EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Data entry in Corporate GxP for GCP and PhV inspections		
Applies to: P-CI-CNC		
Status: **PUBLIC**		Document no.: WIN/INS/2050
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Signature: on File	Signature: on File	Supersedes: n/a
Date: 22-MAR-13	Date: 22-MAR-13	TrackWise record no.: 3693

1. Changes since last revision

New WIN.

2. Records

N/A.

3. Instructions

List of abbreviations

CHMP	Committee for Medicinal Products for Human Use
GCP	Good Clinical Practice
IIR	Integrated Inspection Report
IREQ	Inspection request
MAH	Marketing Authorisation Holder
NCA	National Competent Authority
PhV	Pharmacovigilance

This WIN should be read in conjunction with SOP/INSP/2020: Co-ordination of GCP inspections and SOP/INSP/2045: Co-ordination of Pharmacovigilance inspections.

Click on CorporateGxP database link under Business Applications on the Intranet, enter your login details and password and follow steps below to create an Inspection Request and to enter follow-up data.

Step	Action	Responsibility
Preparation of the IREQ		
Inspection Request State in Corporate GxP: Draft		
1.	Click either on GCP or PhV, as appropriate and click on 'Create Inspection Request'.	AD
2.	On 'Inspection Request' screen fill in: - inspection type: select routine/non-routine; - marketing authorisation status: pre-approval, post-approval; - domain: select as appropriate human or veterinary; *(- historical request: only for inspections requested before October 2010).* Please note: if it is a type II variation or line extension enter the correct EMA number *(e.g. …/II/XXXX or …/X/ZZZZ)* under 'Comments', as it cannot be linked to the relevant procedure. Click on 'Create'.	AD
3.	Fill in the 'Estimated Adoption Date', which is the date when request is adopted by CHMP (date on signed IREQ). Write comments if necessary *(e.g. if target date for IIR has changed, IREQ amendment(s) rationale and dates for adoption etc).* Click on 'Save'.	AD
4.	Go to 'Medicinal Product Groups' under 'Actions' on the right hand side, click and type the product name and click 'Search'. Select the product number. Click on 'Add' *(product name will appear on the left hand side under 'Selected Medicinal Products').*	AD
5.	Click on product name folder. 'Medicinal Products Group Details' will appear on the screen. This information is fed by SIAMED. Click on 'Add/Remove Procedures' and select appropriate procedure. Click on 'Back'.	AD
6.	Click 'Add Clinical Trials' and on the screen, fill in: - protocol number; - title description; - EudraCT number *(if applicable);* - number of investigational sites *(please note that this refers to the total number of sites in the whole study, not only the ones inspected);* - number of patients (total number of patients of the whole study *(not for inspection site but for all trials);* - population type; - Click 'Add Sponsor' and add Sponsor Name/Address *(please note that if the Sponsor and the Applicant are different, both should be*	AD

Step	Action	Responsibility
	added). Click on 'Save'.	
7.	If more Clinical Trials need to be added, click on product name folder on the left hand side and follow steps above under 6.	AD
8.	Go to 'Add Inspection Sites' under 'Actions' on the right hand side, click and select type of site (for each site), type site name, country and click on 'Search'. Select your site if displayed under 'Search results for all CorporateGxP' or if not displayed, create new site. Click on 'Create new Site' and press 'OK' to confirm that you wish to create a new site. Fill in the correct information as follows: - investigator name: Dr Firstname Surname; - site name *(do not enter site number in this line)*; - address and site number *(separate address lines and add site number into the different address fields 1, 2 and 3 etc and do not use any commas)*; - city; - postcode; Click on 'Create New Site'.	AD
9.	On the 'Inspection Site' screen enter GCP Scope from the IREQ template that can be found in DREAM. The Scope needs to be adjusted to the study/site. Tick 'Same Scope' if more than one site and the system will copy this scope for the rest of the sites. Enter 'Fee Weight' *(usually 1.0, however, enter 0 if the inspection is conducted under the national programme as in this case no fee will be invoiced by the EMA)*. Click on 'Save'.	AD
10.	Click on 'Link to Clinical Trial' and link the site to the related trial. Enter number of patients *(it refers to the number of patients in each particular site)*. Click on 'Save'. Click on 'Back to Request' and repeat 'Add Inspection Site' step to enter all sites investigated the product has and link site to the related trial. To amend a site, click on 'Remove Site' and enter the new information *(Note: if site is removed check that scope is entered for remaining site if ticked 'Same Scope' as under point 9)*. Click on 'Save'.	AD
11.	Go to 'Delegate Ownership' under 'Actions' on the right hand side, select owner (Coordinator name) and a Backup. Click on 'Save'.	AD
12.	Go to 'Generate Request References' under 'Actions' on the right hand side and the inspection number will be automatically created by the system. Click on 'Save'.	AD

Step	Action	Responsibility
13.	Go to 'NCAs and Inspectors' under 'Actions' on the right hand side, click and select 'Assign Reporting and Inspection Dates' and enter Reporting date: Target Date of the IIR. Click on 'Save'. Select and enter participating NCAs, Inspectors and Observers and indicate Reporting Inspectorate and Reporting inspector. Click on 'Save'. Select and enter participating 'Third Country Inspectors' *(if applicable).* <u>Please note:</u> Enter 3rd country contact point name first and then change to actual inspector or observer name when receiving inspection report. Click on 'Save'.	AD
14.	Go to 'Inspection Request Status' under 'Actions' on the right hand side, click and enter 'Estimated Adoption *Date' (enter the date when CHMP is adopting the IREQ).* Click on 'Save' *(Inspection Request State is 'DRAFT').*	AD
Inspection Request State in Corporate GxP: Requested		
15.	Click on 'Request' on the right hand side at the bottom of the page. Enter 'Actual Date State Changed' *(enter the date when CHMP is adopting the IREQ).* Click on 'Save'. Click on 'Edit' *(Inspection Request State will change from 'DRAFT' to 'REQUESTED').*	AD
Adoption of the IREQ		
Inspection Request State in Corporate GxP: Adopted		
16.	Click on 'Adopt' on the right hand side at the bottom of the page. Enter 'Actual Date State Changed **(enter the actual date when CHMP adopted the IREQ**).* Click 'Save' *(Inspection Request State will change from 'REQUESTED' to 'ADOPTED').*	AD
17.	Click on 'Amend with state change' on the left hand side at the bottom of the page **only when CHMP needs to adopt** any amendments. When an amendment is required, keep the initial adoption date and make comments explaining the rationale for the amendment and the date it was adopted.	AD
18.	Click on 'Initiate or amend without state change' on the left hand side at the bottom of the page. Click on 'OK' to confirm the move. Go to 'NCAs and Inspectors' on the left hand side of the screen under 'Actions'.	AD
19.	Click and select 'Assign Reporting and Inspection dates'. Select 'Site Reference' and enter 'Start Date' and 'End Date' of the inspection for each site *(click the arrow to view all sites).* Click on 'Add' *(for each site)* and on 'Back'.	AD
20.	Link Inspectors to the sites and specify their role in each site.	AD

Step	Action	Responsibility
	Click on 'Edit' under 'NCA Inspectors' on the screen next to the 'Site Name', repeat step for each site. Click on 'Save'.	
21.	Go to 'Manage Documents' on the right hand side under 'Actions' and select 'Manage Documents'. 'Manage Documents' allows you to link it with DREAM references. In Dream 'Email as Link' the GCP folder of the product of interest and copy and paste this link into the DREAM reference in CorporateGxP. Click on 'Save' and on 'Back'.	AST
22.	Go to 'Initiate Request Details' on the right hand side under 'Actions' and select 'Initiate Request Details' and enter: - first notification to Applicant/MAH; - last notification to NCAs; - tick 'Signed Contracts Received'; - acceptance statement from sites to be inspected; - statement from the Applicant; - third country authorities notified; - comments *(if applicable).* Click on 'Save'.	AST

Initiation of the inspection

Inspection Request State in Corporate GxP: Initiated

Step	Action	Responsibility
23.	Click on 'Initiate' on the left hand side at the bottom of the page. Click on 'OK' *(Inspection will be considered started on sites).* Enter 'Actual Date State Changed' **(enter the first day when the first inspection took place). Please note that this is important for financial purposes!** Click on 'Save' *(Inspection Request State will change from ADOPTED' to 'INITIATED').*	AD

Integrated Inspection Report

Finalise or amend without state change in Corporate GxP

Step	Action	Responsibility
24.	Click on 'Finalise or amend without state change' on the right hand side at the bottom of the page. Confirm with 'OK'.	AD
25.	Click on 'IIR Follow up' under 'Finalise Actions' on the left hand side and enter the following: - receipt of final IIR by EMA; - acceptance of final IIR by EMA; - distribution date of IIR to CHMP; - distribution date of IIR to MAH/Applicant; - follow up required; - payment order generation; - comments *(if applicable)*; Click on 'Save'.	AD
26.	Click on 'Deficiencies' under 'Finalise Actions' on the left hand side. Select site and add deficiencies (findings) under each site.	AST
27.	Click on 'Record Inspection Compliance' under 'Finalise Actions' on	AD

Step	Action	Responsibility
	the left hand side.	
	Enter for each site the following:	
	- site reference;	
	- GCP compliance;	
	- data validity;	
	- recommendations;	
	- comments;	
	Click on 'Save'.	
28.	Click on 'Record Overall Compliance' under 'Finalise Actions' on the left hand side.	AD
	Enter the following:	
	- site reference;	
	- GCP compliance;	
	- data validity;	
	- recommendations;	
	- comments;	
	Click on 'Save'.	
Finalisation of the inspection		
Inspection Request State in Corporate GxP: Finalised		
29.	Click on 'Finalise' under 'States' on the left hand side at the bottom of the page.	AD
	Finalise only when no more changes will take place!	