eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Project plan TISP pilot – medical devices and in vitro diagnostics

Updated: 01.03.2019

Developed by Work Package 4 Joint production of Health technology assessments WP4
Lead Partner: NIPHNO

T1 *Pilot project plan version number*

Version number	Date	Finalised by	Type of document/Modification	Shared with
1.	04.09.2018	NIPHNO	Draft project plan	TISP working group
2.	15.01.2019	NIPHNO	Revised draft project plan	TISP working group
3.	01.04.2019	NIPHNO	Final project plan internal document	TISP working group/Public

Aims and summary

This document provides details of a pilot on a process for Topic Identification, Selection and Prioritisation (TISP) for other technologies than pharmaceuticals (OTs) within the EUnetHTA Joint Action 3 (JA3) work package (WP4) framework. The aim of the pilot is to explore a workflow for voluntary collaboration on TISP for joint assessments (JA) or collaborative assessments (CA) based on the relative effectiveness assessment (REA) model[1]. The pilot will be restricted to medical devices (MDs) and in vitro diagnostics (IVDs). The piloted workflow should be as simple as possible to assure that it can be continued throughout the EUnetHTA JA3 period, and beyond this period. Results of the pilot will also inform the final recommandations on TISP for European collaboration on HTA beyond 2020.

Identification
Topics will be identified (step-1) by EUnetHTA partners based on existing local horizon scanning systems (HSS) and/or other national or regional lists of topics selected or prioritised for HTA (TISP lists). In addition, the EUnetHTA POP-database will be explored as identification source, and stakeholders will be encouraged to suggest topics. All identified topics will be presented in a minimal data-set (MDS).

Selection
The selection[2] process (step-2) from all identified products will be according to a set of pre-specified criteria (e.g. only MDs and IVDs, timelines to fit within EUnetHTA WP4 JA3 production). The updated

[1] **Joint assessments:** EUnetHTA Joint Assessments (JA) are health technology assessments jointly produced by at least four EUnetHTA partners in different European countries. EUnetHTA processes, guidelines and the HTA Core Model® are used for the production of assessments that are subject to extensive review procedures in order to ensure high quality. JAs are centrally coordinated by the WP4 Co-Leads and comprise a broad stakeholder involvement, including the use of a EUnetHTA submission file in addition to a scoping (e-)meeting with industry (1).

Collaborative assessments: EUnetHTA Collaborative Assessments (CA) are primarily produced in non-pharmaceutical technologies. They only differ from the EUnetHTA JAs with regard to coordination, i.e. the project management is performed in a decentralised manner by WP4 Co-Lead and WP4 Activity Centre Department Leads. In CAs, the use of submission file and scoping (e-) meeting with industry are optional. CAs should facilitate timelines that are aligned with national work programs and should contribute to the sustainability of assessment production after 2020 due to decentralised coordination (1).

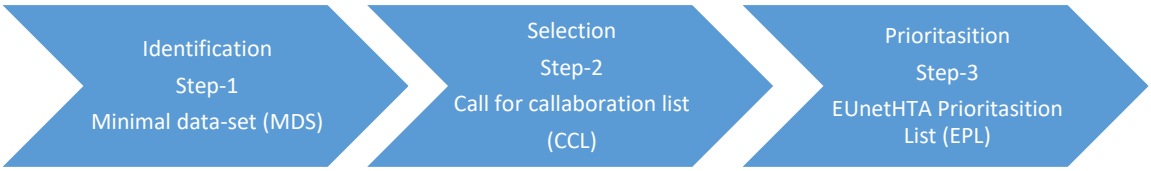
[2] **Selection/filtration:** Application of a set of pre-defined criteria to the identifies technologies, in order to retain the technologies relevant to the pre-determined technology scope and time frame.

MDS will be used for prioritisation by EUnetHTA partners (call for collaboration) using a call for collaboration list (CCL).

Prioritisation
Prioritisation[3] will be based on EUnetHTA partners interest in the topic. No other prioritisation criteria will be applied.

The EunetHTA prioritisation list (EPL) is the final list (step-3) with topics were EUnetHTA WP4 partners have indicated interest to active participate in the assessment.

F1 Steps of the TISP process



The MDS and the CCL will be considered as internal EUnetHTA documents.
The EPL will be made public available.

The following endpoints will be measured:

1. *Availability of data from different sources and barriers for information sharing*
2. *Number of identified topics*
3. *Number of times the same topic has been identified by different sources*
4. *Developmental status of topic when entering the MDS*
5. *Regulatory status of topic when entering the MDS*
6. *Information gaps of the MDS*
7. *Number of selected topics in the final MDS and CCL*
8. *Number of identified topics excluded from the MDS/CCL and reasons for exclusion*
9. *Level of EunetHTA partners with expressed interest in a topic for national setting*
10. *Level of EUnetHTA partners with expressed interest to participate in assessment as author/ co-author or dedicated reviewer*
11. *Level of EUnetHTA partners with expressed interest in national uptake of a EUnetHTA JA or CA on the topic*
12. *Information on topics in the EPL and not in the EPL (number of topics, technology type (MD/IVD), Therapeutic area, Developmental status, Regulatory status)*
13. *Workload connected with each step*

Background

The background for the pilot is described is the ongoing EUnetHTA EP4 work on providing recommendations for Horizon Scanning (HS) and TISP for European cooperation on HTA beyond 2020 and in the recommendations for a EUnetHTA WP4 TISP pilot (1,2). Drafts of these documents were

[3] **Prioritisation:** Application of specific criteria to the selected/filtered technologies with the purpose of retaining for assessment the technologies with greater impact according to the system's/network's capacity for assessment.

prepared by the EUnetHTA WP4 TISP working group in June 2018. The recommendations for the pilot were revised after stakeholder consultation, input from EUnetHTA partners, discussions with the European Medicines Agency (EMA), the EUnetHTA WP4 lead partner, and the EUnetHTA Secretariat. The version of the draft recommendations for the pilot used to inform this project plan, are dated February 2019. The final recommendations for HS and TISP for European cooperation on HTA beyond 2020 are planned to be public available by November 2019.

The present proposal for the pilot is a simplified version of the original recommendations for the pilot. Most importantly, we decided to not pilot the use of prioritisation groups. This was to ensure that the pilot explores a process that is as simple as possible, and that may be continued on a voluntary basis also beyond Joint Action 3.

Tasks and workload

The pilot team

The team for the pilot is constituted of TISP working group authors on OTs. Tasks and anticipated workload related to the pilot are presented in table 2. The EUnetHTA WP4 lead partner NIPHNO will coordinate the pilot.

T2 *Pilot team and tasks*

Name and affiliation	Coordinating tasks	Anticipated workload in working days* (including finalisation of draft recommendations)
Vigdis Lauvrak,WP4 lead NIPHNO, Norway	Overall coordination of pilot; Preparation of project plan; Template preparation MDS; Coordination of identification Preparation of endpoint evaluation report	15 days
Anna Lien Espeland WP4 lead NIPHNO WP4, Norway	Technical support	5 days
Helene Arentz-Hansen EUnetHTA WP4 leadpartner, NIPHNO, Norway	Input to the project plan; Identification and selection based on national data; Preparing a draft of the MDS; Contributing to the content of the MDS; Quality check of output CLL; Input to the endpoint evaluation report	15 days
Judit Erdos, LBI-HTA, EUnetHTA WP4 co-lead other technologies, Austria;	Input to the project plan; Identification and selection based on national data and the EUnetHTA POP-database; Updating the MDS with relevant content for items of the list; Coordination of prioritization preparing the CLL (calls for collaboration based on the MDS); Input to the endpoint evaluation report;	15 days
Antonio Migliore, EUnetHTA WP4 partner, AGENAS, Italy;	Input to the project plan; Identification and selection based on national data; Contributing to the content of the MDS; Input to the endpoint evaluation report;	5 days
Silvia Gabriela Scintee, EUnetHTA WP4 partner, NSPHMPDB, Romania	Input to the project plan; Contributing to identification and selection based on national data; Input to the endpoint evaluation report	2-5 days
Sheryl Warttig /Zoe Garrett EUnetHTA WP7, NICE, UK;	Input to the project plan; Contributing to identification and selection based on national data; Input to the endpoint evaluation report	2-5 days

*Maximum anticipated workload. One work day is equivalent to 8 hours. The workload will depend on availability of national data to be shared. Information on workload spent for the TISP process will be collected as part of the endpoint evaluation.

Additional support
Each author may need to seek support from their own organisation to fulfil their tasks; this will not necessarily influence the total anticipated workload for the pilot.

All EUnetHTA partners will be asked to contribute to identification, all EUnetHTA WP4 members will contribute to prioritisation (answering to the call for collaboration). Reviewers and authors of the EUnetHTA WP4 TISP group with main interest in OTs (see table 3) are in particular anticipated to contribute to identification based on national data. Information on workload for the various steps will be collected as part of the pilot. Reviewers are also anticipated to review the endpoint evaluation report.

T3 *Reviewer team*

Name and affiliation	Tasks	Anticipated workload*
Leonor Varela Lema, Avalia-t, Spain; Luciana Ballini RER, Italy; Mark Finlayson SFOPH/SNHTA, Switzerland; Matthias Menig SFOPH/SNHTA, Switzerland; San Miguel Lorena, KCE, Belguim; Patricia Harrington, HIQA, Ireland; Rossella Di Bidino, EUnetHTA WP4 partner, UCSC, Italy; Anelia Koteva, NCPHA, Bulgaria; Anna Cavazzana, Region Veneto, Italy; Claudia Dima, NIPHB, Romania; Chantal Guilhaume, EUnetHTA WP4 partner, HAS, France; Emmanuel Gimenez Garcia; AQuAS, Spain; Haralampos Karanikas, EKAPTY NKUA, Greece; Heidi Stürzlinger, GOG, Austria; Iñaki Gutiérrez-Ibarluzea, Osteba, Spain;	Contribute to identification and selection based on national data; Review of the endpoint evaluation report	2 days each

* Maximum anticipated workload, the workload will depend on availability of national data to be shared

Details of the pilot

One cycle of the TISP process (see figure 1) will be performed within the pilot's time frame. The cycle will be composed of the following steps:

1. Identification, output: the MDS
2. Selection, output the CLL
3. Prioritisation (call for collaboration), output the EPL

Details for each steps are provided below.

Identification and preparation of the MDS
Responsibility: NIPHNO and LBI-HTA.
All TISP work group members including reviewers should contribute by at least answer questions (see Appendix 1 HS questionnaire) to whether information from national or regional HSS or TISP list is available and may be shared.

Three sources of identification will be explored:

1) EUnetHTA partners and existing local or regional HSS or TISP lists
NIPHNO will contact all EUnetHTA partners by e-mail to answer questions (Appendix 1 HS questionnaire) on whether they are able to share data from a regional or national HSS or a TISP list. Information shared by EUnetHTA partners should be MDs or IVDs in the latest updates of the HSS/TISP lists, and/or topics prioritised for HTA within the last six months.

2) The POP-database of planned and ongoing HTA projects
LBI-HTA will search the POP database for planned projects added within the last 6 months, verify the up-to-dateness of the records and create a list of the eligible projects.

3) Input from stakeholders
NIPHNO will make an announcement using the EUnetHTA home page about the possibility to suggest topics. The EUnetHTA stakeholder e-mail list will be used to ensure awareness on this possibility.

(As regulators of MDs and IVDs do not share structured information, they will not be contacted as part of the pilot. However, the use of information from regulators should become relevant after the launch of the planned EUDAMED database (1, 2)).

Data to be shared should be in English and at least contain a name or description of the technology, the anticipated indication and the name of the manufacturer (that is the CE mark holder or the prospective CE mark holder, also referred to as marked authorisation holder, MAH, or prospective MAH, pMAH).

No confidentiality agreements can be made by the EUnetHTA TISP work group. Information on topics provided to a EUnetHTA partner in confidentiality should not be submitted/shared with the TISP work group as part of the pilot.

NIPHNO will collect (merge) and sort the information, exclude duplicates and populate a draft of the MDS using a specific template (see Appendix 3, Minimal data-set Template).

NIPHNO will ensure that at least a name of the technology, the indication and the name of the manufacturer is provided in this draft. NIPHNO will share the draft MDS with LBI-HTA.

LBI-HTA will check and update the MDS with missing information. If deemed necessary due to a large number of identified topics, LBI-HTA may assign OT-team members from NIPHNO and ASGENAS to contribute to identifying any missing data. It might not be possible or necessary to fill in all information of the MDS for all technologies. The aim is to explore availability of data to be shared and if the process can be repeated once or twice a year.

Selection, updating the MDS and preparation of the CCL
Responsibility: LBI-HTA and OT team members

Topics to be included should fulfil one of the following criteria:

- *MDs and IVDs and medical procedures involving MDs or IVDs*
- *the product is CE marked or anticipated to be CE marked within 12 to 24 months*

There will be no restriction to class of MD or IVD. Topics that do not fulfil these inclusion criteria will be excluded from the MDS. LBI-HTA will be responsible for updating the MDS and to create a CCL that will be sent to EUnetHTA partners in a call for collaboration. The MDS will be considered a EUnetHTA internal document to be shared with WP4 TISP group on the EUnetHTA WP4 TISP workroom.

Topics to be included in the CCL should fulfil the timeframe for initial assessment and reassessments set by EUnetHTA JA3. That means that topics that are not yet CE marked, or that are under assessment or have recently been assessed by EUnetHTA will be retained in the MDS

The format of the CCL will be decided as part of the pilot. The CCL will be considered a EUnetHTA WP4 internal document to be shared with EUnetHTA WP4 partners.

Prioritisation (call for collaboration) and preparation of the EPL
Responsibility: LBI-HTA

LBI-HTA will use the CCL to contact EUnetHTA WP4 partners by a call for collaboration for joint or collaborative assessment to select topics of interest for REA.

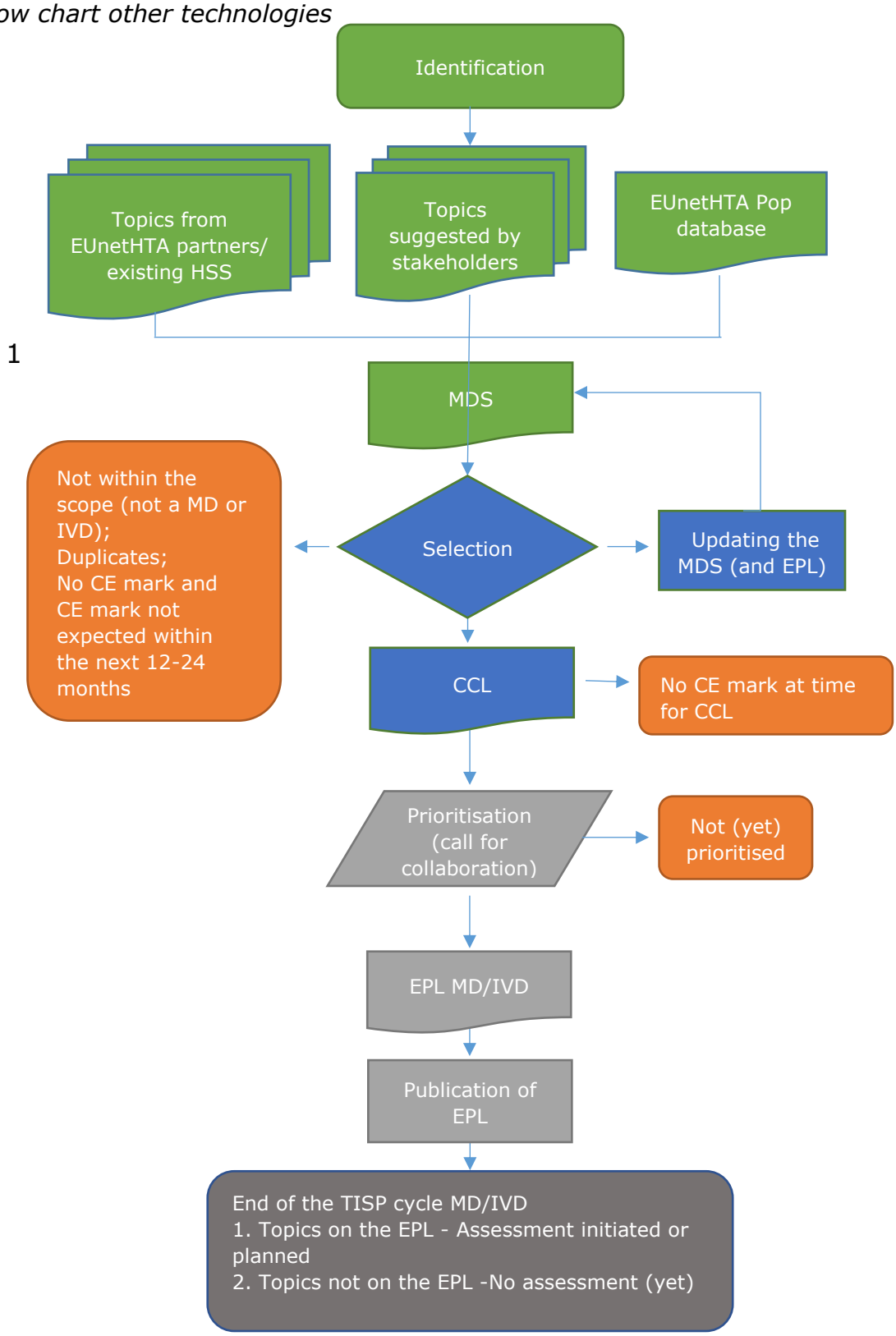
Prioritisation will be based on EUnetHTA partners interest in the topic. No other prioritisation criteria will be applied. Identified topics will be sorted based on the following answers from the call for collaboration

-expressed interest in the topic as relevant for national setting
-expressed interest in national/regional uptake of a EUnetHTA conducted REA
-expressed interest to participate in assessment as author, co-author or reviewer

Topics will be given a score depending on number of partners interested in the topic as relevant for national setting, interest in national uptake of REA, and interest to participate in assessment (score 1 per partner with expressed interest). Topics of no interest score 0. Topics of interest to EUnetHTA partners will be collected an entered to the EPL (see Appendix 4).
The EPL will be made public by the EUnetHTA home page.

The workflow for each cycle is presented in figure 1. Topics not prioritised, will go through a number of cycles before they are excluded. How many cycles and how this will be handled is still under discussion and needs to be agreed on as part of the final recommendations.

F2 Flow chart other technologies



MDS = Minimal data-set, CCL= Call for collaboration list, EPL MD/IVD = EunetHTA Prioritisation List on Medical Devices and In vitro Diagnostics

Endpoint evaluation

Responsibility for endpoint evaluation is presented in table 4.

T4 *Endpoint evaluation and responsibility*

Endpoint	Responsibility
1. *Availability of data from different sources, barriers for sharing* 2. *Number of identified topics* 3. *Number of times the same topic has been identified by different sources*	NIPHNO/ checked by LBI-HTA
4. *Developmental status of topic when entering the MDS* 5. *Regulatory status of topic when entering the MDS* 6. *Information gaps of the MDS* 7. *Number of selected topics in the final MDS and CCL* 8. *Number of identified topics excluded from the MDS/CCL and reasons for exclusion* 9. *Number of EunetHTA partners with expressed interest in a topic for national setting* 10. *Number of EUnetHTA partners with expressed interest to participate in assessment as author/ co-author or dedicated reviewer* 11. *Number of EUnetHTA partners with expressed interest in national uptake of a EUnetHTA JA or CA on the topic* 12. *Information on topics in the EPL and not in the EPL (number of topics, technology type (MD/IVD), Therapeutic area, Developmental status Regulatory status)*	LBI-HTA/ checked by NIPHNO
13. *Workload connected with each step*	Identification: NIPHNO and LBI-HTA Selection and updating the MDS: LBI-HTA Prioritisation: LBI-HTA

The draft endpoint evaluation report will be prepared by NIPHNO. The report will contain a suggestion for a TISP process that may continue throughout the EUnetHTA period, and beyond based on voluntary collaboration and a voluntary coordinating secretariat. Anticipated workload for the different steps and the coordinating secretariat and will be provided. Possibilities and limitations of this approach will be discussed. All TISP authors will provide input to a draft of the endpoint report.

Time frame and milestones

T5 *Time frame and milestones*

Milestones and deliverables	**Planned date daft 2**	**Final plan**
Pilot plan finalised-	01.02.2019	01.03.2019
Pilot start	01.02.2019	01.02.2019
Identification: Start	01.02.2019	
Identification: Reminder sent	15.02.2019	06.03.2019
Identification: Deadline for input	01.03.2019	15.03.2019
Identification: Draft MDS prepared and shared with LBI	15.03.2019	01.04.2019
Selection: MDS Updated CCL prepared	01.04.2019	24.04.2019
Prioritisation: Start (Call for collaboration)	01.04.2019	24.04.2019
Prioritisation: Reminder sent	15.04.2019	08.05.2019
Prioritisation: Publication of EPL	01.06.2019	22.05.2019
Endpoint measure deadline	01.07.2019	01.07.2019
Draft evaluation report	15.08.2019	**23.08.2019**
Review of evaluation report	15.09.2019	**01.10.2019**
Final endpoint evaluation report (Delivered together with the first version of the final recommendations)	**30.10.2019**	**30.10.2019**
EUnetHTA WP6 is contacted to provide a SOP	**30.10.2019**	**30.10.2019**

Deliverables and Transparency

Pilot project plan: Final version on the EUnetHTA home page.
MDS: EUnetHTA internal document – available to EUnetHTA WP4 members.
CCL: EUnetHTA internal document – available to EUnetHTA members.
EPL: Public document on the EUnetHTA homepage.
Endpoint evaluation report: Public document on the EUnetHTA home page.

References

1. EUnetHTA WP4 TISP workgroup, Final recommendations for the pilot (to be available to be available on the EUnetHTA home page)
2. EUnetHTA WP4 TISP, Horizon Scanning, Topic Identification, Selection and Prioritisation for European cooperation on HTA - Draft recommendations – version 6 with stakeholder consultation and results of the pilot incorporated (to be available on the EUnetHTA home page)

Appendices

A1 Questionaire on HSS, TISP lists and EUnetHTA partners ability to share data

The aim of the questionnaire is to collect information on HSS and TISP list and barriers towards collecting and sharing data from such lists. The following was sent to all EUnetHTA partners:

Agency	
Acronym	
Country	
National or regional HSS informing HTA (yes/no)	
URL HSS if availble	
Technology Scope HSS (Pharmaceuticals; MD; IVD; Other)	
National or regional list of topics informing prioritisation of HTA (TISP-list) (yes/no)	
Technology Scope of TISP-list (Pharmaceuticals; MD; IVD; Other)	
URL TISP-list if available	
Is your organization able to collect and share data from the HSS/TISP list for the EUnetHTA pilot? (yes/no)	
Is your organization able to voluntarily collect and share data from the HSS/TISP- list on a regular basis beyond 2020? (yes/no)	
Total anticipated workload for sharing two times a year (in workdays per year)	
Preferred interval for sharing (times per year)	
If you are not able to share the data from your regional or national HSS or TISP list: What are the main barriers for sharing information?	
Comments	

A2 Identification template –MD/IVD

The following added to an Excel sheet:

- ***Technology/Topic definition***
- ***Name of product(s)***
- ***Manufacturer(s)***
- ***Indication (anticipated, including age and sex if applicable)***
- *Therapeutic area*
- *Type of device according to CE marking (MD class, IVD class)*
- *Timeline clinical research (Information on pivotal trials and trial number(s) if available)*
- *Regulatory status Europe (CE mark)*
- *Regulatory status USA (FDA approval)*

- *Estimated launch (best guess)*
- ***Date of entry***
- ***Identified by***
- *Hyperlink to information (if available)*
- *Comments*

Items in bold are obligatory.

A3 Minimal data-set template –MD/IVD

The following added to an Excel sheet:

- ***Technology/Topic definition***
- ***Name of product***
- ***Manufacturers***
- ***Indication (anticipated, including age and sex if applicable)***
- ***Therapeutic area****
- ***Type of device according to CE marking (MD class, IVD class)***
- ***Timeline clinical research (Information on pivotal trials and trial number(s) if available)***
- ***Regulatory status Europe (CE mark)*** *at first entry*
- ***Regulatory status USA (FDA approval)*** *at first entry*
- ***Estimated launch (best guess)*** *at first entry*
- ***Date of entry***
- ***Identified by***
- ***Hyperlink to information (if available)***
- ***Comments identification***
- *Last up-date Minimal data-set*
- *Regulatory status Europe (CE mark) at last update*
- *Regulatory status USA (FDA approval) at last update*
- *Estimated launch (best guess) at last update*
- *Comments to update*
- *EUnetHTA status at entry (Excluded; Not prioritised; Prioritised; Assessment ongoing; Assessment completed)*
- *First call for collaboration*
- *Last call for collaboration*
- *EUnetHTA status at up-date (Excluded; Not prioritised; Prioritised; Assessment ongoing; Assessment completed)*
- *Date for exclusion*
- *Comments to exclusion*

* Categories based on the UK innovation Observatory Speciality filter: details provided here http://www.io.nihr.ac.uk/

Items revealed in bold are identical to the identification template:

A4 EUnetHTA Prioritisation list –MD/IVD

The following added to an Excel sheet:

- ***Technology/Topic definition***
- ***Name of product***
- ***Manufacturers***
- ***Indication (anticipated, including age and sex if applicable)***
- ***Therapeutic area***
- ***Type of device according to CE marking (MD class, IVD class)***
- ***Timeline clinical research (Information on pivotal trials and trial number(s) if available)***
- ***Regulatory status Europe (CE mark)*** *at update*
- ***Regulatory status USA (FDA approval)*** *at update*
- ***Estimated launch (best guess)*** *at update*
- ***Identified by***
- ***Hyperlink to information (if available)***
- *First call for collaboration*
- *Last call for collaboration*
- *EUnetHTA status at up-date (Excluded; Not prioritised; Prioritised; Assessment ongoing; Assessment completed)*
- *Date for exclusion*
- *Comments to exclusion*

Items in bold are identical to the identification template