

FREQUENTLY ASKED QUESTIONS ON DECLARATION OF INTEREST

Who needs to fill in a DOI form?	<p>A DOI form needs to be completed by all the individuals involved in the EUnetHTA activities (e.g. Joint/Collaborative Assessment, Early Dialogue, PLEG pilots etc.), whose work has an impact on scientific contents.</p> <p>For individuals, who are not expected to contribute to exchanges on scientific contents, but still get access to (parts of) draft versions or other documents, e.g. administrative staff, it is sufficient to sign the EUnetHTA Confidentiality Agreement form only.</p>
Will my personal data become publicly available?	<p>No, EUnetHTA will not make the DOI forms public. DOI forms may only be shared with competent authorities/national bodies upon official request and depending on national requirements (section g of the disclaimer of DOI form).</p>
Why is a continuous renewal of the information about potential conflicts of interests needed?	<p>The submitted DOI form is valid for one year. In case your DOI form expires while you are still involved in EUnetHTA activities, you will be alerted and requested to submit a new DOI.</p> <p>You will need to <u>proactively</u> update your DOI form only in case of changes occurring during the validity of the DOI i.e. within one year after submitting the DOI form.</p>
Can I refrain from providing information that I feel is against my privacy?	<p>It is the sole responsibility of the respondent to transparently provide complete information that is relevant for the assessment of a potential conflict.</p> <p>In case the individual refuses to provide information deemed necessary for the purpose of the conflict of interest assessment, he/she will need to be excluded from the specific EUnetHTA activity.</p>

<p>I was involved in a EUnetHTA Early Dialogue as an HTA assessor. Can I still contribute to the Joint/Collaborative Assessment for the same product in the same indication?</p>	<p>Yes. Although information on previous involvement in an Early Dialogue is part of the DOI form (see section “2.2. Consultancy”), it does not per se preclude the involvement of the individual in the Joint/Collaborative Assessment of the same product and for the same indication.</p> <p>If your organisation does not allow to provide details of the EDs you were involved in due to confidentiality constraints, it will be sufficient to state that your organisation provides scientific advice to the industry without providing details on specific procedures.</p>
<p>In which of the following sections shall I report my current and past occupation (“1. Current professional activity/activities”, “2.1. Employment with a company/institution”, “2.2. Consultancy”)?</p>	<p>In section on 1.1 Current professional activity/activities, please add the current professional activity/activities with the start and end date.</p> <p>In case you are currently working in company/institution (definition available in the DOI form) or consultancy, please mention this briefly here and refer to 2.1. or 2.2. respectively, where further details should be provided.</p> <p>Past occupation only needs to be stated in case it refers to a company/institution/consultancy.</p>
<p>I do not know the industry funding of a professional-, clinical-, or patient organization. Is this an issue?</p>	<p>Under “2.6. Professional/Clinical/patient organisations”, we are asking for information on the sources of funding of an organisation.</p> <p>Please check their website for further information or ask them directly. However, in some countries organisations may not be obliged to declare their funding sources, in those cases please state this as well. This information is essential for the conflict of interest assessment and even strictly necessary if you hold any other role in the organisation than regular membership.</p>
<p>Can you further explain to which situations the “indemnification for false or incomplete reporting” refers to?</p>	<p>This paragraph on indemnification for incomplete reporting (section j of the disclaimer) focuses on intentional incomplete or false reporting. The risk of unintentional incomplete reporting is minimised by the detailed information requested in the DOI form.</p>

<p>Do I need to contact my 1st degree family members/partner/household members in order to ask them if they have anything to declare (e.g. if they have shares etc.)?</p>	<p>You are required to declare possible conflict of interests that you are already aware of– this should be added in section 3 “Family and household members interests” of the DOI form.</p> <p>It is your responsibility to make sure the information about 1st degree family members is complete and accurate to the best of your knowledge. There is no need to contact all family/household members to inquire further information from them.</p>
<p>My partner works for a pharmaceutical company. Does this lead to my exclusion?</p>	<p>Not necessarily. Conflict of interest may stem from first-degree family members/partner and/ or household member, however this does not per se lead to an exclusion.</p> <p>The relationship between the technology being assessed and your family member (financial interest, employment etc) as well as your role within the assessment will be carefully considered.</p>