EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

User Manual

EU-RMP Annex 1
(Interface for EudraVigilance)

Visual Basic® Form

Version 5.1 – October 2013

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1. Introduction

This document provides guidance on the population of the EU Risk Management Plan Annex 1 (EU-RMP Annex 1), a structured electronic representation of the EU-Risk Management Plan (EMEA/192632/2006) as referred to in Module V- Risk Management systems of the guidelines on good pharmacovigilance practice (GVP).

The first purpose of the EU-RMP Annex 1 is to facilitate monitoring of identified and potential risks and missing information in relation to suspected adverse reactions reported to EudraVigilance for centrally authorised medicinal products in line with Regulation No. 726/2004. The second purpose is to facilitate the monitoring of risk management activities in the European Union by means of the European Pharmacovigilance Issues Tracking Tool (EPITT). Both EudraVigilance and EPITT are accessible to Medicines Regulatory Agencies in the EEA and the European Medicines Agency.

The EU-RMP Annex 1 shall reflect the final version of the EU-RMP as agreed at the time of the initial CHMP Opinion and any following CHMP Opinions referring to updates to the EU-RMP. The electronic submission to EudraVigilance is due within 30 calendar days after the publication of the European Commission Decision (for new marketing authorisations and updates in the context of line extensions) or 30 calendar days after the receipt of the CHMP Opinion (for all other updates to the EU-RMP).

The EU-RMP Annex 1 is set up as a form in Visual Basic. Following completion of the form an XML file will be generated. The electronic XML file should be sent by secure email (via Eudralink) to

h-eurmp-evinterface@ema.europa.eu

1.1. Purpose

The purpose of this document is to provide guidance for filling in the Visual Basic® Form fields associated with creating, follow up and sending the electronic interface between EU-RMP and EudraVigilance.

1.2. Getting started

The EU-RMP Annex 1 (Visual Basic® Form) is available for download from the EudraVigilance website at **http://eudravigilance.emea.europa.eu/human/EURiskManagementPlans.asp**.

This website provides three different installation packages to suit your operation system (EV Interface installation VB.zip). They contain two files **risksetup.msi** and **setup.exe**. Please download the installation package and extract (unzip) the two setup files and save them to your local system. Start setup.exe to install the application on your local system. Please follow the on-screen instructions.

1.3. How to Use this User Manual

In this document for each section and field of the Visual Basic® Form guidance is provided on which information is requested.

Each section of the Visual Basic® Form (subsequently referred to as 'form') is explained separately, introduced by the respective **Section Header** (dark blue rows). Within each section data fields are grouped together (**Field Group**) and each field group contains several data fields (**Field Name**). The right column labelled **Guidance** explains which information is expected to be submitted in the respective data field. Each section is preceded by the corresponding screen print.

Section		
Field Group	**Field Name** Mandatory fields are highlighted in yellow	**Guidance**

The following Visual Basic® Form sections are accessible from the *Start Page* (↳ chapter 3):

- Administrative Information
- Risks

1.4. Layout of the User Manual

Guidance associated with the field group heading is listed under the heading.

Organisation Information

This field group allows the specification of details of the organisation sending the EU-RMP Annex 1 (electronic interface for EudraVigilance).

You have to specify at least one organisation for each electronic interface.

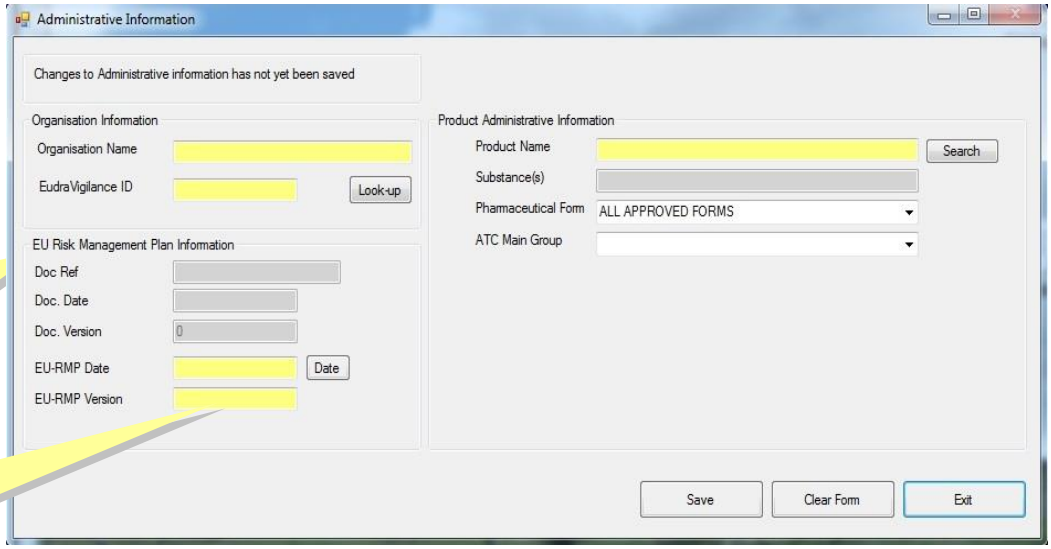
Organisation Information may be saved (press Save) as default for subsequent data entries.

Click functions in the form are framed

Within the guidance text field or field group labels are in italics.

A screen shot of each section or function is provided.

Yellow fields are mandatory, grey fields cannot be populated.



Administrative Information		
Organisation Information	**Organisation Name**	Organisation name as registered in for electronic reporting to EudraVigilance
	EudraVigilance ID	Organisation identifier as used for the EudraVigilance registration process.

The fields you will be filling in are listed in the middle column.

The relevant guidance text is listed in the right column.

2. Form functionalities in alphabetical order

Function	Description
About	Retrieve current version of all look-up tables.
Add / Add	Add a pharmacovigilance or risk minimisation activity,
Add/Modify	Add an additional pharmacovigilance and/or risk minimisation activity.
Clear	Clear a selected pharmacovigilance or risk minimisation activity.
Clear Form	Clear all information from current form.
Clear Search	Clear the search for a Medicinal Product Presentation.
Date	Retrieve a date.
Del	Delete a selected pharmacovigilance/risk minimisation activity from a list-box.
Delete	Delete a selected risk
Download Updates	Download new versions of the Visual Basic Form application including updates to the dictionary files.
Exit	Exit current section and return to *Start Page*.
Load EU-RMP Annex 1	Load a previously saved EU-RMP Annex 1 (XML) into the form.
Look-up	Look-up *EudraVigilance ID* from registered organisations list.
Next …	Switch to next risk as available. To enter a new item click Clear Form to empty data fields.
Previous ….	Switch to previous risk as available.
Quit	Exit the application. All unsaved data will be lost.
Reset Form	Reset the entire form including all sections, sub-sections and data fields.
Save	Save data in the current section.

Function	Description
Save EU-RMP Annex 1	Save EU-RMP Annex 1 to system. The file format is XML. The system will propose a file name using the following information (bold) as entered in the *Administrative Information* section: **Productname**v**1.0**(**01-01-09**).xml Productname — Annex 1 version — Annex 1 version date The file is to be sent via secure Eudralink to h-eurmp-evinterface@emea.europa.eu or by physical media.
Search	Look-up a product, substance or MedDRA term.
Search MedDRA	Look-up MedDRA terms (↳ Chapter 2).
Select	Select a previously added risk, from a list.
Update	Update currently selected risk,

3. Search MedDRA function

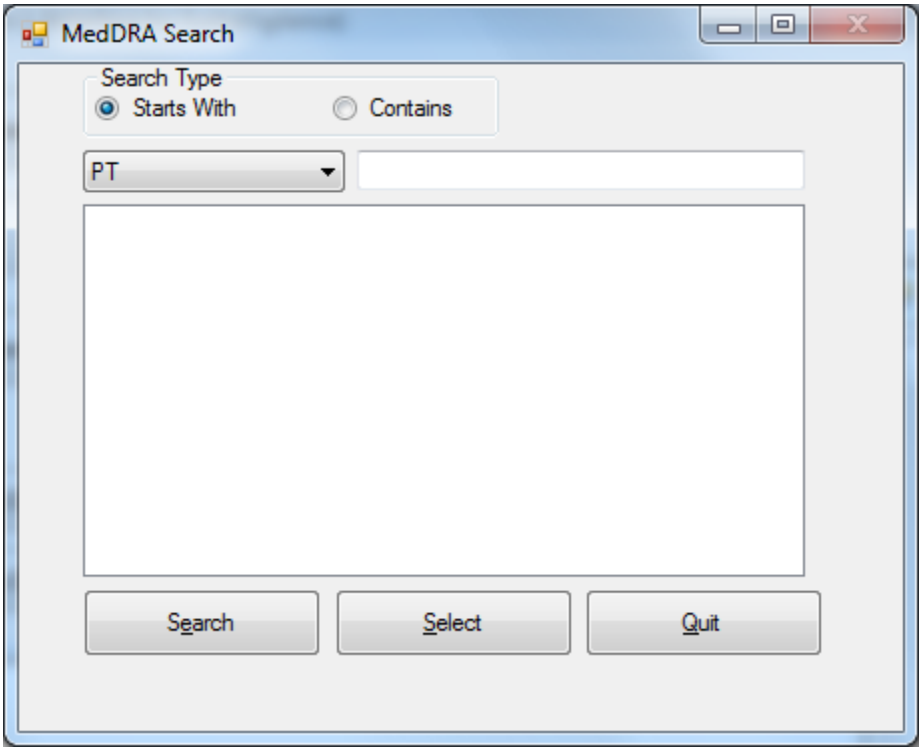
The Search MedDRA function enables the selection of a MedDRA term or Standard MedDRA Query (SMQ) at various levels from a look-up table.

The following MedDRA levels are available:

- MedDRA Preferred Term (PT)
- MedDRA High Level Term (HLT)
- MedDRA High Level Group Term (HLGT)
- MedDRA System Organ Class (SOC)

The following Standard MedDRA Query levels are available:

- Standard MedDRA Query Broad
- Standard MedDRA Query Narrow
- Standard MedDRA Query Child



3.1. How the Search MedDRA function works

1. You have the choice to search for a particular MedDRA term starting with a specific string of characters (e.g. hypertension) or to search a term that contains a specific string of characters (e.g. hypertension). Please select the type of search accordingly.
2. Choose the appropriate MedDRA level from look-up table.
3. Type the characters or word of the desired term into the field next to the selected MedDRA level. Pressing Search will bring up a list of matching terms.
4. Select a term and press Select to include the term in the list of medical terms in the *Medical Terms* sub-section.
5. Alternatively, a term may also be typed directly into the *MedDRA Term/SMQ* field and the system will check for matching terms automatically. To include the typed term press Add.
6. Press Quit to exit.

4. Start Page

The *Start Page* is the main navigation level linking to all sections of the form. Once the sections are populated the corresponding displays to the right show the number of items added/saved. The display colour provides the following information:

Red Information is missing or has not been saved

Green Section is populated

The Download Updates function automatically connects to the internet to retrieve and install updates for the Visual Basic® Form (↳ chapter 2.3) if a corresponding message is displayed.

With Save EU-RMP Annex 1 the XML file is saved to your local system.

XML files may be re-loaded into the form with Load EU-RMP Annex 1 to perform updates.

You may interrupt the population of the Visual Basic® Form at any time to continue later. All information of the currently loaded XML file will be maintained. However to avoid loss of data users are strongly advised to

1. Complete and save the *Administrative Information* section (↳ chapter 4) and
2. Save the EU-RMP Annex 1 to the local system. The system will automatically propose a file name using the following information (bold):

Reset From clears all sections including sub-sections of the form. All unsaved data will be lost.

4.1. Download updates

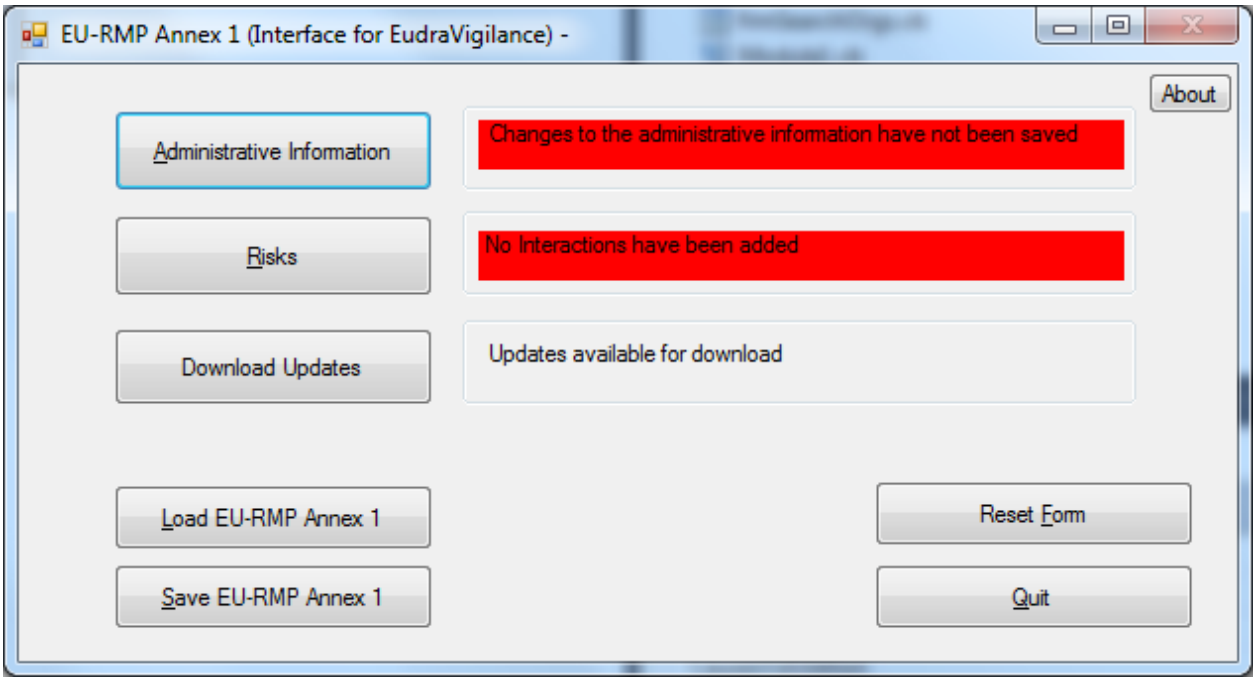
On the *Start page* (↳ chapter 3) the Download Updates function is available.

When starting the application the system automatically checks if new versions and/or updates to the dictionary files are available. If this is the case the *Start Page* displays a corresponding message to the right of the download button.

Before downloading available updates you should save your current work in the application first.

To initiate the download process please press Download Updates. The programme will install new versions and updates automatically.

5. Administrative Information



This section is not repeatable. The *Organisation Information* needs to be submitted only once and may be saved as default for subsequent data entries. The *EU-Risk Management Plan Information* is required for version tracking of future updates of the EU-RMP Annex 1. The application automatically assigns a unique document reference (Doc Ref) to each new Annex 1 file which will be maintained for all subsequent updates. The *Product Administrative Information* determines the medicinal product's active substance(s).

Organisation Information

In the field group *Organisation Information* the *Organisation Name* and *EudraVigilance ID* may be looked-up from a list (↳ chapter 4.1). To include dates the Date function may be used.

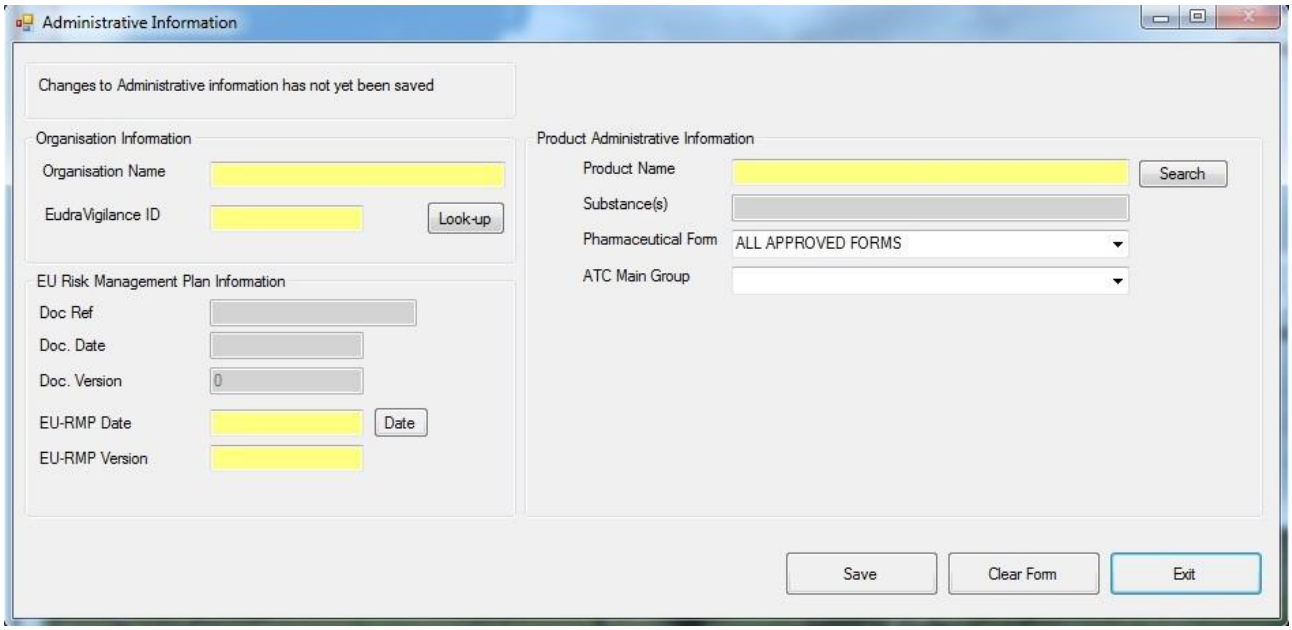
Product Administrative Information

In this section you have to search for your product name by clicking the Search button. All the authorised medicinal product presentations previously entered into the XEVMPD are available.

Select the relevant product from the search results list by clicking Select button. The substance field will be populated automatically (this information is directly linked to the EV code for each medicinal product presentation as available in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)).

Then use the drop-down menu to fill in the pharmaceutical form and ATC main group.

Once population is completed click Save to include the entire *Administrative Information* in the XML file. Press Exit to return to the *Start Page*.



Administrative Information, continued

Administrative Information		
Organisation Information	Organisation Name	Organisation name as registered for electronic reporting to EudraVigilance.
	EudraVigilance ID	Organisation identifier as used for the EudraVigilance registration process. The ID may be either typed or looked-up by using the adjacent Look-up function (↳ chapter 5.1).
EU Risk Management Plan Information	Doc. Ref.	Unique document reference number automatically assigned by the application. This field cannot be edited.
	EU-RMP Date	Date of the EU-RMP version to which the Annex 1 refers.
	EU-RMP Version	Version number of the EU-RMP (as assigned by the organisation) to which the Annex 1 refers.
	Doc. Date	Document date assigned by organisation for tracking purposes.
	Doc. Version	Document version assigned by organisation for tracking purposes.
Product Administrative Information	Product Name	Proposed or approved name of the medicinal product.
	Substance*	Active substance(s) of authorised medicinal product.
	Pharmaceutical Form	Pharmaceutical form of the authorised medicinal product.
	ATC Main Group	• 1st level of ATC code, Anatomical main group

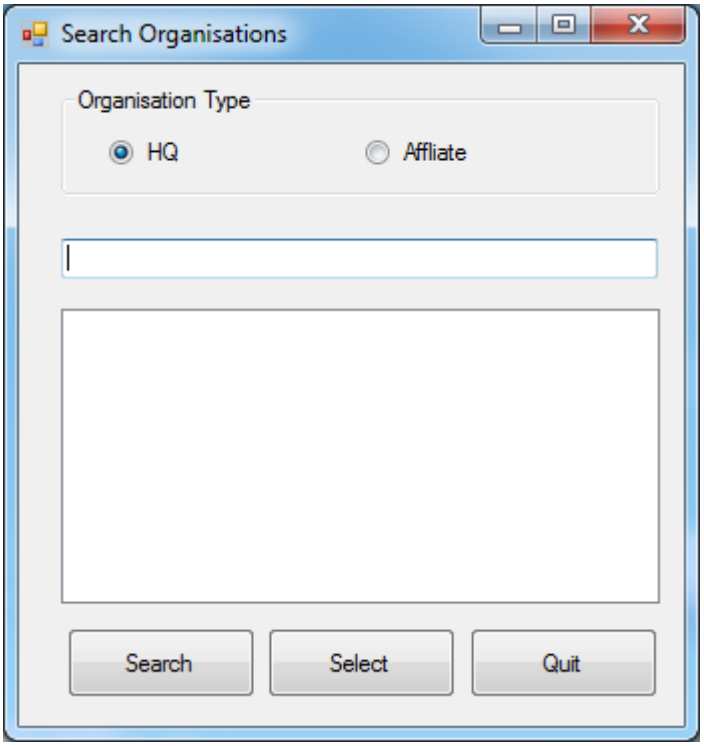
*Please note that this information is directly linked to the unique EV code for each medicinal product presentation as available in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) and no manual population of the marked fields is required.

5.1. Look-up EudraVigilance ID

The *EudraVigilance ID* may be looked-up from a list of organisations registered with EudraVigilance.

Pressing Look-up opens the dialogue box as displayed below.

1. Determine the *Organisation Type* (HQ = Headquarter; Affiliate = affiliated organisation).
2. Type the name or first characters of name of the organisation and press Search.
3. Select an organisation and press Select to include both the *Organisation Name* and *EudraVigilance ID* into the form.
4. Press Quit to exit.



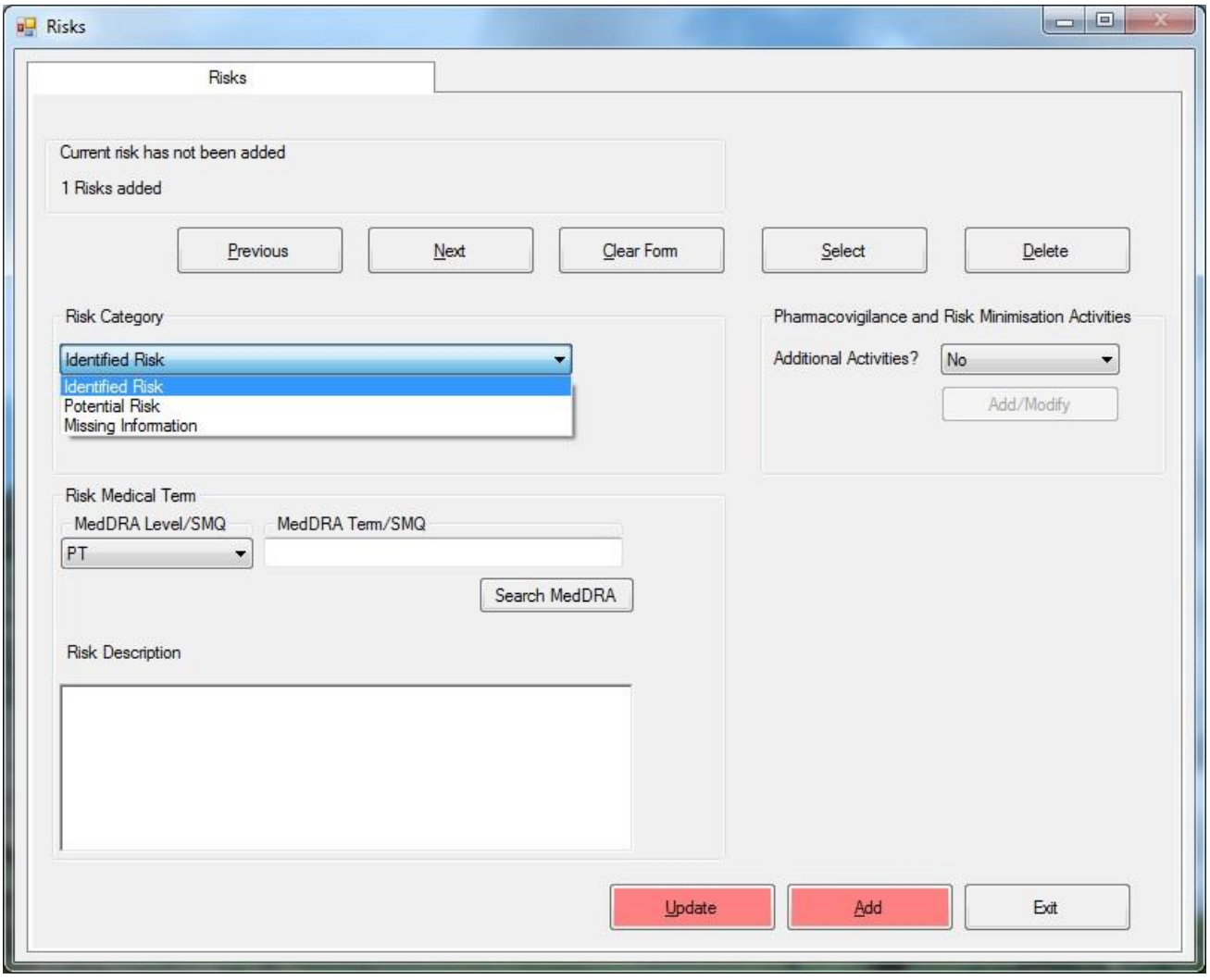
6. Risk(s)

This section provides three risks category, *Identified Risks*, *Potential Risks and Missing information*. These risk categories can be selected using the drop-down menu in the field "Risk Category". Each identified risk is specified by two field groups, *Risk Medical Term*, *Pharmacovigilance and Risk Minimisation Activities*.

6.1. Identified Risk

In line with the EU-RMP wording a brief description of the identified risk should be entered in the second free text field *Risk Description*. The corresponding MedDRA term/SMQ (only one) may either be typed or looked-up by using the Search MedDRA function (↳ chapter 2).

The third field group *Pharmacovigilance and Risk Minimisation Activities* specifies any additional (not routine) pharmacovigilance and risk minimisation activities linked to the identified risk.



Identified Risk(s), continued

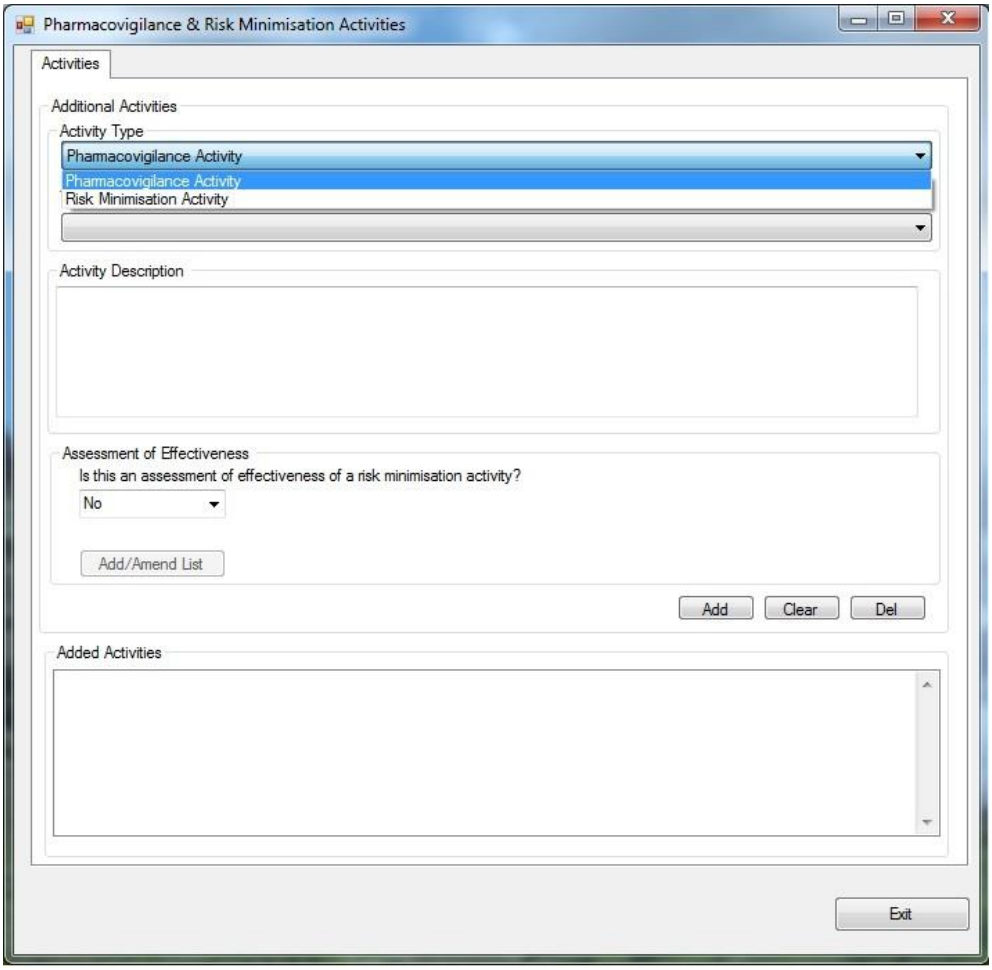
Click Add to include the entire *Identified Risk* in the XML file.

Press the Clear Form button to enter further *Identified Risks*. You may toggle between risks by using the Previous and Next buttons. To look-up a risk press Select and choose risk from list. Click Update to include changes to the current form content. To delete, select a risk from list and press Delete.

To enter an additional pharmacovigilance or risk minimisation activity click Add/Modify to open the dialogue box below. In this section you first have to go through the field additional activity. Then, select which activity type you want to enter, either, *Pharmacovigilance Activities* or *Risk Minimisation Activities*.

6.2. Pharmacovigilance Activities

In activity type, select "Pharmacovigilance Activity".



Identified Risk(s), continued

Select the appropriate type category of pharmacovigilance activity from the list-box. If such category does not exist, please select the category 'Other' and provide details in the free-text field *Additional Details*.

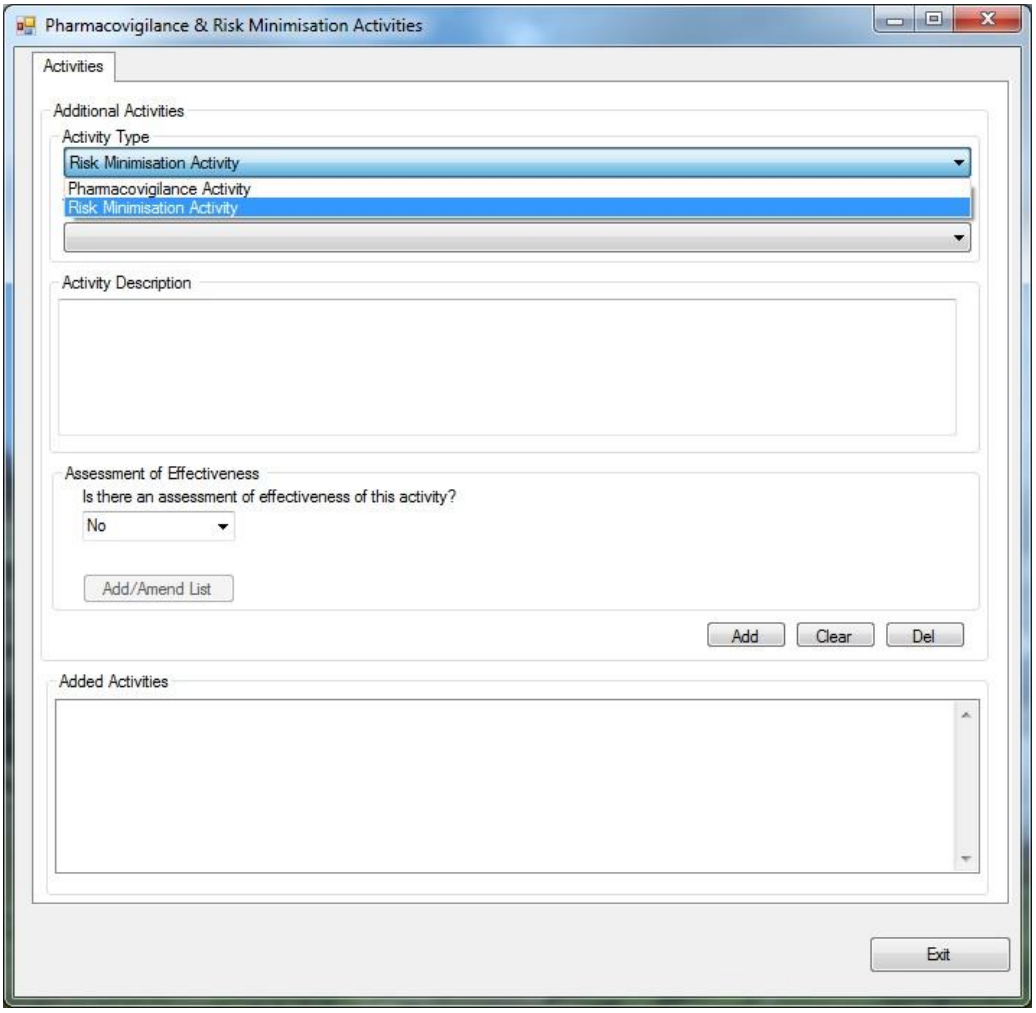
Additional Pharmacovigilance Activities
Active Surveillance - Sentinel Sites
Active Surveillance - Intensive monitoring schemes
Active Surveillance - Prescription Event Monitoring
Active Surveillance - Registry
Observational Study - Cross-sectional Study (Survey)
Observational Study - Cohort Study
Observational Study - Case-control Study
Observational Study - Case Series
Observational Study - Case-crossover
Observational Study - Case-time-control Study
Observational Study - Drug Utilisation Study
Pre-/clinical Studies - Pharmacokinetic Study
Pre-/clinical Studies - Pharmacodynamic Study
Pre-/clinical Studies - Drug Interaction Study
Pre-/clinical Studies - Randomised Controlled Trial
Pre-/clinical Studies - Large Simple Trial
Other

Provide a description of the selected pharmacovigilance activity in the free text field *Activity Description* (e.g. *Study title and EUDRACT number for a post-authorisation safety study*).

Answer the question regarding the assessment of effectiveness of risk minimisation activity. If your answer is "Yes", this pharmacovigilance activity will be reported in a list to match the pharmacovigilance activity with the risk minimisation activity it assesses.

Click Add to include the selected category which will be listed as *Added Activity* in the list-box underneath. Press the Clear button to enter further pharmacovigilance activities. To delete an activity, select activity from list-box and press Del.

6.3. Risk Minimisation Activities



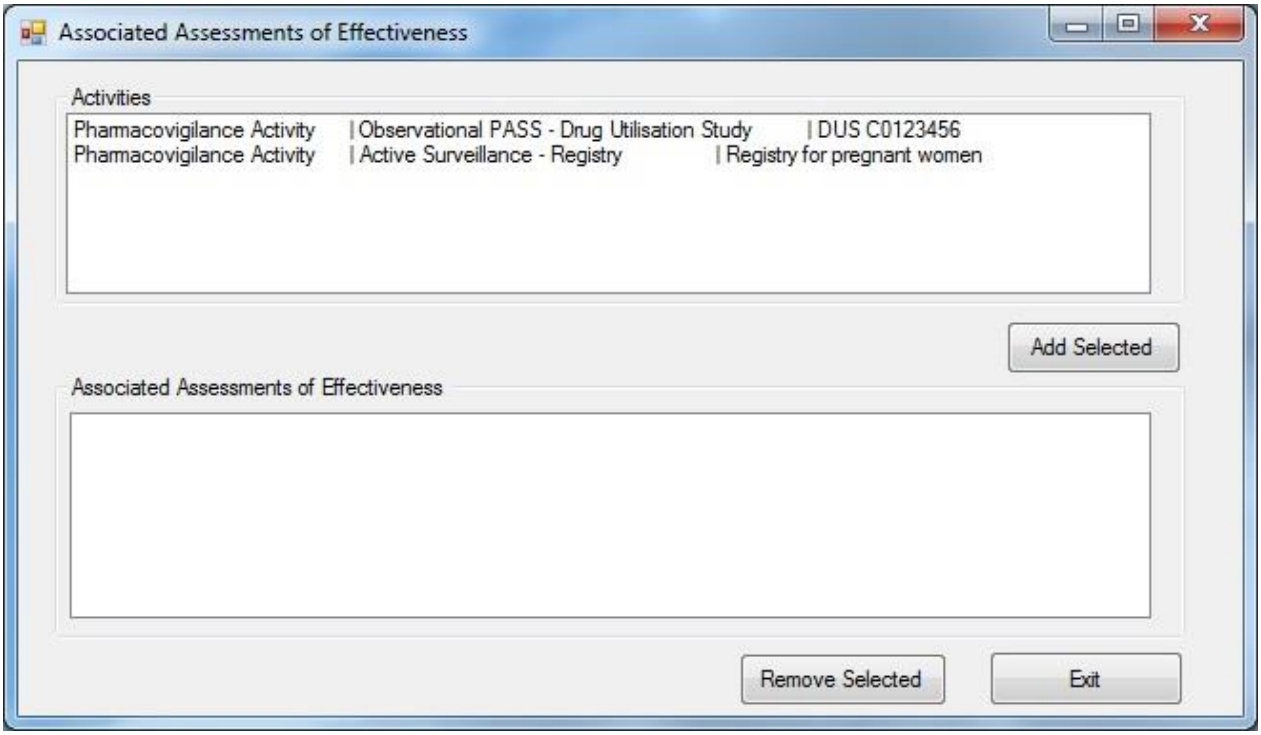
In activity type, select "Risk Minimisation activity". Select the appropriate type category of risk minimisation from the list-box. If such category does not exist, please select the category 'Other' and provide details in the free-text field *Additional Details*.

Additional Risk Minimisation Activities
HCP Education - Dear Healthcare Professional Letter
HCP Education - Physician's guide to prescribing
HCP Education - Pharmacist's guide to dispensing
HCP Education - Prescribing/dispensing algorithm/checklist
HCP Education - Specific training programme
Patient Education - Patient Alert Card
Patient Education - Patient Reminder Card
Patient Education - Patient Information Brochure/Booklet
Other

Provide a description of the selected risk minimisation activity in the free text field Activity*Description* (e.g. *Dear Healthcare Professional Letter key messages*).

Answer the question regarding the assessment of effectiveness of risk minimisation activity. If your answer is "Yes" press the Add/Amend List button. It opens a new window. A list with pharmacovigilance activities shows up. This list contains the activities previously recorded for which you selected "Yes" for the question related to assessment of effectiveness of a risk minimisation. If your pharmacovigilance activity does not appear in the list, return in the section Pharmacovigilance activity, and don't forget to select "Yes" regarding the question for assessment of effectiveness of risk minimisation activity.

Add the Pharmacovigilance Activity planned to minimise the selected risk by clicking on Add Selected. Press Exit to return to the *Activities* form.



Click Add to include the selected category which will be listed as *Added Activity* in the list-box underneath.

Press the Clear button to enter further risk minimisation activities. To delete an activity, select activity from list-box and press Del.

Press Exit to return to the selected *Identified Risk* form. **IMPORTANT!** Click Update to save all changes to the current form before you toggle to the next risk or exit the form.

Press Exit to return to *Start Page*.

Identified Risk(s)		
Risk Medical Terms	Risk Description	Summary description of identified risk(s) consistent with EU-RMP
	MedDRA Level/SMQ	Determination of the level of MedDRA or Standard MedDRA Query (SMQ) by selecting the appropriate level from a look-up table.
	MedDRA Term/SMQ	The most appropriate level of MedDRA or SMQ should be used to capture the medical concept (only one) related to an identified risk (such as the SMQ *Possible drug related hepatic disorders – comprehensive search* for drug induced hepatotoxicity). ↳ Chapter 2 for how to enter a MedDRA term or SMQs.
Pharmacovigilance and Risk Minimisation Activities	Type category *(Pharmacovigilance)*	Selection of type category of **additional** pharmacovigilance activities. Such activities may include active surveillance methods, epidemiological methods for post-authorisation safety studies or pre-clinical and/or clinical trials. If none of the pre-defined categories apply a new activity type may be entered by selecting the category *Other*.
	Assessment of effectiveness	Answer by "Yes" or "No" the question related to the Assessment of Effectiveness of Risk Minimisation.
	Activity Description *(Pharmacovigilance)*	Free text field to provide **additional** pharmacovigilance activity details. This could be the title of a study protocol including EUDRACT number, or the title of an ongoing study including EUDRACT number or an outline of an intensive monitoring scheme using follow-up questionnaires. The information provided in this field should be consistent with the information provided in the EU-RMP.
	Type Category *(Risk Minimisation)*	Selection of type category of **additional** risk minimisation activities. Such activities may include healthcare professional educational programmes, patient educational programmes, limited prescription, or controlled distribution. If none of the pre-defined categories apply a new activity type may be entered by selecting the category *Other*.
	Activity Description *(Risk Minimisation)*	Free text field to provide **additional** risk minimisation activity details. For educational programmes the proposed actions outlined in section 4 (risk minimisation plan) of the EU-RMP should be provided. Otherwise, The information provided in this field should be consistent with the information provided in the EU-RMP.
	Assessment of effectiveness	Answer by "Yes" or "No" the question related to the Assessment of Effectiveness of Risk Minimisation.

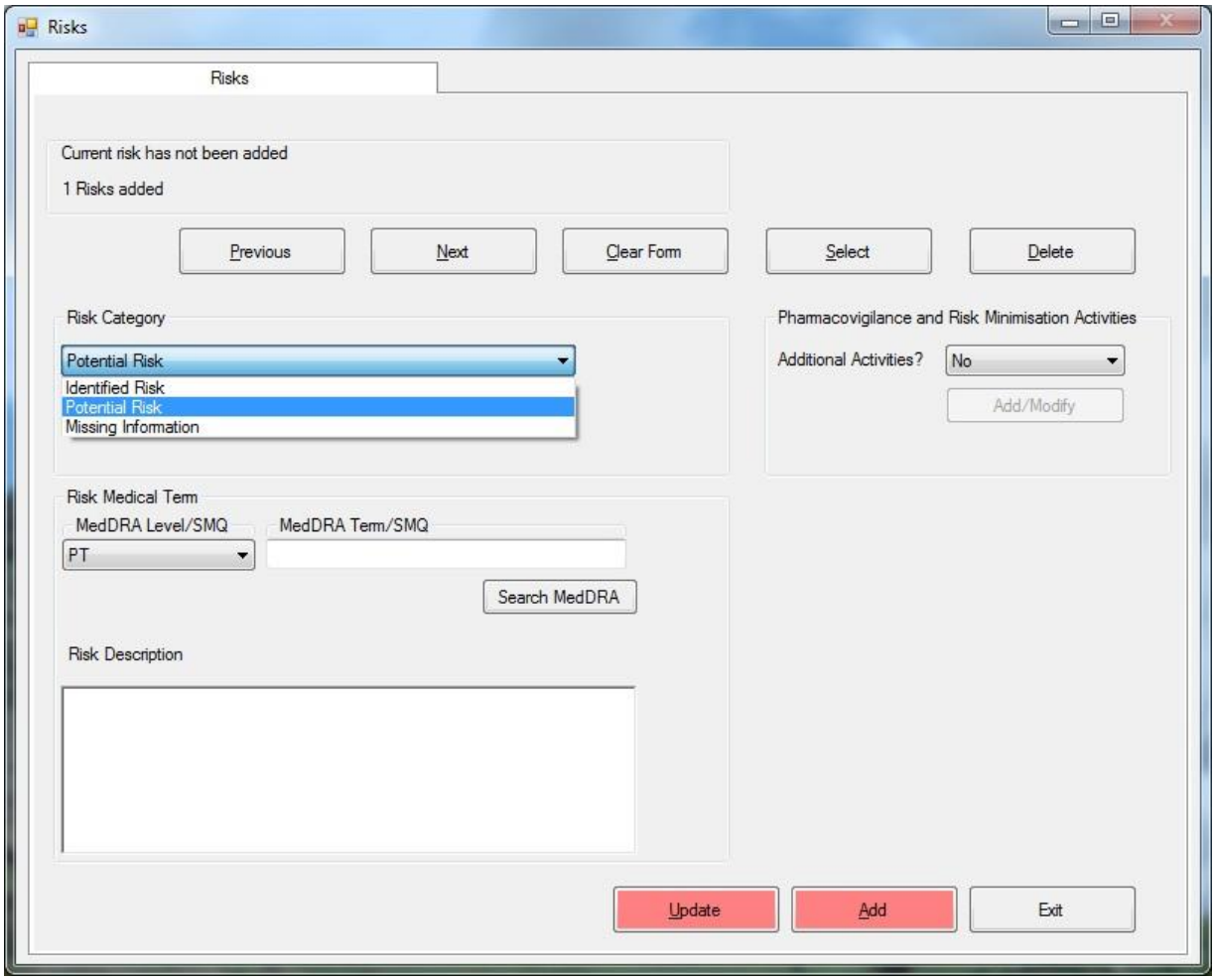
7. Potential Risk(s)

This section provides three risks category, Identified Risks, Potential Risks and Missing information.

Each potential risk is specified by two field groups, Risk Medical Terms, and Pharmacovigilance and Risk Minimisation Activities.

In line with the EU-RMP wording a brief description of the potential risk should be entered in the second free text field Risk Description. The corresponding MedDRA term or Standard MedDRA Query (SMQ) (only one) may either be typed or looked-up by using the Search MedDRA function (↳ chapter 2).

The second field group Pharmacovigilance and Risk Minimisation Activities specifies any additional (not routine) pharmacovigilance and risk minimisation activities linked to the potential risk.



Potential Risk(s), continued

To enter an additional pharmacovigilance or risk minimisation activity click Add/Modify to open the dialogue box as shown previously for identified risks *(↳ Chapter 6.1 Identified Risk) on page 14*.

Click Add to include the entire *Potential Risk* in the XML file.

Press the Clear Form button to enter further *Potential Risks*. You may toggle between risks by using the Previous and Next buttons. To look-up a risk press Select and choose risk from list. Click Update to include changes to the current form content. To delete, select a risk from list and press Delete.

Press Exit to return to *Start Page.*

Potential Risk(s)		
Risk Medical Terms	Risk Description	Summary description of potential risk(s) consistent with EU-RMP
	MedDRA Level/SMQ	Determination of the level of MedDRA or Standard MedDRA Query (SMQ) by selecting the appropriate level from a look-up table.
	MedDRA Term/SMQ	The most appropriate level of MedDRA or SMQ should be used to capture the medical concept (only one) related to a potential risk (such as the SMQ *Possible drug related hepatic disorders – comprehensive search* for drug induced hepatotoxicity). ↳ Chapter 2 for how to enter a MedDRA term or SMQs.

Pharmacovigilance and Risk Minimisation Activities	Type category *(Pharmacovigilance)*	Selection of type category of **additional** pharmacovigilance activities. Such activities may include active surveillance methods, epidemiological methods for post-authorisation safety studies or pre-clinical and/or clinical trials. If none of the pre-defined categories apply a new activity type may be entered by selecting the category *Other*.
	Assessment of effectiveness	Answer by "Yes" or "No" the question related to the Assessment of Effectiveness of Risk Minimisation.
	Activity Description *(Pharmacovigilance)*	Free text field to provide **additional** pharmacovigilance activity details. This could be the title of a study protocol including EUDRACT number, or the title of an ongoing study including EUDRACT number or an outline of an intensive monitoring scheme using follow-up questionnaires. The information provided in this field should be consistent with the information provided in the EU-RMP.
	Type Category *(Risk Minimisation)*	Selection of type category of **additional** risk minimisation activities. Such activities may include healthcare professional educational programmes, patient educational programmes, limited prescription, or controlled distribution. If none of the pre-defined categories apply a new activity type may be entered by selecting the category *Other*.
	Activity Description *(Risk Minimisation)*	Free text field to provide **additional** risk minimisation activity details. For educational programmes the proposed actions outlined in section 4 (risk minimisation plan) of the EU-RMP should be provided. Otherwise, The information provided in this field should be consistent with the information provided in the EU-RMP.
	Assessment of effectiveness	Answer by "Yes" or "No" the question related to the Assessment of Effectiveness of Risk Minimisation.

8. Missing Information

This section is dedicated to capture **missing information** as identified in the EU-RMP Safety Specification with reference to

A. **interactions** with substances or substance classes,

B. the **potential of off-label use** (including off-label paediatric use) or

C. **populations not studied** in the pre-authorisation phase such as

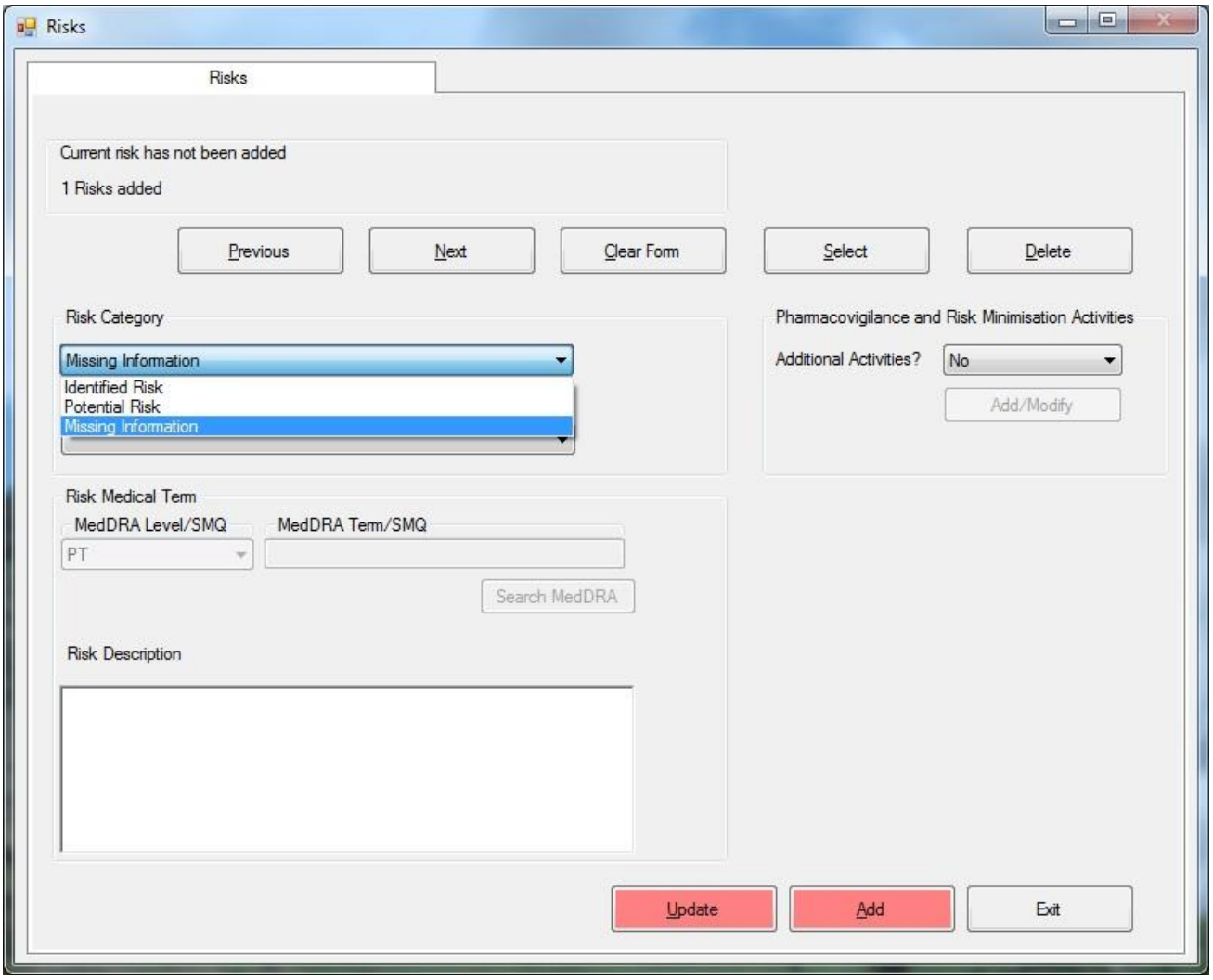
- children
- elderly
- pregnant and lactating women
- patients with relevant co-morbidity such as clinically significant renal, hepatic or cardiac impairment
- patients with disease severity different from that studied in clinical trials
- sub-populations with genetic polymorphisms
- patients of different ethnic origins

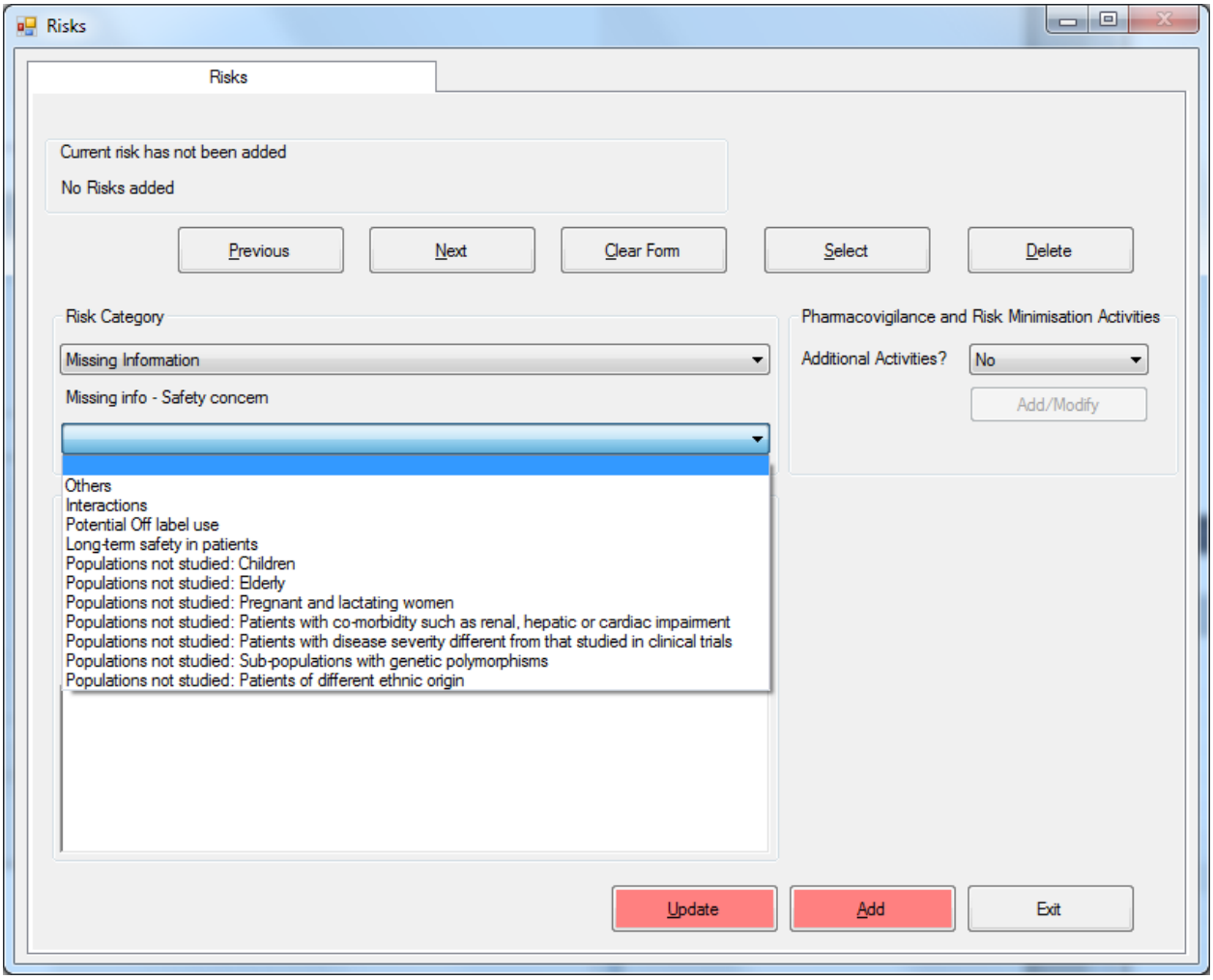
Missing information
interactions with substances or substance classes
potential of off-label use (including off-label paediatric use)
populations not studied in the pre-authorisation phase: children
populations not studied in the pre-authorisation phase: elderly
populations not studied in the pre-authorisation phase: pregnant and lactating women
populations not studied in the pre-authorisation phase: patients with relevant co-morbidity such as clinically significant renal, hepatic or cardiac impairment
populations not studied in the pre-authorisation phase: patients with disease severity different from that studied in clinical trials
populations not studied in the pre-authorisation phase: sub-populations with genetic polymorphisms
populations not studied in the pre-authorisation phase: patients of different ethnic origins

Missing Information, continued

In Risk category, select "Missing information" in the drop-down list.

Then choose one of the terms mentioned above. Select "others" if none of the terms match with the safety specification.





In line with the EU-RMP wording a brief description of the missing information should be entered in the free text field *Risk Description*. The third field group *Pharmacovigilance and Risk Minimisation Activities* specifies any additional (not routine) pharmacovigilance and risk minimisation activities linked to the missing information.

To enter an additional pharmacovigilance or risk minimisation activity click Add/Modify to open the dialogue box as shown previously for identified risks *(Chapter 5.1 Identified Risk) on page 22*.

Click Add to include the entire *Missing information* in the XML file.

Press the Clear Form button to enter further *Missing information*. You may toggle between risks by using the Previous and Next buttons. To look-up a risk press Select and choose risk from list. Click Update to include changes to the current form content. To delete, select a risk from list and press Delete.

Press Exit to return to *Start Page.*

Missing information		
Risk Medical Terms	Risk Description	Summary description of Missing information consistent with EU-RMP
	Look-up table	Selection of the consistent missing information among the proposed terms. Select “others” if none of them match with the safety specification.
Pharmacovigilance and Risk Minimisation Activities	Type category *(Pharmacovigilance)*	Selection of type category of **additional** pharmacovigilance activities. Such activities may include active surveillance methods, epidemiological methods for post-authorisation safety studies or pre-clinical and/or clinical trials. If none of the pre-defined categories apply a new activity type may be entered by selecting the category *Other*.
	Assessment of effectiveness	Answer by “Yes” or “No” the question related to the Assessment of Effectiveness of Risk Minimisation.
	Activity Description *(Pharmacovigilance)*	Free text field to provide **additional** pharmacovigilance activity details. This could be the title of a study protocol including EUDRACT number, or the title of an ongoing study including EUDRACT number or an outline of an intensive monitoring scheme using follow-up questionnaires. The information provided in this field should be consistent with the information provided in the EU-RMP.
	Type Category *(Risk Minimisation)*	Selection of type category of **additional** risk minimisation activities. Such activities may include healthcare professional educational programmes, patient educational programmes, limited prescription, or controlled distribution. If none of the pre-defined categories apply a new activity type may be entered by selecting the category *Other*.
	Activity Description *(Risk Minimisation)*	Free text field to provide **additional** risk minimisation activity details. For educational programmes the proposed actions outlined in section 4 (risk minimisation plan) of the EU-RMP should be provided. Otherwise, The information provided in this field should be consistent with the information provided in the EU-RMP.
	Assessment of effectiveness	Answer by “Yes” or “No” the question related to the Assessment of Effectiveness of Risk Minimisation.

9. Interactions

Each interaction should be logically added in one of the three risk category (Identified Risk, Potential Risk or Missing Information). For the two first categories, please select the MedDRA term "drug interaction" and for Missing Information select the term "interactions" in the look-up table. Add a brief description in the field Risk Description.

The third field group Pharmacovigilance and Risk Minimisation Activities specifies any additional (not routine) pharmacovigilance and risk minimisation activities linked to this interaction.

To enter an additional pharmacovigilance or risk minimisation activity click Add/Modify to open the dialogue box as shown previously for identified risks *(↳ Chapter 5.1 Identified Risk) on page 22*.

Click Add to include the entire *Interaction* in the XML file.

Press the Clear Form button to enter further *Interaction*. You may toggle between risks by using the Previous and Next buttons. To look-up a risk press Select and choose risk from list. Click Update to include changes to the current form content. To delete, select a risk from list and press Delete.

Press Exit to return to *Start Page.*

Interactions		
Risk Medical Terms	Risk Description	Name of the interactive substance(s) or substance class(es) consistent with EU-RMP and proposed or approved Summary of Product Characteristics section 4.5. All labelled interacting substances or substance classes should be covered.
	MedDRA Level/SMQ (identified and potential risk)	Determination of the level of MedDRA or Standard MedDRA Query (SMQ) by selecting the PT level from the look-up table.
	MedDRA Term/SMQ (identified and potential risk)	The MedDRA term "Drug interaction" should be selected. ↳ Chapter 2 for how to enter a MedDRA term or SMQs.
	Look-up table (missing information)	Selection of the consistent missing information among the proposed terms. Select "others" if none of them match with the safety specification.
Pharmacovigilance and Risk Minimisation Activities	Type category *(Pharmacovigilance)*	Selection of type category of **additional** pharmacovigilance activities. Such activities may include active surveillance methods, epidemiological methods for post-authorisation safety studies or pre-clinical and/or clinical trials. If none of the pre-defined categories apply a new activity type may be entered by selecting the category *Other*.

	Activity Description *(Pharmacovigilance)*	Free text field to provide **additional** pharmacovigilance activity details. This could be the title of a study protocol including EUDRACT number, or the title of an ongoing study including EUDRACT number or an outline of an intensive monitoring scheme using follow-up questionnaires. The information provided in this field should be consistent with the information provided in the EU-RMP.
	Type Category *(Risk Minimisation)*	Selection of type category of **additional** risk minimisation activities. Such activities may include healthcare professional educational programmes, patient educational programmes, limited prescription, or controlled distribution. If none of the pre-defined categories apply a new activity type may be entered by selecting the category *Other*.
	Activity Description *(Risk Minimisation)*	Free text field to provide **additional** risk minimisation activity details. For educational programmes the proposed actions outlined in section 4 (risk minimisation plan) of the EU-RMP should be provided. Otherwise, The information provided in this field should be consistent with the information provided in the EU-RMP.

10. Final steps

1. Before you quit the application (Quit) please press Save EU-RMP Annex 1 to save the XML file to your local system and to rename the file if applicable.
2. You may interrupt the population of the Visual Basic® Form at any time to continue later. All information of the XML file currently loaded in to application will be maintained.
3. Please send the XML file by email to h-eurmp-evinterface@ema.europa.eu indicating the **product name**, the **substance** and the **EMEA procedure number** in the subject header. You will receive an acknowledgement reply within 15 days at the latest.