EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Workflow of data entry to scientific memory database		
Applies to: P-CI-CNC		
Status: **PUBLIC**		Document no.: WIN/INSP/2027
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1. Changes since last revision

New WIN.

2. Records

N/A.

3. Instructions

This WIN describes how data on clinical trials are entered in the SMD as part of the validation process of applications submitted to the Agency under the centralised procedure.
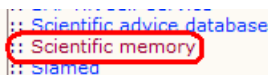
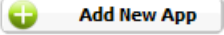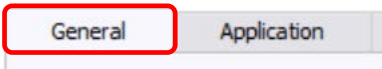### *Documents needed for this WIN*

- "Recommended submission dates for centralised procedures and MRL procedures (new and extension applications)" can be found on EMA external website: Home > Regulatory > Veterinary medicines > Maximum residue limit (MRL) applications.

- GCP validation documents saved in DREAM under Cabinets/01. Evaluation of Medicine/H-C/A-Z/Product folder/07 Inspection/GCP.
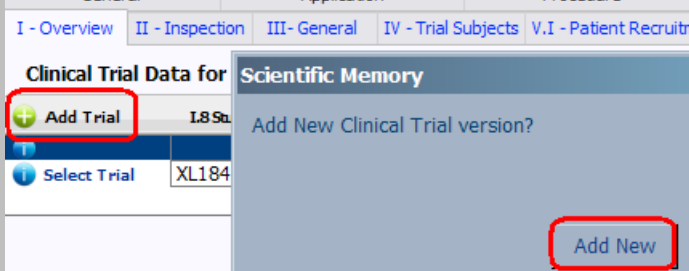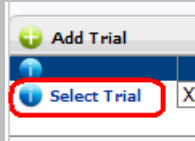
Abbreviations:

- AST   Assistant
- CRO   Contract Research Organisation
- CT   Clinical Trial
- ECTD   Electronic Common Technical Document
- FDA   Food and Drug Administration
- GCP   Good Clinical Practice
- INN   International Non-proprietary Name (active ingredient)
- MRL   Maximum Residue Limit
- P-CI-CNC   Clinical and Non-clinical Compliance section
- SA   Scientific administrator
- Siamed   Sistema de Información Automatizada sobre Medicamentos (Model System for Computer-assisted Drug Registration)
- SMD   Scientific memory database
- WHO   World Health Organisation

Step	Person responsible to enter data		Action
	SA	**GCP Assistant**	
1. Product search	√	√	Open the scientific memory database from Intranet and enter your log in details.
	√	√	Click on "Search" (top right corner) to look for the product.
2. Add new product	√		Check if the product is already in SMD. If product is not listed, add a new product by clicking "Add Product" (top left corner). If the product is already in SMD, click on it and go to step 3.
Name	√		Find the information in Siamed.
EMEA nr.	√		In Siamed. EMEA number has to be in the format EMEA/H/C/123456 (6 digits)
INN	√		Find the information in Siamed. After entering INN, click on "Finish"
Orphan designation		√	Find the information in Siamed.

Step	Person responsible to enter data		Action
Rapporteur		√	Find the information in Siamed.
Co-Rapporteur		√	Find the information in Siamed.
3. Add new application- Trial only	√		Click on "Add new application". **Add New App** Click the Application row to view or click the button above to add a new application. For new applications, enter the application number in the following format: "/0000" For line extensions: "X/xxxx" (xxxx is a 4 digit sequence number to be found in Siamed). Click on "Finish".
General	√		Click on "General" tab and 'Edit' (bottom right corner). General Application
Parent EMEA number	√		Click on "Edit". If applicable, insert the EMEA number of the parent product. The EMEA number has to be in the format EMEA/H/C/123456 (6 digits). This field should be filled in case: • Duplicate applications submitted. • Generic products. All the generic products should be entered in SMD as "children" of the parent that is the first product put on the market. Also for different generics of the same product, it should be checked if the same clinical trial has already been submitted in the application. When the same clinical trial has been submitted for more than one product, then the record for this trial has to be entered only once and in all the other products under the section "Follow up" will be specified that CTs data are NOT entered as they are already in the SMD database under the product named XXX (specify the name of the product.
Parent product name	√		Insert the name of the parent EMEA product in accordance with criteria defined above if applicable.
Multiple Applications	√		If applicable. Multiple Applications: YES will appear automatically in the box if EMEA parent name and number have been added. Otherwise NO will remain by default.
Therapeutic area		√	Find the information in Siamed.
Application	√	√	Click on "Application" tab and "Edit" (bottom right corner). General Application
Company		√	Fill in the name of MAH, find the information in Siamed.
Start of procedure	√	√	At the time when SA is entering data to SMD, the date of Start of procedure is not yet in Siamed. However, the information is already needed in order to plan inspections and track data of the product in SMD. SA: Refer to the Recommended submission dates for centralised procedures and MRL procedures (new and extension applications). AST: Check if the information entered by SA is the same as in Siamed.
Submission date	√		Find the information in Siamed. (if not in Siamed, check the GxP validation e-mail and cross-check if consistent

Step	Person responsible to enter data		Action
			with the mail-in stamp in the cover letter of the MAA).
Rapporteur Original		√	Find the information in Siamed.
Co-Rapporteur Original		√	Find the information in Siamed.
Procedure			
Indication		√	Find the information in Siamed.
Clinical Trials	√		Click on "Clinical trials" tab. Procedure Clinical Trials Create an entry for each trial. Click on "Add trial" and then "Add new". I - Overview II - Inspection III- General IV - Trial Subjects V.I - Patient Recruitm Clinical Trial Data for Scientific Memory Add Trial I.8 Stu Add New Clinical Trial version? Select Trial XL184 Add New Click on "Select trial" and then "Edit" (bottom right corner). Add Trial Select Trial X
Pivotal trial	√		Tick yes or no.
EudraCT nr	√		Find the information in ECTD.
WHO Reg nr	√		Fill in, if applicable.
NCT Number (FDA)	√		Fill in, if applicable.
Sponsor	√		Find the information in ECTD.
Commercial sponsor	√		Tick, if applicable.
Non-commercial sponsor	√		Tick, if applicable.
Full title	√		Find the information in ECTD.
Study ID	√		Find the information in ECTD.
Protocol version nr	√		Enter version, not protocol ID.
Protocol date	√		Enter protocol date, not protocol ID.
Trial having independent Data Monitoring Committee	√		Find the information in ECTD. If the trial is/was having another committee, do not tick yes as this field only refers to independent Data Monitoring Committee.
Study report date	√		Find the information in ECTD.
Start date	√		Find the information in ECTD.
End date	√		Find the information in ECTD.
Trial status	√		If there is an end date, tick completed, otherwise tick on-going.
Number of patients	√		Find the information in ECTD. Always enter the randomised total number and NOT the enrolled number.
Inspection	√	√	Check in the GxP Corporate database if there was a previous GCP inspection of Sponsor, clinical or CRO sites. AD will forward to assistant the information on inspections.
Site inspected		√	Fill in, if applicable.
Site country		√	Fill in, if applicable.
Date of inspection		√	Fill in, if applicable. If there are more sites, put first day

Step	Person responsible to enter data		Action
			of the first inspection. Do not insert date range (from, to). If only month of inspection available and not exact date, put first day of respective month.
Country performing inspection		√	Fill in, if applicable.
III-General			
III.1			
III.1.1 - III 1.13	√		Do not leave empty, tick appropriate fields.
III.2			
III.2.1 - III 2.5	√		Do not leave empty, tick appropriate fields.
III.3			
III.3.1 - III 3.3	√		Do not leave empty, tick appropriate fields.
IV-Trial Subjects			
IV.1-IV.3.7	√		Do not leave empty, tick appropriate fields.
Patient recruitment	√		Send to AST the link to the document containing the information on patient recruitment in DREAM folder.
Region		√	If the country of the trial was not in the EU when the trial started, but was in EU when the trial finished, insert the initial region (example: trial in Czech Republic started 1/6/2002 and finished 1/8/2004, then enter Eastern Europe as the Czech Republic is an EU member since 1/5/2004).
Country		√	SA: send to AST the link to the document containing the information on patient recruitment in DREAM folder. AST: fill in according to the received document.
Number of sites		√	SA: send to AST the link to the document containing the information on patient recruitment in DREAM folder. AST: fill in according to the received document.
Number of patients		√	SA: send to AST the link to the document containing the information on patient recruitment in DREAM folder. AST: fill in according to the received document.
Follow-up	√		SA is responsible for entering any follow-up issues.
CRO	√	√	SA: send to AST the link to the document containing the information on CRO in DREAM folder. AST: fill in according to the received document.
CRO Company		√	Fill in.
Address1		√	Fill in.
Address2		√	Fill in.
Town/City		√	Fill in.
Country/State		√	Fill in.
Postcode/ZIP		√	Fill in.
Country		√	Fill in.
CRO Activity		√	Fill in, if applicable.