



Work instructions

Title: How to create reports from scientific memory database (SMD)		
Applies to: Clinical and Non-Clinical Compliance Section		
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1. Changes since last revision

New WIN.

2. Records

All the reports obtained from the scientific memory database are saved in DREAM under Cabinets/Old EDMS Structure/Operational Units/Inspections/GCP/Scientific Memory . Reports can be created on monthly basis (i.e. when selecting applications for inspection) or as product specific reports.

3. Instructions

All the reports are obtained based on the data contained in the scientific memory database, which has been created in order to track all the applications including new MA applications, line extensions and type II variations received by the Agency.

The objective of this WIN is to describe the steps to be followed in order to:

- 3.1 Access the scientific memory database.
- 3.2 Enter a new product.
- 3.3 Enter data in relation to duplicates/generic applications.
- 3.4 Enter the "child" product information.



3.5 Enter a new application – Trial only information.

3.5.1 Line extensions or type II variations.

3.5.2 New marketing authorisation applications.

3.6 Create reports from scientific memory database, in particular:

3.6.1 Countries report (list of countries involved in a particular clinical trial).

3.6.2 Trial export report.

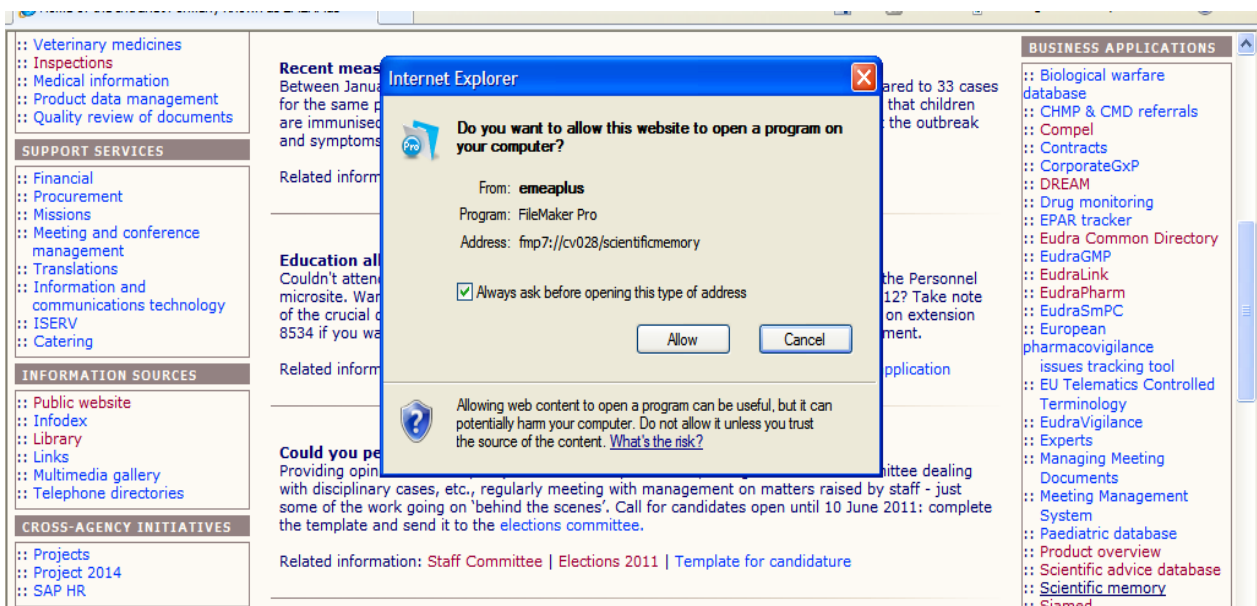
3.6.3 Export as a PDF report.

3.6.4 Inspection report.

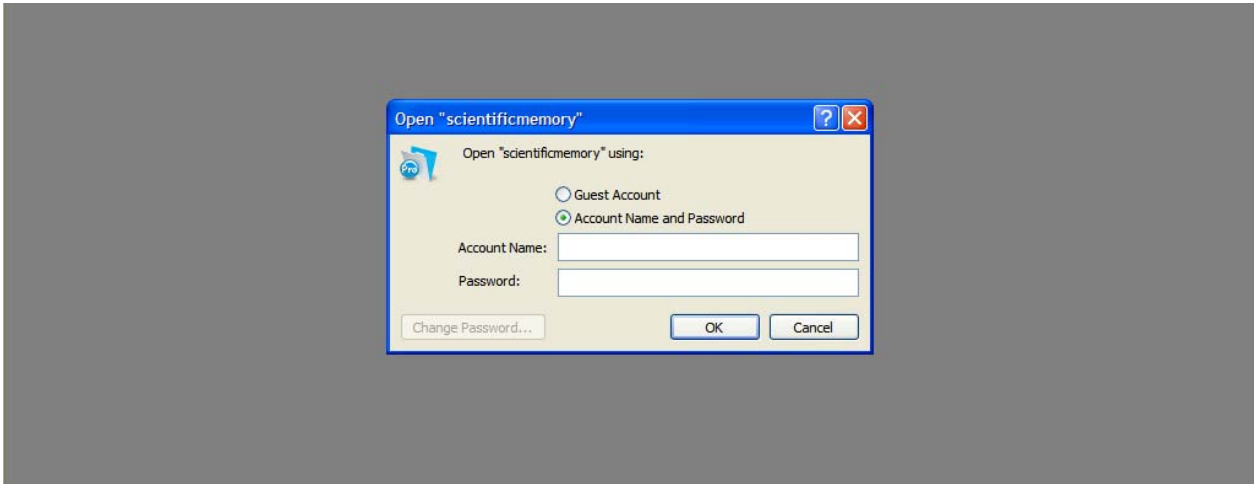
3.6.5 Follow up report.

3.1. Access the scientific memory database:

- Go to the Intranet webpage (formerly known as EMEA plus).
- Click on the link called “Scientific Memory” in the column on the right-hand side
- The following box will open:



- Click on “Allow” and the file maker page will open.
- Enter your credentials on the box as displayed below (the green dot should be by default on “Account Name and Password”) and then click on OK.

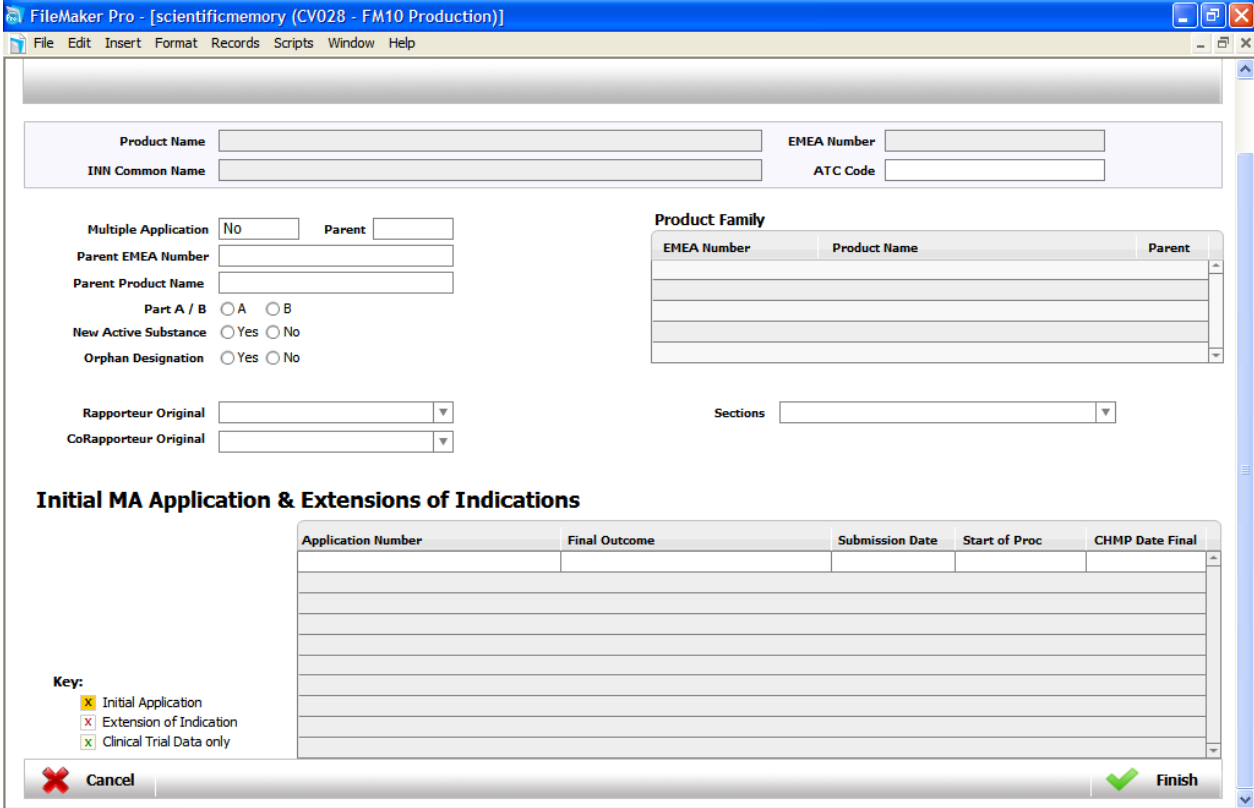


- The full list of products will appear including product name, INN name, ATC code and other identifiers.

3.2. How to enter a new product:

If you search for a product in the SMD database using the search tool on the bar on top and the search does not bring back any results then it means that the product is not in the list and you have to enter a new product in the database.

- Click on "Add product" on the top left and then "Add new". The following screenshot will appear:



The fields displayed have to be filled in, in accordance with the responsibilities as described in the WIN/INSP/2027 Workflow of data entry to scientific memory database.

3.3. How to enter data in relation to duplicates/ generic applications:

With regard to data in connection with duplicates or generic applications to be entered in SMD, it should be taken into account that all information belonging to a product considered as “parent” automatically belong to the “children” for that product. Parent is the first product for which data (including clinical trial data) have been entered in SMD.

Duplicates: When a new product, for which a new application is submitted, is identified as duplicate of another application already submitted and already entered in SMD, this information should be reflected in SMD. For the product that is a duplicate only the boxes “Parent EMEA Number” and “Parent Product Name” as displayed in the screenshot below should be filled in. Once this information is entered, the multiple application box will automatically turn into **YES**.

The screenshot shows a web form for an Initial MA Application. A red circle highlights the 'Parent EMEA Number' and 'Parent Product Name' fields. Other fields include 'Multiple Application' (No), 'Parent' (No), 'Part A / B' (radio buttons A and B), 'New Active Substance' (radio buttons Yes and No), 'Orphan Designation' (radio buttons Yes and No), 'Rapporteur Original' (The Netherlands), and 'C Rapporteur Original' (Estonia). A 'Product Family' table is also visible.

View	EMEA Number	Product Name	Parent

Sections:

Initial MA Application & Extensions of Indications

Click the Application row to view or click the button above to add a new application.

Key:

- Initial Application
- Extension of Indication

Application Number	Final Outcome	Submission Date	Start of Proc	CHMP Date Final
/0000		29/09/2010	21/10/2010	

Generic applications: All the generic products should be entered in SMD as “children” of the parent that is the first product authorised and put on the market. Also for different generics of the same product, repetition of clinical trials data should be avoided.

When different applications for the same generic product are submitted it should be **first** checked if the same clinical trial has been already submitted in previous applications for generics and if data for the same trial has been already entered in SMD. This should be done by checking clinical trial data one by one for all the generics already registered in SMD under the concerned authorised product (“parent”).

When clinical trial data has been already submitted and the record has been already entered in the database, then for the concerned generic products the same clinical trial data does not need to be entered again. For those products (“children”) it is enough to fulfill the fields in the screenshot below including the parent name and parent EMEA number and under the tab “Follow up” specify that clinical trials data are **not** entered as they are already present in the SMD database under the product named **XXX** (specify the name of the product).

In case of generic applications received for the same product when different clinical trials data are provided, then this data should be normally entered under clinical trial section for each product and also the fields in the screenshot below including the parent name and parent EMEA number should be filled in to specify that the generic is a child of the first authorised medicinal product.

It is important to stress that only if ***NEW clinical trials*** data for a generic product have been submitted, and these data have not been entered before in the SMD, then these should be entered into the database for the first time under the clinical trials section for that product as normal.

3.4. How to enter the “child” product information:

Under the information for the product, enter the product name, INN common name and EMEA number. Then under the tab “General”, enter the parent EMEA number and the parent product name. Automatically the field “Multiple applications” will be populated as “Yes” and the field “Parent” as “No”.

The name of the product considered as “child” will appear in the product family box on the right-hand side.

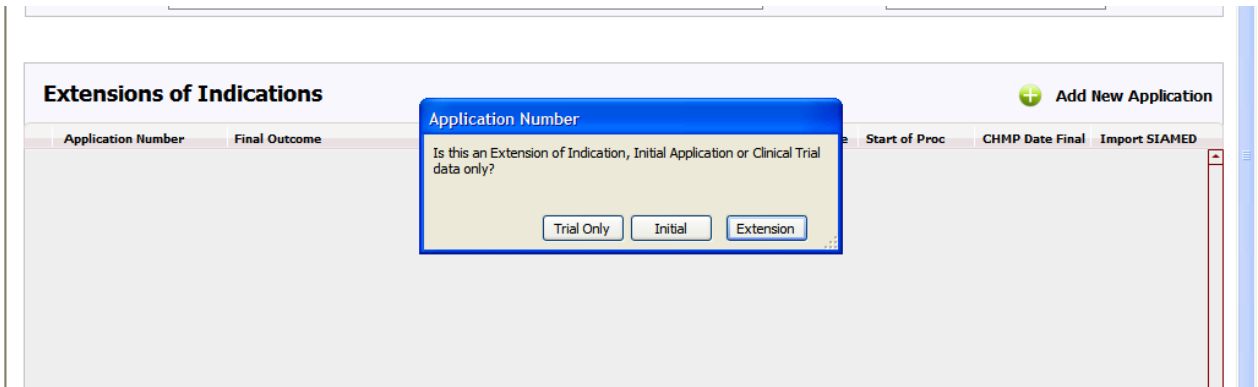
3.5. How to enter a new application – Trial only information:

3.5.1. Line extensions or type II variations

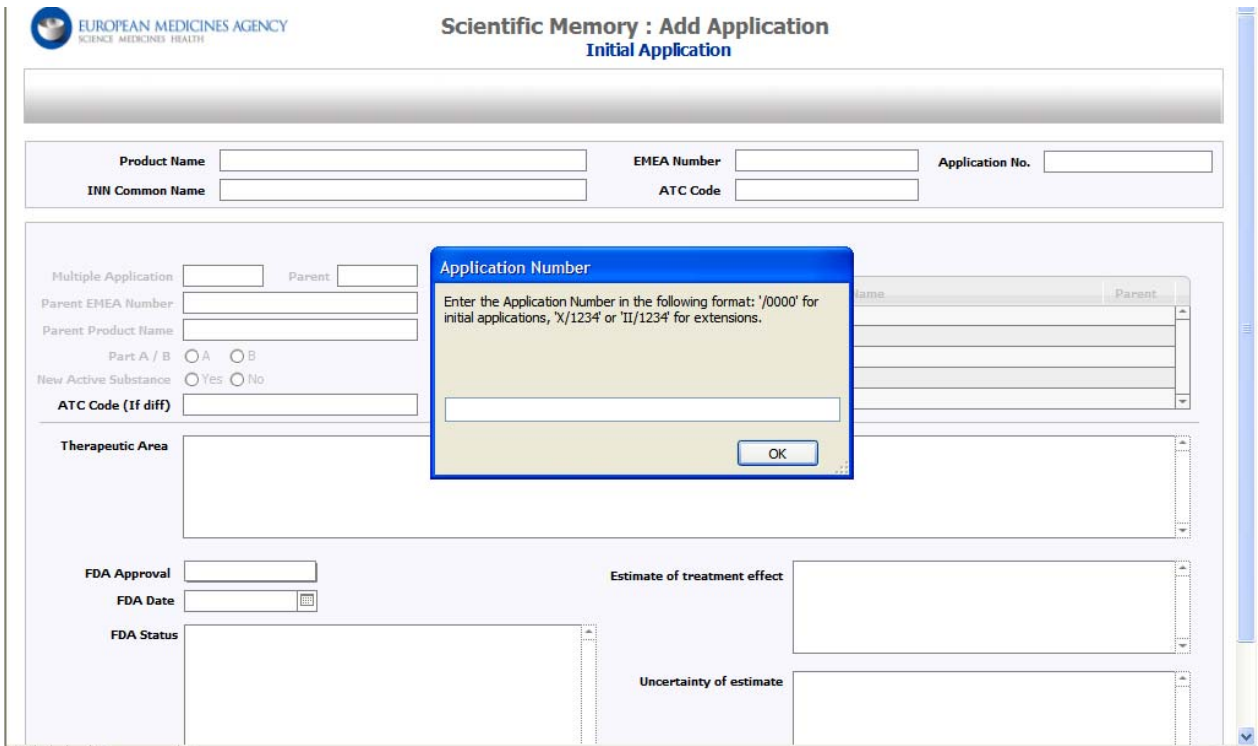
This is for a product already existing in the list and for which new clinical trials data should be entered. Once that you access the system you have the full list of product appearing, then click on “Search” and select “Product”.

- Type in the box on the top left the name of the product that you are searching for and then click on the button on the top right “Perform a search”.
- Data on the product you have searched for will appear on the screen. Click on button “Add a new application”.
- A little box will appear at this stage on the screen, click on “cancel”.
- Then click on the green plus “add new application” and in the screen will appear the following box (screenshot below).

- Click on "Trial only".



- Then enter the name of the application for which you are going to enter the data in SMD. The box below will appear:



- For type II you should type: II/and the number (four digits as 0013).
- For line extension you should type: X/and the number (four digits as 0013).
- Once entered the name, click on OK and then on "Finish" on the bottom right.
- The following screenshot will appear. Clinical trials data have to be entered under the tab "Clinical trials":

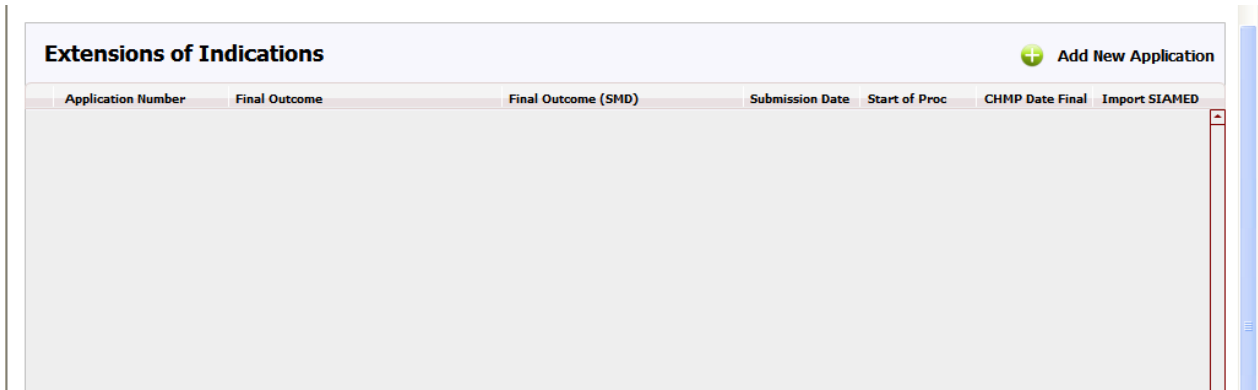
- To enter clinical trial data, click on “Add trial” (on the green plus) and then “Add new”.

- Finally click on “Select trial” on the top left and the line will turn into blue. At this point you can edit and enter the data.

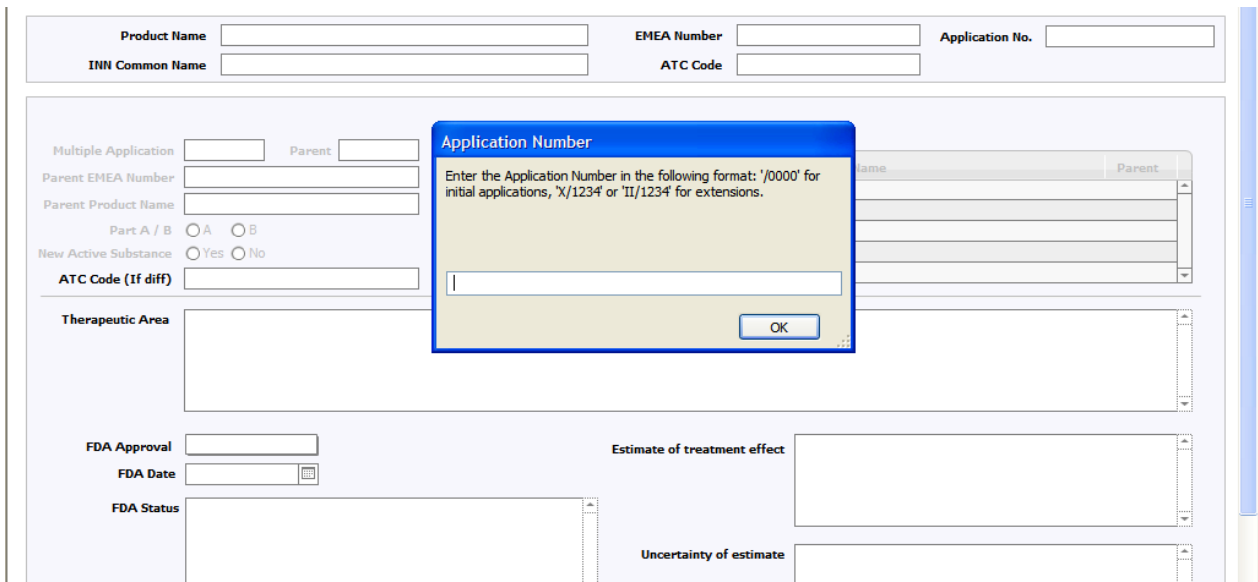
3.5.2. New Marketing Authorisation applications

This is for new products just entered in SMD and for which new clinical trials data should be entered.

- Search for your product and click on “Add new application” on the green plus. The following page will appear:



- Click on "Add new application" on the top right, and the "Trial only" on the box appearing;
- The screenshot (below) will appear and as it is a new MAA you should insert: "/0000" then click on the bottom on the right "Finish".



- The following screenshot will appear and you should click on the tab "Clinical trials".

General Application Procedure Clinical Trials LoQ/BR (D120/90) MO Categorisation Hearing/LoOI Categorisation Generic Application Opinions Re-Examination

Multiple Application No Parent No

Parent EMEA Number

Parent Product Name

Part A / B A B

New Active Substance Yes No

ATC Code (if diff)

Product Family

View	EMEA Number	Product Name	Parent

Therapeutic Area

FDA Approval

FDA Date

FDA Status

Estimate of treatment effect

Uncertainty of estimate

Record created by: pioppol 31/05/2011 19:55:09 Modified by: pioppol 31/05/2011 19:58:51

Print Edit

- And then click on "Add trial" (on the green plus) and then "Add new".

General Application Procedure Clinical Trials LoQ/BR (D120/90) MO Categorisation Hearing/LoOI Categorisation Generic Application Opinions Re-Examination

I - Overview II - Inspection III - General IV - Trial Subjects V.I - Patient Recruitment V.II - Patients Exposed VI - Demographics VII - Results Follow Up

Clinical Trial Data for

Add Trial I.8 Study ID/Protocol ID I.7 Full Title Of The Trial I.12 Study Report Date I.15 Trial Status

SMD Trial Number

I Pivotal Trial Yes No

I.1 Eudra CT Number (A.2)

I.2 WHO Reg Number

I.3 NCT Number (FDA)

I.4 Sponsor (B.1)

I.5 Commercial Sponsor (B.3.1) Yes No I.6 Non Commercial Sponsor Yes No

I.7 Full Title Of The Trial (A.3)

I.8 Study ID/Protocol ID

I.9 Protocol Version No

I.10 Protocol Date

I.11 Trial Having Independent Data Monitoring Committee Yes No

I.12 Study Report Date

I.13 Trial Start Date

I.14 Trial End Date

I.15 Trial Status Ongoing Completed

I.16 Number Of Patients

Countries Report Trial Export Export as PDF Print Edit

- Finally click on "Select trial" on the top left and the line will turn into blue. At this point you can edit and enter the data.

3.6. How to create reports from Scientific Memory Database

You can create the reports: "Countries report", "Trial report", "Export as PDF" and "Inspection report" regardless of the product that you have selected. Go to the page "List of products" and select one product randomly in order to start the process. For the selected product, click on one of the rows displayed in the box "Initial MA Applications & Extension of indications". Applications can be selected randomly (i.e. can be selected /0000 or II/1234 or X/1234).

Click on the tab "Clinical trials"

For "Countries report", "Trial report" and "Export as PDF" you have to go under the tab **I-Overview**. Here, on the bottom left you have the two Excel reports "Countries report" and "Trial report" and on the bottom right you have "Export as PDF".

3.6.1. Countries report

Click OK on "Create an Excel report". When the box as in the screenshot below appears, enter the timeframes of your interest in the format DD/MM/YYYY **separated by three dots (i.e. DD/MM/YYYY...DD/MM/YYYY)**. Note that in this case the report is created based on the **Procedure start date**. The Excel report is automatically saved on your desktop and it should be manually imported in DREAM under the following path: Cabinets/Old EDMS Structure/Operational Units/Inspections/GCP/Scientific Memory.

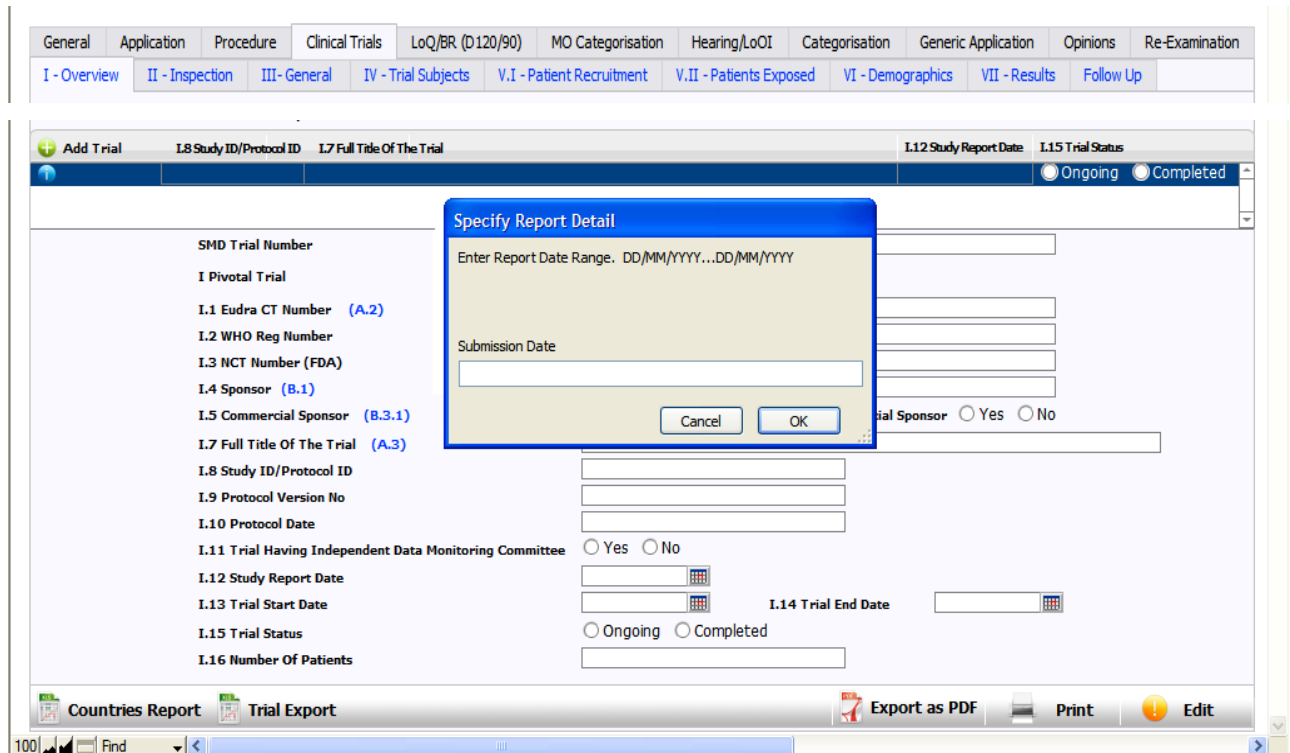
The screenshot displays the 'Clinical Trials' tab in the DREAM application. A 'Specify Report Detail' dialog box is open, prompting the user to enter a report date range (DD/MM/YYYY...DD/MM/YYYY) and a procedure start date. The background shows the 'Clinical Trials' tab with various fields for trial information, including SMD Trial Number, I Pivotal Trial, I.1 Eudra CT Number (A.2), I.2 WHO Reg Number, I.3 NCT Number (FDA), I.4 Sponsor (B.1), I.5 Commercial Sponsor (B.3.1), I.7 Full Title Of The Trial (A.3), I.8 Study ID/Protocol ID, I.9 Protocol Version No, I.10 Protocol Date, I.11 Trial Having Independent Data Monitoring Committee (Yes/No), I.12 Study Report Date, I.13 Trial Start Date, I.14 Trial End Date, I.15 Trial Status (Ongoing/Completed), and I.16 Number Of Patients. The bottom of the screen shows the 'Countries Report' and 'Trial Export' buttons, along with 'Export as PDF', 'Print', and 'Edit' options.

3.6.2. Trial export report

Click OK on "Create an Excel report". When the box as in the screenshot below appears, enter the timeframes of your interest in the format DD/MM/YYYY **separated by three dots (i.e. DD/MM/YYYY...DD/MM/YYYY)**. Note that in this case the report is created based on the

Submission date. The Excel report is automatically saved on your desktop and it should be manually imported in DREAM under the following path: Cabinets/Old EDMS Structure/Operational Units/Inspections/GCP/Scientific Memory.

Note: In the "Trial export" report the PTL names appear under column G as "Project Manager: Full name_C". This information is taken from the tab "Application".



3.6.3. Export as a PDF report

This report should be used in order to group all the information that is contained under the sections: General, Application, Clinical trials (only sections of P-CI-CNC concern i.e. I- V.I and Follow up) in one unique document. Once created, the PDF is automatically saved on your desktop and it should be manually imported in DREAM under the following path: Cabinets/Old EDMS Structure/Operational Units/Inspections/GCP/Scientific Memory.

To generate the Inspection report, it is necessary to go under the tab **II-Inspection.**

3.6.4. Inspection report

This report is created for obtaining information on inspections performed on applications received in a particular period of time. The query will select applications based on the submission date entered. Go under section II-Inspections and click on the icon "Trial Export", click OK on "Create an Excel report". Enter the timeframes of your interest in the format **DD/MM/YYYY separated by three dots (i.e. DD/MM/YYYY...DD/MM/YYYY)**. Note that in this case the report is created based on the **Submission date.** You can obtain this report in relation to applications (submission dates) received in a selected timeframe regardless of the original product from which you access

this report. The report is automatically saved on your desktop and it should be manually imported in DREAM under the following path: Cabinets/Old EDMS Structure/Operational Units/Inspections/GCP/Scientific Memory.

Note: The functionality under the tab "Inspection" to export the inspection reports as PDF is not currently in use.

3.6.5. Follow up report

This report is used by the scientific administrators to have an overview of the products of their concern and the related status (if follow up is needed or not). In order to obtain the report for follow up, go to "Search" and then "Applications". Then click on the tab "Clinical trials" and go under the tab "Follow up". From the drop-down list P-CI-CNC-coordinator select the name of your interest, scroll up and then click on "Perform a Search". The full list of products that contain the coordinator's name selected will appear on the screen. The report can be saved as PDF and also as Excel on the screen and it should be manually imported in DREAM under the following path: Cabinets/Old EDMS Structure/Operational Units/Inspections/GCP/Scientific Memory.

In order to obtain the Excel report, click on the icon "Export as Excel P-CI-CNC". Comments related to the issues to be followed up will appear in the last column of the Excel report.

Note: It is important to update the section "Follow up" once received responses from the companies to the issues identified at the time of validation. The scientific administrators are responsible to follow the product life-cycle for which they are appointed PTMs. Once that the responses have been received from the companies, the scientific administrators should enter in the database the data under the sections of their concern and provide the assistants with the data to be entered under the sections of their concerns (i.e. the list of patients recruited by sites). **The scientific administrators** are responsible for ticking the box for follow up as **NO** once all the issues have been addressed satisfactorily.