EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

e-DoI and e-CV submission: Why – Who – What – How ?

Training session for patients and consumers involved in EMA activities – 25 November 2014

Presented by Luc Van Santvliet
Scientific Committee Support Department

An agency of the European Union

What the legislation says

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

Members of […] 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 ...

EMA policy on handling of conflicts of interests of scientific committees' members and experts

Applies to:

- Scientific committee members and alternates
- Experts involved in Agency 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

Requirements for involvement in EMA activities: Experts database

Experts must be included in Experts database prior to first appointment

- Signed **nomination form**
  - Signed by Head of NCA (MS experts) or Head of Division (EMA experts)
- Up-to-date **e-DoI** signed/validated by the expert
- Up-to-date **e-CV** (required to validate/sign e-DoI)
- Request for creation of new expert in Experts database
  - from NCA (MS experts) or Experts database coordinator (EMA experts)

Completion of e-DoI

Direct interests – °current, *within past 5 years

- Employment with a company°*
- Consultancy for a company°*
- Strategic advisory role for a company°*
- Financial interests°
- Ownership of a patent for a medicinal product°

Definitions and explanatory notes in e-DoI form

Completion of e-DoI

Indirect interests – °current, *within past 5 years

- Principal investigator°*
- Investigator°*
- Grant or other funding to instituion/organisation°

- Direct interests of household members° *(resulting as indirect interest of the individual)*

Completion of e-CV

- Work experience
- Education/training
- Expertise, Publications, Projects, Memberships, Other

- Tick box for 'Patient representative' – if ticked, further completion of e-CV is not mandatory, but recommended for committee member

Online editor or download from Europass in EMA Meetings Portal

e-DoI validity

- Valid for 1 year

  Experts database sends automated e-mail to expert, approx 1 month before expiry, requesting to update e-DoI
- (up-to-date) e-CV required before validation of e-DoI
- Important

  If anything changes in profile (e.g. organisation gets additional grants/funding from pharma industry), expert must update and resubmit e-DoI

How to submit e-DoI and e-CV

- Complete blank nomination form
- Return to NCA or EMA by e-mail
- Complete e-DoI (blank form or current e-DoI)
- 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 e-mail with xml file attached (webmail)
- When receiving a confirmation e-mail, click on the link in the e-mail
- Log in with single-sign-on credentials (same as for MMD, Eudralink, MMS – provided by the Agency)

How to submit e-DoI and e-CV

- In MMSe, go to the Curriculum Vitae tab
- Tick the box 'I am a patient representative'
- Update e-CV as appropriate or upload a new version of CV from the Europass website
- Tick the box 'I confirm my CV is up-to-date' (bottom of page)
- Click on 'Submit CV'
- In MMSe, go to the Declaration of interests tab
- Tick 'I confirm the information declared on this form is accurate to the best of my knowledge and I acknowledge that ...'
- Click on 'Validate selected submission'

Nomination Form for European Experts

*This form requires Adobe **Acrobat Reader version 7.0***

Please fill in all sections of the Nomination Form as required:

- Mandatory fields for Experts are indicated with
- After completion click Submit by Email, type in the ***To:*** field the e-mail address of your Contact Point
- Click Print Form to keep a record of this form

Title:

1. Last Name:

Gender: ◯ Male ◯ Female

First Name:

3. National of:

4. Professional Address

Organisation Name:

Address:

Postal code: City:

Country:

5. Business Tel:

6. Business Fax:

7. Business E-mail:

8. Qualifications - Degrees, Diplomas and Professional Affiliations [i]:

9. Present position and time in current assignment [ii]:

10. General Category of Activities

	H [iii]	V [iv]
Medicines Evaluation Biologicals/Biotechnology products:	☐	☐
Chemicals:	☐	☐
Herbal/Traditional Products:	☐	☐
Inspections:	☐	☐
Pharmacovigilance:	☐	☐

11. Specific Functional Expertise [vi]

Quality	H [vii]	V [viii]
Biotechnology products:	☐	☐
Immunologicals/Biologicals:	☐	☐
Vaccines:	☐	☐
Blood products:	☐	☐

12. Availability

- ☐ Dossier Evaluation
- ☐ Scientific Advice
- ☐ Guidelines

Other Specify:

15. Detailed Areas of Expertise

(Please select main areas only)

15.a Quality

Chemicals:

- Analytical chemistry
- Synthetic chemistry
- Development pharmaceutics
- Stability
- Phytochemistry
- Radiopharmaceuticals
- Premixes for medicated feed production
- Drug/Device combinations
- Packaging
- Manufacture of medicines
- Peptide chemistry
- Medicinal gasses
- Structural similarity

Biotechnology products:

- Development genetics
- Genetic engineering: expression factor
- Cell culture - Fermentation
- Protein purification
- Protein analysis - characterisation; purity testing; biological assay
- Virology: validation of inactivation/removal steps; cell blank qualification; choice of viruses
- Microbiological testing
- Monoclonal antibodies
- Blood products
- Allergens
- Vaccines
- Gene therapy
- Cell therapy
- Tissue engineering
- Plant biotechnology
- Nanobiotechnology

Risk Assessment of GMOs:

- Vaccines
- Gene therapy/ biotechnology
- Transgenic plant

Manufacturing Process, Development and Validations:

- Blood products
- Biological products
- Biotechnology products
- Vaccines
- Cell therapy

15.b Pre-Clinical

- Toxicology
- General toxicology:
  - Acute/chronic toxicity, etc
- Special toxicology:
  - In vitro toxicology
  - Immunotoxicity
  - Reproduction toxicity
  - Genetic toxicity
  - Carcinogenicity
  - Toxicokinetics
- Pharmacology in laboratory and target animals
- Pharmacodynamics
- Pharmacokinetics
- Pathology
- Environmental Risk Assessment
- Residue safety assessment
- Behavioural toxicology
- Occupational toxicology
- Microbiology:
  - Bacteriology
  - Parasitology
  - Mycology
  - Virology
- Safety Pharmacology

15.c Clinical

(Please select 2-3 areas only)

- AIDS
- Anaesthesiology
- Intensive care
- Internal medicine
- Ophthalmology
- Organ transplantation
- Plastic Surgery
- Pneumology / Respiratory

15.g Patient / Consumer Representation

- [ ] Patients *
- [ ] Consumers
- [ ] Policy issues
- [ ] Communication
- [ ] Advocacy
- [ ] Medicines' Safety
- [ ] Social Sciences

- [ ] Other (please specify):

* If you have patients experience in a specific therapeutic area, please indicate in section 15.c Clinical

Public Declaration of Interests and Confidentiality Undertaking

INSTRUCTIONS

This document consists of three parts, your **Personal Details**, the **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 adviced that once you have submitted and signed the form, the Agency will publish your declaration of interests on its website.

SECTION 1: PERSONAL DETAILS

First name:	
Last name:	
Organisation / company:	
Country:	
E-mail address:	
Type of activity:	EMA Expert (nominated for involvement in EMA activities)

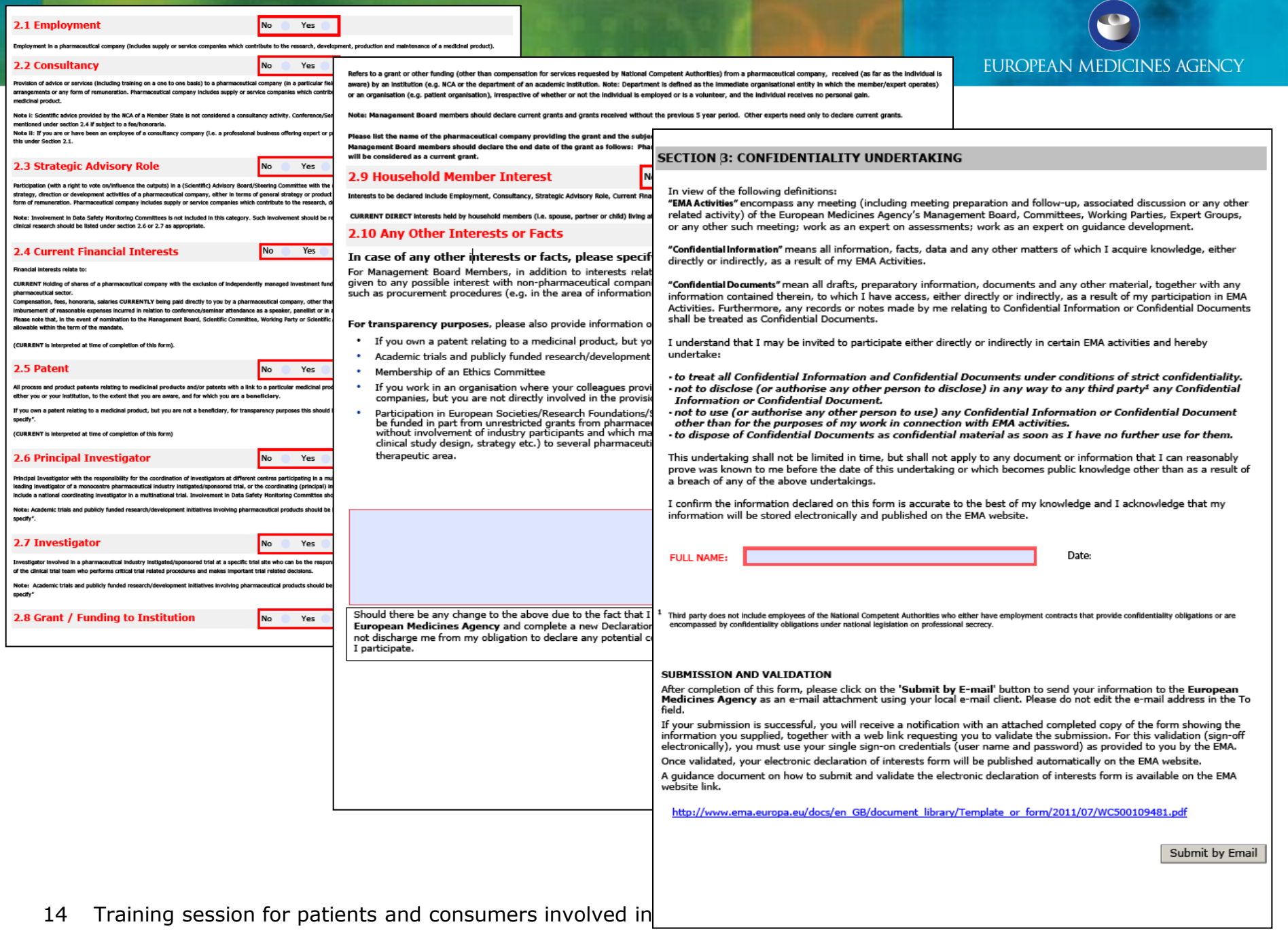
WARNING - If you are already registered in the EMA's Experts database you should not fill in this blank form but rather ask for your original form.
NOTE: Please write yourfull first and last name as mentioned on your identity card/passport.

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 past 3 years should be declared. In the case of 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 past interests from you 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 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:



2.1 Employment

No Yes

Employment in a pharmaceutical company (includes supply or service companies which contribute to the research, development, production and maintenance of a medicinal product).

2.2 Consultancy

No Yes

Provision of advice or services (including training on a one to one basis) to a pharmaceutical company (in a particular fiel
arrangements or any form of remuneration. Pharmaceutical company includes supply or service companies which contrib
medicinal product.

Note I: Scientific advice provided by the NCA of a Member State is not considered a consultancy activity. Conference/Se
mentioned under section 2.4 if subject to a fee/honoraria.
Note II: If you are or have been an employee of a consultancy company (i.e. a professional business offering expert or p
this under Section 2.1.

2.3 Strategic Advisory Role

No Yes

Participation (with a right to vote on/influence the outputs) in a (Scientific) Advisory Board/Steering Committee with the
strategy, direction or development activities of a pharmaceutical company, either in terms of general strategy or product
form of remuneration. Pharmaceutical company includes supply or service companies which contribute to the research, d

Note: Involvement in Data Safety Monitoring Committees is not included in this category. Such involvement should be re
clinical research should be listed under section 2.6 or 2.7 as appropriate.

2.4 Current Financial Interests

No Yes

Financial interests relate to:

CURRENT Holding of shares of a pharmaceutical company with the exclusion of independently managed investment fund
pharmaceutical sector.
Compensation, fees, honoraria, salaries CURRENTLY being paid directly to you by a pharmaceutical company, other tha
imbursement of reasonable expenses incurred in relation to conference/seminar attendance as a speaker, panellist or in
Please note that, in the event of nomination to the Management Board, Scientific Committee, Working Party or Scientific
allowable within the term of the mandate.

(CURRENT is interpreted at time of completion of this form).

2.5 Patent

No Yes

All process and product patents relating to medicinal products and/or patents with a link to a particular medicinal proc
either you or your institution, to the extent that you are aware, and for which you are a beneficiary.

If you own a patent relating to a medicinal product, but you are not a beneficiary, for transparency purposes this should
specify".

(CURRENT is interpreted at time of completion of this form)

2.6 Principal Investigator

No Yes

Principal Investigator with the responsibility for the coordination of investigators at different centres participating in a mu
leading investigator of a monocentre pharmaceutical industry instigated/sponsored trial, or the coordinating (principal) in
include a national coordinating investigator in a multinational trial. Involvement in Data Safety Monitoring Committee sh

Note: Academic trials and publicly funded research/development initiatives involving pharmaceutical products should be
specify".

2.7 Investigator

No Yes

Investigator involved in a pharmaceutical industry instigated/sponsored trial at a specific trial site who can be the respon
of the clinical trial team who performs critical trial related procedures and makes important trial related decisions.

Note: Academic trials and publicly funded research/development initiatives involving pharmaceutical products should be
specify"

2.8 Grant / Funding to Institution

No Yes

Refers to a grant or other funding (other than compensation for services requested by National Competent Authorities) from a pharmaceutical company, received (as far as the individual is aware) by an institution (e.g. NCA or the department of an academic institution. Note: Department is defined as the immediate organisational entity in which the member/expert operates) or an organisation (e.g. patient organisation), irrespective of whether or not the individual is employed or is a volunteer, and the individual receives no personal gain.

Note: Management Board members should declare current grants and grants received without the previous 5 year period. Other experts need only to declare current grants.

Please list the name of the pharmaceutical company providing the grant and the subje
Management Board members should declare the end date of the grant as follows: Pha
will be considered as a current grant.

2.9 Household Member Interest

N

Interests to be declared include Employment, Consultancy, Strategic Advisory Role, Current Fina

CURRENT DIRECT interests held by household members (i.e. spouse, partner or child) living a

2.10 Any Other Interests or Facts

In case of any other interests or facts, please specif

For Management Board Members, in addition to interests relat
given to any possible interest with non-pharmaceutical compan
such as procurement procedures (e.g. in the area of information

For transparency purposes, please also provide information o

- If you own a patent relating to a medicinal product, but yo
- Academic trials and publicly funded research/development
- Membership of an Ethics Committee
- If you work in an organisation where your colleagues provi
companies, but you are not directly involved in the provisi
- Participation in European Societies/Research Foundations/S
be funded in part from unrestricted grants from pharmace
without involvement of industry participants and which ma
clinical study design, strategy etc.) to several pharmaceuti
therapeutic area.

Should there be any change to the above due to the fact that I
European Medicines Agency and complete a new Declaratio
not discharge me from my obligation to declare any potential c
I participate.

SECTION 3: CONFIDENTIALITY UNDERTAKING

In view of the following definitions:
"EMA Activities" encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the European Medicines Agency's Management Board, Committees, Working Parties, Expert Groups, or any other such meeting; work as an expert on assessments; work as an expert on guidance development.

"Confidential Information" means all information, facts, data and any other matters of which I acquire knowledge, either directly or indirectly, as a result of my EMA Activities.

"Confidential Documents" mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in EMA Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

I understand that I may be invited to participate either directly or indirectly in certain EMA activities and hereby undertake:

- ***to treat all Confidential Information and Confidential Documents under conditions of strict confidentiality.***
- ***not to disclose (or authorise any other person to disclose) in any way to any third party[1] any Confidential Information or Confidential Document.***
- ***not to use (or authorise any other person to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with EMA activities.***
- ***to dispose of Confidential Documents as confidential material as soon as I have no further use for them.***

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:

[1] Third party does not include employees of the National Competent Authorities who either have employment contracts that provide confidentiality obligations or are encompassed by confidentiality obligations under national legislation on professional secrecy.

SUBMISSION AND VALIDATION

After completion of this form, please click on the **'Submit by E-mail'** button to send your information to the **European Medicines Agency** as an e-mail attachment using your local e-mail client. Please do not edit the e-mail address in the To field.

If your submission is successful, you will receive a notification with an attached completed copy of the form showing the information you supplied, together with a web link requesting you to validate the submission. For this validation (sign-off electronically), you must use your single sign-on credentials (user name and password) as provided to you by the EMA.

Once validated, your electronic declaration of interests form will be published automatically on the EMA website.

A guidance document on how to submit and validate the electronic declaration of interests form is available on the EMA website link.

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

Submit by Email

"Confidential Documents" mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in EMA Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

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- ***not to use (or authorise any other person to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with EMA activities.***
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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: John Papadopoulos Date:

[1] Third party does not include e… encompassed by confidentialit… …ty obligations or are

SUBMISSION AND VA…

After completion of this… …the **European Medicines Agency** as… …address in the To field.

If your submission is su… …rm showing the information you supplie… …lidation (sign-off electronically), you must use your single sign-on credentials (user name and password) as provided to you by the EMA.

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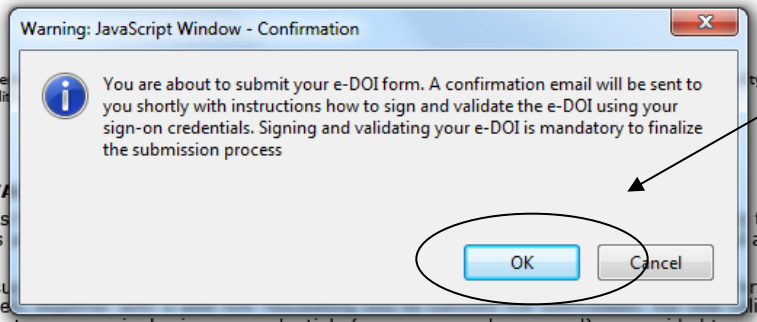
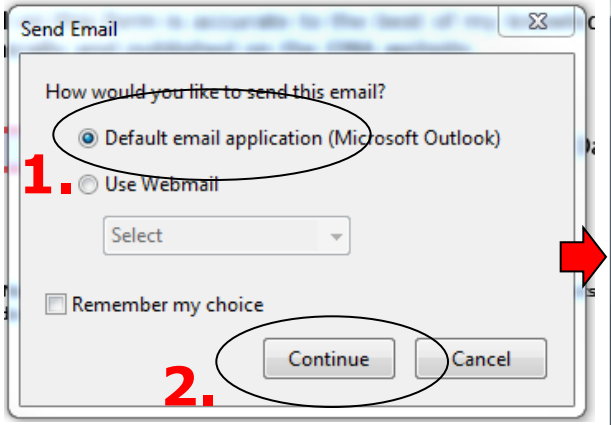


2.

1.

Submit by Email

Outlook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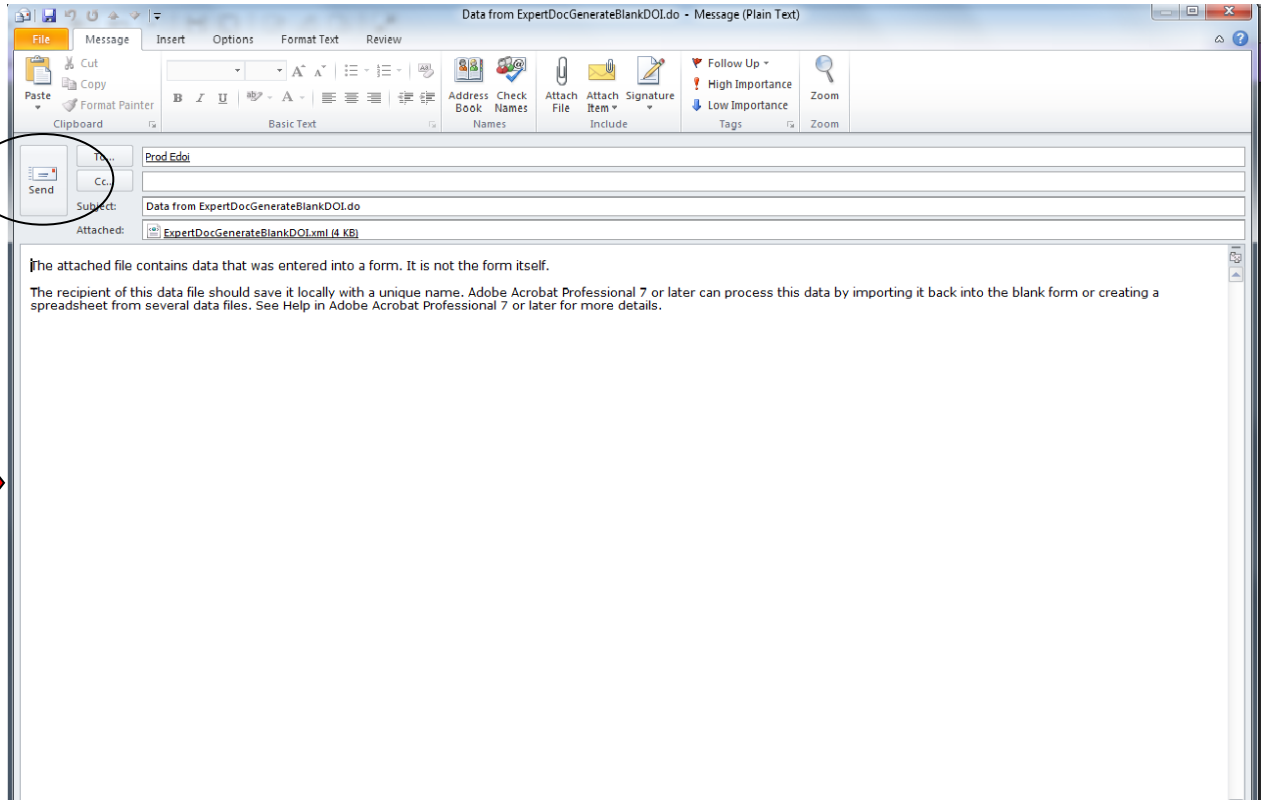
Default email application (Microsoft Outlook)
Use Webmail
Select
Remember my choice
Continue
Cancel
1.
2.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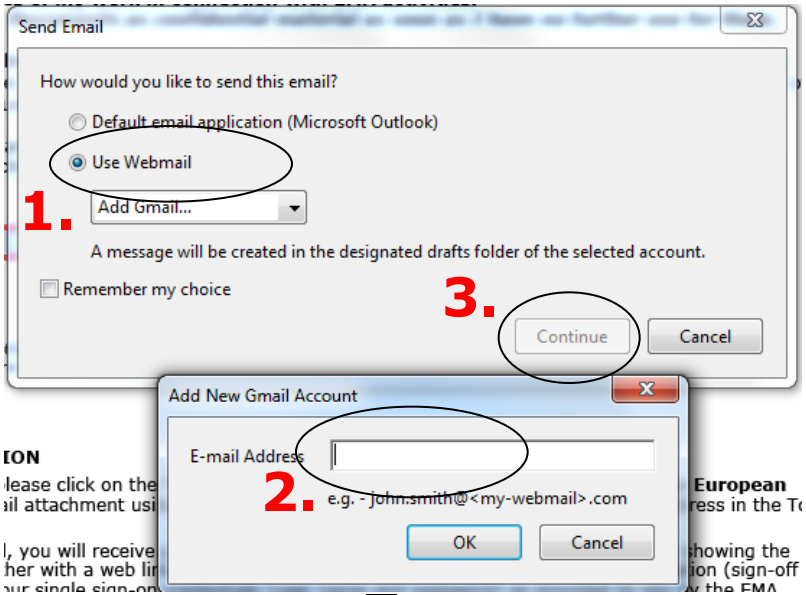
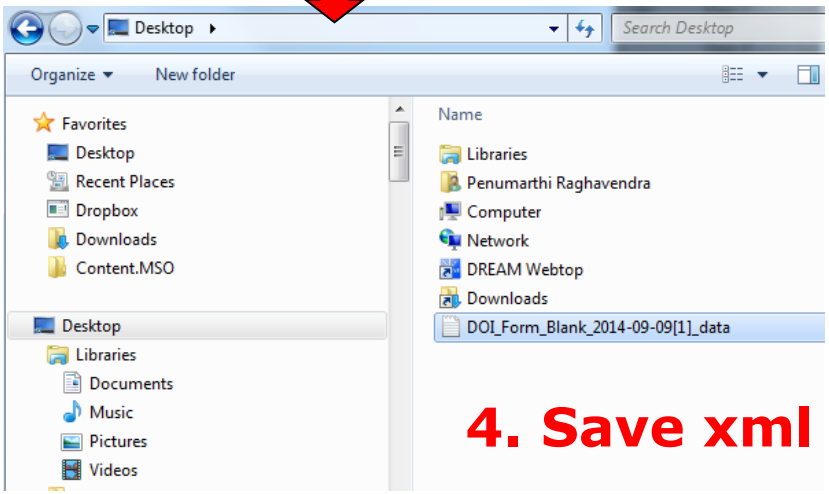
Message
Insert
Options
Format Text
Review
Send
Prod Edoi
Data from ExpertDocGenerateBlankDOI.do
ExpertDocGenerateBlankDOI.xml (4 KB)
The attached file contains data that was entered into a form. It is not the form itself.
The recipient of this data file should save it locally with a unique name. Adobe Acrobat Professional 7 or later can process this data by importing it back into the blank form or creating a spreadsheet from several data files. See Help in Adobe Acrobat Professional 7 or later for more details.
3.

Webmail





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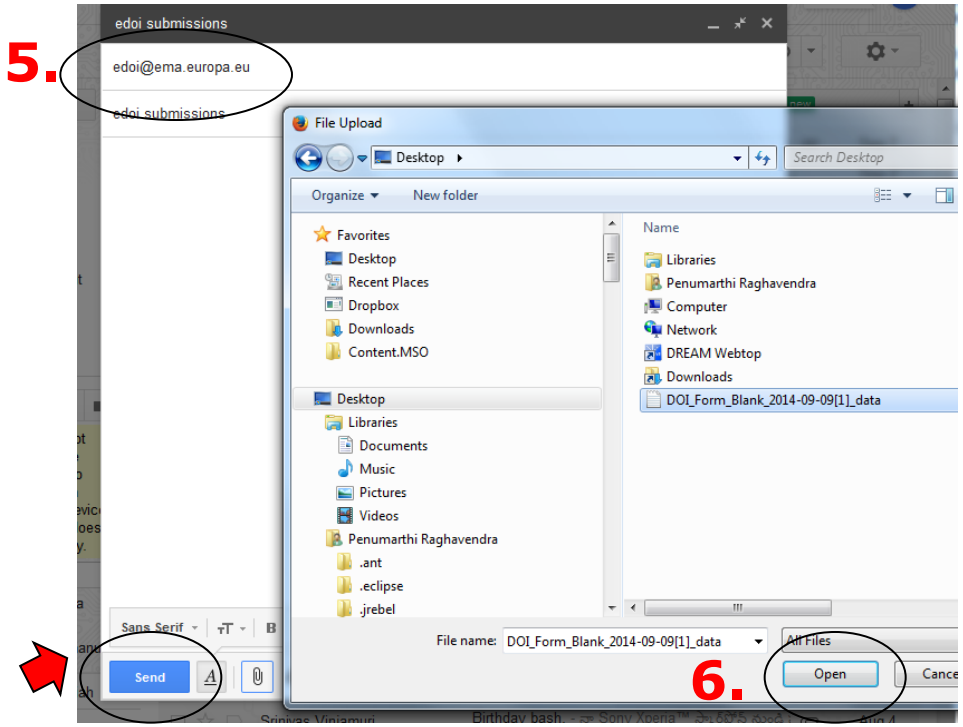

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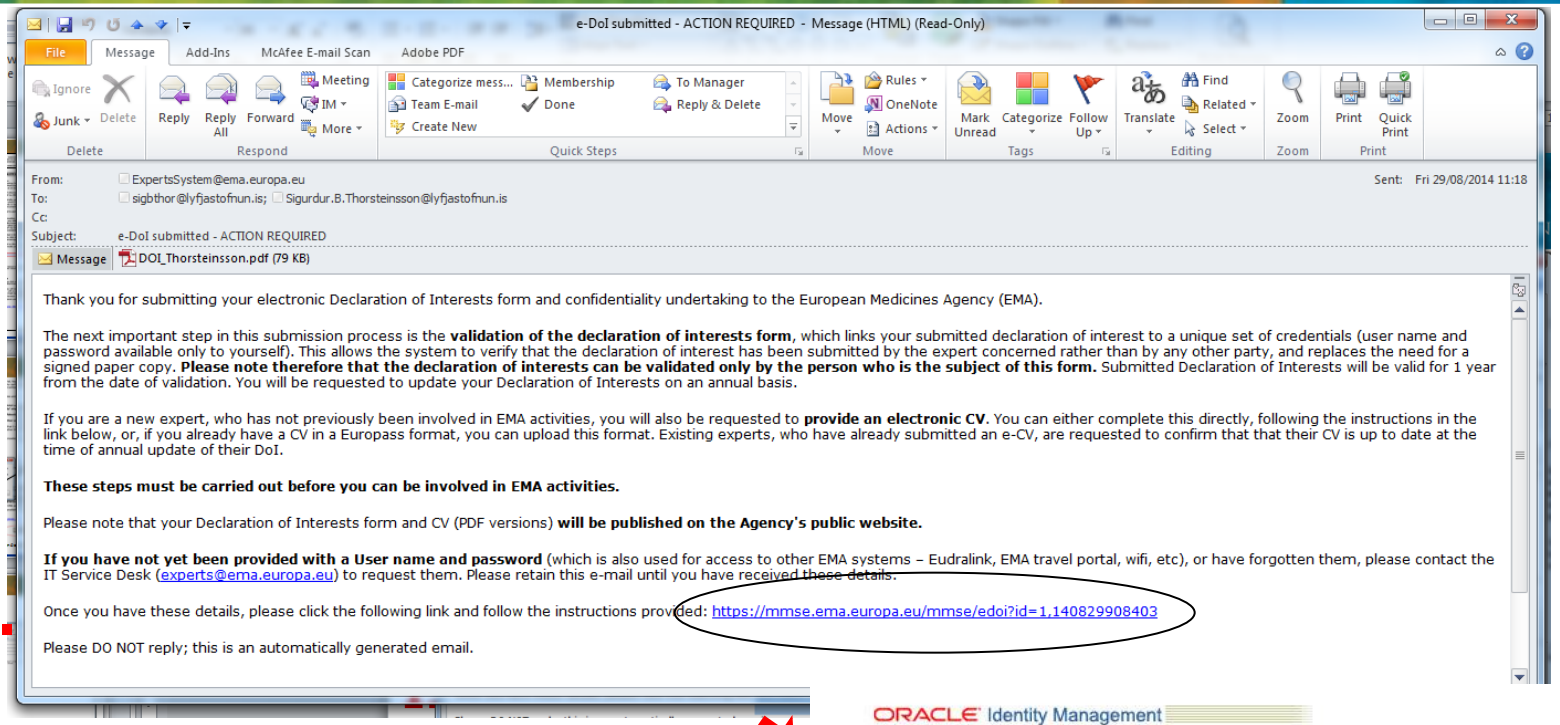
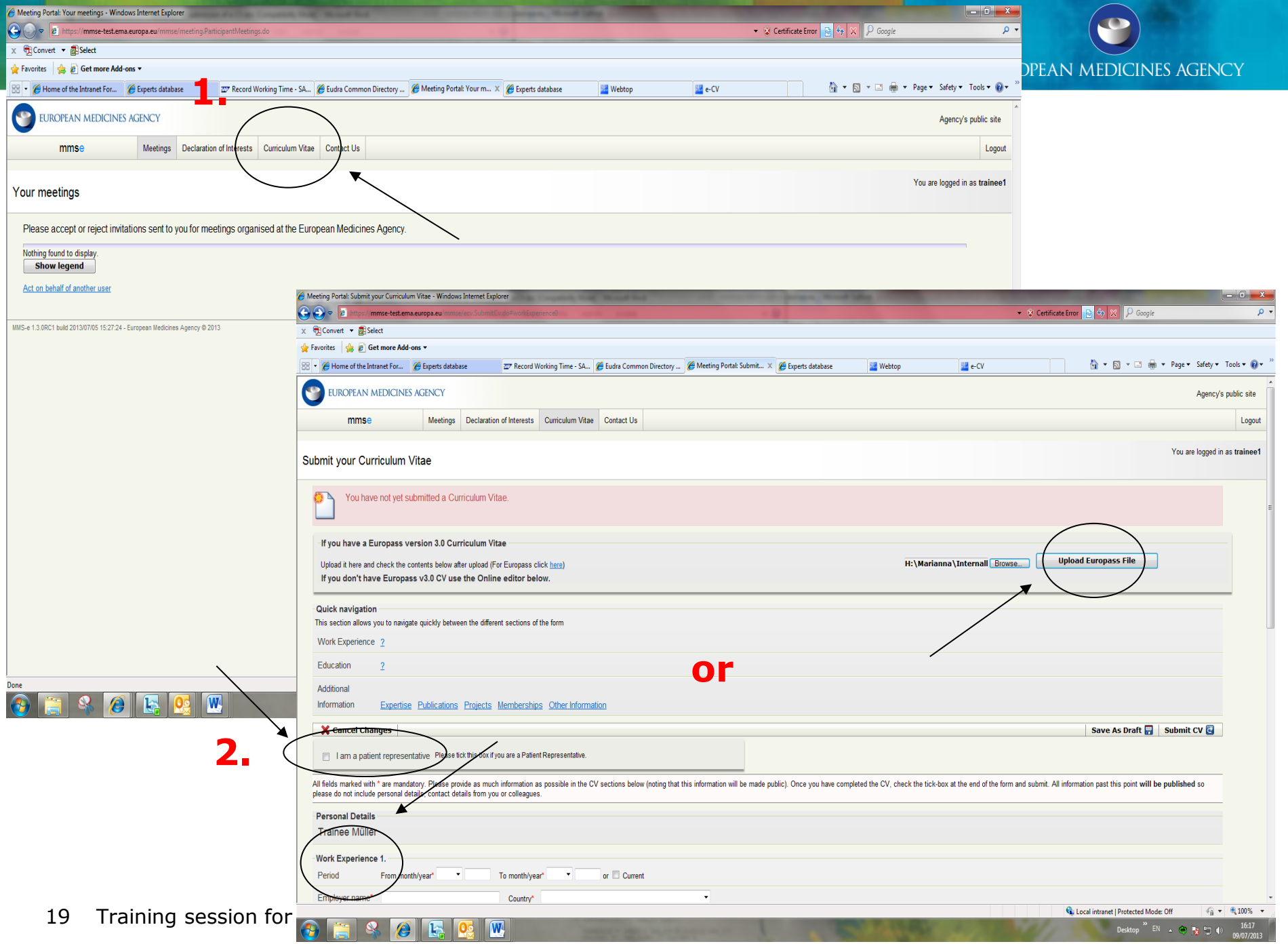
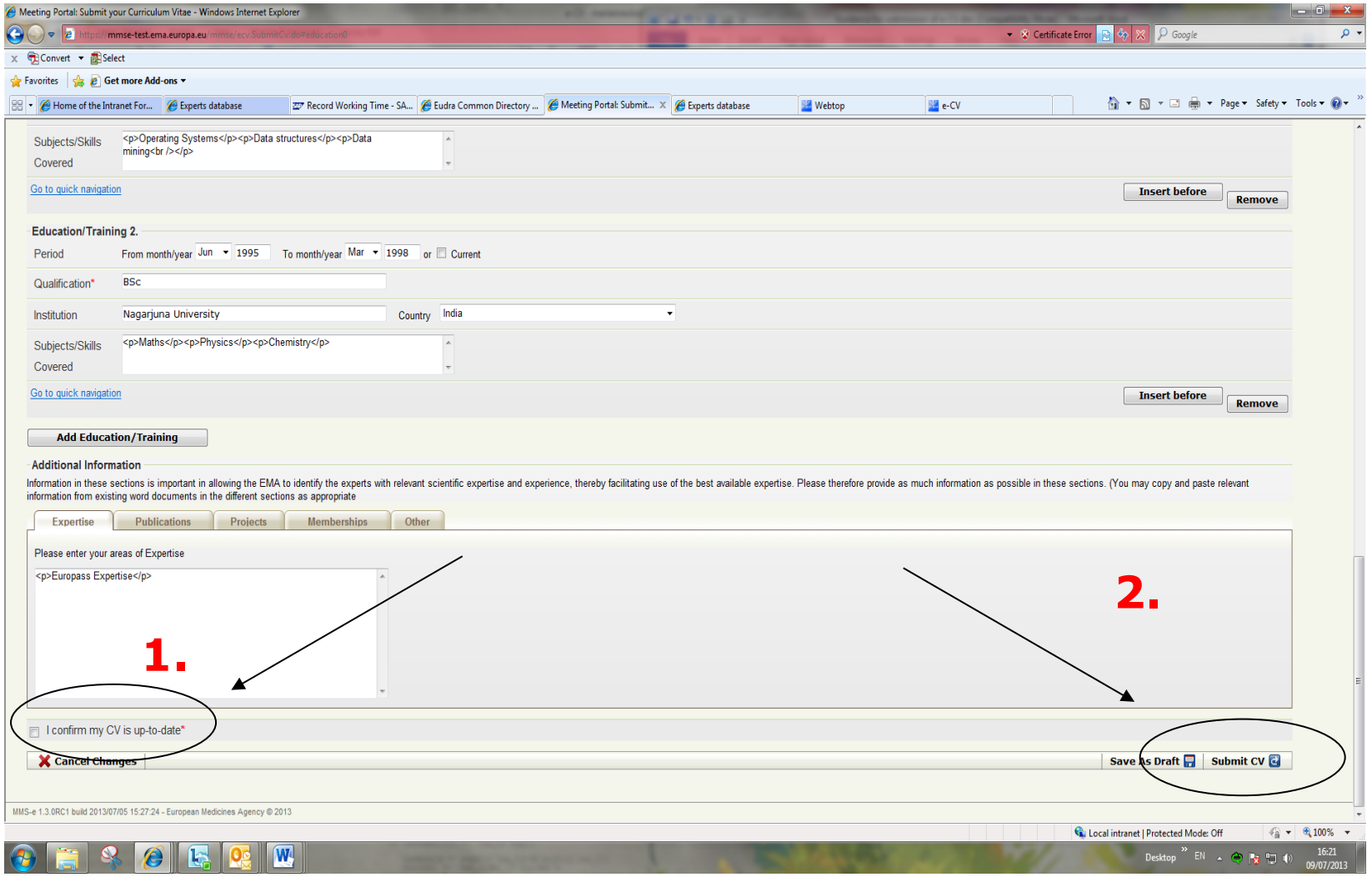
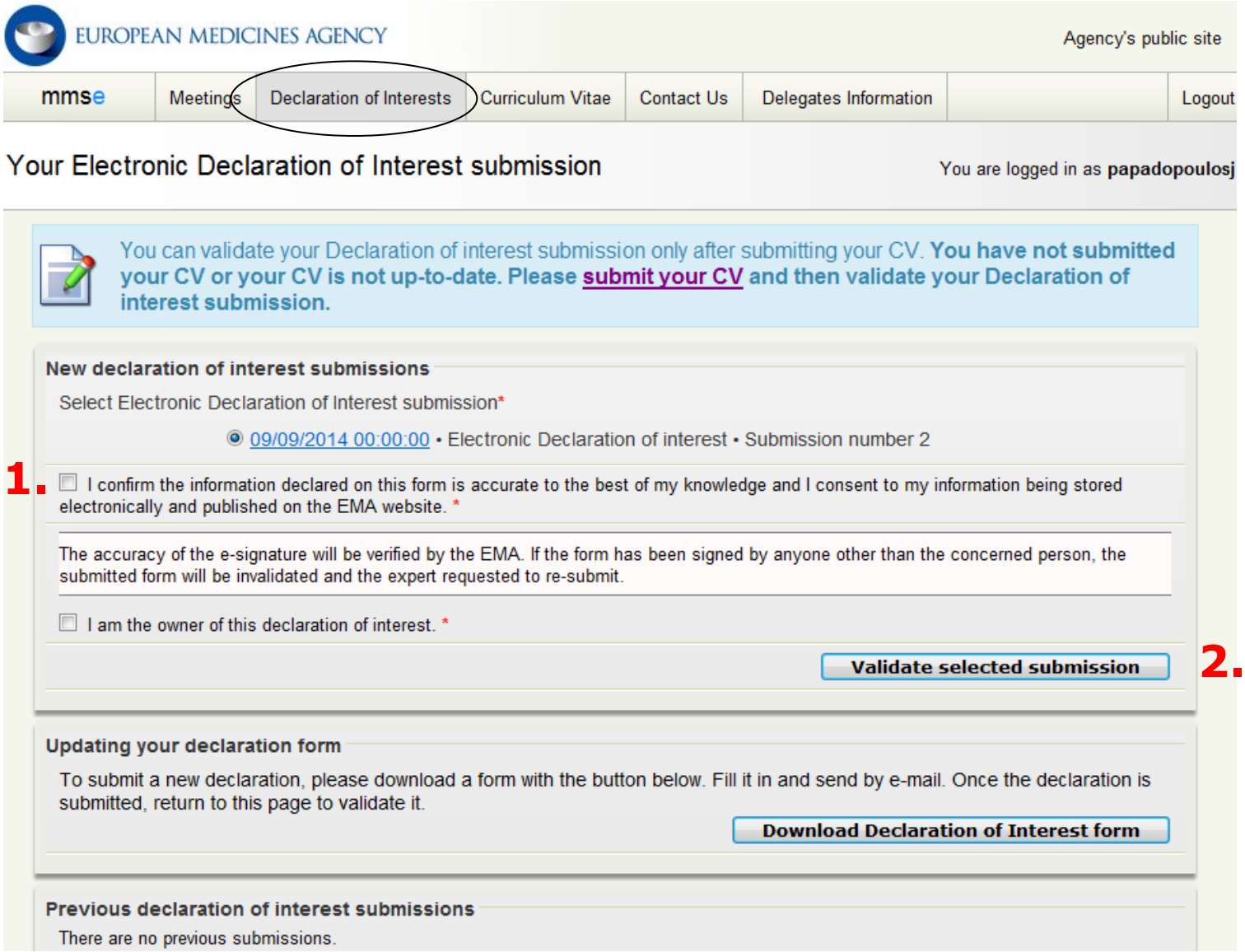

e-DoI submitted - ACTION REQUIRED - Message (HTML) (Read-Only)
From: ExpertsSystem@ema.europa.eu
Sent: Fri 29/08/2014 11:18
To: sigbthor@lyfjastofnun.is; Sigurdur.B.Thorsteinsson@lyfjastofnun.is
Subject: e-DoI submitted - ACTION REQUIRED
DOI_Thorsteinsson.pdf (79 KB)
Thank you for submitting your electronic Declaration of Interests form and confidentiality undertaking to the European Medicines Agency (EMA).
The next important step in this submission process is the validation of the declaration of interests form, which links your submitted declaration of interest to a unique set of credentials (user name and password available only to yourself). This allows the system to verify that the declaration of interest has been submitted by the expert concerned rather than by any other party, and replaces the need for a signed paper copy. Please note therefore that the declaration of interests can be validated only by the person who is the subject of this form. Submitted Declaration of Interests will be valid for 1 year from the date of validation. You will be requested to update your Declaration of Interests on an annual basis.
If you are a new expert, who has not previously been involved in EMA activities, you will also be requested to provide an electronic CV. You can either complete this directly, following the instructions in the link below, or, if you already have a CV in a Europass format, you can upload this format. Existing experts, who have already submitted an e-CV, are requested to confirm that that their CV is up to date at the time of annual update of their DoI.
These steps must be carried out before you can be involved in EMA activities.
Please note that your Declaration of Interests form and CV (PDF versions) will be published on the Agency's public website.
If you have not yet been provided with a User name and password (which is also used for access to other EMA systems – Eudralink, EMA travel portal, wifi, etc), or have forgotten them, please contact the IT Service Desk (experts@ema.europa.eu) to request them. Please retain this e-mail until you have received these details.
Once you have these details, please click the following link and follow the instructions provided: https://mmse.ema.europa.eu/mmse/edoi?id=1.140829908403
Please DO NOT reply; this is an automatically generated email.
1.


ORACLE Identity Management
Sign In
OK
Cancel
Sign In
Enter your Single Sign-On user name and password to sign in.
User Name papadopoulosj
Password
OK
Cancel
2.


1.
EUROPEAN MEDICINES AGENCY
Agency's public site
mmse
Meetings
Declaration of Interests
Curriculum Vitae
Contact Us
Logout
Your meetings
You are logged in as trainee1
Please accept or reject invitations sent to you for meetings organised at the European Medicines Agency.
Nothing found to display.
Show legend
Act on behalf of another user
Submit your Curriculum Vitae
You have not yet submitted a Curriculum Vitae.
If you have a Europass version 3.0 Curriculum Vitae
Upload it here and check the contents below after upload (For Europass click here)
If you don't have Europass v3.0 CV use the Online editor below.
H:\Marianna\Internall
Browse...
Upload Europass File
Quick navigation
This section allows you to navigate quickly between the different sections of the form
Work Experience ?
Education ?
Additional Information
Expertise Publications Projects Memberships Other Information
or
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 Müller
Work Experience 1.
Period
From month/year*
To month/year*
or
Current
Employer name*
Country*
2.


Meeting Portal: Submit your Curriculum Vitae - Windows Internet Explorer
Subjects/Skills Covered
Operating Systems Data structures Data mining
Go to quick navigation
Insert before
Remove
Education/Training 2.
Period
From month/year Jun 1995 To month/year Mar 1998 or Current
Qualification*
BSc
Institution
Nagarjuna University
Country
India
Subjects/Skills Covered
Maths Physics Chemistry
Go to quick navigation
Insert before
Remove
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
Europass Expertise
1.
2.
I confirm my CV is up-to-date*
Cancel Changes
Save As Draft
Submit CV
MMS-e 1.3.0RC1 build 2013/07/05 15:27:24 - European Medicines Agency © 2013


EUROPEAN MEDICINES AGENCY
Agency's public site
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Meetings
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e-DoI and e-CV submission guidance

- Guidance document on e-DoI submission:

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

- Guidance document on e-CV submission:

https://mmse.ema.europa.eu/mmse/jsp/welcome/Guidance_for_submission_of_e-CV.pdf

Transparency

- Publication of e-DoI and e-CV in pdf format as well as risk level of all active experts on EMA website in European experts list

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/experts.jsp&mid=WC0b01ac058043244a

Revision of EMA policy on handling of declarations of interests

- Implementation date: 30 January 2015
- e-DoI form – version 2: required for involvement in activities after 30 January 2015, can be submitted by experts in advance of that date
- Publication of completed e-DoI – version 2 on website on 30 January 2015
- Some of the changes:
  - Change in section 2.1 Employment – expert to tick function of employment
  - Family members interests
  - Calculation of interest level (3 years)
  - Revision of restrictions applicable to experts with declared interests

Questions