eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA 21

Project Plan

D7.1 – GUIDANCE FOR THE INTERACTION BETWEEN HTD AND HTA

Version 1.0, 03/12/2021

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DOCUMENT HISTORY AND CONTRIBUTORS

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

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The w ork in EUnetHTA 21 is a collaborative effort. While the agencies in the Hands-on Group w ill be actively w riting 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) w ill review and discuss several drafts of the deliverable prior to validation. Afterwards the Consortium Executive Board (CEB) w ill endorse the final deliverable prior to publication. For further information on stakeholder involvement in this deliverable, please see section 3.2.

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LIST OF ABBREVIATIONS

CA	Collaborative Assessment
CEB	Consortium Executive Board
CSCQ	Committee for Scientific Consistency and Quality
ED	Early Dialogue
EU	European Union
EUnetHTA	European Network of Health Technology Assessment
FAQ	Frequently Asked Questions
FMC	Future Model of Collaboration
HoG	Hands-on Group
HTA	Health Technology Assessment
HTAb	Health Technology Assessment Body
HTD	Health Technology Developer
JA3	Joint Action 3
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
SOP	Standard Operating Procedure

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 7.1 on guidance for the interaction between HTA experts and Health Technology Developer (HTD) during Joint Clinical Assessments (JCA)/Collaborative Assessments (CA) and Joint Scientific Consultations (JSC).

2 BACKGROUND

Already in EUnetHTA JA3 over 58 consultations took place including both JCA/CA and JSC. There are a number of contact points between HTDs and JCA/CA & JSC authoring teams and project managers during the production process. Through these procedures in JA3, great experience has been gained and input was received from all stakeholders, including HTDs.

A clear consistent approach must be taken in all interactions with HTDs and for all types of HTA production. Standard operating procedures (SOPs) and guidelines have been created in order to support the interaction between authoring teams and HTDs during JCA/CA. These documents require further refinement to address divergent views as described in section 7.2.1. A full suite of procedures, guidelines and templates (Table 2.1) have been developed during the JSC in JA3 and there was very little divergent opinion; some refinements will be required as per some minor challenges. Those challenges of interaction with HTD have been discussed in the technical offer and FMC white paper and they serve as the background for this deliverable.

Table 2.1. Existing EUnetHTA documents

Title of document	Scope of document
JSC	
Template EUnetHTA ED Early Dialogue Request Form (A6)	EUnetHTA Early Dialogue Request Form
Template EUnetHTA Short Study Information (A7)	Template with important key points of a clinical trial.
Template EUnetHTA Multi-HTA ED Pharma Briefing Book (03-07-20) (A8)	This template is to be used by companies willing to submit an overview of relevant information necessary to support a EUnetHTA multi-HTA Early Dialogue discussion
Template EUnetHTA ED Parallel Consultation Briefing Document (A9)	Parallel Consultation Briefing Document
Template ED Applicant's Written Response (A10)	Template for written response bythe HTD to the List of Issues
JCA – medicinal products	
Industry Procedure Manual incl. frequently asked questions (FAQ)	Procedure manual which outlines the production process and relevant steps for the HTD, including which templates, tools, guidance are relevant for the specific assessment FAQ is a webpage, outlining most relevant questions for HTD, focused on acquisition of new compounds.
Letter of Intent Template	Template, structuring the information needs at the absolute start of an assessment. Official letter that needs to be signed by the participating HTD.
Scoping Document Template	Template, structuring the information needs at a more advanced step in the scoping of an assessment
Fact check guidance for manufacturer	Guidance for the HTD on the factual accuracy check, including a checklist on what is considered within the scope of a factual accuracy check.
Submission Requirements	Guidance on what data is required in the JCA/CA submission and what the publication and citation policy is
Submission Dossier	Template outlining the information needs and structure at time of data submission
JCA/CA – medical devices	

Industry procedure manual incl. FAQs	Procedure manual which outlines the production process and relevant steps for the HTD, including which templates, tools, guidance is relevant for the specific assessment
Topic proposal form for stakeholders	Template in which stakeholders can propose topics for a JCA/CA
Fact check guidance for manufacturer	Guidance for the HTD on the factual accuracy check, including a checklist on what is considered within the scope of a factual accuracy check.
Submission Requirements	Guidance on what data is required in the JCA/CA submission and what the publication and citation policy is
Submission Dossier	Template outlining the information needs and structure at time of data submission
Open Letter to Editors	This is an open letter, written by the Chair of the EUnetHTA Executive Board, Niklas Hedberg. It expresses commentary on the role of EUnetHTA within European HTA, and that of scientific journals.

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 objective of this deliverable is to tackle some of the challenges experienced in JA3 for "other technologies" and "pharmaceutical technologies" (e.g., among some HTD there was limited HTA awareness and no clear understanding of the role of HTA bodies versus regulatory bodies; how to deal with incomplete submission dossiers and commercially sensitive and academic in-confidence data; at which point in time additional interaction with the HTD is required). 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.

1. To produce a practical guidance for HTA/HTD interaction, by defining objectives and extent of interaction between HTA agencies and HTD for JCA/CA and JSC;
    - Interactions to take place between these parties during the production of JCA/CA and JSC should be identified (e.g. what is the objective of the scoping meeting, what are time point for interactions and which questions can be asked by the assessor and co-assessor, in case of an incomplete dossier can further interaction be established);
    - Develop a standardized feedback questionnaire for HTD to share their experiences in a structured way.
2. To define a process for handling commercially sensitive and academic in-confidence data;
    - This process could address the distinction between commercially sensitive and academic in-confidence data with clear guidance to HTD on EUnetHTA's position on these.
3. To create a procedure and framework for the factual accuracy check (if decided to continue this as a process step) if HTD have submitted a dossier;
    - In case this is accepted as a process step, a procedure and framework for such a factual accuracy check should be developed and the process of JA3 should be used as a starting point.
4. Update the Frequently Asked Questions and procedure manual of JA3 to increase awareness and understanding of the JCA/CA procedures for HTD;
5. Provide a definition of an incomplete Submission Dossier and outline a procedure for managing incomplete submissions.

3.1 Methods to achieve the objectives

During the development of this deliverable, the future EU HTA regulation will be used as a starting point. In addition, all existing documents guiding and an analysis of the experiences of JA3 regarding interaction between HTA experts and HTD in both JCA and JSC will be scrutinised. Based on this input, challenges with such interaction will be mapped and a suggestion for improvements will be made (especially the reasons for incomplete submission dossiers will be analysed). Procedures and documents existing in JA3 will be used as a basis and will be fine-tuned. The evaluation of the factual accuracy check as conducted in JA3 shall be used as a basis to continue the discussions on the need for such a check in JCA/CA. The CSCQ will be asked for further input about the content of the Factual Accuracy Check and how this is done on different national levels. In this way the national experiences can be mapped within the EUnetHTA21 consortium.

Continue discussion with HTA agencies: In order to achieve the objectives, collect information on national practice amongst HTA agencies on:

- Factual accuracy check of project plans and draft JCA/CA reports;
- Incomplete submission dossier or how to deal with no submission from HTD;
- Commercially sensitive and academic in-confidence data (the future EU HTA regulations serves as the basis and in addition national procedures regarding handling confidential data could be mapped)

3.2 Stakeholder inclusion

EUnetHTA 21 Stakeholder Pool is composed of HTA bodies (HTAb) outside of EUnetHTA 21 consortium, as well as stakeholder groups on patients, health technology developers (HTD), healthcare professionals (HCP), payers, and regulatory agencies from the EU/EEA countries.

Non-consortium HTAb (i.e. those not part of the EUnetHTA 21 consortium) who will be involved in the future subgroups of the HTA Regulation, should participate in the development of this project in order to ensure the deliverables are applicable to all European HTAb. They should be consulted at the beginning of the project. Additionally, they will also be invited to review, in parallel to that of the Committee for Scientific Consistency and Quality (CSCQ), the 1st draft of the deliverable and the pre-final draft that will be submitted for public consultation.

Furthermore, the HOG will consult with HTD during development of the deliverable.

Other members of the EUnetHTA 21 Stakeholder pool will also be involved in this project. Their involvement will include, at minimum, participation in an informational kick-off meeting and regular stakeholder fora. They will also be invited to contribute to the work through public consultation.

3.3 Mode of collaboration and frequency of meetings

The work will be distributed evenly between the agencies of the 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 monthly meetings, to update each other on the progress. In addition, when needed, the HOG will also have regular meetings with the other relevant HOGs.

3.4 Timelines

Table 3.1. Timetable

Milestones	Start date	End date
Project duration	14/03/2022	30/09/2022
1st Draft deliverable	14/03/2022	26/04/2022
Public consultation	20/07/2022	19/08/2022
Validate final version deliverable (CSCQ)	13/09/2022	
Endorsement final version deliverable (CEB)	28/09/2022	
Estimated finalisation date of the deliverable *	30/09/2022	

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