In this video we will take you through a step by step process of how to complete and submit the forms required by all experts participating in EMA activities…

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What the legislation says

Extract from Article 63(2) of Regulation (EC) No 726/2004

Members of […] the committees, rapporteurs and experts **shall not have** financial or other **interests in the pharmaceutical industry which could affect their impartiality**.

They shall undertake to act in the public interest and in an independent manner, and shall make an **annual declaration of their financial interests**. All indirect interests which could relate to this industry shall be entered into a register held by the Agency which is accessible to the public, on request, at the Agency's offices ...

The EMA has a policy on the handling of declarations of interests, which is a requirement of the Regulation that is shown here.

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EMA Policy on the handling of declarations of interests of committees' members and experts

Right balance between access to leading experts and guaranteeing experts have no ties to industry affecting their independence and impartiality

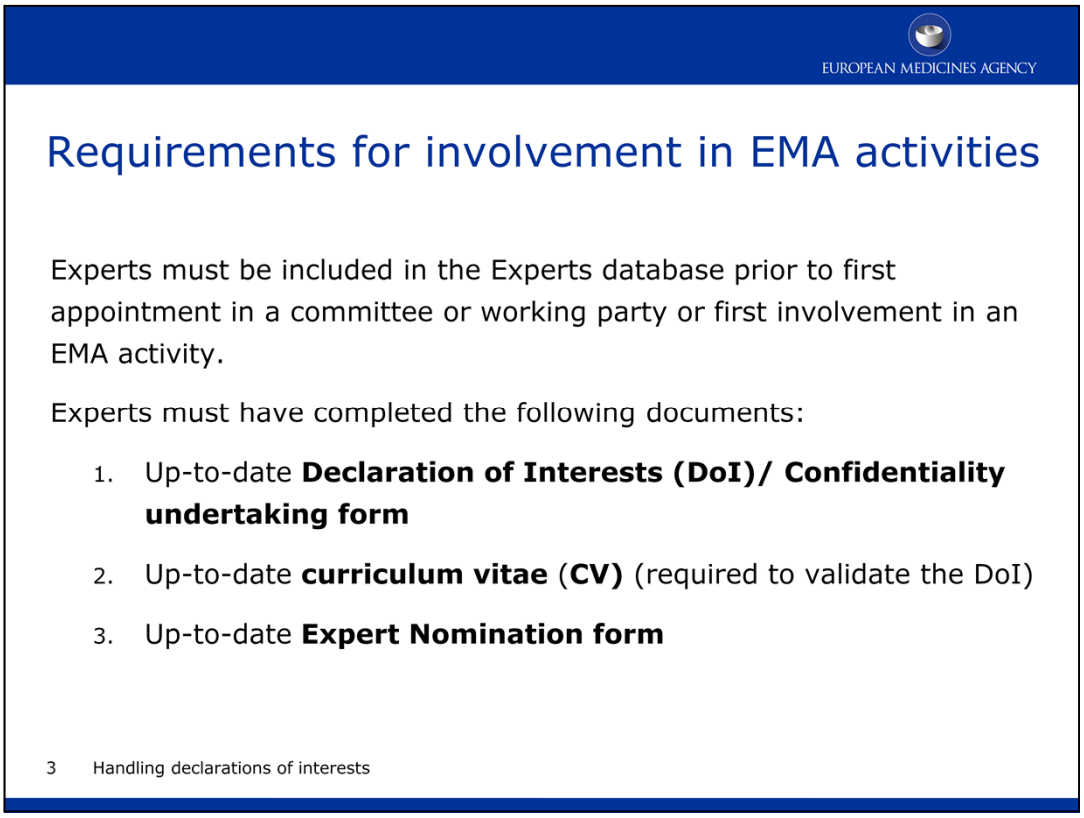
Applicable to

- Scientific committee and working party members and alternates
- Experts involved in EMA activities
  - In the context of authorisation and surveillance of medicinal products for human and veterinary use
  - Meeting attendance
  - Involvement in scientific assessment and guidance development
  - Participation in inspections

The spirit of the policy is to strike the right balance for involving experts in EMA activities.

All experts need to demonstrate their independence and impartiality.

This applies to members and alternates of scientific committees and working parties as well as other experts involved in any Agency activities.



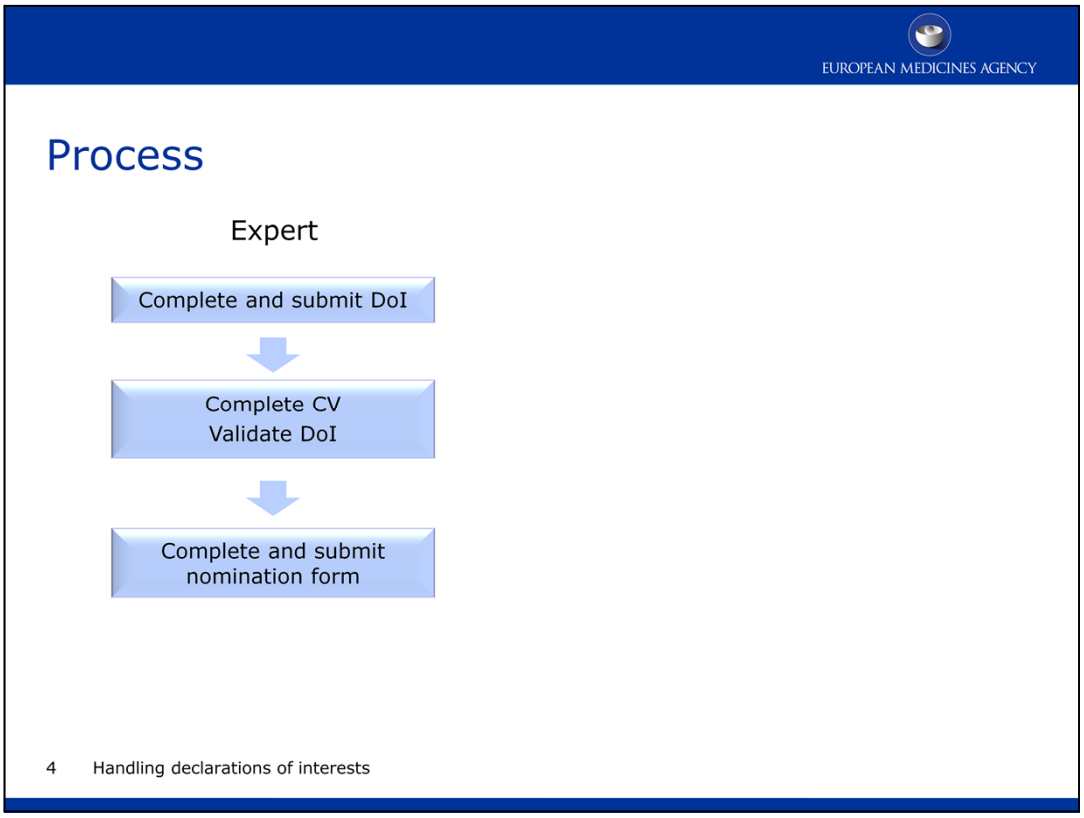
To participate in EMA activities, an expert must first be included in the Experts database.

They must complete

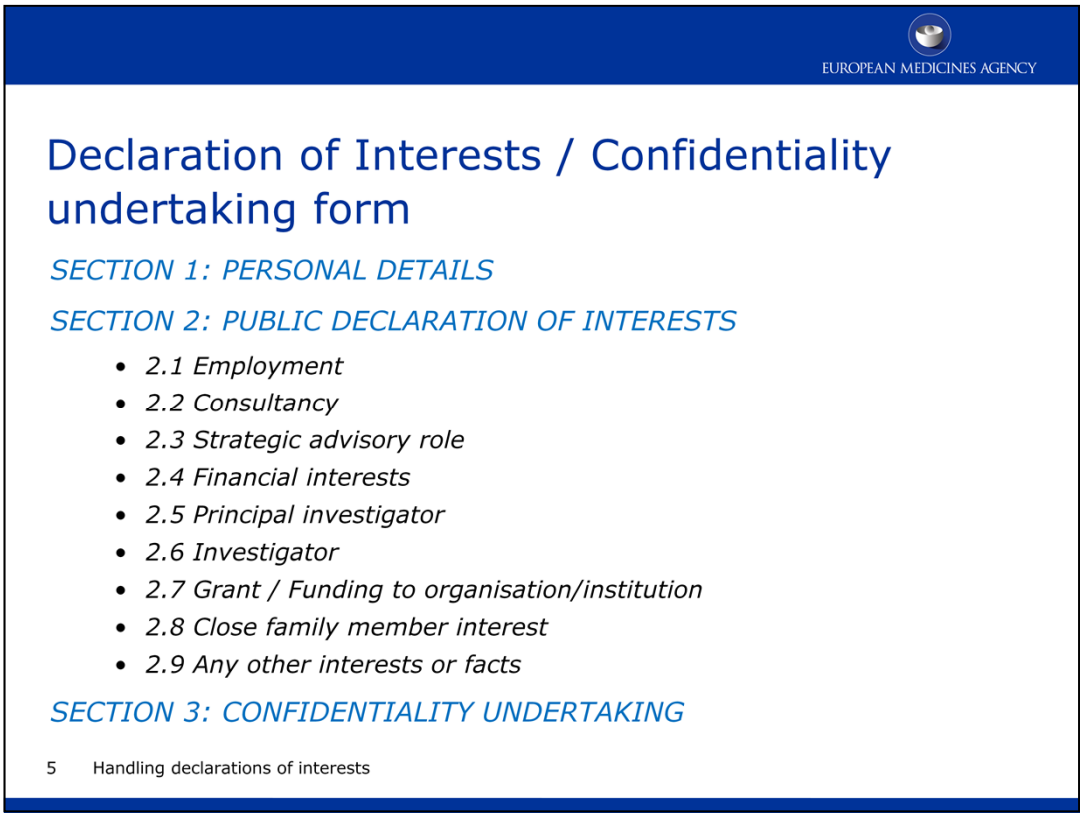
A Declaration of interests and confidentiality form,

a curriculum vitae

and an expert nomination form.



In the next few minutes we will take you through the process of completing and submitting these 3 documents.

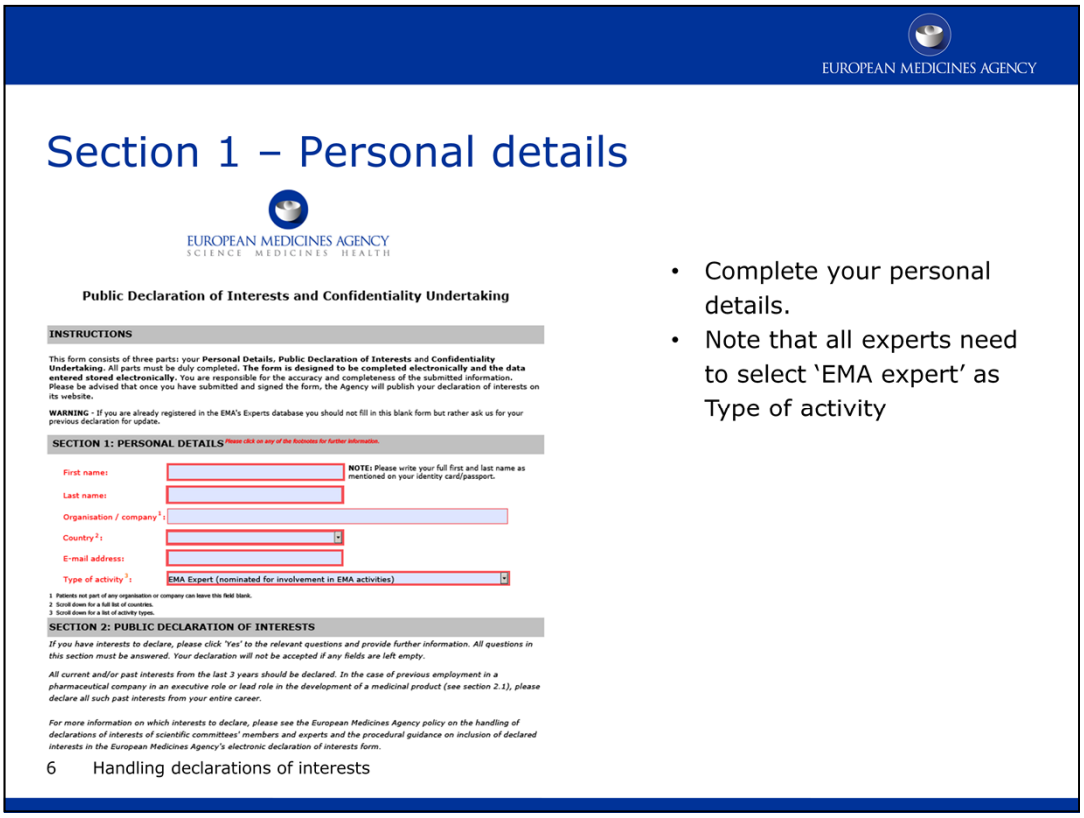


Let's begin with the Declaration of Interests and Confidentiality form. This document consists of 3 sections:

Personal details,

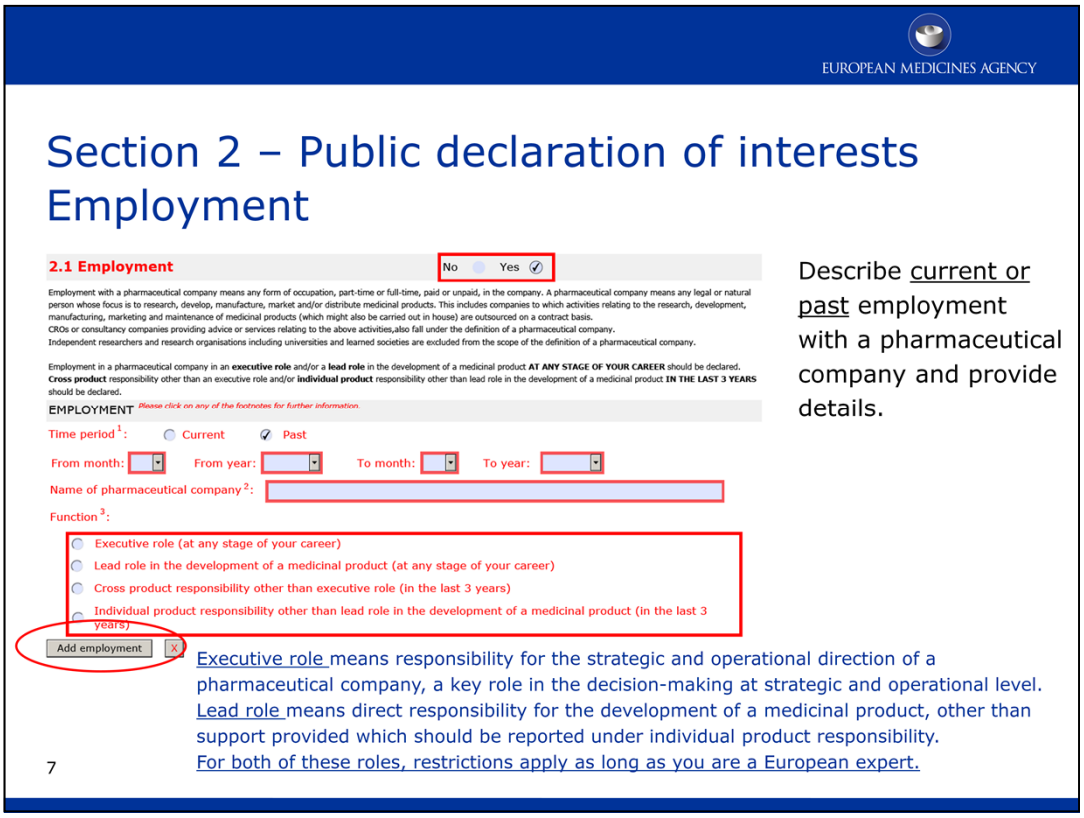
Declaration of Interests

and the Confidentiality undertaking.



In Section 1 of the DoI form, complete the details requested.

Please ensure that you use your first and last name as they appear on any official identification papers such as a passport or identity card.



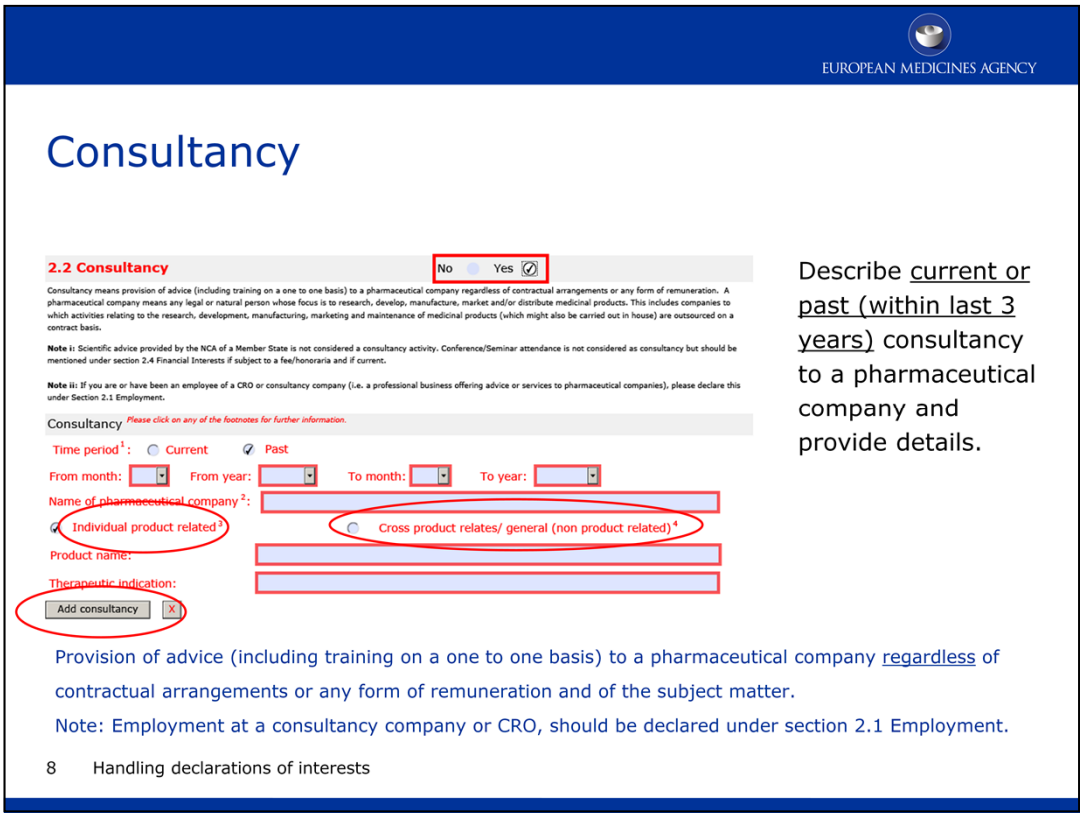
In section 2.1, you must provide information on any employment with a pharmaceutical company.

Employment in an executive role or lead role in the development of a medicine at any stage of your career should be declared.

All other employment should be declared if it us current or within the last 3 years.

This information should correspond with what you show in your CV.

You can add more information by clicking on ‘add employment’.



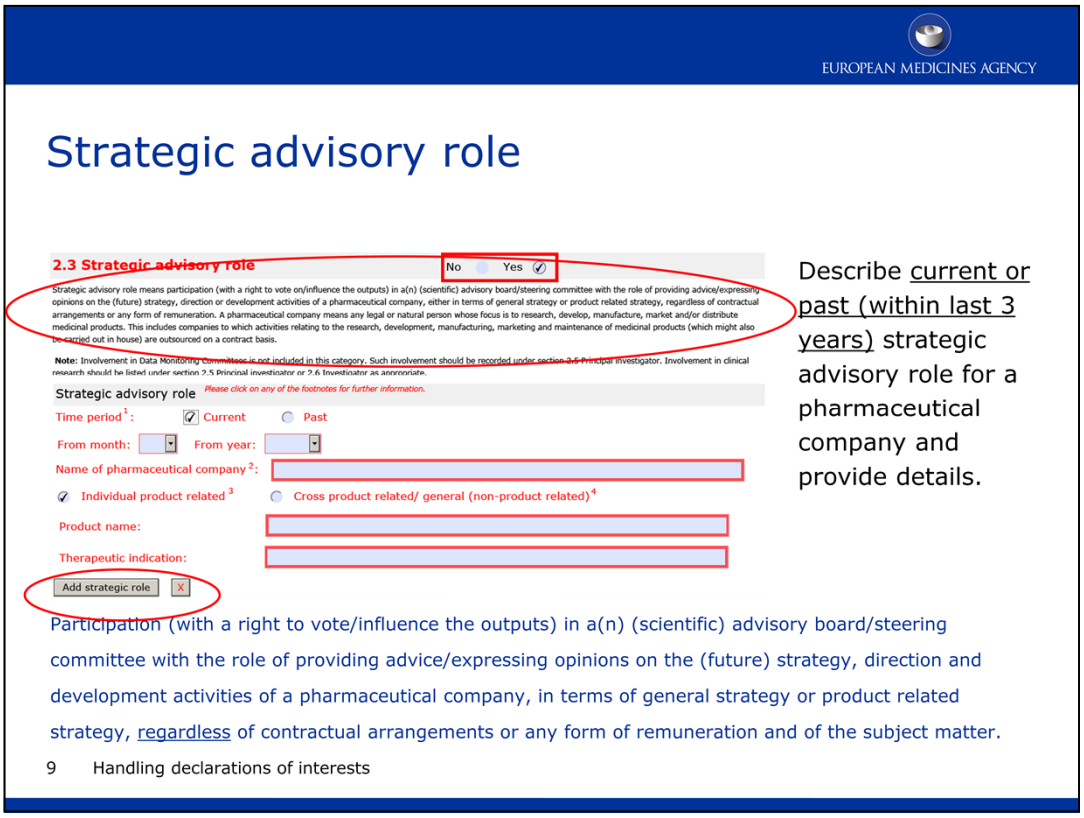
In section 2.2, you must describe any consultancy activities with a pharmaceutical company that are current or within the past 3 years.

Consultancy is considered any occasion that you engage with a pharmaceutical company regardless of the subject.

This does not include participation in public meetings such as conferences

Select whether your involvement was related to an individual medicinal product or if it was cross product or non-product related.

Additional activities can be added.



Any strategic advisory role for a pharmaceutical company needs to be declared regardless of the topic or whether you were paid for this activity.

A strategic advisory role is where you have a voting right or can influence company decisions – please refer to the definition for full details

More than one activity can be added as required.

Declare any current financial interests in a pharmaceutical company in section 2.4.

These includes

- shares in a pharmaceutical company,
- fees or honoraria paid by a company directly to you in a personal capacity
- patents relating to a medicine for which you are the patent owner or a direct beneficiary.

Fill in the name of the pharmaceutical company and the type of financial interest.

Use the add button to declare more interests.

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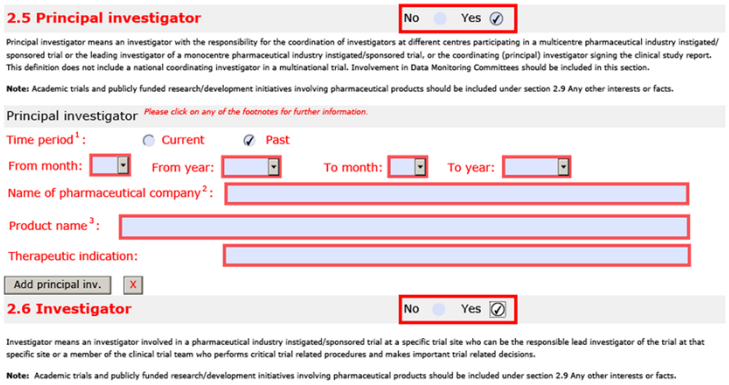
Principal investigator – investigator



Describe current or past (within last 3 years) principal investigator and investigator and provide details.

Involvement in a clinical trial instigated/sponsored by a pharmaceutical company as principle investigator (2.5) or investigator (2.6)

In sections 2.5 and 2.6, you must declare if you have been a principle investigator or an investigator in a clinical trial sponsored by a pharmaceutical company.

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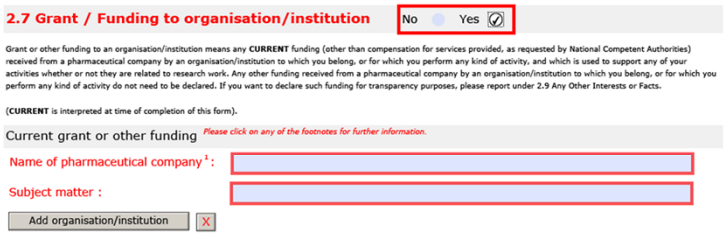
Grant or funding to organisation/ institution



Describe <u>current</u> grants or funding from a pharmaceutical company and provide details.

Any funding received from a pharmaceutical company by an organisation/institution to which the expert belongs, or for which he/she performs any kind of activity, and which is used to support any activity of the expert whether or not it is related to research work.

If the organisation or institution to which you belong, currently receives grants or funding from a pharmaceutical company and you and your activities at your organisation or institution benefit directly from these grants or funding, then this needs to be described uncer section 2.7.

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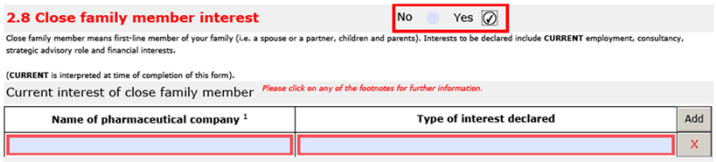
Close family member interest

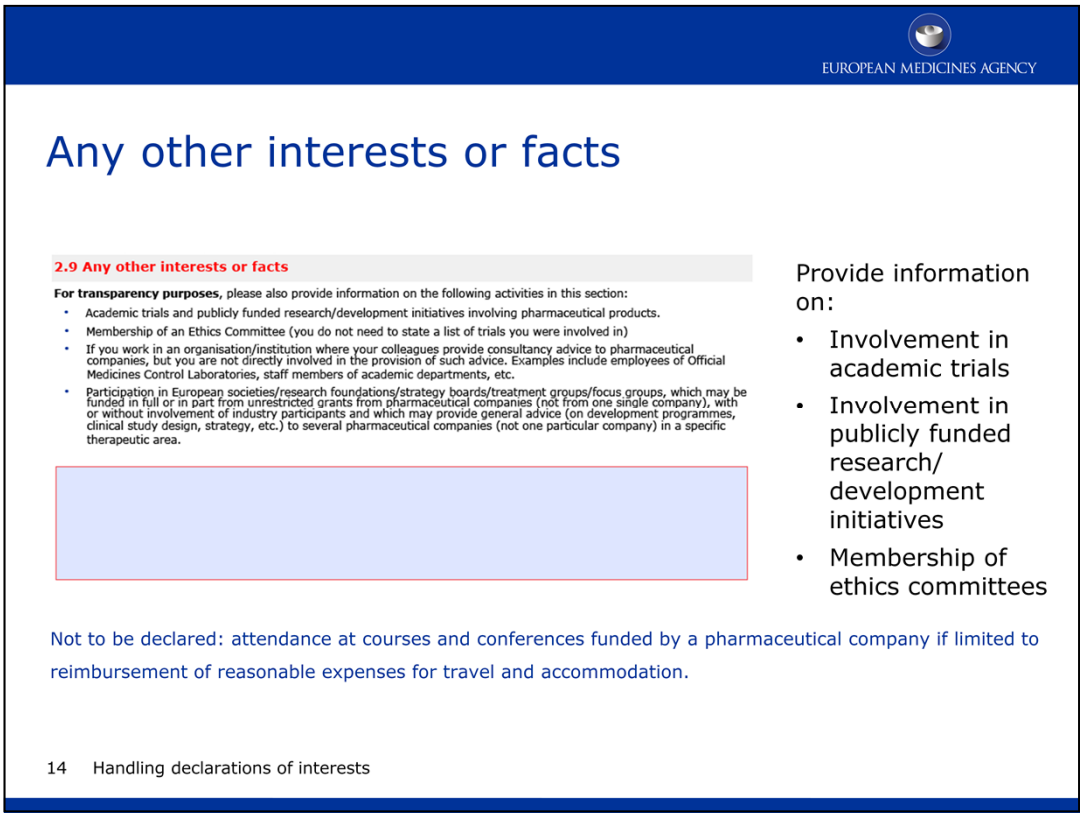


Describe <u>current</u> interests of close family members in a pharmaceutical company and provide details.

Current employment, consultancy, strategic advisory role, financial interests of spouse/partner, children or parents, to the best of your knowledge.

If your close family members, being your spouse or partner, children or parents, have current interests in a pharmaceutical company, you must declare it in section 2.8.

This includes employment, consultancy, strategic advisory role and financial interests.



Other information for transparency purposes can be provided in section 2.9

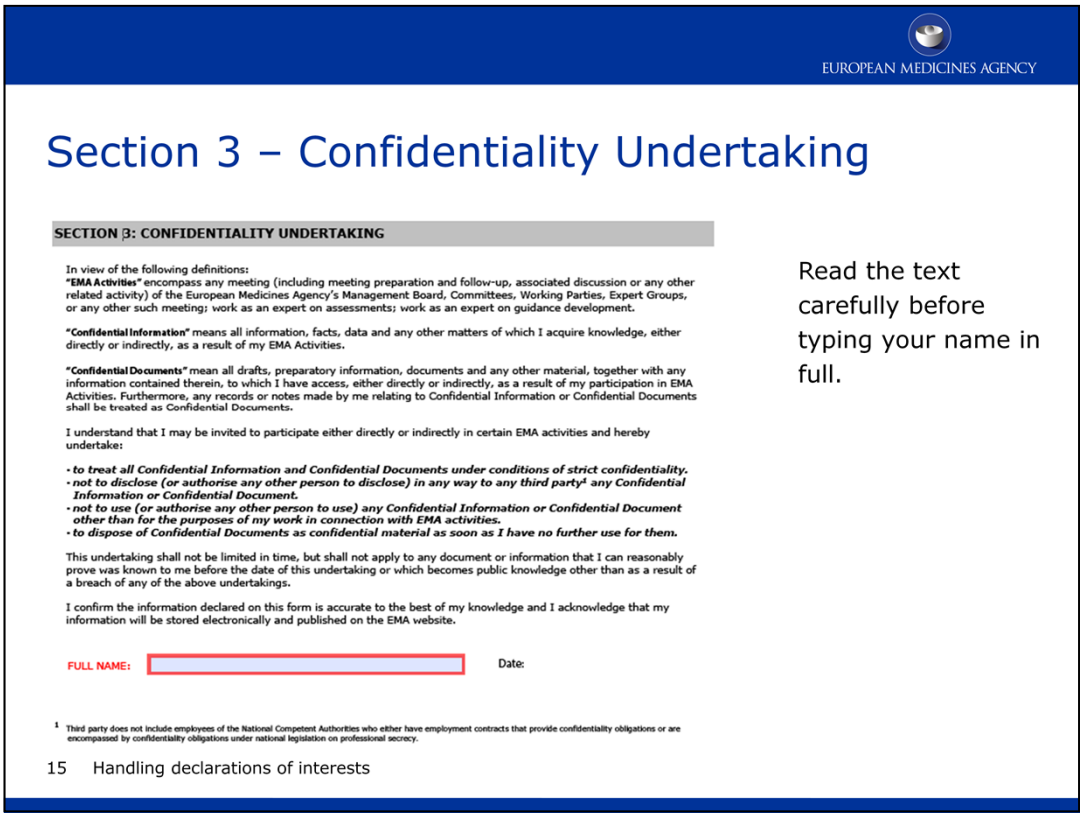
These include

- Involvement in academic trials
- Involvement in publicly funded research/development initiatives
- Membership of ethics committees

No restrictions in participation in EMA activities apply to this information .

Attendance at courses and conferences funded by a pharmaceutical company do not need to be declared if the funding is limited to reimbursement of reasonable expenses for travel and accommodation.

Any payment beyond these reasonable expenses, e.g. a speaker's fee, is considered a financial interest and should be declared in section 2.4.



Read the text carefully before typing your name in full.

In this final section of the DoI form, it is important to carefully read the information regarding confidential information and documents.

By including your full name in the red box in this section, you confirm the interests declared and your undertaking regarding confidentiality.

The date will be filled in automatically once you submit the form.

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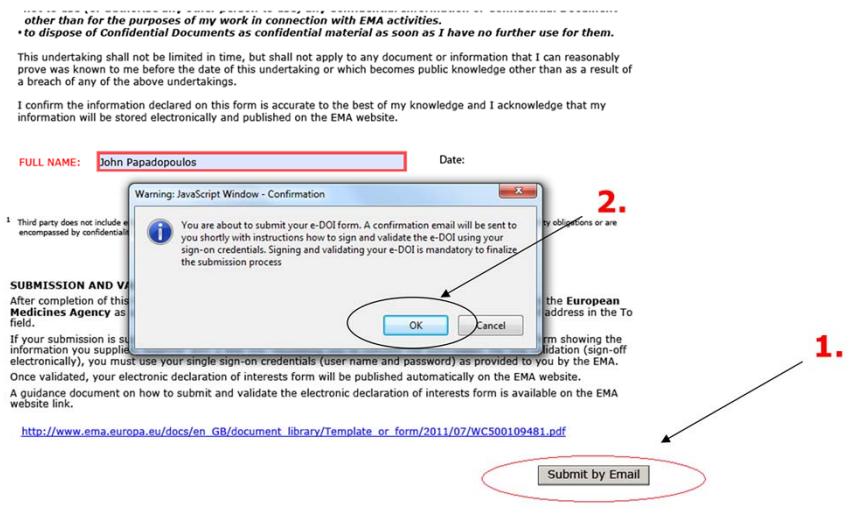
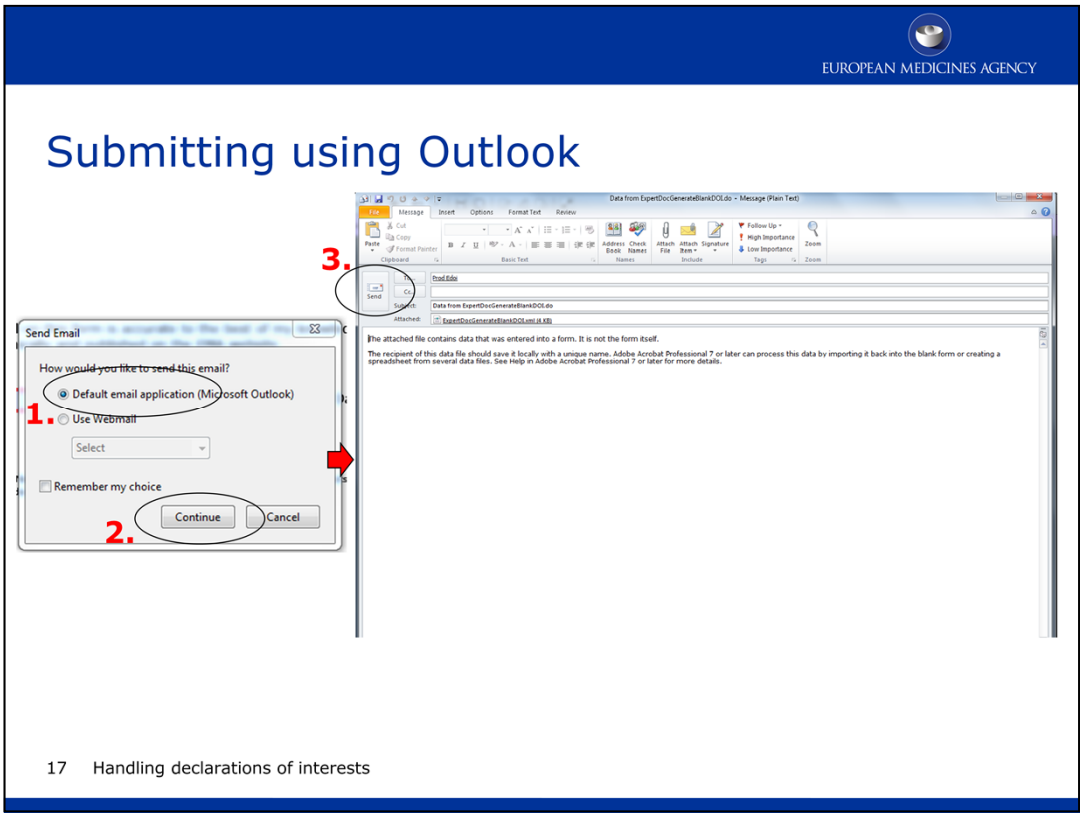
Submitting your declaration of interests form



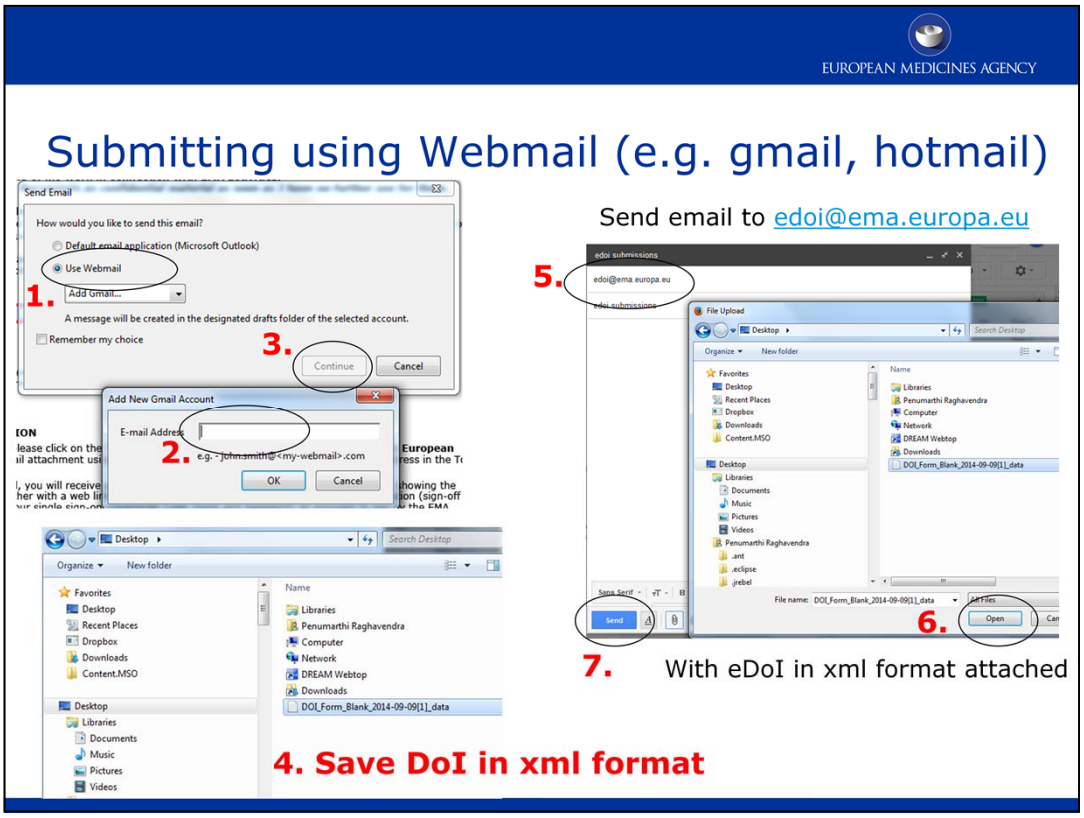
When the DoI form is completed and you are ready to submit it to EMA, click on the ‘submit by email’ button at the end of the form and click ‘OK’ on the window that will appear.



If you use Outlook for your emails, select this as your method for sending and then click ‘Continue’.

An xml version of your DoI is automatically generated and added as an attachment to an email message addressed to the EMA.

Do not change anything in this email message. Simply click on the ‘send’ button.



If you do not use outlook, you can select a web based mail such as gmail, hotmail etc.

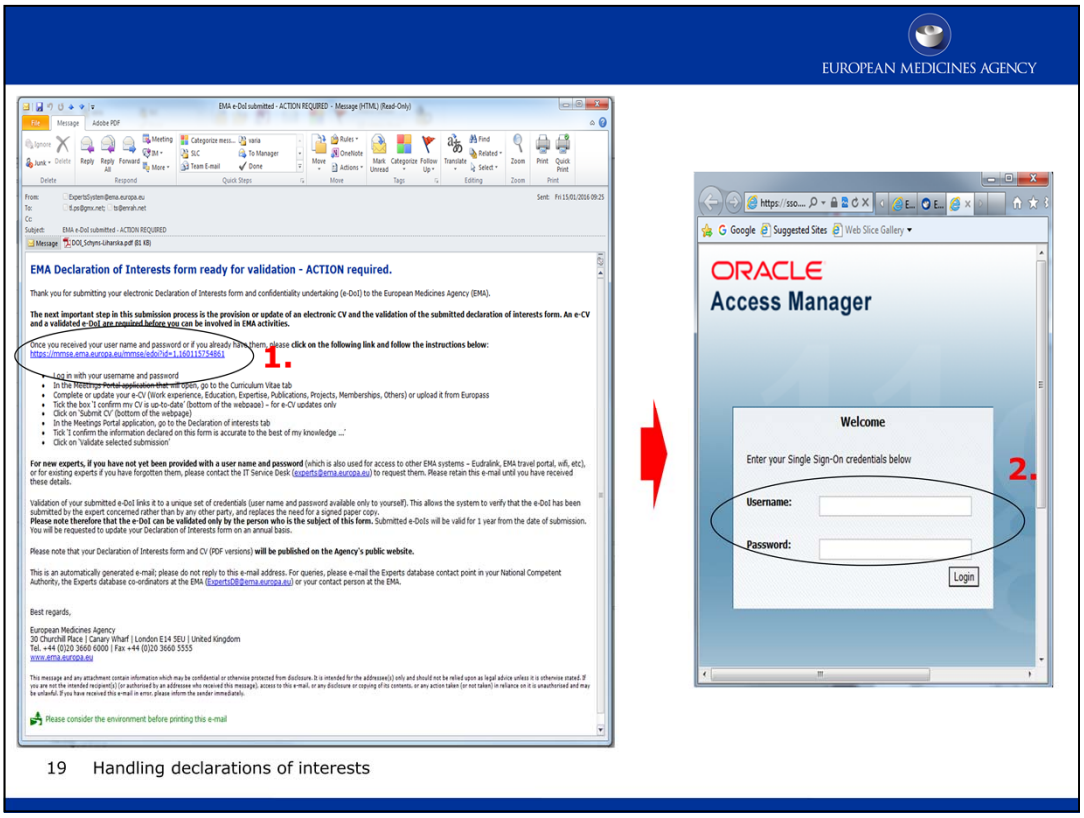
Select the Use Webmail option and select an existing email address from the drop-down list or add a new address by typing your email address in the window that appears when you select add mail.

Click on ‘continue’.

You will need to manually save your DoI which will have the extension .xml. You can save this file where you like on your computer.

You will then need to open your webmail account, go to your normal email box and ‘compose’ an email to the email address shown here edoi@ema.europa.eu

You will need to make sure you attach the xml file from wherever you saved it and click on send.



After you have sent the email to EMA, you will receive a confirmation e-mail. If you do not receive this email immediately, contact the IT service desk or your EMA contact person.

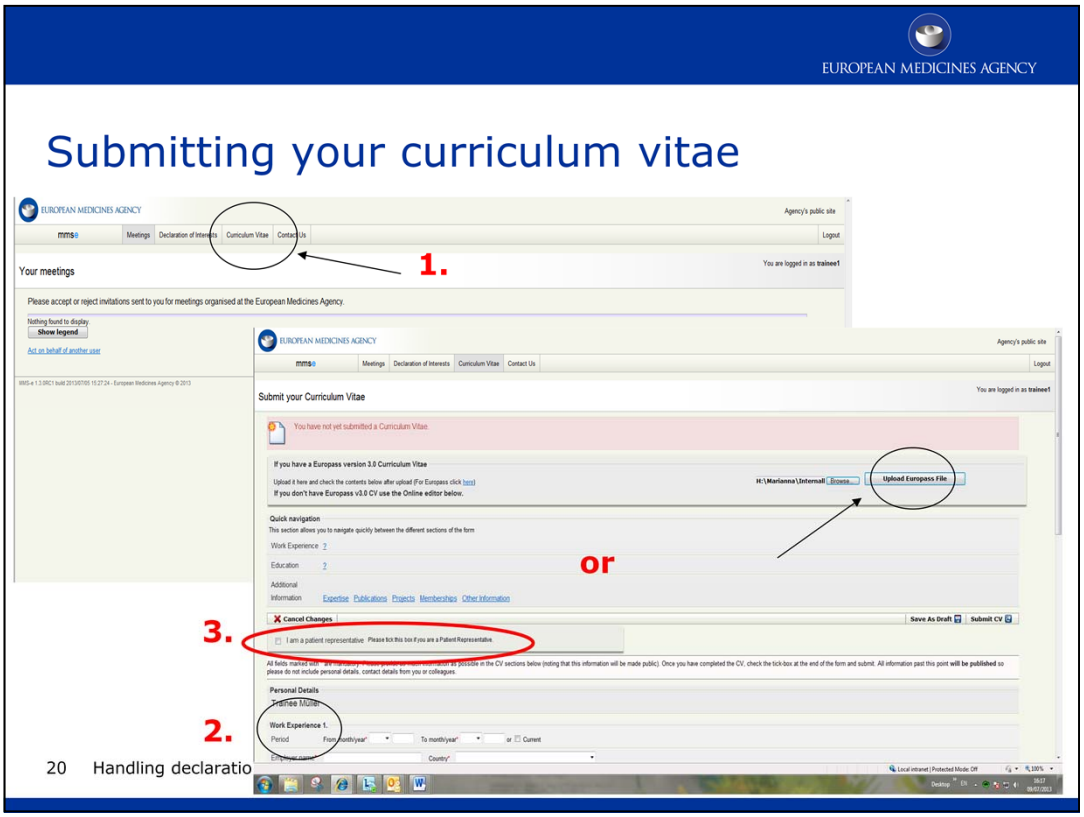
Do not delete this email, as you will need the link to access the EMA system for validation of your DoI.

You should receive a second email with single-sign-on credentials (a username and password)

If you already have your username and password from other EMA tools such as MMD or Eudralink, you can use them.

If you did not receive any credentials, please contact the IT Service Desk – the details are provided at the end of this video.

Click on the link in the email and login to the EMA system with your username and password.



In order to validate your DoI you will first need to submit a curriculum vitae.

To do this - Go to the Curriculum vitae tab.

There is the option of using the online editor in the system directly or uploading your own Europass CV as shown here.

If you are a patient, you can use the Tick box option for ‘Patient representative’ as shown here.

In this case, further completion of the CV is not mandatory, but still required if you have relevant experience.

In all cases, please make sure that your CV matches with your DoI.

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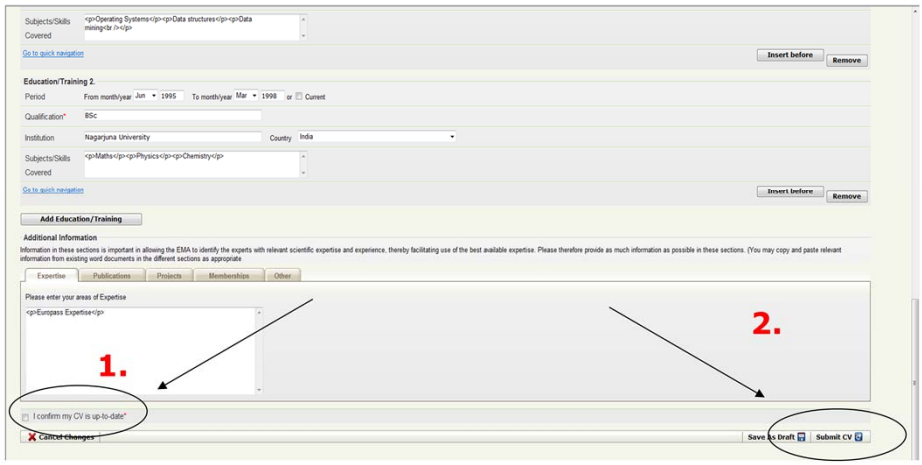
Submitting your curriculum vitae

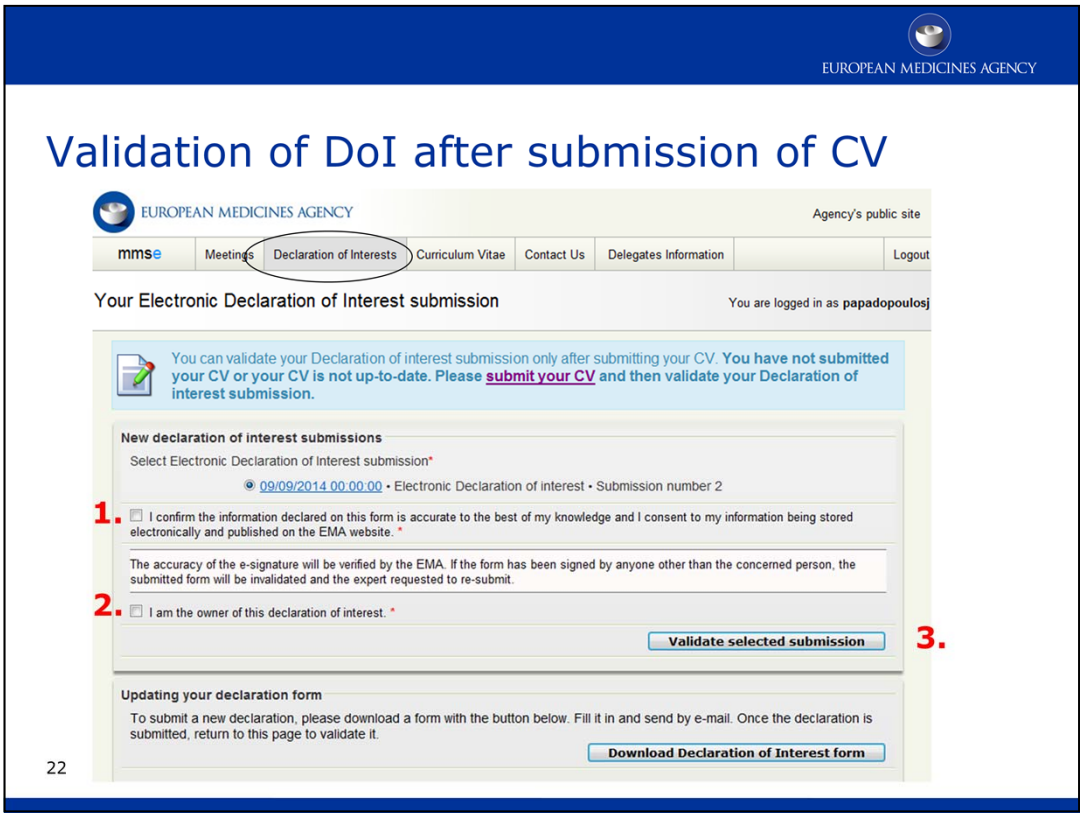


Further information on expertise, publications, projects and memberships can also be provided.

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.

Then click on ‘Submit CV’.

Scroll back up to the top of the page and go to the Declaration of interests tab.



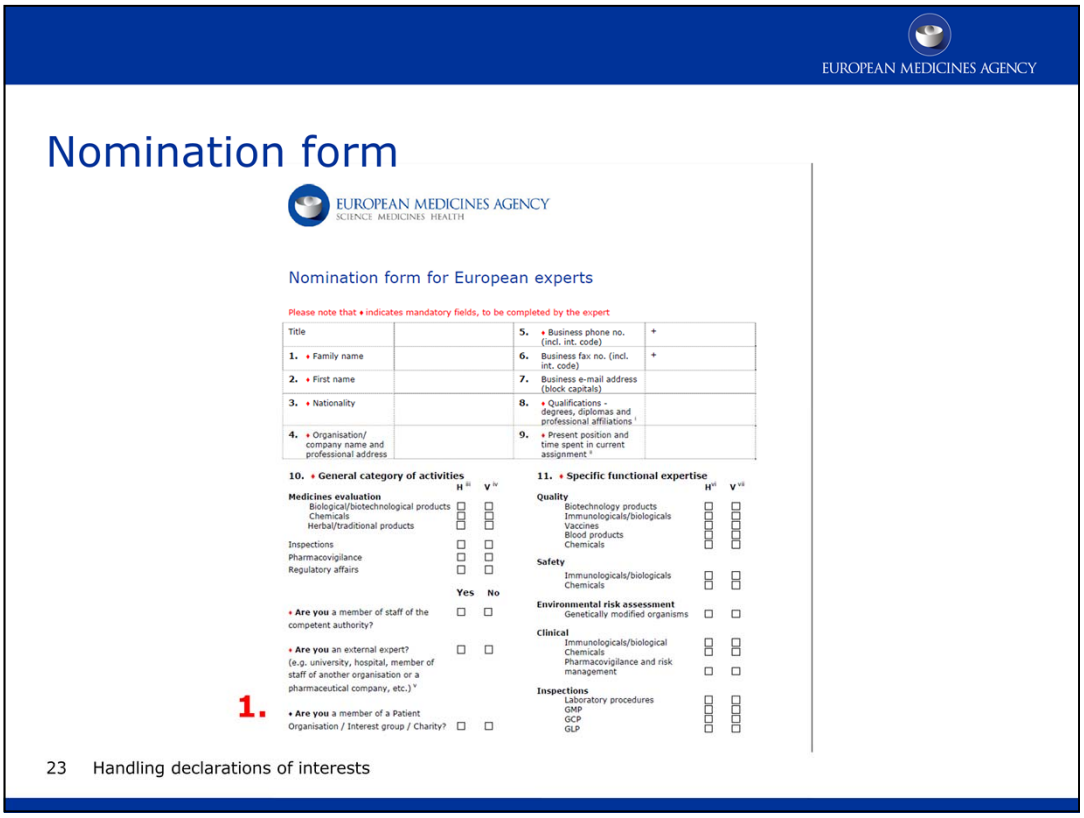
Select the submitted DoI that you want to validate.

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'.

You must also tick the 'I am the own of this declaration of interest box' .

Finally click on the 'Validate selected submission' button.

This concludes the submission and validation of your DoI and CV.

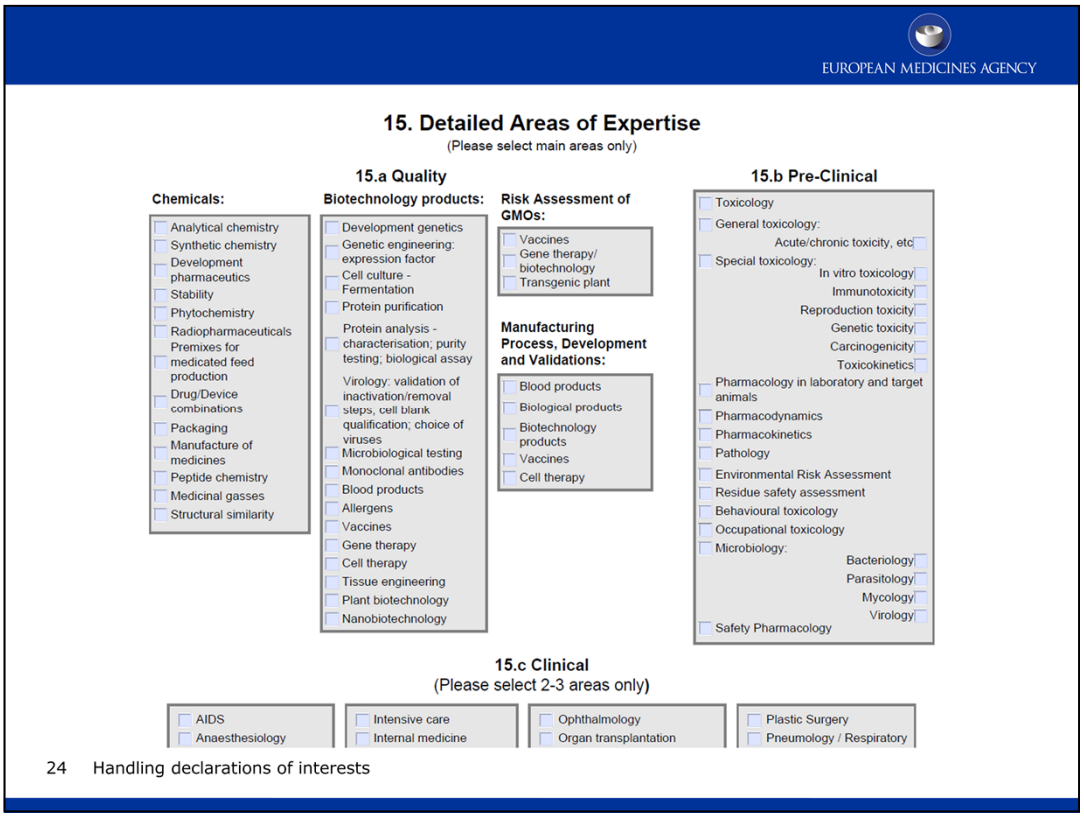


The final document to complete is what is the nomination form for European experts. All experts need to complete this form to indicate one or more areas of expertise.

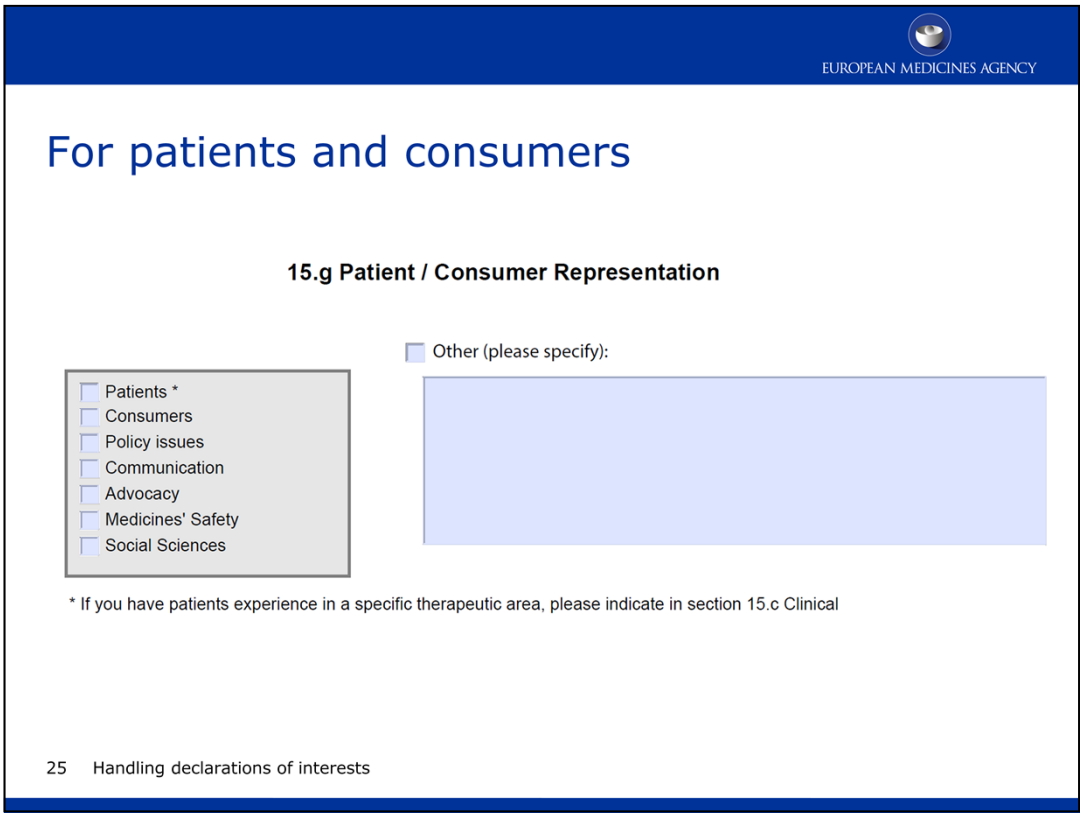
On the first page, please complete your details and indicate the general categories of activities and specific functional expertise applicable to you.

If you are a patient representative, you can select the ‘I am a member of a patient organisation/interest group or charity’ box.

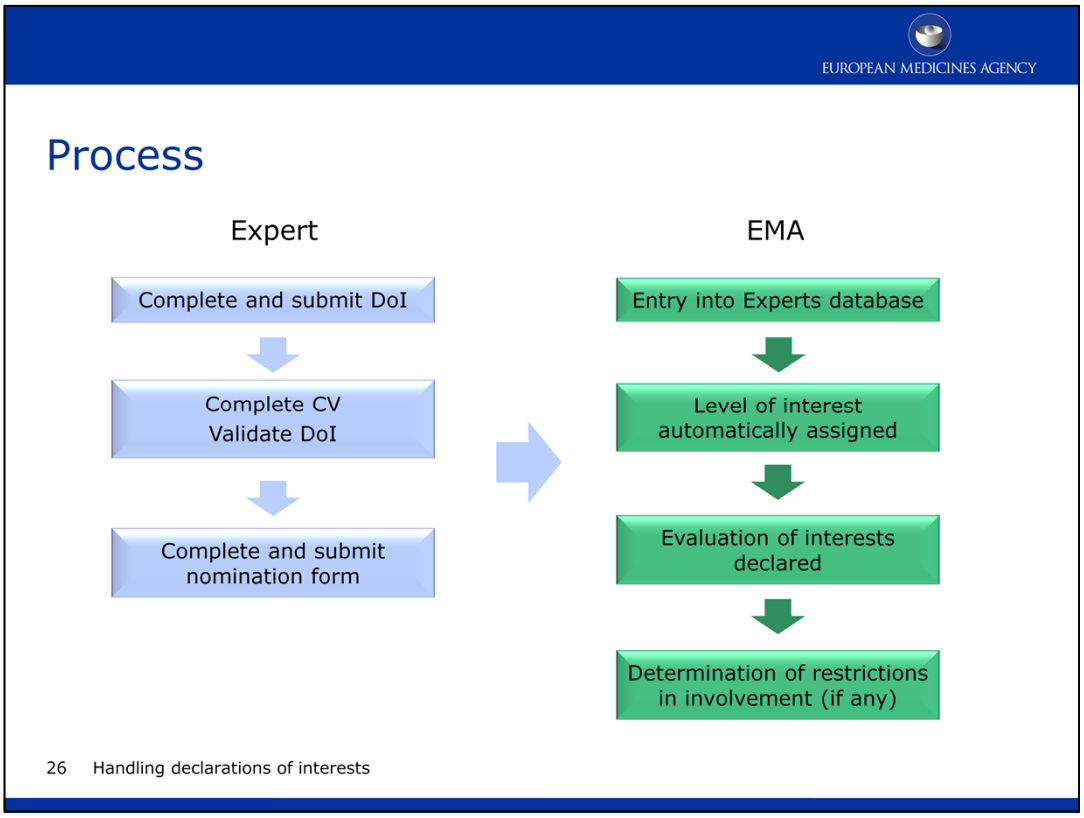
There is no need to sign this form.



If you have any specific areas of expertise, please indicate them here. Otherwise please leave them blank



For patient and consumer representatives, please select the appropriate boxes in section 15g

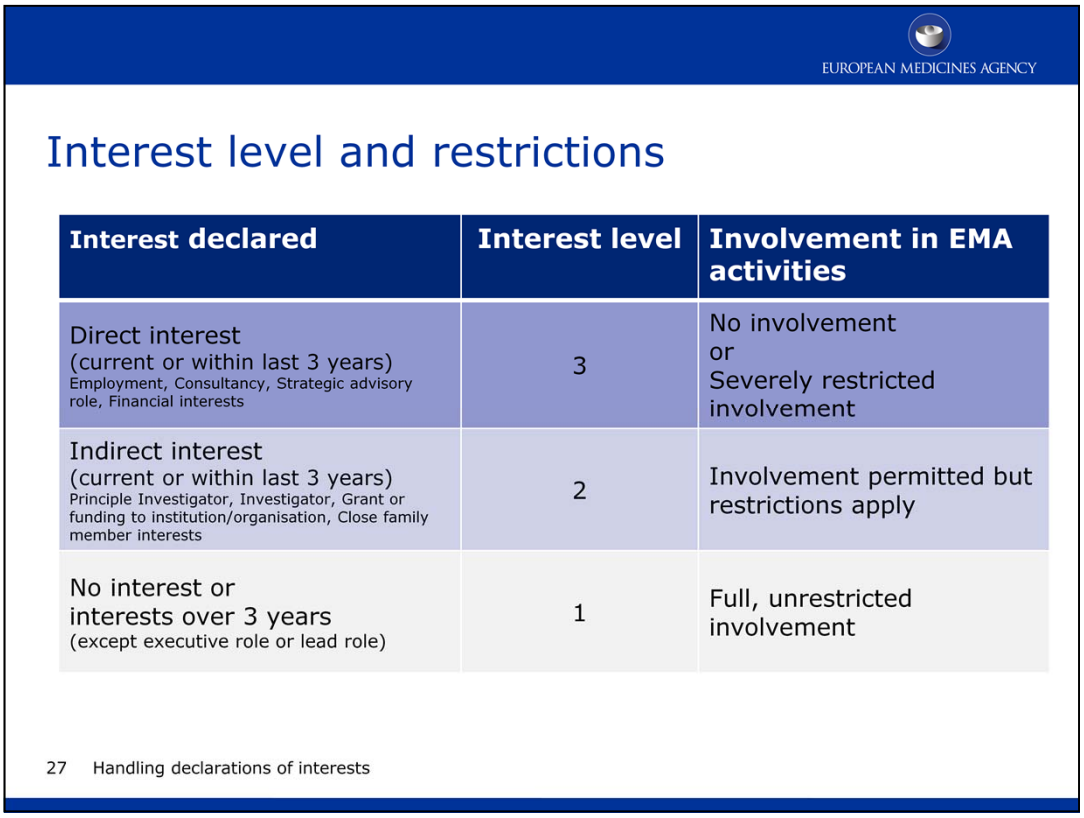


If you are an expert nominated by the EMA, return the completed form to your contact person at EMA.

For experts nominated by an EU member state, you should return this form to your contact point in the national agency.

Once EMA has received the three documents, we will progress with your inclusion into the Experts database.

An interest level will be assigned based on your declared interests. Your interests are evaluated to determine if you can be involved in EMA activities and if any restrictions apply.



The type of interests declared determine the interest level.

Interest level 3 applies to direct interests in a pharmaceutical company such as employment,

Interest level 2 for indirect interests such as principal investigator and

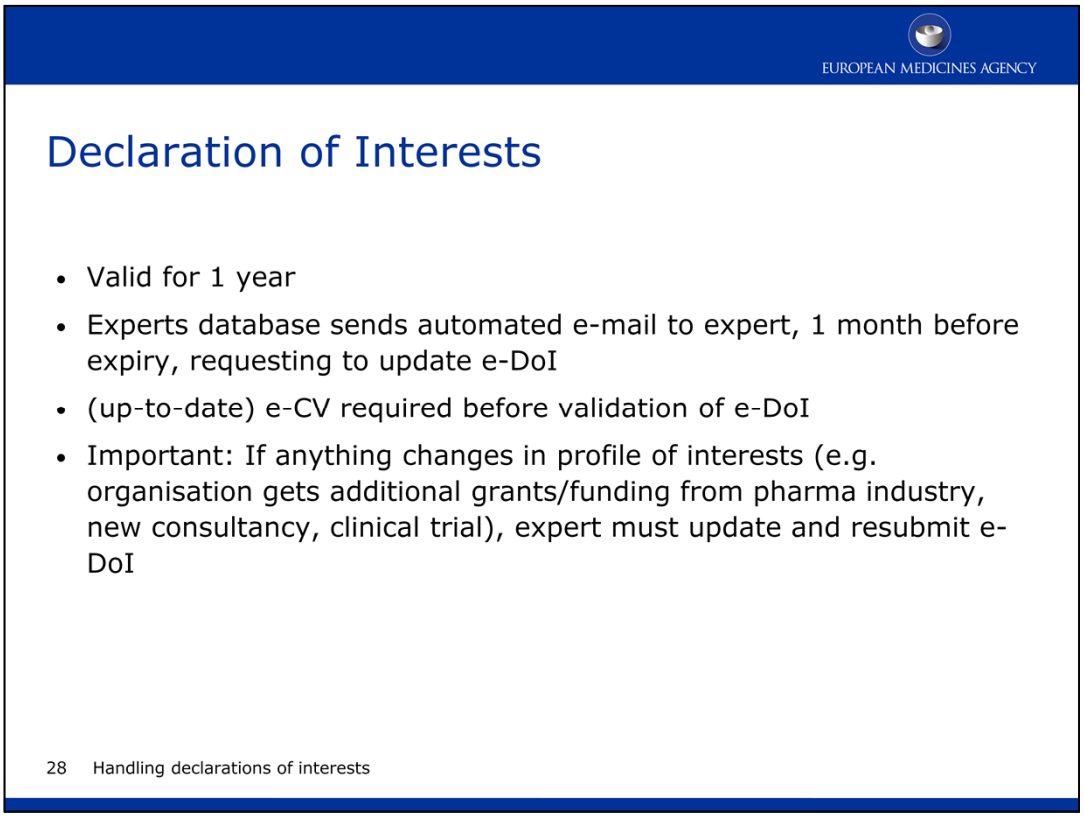
interest level 1 is where no interests are declared or if interests are older than 3 years, except for employment in an executive or lead role.

Interest level 1 experts have no restrictions in EMA activities.

For interest level 2 or 3 experts, restrictions on involvement apply depending on the interest declared and on the EMA activity.

Some interests such as current employment in a pharmaceutical company results in no involvement in any EMA activity.

For more details please go to the policy document.



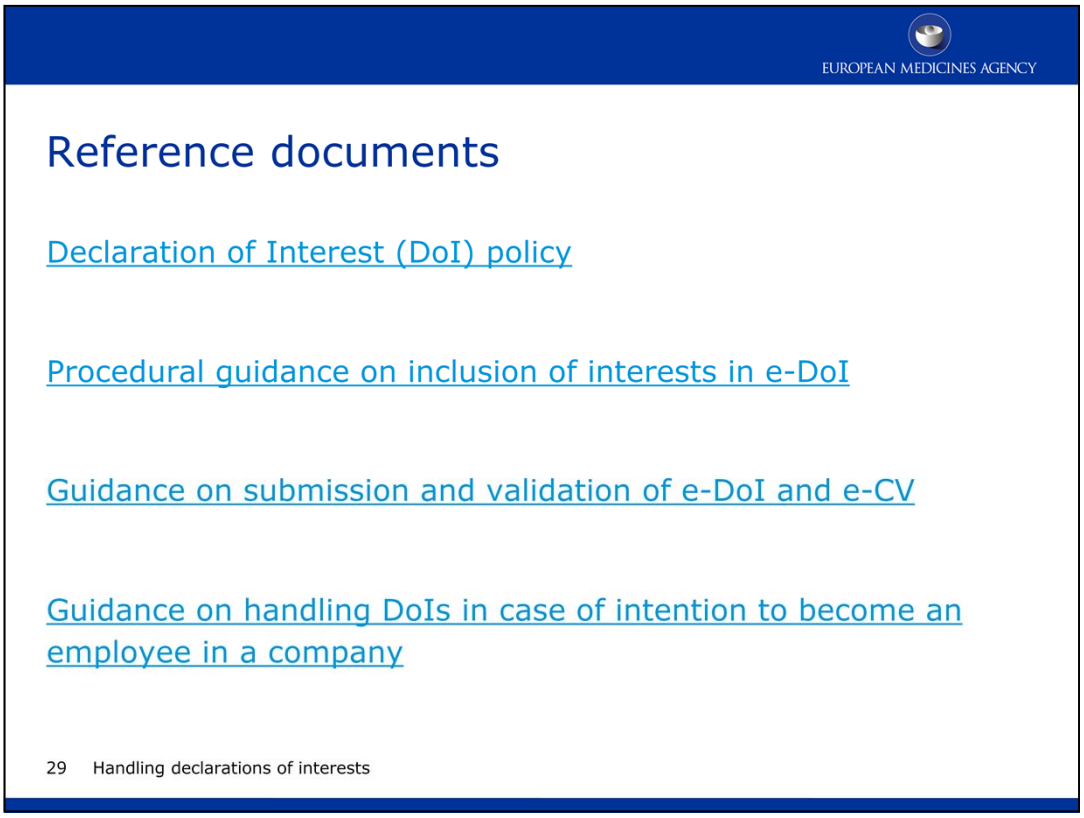
Finally,

Your DoI is valid for one year.

One month before it expires, you will receive an email requesting you to update it.

You can only validate your updated DoI if you update your CV or confirm that it is still up-to-date.

Please note that if your circumstances change during the year, it is important to inform the Agency by submitting an updated DoI.



More information on delarations of interests can be found in the policy and its guidance documents.

Please click on the links available in the pdf version of this talk.

Please also visit our dedicated webpage or consult our Frequently Asked Questions section.

For any technical issues, please contact the IT service desk at https://servicedesk.ema.europa.eu