



# **EUnetHTA Procedure Guidance for handling Declaration of Interest (DOI) and EUnetHTA Confidentiality Agreement (ECA) forms**

**Version 1.2**



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## Version log

Version	Date	Description
V1.0	Apr 2019	Final version after consultation with EUnetHTA WP4 and WP5 partners
V1.1	Nov 2019	Revised version because DOICU was split up into DOI and ECA forms
V1.2	May 2021	Revised version including clarification of processes

## EUnetHTA Procedure Guidance for handling Declaration of Interest (DOI) and EUnetHTA Confidentiality Agreement (ECA) forms

### OBJECTIVE

This document has been developed for transparent description of EUnetHTA JA3 processes in handling conflict of interest declared in the EUnetHTA Declaration of Interest (DOI) form. Its aim is to assist in decision-making on the involvement of individuals into EUnetHTA JA3 activities in terms of presence of conflicts based on the assessment of interests declared. This procedure equally applies for individuals representing HTA bodies participating in a EUnetHTA task (internal) and experts (external).

### DEFINITIONS

Conflict of Interest (CoI) - is a situation in which the interests of a participant to joint production are likely, by their nature or intensity, to question its independence or impartiality.

Assessment team (WP4)/Early Dialogue Committee (EDC, WP5A)/Post-Launch Evidence Generation (PLEG) pilot team (WP5) - the individuals representing an HTA body participating in a EUnetHTA task - author (WP4)/EDC Scientific Coordinator (WP5A)/ PLEG Coordinator (WP5B), co-author (WP4)/EDC Rapporteur (WP5A), dedicated reviewer (WP4)/EDC except for EDC Scientific Coordinator and EDC Rapporteur (WP5A)/ PLEG pilot participant (WP5B);

Author (WP4)/EDC Scientific Coordinator (WP5A)/PLEG coordinator (WP5B) - an individual representing an HTA body participating in a EUnetHTA task and responsible for undertaking a single (or set of) task(s), and for the quality and timing of the task(s);

EUnetHTA COI Committee – it consists of one representative of the EUnetHTA Secretariat, two representatives of WP4 (Co-Lead partner) and one representative of WP5 (Lead/Co-Lead partner).

Expert (external) – an individual who is not technical staff of an HTA body involved in EUnetHTA, e.g. including but not limited to the following: health care professional (HCP), academics, epidemiologist, economist, patient, patient representative, consumers, citizens etc.

Project Manager - a person at the Co-Lead partner or Activity Centre Department Lead of WP4 Other Technologies responsible for coordinating jointly produced assessments;

EUnetHTA task - jointly produced assessment (WP4), Early Dialogue (ED, WP5A), PLEG pilot (Product-specific pilot and registry-specific pilot WP5B) or other joint work (activities related to any EUnetHTA Deliverable) which require management of conflict of interest.

## RESPONSIBILITIES

### The EUnetHTA Secretariat (ZIN) is responsible for:

- Setting up and maintaining a database for the completed DOI/ECA forms with an overview of the interest that has been declared. The respective EUnetHTA COI Committee decisions including a summary of the analysis for the individual should be documented in addition. This database is only accessible to a limited number of individuals within EUnetHTA (see <https://eunetha.eu/doi/>).
- Informing the relevant individual to update his/her DOI form when a DOI form is expired. The DOI form is valid for 1 year based on the signature date of the individual.

### WP5 Lead and Co-Lead Partner/WP4 Project Manager is responsible for:

- Defining the context of the task: the sources of the actual conflicts, based on the technology under assessment, a comparator, or a relevant technology under development and indication(s) considered within a task. For jointly produced assessments, the Project Manager defines the context of the task based on the information provided by the author.
- Consulting EUnetHTA Secretariat/database about the existence and/or status (updated or not) of DOI forms, prior to requesting the individual to complete them (to avoid requesting individuals to complete the forms repeatedly).
- Providing the DOI/ECA forms to any individual invited to be involved in the task prior to commencement of any work in specific projects. The completed forms should be returned 2 weeks prior to the commencement of any specific task to WP5 Lead and Co-Lead Partner/WP4 Project Manager, otherwise the individual cannot be involved in the task.
- Reviewing the DOI forms to evaluate if the information provided is complete (formal evaluation).

*Note: DOI form should be filled in with sufficient detail. WP5 Lead and Co-Lead Partner/WP4 Project Manager (or WP4 Co-Lead Partner) can decide to contact the individual in order to clarify information if there is information missing or incorrect. Clarifying information should be focussed on the nature of the information provided to enable further evaluation of the presence of conflict of interest.*

- Securing the collection of expert background based on the information asked in the DOI form (i.e. expertise in the field related to the task, potential involvement in trials, any membership in associations, etc.) including additional research on the validity of the data provided and specifically if no conflict exists beyond the data provided by the individual in the DOI form.
- Sharing the DOI/ECA forms (including related annex and supporting documents if applicable) for inclusion in the database.
- Sharing the DOI forms (including related annex and supporting documents if applicable) with the EUnetHTA COI Committee for review.

### EUnetHTA COI Committee is responsible for:

- Evaluation of the presence of actual conflicts of interest (except for ED activities) according to this procedure (see section "Evaluation", p. 4-5) within 10 working days. Based on the DOI form (including related annex and supporting documents if applicable) the EUnetHTA COI Committee takes a decision on the inclusion or exclusion of an individual.

*Note: The evaluations will be conducted specifically for the task for which the individual has been requested to be involved. Thus, the decision of the EUnetHTA*

*COI Committee concerning the involvement of an individual is valid solely for the requested task.*

- Sharing the decision together with a short summary of the analysis with the dedicated Project Manager (WP4)/PLEG Coordinator (WP5B). In case of follow up questions or identified COI, the individual is then being contacted.

**Any individual participating in a specific EUnetHTA task, including individuals representing HTA bodies participating in EUnetHTA activities or experts (external), is responsible for:**

- Filling out the DOI form to reflect his/her actual situation to the best of his/her knowledge and belief. The DOI form should be completed in sufficient detail to enable the evaluation and the decision upon the inclusion or exclusion of the individual for the task.
- Filling out, signing and returning the completed DOI form within the timeline given (2 weeks prior to the commencement of any specific task) in a signed and scanned version of the completed DOI form to WP4/WP5 Lead and Co-Lead Partner/WP4 Project Manager. Any individual not returning her/his DOI form on time cannot be involved in the task. In case of clarifying questions from WP4/WP5 Lead and Co-Lead Partner/WP4 Project Manager, the individual is required to provide requested information in the given timeframe if they would like to participate in the given task.
- Promptly notifying WP4/WP5 Lead and Co-Lead Partner/WP4 Project Manager about any changes due to the fact that he/she acquires additional interests and complete a new DOI form detailing the changes.

## EVALUATION

The EUnetHTA COI Committee evaluates the presence of any potential conflict of interest declared in the DOI form to decide upon the inclusion or exclusion of an individual with regard to the task. The EUnetHTA COI Committee takes responsibility for ensuring that the DOI procedure is properly followed and implemented.

The decision on the inclusion or exclusion of an individual for the task is taken by the EUnetHTA COI Committee following the evaluation. The panel consists of the EUnetHTA Secretariat, two representatives of a WP4 Co-Lead Partner, and one representative of a WP5 Lead/Co-Lead Partner. The members should not be directly involved in the specific task. However, the representatives of the WP4/WP5 Lead/Co-Lead Partner may consult the assessment team/PLEG pilot team prior to the decision. In total, there are three votes and a decision is made by a majority vote.

For ED activity, the evaluation of CoIs is carried out by the WP5A Lead and Co-Lead in order to respect the confidentiality of the dossier, knowing that the risks of conflict are much less in view of the consulting activity with industry. A summary of the evaluation for each ED is reported in the DOI database.

A potential CoI occurs when an individual provides at least one statement other than 'no' as an answer to the questions from 2.1-3. in the DOI form. Also the section 1.1. (current activities) is critically checked as this may have potential conflicts of interest.

Once the potential conflict is found, the EUnetHTA COI Committee has to consider if this conflict leads to the exclusion of the individual from the task.

## Major conflict

The following situations lead to the exclusion of the individual from the task<sup>1</sup>:

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<sup>1</sup> Interests related to family and household members will be assessed on a case-by-case basis.

1. Principal investigator of or contributing considerably to the design of a study (industry-sponsored) which is aimed at evaluating the technology under assessment, a comparator, or a relevant technology under development.  
*Note: For Joint and Collaborative Assessments this relates to studies that are included in either the effectiveness (EFF) or safety (SAF) domain of the assessment.*
2. Provision of paid or unpaid advisory or consultancy services (e.g., participation on an industry-sponsored advisory board) related to the technology under assessment, a comparator, or a relevant technology under development.
3. Employment at a company producing the technology under assessment, a comparator, or a relevant technology under development; employment at a consultancy or contract research organisation providing services related to the technology under assessment, a comparator, or a relevant technology under development; or employment by relevant lobby group.
4. Being current member of an association (patient or HCP organisation) funded mainly by the industry (>40 % of association budget).
5. Currently receiving funds for research activities related specifically to the technology under assessment, a comparator, or a relevant technology under development.  
*Note: Funds may come from companies or from relevant lobby groups and can include research group/laboratory funded by industry or relevant lobby groups.*
6. Having a current financial interest (e.g. holding shares or the like) in the industry producing the technology under assessment, a comparator, or a relevant technology under development or a financial interest in industrial sector funds.
7. Covering/subsidising travel costs including fee waivers or paying a honorarium (two or more by the same company within the last 3 years), for delivering a presentation on a topic specific to the technology under assessment, a comparator, a relevant technology under development (e.g. targeting same indication) or for attending conferences/meetings sponsored by only one company producing either the technology under assessment, a comparator, or a relevant technology under development.
8. Being an active participant (e.g. clinical expert, rapporteur or co-rapporteur) in Scientific Advice Working Party (SAWP); Early Dialogues Committee (EDWP) or Committee for Medicinal Products for Human Use (CHMP) and EUnetHTA authoring teams simultaneously for the same product in the same indication.

An individual can still be included in a EUnetHTA task, if interests under the above mentioned points 5 and 6 occurred in the past and thus are no longer existing.

Under exceptional circumstances (e.g. lack of available experts without CoI for a rare/ultra-rare disease), EUnetHTA may still seek the expert opinion of an individual with an existing CoI. Assessment team/PLEG pilot team should be informed that the expert involved in the procedure has links and that we are within the framework of an exception to the CoI rules. However, in such cases the expert shall not have access to any document requiring confidentiality and should only give advice on a predefined set of questions posed by the assessment team/PLEG pilot team.

This list is not exhaustive and does not prevent from careful consideration of other potential conflicts of interest.

## UNDERLYING DOCUMENTS

The preparation of this procedure involved the following main documents:

- EUnetHTA JA2 Declaration of Interest and Confidentiality Understating-FINAL -STATEMENT ON TERMS OF PARTICIPATION AND EXTERNAL ACTIVITIES OF EXPERTS (potential conflict of interest and confidentiality undertaking), 20140502 (as endorsed by Plenary Assembly, Madrid, 2014.04.10).
- EUnetHTA Standard Operating Procedures (SOP) Manual, EUnetHTA Joint Action2; 2012-15; Developed by the EUnetHTA Secretariat July 2013; Amended and approved April 2014
- Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies, 10 December 2013, [http://europa.eu/agencies/documents/2013-12-10\\_guidelines\\_on\\_conflict\\_of\\_interests\\_en.pdf](http://europa.eu/agencies/documents/2013-12-10_guidelines_on_conflict_of_interests_en.pdf)
- The European Medicines Agency Code of Conduct, EMA/385894/2012, 23 May 2013, [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2009/10/WC500004924.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004924.pdf)