EUnetHTA 21

Project Plan

D7.5 GUIDANCE FOR IDENTIFYING AND HANDLING CONFLICT OF INTEREST (COI) AND DECLARATION OF INTEREST (DOI) FORMS AND EUNETHTA CONFIDENTIALITY AGREEMENT (ECA) FORMS

Version 1.0, 03/12/2021

Template version 1.0, 30/09/2021

DOCUMENT HISTORY AND CONTRIBUTORS

Version	Date	Description
V1.0	**03/12/2021**	Final Project Plan

Disclaimer

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The work in EUnetHTA 21 is a collaborative effort. While the agencies in the Hands-on Group will be actively writing the deliverable, the entire EUnetHTA 21 consortium is involved in its production throughout various stages. This means that the Committee for Scientific Consistency and Quality (CSCQ) will review and discuss several drafts of the deliverable prior to validation. Afterwards the Consortium Executive Board (CEB) will endorse the final deliverable prior to publication. For further information on stakeholder involvement in this deliverable, please see section 3.2.

Copyright

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LIST OF ABBREVIATIONS

CA	Collaborative Assessment
CEB	Consortium Executive Board
COI	Conflict of Interest
CSCQ	Committee for Scientific Consistency and Quality
DOI	Declaration of Interest
ECA	EUnetHTA Confidentiality Agreement
EUnetHTA	European Network of Health Technology Assessment
GDPR	General Data Protection Regulation
HTA	Health Technology Assessment
HTAb	Health Technology Assessment Body
HOG	Hands-on Group
HCP	Health Care Provider
JA3	Joint Action 3
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation

1 INTRODUCTION

In the technical offer, submitted on 04/05/2021, deliverables for the production of transversal tasks have been defined.

This Project Plan describes the objectives, approach and timelines for the deliverables under D7.5 on Guidance for identifying and handling conflict of interest (COI), declaration of interest (DOI) forms and EUnetHTA confidentiality agreement (ECA) forms.

2 BACKGROUND

In EUnetHTA JA3, the Declaration of Interest form (DOI) and EUnetHTA Confidentiality Agreement (ECA) have been revised after a broad consultation with all EUnetHTA JA3 partners. The objective of the consultation of the DOI form was to 1) understand which questions to ask and 2) to understand which situations could result in a major Conflict of Interest. Furthermore, in JA3 a Conflict of Interest Committee (COIC) was established, so that consistent decision could be made for the involvement of experts (health technology assessment (HTA), patients and external experts) in joint clinical assessment or collaborative assessment (JCA/CA) and a DOI database was set up to store DOI forms to help the operations of the COI Committee.

Experiences from JA3 showed that the updated DOI form and guidance worked really well as it provided a structured framework to assess the COI information against. However, some challenges remain as guidance is needed how to handle cases of COI when dealing with (ultra) rare diseases; apart from this, the GDPR compliant operations of the DOI database has to be ensured.

Table 2.1. Existing EUnetHTA documents

Title	Scope
Declaration of Interest (DOI) form (Annex A-2.8-1 of Tender documentation)	This form standardises the declaration of interests prior to any engagement in a JCA/CA or JSC. Each individual (HTA assessor/co-assessor, Project Manager, patient representative, external expert etc.) needs to sign a Declaration of Interest (DOI) form. The DOI form is designed to specifically address conflict of interest (COI) and assists in the decision-making process concerning the involvement of individuals in EUnetHTA activities, whether as internal representatives of an ongoing activity or as external experts, based on a transparent assessment of interests declared within the form. The DOI form is valid for one year regardless of the particular activities within the project; however, the DOI forms need to be assessed with each new involvement in an activity. The use of the DOI form will be continued over the duration of the activity.
Confidentiality Agreement (Annex A-2.8-2 of Tender documentation)	This form standardises the agreement of keeping confidential information and confidential documents under strict confidentiality. Each individual (HTA assessor/co-assessor, Project Manager, patient representative, external expert etc.) needs to sign a EUnetHTA Confidentiality Agreement (ECA) form per activity he/she is involved in. The use of the ECA form will be continued over the duration of the activity.
EUnetHTA Procedure Guidance for handling Declaration of Interest (DOI) and Confidentiality Agreement forms (Annex A-2.8-3 of Tender documentation)	A procedure guidance for handling DOI and ECA was implemented during EUnetHTA JA3, by extending the procedure guidance as developed in earlier joint actions, and a centralised process of collection and evaluation of DOI forms was established.

	The procedure is expected to be continued, however, the DOI guidance procedure should be refined for the involvement of clinical experts with a potential COI in the JCA/CA for (ultra) rare diseases
Non-disclosure agreement (NDA) for the handling of EUnetHTA Conflict of Interest forms and access to the EUnetHTA Conflict of Interest Database	This agreement ensures that DOI Information is used by COIC members solely for performing Conflict of Interest assessment as outlined in the relevant EUnetHTA guidelines and that members will not use the provided DOI Information in any other fashion, form, or manner or for any other purpose. All individuals that have access to the DOI database need to sign the non-disclosure agreement.

3 OBJECTIVE AND METHODS

For all of the objectives below the future EU HTA regulation will serve as the basis and the past JA3 experiences will be taken into account.

The objectives of this deliverable is to:

- Continue the operations of the Conflict of Interest Committee based on previous joint work on already existing DOI and ECA procedures document templates and guidance;
- Revision of the DOI procedure in order to fully cover the cases of (ultra) rare disease, where a potential conflict of interest may exist when involving clinical experts;
- Maintain the DOI database over the course of the activity, clear of any General Data Protection Regulation (GDPR) concerns.

3.1 Methods to achieve the objectives

3.1.1 Continue the operations of the Conflict of Interest Committee

The Conflict of Interest Committee will be maintained and will be involved in assessing the DOI information of each individual involved in any type of Joint Work (i.e. JCA/CA and/or JSC). Management of COI will be conducted throughout the entire contract.

The DOI and ECA form, as well as the accompanying guidance document, as developed in JA3 worked well. Therefore, it is important to continue to use these forms, guidance document, database, management tools and COI Committee. It is important that all DOI forms of all individuals participating in a JCA/CA and JSC are evaluated in the same, central manner, while adhering to the Procedure Guidance on Handling Declaration of Interest (DOI) and Confidentiality Agreement forms.

3.1.2 Revision of the DOI procedure

The DOI Guidance and process to deal with COI in case of (ultra) rare diseases will be evaluated and updated, in order to ensure relevant expertise is captured in the production of JCA/CA and JSC.

It will be evaluated in how many cases the DOI guidance limited the ability to include clinical experts in a JCA/CA in preceding joint actions. Then, it will be discussed within the hands-on group, in close collaboration with hands-on groups of the production of JCA/CA and JSC and the hands-on groups for patient and clinical expert involvement, how the process could be improved.

3.1.3 Maintain the DOI database

In order to have an efficient COI evaluation process, it is important to maintain the DOI database (all individuals that have access to the DOI database need to sign the NDA). To be able to continue the use of the DOI database, the GDPR compliance needs to be further investigated.

To ensure the DOI database and the handling of personal information in the DOI and ECA forms is conform GDPR, the technicalities of the database will be discussed with the IT officer and also with a legal department. Coordination with the hands-on groups under D8.11 is essential to ensure the

consistent application of the GDPR. It should be evaluated if adaptations of the procedure to the GDPR lead to the necessity of adapting the DOI and ECA forms.

The database is going to maintained in accordance with what is already described in the EUnetHTA Procedure Guidance for handling Declaration of Interest (DOI) and Confidentiality Agreement forms. The Guidance may be further elaborated on top of what is essential to ensure GDPR compliance.

The information on the EUnetHTA website (https://www.eunethta.eu/doi/) regarding access should also reflect changes carried out under the current deliverable.

3.2 Stakeholder inclusion

To ensure the deliverable will be according to the needs of HTA organisations, it is important that HTAb from the EUnetHTA network are consulted and other stakeholders (i.e. patient and clinicians) are informed to ensure adherence to this procedure.

Such consultation by HTAb will take place along the Committee of Scientific Consistency and Quality (CSCQ) review procedure. Other stakeholders will be informed after final deliverables endorsed by the Consortium Executive Board (CEB). Since the presence of a COI may negatively impact the usability of a JCA/CA (or in some cases, joint scientific consultations (JSC)) on a national level, it is important that these procedures are consulted with the wider EUnetHTA network.

4 ORGANISATION OF THE WORK

4.1 Mode of collaboration and frequency of meetings

The work will be distributed evenly between the agencies of the hands-on group (HOG). All HOG members will review each other's work prior to review by the CSCQ. The HOG will appoint one agency to interact with the three CSCQ configurations and the CEB.

The HOG will have meetings/email updates when needed, but at least bi-weekly meetings, to update each other on the progress. In addition, when needed, the HOG will also have regular meetings with the other relevant HOGs.

4.2 Timelines

Table 4.1. Timetable

Milestones	Start date	End date
Project duration	27/09/2021	29/04/2022
1st Draft deliverable	27/09/2021	27/10/2021
Public consultation	N/A	N/A
Validate final version deliverable (CSCQ)	15/03/2022	
Endorsement final version deliverable (CEB)	26/04/2022	
Estimated finalisation date of the deliverable *	29/04/2022	

*publication date may fluctuate depending on the outcome of the Consortium Executive Board endorsement