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Guidance for submission and validation of electronic declaration of interests and electronic curriculum vitae

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1. Scope

This guidance document details the steps for the submission of the electronic declaration of interests (e-DoI) to the European Medicines Agency (EMA) and for the submission of the electronic curriculum vitae (e-CV) and validation of the submitted e-DoI using the EMA Meeting Portal (MMSe).

In summary, the following steps are required to submit an e-DoI and e-CV:

- Complete e-DoI (blank form for new experts or current e-DoI for update for existing experts)



- Click on 'Submit by email' and click 'OK'
- Select method of sending and click 'Continue'
- Send the automatically generated e-mail (Outlook) or create and send an e-mail with e-DoI in xml format attached (webmail)
- When receiving confirmation e-mail, click on link in e-mail
- Log in with single-sign-on credentials (same as for MMD, Eudralink, MMS – provided by EMA)
- In MMSe, go to Curriculum Vitae tab
- Tick box 'I am a patient representative' if applicable
- Update e-CV as appropriate or upload a new version of CV from the Europass website
- Tick box 'I confirm my CV is up-to-date' (bottom of page)
- Click on 'Submit CV' (bottom of page)
- In MMSe, go to Declaration of Interests tab
- Select submitted e-DoI
- Tick 'I confirm the information declared on this form is accurate to the best of my knowledge and I acknowledge that ...'
- Tick box 'I am a patient representative' if applicable
- Click on 'Validate selected submission'

2. Electronic declaration of interests form

2.1. New experts

New experts nominated for involvement in an EMA activity will be provided with a blank electronic declaration of interests and confidentiality undertaking (e-DoI) form (see figure 1) by the contact point of the nominating authority - either the National Competent Authority (NCA) (for member state nominations) or the EMA (for EMA nominations).

In order to properly see and complete the e-DoI form, Adobe Acrobat Reader version 7.0 or above needs to be installed on your computer. If this is not the case, use one of the links provided below to download it for free:

If you work on a Windows system:

<http://get.adobe.com/reader/?promoid=HRZAC>

If you work on a Mac system:

<http://www.adobe.com/support/downloads/product.jsp?platform=macintosh&product=10>

Figure 1. Blank e-DoI form

Public Declaration of Interests and Confidentiality Undertaking

INSTRUCTIONS

This form consists of three parts: your **Personal Details**, **Public Declaration of Interests** and **Confidentiality Undertaking**. All parts must be duly completed. **The form is designed to be completed electronically and the data entered stored electronically.** You are responsible for the accuracy and completeness of the submitted information. Please be advised that once you have submitted and signed the form, the Agency will publish your declaration of interests on its website.

WARNING - If you are already registered in the EMA's Experts database you should not fill in this blank form but rather ask us for your previous declaration for update.

SECTION 1: PERSONAL DETAILS Please click on any of the footnotes for further information.

First name:	<input style="width: 95%;" type="text"/>	NOTE: Please write your full first and last name as mentioned on your identity card/passport.
Last name:	<input style="width: 95%;" type="text"/>	
Organisation / company¹:	<input style="width: 95%;" type="text"/>	
Country²:	<input style="width: 95%;" type="text"/>	
E-mail address:	<input style="width: 95%;" type="text"/>	
Type of activity³:	<input style="width: 95%;" type="text" value="EMA Expert (nominated for involvement in EMA activities)"/>	

SECTION 2: PUBLIC DECLARATION OF INTERESTS

If you have interests to declare, please click 'Yes' to the relevant questions and provide further information. All questions in this section must be answered. Your declaration will not be accepted if any fields are left empty.

All current and/or past interests from the last 3 years should be declared. In the case of previous employment in a pharmaceutical company in an executive role or lead role in the development of a medicinal product (see section 2.1), please declare all such past interests from your entire career.

For more information on which interests to declare, please see the European Medicines Agency policy on the handling of declarations of interests of scientific committees' members and experts and the procedural guidance on inclusion of declared interests in the European Medicines Agency's electronic declaration of interests form.

I do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests in the pharmaceutical industry I have currently (at the time of completion of the form) or have had (in the last 3 years and in case of previous employment in an executive role or lead role in the development of a medicinal product at any stage of my career) are those listed below:

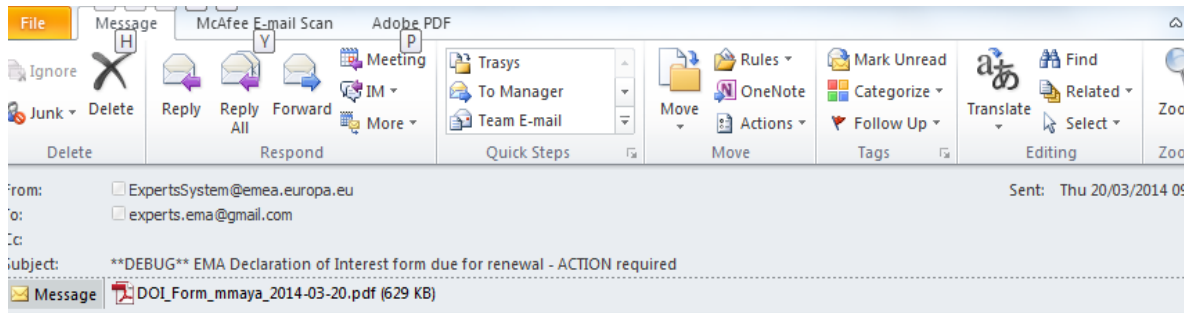
2.2. Existing experts

The e-DoI must be completed and updated at least on an annual basis. Automated e-mails are sent to existing experts one month before the current e-DoI is due for renewal (see figure 2).

Existing experts can update their e-DoI at any point in time, e.g. to declare additional interests. You can request your current e-DoI for update from the Experts database co-ordinators at the EMA (expertsdb@ema.europa.eu), your contact person at the EMA or the contact point at your NCA. Alternatively, you can download your current e-DoI from MMSe (see figure 3).

Existing experts should not use a blank e-DoI form.

Figure 2. Automated e-mail for renewal of e-DoI



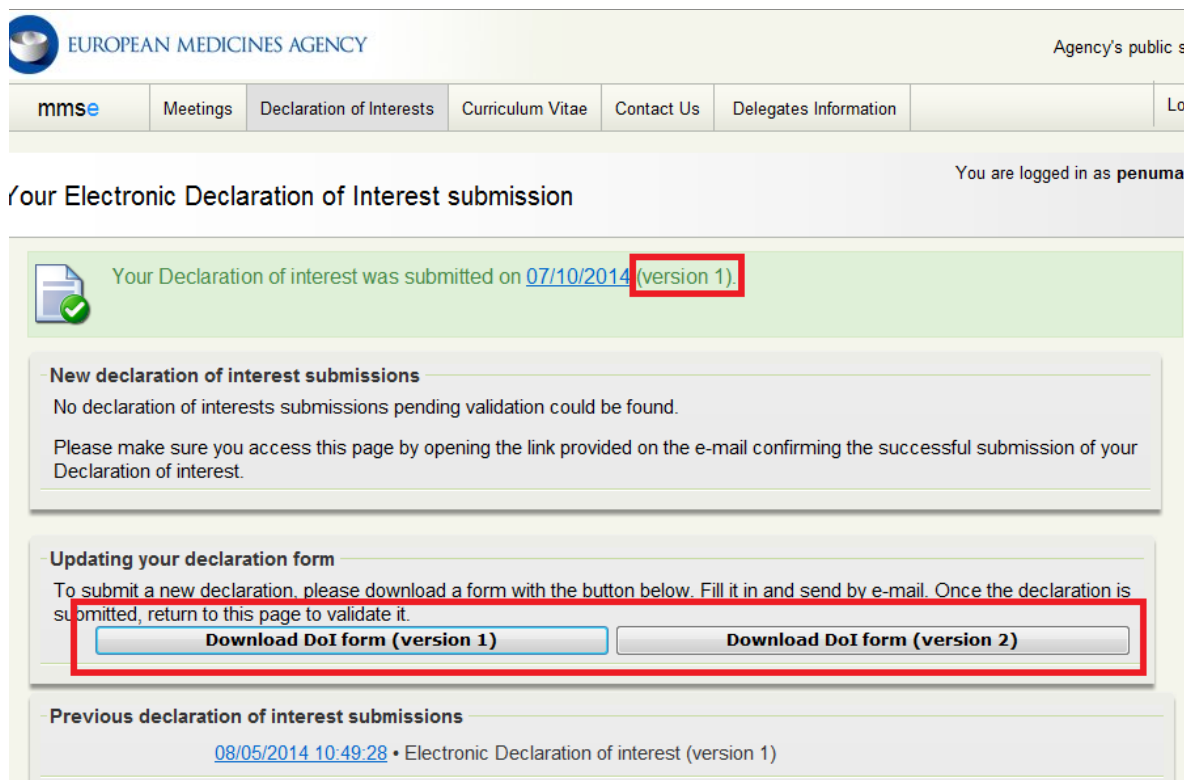
EMA Declaration of Interest form due for renewal - ACTION required.

Dear Maria Maya

In line with Article 63.2 of Regulation EC 726/2004, and with the EMA Policy on the Handling of Conflicts of Interest, all experts involved in EMA activities are required to make an annual declaration of Interests.

Your Annual EMA Declaration of Interest form is now due for renewal. **Please complete the attached form and submit as soon as possible, following the instructions provided. Please also review and update your e-CV.** Please note that, in the event that an updated updated DoI form and/or CV are not available before the date of expiry of your current documents (i.e. date of signature on DoI/review of the CV are older than 1 year), you will not be able to participate in EMA activities until this update is provided.

Figure 3. Download current e-DoI form from MMSe



3. Completion of the e-DoI form

- Complete all mandatory fields and all parts of the e-DoI form relevant to you (see figure 4 and 5).

Figure 4. Example of completed section 1 of e-DoI

Public Declaration of Interests and Confidentiality Undertaking

INSTRUCTIONS

This form consists of three parts: your **Personal Details**, **Public Declaration of Interests and Confidentiality Undertaking**. All parts must be duly completed. **The form is designed to be completed electronically and the data entered stored electronically.** You are responsible for the accuracy and completeness of the submitted information. Please be advised that once you have submitted and signed the form, the Agency will publish your declaration of interests on its website.

WARNING - If you are already registered in the EMA's Experts database you should not fill in this blank form but rather ask us for your previous declaration for update.

SECTION 1: PERSONAL DETAILS Please click on any of the footnotes for further information.

First name: **NOTE:** Please write your full first and last name as mentioned on your identity card/passport.
Last name:
Organisation / company¹:
Country²:
E-mail address:
Type of activity³:

SECTION 2: PUBLIC DECLARATION OF INTERESTS

If you have interests to declare, please click "Yes" to the relevant questions and provide further information. All questions in this section must be answered. Your declaration will not be accepted if any fields are left empty.

Figure 5. Example of completed section 2.1 of e-DoI

2.1 Employment No Yes

Employment with a pharmaceutical company means any form of occupation, part-time or full-time, paid or unpaid, in the company. A pharmaceutical company means any legal or natural person whose focus is to research, develop, manufacture, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, marketing and maintenance of medicinal products (which might also be carried out in house) are outsourced on a contract basis. CROs or consultancy companies providing advice or services relating to the above activities, fall under the definition of a pharmaceutical company. Independent researchers and research organisations including universities and learned societies are excluded from the scope of the definition of a pharmaceutical company.

Employment in a pharmaceutical company in an **executive role** and/or a **lead role** in the development of a medicinal product **AT ANY STAGE OF YOUR CAREER** should be declared. **Cross product responsibility** other than an executive role within a company and/or **individual product responsibility** other than lead role in the development of a medicinal product **IN THE LAST 3 YEARS** should be declared.

EMPLOYMENT Please click on any of the footnotes for further information.

Time period¹: Current Past
From month: **From year:** **To month:** **To year:**
Name of pharmaceutical company²:
Function³:

- Executive role (at any stage of your career)
- Lead role in the development of a medicinal product (at any stage of your career)
- Cross product responsibility other than executive role (in the last 3 years)
- Individual product responsibility other than lead role in the development of a medicinal product (in the last 3 years)

Title or role within the company:

EMPLOYMENT Please click on any of the footnotes for further information.

Time period¹: Current Past
From month: **From year:** **To month:** **To year:**
Name of pharmaceutical company²:
Function³:

- Executive role (at any stage of your career)
- Lead role in the development of a medicinal product (at any stage of your career)
- Cross product responsibility other than executive role (in the last 3 years)
- Individual product responsibility other than lead role in the development of a medicinal product (in the last 3 years)

Product name	Therapeutic indication	Add
<input type="text" value="Product x (active substance Y)"/>	<input type="text" value="Indication z"/>	<input type="button" value="X"/>

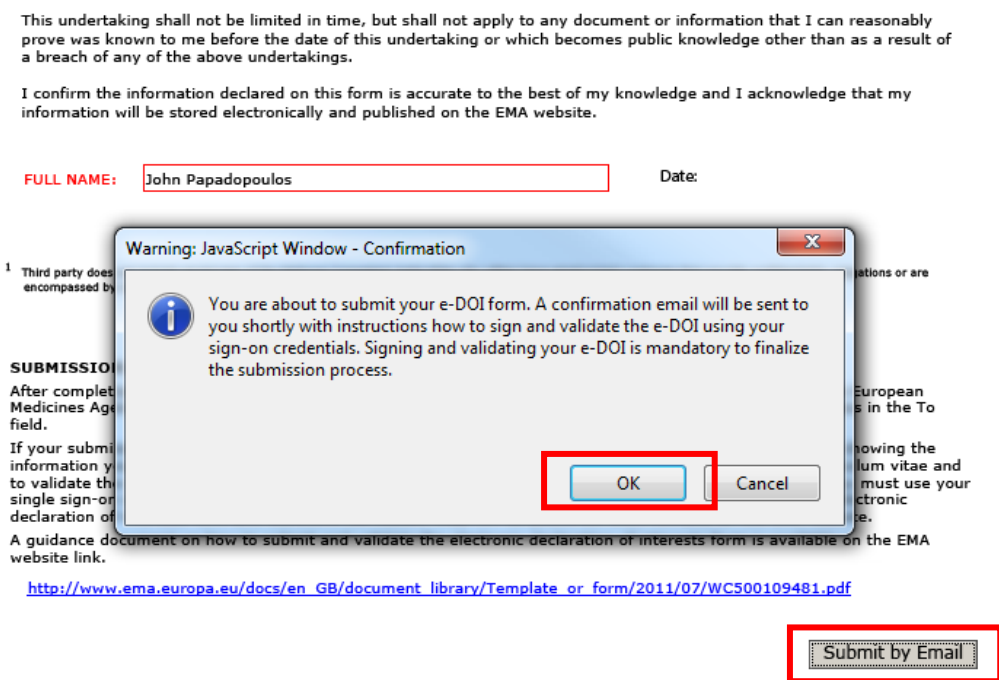
4. Submission of the e-DoI form

- After completing the e-DoI form, click on the '**Submit by Email**' button at the end of the document (see figure 6).

Note: It is strongly advised to save the completed form in pdf format on your computer prior to submission in case it has to be re-submitted or amended after the first submission. As the submitted form is converted to an xml format, it will be impossible to send it back to you to amend/update before the final signature and validation.

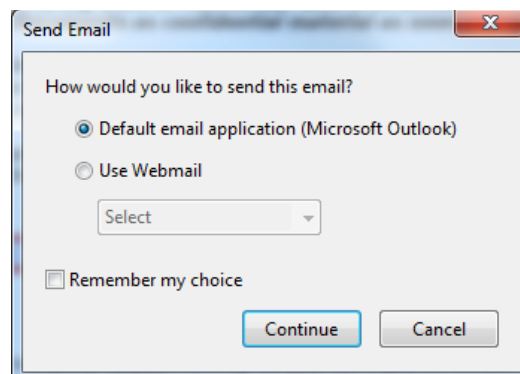
- A pop-up window will appear stating a confirmation e-mail will be sent shortly to the sender of that form. Read the message carefully and press '**OK**' (see figure 6).

Figure 6. Submission of completed e-DoI



- A new pop-up window will appear (see figure 7). Select the method for submitting the e-DoI depending on the e-mail system you are using.

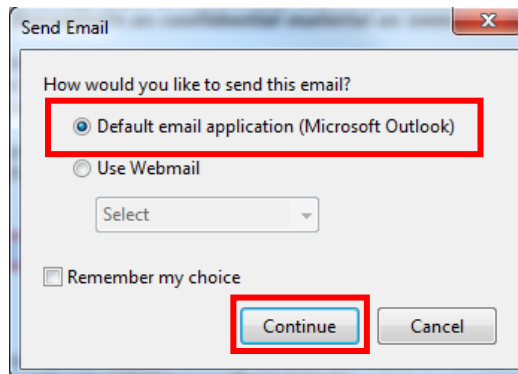
Figure 7. Pop-up window for selection of method of submission of e-DoI



4.1. Submission of the e-DoI using outlook

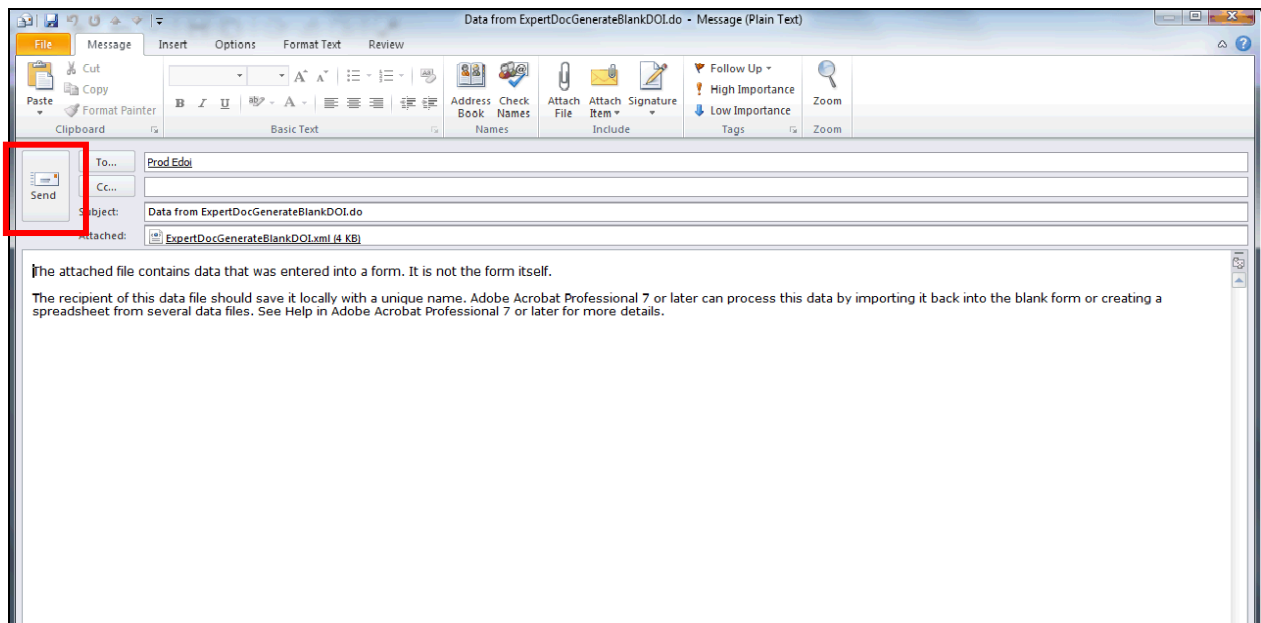
- If you are using Outlook (or the equivalent) on your computer, select the '**Default email application (Microsoft Outlook)**' option to send the file (see figure 8).
- Click on '**Continue**'.

Figure 8. Pop-up window with Outlook selected as method of submission of e-DoI



- An e-mail with the DoI in xml format attached will be created (see figure 9). Do not delete the e-mail address in the To... field or any content from the body of the e-mail.
- Click '**Send**' to submit the e-mail to the EMA.

Figure 9. Automatically generated e-mail to submit DoI in xml format



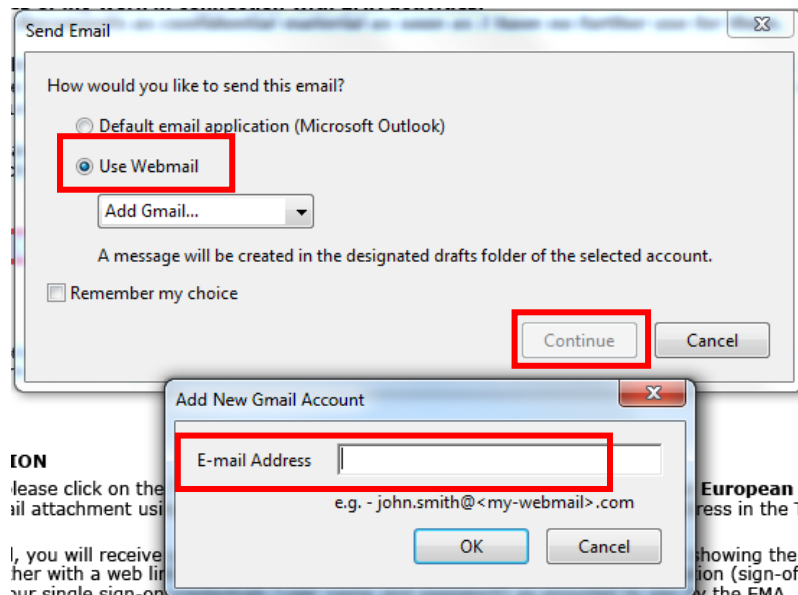
- You will receive an e-mail within 10 minutes, informing you if the submission was successful or not. Continue with section 5.

4.2. Submission of the e-DoI using webmail (Gmail™, Hotmail™, Yahoo™, ...)

- If you are using a web based e-mail system (Gmail™, Hotmail™, Yahoo™, ...) on your computer, select the '**Use Webmail**' option to send the file (see figure 10).

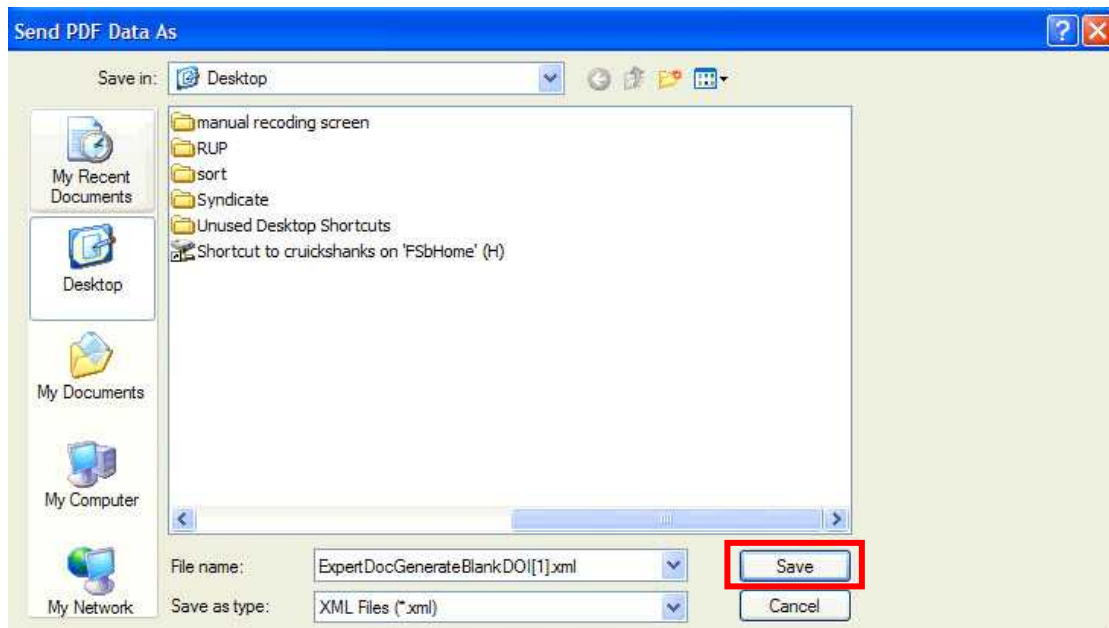
- Select an existing or add a new e-mail address for the web based e-mail system and click '**Continue**'.

Figure 10. Pop-up window with webmail selected as method of submission of e-DoI



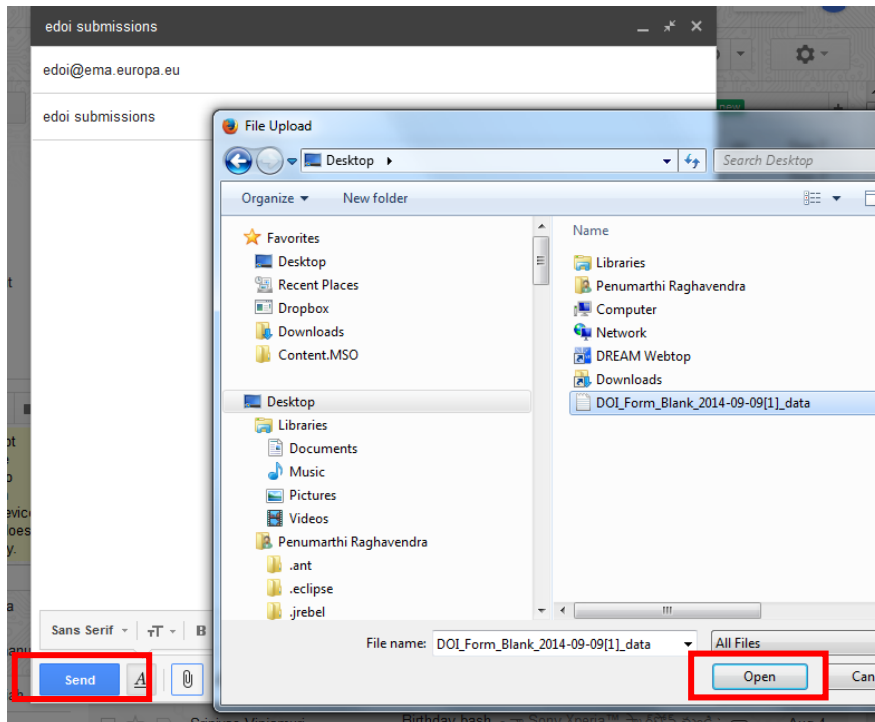
- You will be prompted to save the DoI in xml format on your computer prior to sending it (see figure 11). Click '**Save**'.

Figure 11. Save e-DoI in xml format on computer



- The **Use Webmail** option requires you to send the e-DoI form manually using your internet e-mail service. Create an e-mail and attach the xml file you saved on your computer (see figure 12). Ensure there is text in the body of the e-mail, e.g. '*Please see attached my e-DoI form*'.
- Send the e-mail to edoi@ema.europa.eu

Figure 12. Example of webmail to submit e-DoI form in xml format

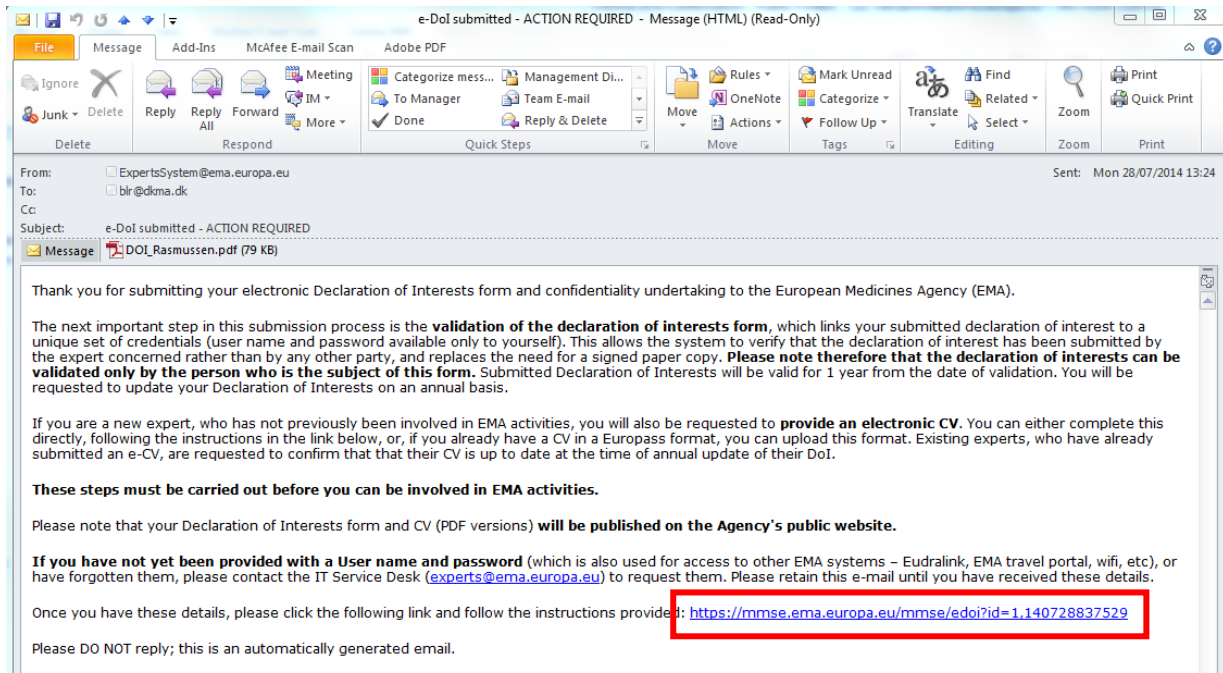


- You will receive an e-mail within 10 minutes, informing you if the submission was successful or not. Continue with section 5.

5. Confirmation of submission e-mail

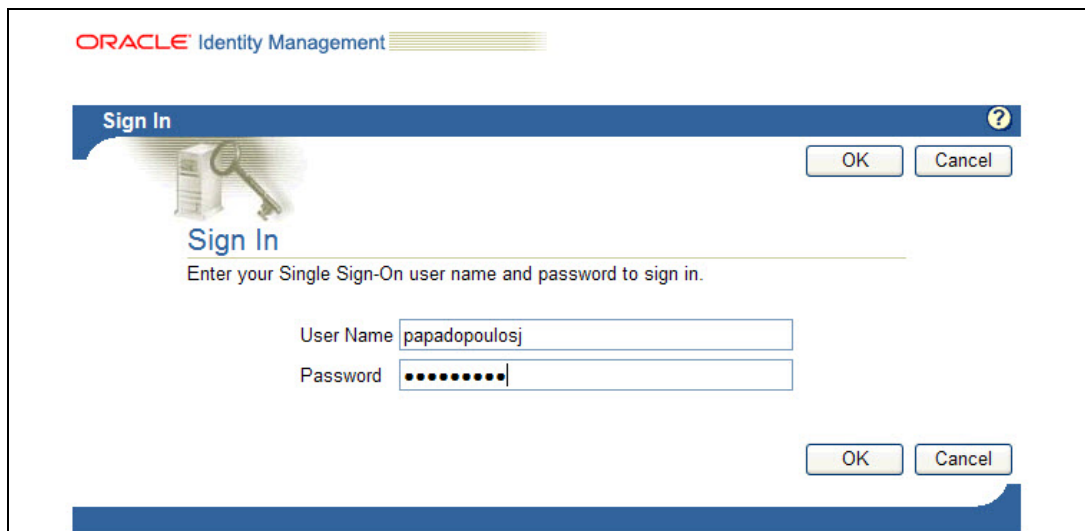
- If the submission of your e-DoI is unsuccessful, you will receive an e-mail, informing you on the reason why it was unsuccessful. Please take the appropriate action and resubmit the e-DoI.
- If your submission is successful, you will receive a confirmation e-mail, along with a completed copy (pdf, read-only) of the e-DoI form with instructions to submit an e-CV and to validate the submitted e-DoI form (see figure 13).
Note: The copy of the e-DoI form attached to that e-mail will be used for publication on the EMA website once your name has been added to the European Experts database.
- Click on the **link in the confirmation e-mail** to login to the EMA Meetings Portal (MMSe) for submission of an e-CV and validation of the submitted e-DoI.

Figure 13. Confirmation e-mail of successful submission of e-DoI



- A sign in window for MMSe will appear (see figure 14).
- Use the single sign-on credentials (user name and password) provided to you by the EMA. If you are a new expert and have not yet been assigned your single sign-on credentials or if you are an existing expert and have forgotten your user name and password, please contact the service desk (experts@ema.europa.eu) to request them.
- Click 'OK'.

Figure 14. Sign-in window

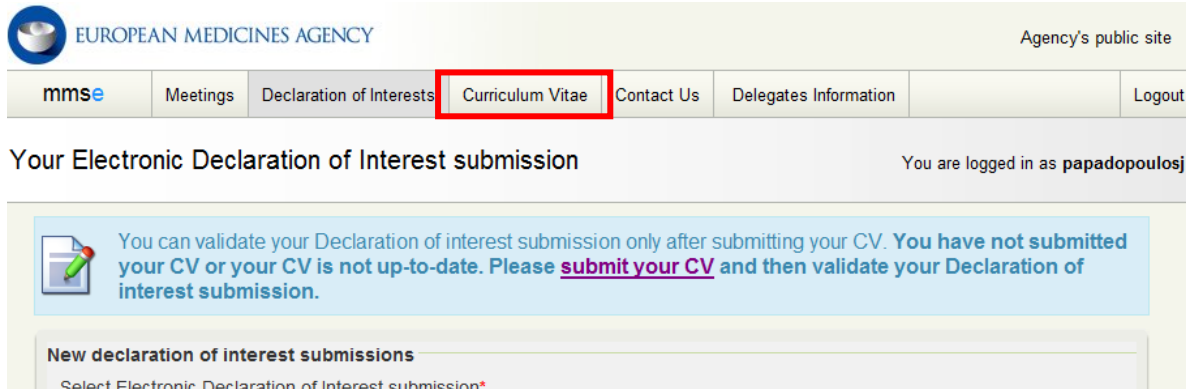


6. Submission of the e-CV

Before the submitted e-DoI can be validated, new experts need to provide an e-CV and existing experts need to update their e-CV in MMSe. If no update of an existing e-CV is required, go directly to section 6.4.

- Select the **Curriculum Vitae** tab in MMSe (see figure 15).

Figure 15. Select the Curriculum Vitae tab



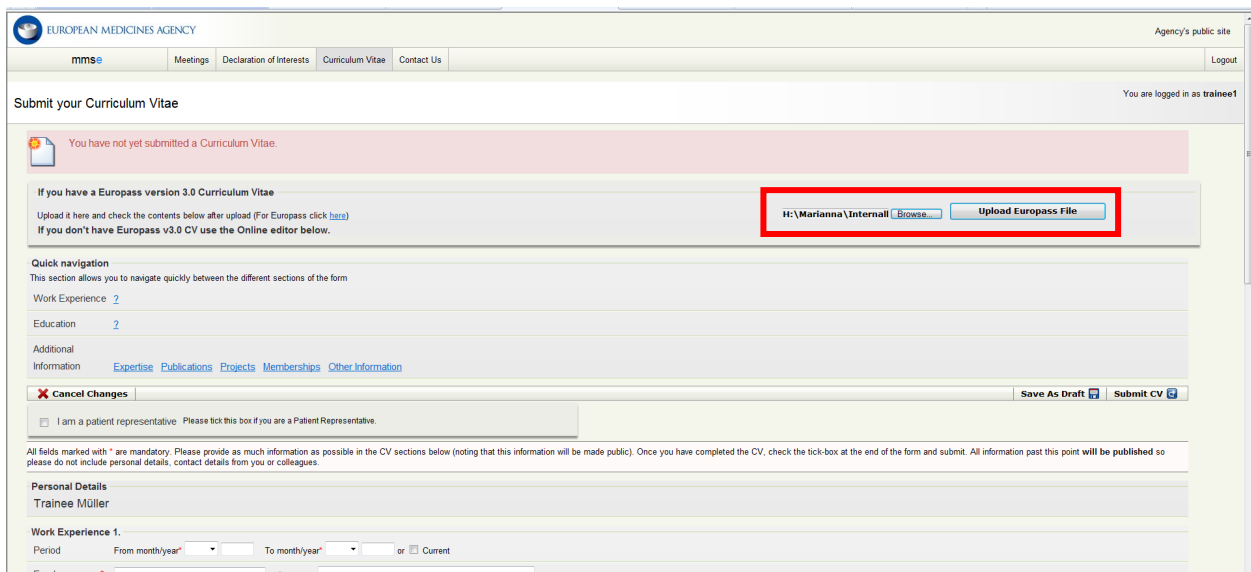
The screenshot shows the EMA MMSe website interface. At the top, there is a navigation menu with tabs: 'mmse', 'Meetings', 'Declaration of Interests', 'Curriculum Vitae' (highlighted with a red box), 'Contact Us', 'Delegates Information', and 'Logout'. Below the navigation menu, the page title is 'Your Electronic Declaration of Interest submission' and the user is logged in as 'papadopoulosj'. A blue banner message states: 'You can validate your Declaration of interest submission only after submitting your CV. You have not submitted your CV or your CV is not up-to-date. Please submit your CV and then validate your Declaration of interest submission.' Below this, there is a section for 'New declaration of interest submissions' with a link to 'Select Electronic Declaration of Interest submission*'.

- Select a method to provide your e-CV, i.e. uploading a CV in the Europass format (continue with section 6.1) or completing the CV in MMSe (continue with section 6.2). If no update of an existing e-CV is required, go directly to section 6.4.

6.1. Upload the CV in the Europass format

- **If you already have a CV in the Europass format, you can upload this** by clicking on the 'Browse' button, selecting the file from your computer and then clicking on 'Upload Europass File' (see figure 16). This will complete the Work Experience and Education/Training sections of the electronic CV.

Figure 16. Upload of e-CV in Europass format



The screenshot shows the 'Submit your Curriculum Vitae' form in the MMSe system. A red banner at the top states: 'You have not yet submitted a Curriculum Vitae.' Below this, there is a section for 'If you have a Europass version 3.0 Curriculum Vitae' with an 'Upload Europass File' button highlighted by a red box. The form includes a 'Quick navigation' section with links for 'Work Experience', 'Education', and 'Additional Information'. At the bottom, there are fields for 'Personal Details' (Trainee Müller) and 'Work Experience 1' (Period, From month/year, To month/year, or Current, Employer name, Country).

- Continue with section 6.3.

6.2. Complete the CV in MMSe (no CV in the Europass format available)

- If you do not have a Europass format CV available, you can complete the Work experience and Education/Training section in MMSe directly.
Note: Mandatory fields in these sections are marked with an asterisk.
- Provide your **work experience** details (see figure 17). You can add more than one work experience by clicking the 'Add work experience' button.

Figure 17. Work experience section in e-CV

The screenshot shows the 'Work Experience 1.' section of the e-CV form. The form is highlighted with a red border. It contains the following fields: 'Period' with dropdowns for 'From month/year', 'To month/year', and a radio button for 'Current'; 'Employer name*' with a text input; 'Country*' with a dropdown menu; 'Position*' with a text input; and 'Activities' with a text input. Below the form is a button labeled 'Add Work Experience', which is also highlighted with a red box. The form is part of a larger interface with tabs for 'Information', 'Expertise', 'Publications', 'Projects', 'Memberships', and 'Other Information'.

- Provide your **education/training** details (see figure 18). You can add more education/training details by clicking the 'Add Education/Training' button.

Figure 18. Education/Training section in e-CV

The screenshot shows the 'Education/Training 1.' section of the e-CV form. The form is highlighted with a red border. It contains the following fields: 'Period' with dropdowns for 'From month/year', 'To month/year', and a radio button for 'Current'; 'Qualification*' with a text input; 'Institution' with a text input; 'Country' with a dropdown menu; 'Subjects/Skills' with a text input; and 'Covered' with a text input. Below the form is a button labeled 'Add Education/Training', which is also highlighted with a red box. The form is part of a larger interface with tabs for 'Information', 'Expertise', 'Publications', 'Projects', 'Memberships', and 'Other Information'.

- Continue with section 6.3.

6.3. Provide additional information

- Provide **additional information**, i.e. expertise, publications, projects, memberships or others as appropriate (see figure 19). You can copy and paste relevant information from existing word or other documents in the different sections as appropriate. Please provide as much information as possible in these sections.

Please do not include personal details (e.g. date of birth, name of spouse or children, telephone numbers).

Figure 19. Additional information in e-CV

Period From month/year To month/year or Current

Qualification*

Institution Country

Subjects/Skills Covered

[Go to quick navigation](#) **Insert before**

Add Education/Training

Additional Information

Information in these sections is important in allowing the EMA to identify the experts with relevant scientific expertise and experience, thereby facilitating use of the best available expertise. Please therefore provide as much information as possible in these sections. You may copy and paste relevant information from existing word documents in the different sections as appropriate

Expertise Publications Projects Memberships Other

Please enter your areas of Expertise

Type or copy/paste text from your existing CV into individual tabs here, as appropriate

I confirm my CV is up-to-date*

- If you are a **patient representative**, tick the box 'I am a patient representative' (see figure 20). This text will automatically appear in the section on expertise. Also as a patient representative, you are expected to complete the e-CV if you have experience related to medicinal products and/or have engaged in any activities with pharmaceutical industry.

Figure 20. Tick box for patient representatives

Information Expertise Publications Projects Memberships Other Information

Cancel Changes **Save As Draft** **Submit CV**

I am a patient representative. Please tick this box if you are a Patient Representative.

All fields marked with * are mandatory. Please provide as much information as possible in the CV sections below (noting that this information will be made public). Once you have completed the CV, check the tick-box at the end of the form and submit. All information past this point will be published so please do not include personal details, contact details from you or colleagues.

Personal Details

Trainee Peeters

Work Experience 1.

Period From month/year* To month/year* or Current

Employer name* Country*

Position*

Activities

[Go to quick navigation](#) **Insert before**

Add Work Experience

Education/Training 1.

Period From month/year To month/year or Current

Qualification*

Institution Country

Subjects/Skills Covered

[Go to quick navigation](#) **Insert before**

Add Education/Training

Additional Information

Information in these sections is important in allowing the EMA to identify the experts with relevant scientific expertise and experience, thereby facilitating use of the best available expertise. Please therefore provide as much information as possible in these sections. You may copy and paste relevant

6.4. Submit the e-CV

- Confirm that your CV is up-to-date and ready for submission **by ticking the box 'I confirm my CV is up-to-date' at the very bottom of the screen** (see figure 21).

Figure 21. Tick box for up-to-date e-CV

The screenshot shows a web form for submitting an e-CV. It includes sections for 'Subjects/Skills Covered', 'Education/Training 2', and 'Additional Information'. The 'Additional Information' section has tabs for 'Expertise', 'Publications', 'Projects', 'Memberships', and 'Other'. The 'Expertise' tab is active, showing a text area with 'Europass Expertise'. At the bottom of the form, the checkbox 'I confirm my CV is up-to-date' is checked and highlighted with a red box. Other buttons at the bottom include 'Cancel Changes', 'Save As Draft', and 'Submit CV'.

- Submit your CV by clicking on the **'Submit CV'** button (see figure 22).

Click on the 'Save as Draft' button if you wish to finalise the CV at a later time. The CV will be saved as a draft in MMSe.

Figure 22. Submission of e-CV

This screenshot is identical to Figure 21, showing the same e-CV submission form. In this view, the 'I confirm my CV is up-to-date' checkbox is checked, and the 'Submit CV' button at the bottom right is highlighted with a red box.

- You can view your submitted CV in the format in which it will be published on the EMA website by selecting the **'(View PDF)'** link (see figure 23).

Figure 23. View submitted e-CV

7. Validation of the e-DoI submission

An e-DoI submission can only be validated in MMS if an e-CV is submitted (new experts) or if the e-CV is updated (existing experts).

- Select the **Declaration of Interests** tab in MMS (see figure 24).


Figure 24. Select the Declaration on Interests tab

- Select the submitted e-DoI that you want to validate (see figure 25).
- Tick the **box 'I confirm** the information on this form is accurate to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website'.
- If you are a **patient representative**, tick the box 'I am a patient representative'.
- Click on the '**Validate selected submission**' button.

Figure 25. Validation of submitted e-DoI

mms ^e	Meetings	Declaration of Interests	Curriculum Vitae	Contact Us	Delegates Information	Logout
------------------	----------	--------------------------	------------------	------------	-----------------------	--------

Your Electronic Declaration of Interest submission You are logged in as **papadopoulosj**

 Please validate your submission by selecting a Declaration of interest submission and clicking on the Validate selected submission button. If you see more than one submission, it is because you have submitted the form multiple times. In that case, please select the one you want to validate. Other submissions will be discarded.

New declaration of interest submissions

Select Electronic Declaration of Interest submission*

[09/09/2014 00:00:00](#) - Electronic Declaration of interest - Submission number 2

I confirm the information declared on this form is accurate to the best of my knowledge and I acknowledge that my information will be stored electronically and published on the EMA website. *

The accuracy of the e-signature will be verified by the EMA. If the form has been signed by anyone other than the concerned person, the submitted form will be invalidated and the expert requested to re-submit.

I am the owner of this declaration of interest. *

[Validate selected submission](#)

Updating your declaration form

To submit a new declaration, please download a form with the button below. Fill it in and send by e-mail. Once the declaration is submitted, return to this page to validate it.

[Download Declaration of Interest form](#)

Previous declaration of interest submissions


There are no previous submissions.

- A confirmation of a successful validation will appear (see figure 26).

Figure 26. Successful validation of submitted e-DoI

mms ^e	Meetings	Declaration of Interests	Curriculum Vitae	Contact Us	Delegates Information	Logout
------------------	----------	--------------------------	------------------	------------	-----------------------	--------

Your Electronic Declaration of Interest submission You are logged in as **papadopoulosj**

 Your Declaration of interest was submitted on [09/09/2014](#). It needs to be renewed by **09/09/2015**.

New declaration of interest submissions

No declaration of interests submissions pending validation could be found.

Please make sure you access this page by opening the link provided on the e-mail confirming the successful submission of your Declaration of interest.

Updating your declaration form

To submit a new declaration, please download a form with the button below. Fill it in and send by e-mail. Once the declaration is submitted, return to this page to validate it.

[Download Declaration of Interest form](#)

Previous declaration of interest submissions

There are no previous submissions.

- Your e-DoI and e-CV will be published automatically on the EMA website once the details from your nomination form have been entered into the European Experts database (new experts) or automatically following a successful validation of your e-DoI (existing experts).