



12 November 2020
EMA/575867/2020 – Revision 2

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

Table of Contents

1. Scope	2
2. EMA account	2
3. Electronic declaration of interests form	3
3.1. New experts	3
3.2. Existing experts	4
4. Completion of the e-DoI form	5
5. Submission of the e-DoI form	7
5.1. Submission of the e-DoI using Outlook	8
5.2. Submission of the e-DoI using webmail (Gmail™, Hotmail™, Yahoo™, ...)	8
6. Confirmation of submission e-mail	11
7. Submission of the e-CV	13
7.1. Complete the CV in MMSe - work experience and training	13
7.2. Provide additional information	14
7.3. Submit the e-CV	15
8. Validation of the e-DoI submission	16



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:

- Create an EMA account (only for new experts who do not yet have an EMA account)
- Complete the 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 the method of sending and click 'Continue'
- If using Outlook: send the automatically generated e-mail with the e-DoI in xml format attached
- If using webmail: save the automatically generated DoI in xml format on computer, create an e-mail with the e-DoI in xml format in attachment and send the e-mail to edoi@ema.europa.eu
- If 'EMA e-DOI received. Please await further instructions' e-mail received, create an EMA account (if you do not yet have an EMA account) or if an EMA account already created, wait for the account to be verified.
- When receiving the confirmation e-mail 'EMA e-DOI submitted-action required', click on the link in the e-mail
- Log in with single-sign-on credentials (username and password)
- In MMSe, go to the Curriculum Vitae tab
- Tick the box 'I am a patient representative' if applicable
- Complete or update the e-CV fields
- Tick the box 'I confirm my CV is up-to-date' (bottom of page)
- Click on 'Submit CV' (bottom of page)
- In MMSe, go to the Declaration of Interests tab
- Select the 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 the box 'I am the owner of this declaration of interest'
- Click on 'Validate selected submission'

2. EMA account

If you do not yet have an EMA account (EMA user name and password), please open one via the EMA Account Management Portal (<https://register.ema.europa.eu>).

If you already have an EMA account allowing you to access EMA hosted websites or online applications (e.g. Eudralink, MMD, EMA (IT) Service Desk portal), there is no need for further action and you can use the same username and password to submit the e-CV and validate the DoI in the next steps of the process.

If you need to recover a forgotten username or reset your password, please visit the EMA Account Management Portal (<https://register.ema.europa.eu>).

3. Electronic declaration of interests form

3.1. 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 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:

3.2. 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 download your current e-DoI from MMSe (see figure 3). Alternatively, 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.

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

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

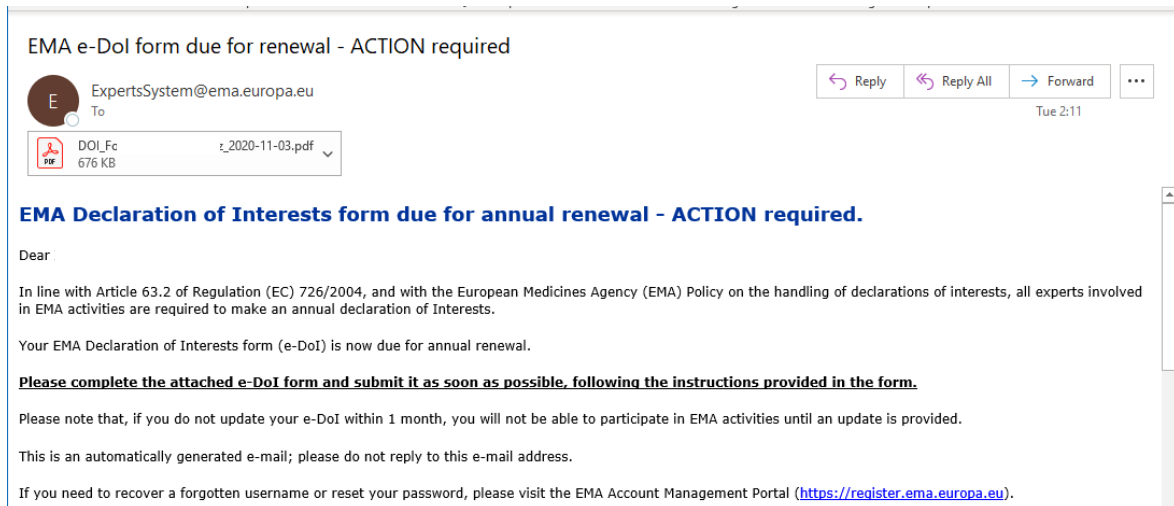
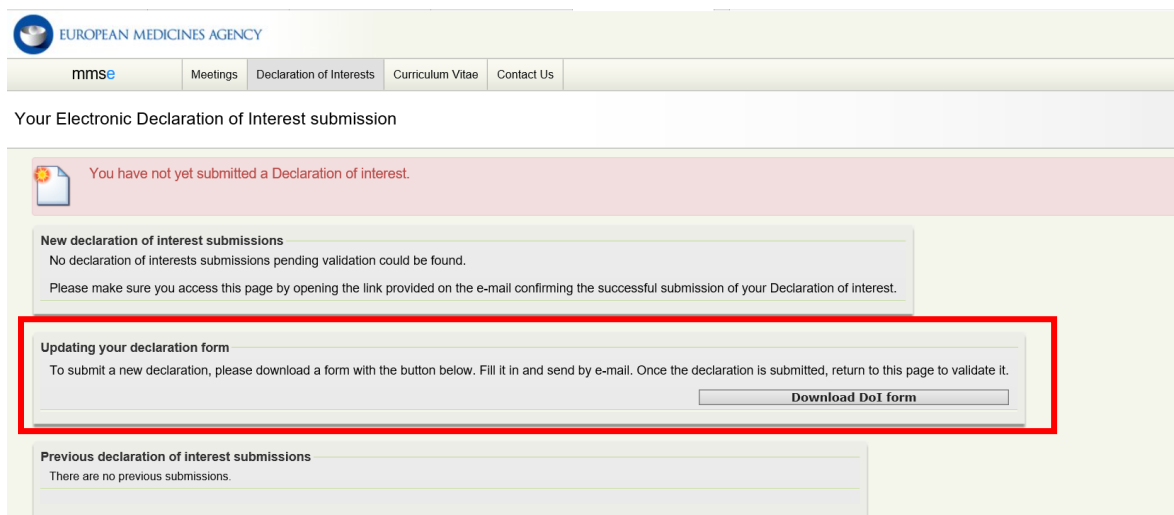


Figure 3. Download current e-DoI form from MMSe



4. 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, also 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 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 A"/>	<input type="button" value="X"/>

5. 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 the form. Read the message and press '**OK**' (see figure 6).


Figure 6. Submission of completed e-DoI

This undertaking shall not be limited in time, but shall not apply to any document or information that I can reasonably prove was known to me before the date of this undertaking or which becomes public knowledge other than as a result of a breach of any of the above undertakings.

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.

FULL NAME: Date:

Warning: JavaScript Window - Confirmation

 You are about to submit your e-DOI form. A confirmation email will be sent to you shortly with instructions how to sign and validate the e-DOI using your sign-on credentials. Signing and validating your e-DOI is mandatory to finalize the submission process.

http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2011/07/WC500109481.pdf

- 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 submission method for e-DoI

Send Email

How would you like to send this email?

Default email application (Microsoft Outlook)

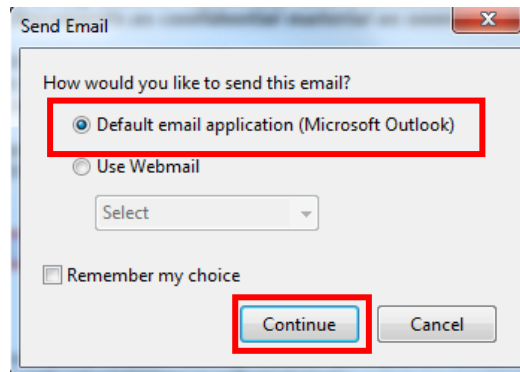
Use Webmail

Remember my choice

5.1. Submission of the e-DoI using Outlook

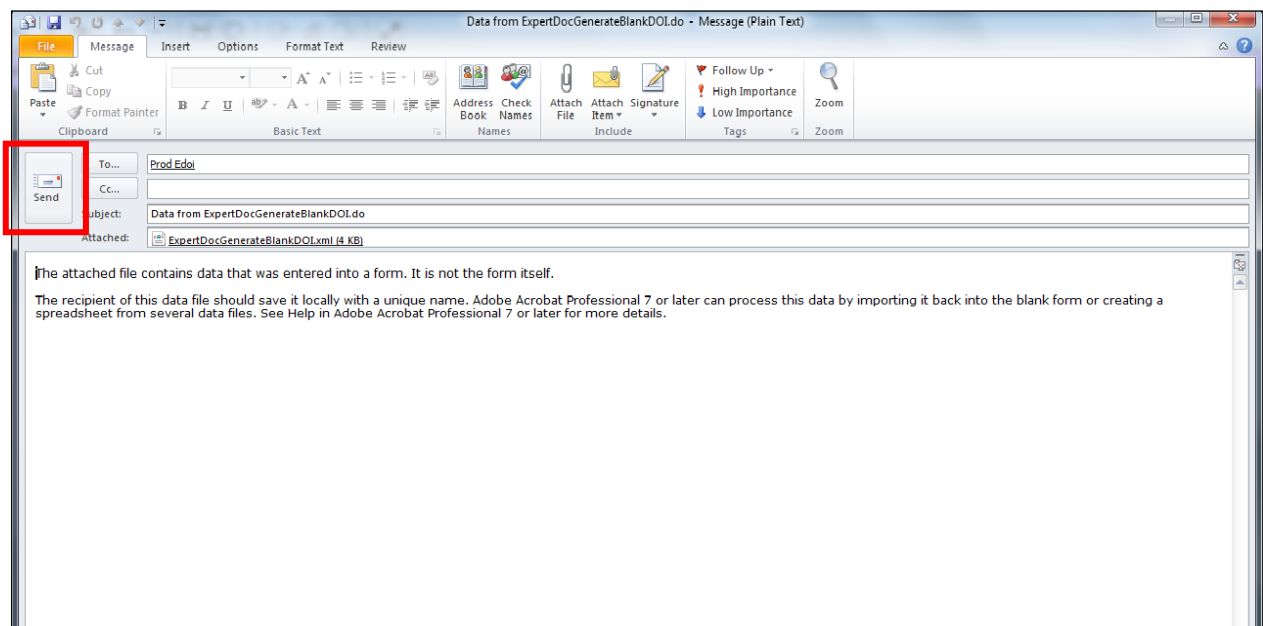
- If you are using Outlook (or the equivalent) on your computer, select the '**Default email application (Microsoft Outlook)**' option to send the file (see figure 8).
- Click on '**Continue**'.

Figure 8. Pop-up window with Outlook selected as submission method for 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



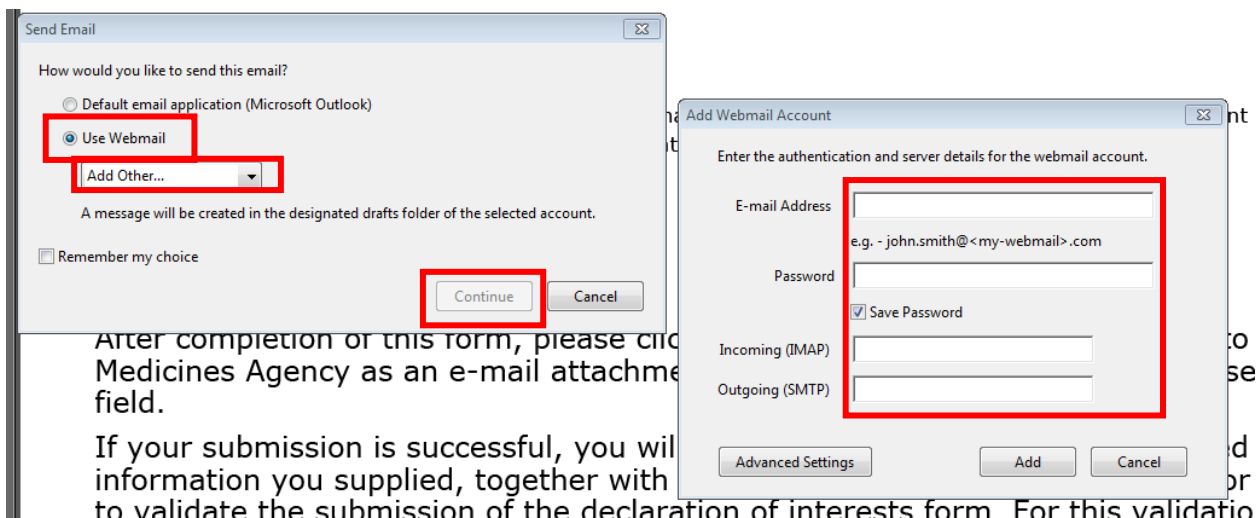
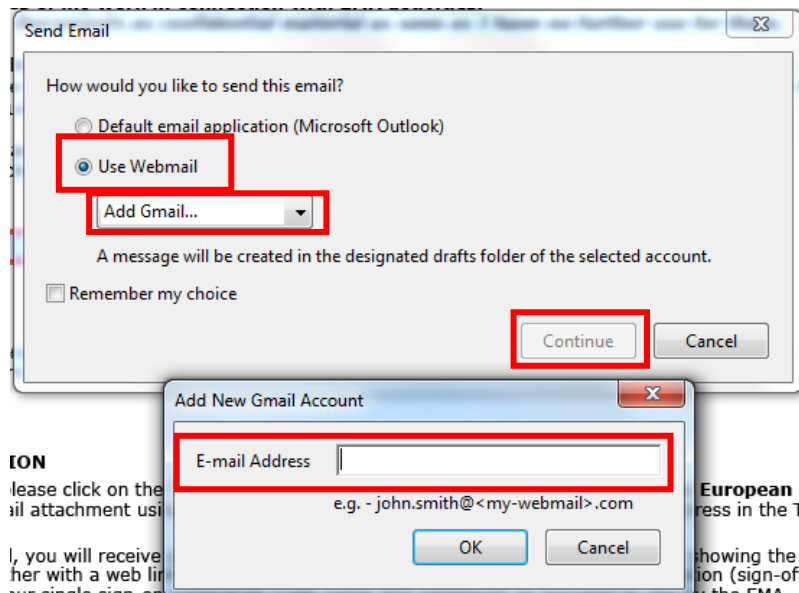
- You will receive an e-mail within approximately 10 minutes, informing you if the submission was successful or not. Continue with section 6.

5.2. 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).

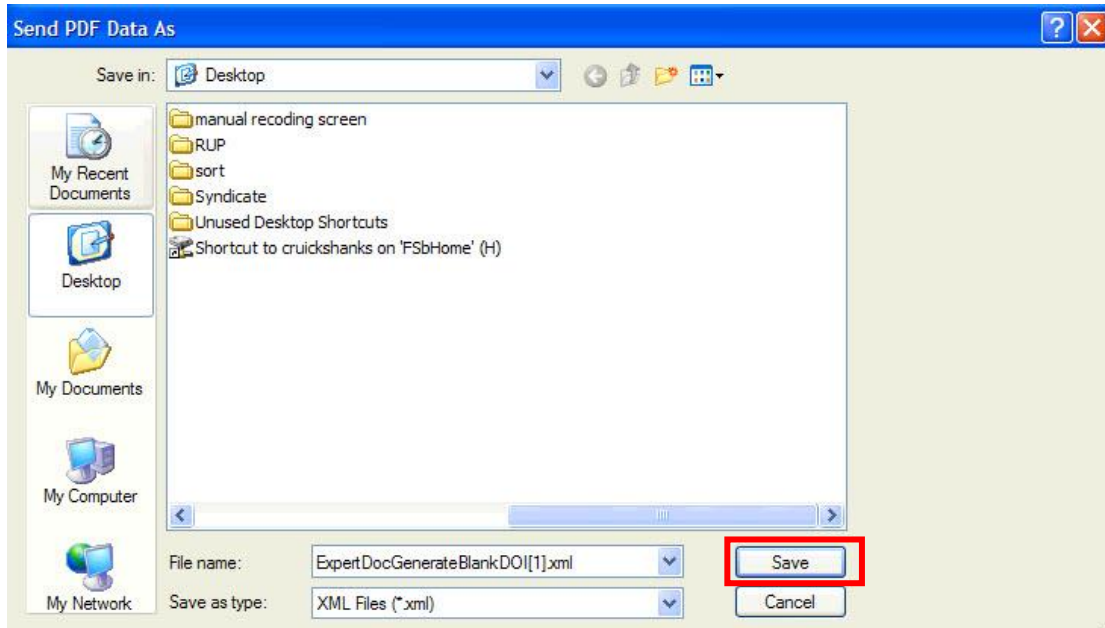
- Select an existing or add a new e-mail address for the web-based e-mail system and click 'Continue'.
- Enter the relevant e-mail address and if applicable details of your e-mail provider. Click 'OK' or 'Add'.

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



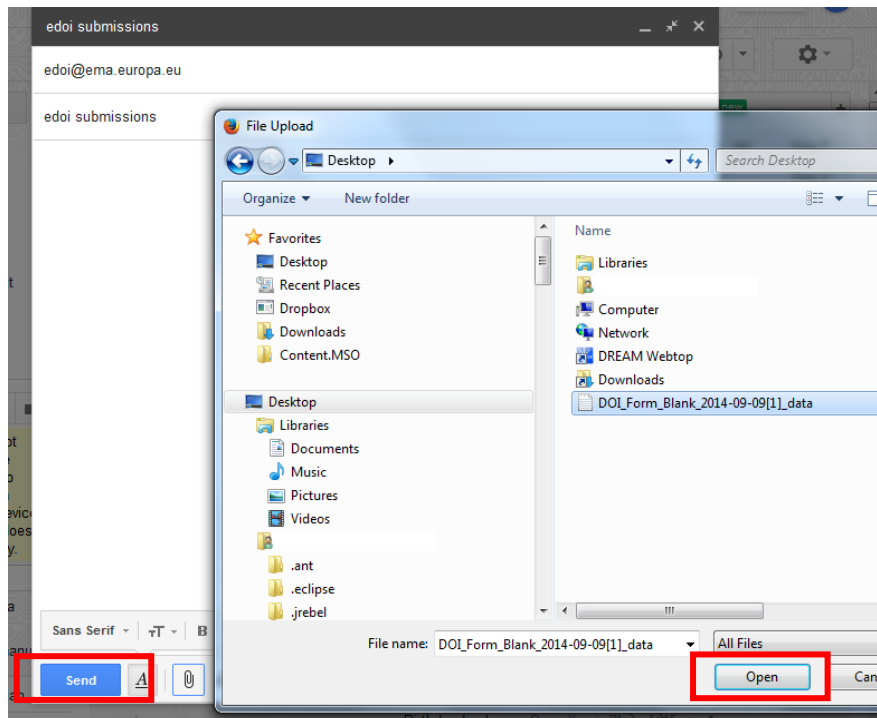
- You will be prompted to save the DoI in xml format on your computer prior to sending it (see figure 11). Click 'Save'.

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 approximately 10 minutes, informing you if the submission was successful or not. Continue with section 6.

6. 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, but you do not have an EMA account or your EMA account needs to be verified, you will receive an 'EMA e-DOI received. Please await further instructions' e-mail (see figure 13).
- If your submission is successful and you already have an EMA account which does not need to be verified, you will receive an 'EMA e-DOI submitted-action required' confirmation e-mail, along with a completed copy (pdf, read-only) of the e-DoI form and instructions to submit an e-CV and to validate the submitted e-DoI form (see figure 14).

Note: The copy of the e-DoI form attached to that e-mail will be used for publication on the EMA website once you have 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. 'EMA e-DOI received. Please await further instructions' e-mail of successful submission of e-DoI

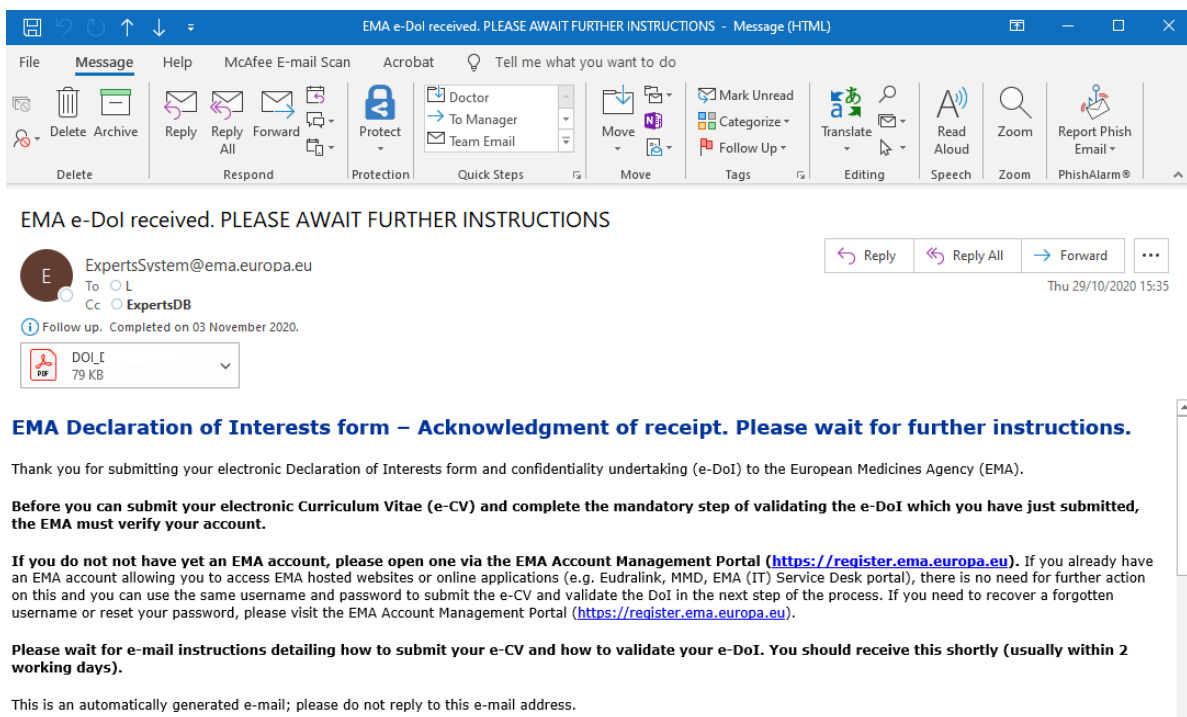
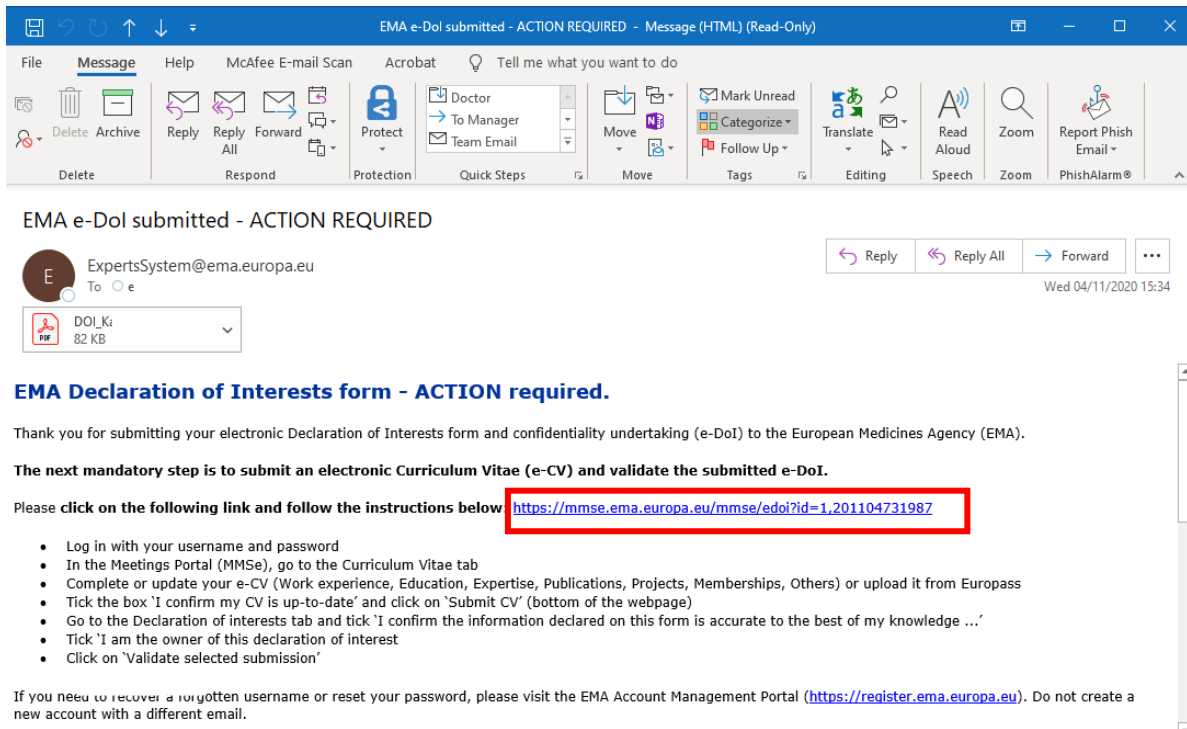
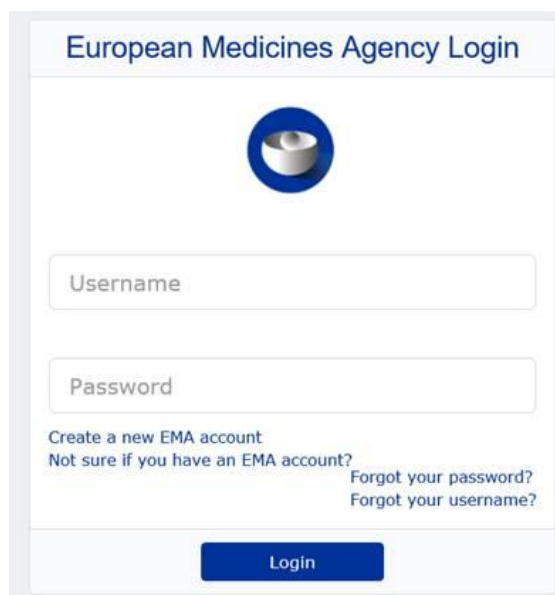


Figure 14. 'EMA e-DOI submitted-action required' confirmation e-mail of successful submission of e-DoI



- A sign in window for MMSe will appear (see figure 15).
- Use your single sign-on credentials (username and password).
 If you are a new expert and you do not have single sign-on credentials, please open EMA Account via the EMA Account Management Portal (<https://register.ema.europa.eu>).
 If you are an existing expert and have forgotten your username and password, please visit the EMA Account Management Portal (<https://register.ema.europa.eu>).
- Click '**Login**'.

Figure 15. Sign-in window

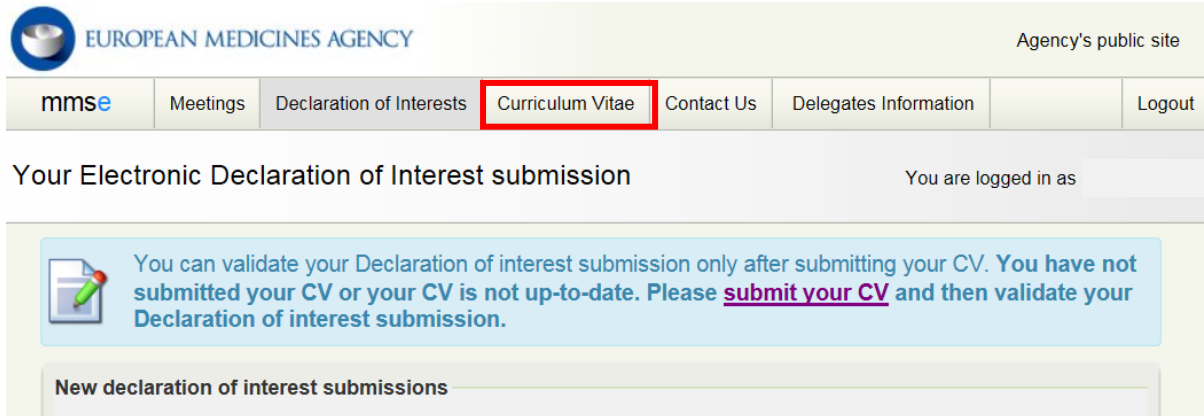


7. Submission of the e-CV

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 7.3.

- Select the **Curriculum Vitae** tab in MMSe (see figure 16).

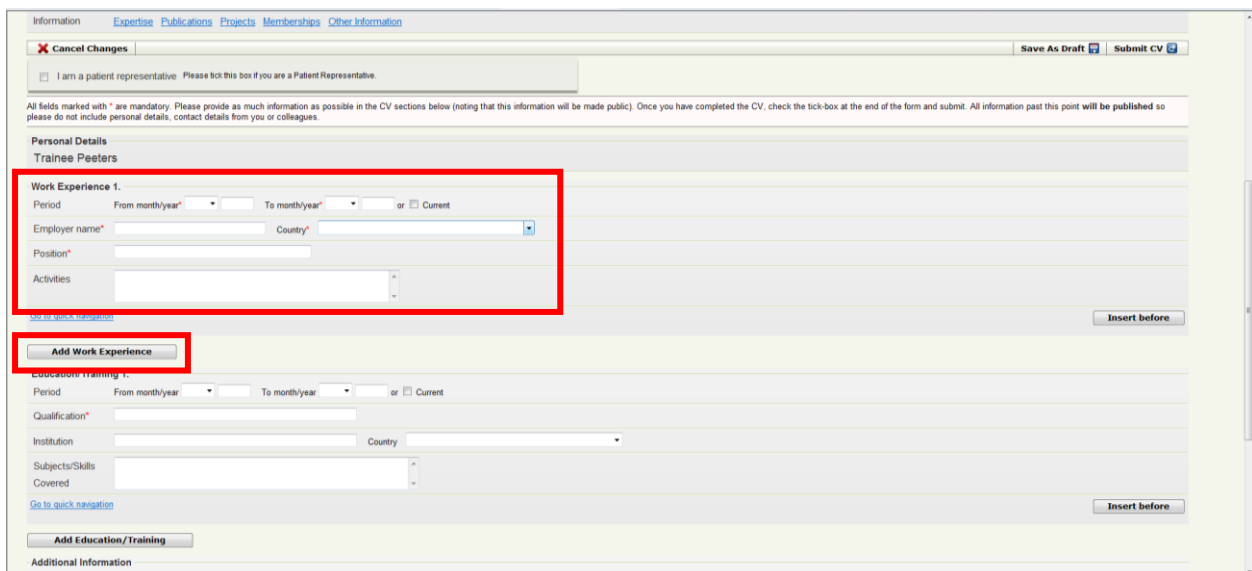
Figure 16. Select the Curriculum Vitae tab



7.1. Complete the CV in MMSe - work experience and training

- **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



- 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

7.2. 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.
Note: 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

- 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. As a patient representative, you are only 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

The screenshot shows the 'Information' tab of an e-CV form. At the top, there is a 'Cancel Changes' button with a red 'X' icon. Below it, a red rectangle highlights a tick box labeled 'I am a patient representative' with the text 'Please tick this box if you are a Patient Representative.' To the right of this are 'Save As Draft' and 'Submit CV' buttons. The form contains sections for 'Personal Details', 'Work Experience 1.', and 'Education/Training 1.', each with various input fields and 'Insert before' buttons. At the bottom, there is an 'Additional Information' section with tabs for 'Expertise', 'Publications', 'Projects', 'Memberships', and 'Other'. The 'Expertise' tab is active, showing a text area for 'Please enter your areas of Expertise' with the text '<p>Europass Expertise</p>'. At the very bottom, there is a 'Cancel Changes' button and 'Save As Draft' and 'Submit CV' buttons.

7.3. 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 the 'Additional Information' section of the e-CV form. It features tabs for 'Expertise', 'Publications', 'Projects', 'Memberships', and 'Other'. The 'Expertise' tab is active, showing a text area for 'Please enter your areas of Expertise' with the text '<p>Europass Expertise</p>'. Below this, a red rectangle highlights a tick box labeled 'I confirm my CV is up-to-date'. At the bottom right, there are 'Save As Draft' and 'Submit CV' buttons. The footer of the page reads 'MMS-e-13 BR/1 2013/07/05 15:27:24 - European Medicines Agency © 2013'.

- 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

- 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).

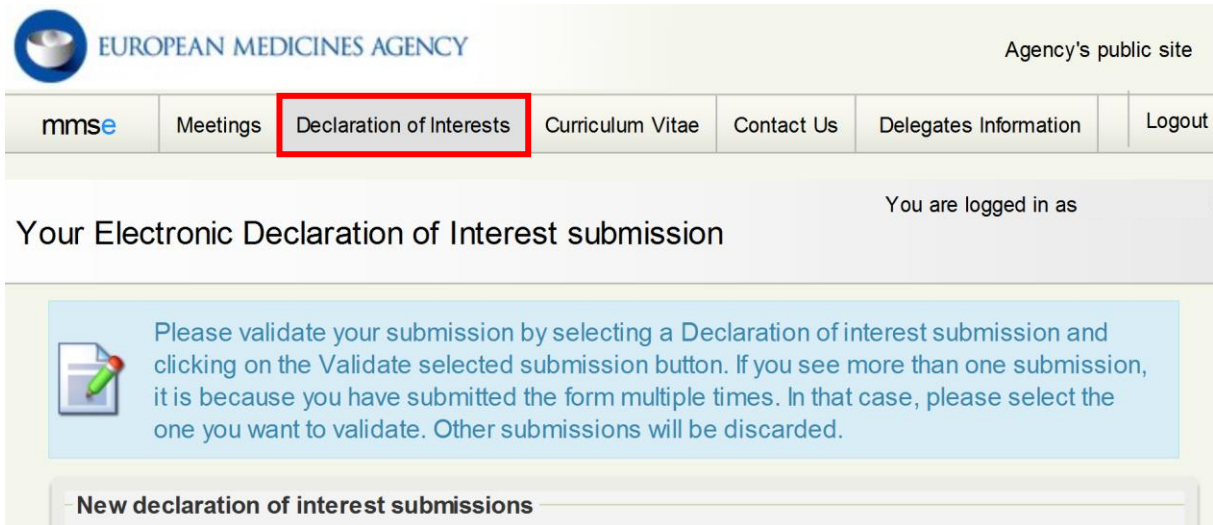
Figure 23. View submitted e-CV

8. 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) as described in section 7.

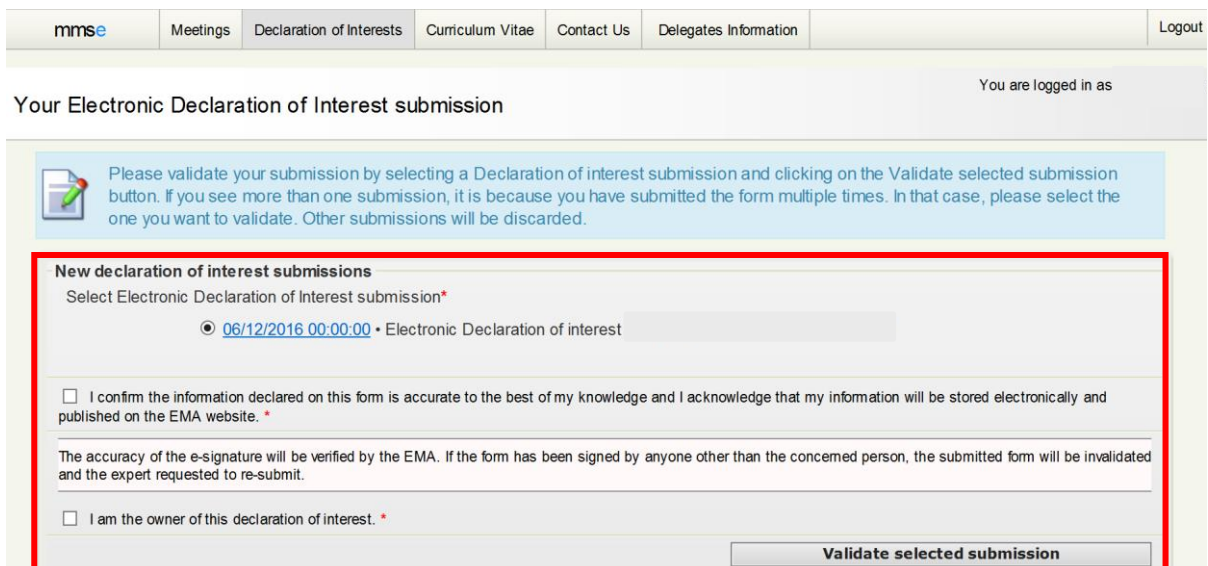
- Select the **Declaration of Interests** tab in MMS (see figure 24).

Figure 24. Select the Declaration on Interests tab



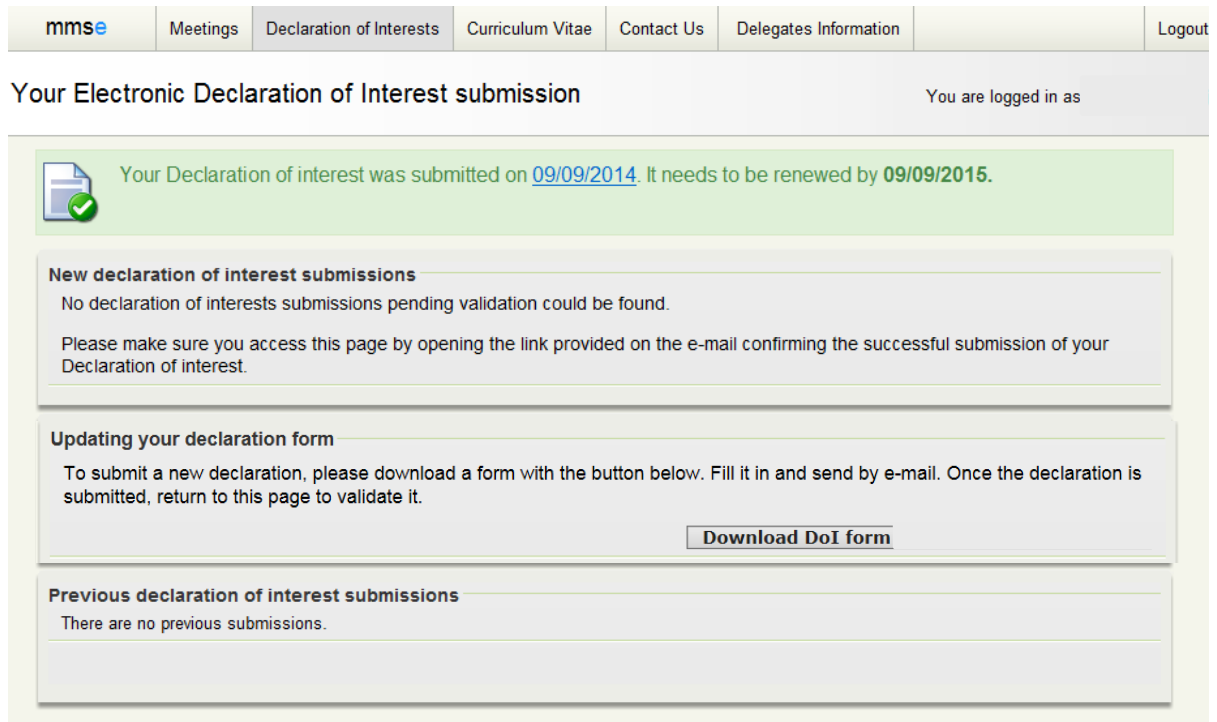
- Select the submitted e-DoI that you want to validate (see figure 25).
Note: In case you submit more than one e-DoI, you will receive a confirmation e-mail for each submission, each containing a different link to MMSe. All submissions will be listed in MMSe. Please ensure to select the e-DoI in MMSe for validation that corresponds to the confirmation e-mail and the link that you used to login to MMSe.
- 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**'.
- Tick the box '**I am the owner of this declaration of interest**'.
- Click on the '**Validate selected submission**' button.

Figure 25. Validation of submitted e-DoI



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

Figure 26. Successful validation of submitted e-DoI



The screenshot shows the 'mms.e' website interface. The navigation menu includes 'Meetings', 'Declaration of Interests', 'Curriculum Vitae', 'Contact Us', 'Delegates Information', and 'Logout'. The page title is 'Your Electronic Declaration of Interest submission' and it indicates the user is logged in. A green notification box states: 'Your Declaration of interest was submitted on 09/09/2014. It needs to be renewed by 09/09/2015.' Below this, there are three sections: 'New declaration of interest submissions' (no pending submissions), 'Updating your declaration form' (with a 'Download DoI form' button), and 'Previous declaration of interest submissions' (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 after the successful validation of your e-DoI (existing experts).