eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA WP5 Joint Action 2

Apply(ing) the HTA Core Model for Rapid Relative Effectiveness Assessment (REA) for national/local adaptation and reporting

PROCEDURE MANUAL WP5 STRAND B: RAPID ASSESSMENTS OF OTHER HEALTH TECHNOLOGIES SUCH AS MEDICAL DEVICES, SURGICAL INTERVENTIONS OR DIAGNOSTICS

V3 –29th April 2013

Version log

Version number	Date	Name (Initials)	Comment
V1	20/12/2012	AN	V1 was sent to WP5 members for comments (consultation period: 20 Dec 2012 – 21 Jan 2013)
V2	15/03/2013	AN	Comments from WP5 members were processed and alterations were made based on the discussion at the first WP5 JA2 meeting in Diemen in February 2013 V2 was sent to the WP5 Stakeholder Advisory Group (SAG) for consultation (consultation period: 18 March 2013 – 5 April 2013)
V3	29/04/2013	AN	Comments from the WP5 Stakeholder Advisory Group were processed and alterations based on these comments were incorporated

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Acronyms – Abbreviations

A	(in the project phase titles) stands for Assessment
C	(in the project phase titles) stands for Consultation
CT	Coordination team for the pilot project that is the LBI-HTA
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HTA	Health Technology Assessment
HTA Core Model	Generic model for creating and presenting HTA information as assessment elements. A tool of EUnetHTA Collaboration.
JA	Joint Action
JA2	Joint Action 2
LBI-HTA	Ludwig Boltzmann Institute for Health Technology Assessment
P	(in the project phase titles) stands for Project Plan (Protocol)
PICO	Abbreviation used for scoping: P=population, I=intervention, C=comparison, O=outcome
POP	Planned and On-going Projects
R	(in the project phase titles) stands for Review
REA	Relative effectiveness assessment
SAG	Stakeholder Advisory Group
WP	Work Package

Introduction

Objective of this Procedure manual

This manual guides the production of pilot rapid assessments for other health technologies such as medical devices, surgical interventions or diagnostics.

Background information on WP5 JA2

EUnetHTA Joint Action 2 (JA2) is a joint action between the European Commission and Member States. Its aim is to develop a sustainable network of health technology assessment (HTA) agencies and information resources to inform health policy making. EUnetHTA JA builds on the earlier EUnetHTA Projects 2006-08, 2009-2012 and several other European projects.

The aims of the Work Package 5 (WP5) of EUnetHTA JA2 are to

1) test the capacity of national HTA bodies to collaboratively produce structured rapid core HTA information on pharmaceuticals (Strand A) and other health technologies, such as medical devices, surgical interventions or diagnostics (Strand B).

2) test the application (translation) of those collaboratively produced HTAs in national/local contexts.

3) develop and test models and tools as well as production processes to support collaborative and national/local production

ad 1) Testing and piloting collaborative production

At least 4 pilot rapid assessments on other technologies such as medical devices, surgical interventions or diagnostics containing rapid HTA information based on structured core information from the HTA Core Model for Rapid Relative Effectiveness (REA) of pharmaceuticals will be collaboratively produced.

One organisation will serve as the authoring organisation or institution (first/lead author), whereas at least one other organisation or institution will serve as co-author. A pool of dedicated reviewers (+/- 5 different institutions originating from Strand B members) will take part in the reviewing process.

Ad 2) Transferring rapid HTA or parts of the information into national/local reports

All WP5 members are expected to put an effort into adaptation of pilot rapid assessments produced within WP5 into national/local reports. This may take two forms: either the whole pilot rapid assessment can be used as a local report when referenced accordingly, or only parts of the pilot assessment can be used for national/local reports (e.g. conclusions/discussion are reformulated).Within Strand B, this should result in about 10 national/local reports based on the pilot assessments.

ad 3) Development and testing of models and tools as well as production processes to support collaborative and national production

During joint production of pilot assessments, the following products will be tested and developed based on the experience gained:

- the 'HTA Core Model REA" of pharmaceuticals
- the "HTA Core Model for Rapid Assessment of other health technologies".

Objective of the pilots

The purpose of the pilots is to produce pilot rapid assessments based on cross-border collaboration and to test the usability of the HTA Core Model for rapid REA including guidelines for other technologies. Relevant outcomes of the pilot are:

- pilot teams' perception about the about cross- border collaboration in producing a rapid pilot assessment by using a standardized survey
- WP5 members perception on the usability/readability of the pilot rapid assessment
- the duration of the assessment
- the workload (in terms of working hours)
- pilot teams' perception on the applicability of the HTA Core Model for rapid REAs and the guidelines to other technologies

Identifying collaborating partners and responsibilities

Topic selection and building the pilot's teams

Selection of topics and identification of collaborating partners includes two potential ways.

a) Model 1: "Call for collaboration" (active brokering) to find partners:
Authoring organisations or institutions have identified relevant topics out of their own work-programs. They submit their topics/indications as well as suggested time-frames (see Call for collaboration Form) to the coordination team (CT) that is the LBI-HTA. The CT will send out the "Call for collaboration Form" asking Strand B members to express their interest in acting as co-authors or reviewers.

b) Model 2: individually contacting partners with similar work programs based on the "Planned and Ongoing Projects" (POP) database:
Topics for collaboration could be identified, either by Strand B members or by the LBI-HTA, via the POP database or based on spontaneous reactions to POP-alerts on similar work-programs between several agencies. When there is an overlap in topics listed between the authoring organisation and other Strand B members, authoring organisations may contact the respective organisation(s) themselves or they may ask the CT for assistance.

Other forms of topic selection/collaboration may also be tested during the production of pilot assessments. For example, if topics are submitted by manufacturers to the CT, these topics will be distributed amongst authoring organisations or institutions of Strand B asking them for expressions of interest in compiling a pilot rapid assessment on the proposed topic.

Regardless of the method of topic selection, no additional work-load should be imposed on participating organisations or institutions, but topics should be relevant for the work programs of the respective organisations or institutions.

Pilot's team

Every team involved in the production of a pilot rapid assessment will be composed of:

- first author(s) (from 1 authoring organisation or institution)
- co-author(s) (from ≥1 co-authoring organisation or institution)
- a pool of dedicated reviewers (from 2 – 5 reviewing organisations or institutions)
- external reviewer(s)
- coordination team (CT) (LBI-HTA).

Specific roles and tasks of team members are described below:

1) **First authors** – have *a leading role* in both main phases of the pilot project: scoping and production of the pilot. They are responsible for management of the pilot and together with co-authors they take active part in its production.

After having identified collaborating organisations or institutions, they draft a Project Plan (see Template: Project Plan) which includes details on search of information, formulated research questions, planned methodologies, co-operation with co-authors and plans for involving external clinical experts ("peer-review") and present it to co-authors, reviewers and the coordination team.

They send the draft Project Plan for consultation (for a period of 10 working days) to the respective manufacturer(s) and they inquire further information (e.g. available evidence, C/E mark). Since results and conclusions of the pilot rapid assessments must be based on publicly available information only, authors should strive to use only such information.

First authors take into consideration comments on the draft Project Plan received from dedicated reviewers, the manufacturer(s), the public and the WP5 Stakeholder Advisory Group (SAG).

They lead the production of the first draft of the pilot rapid assessment, take into consideration and answer the dedicated reviewers' comments and suggestions on the first draft and the comments from external reviewer(s), manufacturer(s) and Strand B members on the second draft of the pilot assessment. Then, they produce the final version of the pilot.

Authoring organisations are also expected to translate the pilot rapid assessment into national/local reports.

2) **Co-author(s)** – play a supportive role during the Project Plan development and scoping phase and take active part in the production of pilot rapid assessments.

During the scoping phase they support first authors in drafting the Project Plan. They accept the Project Plan and agree on timelines proposed in the document and they participate in amending the Project Plan according to comments received from the manufacturer(s), the public and the WP5 SAG.

They take an active part in the production of the pilot rapid assessment, together with first authors they consider comments and suggestions for changes collected from dedicated reviewers, the manufacturer(s), from external clinical expert(s), WP5 members as well as other potential stakeholders.

Co-authoring agencies are also expected to translate the pilot rapid assessments into national/local reports.

Model(s) for collaboration of First authors and Co-Authors

First authors and co-authors: Even though there is a close cooperation between authors during the production of pilot rapid assessment, the roles of the first author of co-author should be flexible enough so as they could cooperate in a way that is the most convenient and efficient from their point of view. It is suggested that decisions about the division of work is decided at the very beginning of the pilot .The suggested mode of action is that the first authors will be involved in the production of all domains, including data extraction from clinical trials, finding answers to the questions listed in the Project Plan and writing the report, whereas co-authors will follow and verify every step taken by the first author during production of the report, including extraction of the data and verification of references. Nonetheless, there might be several other ways of dividing tasks and responsibilities and if appropriate and feasible other collaboration models may be tested during the production of the pilots.

3) **Reviewers** – play a supportive role in both phases of the project: scoping and production of pilot rapid assessments.

Reviewers support authors from the very beginning of the project. They will participate during scoping and they will be consulted for the draft Project Plan. They accept the Project Plan and agree on timelines. In cases of disagreement between author(s) and co-author(s), dedicated reviewers will be consulted.

Their major task is to review the first draft of the pilot rapid assessment and to send comments and suggested changes to authors.

Selection of dedicated reviewers may be based on their willingness to translate pilot rapid assessments into national/local reports.

4) **Coordinating office** – coordinates work within the pilots and between pilots.

They produce the Work Plan and Procedure Manual for piloting rapid assessments; they develop a template for the rapid assessments and templates for dedicated reviewers. They facilitate identification of topics using the POP database and they assist in building the pilot's teams. They support communication within the pilot teams. The CT is responsible for making the draft Project Plan available on the EUnetHTA website and for informing the WP5 SAG on the availability of the draft Project Plan.

Project management

Working instructions for pilot authors

Basic documents/tools the team has to use are:

- HTA Core Model for Rapid Relative Effectiveness Assessment (REA) (see HTA Core Model for Rapid REA) & Guidelines on methodological issues (Guidelines) produced within Joint Action 1 (JA1) WP5
- This Procedure Manual
- Other HTA Core Model Applications (e.g. for Diagnostics, Surgical and Medical interventions, Screening)
- Template for pilot rapid assessments
- Whenever possible, the HTA Core Model Online tool will be used for the pilot assessments.
- Submission file for manufacturers (if possible and applicable).

The instructions in this Procedure Manual divide the tasks into four main phases: **project planning (protocol), assessment, review and consultation**. These four phases are further divided into numbered sections.

- **Project planning phase** (marked with P) includes scoping, searching of information, formulating research questions, and planning methodologies. The objective of this phase is to develop a final Project Plan, including timelines, a list of all relevant questions to be answered and methodologies intended to be used in the assessment.
- **Assessment phase** (marked with A) includes finding answers to the questions using the outputs of the protocol phase, the methodological guidance in the HTA Core Model for rapid REA, and the guidelines. The objective of this phase is that each pilot team of authors provides a pilot rapid assessment including result cards.
- **Internal Review phase** (marked with R) includes review of the assessment. The objective of this phase is to collect and address comments and suggestions for changes from dedicated reviewers.
- **External Review and Consultation phase** (marked with C) includes consultation of the assessment with WP5 members, at least 1 clinical expert, the manufacturer(s) and other potential stakeholders (e.g. physicians, patients) to allow mutual societies to be included in this consultation. The objective of this phase is to collect and address comments and opinions from all interested parties.

Communication

Internal communication

Managing the pilot rapid assessments

The authors work mostly on text documents. The authors should clearly mark changes they make in the draft document; either using the track changes option or using different colours or fonts. Only the first author has the right to accept or reject the changes to form a new draft or a complete document. Reviewers should provide their comments through the comments table.

The teams can decide whether they circulate the drafts as email attachments, or use the Document Library on the EUnetHTA Intranet site:

Brief guidance to the Document Library:

1- Log in to the intranet from the EUnetHTA website: http://www.eunethta.eu/

2- Once logged into the Intranet, click on the icon ‘Groups’

3- Once there, select 'WP5- Rapid HTA Pilots'

4- Click on 3rd icon from the left: 'Document Library'

5- Select the Folder 'WP5 Deliverables'

6- From there, select the relevant 'Book' from those listed.

7- Within the 'Book', the latest version of the documents are listed as hyperlinks

8- Right click the file and 'save as'. The document can now be edited from a local computer

9- Be sure to select the 'track changes option' from the document,

10- When finished working on the document, return to the Book chapter and upload the latest version of the document.

11- Then select which members to notify of the newly uploaded document.

Full process is described (with screenshots) on p. 26-30 of the Intranet user manual https://intranet.eunethta.eu/system/files/eunethta_intranet_user_manual_1.pdf.

EUnetHTA Intranet WP5 group

Relevant documents will be stored at the EUnetHTA Intranet site. You can access the Intranet site by clicking the "Access our Intranet" in the bottom left corner of the EUnetHTA public webpage http://www.eunethta.eu/ . Or directly entering https://intranet.eunethta.eu/user/ .There you should have direct access to the WP5 Workroom (listed under "My workrooms" on the right). There is a guide for the use of the EUnetHTA Intranet site: https://intranet.eunethta.eu/system/files/eunethta_intranet_user_manual_1.pdf. If you don't have the username and password to enter, please contact directly the Secretariat: Inge Merete-Skov [INS@SST.DK].

E-meetings

There is an e-meeting facility, Saba centra, available for EUnetHTA projects. The coordinator will set up e-meetings and send the invitations to the participants if required. Pilot teams may also use Saba centra to facilitate their own internal meetings. However, only Associated Partners (APs) can set up an e-meeting, with up to 15 participants. All partners can participate.

At the Intranet site you can find a pdf-guide for Saba Centra https://intranet.eunethta.eu/system/files/saba_centra_7-6_essentials_guide.pdf

External communication

The draft Project Plan will be available for public consultation on the EUnetHTA website. The WP5 SAG and the manufacturer(s) will also be given the opportunity to comment on the draft Project Plan. There will be a consultation of the pilot rapid assessment with WP5 members and the manufacturer(s), but there will be no public consultation for seeking further feedback for the pilots.

Consequently, communicating the results of the assessment in any form, e.g. poster or oral presentation, publication in any report series or international journal is not recommended before it is discussed in WP5.The individuals who plan on presenting the process feasibility and outcomes of the pilots in any form, either in the form of article, abstract or oral presentation, should coordinate this activity in advance with WP5.

Process of producing the Pilots

A schematic overview of the organisation of the process of the pilots is included in Figure 1 (general processes and overview on stakeholder involvement), Figure 2 (scoping phase) and Figure 3 (assessment phase). These overviews should be read as an ideal picture due to the high possibility of divergence (e.g. deviations from timelines).

Figure 1: Schematic overview on general processes and on stakeholder involvement in the pilots:

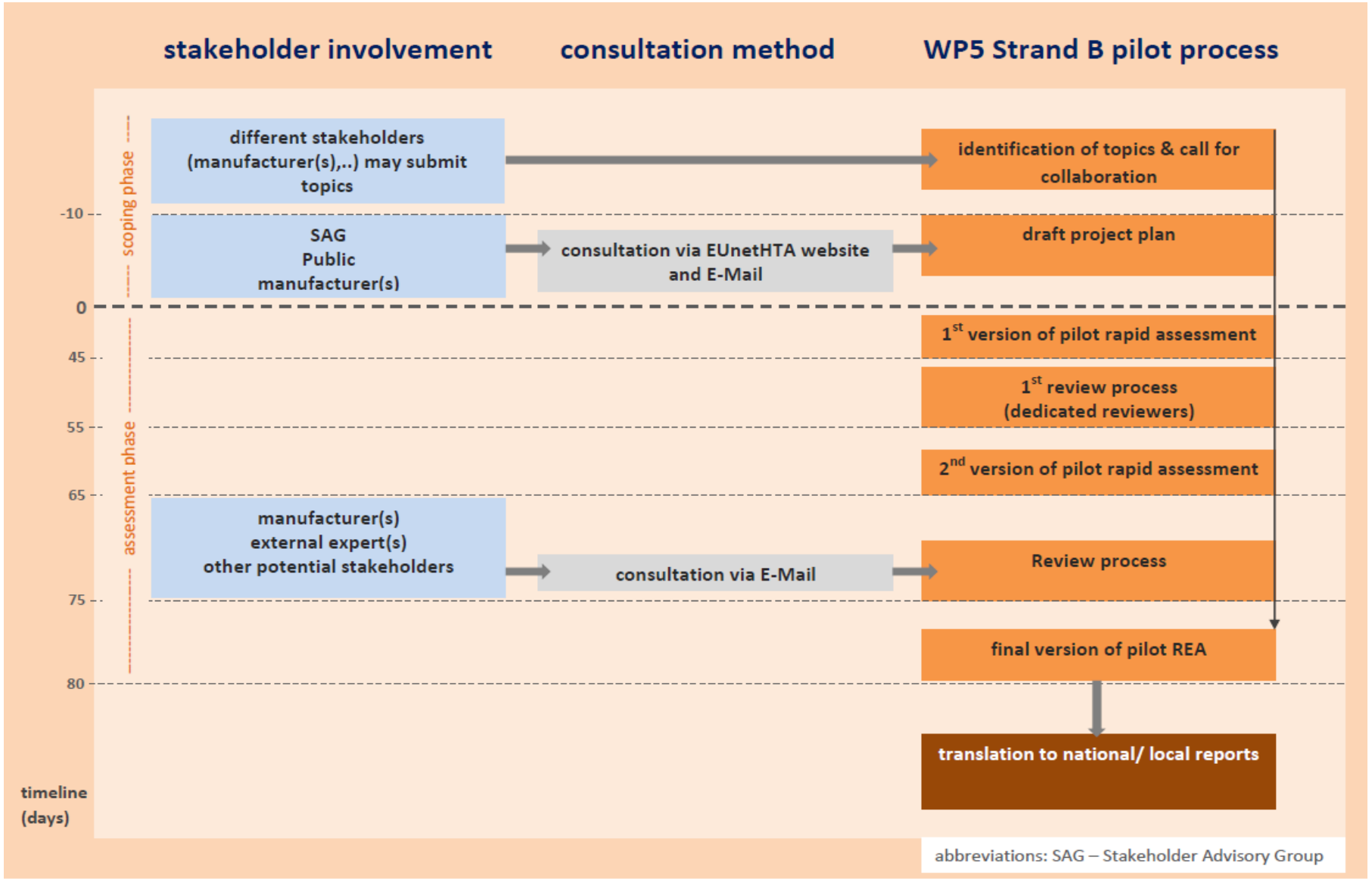


Figure 2. Schematic overview on scoping phase

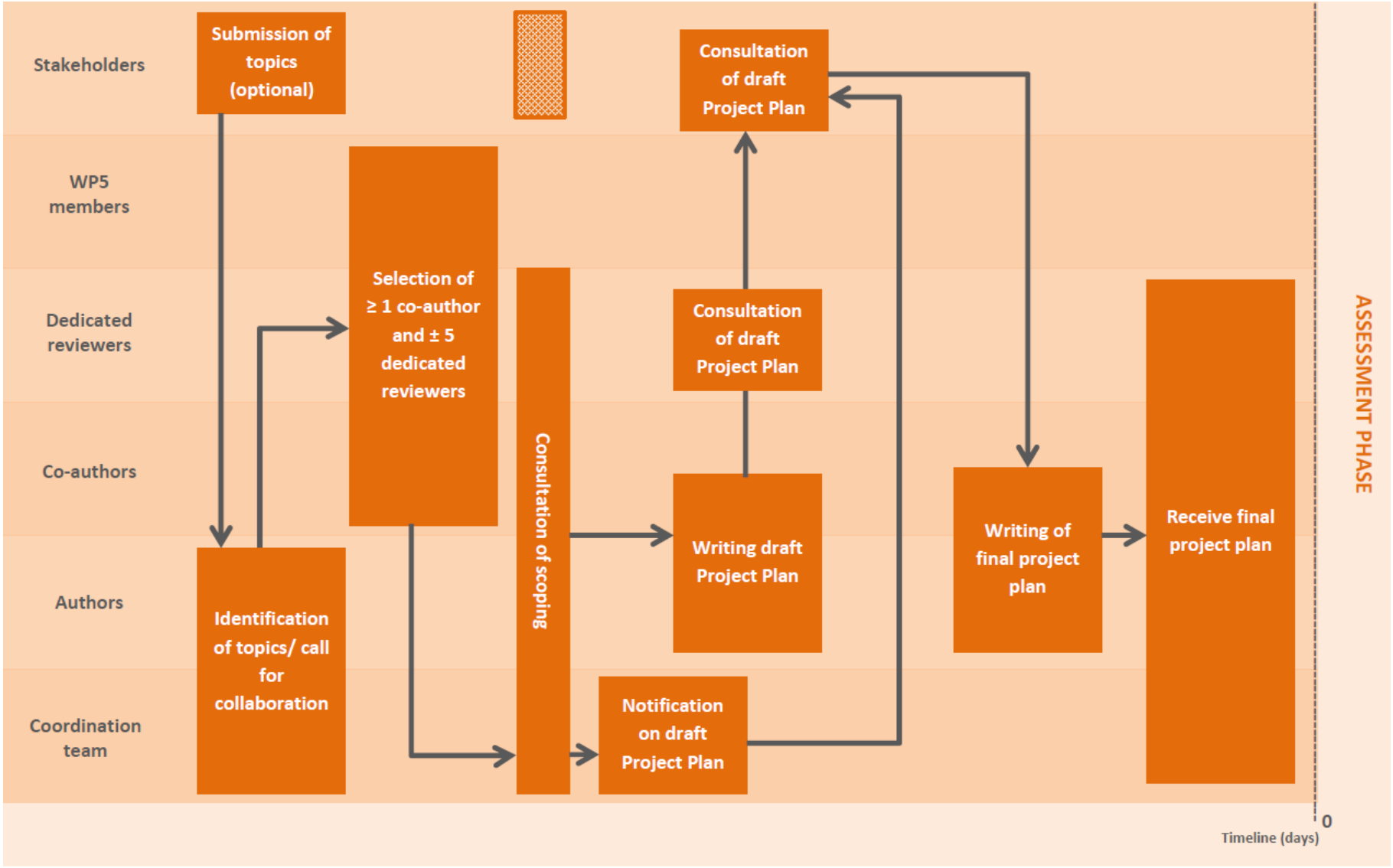
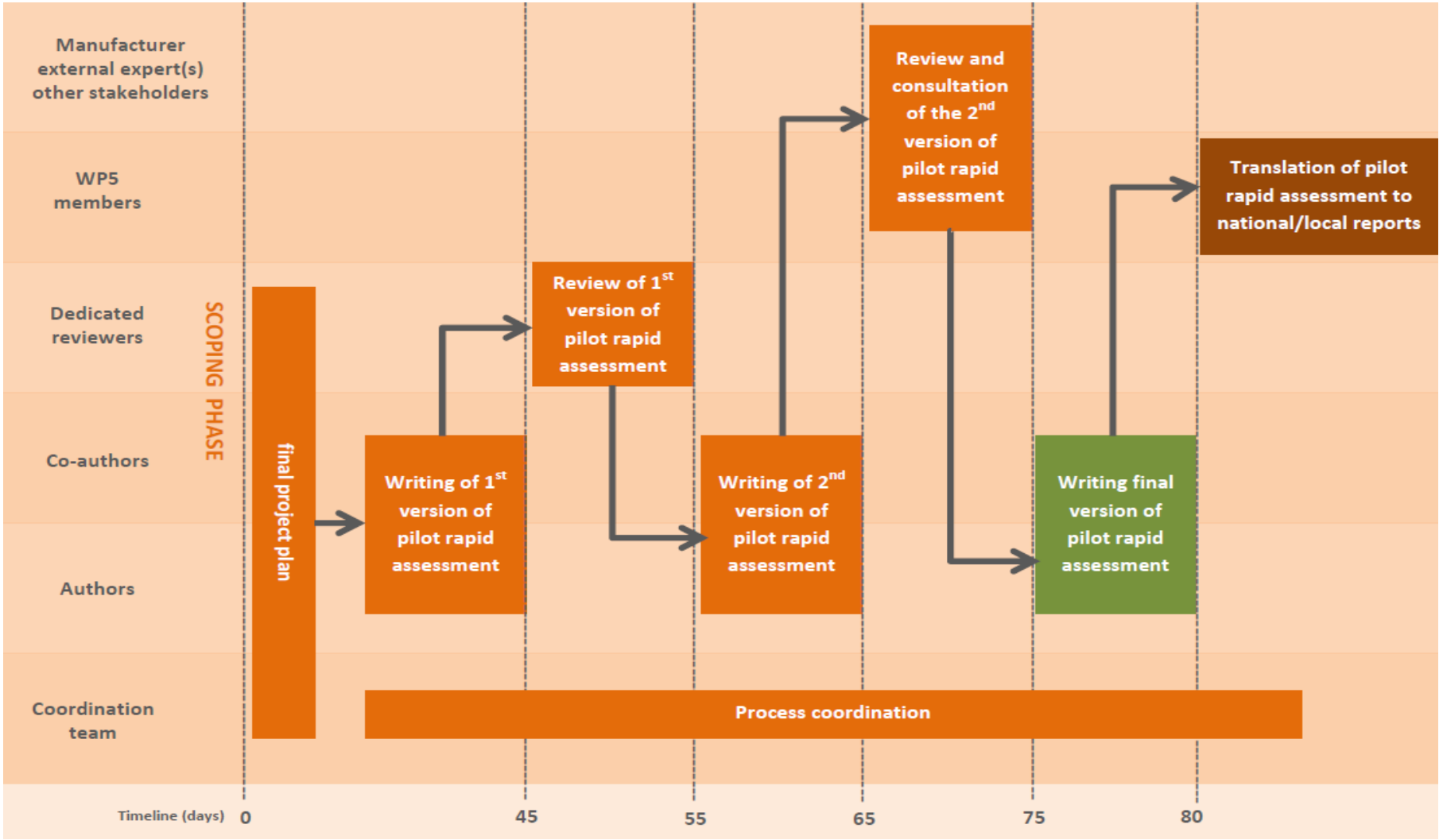


Figure 3. Schematic overview on assessment and consultation phase



Proposed schedule of Pilots

Project Planning Phase				
Start [working days]	**End [working days]**	**Activity**	**Target group**	**Parties involved**
-	-	Call for collaboration	Strand B members	Authoring agencies, CT
		Identification of topics via POP database	Strand B members	
-	-	Consultation of scoping	Co-authors, dedicated reviewers, other potential stakeholders	Authors, (CT)
-	-	Notification on draft Project Plan	WP5 SAG	CT
-	-	Draft Project Plan	WP5 SAG, Public, manufacturer(s)	Authors, Co-Authors, dedicated reviewers, CT
XX	XX + 10 days	Consultation of draft Project Plan	Authors, Co-Authors, dedicated reviewers	WP5 SAG, Public, manufacturer(s)
-	-	Final Project Plan	dedicated reviewers, CT	Authors, Co-Authors, (CT)
Pilot rapid assessment phase				
0	45	Writing first draft pilot assessment	Dedicated reviewers	Authors, Co-authors
45	55	Review by pool of ± 5 dedicated reviewers	Authors, Co-Authors	Dedicated reviewers
55	65	Writing second draft pilot assessment	Strand B members, at least 1 clinical expert, manufacturer(s), other potential stakeholders	Authors, Co-authors
65	75	Review and consultation of the second draft pilot assessment	Authors, Co-Authors	Strand B members, at least 1 clinical expert, manufacturer(s), other potential stakeholders
75	80	Writing final version of pilot rapid assessment	WP5 members	Authors, Co-Authors
80	-	Translation of pilot rapid assessment to national/local reports	National HTA organisations or institutions	WP5 members, members from other WPs

P1 Scoping the project

The **scope** of the project should be discussed and clearly defined at the beginning of the project.

The **first step** in a rapid assessment is to specify what exactly should be assessed (e.g. the scope) following the so-called PICO structure where the letters stands for.

- Population / patients with the disease of interest
- Intervention(s), i.e. the technology under assessment
- Comparison(s), that should serve as reference
- Outcomes which encompass the endpoints for assessing effectiveness and safety

Template to be used: Table 3 (Project Scope and Objectives) of the Project Plan Template, section 3.0. For other relevant considerations regarding the PICO elements see the HTA Core Model for Rapid REA (section 2.2).

The PICO will drive the evaluation in all domains. Population, intervention and comparison will generally be the same for all domains. However, there may be sometimes the need to deviate from the scope due to e.g. a subpopulation of special interest or a lack in data of the population defined in the scope.

If external experts are involved in a WP5 pilot, conflict of interest declarations will be collected from them regarding the topic. External experts who declare a conflict of interest will be excluded from parts of or the whole work under this specific topic. However they still may be included in work under other pilots.

P2 Selecting relevant research questions

This phase involves:

- Selecting relevant HTA Core Model Applications
    - Selecting relevant issues from the Assessment elements table of the HTA Core Model for rapid REA.
    - Selecting further relevant issues from the Assessment elements tables of other HTA Core Model Applications (e.g. medical and surgical Interventions, screening technologies)
- Translating the selected issues (generic questions) into actual research questions (answerable questions).

  For a detailed explanation of how to proceed see section 2.4 of the HTA Core Model for Rapid REA.

Selecting relevant issues from HTA Core models

The most important output of this phase is to retrieve a set of pragmatic and answerable questions for the pilot teams to continue with.

The authors go through the generic questions, i.e. issues, in the assessment table of every domain in the HTA Core Model for rapid REA. The teams go through these issues, one by one, defining whether the question is relevant for this topic. Even though production of pilot rapid assessments on other technologies may be similar to those of pharmaceuticals, the HTA Core Model for rapid REA is targeted on pharmaceuticals. Thus authors must also consider if issues of other applications of the HTA Core Model (e.g. on medical and surgical interventions or diagnostics or screening which can be found here: https://fio.stakes.fi/htacore/ViewHandbook.aspx) are relevant. Which issues are selected will eventually be based on the authors' own expertise, the literature retrieved, and possibly consultations with experts.

Defining a question as 'relevant' means that it should be assessed. Therefore, the word 'relevance' should be interpreted here as 'relevant in general and relevant enough in order to be answered in this rapid assessment'. Assessing relevance is not straightforward: the team should avoid identifying 'artificial' relevance (meaning every issue is considered as relevant), but should not reject issues too easily as non-relevant either. A brief justification should be provided for those elements that are regarded as not-relevant. This information may be useful for readers of the pilot.

Formulating research questions

In this phase authors should translate the issues, i.e. the generic questions in the relevant assessment element table, into actual research questions. One issue usually translates into one actual research question, but sometimes there is a need to translate the single issue into two or more actual research questions. The word 'research question' is probably not always appropriate, as not all questions require scientific research (e.g. systematic review) in order to be answered. The answer may also be retrieved from a suitable registry or by expert consultation.

Examples from the multislice CT coronary angiography pilot:

In ethical domain the issue *"Does the implementation or use of the technology challenge patient autonomy?"* was translated into a research question *"Does the implementation or use of MSCT coronary angiography challenge patient autonomy?"*.

An issue in the Health problem and current use domain "How many people belong to the specific target group?" was translated into two research questions "What is the incidence of coronary artery disease (CAD)?" and "What is the incidence of cases presenting with angina symptoms but with low to moderate probability of CAD?"

Template to be used: Table 5 (Assessment elements and translating research questions) of the Project Plan template, section 4.0.

P3 Plan for methodologies of pilot assessments

In this phase the authors should plan and report the methodologies to be used in the assessment phase, within particular domains. The authors do not need to provide a plan for every single research question separately, but rather a more general plan on domain level. The methodology section in the HTA Core Model for rapid REA and the Guidelines are the guiding documents for this task, but depending on the type of technology being assessed other HTA Core Models (e.g. for diagnostics, screening, surgical or medical interventions) must be considered.

It is not always possible to anticipate all methodological issues in the planning phase. If there is a need in the assessment phase to deviate from the Project Plan, this should be reported in the result card's methods section. No changes should be made to the plan afterwards.

Not all research questions require a thorough systematic review, and in some research areas there are no established quality assessment criteria for information. This should be also reported for transparency.

Following issues should be reported:

- Plan for information retrieval: sources and search terms for locating domain specific information, inclusion/exclusion criteria for studies or other information, in terms of content, methods and quality.
- Plan for handling the published data: do a systematic review, cite recent reviews, "screen until saturated" etc.
- Plan for finding information when there is no published data: From web sites of organisations, discussion forums, registers: Performing survey (questionnaire, interview): Other type of own research (analysis of primary data, modelling etc).
- Quality assessment tools or criteria planned to be used
- Plan for synthesis: evidence table, plan for meta-analysis or qualitative synthesis, use of GRADE, etc.

Template to be used: Table 4a (Project approach and method) and Table 4b (Preliminary evidence) of the Project Plan template,
section 4.0.

Domain specific search

Authors can complement the basic search by a domain specific search. Sometimes single research questions may require additional tailored searches. Guidance on domain specific searches can be found in the HTA Core Model for rapid REA.

P4 Compiling the final Project Plan

This phase should result in the compilation of the final Project Plan by summarising steps P1-P3 in a draft Project Plan. This draft will be subject of consultation with the WP5 SAG, the Public and the manufacturer(s). Comments received will have to be taken into account by the authors prior to compilation of the final Project Plan. The final Project Plan including deadlines for production of the draft versions of the pilot rapid assessment, the review, consultation with WP5 members and manufacturer and finalisation of the pilot, should be sent to the dedicated reviewers. An annex to the Project Plan including confidential information (such as contact details of project team members) will only be shared with the project team (author, co-author, dedicated reviewers and coordination team).

A5 Assessment phase

The assessment phase will result in the compilation of a first draft of the pilot rapid assessment. In this phase authors have their Project Plan completed (phases P1-P4). They have prepared the list of research questions, have thus identified the most important HTA Core Model Application for their assessment and have prepared a plan of methodologies to be used. Now, they enter the actual assessment phase (Template to be used: "Pilot rapid assessment template on other health technologies using the draft HTA Core Model for Rapid Relative Effectiveness Assessment").

The teams are composed of first authors and co-authors who work at a distance, and the language used is English. The basic structure to be followed is the HTA Core Model for rapid REA, which splits the assessment into elements. One **assessment element** represents one research question and the meta-data that describes its relations. Instead of doing a single search and a single report, the authors produce **domain reports**, which all are further divided into several **result cards.** A result card contains the answer to the research question in the assessment element.

Result cards

Result card is a template that contains fields for

- the research question,
- the methods that have been used to answer the question,
- the answer itself (the result),
- a possible comment,
- the references you used to answer the question, and
- estimate of importance and transferability of the information.

Reporting in the form of assessment element cards (and not plain text) results in redundancies that cannot be avoided. The result cards should function as stand-alone pieces of information. Therefore, each of them should contain a complete description of each field. No cross references like "see methods used in previous card" are acceptable. This means that there is most likely a need to copy and paste some information, e.g. references, from one card into other result cards.

In the 'result' field it is important to strictly focus on answering only the question. Authors in the previous Core HTA projects found it tempting to provide some background information for the beginning of the text to make the result more attractive to read. This makes the answers unnecessarily long, and it most likely repeats the information that is given in a more thorough and systematic way in the result cards of the two first domains (Health problem and current use and Description and technical characteristics of the technology).

It is important to report also the missing methods or results, e.g. by stating that "we used no quality assessment tool", or "we could not find any information on this issue".

Writing instructions for each field of the result card

Name of the field	Content
ID	The 5 digit identification code of the assessment element
Research question	Copy the research question from Table 3
Methods	In this section you should report the methods that you actually used for answering the research question. • Source of information: tick basic search or domain search if you used them, there is no need to copy them in this field. If you did additional search, describe it here or using Table 2. • Describe the inclusion/exclusion criteria you used for selecting studies. • Describe whether this is a systematic or unsystematic review or whether you decided to cite a recent good quality report. • Describe if you did own research: survey, modelling etc. • Describe the quality assessment criteria you used in this result card. • Describe the methods you used to e.g. to calculate new summary estimates, meta-analysis, or if you used any formal quantitative or qualitative method to synthesise data.
Result	The reader should get an idea of the nature and magnitude or frequency of the event to occur, and the overall robustness of the evidence behind this statement. There are several ways to provide this information. In many answers plain text is sufficient; in others an evidence table would be illustrative to add. Some teams may like to use GRADE or other instrument to provide overall view of the results. Mark citations in the text in the form of: [Surname of first author Year]. **Please note that this part should only focus on results, i.e. presentation of data, not interpretation.**
Comment	Use this field to add comments for the methods used, or the reliability of the results. E.g. problems in identifying information or quality of information, pending research, or need for further research.
References	Provide a list of references used to answer this research question. For referencing the Reference Style and Format according to the Uniform Requirements from the International Committee of Medical Journal Editors has to be used. Information can be found: http://www.icmje.org/manuscript_1prepare.html The Style follows the Vancouver style: List the references in alphabetical order. If there is more than one reference from an author, list them in the order of publication (most recent first). If there is more than one references from an author from the same year, list them in the alphabetical order of the title, and separate them with a, b, etc.
Estimating importance and transferability	The HTA Core Model of rapid REA provides an estimate of importance and transferability for each assessment element. In the generic model it is a very rough estimate, while importance and transferability depend on the nature of the technology, and on the evidence base behind it. Therefore we would like to gather authors' estimates on the actual importance and transferability of the pieces of information provided for this particular result card.

Template to be used: Appendix 2 (Result Cards) of the Pilot Rapid Assessment Template.

For guidance on how to collect and analyse data see section 2.5 (page 23) of the HTA Core Model for Rapid REA .

A6 Writing domain chapters

In this phase authors should produce a compiled chapter per domain. The structure of the domain reports includes: a chapter for domain methodologies, the results (a collection of result cards), and a domain discussion.

Template to be used: Chapter 2-5 (and 6, if relevant) of the Pilot Assessment Template.

A7 Summary Section

The intention of the summary section is to present a meaningful overview of the domain reports. Special emphasis is on the aggregation of data on intended (effectiveness domain) and unintended effects (safety domain) in order to assess the net benefit.

Template to be used: "Summary of relative effectiveness of [XXX]" of the Pilot Assessment Template.

For more guidance on how to produce the summary see section 2.9 of the HTA Core Model for Rapid REA of pharmaceuticals.

A8 Compiling the pilot assessment

First authors compile a first version of the pilot assessment with input from the CT. One task is to screen for potential overlaps. The general structure of the report is:

COVER SHEET

SUMMARY OF RELATIVE EFFECTIVENESS OF XXXXX

LIST OF ABBREVIATIONS

1. SCOPE
2. HEALTH PROBLEM AND CURRENT USE OF THE TECHNOLOGY
    a. METHODS
    b. MAIN RESULTS
    c. DISCUSSION
3. DESCRIPTION AND TECHNICAL CHARACTERISTICS OF TECHNOLOGY
    a. METHODS
    b. MAIN RESULTS
    c. DISCUSSION
4. SAFETY
    a. METHODS
    b. MAIN RESULTS
    c. DISCUSSION
5. CLINICAL EFFECTIVENESS
    a. METHODS
    b. MAIN RESULTS
    c. DISCUSSION

6. POTENTIAL ETHICAL; ORGANISATIONAL; SOCIAL AND LEGAL ASPECTS (optional)
7. REFERENCES

APPENDICES

R9 Internal Review phase

Authors of the pilot send their first version (draft) of the rapid pilot assessment to several dedicated reviewers consisting of WP5 Strand B members on the 45th day after starting the production.
Reviewers are prepared to dedicate their time and efforts towards a thorough reviewing process according to the timelines indicated in the Project Plan. They control the phases of the pilot rapid assessment production (A5-A8), including check of references and send their comments to authors using the template for reviewers within 10 working days.
Authors are prepared to process the reviewers' comments and possible suggestions for changes within the next 10 days, starting from 55th day of the project. On the 65th day authors send their feedback to reviewers and the second draft of the pilot rapid assessment is ready.
Of note, the indicated timeframes are a proposal but are not mandatory - deviations may occur.

C10 External Review and consultation

The external review as well as the consultation phase should start on the 65th day of the rapid pilot assessment production process. Authors send the second and confidential draft of the pilot rapid assessment to at least 1 clinical expert, to Strand B members, the manufacturer(s) and possibly also to other stakeholders (e.g. European Federations of Physicians or/and Patients)
All consulted parties know the timelines beforehand, as communicated in the Project Plan, and are ready to provide their input within 10 working days using the consultation templates.
Clinical expert(s) for external review should be representatives of acknowledged clinical societies and will not have been directly involved as primary investigators of studies assessing the respective technology. If needed, other experts (e.g. statisticians) may be invited as external reviewers.
Starting from 75th day authors produce the final rapid assessment. The final version of the pilot rapid assessment should be ready on the 80th day of process and is sent to the CT for further technical and editorial amendments. At the same time dedicated reviewers and other WP5 members put their efforts into adaptation of pilot rapid assessment into national/local reports.
Of note, the indicated timeframes are a proposal but are not mandatory - deviations may occur.

Collecting process related data throughout the project

Data on the following outcomes of the project will be collected by the coordinators:

- pilot teams' perception about the about cross- border collaboration in producing a rapid pilot assessment by using a standardised survey
- WP5 members perception on the usability/readability of the pilot rapid assessment reports
- the duration of the assessment
- the workload (in terms of working hours)
- pilot teams' perception on the applicability of the HTA Core Model for rapid REAs and the guidelines to other technologies

This will be done through developing a standard evaluation form for the pilots.

Coordination Team

The pilot rapid assessment on other technologies is coordinated by the LBI-HTA. Contact details:

Claudia Wild	Tel: +43/1/236 81 19 - 12	claudia.wild@hta.lbg.ac.at
Anna Nachtnebel	Tel: +43/1/236 81 19 - 23	anna.nachtnebel@hta.lbg.ac.at
Julia Mayer	Tel: +43/1/236 81 19 - 19	Julia.mayer@hta.lbg.ac.at

Appendix 1: Definitions

Back up

HTA Core Model: A structured manner of creating and presenting HTA information as assessment elements. Some elements are prioritized over others to support European collaboration through defining them as "core elements".

Assessment element: The basic unit of the model. Defines a piece of information that describes the technology or the consequences of implications of its use, or any other implication that is relevant for the assessment, such as the patients and the disease for which it is applied. Each assessment element contains an "issue", which is a question that should be answered in an HTA. Not all issues, however, are relevant to all technologies/settings, and hence their relevance is considered separately for each assessment. Elements are defined through a combination of domain, topic and issue.

Domain: A wide framework within which technology is considered. It provides an angle of viewing the use, consequences and implications of technology. A standard set of domains is used in the HTA Core Model.

Topic: A more specific area of consideration within the domains. One domain is divided into several topics. Similar topics may be addressed within more than one domain.

Issue: An even more specific area of consideration within any of the topics. One topic typically consists of several issues, but it may also contain only one issue. An issue is always expressed as a question that can be answered through answering one or more research questions.

Application of the HTA Core Model: Different kinds of technologies (e.g. surgical interventions or pharmaceuticals) may require different questions to be asked in an assessment and the answers to the questions may require different research methods. An application of the HTA Core Model is built for assessing a specific kind of health technology. Different applications all draw from the same pool of assessment elements, but not all elements are used in all applications. Currently four applications exist, one for medical and surgical interventions, one for diagnostic technologies, one for screening and one for rapid REAs of pharmaceuticals. More applications will be developed in the future.

Element card: Each assessment element is connected to an element card, which provides tangible information on the element and its relations to other elements. A card may provide advice on how to answer the question defined by the element. Two characteristics within a card (importance and transferability) define whether an element is a "core element" or "non-core element". While assessment elements are generic (i.e. one element can belong to several applications of the HTA Core Model), element cards are application-specific (i.e. the cards describing an element within different applications may be different).

Structured HTA information: Information on any aspect of health technology that has been created through answering the issues defined in the assessment elements of the HTA Core Model.

Core HTA information: Any information on a technology that has been produced through answering the issue defined in a core element, or a collection of such information. This information is very likely to be useful in the European context (i.e. also in another country) due to its importance and/or transferability.

Core HTA: An actual assessment that a) has been conducted using the HTA Core Model and b) has considered all core elements of all 9 domains. (Note: through this consideration some elements may be defined as irrelevant, but that should be documented). A Core HTA contains a chapter that draws together key findings of various domains, but does not make recommendations regarding the use of technology. Through the wide scope, focus on core elements and the summary chapter, a Core HTA gives an overview of a technology that is likely to be useful in the European context. A Core HTA can be used as a basis for producing local HTA reports that take into account local circumstances (e.g. epidemiology, organisation, resources, values).

HTA Core Model for rapid REA of pharmaceuticals: A model that was developed to conduct rapid relative effectiveness assessments of pharmaceuticals. A rapid assessment is an assessment of a specific technology within a limited timeframe in comparison with one or more relevant alternative interventions. It can be the assessment of a new pharmaceutical launched into the

market, or the (re)assessment of a pharmaceutical for a new indication or when new relevant data are available. The model for rapid REA contains four of the nine domains of the HTA Core Model (first four domains). For these domains a subset of the assessment elements of the HTA Core Model are included.

Appendix 2: Templates

Back to Introduction

Call for collaboration Form

[Agencies name] is seeking agencies interested in collaborating on [proposed short title].

Authors:

Agency's name:	[State your agency's name]
Author's Name and contact details:	[Give the name(s) contact details of the author(s)]

Project:

Proposed project title:	[Indicate the full title of the planned project]
Duration:	[Proposed start date (DD/MM/YYYY) – proposed end date (DD/MM/YYYY)]
Calling for:	[Co-author and Reviewers (choose the according roles you are looking for)]
Date of call:	[DD/MM/YYYY]

Expressions of interest:

Until:	[Indicate the exact date (DD/MM/YYYY) until when you need expressions of interest]
To whom:	If your agency is interested, answer to [add here the e-mail address of the main contact of your agency] and to **anna.nachtnebel@hta.lbg.ac.at** and indicate which role (co-author, reviewer) your agency is interested in.

Proposed PICO Question:

Description	**Project scope**
Population	*Describe at least the population and the intervention, details on comparators and outcomes **can** be added already at this stage.*
Intervention	
Comparison	
Outcomes	

Proposed timetable for the pilot assessment:

Milestones/Deliverables	Start date	End date
Project duration	**[DD/MM/YYYY]**	**[DD/MM/YYYY]**
Scoping phase	[DD/MM/YYYY]	[DD/MM/YYYY]
Consultation of draft Project Plan with dedicated reviewers	[DD/MM/YYYY]	[DD/MM/YYYY]
Contact with manufacturer(s) (request for further information)	[DD/MM/YYYY]	[DD/MM/YYYY]
Consultation of draft Project Plan (public consultation,WP5 SAG, manufacturer(s))	[DD/MM/YYYY]	[DD/MM/YYYY + 10 days]
Final Project Plan	[DD/MM/YYYY]	[DD/MM/YYYY]
Assessment phase	[DD/MM/YYYY]	[DD/MM/YYYY]
First draft available	[DD/MM/YYYY]	[DD/MM/YYYY]
Review by dedicated reviewers	[DD/MM/YYYY]	[DD/MM/YYYY]
Second draft available	[DD/MM/YYYY]	[DD/MM/YYYY]
Review by ≥ 1 external clinical expert, WP5 Strand B members, manufacturer(s) and by other potential stakeholders	[DD/MM/YYYY]	[DD/MM/YYYY]
Final pilot rapid assessment	[DD/MM/YYYY]	[DD/MM/YYYY]

Project Plan

A. VERSION LOG

Each (significant) modification should be marked with a new *version* number (Vx). Minor modifications may be marked within versions (Vx.y) *Each new version to be communicated with the project team.*

Version number	Date	Name (Initials)	Modification	Reason for the modification
V1	DD/MM/YY		[Number of chapter modified; e.g. B 1.0]	[e.g. change of participants]
V2	DD/MM/YY			
V3	DD/MM/YY			
V4	DD/MM/YY			
V5	DD/MM/YY			

B. PROJECT PLAN

1.0 PARTICIPANTS

All individuals actively participating in the project – including participants from collaborating partner (EUnetHTA Associate) organisations.

Table 1. Project participants

#	Name	Role in the project	Agency	Individual's expertise	Country
1.		Author(s)		Health economics	
2.		Co-Author(s)			
3.		Reviewer			
4.		Reviewer			
5.		Reviewer			
6.		Reviewer			
7.		Reviewer			
8.		External Reviewer(s)			

1.1 PROJECT STAKEHOLDERS

Please describe/list project stakeholders*.

Table 2. Project stakeholders

Organisation	Contact (name, e-mail, tel)	Comments

2.0 PROJECT INTRODUCTION/ RATIONALE

Project introduction/ rationale
The rational for this pilot assessment report is to test the capacity of national HTA bodies to collaboratively produce structured rapid core HTA information on pharmaceuticals (strand A) and other medical technologies, such as medical devices, surgical interventions or diagnostics (strand B). In addition, the application (transportation) of those collaboratively produced HTAs in the national contexts will be tested.

* Here the term "stakeholder" has a generic meaning that goes beyond (yet may include) the identified EUnetHTA Stakeholder groups (as described in the EUnetHTA Stakeholder Policy).

3.0 PROJECT SCOPE AND OBJECTIVES

	List of project objectives	Indicator (and target)
1.	To test the capacity of national HTA bodies to collaboratively produce structured rapid core HTA	Production of 1 pilot rapid assessment
2.	To test the application of these collaboratively produced rapid assessments into a national/local context	Production of ≥1 national/local report per pilot rapid assessment

This pilot rapid assessment addresses the research question whether [Name of technology] in [intended target population] is more effective and/or safer than [add comparator(s)].

Table 3. Project Scope: PICO

Description	Project scope
Population	*Describe the disease or health condition of interest. Provide ICD-10 code and MeSH-terms for it.* *Describe the target population; possible limitations for instance in age, sex, severity, stage or risk (e.g. men over 65, in low to moderate risk of having the disease, or adult patients with grades 3-4 disease). Provide Mesh-terms.* • *Describe the intended use of the technology: treatment or prevention, first line/second line treatment,*
Intervention	*Describe the intervention detailed enough to distinguish it from relevant other technologies: administration modes. Provide MeSH term if applicable.*
Comparison	*Describe the comparators for this assessment. The technology can be compared to e.g. another specific technology, management pathway without the technology, usual care, not doing anything, or placebo.* ***Include the rational for choosing the comparator.*** *Provide MeSH-terms – if applicable.* *See the guideline 'Comparators and comparisons – Criteria for the choice of the most appropriate comparator(s)*
Outcomes	*Describe the most important effectiveness and safety outcomes for this assessment.* ***Include the rational for choosing the*** *outcomes.* *See the guideline 'Endpoints used for REA of pharmaceuticals'.*
Study design	*Describe which study designs will be considered within this assessment.* *If applicable, differentiate between efficacy and safety.*

4.0 PROJECT APPROACH AND METHOD

Please concisely describe the overall approach to be taken ie, what will be done and how. Also provide a justification why certain methods have been chosen: e.g.

- State which HTA Core Model Application will be the primary source for selecting assessment elements
- Plan for information retrieval: sources and search terms for locating domain specific information, inclusion/exclusion criteria for studies or other information, in terms of content, methods and quality.
- Plan for handling the published data: do a systematic review, cite recent reviews, "screen until saturated" etc.
- Plan for finding information when there is no published data: From web sites of organisations, discussion forums, registers: Performing survey (questionnaire, interview): Other type of own research (analysis of primary data, modelling etc).
- Quality assessment tools or criteria planned to be used
- Plan for synthesis: evidence table, plan for meta-analysis or qualitative synthesis, use of GRADE, etc.

Table 4a. Project approach and method

Project approach and method

Table 4b. Preliminary Evidence

Preliminary evidence table Please provide information on what kind of data your planning to extract from the studies included
[Author, year, reference number]
[Study identifier, e.g. NCT number]
[Country]
[Sponsor]
[Comparator]
[Study design]
[Number of patients]
[Patient characteristics]
[Author Disclosure (Conflict of interest)]
[Add any other relevant information you are planning to extract]
[Add any other relevant information you are planning to extract]
[Add any other relevant information you are planning to extract]
[Add any other relevant information you are planning to extract]
Outcomes
Effectiveness
[Add here relevant efficacy outcomes]
[Add here relevant efficacy outcomes]
[Add here relevant efficacy outcomes]
[Add here relevant efficacy outcomes]
[Add here relevant efficacy outcomes]
[Add here relevant efficacy outcomes]
[Add here relevant efficacy outcomes]
Safety
[Add here relevant safety outcomes]
[Add here relevant safety outcomes]
[Add here relevant safety outcomes]
[Add here relevant safety outcomes]

Selected assessment elements

The table shows the assessment elements and the translated research questions that will be addressed in the assessment. They are based on the assessments elements contained in the document "Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals". Additionally, assessment elements from other EUnetHTA Core Model Applications (for medical and surgical

interventions, for diagnostic technologies or for screening) have been screened and included/merged with the existing questions if deemed relevant.

Table 5. Assessment elements and translating research questions

ID	**Domain**	**Topic**	**Issue** *[copy all the generic questions from the Model for Rapid REA or other HTA Core Model applications in this column]*	**Relevance in this assessment Yes/No**	**Reason for non-relevance/ Preliminary research question(s)** *[If you selected yes, translate the generic issue into actual research question(s). If you selected no, provide an explanation why you deemed this element as not relevant.]*	**Source of assessment element**
[add the issue ID, eg A0001]	[Add the domain name]	[Add the according topic]	[Add the issue (i.e. research question) as pre-defined in the respective according Core Model Applications]	[Indicate if the according issue was considered relevant]	[Add the formulated research question]	[Indicate from which HTA Core Model Application the assessment element was selected from: REA Model, Model for Medical Surgical Intervention, Diagnostics, Screening]

Checklist for potential ethical, organisational, social and legal aspects

The following checklist should be considered in order to determine whether there are specific ethical, organisational, social and legal aspects which also need to be addressed. Since the assessment is comparative in nature, only new issues should be dealt with, which arise from a difference between the technology to be assessed and its major comparator(s). Already known problems/issues with regard to ethical, organisational, social and legal aspects which are common to the technology to be assessed and its comparator(s) will, as a rule, not be addressed, as it is not to be expected that the addition of a new technology will lead to changes.
If a question is answered with 'yes', further analysis of these issues may be warranted. If they are answered with no, the domains need not be dealt with further.

Table 6. Checklist for potential ethical, organisational, social and legal aspects.

1. Ethical	
1.1. Does the introduction of the new technology and its potential use/nonuse instead of the defined, existing comparator(s) give rise to any new ethical issues?	Yes/No
1.2. Does comparing the new technology to the defined, existing comparators point to any differences which may be ethically relevant?	Yes/No
2. Organisational	
2.1. Does the introduction of the new technology and its potential use/nonuse instead of the defined, existing comparators require	Yes/No

organisational changes?	
2.2. Does comparing the new technology to the defined, existing comparators point to any differences which may be organisationally relevant?	Yes/No
3. **Social**:	
3.1. Does the introduction of the new technology and its potential use/nonuse instead of the defined, existing comparator(s) give rise to any new social issues?	Yes/No
3.2. Does comparing the new technology to the defined, existing comparators point to any differences which may be socially relevant?	Yes/No
4. **Legal**:	
4.1. Does the introduction of the new technology and its potential use/nonuse instead of the defined, existing comparator(s) give rise to any legal issues?	Yes/No
4.2. Does comparing the new technology to the defined, existing comparators point to any differences which may be legally relevant?	Yes/No

5.0 ORGANISATION OF THE WORK

5.1 MILESTONES AND DELIVERABLE(S)

Table 7. Milestones and Deliverables

Milestones/Deliverables	**Start date**	**End date**
Project duration	[DD/MM/YYYY]	[DD/MM/YYYY]
Pilot's team building	[DD/MM/YYYY]	[DD/MM/YYYY]
Scoping phase	[DD/MM/YYYY]	[DD/MM/YYYY]
Consultation of draft project plan with dedicated reviewers	[DD/MM/YYYY]	[DD/MM/YYYY]
Contact with manufacturer (request for further information)	[DD/MM/YYYY]	[DD/MM/YYYY]
Consultation of draft Project Plan (public consultation, WP5 SAG, manufacturer)	[DD/MM/YYYY]	[DD/MM/YYYY] (+10 working days)
Final Project Plan	[DD/MM/YYYY]	[DD/MM/YYYY]
Assessment phase	[DD/MM/YYYY]	[DD/MM/YYYY]
First draft available	[DD/MM/YYYY]	[DD/MM/YYYY]
Review by dedicated reviewers	[DD/MM/YYYY]	[DD/MM/YYYY]
Second draft available	[DD/MM/YYYY]	[DD/MM/YYYY]
Review by ≥ 1 external clinical expert, manufacturer(s) and by Strand B members	[DD/MM/YYYY]	[DD/MM/YYYY]
Final pilot rapid assessment	[DD/MM/YYYY]	[DD/MM/YYYY]
Local Reports (if applicable)		
Local (national or regional) REA N°1 [*Institution, country*]		
Local (national or regional) REA N°2 [*Institution, country*]		

5.2 MEETINGS

Besides face-to-face meetings mentioned in the Work Plan of WP5, no further face-to-face meetings are planned for this specific project.

Up to 4 e-meetings may be scheduled for this pilot rapid assessment (see section 6.0), if considered necessary.

6.0 COMMUNICATION

Please define the communication requirements for the project and how information will be distributed to ensure project success.
Here's an example of organisation of communication - please choose and edit those relevant and add other types as needed.

Table 8. Communication

Communication Type	Description	Date	Format	Participants/ Distribution
Project Plan draft with timelines	Review of methods and assessment elements chosen, discussion of time-lines	[DD/MM/YYYY]	E-mail (e-meetings to be planned here - optional)	Author(s), Co-author(s), dedicated reviewers, Coordinating Team
Final Project Plan	Review of methods and assessment elements chosen, discussion of time-lines considering comments from WP5 SAG, public, manufacturer(s)	[DD/MM/YYYY]	E-mail (e-meetings to be planned here - optional)	Author(s), Co-author(s), dedicated reviewers, Coordinating Team
First draft of the pilot assessment	To be reviewed by dedicated reviewers	[DD/MM/YYYY]	E-mail (e-meetings to be planned here - optional)	Dedicated reviewers
	To discuss comments of dedicated reviewers (optional)	[DD/MM/YYYY]	E-Mail (e-meetings to be planned here - optional)	Author(s), co-author(s), dedicated reviewers
Second draft of the pilot assessment	To be consulted with ≥1 clinical expert, WP5 members, manufacturer(s), other potential stakeholders	[DD/MM/YYYY]	E-mail	≥1 clinical expert, WP5 members, manufacturer(s), other potential stakeholders

6.1 DISSEMINATION PLAN

The final pilot rapid assessment will be distributed as laid-out in the Work Plan of WP5.

7.0 COLLABORATION WITH STAKEHOLDERS

The WP5 SAG as well as the public will be invited to comment on the Project Plan for this pilot rapid assessment. The project plan will be made publicly available on the EUnetHTA website for a period of 10 days.
Further the manufacturer(s) will also receive the draft Project Plan and will be asked for further information (e.g. C/E mark, on-going studies, available evidence).
Collaboration with other stakeholders
Whenever feasible, please describe any foreseen collaboration with other stakeholders (e.g. European Federations of Physicians or/and Patients)

8.0 COLLABORATION WITH EUnetHTA WPs

For the individual pilot rapid assessment, no collaboration with other WPs is planned.

9.0 RESOURCE PLANNING

Please estimate the expected input in terms of human and financial resources necessary to achieve the project objectives.

9.1 HUMAN RESOURCES

Table 9. Human resources

Role	Total number of person days	Source	
		Staff of participating organisations	Subcontracting
Author	60 person days	60 person days	-
Co-Author	30 person days	30 person days	-
Reviewer	3 person days each	3 person days each	-
External reviewer	5 person days	-	5 person days

11.0 CONFLICT OF INTEREST MANAGEMENT

Conflicts of interest will be handled according to EUnetHTA JA2 Conflict of Interest Policy. As conflict of interest may be topic dependent, conflict of interest declarations will be collected from authors and reviewers involved in a specific pilot assessments. Authors and reviewers who declare conflict of interest will be excluded from parts of, or the whole work under this specific topic. However, they may still be included in other pilots.
If external experts are involved in WP5 a conflict of interest declarations will be collected from them regarding the topic. External experts who declare conflict of interest will be excluded from parts of, or the whole work under this specific topic. However, they may still be included in other pilots.

12.0 EXPECTED OUTCOME(S)

Please briefly describe the expected project outcomes, i.e., changes that occur as a result of the project when the objectives are reached.

Project outcome(s)
The capacity of national HTA bodies to collaboratively produce structured rapid core HTA and the translation into local reports will have been proven. Redundancies will have been reduced and therefore efficiency gains achieved. Applicability of the HTA Core Model for rapid REAs to other technologies will have been elicited and the Model accordingly adapted.

C. REFERENCES

Please include any documents supporting the project rationale/implementation.