



Work instructions

Title: EU-RMP annex 1: validation		
Applies to: Risk Management Section		
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1. Changes since last revision

Modified to take into account the extended scope of the EU-RMP annex 1 to monitor risk management activities for centrally authorised products in the EU by means of the European Pharmacovigilance Issues Tracking Tool (EPITT).

2. Records

All the documents related to the EU-RMP Annex 1 activities are stored at the following locations:

- EPITT Risk Management Module User Guide: EPITT RMPS module, button "RMPs Guide"
- EPITT RMP records: EPITT RMPs module
- EU-RMP Annex 1 files: Document Records Electronic Archive Management (DREAM)
- EU-RMP Annex 1 correspondence: H-EURMP-EVINTERFACE mailbox
- EU-RMP PDFs:
 - These files are saved in the following DREAM folder:
Cabinets/Old EDMS Structure/Operational Units/Human/Post/PHVSE/Risk management/EPITT RM Module EU-RMP PDFs
 - The file naming convention is described in the next section in Step 2.
- Excel table to inform PTM-RMs of not-validated EPITT RMP records:
Cabinets/Old EDMS Structure/Operational Units/Human/Post/PHVSE/Risk management/Thomas/7 Projects/EPITT RM Module/Validation SOP3291-WIN3292



3. Instructions

This WIN refers to: **SOP/H/3291**: 'Handling and validation of EU-RMP annex 1'.

The EPITT Risk Management Plans (EPITT RMPs) module provides the EPITT users with the content of the EU-RMP Annex 1 files, which are the electronic representation of EU-RMPs. EU-RMP Annex 1 files loaded into EPITT are referred to as EPITT RMP records.

This WIN describes the steps the Risk Management Plan Product Team Member (PTM-RM) and PTM-RM secretary needs to follow to carry out the validation of EPITT RMP records. The validation focuses on, but is not limited to, the additional pharmacovigilance and risk minimization activities provided in the EPITT RMP record against the PDF version of the corresponding EU-RMP.

The PTM-RM starts the EPITT RMP record validation when notification has been received from the Data Collection and Management Section (DCM) informing that an EU-RMP Annex 1 file has been uploaded and flagged "not validated" in the EPITT RMPs module (see WIN/H/3312).

The following main steps are described:

Step #	Task	Responsible
Step 1	Retrieve "not validated" EPITT RMP records and enter responsible staff details	PTM-RM assistant
Step 2	Retrieve and save corresponding EU-RMP PDFs in dedicated folder in DREAM and inform PTM-RMs	PTM-RM assistant
Step 3	Perform validation of EPITT RMP records	PTM-RM
Step 4	Communicate outcome of validation	PTM-RM

Step 1 Retrieve "not validated" EPITT RMP records and enter responsible staff details

1. Open the URL for EPITT in internet browser (see Figure 1):

<fmp7://fmapps.eudra.org/PhVWP+Tracking>

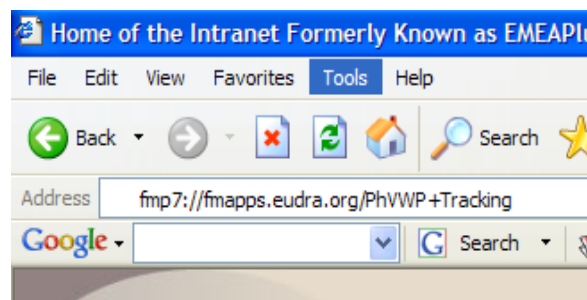


Figure 1

2. Log on to EPITT with EPITT account name and password (see Figure 2).

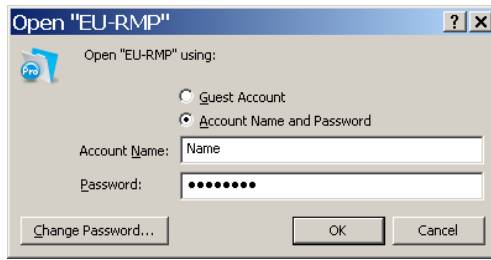


Figure 2

3. Click on RMPs (top right register) and then on RMPs (lower left; see Figure 3).

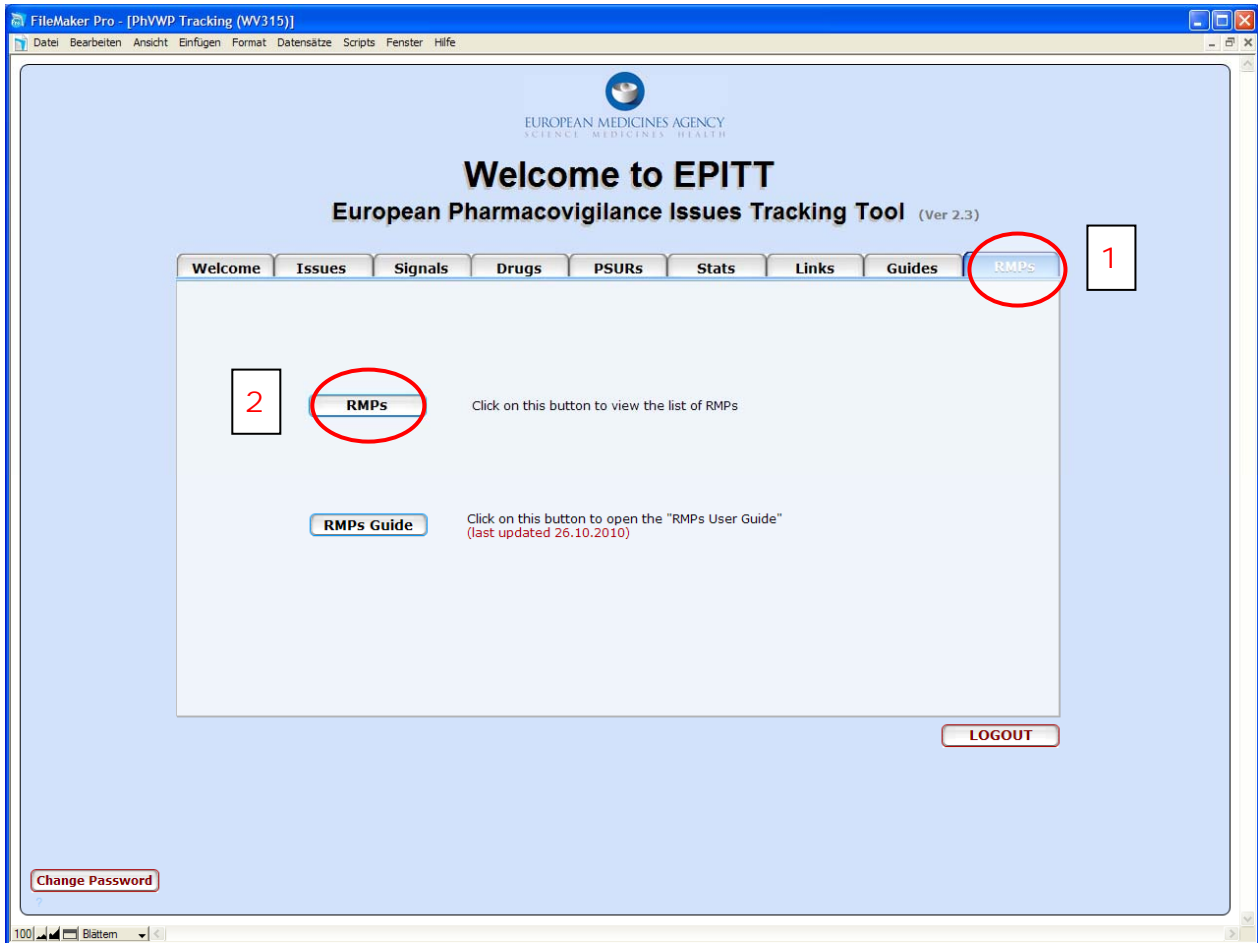


Figure 3

4. Retrieve “not validated” EPITT RMP records and enter responsible staff details.

1. Click on the “Advanced” button in the “Search” tab (center top; see Figure 4a).

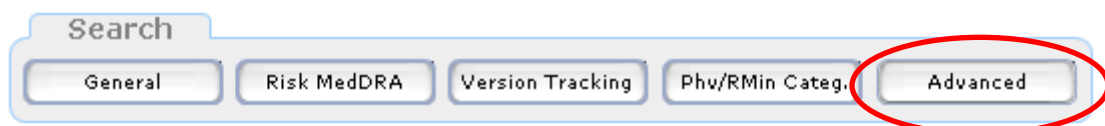


Figure 4a

2. Click on the “Go” button (left; see Figure 4b).

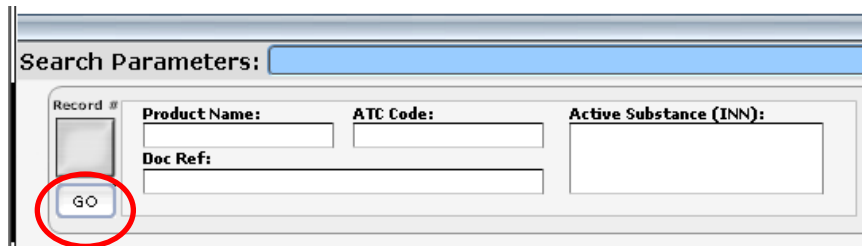


Figure 4b

3. Click on the “N” button in the navigation panel (lower right, see Figure 4c). Press enter. The General Information tab of the first not validated EPITT RMP record will be displayed.

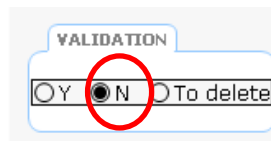


Figure 4c

The record counter on the top right corner (see Figure 4d) indicates the current record number out of the total number of non-validated EPITT RMP records which have been retrieved.



Figure 4d

4. In the data field labelled RMTM, enter the name of the PTM-RM responsible for the currently displayed product according to the product team allocations in SIAMED.

5. In the data field labelled PTL, enter the name of the Product Team Leader (PTL) responsible for the currently displayed product according to the product team allocations in SIAMED.

6. In the data fields labelled Rapporteur and Co-Rapporteur, enter the names of the Rapporteur and Co-Rapporteur appointed for the currently displayed product according to the product team allocations in SIAMED.

7. Check-out the Excel table mentioned in section **2. Records**. Add the product name, the EU-RMP version and EU-RMP date, as displayed under the EPITT RM General Information tab, and the name of the responsible PTM-RM, as provided under 4 above. Check-in the Excel table.

8. Click on the right blue arrow in the record counter (top right, see Figure 4e) to go to the next not-validated EPITT RMP record. Repeat steps 4 – 8 until no further non-validated EPITT RMP records can be retrieved.



Figure 4e

Step 2 Retrieve and save corresponding EU-RMP PDFs in dedicated folder in DREAM and inform PTM-RMs

1. Retrieve in "EURS is Yours" the EU-RMP PDFs with the product name and EU-RMP version (number and date) added to the Excel table mentioned in **Step 1.4.7**.
2. Save each EU-RMP PDF locally on the desktop, naming it "PRODUCTSHORTNAME-RMPvX.X-DDMMYY" (X.X is the version number, dd the version date day, MM the version date month in digits and yy the last two digits of the version date year) to match the EPITT RMP record.
3. Import the renamed EU-RMP PDFs to

Cabinets/Old EDMS Structure/Operational Units/Human/Post/PHVSE/Risk management/EPITT RM Module EU-RMP PDFs

Set the document category to "Plan".
4. Delete the EU-RMP PDFs from the desktop.
5. Send an e-mail with a link to the Excel table mentioned in **Step 1.4.7** to P-PV-RM Administrators, cc H-RM, informing them of the new EPITT RMP records and the corresponding EU-RMP PDFs in DREAM.

Step 3 Perform validation of EPITT RMP records

1. Perform **Step 1.1 to 1.3**.
2. Retrieve "not validated" EPITT RMP records listed in the above mentioned Excel table by searching ("A") or browsing ("B"):
 - A. Searching
 1. Click on the "General" button in the "Search" tab (top left; see Figure 5).

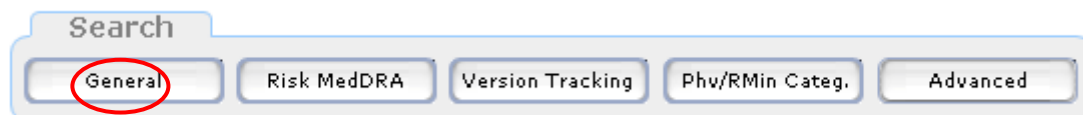


Figure 5

2. Find the concerned product by entering your name in the last row ("EMA RMTM") and clicking on "Find" (see Figure 6a).

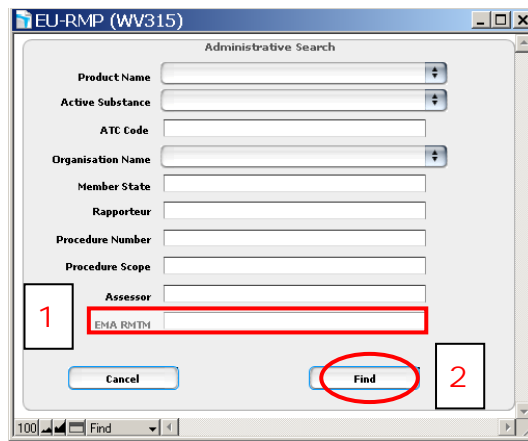


Figure 6a

3. Click on the yellow spot (for “not validated”) at the bottom left (Figure 6b).

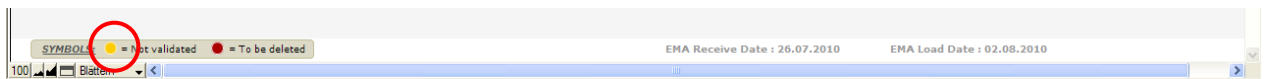


Figure 6b

B. Browsing

1. Click on the sidebar (see Figure 7) and move it down.

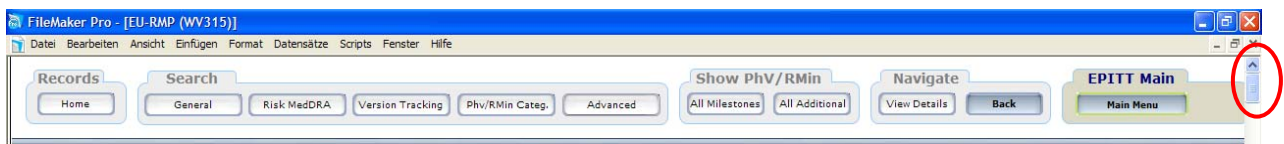


Figure 7

3. The EPITT RMP record to be validated is marked with a yellow spot on the left hand side as “not validated” (see Figure 8). Valid EPITT RMP records do not carry any marker.



Figure 8

4. Click on the record # to be validated (left, see Figure 8). The General Information tab of the selected record will be displayed.
5. Click on “Print form” (bottom right, see Figure 9).

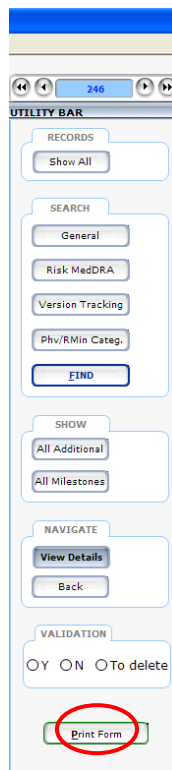


Figure 9

- When prompted to choose either to hide or show MedDRA terms click on "Hide" (see Figure 10).

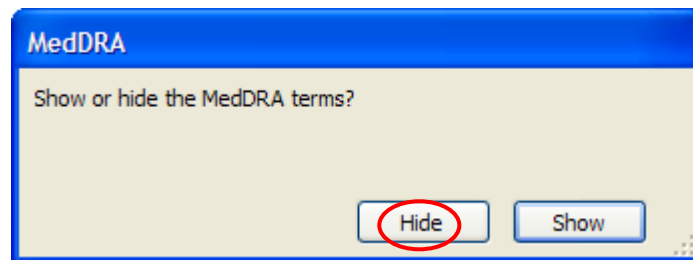


Figure 10

- When prompted to choose to print or to create a PDF rendition click on "PDF" (see Figure 11), tick "open file automatically" (bottom of pop-up) and save this "EPITT RMP record PDF rendition" locally (e.g. desktop) under any name.

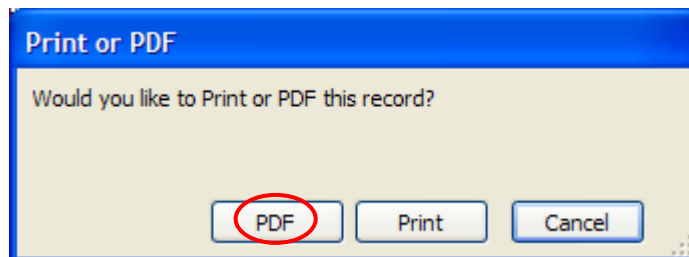


Figure 11

- Open in "Cabinets/Old EDMS Structure/Operational Units/Human/Post/PHVSE/Risk management/EPITT RM Module EU-RMP PDFs" the EU-RMP PDF with the same product name, EU-

RMP version number and EU-RMP version date printed on top of the EPITT RMP record PDF rendition (see Figure 12).

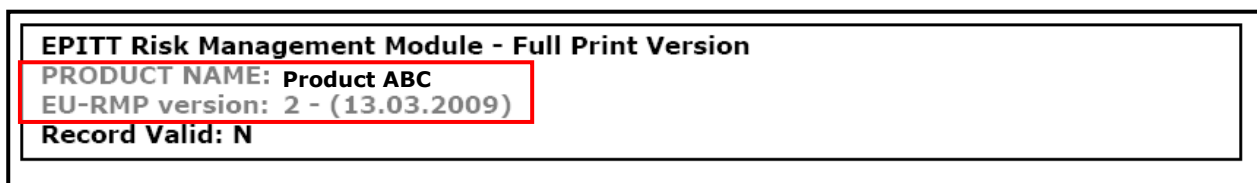


Figure 12

9. Compare the content of the EPITT RMP record PDF rendition, checking whether the data provided under the header “Administrative Information” match the EU-RMP PDF:

- Organisation Name
- EU-RMP Date
- EU-RMP Version
- Product name
- Active substance name (Substance)

10. On the EPITT RMP record PDF rendition, check whether the following items under the header “Administrative Information” have a plausible entry (e.g. “next PSUR date” not in the past):

- Qualified Person for Pharmacovigilance (QPPV)
- E-mail Address of QPPV (E-mail Address)
- Next PSUR Date
- Commission Decision Date (Comm. Dec. Date; as applicable)

On the EPITT RMP record PDF rendition, check whether the sections “identified risk descriptions”, “potential risk descriptions” and “missing information descriptions” are compatible with the safety concerns listed in Section 5 “Summary of the EU Risk Management Plan” (ref. Template for EU Management Plan (EU-RMP), Cabinets/13. Projects/2001 review/EMEA consequences/Public implementation/Risk Management/Risk Management guideline/Template) and - if further detailed in EPITT - section 1.5.2: “Details of important identified and potential risks (including newly identified)” of the EU-RMP PDF. “Compatible” in this context refers to the key information in the respective data fields to be consistent between EU-RMP PDF and EPITT RMP record PDF rendition.

11. On the EPITT RMP record PDF rendition, check whether the ‘Pharmacovigilance Activity Descriptions’ and ‘Risk Minimisation Activity Descriptions’ are compatible with the proposed additional pharmacovigilance and risk minimisation activities listed in section 5 “Summary of the EU Risk Management Plan” of the EU-RMP PDF.

In addition, use sections 2.2 “Summary of safety concern and planned pharmacovigilance actions” and 4 “Risk Minimisation Plan” of the EU-RMP PDF for comparison. “Compatible” in this context means that key information is consistent between the EU-RMP PDF and the EPITT RMP record PDF

rendition in the respective data fields with focus on the correct choice of categories of additional pharmacovigilance and risk minimisation activities, the provision of details including reference to planned or finalised study protocols (e.g. by EUDRACT number) or key elements and messages of the proposed educational material, as applicable.

12. On the EPITT RMP record PDF rendition, check whether the Milestone lines (see Figure 13) match the milestones listed in section 2.6: "Summary of outstanding actions, including milestones" of the EU-RMP PDF.

In addition, use sections 2.3: "Detailed action plan for specific safety concerns" and 2.4: "Overview of study protocols for the pharmacovigilance plan" of the EU-RMP PDF for comparison. "Matching" in this context refers to the key information in the respective data fields to be consistent between EU-RMP PDF and EPITT RMP record PDF rendition with focus on milestones which could be defined by a date and/or an event (e.g. availability of interim study report).

Pharmacovigilance Activity Description:	
Activity Type:	Active Surveillance - Registry
Milestone Date Additional Details:	Y With each PSUR

Figure 13

Step 4 Communicate outcome of validation

A. The outcome of the validation is satisfactory.

When the outcome of the validation performed in step 3 is satisfactory and the EPITT RMP record PDF rendition is consistent with the corresponding EU-RMP PDF mark the EPITT RMP record valid by clicking on the "Y" button in the navigation panel (lower right, see Figure 14). Close the EPITT RMPs module (by clicking on the "X" at top right) and related working files.

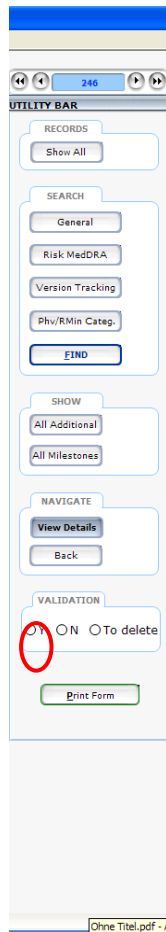


Figure 14

B. The outcome of the validation is not satisfactory.

When the outcome of the validation performed in **Step 3** is not satisfactory and the EPITT RMP record PDF rendition is considered inconsistent with the corresponding EU-RMP PDF proceed as follows:

1. Mark the EPITT RMP record for deletion by clicking on the "To delete" button in the navigation panel (lower right, see Figure 15).



Figure 15

2. Retrieve the e-mail sent for submission of the respective EU-RMP Annex 1 file in the 'H-EURMP-EVINTERFACE' mailbox, using the Outlook search function, and click on "reply" to send an e-mail to the sender.
3. Copy in the 'Cc' field the e-mail address of:
 - The Qualified Person for Pharmacovigilance (QPPV), as provided in the EPITT RMP record PDF rendition (see Figure 16, #1).
 - H-EURMP-EVINTERFACE,
 - H-RM,
 - The product-specific mailbox,
 - The PTL.

ADMINISTRATIVE INFORMATION	
Organisation Information	
Organisation Name:	
EudraVigilance ID:	
QPPV:	Alan.Smith@xxx.com 1.
Email Address:	
Postal Address:	
Risk Management Plan Information	
EU-RMP Date:	Freitag, 13. März 2009 3.
EU-RMP Version:	2
EU-RMP DLP:	Donnerstag, 1. April 2010
Annex 1 Date:	Mittwoch, 5. August 2009
Annex 1 Version:	1
Product Administrative Information 2.	
Product Name:	Product ABC

Figure 16

4. In the 'Subject' field, enter as reference: *Product Name* EU-RMP Annex 1 Version *Annex 1 Version of Annex 1 Date*: EMA Comments (copy text in italic from EPITT RMP record PDF rendition: see Figure 16 #2 (e.g. "*Product ABC EU-RMP Annex 1 Version 1 of 05.08.2010: EMA Comments*").
5. Enter the following text:

Dear Sir/Madam,

We have reviewed the above mentioned EU-RMP Annex 1 file, and comparison with the corresponding EU-RMP version *RMP version of RMP Date* (e.g., "EU-RMP version 2 of 13 March 2009", see Figure 16 #3) identified the following issues:

Option 1: list issue(s), making reference to the concerned sections/data fields where a mismatch was identified

Option 2: add comments to the ANNEX 1 PDF, attach it and write: See attachment.

Could you please correct these issues and submit a revised EU-RMP Annex 1 file with a new version number and date via EudraLink to h-eurmp-evinterface@ema.europa.eu **within 15 calendar days of the EU Commission decision or - if already occurred - within one week after receipt of this e-mail.**

In case of a technical issue, please contact the EudraVigilance info- and help line of the EMA at +44 20 7523 7523 or at eudravigilance@ema.europa.eu. Please do not hesitate to contact me, should you have any other questions.

Kind regards,

Your external electronic signature

6. Flag the e-mail for follow-up in one week and send the e-mail.
7. Close the EPITT RMPs module and related working files.
8. Follow-up with the MAH/QPPV if no updated EU-RMP Annex 1 file has been received within two weeks.