. The role of the RI is to coordinate the preparation, conduct and reporting of the inspection procedure. The RI acts as the main communication point between the inspection team and the EMA Inspections Office, the rapporteurs and the CHMP. The RI is responsible for preparing the IIR summarising the outcome of the site inspections within the procedure. The responsibilities of the RI are described in **INS-GCP-2**.

[1] Points to consider for the selection of applications for inspection

The RI may also be the lead inspector (see below) or supporting inspector for one or more site inspections.

3.2.5. Lead inspector

The lead inspector (LI) is responsible for the conduct and reporting, including the IR, of one or more site inspections in the procedure as agreed with the RI. The responsibilities of the LI are described in procedure INS-GCP-2.

3.2.6. Supporting inspectorate

The supporting inspectorate is the NCA from an EU/EEA member state that works alongside the reporting inspectorate in the conduct of an inspection procedure. Inspectors from the supporting inspectorate may act as LI for one or more site inspections in the procedure, as agreed with the RI.

3.2.7. Supporting inspector

The supporting inspector is designated by the supporting inspectorate to participate in the conduct of one or more inspections in the procedure. The RI may also be a supporting inspector in one or more site inspections.

3.2.8. Trainee inspector

Inspectors in training may participate in the inspection procedure as trainees to gain the necessary experience in accordance with Article 4 of **Commission Implementing Regulation (EU) 2017/556**. MSs shall ensure that trainees are bound by the same confidentiality rules as inspectors, and that they are aware of the applicable rules as regards confidentiality and the protection of personal data.

3.2.9. Observer

Local inspectorate or other officials of the union may observe an inspection.

3.2.10. EMA inspection coordinator

An EMA inspection coordinator is assigned to support the organisation of the inspection and to act as the communication point in the EMA Inspections Office.

4. Steps of the procedure

The inspection is integrated into the MAA assessment process. Appendix 1 contains process maps illustrating the designation of the reporting inspectorate and lead inspectors. Appendix 2 contains a tabular presentation of the time intervals involved in the different steps of the inspection process.

4.1. Preparation and adoption of the inspection request

4.1.1. For-cause inspection

To request a for-cause GCP inspection, the assessor identifying the need for the inspection should contact the GCP inspectors within their NCA as well as the Product Lead (PL) and EMA Inspections Office. The selection of sites to be inspected and the determination of the scope of the inspection are based on the concerns identified in the application and the inspection request is prepared

collaboratively between the rapporteurs (and their assessors), and the EMA Inspections Office. The selection of sites and the scope of the inspection may be further refined through discussion with the potential inspectorates/inspectors. The GCP concerns and inspection request are reflected in the assessment report by the rapporteurs.

The inspection request should clearly state the grounds and scope of the inspection procedure, the site(s) and, if applicable, a list of specific questions to be addressed during the inspection as well as any other issues relevant to the inspection. Where the CHMP considers that a GCP inspection is appropriate, the CHMP adopts the request.

4.1.2. Routine inspection

The applications, trials, and sites to be inspected as well as the scope of the inspection procedure are proposed by the EMA Inspections Office. A list of applications validated in the previous two months is sent to the NCAs to receive their potential input into the selection of applications for routine inspection. The draft proposal for a routine inspection procedure is circulated to the NCAs for confirmation of resources in the week before the CHMP meeting. The NCAs are given an opportunity to comment on the inspection request prior to its finalisation and adoption by the CHMP.

The GCP inspection request is reflected in the Day 80 assessment report by the rapporteurs.

4.1.3. Integrated inspection report target date

The target date for the provision of the IIR is set out in the inspection request. For routine inspection procedures the target date is usually two weeks before Day 150 at the latest. Meeting the target date will sometimes not be possible, especially in case of for cause inspections. In all cases, the final IIR should be available in time to be addressed in the response to the Day-180 list of outstanding issues (LoOI).

4.2. Designation of inspectorates

Designation of the inspectorates is done in parallel with the preparation of the inspection request for CHMP adoption. A contact point for the purpose of deciding an inspectorate's availability to perform an inspection is appointed by each NCA and notified to the Agency. The proposal for an inspection procedure is sent by the EMA Inspections Office simultaneously to each NCA contact person for information and an indication of availability to participate in the inspection procedure is requested. The NCAs are expected to respond to the request for availability as soon as possible and no later than the last day of the CHMP meeting, to allow for the finalisation of the inspection request for adoption.

When it is not feasible for an inspectorate to carry out the requested parts of the inspection procedure, the NCA may ask, in coordination with the EMA, another inspectorate to conduct or assist in the inspection (in accordance with Article 9(4) and 10(8) of **Commission Implementing Regulation (EU) 2017/556**).

There are normally two MSs involved in an inspection procedure (reporting inspectorate and supporting inspectorate). Adding an additional supporting inspectorate from a third MS is possible if needed to ensure sufficient resources and expertise within the inspection team. Appointing more than two inspectorates does not affect the fees paid by the applicant. If in exceptional circumstances there is a need to designate only one inspectorate for an inspection procedure, this must be justified and documented.

4.2.1. Designation of the reporting inspectorate

For routine GCP inspection procedures, the reporting inspectorate will be designated by the EMA Inspections Office according to the following sequence, subject to the availability of inspector(s), or unless otherwise agreed:

- Inspectorate from the rapporteur or co-rapporteur MS;
- Inspectorate from other EU/EEA MS.

In the case of 'for-cause' inspections, the RI should come from the inspectorate of the rapporteur or co-rapporteur country.

The reporting inspectorate should preferably participate in all site inspections. If this is not possible the reporting inspectorate should participate in at least one site inspection with the agreement of the inspection team.

4.2.2. Designation of the supporting inspectorate

The supporting inspectorate is designated in the same sequence as the reporting inspectorate. If the site where the inspection is planned to take place is within an EU MS, that MS is asked to take on the role of supporting inspectorate. (See decision tree in appendix.)

4.3. Designation of the inspection team

Each inspectorate should designate at least one appropriately qualified inspector (in accordance with **(EU) 2017/556** Article 4) to be part of the inspection team. The MSs are responsible for ensuring that the qualifications, experience, and training of the inspectors fulfill the requirements of Article 4 of **Commission Implementing Regulation (EU) 2017/556**, and that there are no conflicts of interest (Article 5 of the same regulation). EMA checks the Declaration of Interests (DoI) of inspectors involved in inspection procedures related to the centralised procedure, according to EMA policy.

The roles in the inspection team shall be decided in accordance with the decision tree in the appendices or agreed with the inspection team. The RI is responsible for informing the EMA about the roles (LI, supporting inspector) of inspectors at each site. For each selected site, one LI should be designated (this may be the same or different inspectors for the different sites selected). The composition of the inspection team should take the below principles into account.

- Inspections at each site will normally be conducted by inspectors from two different MSs. However, upon agreement among the concerned NCAs and the EMA Inspections Office, inspections could be carried out, under exceptional circumstances, only by inspectors from one MS. Justification for only one MS must be documented.

- The inspection team should consist of an adequate number of inspectors and necessary expertise to conduct the inspection procedure. Inspection teams are typically composed of two to three inspectors per site, unless additional inspectors are justified (e.g. in case of a complex trial, large number of trial participants, large amount of data, inspection of sponsor's activities, systems or aspects requiring specific expertise or experience, and in the case of a for-cause inspection).

- The RI, taking into consideration the appropriate use of inspection resources and the appropriate conduct of the inspection procedure, should consider the composition of the inspection team at each site. Rationale for the team composition should be documented and well-justified in case of large inspection teams. The RI should liaise with the inspectors in the inspection team and the EMA Inspections Office to agree on the composition of the inspection team at each site prior to

announcing the inspection to the sites. EMA collaborates with the MSs to promote the efficient use of inspection resources.

4.3.1. Trainee inspectors

When the LI considers there is room to involve another inspector from his/her MS or a different MS for training purposes, this inspector will act as a trainee inspector. Such trainee participation will not give rise to a share of the inspection fee. The travel expenses of the trainee will not be covered by the applicant. The trainee inspector will act as a member of the inspection team and should be granted access to the inspected documents, data and premises, similarly to inspectors. The same rules for confidentiality and DoI will apply for the trainee inspector as for other inspectors. **Note:** This does not preclude sufficiently qualified inspectors (per Article 4 of the **Commission Implementing Regulation EU 2017/556**), using the inspection as an opportunity to further develop in more complex areas in the role as a supporting inspector, provided they contribute to inspection activities within their competence as inspectors.

4.4. Communication of the inspection request

After the confirmation of resources for the inspection procedure, the EMA inspection coordinator opens an inspection case in IRIS[2] and enters the details of the inspection as well as the IIR target date. A notification is sent from IRIS to the Product Lead (PL), rapporteurs and inspectors for them to review the case. After adoption by the CHMP, the inspection coordinator confirms the adoption of the inspection to the rapporteurs, the PL, and the concerned inspectors in IRIS. Simultaneously, the inspection is announced by the EMA Inspections Office via a separate IRIS notification to the applicant.

In the inspection announcement from the EMA, the applicant is requested to confirm in writing that the sites accept to be inspected in line with the **Guidance for applicants/MAHs involved in GMP, GCP and GVP inspections coordinated by EMA**. The applicant should liaise with the RI prior to providing the documents to ensure alignment on the appropriate format and content. The EMA Inspections Office facilitates communication between the inspection team and the applicant.

EMA will contact local authorities in third countries as appropriate.

Any change to the inspection request must be justified, approved by the EMA Inspections Office and adopted by the CHMP. Changes are communicated to the applicant by the EMA inspection coordinator.

4.5. Inspection procedure preparation

Once the inspectorates and the inspection team have been assigned, the preparation for the inspection procedure begins in accordance with **INS-GCP-2**.

4.5.1. Technical preparation

The technical preparation of the inspection procedure is detailed in a separate procedure (refer to **INS-GCP-2**).

[2] EMA's regulatory and scientific information-management platform

4.5.2. Coordination of travel and accommodation arrangements

The inspectors make contact directly with the applicant, who is asked to facilitate the inspectors' travel and accommodation arrangements, as per the inspectors' national procedures.

4.6. Site inspection

The conduct of the inspections is described in a separate document (refer to **INS-GCP-3**) with appendices by type of site.

4.7. Inspection reporting

The preparation of inspection reports is detailed in a separate procedure (**INS-GCP-4**).

Following the site inspections, in cases where issues are identified that require further follow-up or that could significantly affect the rights, safety and wellbeing of patients or the credibility of the data, the RI should submit a preliminary outcome report to the rapporteurs. Communication between the RI and the rapporteurs should take place with support from the EMA Inspections Office.

For each inspected site, the LI prepares an IR. The RI is responsible for preparing the IIR and uploading it in IRIS.

The EMA inspection coordinator validates the IIR. In case any correction is required, the coordinator contacts the RI. After successful validation, the inspection coordinator makes the report available (via IRIS) to the rapporteurs and CHMP, and thereafter the applicant.

4.8. Further consultations and CHMP opinion

In the case of inspection findings with potential impact on the MAA assessment, the RI and/or relevant members of the inspection team should be available, as necessary to interact with the assessors and the CHMP to facilitate the resolution of the issues in the context of the assessment procedure.

The EMA Inspections Office facilitates the assessment of the impact of findings on the application and together with the PL ensures that the European Public Assessment Report includes information on the GCP inspections as applicable.

4.9. Record keeping and archiving

The EMA inspection coordinator is responsible for managing and archiving the inspection in IRIS, including relevant communication.

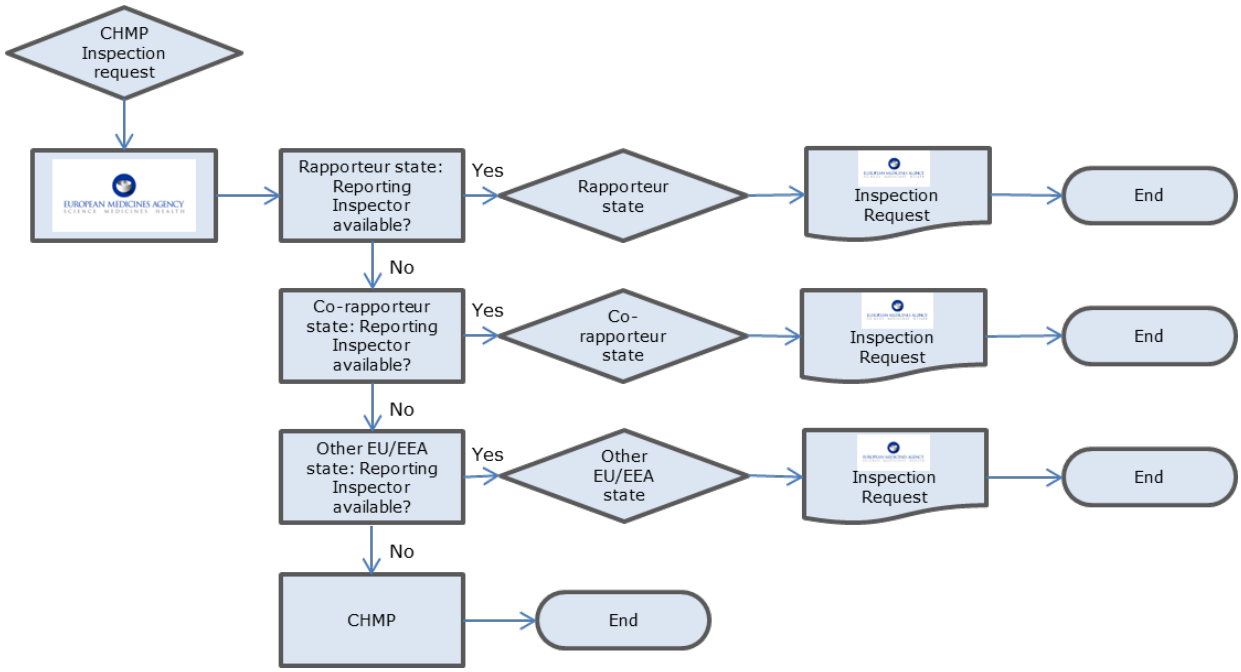
The RI and LI are responsible for maintaining and archiving the local and central inspection files in accordance with appendix VI of INS-GCP-3, as well as recording the required inspection information in CTIS as applicable.

5. Appendices

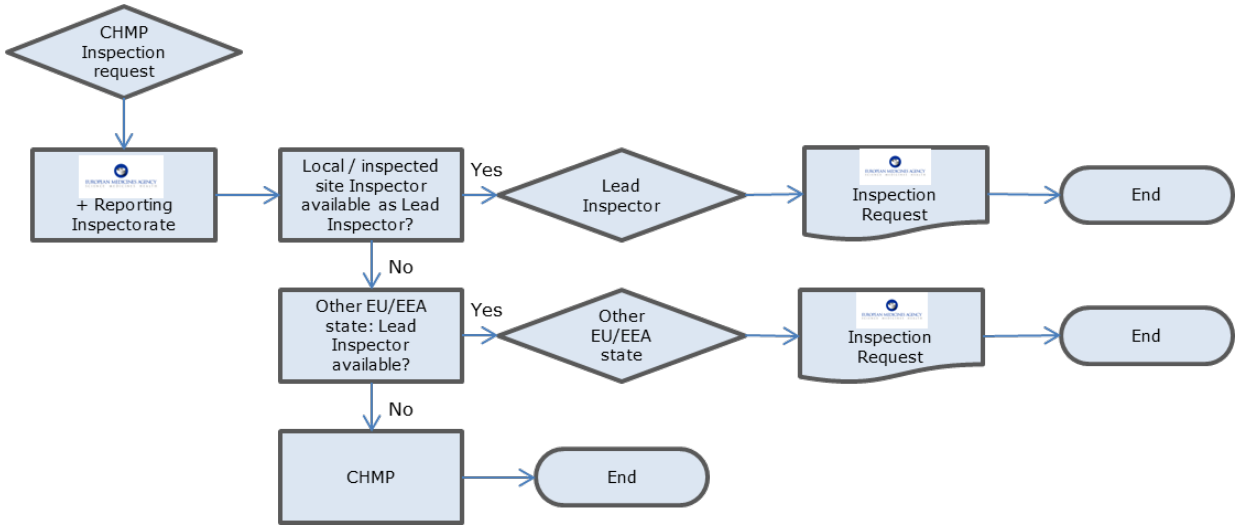
5.1. Appendix 1: Process maps for the designation of inspectorates and inspectors involved

- Reporting inspectorate.
- Lead inspectors (sites in EU/EEA countries).
- Lead inspectors (sites in third countries).

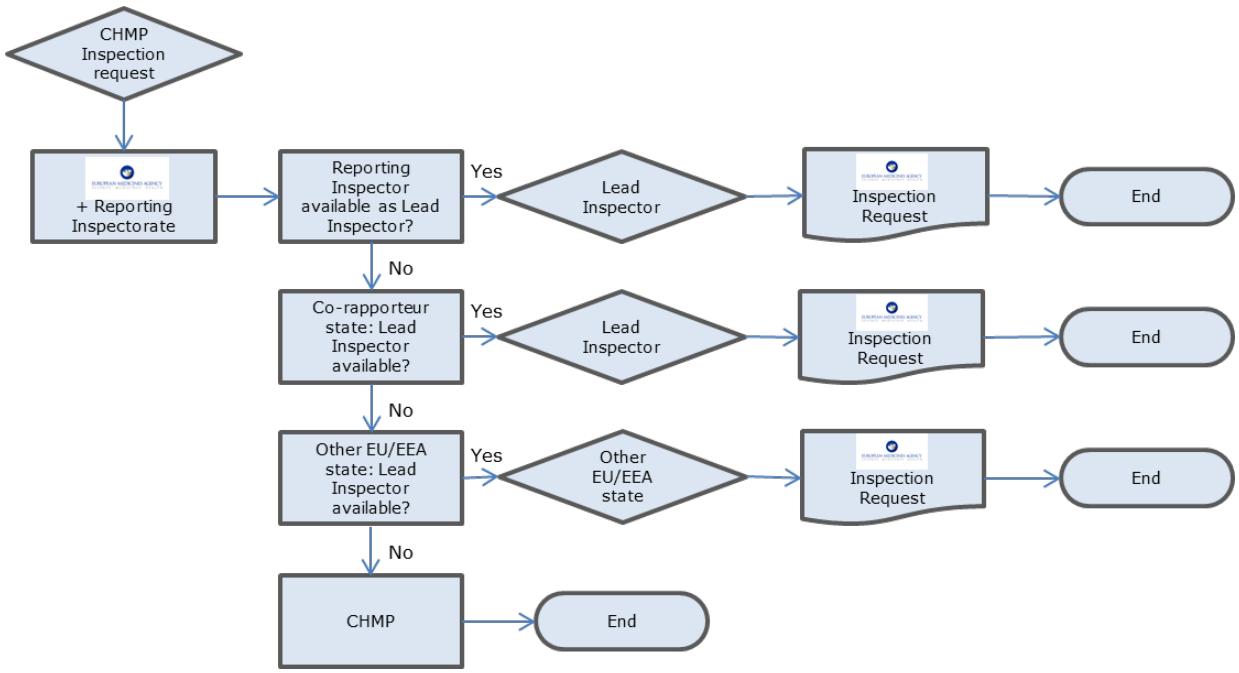
5.1.1. Process Map: Decision tree for the selection of the reporting inspectorate



5.1.2. Process Map: Decision tree for the selection of lead inspectors for GCP inspections in EU/EEA countries



5.1.3. Process Map: Decision tree for the selection of lead inspectors for GCP inspections in third countries



5.2. Appendix 2: Process steps and their projected time intervals.

Table of process steps and their projected time intervals.

Table 1. Activities related to GCP inspections requested by CHMP: indicative* time schedule

STEPS OF THE PROCEDURE	TIME ALLOWED
1. Early activities of EMA Inspections Office/CHMP: • request for a GCP inspection procedure; • initial selection of sites; • set up of overall time schedule; • designation of the reporting and supporting inspectorates; • first contacts between EMA Inspections Office and inspectorates concerned; • notification of the inspection to applicant.	To be determined by the EMA Inspections Office/CHMP Notify reporting inspectorate and other inspectorate(ies) within 10 working days of CHMP meeting. Notify applicant and request necessary documents for inspection procedure preparation within 10 working days of CHMP meeting. Applicant to respond within 10 working days of the announcement of the inspection procedure, or otherwise agreed with the reporting inspector.
2. Inspection procedure preparation: • notification/announcement of site inspections; • preparation of the inspection plan; • obtaining and reviewing required documents; • finalisation of travel arrangements with the applicant.	[20] days* after the delivery of the documents requested from the applicant to the inspectorates.
3. Site inspection	[30] days*

STEPS OF THE PROCEDURE	TIME ALLOWED
4. Writing and circulation of the reports: • writing of the inspection report; • responses from the inspectee/party(-ies) responsible; • writing addendum of the inspection report – evaluation of responses; • writing of the IIR and transmission to EMA Inspections Office/CHMP.	[15] days* [15] days* [10] days* [10] days* Total: [50] days*
5. Validation of the IIR by the EMA Inspections Office for adherence to applicable reference texts and procedures	[5] days*

Note: the numbers in brackets refer to calendar days

* Times allowed to complete each step of the initiation, conduct and termination of the inspection are provided in this table. These times, shown in square brackets, should be considered as indications and can be modified if necessary.