EUnetHTA 21

Project Plan

D4.7.3 EUDAMED DATA REPORTING TEMPLATE
D4.7.4. GUIDANCE FOR EUDAMED-BASED TISP PROCESS

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DOCUMENT HISTORY AND CONTRIBUTORS

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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.

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LIST OF ABBREVIATIONS

AIHTA	Austrian Institute for Health Technology Assessment GmbH
CA	Collaborative Assessment
CEB	Consortium Executive Board
CSCQ	Committee for Scientific Consistency and Quality
EPL	EUnetHTA Prioritisation Lists
EUDAMED	European Database on Medical Devices
EUnetHTA	European Network of Health Technology Assessment
FDA	Food and Drug Administration
HAS	Haute Autorité de Santé
HCP	Health Care Professional
HTA	Health Technology Assessment
HTD	Health Technology Developer
IDE	Investigational Device Exemption
IVD	In-vitro Diagnostics
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
MD	Medical Device
MDCG	Medical Device Coordination Group
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
REA	Relative Effectiveness Assessments
SOP	Standard Operating Procedure
SSCP	Summary of Safety and Clinical Performance
TISP	Topic identification, selection and prioritisation

1 INTRODUCTION

In the technical offer, submitted on 04/05/2021, deliverables for the production of Joint Clinical Assessment/Collaborative Assessment (JCA/CA) of high-risk medical devices (MD) or in-vitro diagnostics (IVD) have been defined. An agreed topic identification selection and prioritisation (TISP) System is a prerequisite for JCA of "other technologies".

This Project Plan describes the objectives, approach and timelines for the deliverable D4.7.3 on EUDAMED data reporting template and D4.7.4. Guidance for EUDAMED-based Topic identification, selection and prioritisation (TISP) process.

2 BACKGROUND

In EUnetHTA JA3, 27 JCA/CA of medical devices or diagnostics were conducted. These JCA/CA of so-called "other technologies" covered a wide range of products, of which only risk class IIb and III for medical devices and risk class D for in-vitro-diagnostics/IVD are candidates in the future HTA regulation. For other technologies, topic suggestions in EUnetHTA JA3 have primarily been based on suggestions from partners planning an HTA who would like to undertake this as a EUnetHTA Joint or Collaborative Assessment. Also, topics could be proposed by stakeholders (industry, patient organisations, and the public). The majority of these suggestions did not lead to calls for collaboration because they were out of scope or too vague. In this context, uptake of the assessments was limited.

During JA3, a group of EUnetHTA partners piloted a topic identification, selection, and prioritisation (TISP) workflow to see if a more active voluntary topic identification process and a EUnetHTA Prioritisation List (EPL) based on this could ease the choice of topic for a Joint or Collaborative Assessment, while increasing the uptake of assessments. The EPL comprised 18 topics and was published in July 2019 i.e. it came very late in JA3. It was based on EUnetHTA partners' interest in topics identified through a public call for proposals, the planned and ongoing projects (POP)-database, and EUnetHTA partners' lists of potentially relevant topics. No topics were proposed by industry. Three assessments were carried out based on the EPL. AIHTA contacted the agencies who had expressed interest in the topics of the EPL. However, no additional assessments were initiated as the partners had either other priorities, no resources for EUnetHTA collaboration, or the topic became obsolete for them. In the TISP project, it was observed that some partners had their topics prioritised once or twice a year, while others had to act on very short notice based on commissions. Differences in assessment prioritisation among partners might also have been caused by legal rules of procedure imposing timelines and by applying different procedures such as relying on industry-based submission. Partners with the need to act on short notice were not able to react to the EPL. To be successful, the EPL list must be consistent with the national priorities, since one cannot expect that the partners' national commissioning systems adapt in due time.

Therefore, also in absence of a central database of CE-marked products, no valid TISP could be established during JA3. However, the TISP working group prepared a set of recommendations for TISP. It was noted that cooperation with regulatory authorities on medical devices and in-vitro diagnostics needs to be further explored, in particular the planned European database on medical devices (EUDAMED) to be available in 2022, should provide means for structured data to be available. With EUDAMED there is an opportunity for a comprehensive list of products for prioritisation and selection. Accordingly, the **TISP - process will be refined based on results from EUDAMED and a regular process for topic selection will be set up**.

Regular (monthly) screening of EUDAMED (when it is open to public) for class IIb/ III medical devices and class D in-vitro diagnostics is foreseen. The creation of EUDAMED is one of the key aspects of the new rules on medical devices (Regulation (EU) 2017/745) and in vitro diagnostic medical devices (Regulation (EU) 2017/746). EUDAMED aims to enhance overall transparency, including providing better access to information for the public and healthcare professionals, and to enhance coordination between the different Member States in the EU. It is not decided yet which of the information modules will be open to the public, but EUDAMED is expected to be a highly valuable source for a more structured and systematic approach to prioritisation and topic selection for JCAs. However, **in case EUDAMED is not fully operational in 2022**, or not sufficient information in enough detail is available for the public or

to HTA bodies, **other sources of information (including horizon scanning documents) will be taken into account**.

Table 2.1. Existing EUnetHTA documents

Title	Scope
EUnetHTA "Recommendations for Horizon Scanning, Topic Identification, Selection and Prioritisation for European Cooperation on Health Technology Assessment" https://eunethta.eu/wp-content/uploads/2020/04/200305-EUnetHTA-WP4-Deliverable-4.10-TISP-recommendations-final-version-1.pdf	The document provides recommendations that are generic in the sense that they are valid for different models of European cooperation on HTA. The main conclusion is that transparent, unbiased and efficient horizon scanning services should inform prioritisation of European cooperation on HTA. The authors used a process involving questions adapted from the EuroScan toolkit, selected background literature, collaboration with the European Medicines Agency (EMA), a review process and stakeholder input to draft recommendations.
Pilot for topic identification selection and prioritisation (TISP) – Endpoint evaluation other technologies https://www.eunethta.eu/wp-content/uploads/2020/04/200109-TISP-Pilot-EPER-OT-Final.pdf	A pilot was conducted to explore a workflow for voluntary collaboration on a TISP process for relative effectiveness assessments (REAs) on medical devices and in-vitro diagnostics. The process was designed to be as simple as possible and included three steps: identification, selection and prioritisation of possible topics for REA. A three-step process was set up were each step resulted in a product/list: A minimal dataset (MDS), a call for collaboration list (CCL) and the EUnetHTA prioritisation list (EPL). Results of the pilot were used to inform the final recommendations on a TISP system for European collaboration on HTA beyond 2020.
Project plan TISP pilot – medical devices and in vitro diagnostics https://www.eunethta.eu/wp-content/uploads/2019/03/190301-Project-plan-TISP-OT-Final.pdf	This document provides details of a pilot on a process for TISP in medical devices and in vitro diagnostics
EUnetHTA Standard Operating Procedure (SOP) Topic Identification OT-01-TopIdent, 2020 (including Topic Proposal Form for EUnetHTA Partners and Topic Proposal Form for Stakeholders)	The SOP describes the identification process of topics for REAs in other technologies, in JA3: topics were mainly suggested by EUnetHTA partners and very rarely from external stakeholders. No active identification of topics was done apart from the TISP/EPL pilot, which is described in the above mentioned documents.

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:

- Explore other sources of information (e.g. horizon scanning documents) for identifying products (class IIb/ III medical devices and class D in-vitro diagnostics). In case EUDAMED is not fully operational in 2022 (current date of launch is May 2022), or if not sufficient information in enough detail is available for the public or to HTA bodies, a back-up strategy needs to be prepared;
- Consensually develop and define a process description for screening of EUDAMED;
- Consensually develop and define a EUDAMED-based process description for TISP.

3.1 Methods to achieve the objectives

3.1.1 Objective 1: Explore other sources of information (e.g. horizon scanning documents) for identifying products (class IIb/ III medical devices and class D in-vitro diagnostics)

In case EUDAMED is not fully operational in 2022 (current date of launch is May 2022), or if not sufficient information in enough detail is available for the public or to HTA bodies, a back-up strategy needs to be prepared. Therefore, the following steps will be taken, if needed, to develop an alternative strategy to identify a list of possible products, which can be prioritized. Selected products can then be assessed as JCAs in EUnetHTA21.

- Create an Excel file based on a data reporting template with minimum data requirement (use minimum data requirements from the TISP/EPL pilot from JA3 as a starting point);
- Scan Food and Drug Administration (FDA)-website (and other international regulators) for products with break-through designation;
- Scan FDA-website (and other international regulators) for products with ongoing Investigational Device Exemption (IDE)-approval trial;
- Involve all EUnetHTA partners with submission-systems e.g. HAS, AIHTA, National Institute for Health and Care Excellence (NICE) - interventional procedures;
- Scan Horizon Scanning Systems e.g. National Health Service (NHS) innovation observatory, International Horizon Scanning Initiative (IHSI);
- Contact and involve MedTech Europe on products in pipeline;
- Contact with Healthcare Professionals (HCP) on products in pipeline in resp. areas of expertise;
- Contact the Medical Device Coordination Group (MDCG) in order to evaluate the possibility of receiving a list of products that underwent review/scrutiny process (in collaboration with the hands-on group on D7.4.2 MDCG-EUnetHTA;
- Contact patient organisations (focus on organisations in domains where many MD/IVD are under development).

There will be close collaboration with the hands-on group on D4.7.2 Framework for Assessment of high-risk medical devices and IVD and D4.7.1 Synthesis of national requirements – the same organisations (AIHTA and HAS) are part of these groups, which will facilitate the work.

3.1.2 Objective 2: Define a process description for screening of EUDAMED

The following steps will be taken in order to achieve the objective and to create a EUDAMED data reporting template (D4.7.3.):

- Monitor the status of EUDAMED (and identify functional specifications of the database). Even if EUDAMED is not fully functioning, the summary of safety and clinical performance (SSCP) should be available upon request[1]. It should be evaluated which information the SSCP will contain, how to get access to it, and if relevant data can be extracted for a possible list of products;
- Set up and pilot a data reporting format and requirements (minimum data requirements) needed for prioritisation and evaluate it;
- Pilot the time needed for collecting the data from EUDAMED.

[1] https://ec.europa.eu/health/sites/default/files/md_eudamed/docs/md_eudamed_fs_v4_1_en.pdf

3.1.3 Objective 3: Define a EUDAMED-based process description for TISP

The first step of a TISP process for JCA is to identify relevant topics. In addition, mechanisms for monitoring the identified topics need to be in place. In this respect, an efficient and defined TISP process is an important means to support the aims of European cooperation on HTA.

The following steps will be taken in order to achieve the objective and to create a guidance for the TISP process (D4.7.4.):

- Define the participants of each process step (who can suggest topics, who is doing the prioritisation);
- Define the frequency of the TISP process and the time points within the year;
- Define the time needed for a TISP cycle;
- Pilot the TISP process and evaluate it (for at least 6 to 12 months);
- Estimate the total number of assessments concerned per year (class IIb/ III medical devices and class D IVD, as defined by the HTA regulation);
- Update the EUnetHTA SOP on Topic Identification (OT-01-TopIdent), which so far includes a process description for topic proposals from EUnetHTA partners and external stakeholders.

Some exchange and interaction will take place with the hands-on group responsible for D7.4.2 MDCG-EUnetHTA. The interaction of EUnetHTA 21 in the prioritisation and selection of technologies for JCA/CA that have undergone a MDCG review/scrutiny process is envisaged.

Furthermore, the hands-on group working on the production of JCA/CA for medical devices (D5.4.1.) will be kept informed.

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 be invited to review, at the same time as 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.

In addition, the Hands-on Group (HOG) will consult specifically HTD, patients and HCP associations in order to collect additional information on Health Technologies under development. Furthermore, the HOG aims to consult on a regular basis relevant regulatory bodies 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.

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 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 hands-on group will have meetings/email updates when needed, but at least monthly meetings, to update each other on the progress. In addition, the hands-on group will also have regular meetings with the relevant other hands-on groups, namely D7.4.2 MDCG-EUnetHTA, the hands-on group on D4.7.2 (Framework for Assessment of high-risk medical devices and IVD) and D4.7.1 (Synthesis of national requirements). The hands-on group working on the production of JCA/CA for medical devices (D5.4.1.) will be kept informed.

4.2 Timelines

Table 4.1. Timetable

Milestones	Start date	End date
Project duration	26/10/2021	30/09/2022
1st Draft deliverable	26/10/2021	23/02/2022
Public consultation	06/06/2022	05/07/2022
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