



EUnetHTA Procedure Guidance for handling Declaration of Interest and Confidentiality Undertaking (DOICU) Form.

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 and Confidentiality Undertaking (DOICU) 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

Assessment Team (WP4)/Early Dialogue Committee (EDC, WP5) - the individuals representing an HTA body participating in a EUnetHTA task – Author (WP4)/EDC Scientific Coordinator (WP5), Co-author (WP4)/EDC Rapporteur (WP5), Dedicated Reviewer (WP4)/EDC except for EDC Scientific Coordinator and EDC Rapporteur (WP5);

Author (WP4)/EDC Scientific Coordinator (WP5) - 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 (the Senior Scientific Officer (SSO), one representative of WP4 (Lead/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 Center Department Lead of WP4 Other Technologies responsible for coordinating jointly produced assessments;

EUnetHTA task - jointly produced assessment (WP4), Early Dialogue (ED, WP5) or other joint work (activities related to any EUnetHTA deliverable) which require management of the conflict of interest.

RESPONSIBILITIES

The EUnetHTA Secretariat (ZIN) is responsible for:

- Setting up and maintaining a database for the completed DOICU 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 should be accessible to EUnetHTA Secretariat staff and to all EUnetHTA partners.

- Informing the relevant individual to update his/her DOICU form when a DOICU form is expired. The DOICU form is valid for 1 year based on the signature date of the individual.
- Securing transparency with a website including DOICU information (except affiliation for data privacy reasons).

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 DOICU forms, prior to requesting the individual complete them (to avoid requesting individuals complete the forms repeatedly).
- Providing the DOICU form 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 DOICU forms to evaluate if the information provided is complete (formal evaluation).

Note: The DOICU 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 DOICU 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 DOICU form.
- Sharing the DOICU forms (including related annex and supporting documents if applicable) with the Secretariat for inclusion in the database.
- Sharing the DOICU forms (including related annex and supporting documents if applicable) with the EUnetHTA COI Committee and in parallel with the assessment team/Early Dialogues Committee (EDC) for review.

EUnetHTA COI Committee is responsible for:

- Evaluation of the presence of actual conflicts of interest according to this procedure (see section "Evaluation", p. 3-5) within 10 working days. Based on the DOICU 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 done 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 assessment team/Early Dialogues Committee (EDC), the EUnetHTA Secretariat as well as the individual whose conflict of interest has been assessed.

The assessment team/Early Dialogues Committee (EDC) is responsible for:

- Reviewing the DOICU form (including related annex and supporting documents if applicable) in parallel with the EUnetHTA COI Committee against national provisions that

need to be taken into consideration, in addition to these guidelines and the decision of the EUnetHTA COI Committee.

- If an individual representing an HTA body participating in EUnetHTA activities (assessment team/Early Dialogues Committee (EDC) considers that the decision of the EUnetHTA COI Committee on the conflict of interest does not comply with his/her agency's (national) conflict of interest rules, he/she can re-consider his/her participation to the task. However, the final decision of the partner on the participation must be communicated to the EUnetHTA COI Committee within 5 working days after the decision and a summary of the analysis has been shared by the EUnetHTA COI Committee.

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

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

EVALUATION

The EUnetHTA COI Committee evaluates the presence of any potential conflict of interest declared in the DOICU 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 DOICU 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 Senior Scientific Officer (SSO), one representative of a WP4 Lead/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/Early Dialogues Committee (EDC) prior to the decision. In total there are 3 votes and a decision is made by a majority vote.

A potential conflict of interest occurs when an individual provides at least one statement other than 'no' as an answer to the questions from 2.1-2.3 in the DOICU form.

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 task¹:

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 a current member of an association (patient or HCP organization) 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 an 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.

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 for a rare/ultra-rare disease), EUnetHTA may still seek the expert opinion of an individual with an existing COI. 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/EDC.

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

¹ Interests related to family and household members will be assessed on a case by case basis.

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
- 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