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HTA Core Model® Online User guide
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WP 8 Lead Partner: National Institute for Health and Welfare

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1. Online tool at a glance

Open the HTA Core Model® online at [www.corehta.info](http://www.corehta.info). (If you do not have a EUnetHTA id, please register as a new user [click Log in]). After logging in you will see all the projects you have been added to as a member. Each project is processed in five phases.

**Phase I Starting a project and defining its basic features** (Project leader PL = owner)
1. Start a new project by clicking the link at My projects page.
   1. Name the project, select model version and collection type and add technology short name (see Starting a new project).
   2. Define the project scope: add at least the information marked with Required for protocol design (see Project scope).
2. Save the project.
3. Add members to the project (My projects page) and define their roles (can be done at any time during the project). Define your own roles as well (see Adding a new participant).

**Phase II Protocol design** (Primary investigator PI & investigator I)
Build a protocol for your domain (see Protocol design):
4. Consider the relevance of each assessment element (question). You may provide a rationale for the irrelevance or add other notes for the project group. Bear in mind that the notes for irrelevant issues will become public. (For more information click links to assessment elements (id), clarification and instructions on the domain specific page).
5. Modify the research questions suggested by the tool and add new questions if needed. Save.
6. You may change the order of the issues and topics at any time during the process by dragging and dropping. Save the order.
5. Edit the frame (technology, intended use of technology, comparison) of the domain if the general scope needs editing for a particular domain.
6. View the domain and lock it, when all the elements have been considered. (Core HTA percentage in questions column => 100 %, other project types > 0).
   Note! Only PI can unlock the domain for changes (possible as long as the whole protocol is not locked).
Finish the protocol design and lock it (PL):
7. Enter any missing information to complete the protocol definition (if possible, add also those the program does not require for locking the protocol, especially keywords.)
8. Lock the protocol.
View the last saved protocol with or without methodological guidance, or the list of research questions at any time.

**Changing the protocol**
Changes are possible if there are no results entered in the tool. PL must unlock the protocol first and then PI can unlock the domain to be changed. After modifications are ready the PI or I locks the domain and PL locks the protocol. Note that the changes in the protocol may change the correspondent word templates (for results).

**Phase III Research (PI, I)**
9. Download the appropriate Word templates for writing the contents of each domain (core HTAs and free selection of assessment elements) or the whole project (Rapid HTAs).
   For references see reference management guidance for RefWork or EndNote.
Phase IV Results (PI, I)

10. You can enter the results for different sections in any order. Mark each level (result card, domain, collection) complete for publishing.

A. Core HTAs (see Features specific for core HTAs)
   - Enter the results and general contents of a domain a) online or b) by uploading the template (PI)
     - Note! Uploading overwrites all the existing information.
     - Edit answers, mark complete. (PI, I)
     - Modify general contents of the domain online. Mark each section complete. (PI)
   - Enter general texts for collection online (PL)
     - Mark each section of the information complete.
   - Mark collection complete. (PL)

B. Rapid HTAs (see Features specific for Rapid assessments)
   - Enter the results and general contents either a) online or by uploading the template for domain-specific contents (PI).
     - Note! Uploading overwrites all the existing information.
   - Modify the answers. Mark complete if checkbox available.
   - Modify general texts of the collection.

11. Publishing a draft is possible at this phase (PL). Select the publicity: a) you project members only, b) EUnetHTA members or c) public.

Phase V: View and Submit

12. View the contents and ensure that the contents are as you intended.
13. Add or modify metadata, e.g. keywords (unlock the protocol, edit definition and lock the protocol again) (PL)
14. When everything is ready, contact eunethta@thl.fi and request publishing your work.
2. General

The HTA Core Model® Online (www.corehta.info) contains 1) an online tool for producing and publishing HTA information according to the HTA Core Model and 2) a database of produced information. This guide is intended to help you use the basic features of the online tool. For information on the actual assessment process, please refer to the HTA Core Model® User Guide.

2.1 Creating an account

In order to use or test the tool you need an account. If you are employed by a EUnetHTA member agency you should use your EUnetHTA id (for more information, see www.eunethta.eu).

If you are not entitled to a EUnetHTA id, you can create a specific account within the tool, but you can not use this account for any other EUnetHTA tools. Click Log in in the menu and follow the instructions.

2.2 Registering the use

The HTA Core Model® is registered trade mark and subject to Terms of Use.

When using the non-commercial license, registering the use is recommended but not obligatory if you use the HTA Core Model® for producing HTA information. If you plan to use the Model within information systems (including computer software and online services, databases and web sites), registration is required (click Model use in the menu).

When using the commercial license, registration is obligatory for all purposes of use.

Note! A separate registration is required for each product (e.g. assessment project, report, journal article, information system) you use the HTA Core Model for.

2.3 Testing the tool

For testing the tool please use the test version available at meka.thl.fi/htacoretest/. For a quick test you can use the tool as explained in chapter Project definition. The test environment is mostly similar to the actual production site, but some differences may exist.
## 2.4 Terminology used in the online tool

Abbreviations used in this guide: Project leader PL; Primary investigator PI; Investigator I

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix</td>
<td>An appendix can be specific for a collection, a domain or an assessment element (result). Supported attachment/image file types are pdf, zip, png, jpg/jpeg and gif.</td>
</tr>
<tr>
<td>Application</td>
<td>Application (or “model”) is a set of assessment elements which has been designed for assessing specific type of health technology (diagnostics/ medical and surgical/ pharmaceutical/screening). Separate applications exist for extensive core HTAs and for rapid HTAs. For a list of applications see the HTA Core Model User Guide Appendix 2.</td>
</tr>
<tr>
<td>Assessment element, AE</td>
<td>Basic unit of the model, which is defined through a combination of domain, topic and issue (question). One element can belong to several applications.</td>
</tr>
<tr>
<td>Collection</td>
<td>Standardised set of HTA information. A collection consists of result cards: general content (introduction, summary, discussion) and (optional) appendices. The way it is displayed to users depends on the collection type.</td>
</tr>
<tr>
<td>Collection type</td>
<td>Defines the contents and the amplitude of the analysis: a) core HTA (all domains, every assessment element), b) free selection of domains, c) rapid HTA.</td>
</tr>
<tr>
<td>Core/noncore element</td>
<td>In Core HTA projects the most significant, elements of a model are identified as core elements and in rapid HTAs mandatory (respectively noncore and non-mandatory).</td>
</tr>
<tr>
<td>Core HTA collection</td>
<td>Type of HTA information in which each core assessment element in every domain must be considered.</td>
</tr>
<tr>
<td>Domain</td>
<td>A wide perspective within which technology is considered. There are nine domains. One domain consists of several topics (e.g. mortality). See List of domains.</td>
</tr>
<tr>
<td>Element card</td>
<td>Provides information on an assessment element and its relations to other elements as well as guidance on answering the questions (e.g. information sources). Element cards are application-specific.</td>
</tr>
<tr>
<td>EUnetHTA Collection</td>
<td>A collection published through a process controlled by EUnetHTA. The contents of non-EUnetHTA collections are the sole responsibility of their producers.</td>
</tr>
<tr>
<td>Framing</td>
<td>Domain-specific description on technology, its intended use and comparison. Not in use in rapid assessments.</td>
</tr>
<tr>
<td>Issue</td>
<td>A specific area of consideration within a topic. An issue is expressed as a generic question, potentially applicable to any health technology. The user can include or exclude an issue in/from each project. Included issues are translated to one or a few research questions.</td>
</tr>
<tr>
<td>Locking (domain/protocol)</td>
<td>Protects the protocol or domain from being unintentionally edited or deleted.</td>
</tr>
<tr>
<td>Model application</td>
<td>A subset of the HTA Core Model planned for assessing a specific kind of health technology. See application. Sometimes the term 'Model' (with capital M) is used as an abbreviation of the 'HTA Core Model'.</td>
</tr>
<tr>
<td>Phase</td>
<td>The project is divided into five phases or steps: 1) project definition 2) protocol design 3) research 4) results 5) view and submit</td>
</tr>
<tr>
<td>Project definition (phase/step 1)</td>
<td>Information required for setting up a project in the tool: 1) Model and Collection type (=&gt; set of assessment elements available) 2) Scope 3) Members and their roles</td>
</tr>
<tr>
<td>ProjectID</td>
<td>Research questions of a project each get a domain specific id e.g. CUR1, CUR2 etc. N/A when the issue is irrelevant or undefined.</td>
</tr>
<tr>
<td>Project leader, PL</td>
<td>Owner of the project. Project leader has all user rights for his/her project in the tool.</td>
</tr>
<tr>
<td>Term</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>-------------</td>
</tr>
<tr>
<td>Project protocol (phase/step 2)</td>
<td>A project protocol defines the scope and research questions of each project in the online tool. Status of an protocol can be <em>unlocked</em> or <em>unlocked</em> . .</td>
</tr>
<tr>
<td>Research question</td>
<td>See ‘issue’.</td>
</tr>
<tr>
<td>Relevance</td>
<td>Relevance of an issue: Basically relevant = included; irrelevant = excluded / undefined (skipped).</td>
</tr>
<tr>
<td>Research question</td>
<td>A project-specific question made of a generic issue of the HTA Core Model.</td>
</tr>
<tr>
<td>Result card</td>
<td>Compilation of the answers to the research questions derived from one assessment element. If more than one research question was made of a single assessment element, all answers are displayed in the same result card.</td>
</tr>
<tr>
<td>Role (participant)</td>
<td>Each member of a project is given a role on the domain level: Primary investigator/Investigator/Informatician/Reviewer. See Appendix 1 User’s rights.</td>
</tr>
<tr>
<td>Topic</td>
<td>A specific area of consideration within the domains. One topic consists of 1 - n issues (generic questions).</td>
</tr>
<tr>
<td>Scope</td>
<td>Description of the key characteristics of the project: technology and its intended use; target condition; target population; comparison; main outcomes. See also domain framing.</td>
</tr>
<tr>
<td>Version</td>
<td>Version of the model application (e.g. 2.0). The online tool uses always the latest version.</td>
</tr>
</tbody>
</table>

### 2.5 Domains

<table>
<thead>
<tr>
<th>Domains</th>
<th>Core HTA</th>
<th>Rapid HTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Health Problem and Current Use of the Technology</td>
<td>CUR</td>
<td>x</td>
</tr>
<tr>
<td>B. Description and technical characteristics of technology</td>
<td>TEC</td>
<td>x</td>
</tr>
<tr>
<td>C. Safety</td>
<td>SAF</td>
<td>x</td>
</tr>
<tr>
<td>D. Clinical Effectiveness</td>
<td>EFF</td>
<td>x</td>
</tr>
<tr>
<td>E. Costs and economic evaluation</td>
<td>ECO</td>
<td>x</td>
</tr>
<tr>
<td>F. Ethical analysis</td>
<td>ETH</td>
<td>x</td>
</tr>
<tr>
<td>G. Organizational aspects</td>
<td>ORG</td>
<td>x</td>
</tr>
<tr>
<td>H. Social aspects</td>
<td>SOC</td>
<td>x</td>
</tr>
<tr>
<td>I. Legal aspects</td>
<td>LEG</td>
<td>x</td>
</tr>
<tr>
<td>Other aspects</td>
<td></td>
<td>x</td>
</tr>
</tbody>
</table>
2.7 My projects - page

After logging in you will see a list of all the projects you attend either as a leader or as a member.

Click Start new project to create a project.

Click Home (or Project home from the left-side-menu) to open the project’s home page.

If you have created an account (i.e. you are not a EUnetHTA-member) you can change your password and other information (name, e-mail etc.) in your settings (click Settings of... at the bottom of the My projects page).

3. Assessment project in the tool

3.1 Creating a new project (Project leader, PL)

The user starting the project in the tool will become the project leader. As a project leader you have all the rights, but you do not have any specific role in the assessment unless you define it as described in chapter Project group.

1. Click Start new project on My projects page.
2. Name the project. You can edit the name any time the protocol is unlocked. Give a short descriptive name which is used everywhere in the tool. It is not the final name of the collection.
3. Select a model version and collection type depending on what kind of assessment you plan to conduct:
   A. Model = HTA Core Model application => Collection type is either
       - Core HTA: All domains and each assessment element within each domain must be considered i.e. included, excluded or skipped.
       - Some information on the technology: one or more assessment elements of selected domains must be considered.
   B. Model = Rapid REA application => collection type = Rapid relative effectiveness (always)
   Note! These selections can not be changed later on.
   In addition, for quick testing only, you can select
   C. Model: Short demo application
      => only two domains to consider: Clinical Effectiveness (with four issues) and Legal (with two issues)
      - Core HTA: both domains and all issues must be considered.
      - Some information on the technology: in both domains at least one issue must be considered.
4. Fill in technology short name.
5. Save the project. The project has now its own home page, which you can open any time by clicking Project Home under heading This Project in the left side menu.

In the project menu you can see the five phases of the production process of an HTA:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project home</td>
<td>Viewing the scope, managing members and their roles (project leader)</td>
</tr>
<tr>
<td>Project definition</td>
<td>Naming the project, selecting the application and collection type, defining the scope</td>
</tr>
<tr>
<td>Protocol design</td>
<td>Considering the relevance for assessment elements, translating generic issues into research questions</td>
</tr>
<tr>
<td>Research</td>
<td>Downloading the word templates for answering the questions, answering research questions; adding and modifying general texts.</td>
</tr>
<tr>
<td>Results</td>
<td>Entering the contents in the tool or by uploading the word templates; Publishing a draft.</td>
</tr>
<tr>
<td>View and submit</td>
<td>Viewing the collection as it will be published.</td>
</tr>
</tbody>
</table>

3.1.1 Project group

A project can have an unlimited number of users participating in various roles listed below. The roles of each participant are defined separately for each domain.

On Project home page the project leader can add, edit (roles) and remove the participants of the project at any time during the project. Note that each member must create a personal account before he or she can be added to the group.

Each member of the group gets a role (Primary investigator / Investigator / Reviewer / Informatician) in at least one domain (see Appendix 1. User’s rights).
Adding a new participant

1. Click **Add participant** (Project home page)
2. Search for participants by person’s name or by organization.
3. Click **Add** to add a new member.
4. Define role(s) of the participant for each domain
5. **Save and return** will take you back to the **Participants** page.

**Note!** As a project leader you have all the rights, but you do not have any specific role unless you define it (i.e. add yourself as a new participant) as described.

Click **Edit** to
- a) edit roles or
- b) remove the participant
3.2 Phase 1: Project definition (scope) for all assessments (PL)

In this phase the project leader defines the project *scope* i.e. the key characteristics of the project. What is entered here should be agreed-on with all key participants of the project.

The tool uses several of these fields to formulate text automatically (for research questions etc.). Consequently, certain fields must be filled in before proceeding to define the research questions.

You can make changes to the data on this page at any time when the protocol is unlocked.

**Technology short name(s)**

Describe the technology to distinguish it from other relevant technologies. Enter the name (+ possible abbreviation/acronym) of the technology with a short description. Domain-specific framing possible (protocol design, phase 2)

**Intended use of the technology**

Intended use of the technology in this particular assessment. Select one or more choices. Required to start the protocol design (step 2). Domain-specific framing possible.

**Target condition**

1) Identify and 2) describe the disease or health condition that is targeted by the use of the technology.

**Target population:**

Select group(s), sex and age (for selection see picture 2). Required to start the protocol design (step 2)

* a) further details + b) free definition

a) Include a short additional description of the population e.g. "at office work" b) Give an overall description of the population.

(e.g. age: select Adult + Elderly and specify in text 50 - 70 years)

**Comparison**

Select one or more choices: Placebo / Not doing anything / Specified other technology/usual care (specify). Domain specific-framing possible.

**Outcomes**

Describe the main outcomes of the project considering each domain. This is a voluntary step likely to help steering the research group's efforts in the assessment.

**Project metadata:**

Add MeSH terms; and if relevant, ATC codes, ICD codes; free keywords.
3.3 Phase 2: Protocol design (PI, I)

3.3.1 Core HTAs

In the Protocol design phase the investigators select and edit the actual research questions for the domains to be included in their project. In this phase you can

1. consider the relevance of assessment elements (i.e. include or exclude) and make the practical research questions. If you are making a core HTA, you have to consider all the core assessment elements in every domain.
2. define a domain-specific framing (optional).
3. lock the domain once the research questions and framing are complete (PI, I).
4. view the protocol and lock it (PL).

In order to start protocol design the scoping (Project definition) must be mostly done, and in order to lock the protocol the scope must be finalized.

3.3.1.1 Relevance and research questions (Topics and issues)

Click domain-specific Edit in the Research question column to open the window for relevance and questions.

- The window has two sections with their own saving buttons (functions). The program gives you a notice if you try to move from one section to another without saving the changes first.
- As the primary investigator or investigator you can edit the issues (relevance, questions) and change the order of the topics and issues as long as the domain or protocol is unlocked. You may re-edit the relevance of assessment elements and research questions within a domain as many times as you wish.

### Columns and functions

**Research questions**

Percentage of assessment elements (questions) considered (i.e. included or excluded).

*Edit => View* after the domain has been locked. You can see all the issues (relevant/irrelevant/consider later) and notes added in them.

**Framing** (=> scope modifications)

Domain-specific framing. Edit if the general framing is not suitable for the domain.

*Edit => View* after the domain has been locked. Modified framing can be seen in the protocol.

**Domain status**  Unlocked

*Lock  => Locked (=> Unlock activated)*

**Protocol status:** Lock-button becomes visible, when all the domains have been locked.

*View protocol/questions* for seeing the protocol such as it was last saved. Includes all the relevant questions.
1. Consider relevance of the issue. You can add a note regarding your choice (see Instructions). The note can be seen by your group (View domain and choose the element on the list)
   Choose
   a. include, if you regard the issue relevant for your assessment. The research question field suggested by tool will be activated.
   b. exclude, if the issue is not relevant\(^2\). The issue will be left out of the study. In core HTAs you must give an explanation for excluding.

   **Note!** Excluding the issue empties the question box. If you wish to include the issue later on, copy the question from the list or write a new question.

   The reason for excluding the issue is required for Core HTAs. It will be published in the final report.
   c. consider later, if you can’t make the decision yet.
   d. skip: This option is available only if the issue is marked non-core (collection type = core HTA). The values of transparency and importance of the issue are low. Thus it is possible to skip the issue without explanation.

2. Add the question(s). You can modify the question suggested by the tool or leave it as it is. Include only one question per box!

   **Note!** If there are two technologies mentioned in the project scope (Technology short name), the tool may suggest either a) one question which is common for both technologies or 2) same question for each technology separately (e.g. Target condition issue A009)

3. Save the issue:
   a. Save & next => next issue (in the list) with or without relevance
   b. Save & next undefined => next issue without relevance (empty or consider later; in the list ‘undefined’).
   c. Save & close closes the window.

   **Note!** The program complains about missing relevance if you try to save an issue without relevance. You can choose another issue from the list or leave the page by clicking the project menu.

4. For removing an existing question unselect the checkbox next to the question (Keep).

On the Protocol design –page you see the percentage value of completed issues (relevant + irrelevant). When re-entering, you will see the first issue that has not been considered yet.

---

\(^2\) There are a few core elements which can be excluded even though the issue is relevant.
Note! If you change the relevance, the 'keep' mark may disappear and you cannot save the issue. In that case just tick the 'keep' box again.

Changing the order: Lists of the topics and issues
At the bottom of the page you can view and reorder the topics and issues. Please note the following:

- In the list there are the generic questions (issues) suggested by tool. The easiest way to view all the questions including those you have modified or added is to view List of protocol questions (link on the Project design page).
- You can move the issues within a topic but not from one topic to another.
- If you mark an issue irrelevant the issue will be moved to the last place within the topic. You cannot move irrelevant issues.
- If you mark all the issues within a topic irrelevant the topic is moved to the bottom of the page.
- You cannot move the topic if you have marked all its issues irrelevant.

1. Click an issue for editing the relevance or questions.
2. Change the default order of the topics and issues at any time of the process. Drag and drop a topic or an issue to change their order.
3. Save the order (Save order button above and below the list)

Project ID

- Project ID = N/A as long as the issue is irrelevant or undefined.
- The project ID of a relevant issue (research question) = DOM1, DOM2, DOM3... where DOM refers to the domain and number to the order of the issues (questions) within the domain. The number changes if you rearrange the issues after you have marked them relevant or if you mark the issue irrelevant.
- Issues which belong to two different domains have a combination ID (e.g. SAF4/ EFF1).
- When entering the results the same ID is used to identify the questions. Project ID = Research question ID. If you have defined more than one research questions per issue, they are marked a, b, c... => DOM2a, DOM2b etc.

Example: Assessment element C0008: How safe is the technology in relation to the comparator(s)

Questions suggested by the tool:
SAF2a How safe is technology X in relation to the comparator(s)
SAF2b How safe is technology Y in relation to the comparator(s)
3.3.1.2 Framing of the domain

If the project scope is not suitable for the analysis within your domain, you may change it through domain framing. This is an optional process that should be used only if it makes your work more feasible. The project scope should always be included within the new frame of analysis. Click Edit (in framing column) and fill in the appropriate fields: technology description, intended use of technology, comparison, more information on framing. Save.

3.3.1.3 Locking a domain (PI, I)

Once you have completed defining the questions for a domain, lock it. Locking the domain informs the project leader that your group has finished considering the issues and that you are ready to start looking for answers. Lock-button of the domain will be visible (activated) for primary investigators and investigators as follows:

a. If the collection type = a core HTA and you have considered (included, excluded or skipped) all the issues within a domain, the percentage in the questions-column = 100.

b. In other types of projects (free selection) you have included, excluded or skipped at least one issue of the domain => percentage in the questions-column is more than 0.

After locking the domain, Unlock-button is visible for primary investigators. Investigators are not allowed to unlock a domain.

3.3.1.4 Locking the protocol (PI)

Locking the protocol indicates that the project is ready to move to the next phase, i.e. finding answers to the questions defined by the protocol.

The protocol can be locked (Lock-button visible), when

- the scope has been completed
- all the domains with or without any information have been locked.

After locking the protocol you cannot change any part of the protocol (project information, questions, frames) unless you unlock the project first. Only project leader can unlock the protocol to prevent unintended changes.

3.3.1.5 Editing a locked protocol

If you wish to edit any part of the scope or protocol, the project leader must first unlock it (Protocol design/Unlock-button). Unlock next the domain(s) that will be changed and make the changes (e.g. edit the research questions). After editing, lock the domain(s) and the protocol.
### 3.3.2 Rapid assessments

In the Protocol design phase the (primary) investigators select and edit the research questions for their domains. In this phase you can:

1. make the practical research questions on selected domains and topics.
2. lock the domain once the research questions are complete.
3. view the protocol and lock it.

Note! In order to start protocol design the scoping (Project definition) must be mostly done, and in order to lock the protocol the scope must be finalised (for details see Project scope)

#### 3.3.2.1 Research questions (PI, I)

**Research questions**

*Edit => View* after the domain has been locked.
- You can see all the issues and notes.

**Status**

- *No questions* => *completable* if you have saved at least one issue with a question.
- *Status = incomplete* if you have ticked an issue, but left it without questions.

**Complete**

*Domain unlocked*
- Lock => *Locked* (=> Unlock activated)

*Protocol unlocked*: Lock-button will be visible when you have locked all the domains.

**View protocol/questions** shows the protocol such as it was last saved.

**Tick** a relevant issue to

- a) formulate the research questions. You can use the question suggested by the tool or modify it.
- b) add more questions on the same issue. Only one question per box!
- c) edit or remove the questions.
- d) add a note for your research group.

**Note!** For every selected issue you must save at least one question.

**Unselect** an issue to remove it with all the questions.

**Change** the default *order* of the topics and issues at any time of the process.

**Click to move** the topic.
- Drag and drop a topic or an issue to change their order.
3.3.2.2 Locking a domain (PI, I)

Once you have completed defining the questions for a domain, lock it. Locking the domain informs the project leader that your group has finished considering the issues and that you are ready to start looking for answers.

After locking Unlock-button is available for primary investigators. Investigators are not allowed to unlock a domain.

3.3.2.3 Locking the protocol (PI)

Locking the protocol indicates that the project is ready to move to the next phase, i.e. finding answers to the questions defined by the protocol.

The protocol can be locked (Lock-button visible), when

- the scope has been completed
- all the domains with or without any information have been locked.

After locking the protocol you cannot change any part of the protocol (project information, questions, frames) unless you unlock the project first. Only project leader can unlock the protocol to prevent unintended changes.

3.3.2.4 Editing a locked protocol

If you wish to edit any part of the scope or protocol, the project leader must first unlock it (Protocol design/Unlock-button). Unlock next the domain(s) that will be changed and make the changes (e.g. edit the research questions). After editing, lock the domain(s) and the protocol.

3.3.3 Viewing the protocol (all assessments)

You can view the protocol at any time during the protocol design process. The protocol may be missing some of the unfinished content until the design process is completed and the protocol locked.

You can view the protocol with or without the methodological guidance (methodological guidance is at the end of the protocol). The list of research questions is an easy way to view all the questions without other content.

The complete project protocol contains the following:

- A list of research questions that the project should seek answers to
- Domain-specific methodological guidance
- Issue-specific guidance for information sources
- A list of assessment elements that were regarded as irrelevant in the context of the technology under assessment and brief notes on such choices.

Modified (domain specific) framing can be seen at the beginning of the domain (issues and questions)
3.4 Phase 3: Research – all assessments

In this phase researchers are set to find answers to the research questions defined in Phase 2. The Online Tool Phase 3 contains MS Word templates and further technical instructions for conducting the research and collecting the results, as well as handling references to other studies. It is highly recommended that you use the available templates, as they contain the basic structure needed to enter results in Phase 4.

Note! You must download a new template every time you have changed the protocol (questions) to avoid errors when uploading.

A Core HTAs: domain-specific templates available for general text (introduction, summary etc.) and answers.

B Rapid HTAs: one template covering all parts of the assessment.

Follow all available technical instructions in the MS Word templates, since omitting them will prevent your collection from being displayed correctly.

- You can modify only the yellow fields within brackets.
- Notice that when you upload the template for adding results, all the information in the yellow fields will be stored into your collection. That is why you must clear the fields from any instructions either on the template or later using the online tool’s editing features. If you have not included text in some fields of the template, the corresponding fields in the tool will be emptied (or written over with the template instructions).

3.4.1 Citations and references

You should create in-text citations and reference lists using the Uniform style. For technical reasons replace the parentheses ( ) in in-text citations with curly brackets { }. After these changes your in-text citations should look like this:

The recent study by Smith et al. {12, 17-19} is clearly stated to be retrospective.

You can make the changes by hand in your word processing program (e.g. Word). If you are using a reference management software (e.g. EndNote, RefWorks), you can edit the Uniform output style to automatically make the changes. For more information see RefWorks and EndNote guidance in the tool.

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3 For more information, see Uniform Requirements for Manuscripts Submitted to Biomedical Journals: http://www.nlm.nih.gov/bsd/uniform_requirements.html.
3.5 Phase 4: Results

Information within any collection is divided into three levels: collection, domain, result card. Investigators (PI, I) can start entering the results in the tool after the protocol has been locked by the project leader (in phase 2, protocol design).

In this phase you can
1. enter the results either by uploading from a word document or editing directly in the tool.
2. mark each level complete: 1. result cards => 2. domains => 3. collection.
3. publish a draft.

Important! If you wish to enter information by uploading a word template (from phase 3) you should do it first since uploading will overwrite all the corresponding information saved in the tool. If you have not included text in some fields of the template the corresponding fields in the tool will be emptied (or written over with the instruction texts of the template).

3.5.1 Features common to all project types

3.5.1.1 Uploading a template (PI)

1. Click Upload results from word template.
2. Find the template on your hard disk or any other storage device, select it and click Upload.

Be sure that you upload the latest version of the template. If you have changed the protocol after downloading a template (phase 3), you may see a message 'couldn't find a heading'.

3.5.1.2 Attachments of the collection

All the downloaded attachments are available for any part of the collection. You can add appendices on each level of the assessment and use them in any part of the collection.

Supported attachment/image file types are pdf, zip, png, jpg/jpeg and gif. The maximum permitted file size of an attachment is 2048 kilobytes.
Click **Add attachment** in top-left corner of the editing tool.

1. Find the template on your hard disk or any other storage device, select it and click **Upload**.
2. Add a code and click **Add file**. The attachment is now available for any part of the collection.
3. Click **Add to text**.

There is also an **Delete**-button. Use it only if you are absolutely sure, that the attachment is not used in any part of the collection. Deleting an attachment

### 3.5.2 Features specific for core HTAs

There are several ways to enter the results on different levels:

- Result cards: upload the domain specific template and/or edit in the tool.
- Domain level: upload the domain specific template and/or edit in the tool.
- Collection level: edit the contents in the tool.

Results can be added and modified on every level in any order.

There are several fields with *complete* check box. You must tick all of them (even though left empty) to define the general texts of the domain or collection complete. For answers there is only one box at the bottom of the page.

1. When all the answers and general texts of the domain have been completed **mark** the domain **complete**.
2. When all the domains and general texts of the collections are completed **mark** the collection **complete**.

**Note!** If you use a domain-specific word template you should upload it first, since uploading will overwrite all the existing information.
COLLECTION LEVEL

1. Click any edit to add collection-level contents.
2. Mark the page complete (at the bottom of the page).

DOMAIN LEVEL

1. Always begin by downloading domain-specific word template
2. After that add or modify in any order:
   - general text of the domain and mark each section complete.
   - answers and mark them complete.
3. When all the contents of the domain are completed click Mark complete

ANSWER

Answer for TEC1: What is ASA and the comparator(s)? Something ADDED here.

Method

• Data
• Model
• Analysis
• Conclusion

(Relevant for the domain methodology used to answer this question)
3.5.3 Features specific for Rapid assessments

1. If you wish to upload a word template for results, download it at first.
2. Click
   - *Edit project info* to add collection-level info e.g. collection name, publishing organizations, editors. Save.
   - *Edit project texts* to modify the general text you uploaded eg. scope, methods etc. Click *Edit this section*, tick complete and save. This must be done even though you don’t change anything or you leave the field empty.
   - *Edit results* to modify the domain-specific texts you uploaded eg. results, discussion. Save.
   - After you have finished editing answers *mark* the domain *complete* (*Mark complete*/incomplete)
3.5.4 **Publish a draft**

In this phase you can also publish a draft version of your work. It can be used e.g. for internal review or external peer review or public consultation. You can select different levels of publicity. Notice that the visual design of the drafts differs from that of the final published collection.

![Draft publishing interface](image)

### 3.6 Phase 5: View and submit

In this phase you can view the final collection in the format it will have once published. Review all contents one more time to ensure that the final collection contains all materials it is supposed to contain. Notice that only projects owned by EUnetHTA member agencies can be published within the HTA Core Model Online. Once the work is ready, please contact the HTA Core Model Online administrations and request publishing of your work. Send an email to eunethta@thl.fi and provide the following information:

- Your name, email and phone number
- Name of the EUenetHTA member agency that owns the project
- Name of the collection to be published
- Id number of the collection to be published. It is displayed in the address bar of your browser when you view the collection in phase 5. The number is indicated at the end of the URL after an equals sign (if you see e.g. “=501”) at the end of the address, the Id is 501.

The administrators will publish your collection as soon as possible, usually within a few days or a week.
4. Local reports

4.1 Using a collection for a local report

If you wish to make a local report based on a EUnetHTA collection, you can easily convert it to a MsWord document.

1. Click Make a local report in the menu (below Adaptation).
2. Select the collection you want to use. The collection opens and all contents are displayed.
3. Save the collection as html-text (Select Save as... from the menu of your browser or by using the secondary (usually right-side) mouse button.
   Depending on the browser you use, you can choose in which format the file is saved. Choose “web page, full”, “html” or something similar to save the contents on your hard disk or any storage medium. Choose any name you prefer for the file.
4. Open the text with your word processor. In order to see the file in the File-Open dialogue of MS Word, you must choose the file types displayed. Select “All files” or “Web pages” to be able to select the saved page.
5. Convert the file to MS Word format by choosing Save as and selecting the appropriate file type from the File-Save as dialogue.

Now you have all contents of the core HTA information collection as a MS Word file. You can utilize the materials to make your local report, but please respect the intellectual property rights of the original authors and the publisher. As with any scientific work, you can cite materials written by others. If you want to use extensive parts of the text as such, or if you want to use tables or images included in the collection, you should contact the primary publisher of the original collection and ask for a permission to use the materials.

4.2 Registration of a local report

The EUnetHTA Policy for the HTA Core Model and core HTA information requires that users of core HTA information must provide an English language summary of the final conclusions of their local report.

1. Click Local report in the menu to enter the information.
2. Add titles of your local report in original language and in English
3. Give information on the collections you used:
   - Select (Tick) collection(s) and domain(s) you have used in your local report (you must always tick also the collection).
   - Select the role of sources to inform how significant the sources have been for your report.
4. Enter metadata:
   - editors or authors; primary producer + contact url; country; publication date
   - keywords: Describe the theme of your work. Use MeSH (Medical subject headings) or select the terms otherwise. Also codes (e.g. ICD, ATC) can be used.
   - (optional) description (4 000 characters) to describe the contents in few sentences.
5. Enter suggested citation
6. Add link(s) to your local report:
   - Select type (full report/abstract) and language
   - Enter url. If all the documents are listed on a single page, provide a link to that page.
7. Add summary/conclusions (15 000 characters)
8. Add data on yourself: name, (organization), e-mail
9. Tick I give my permission to publish the information contained on this page.
10. Submit registration.
## 5. Appendices

### 5.1 Appendix 1. User’s rights

<table>
<thead>
<tr>
<th>Leader</th>
<th>Primary investigator</th>
<th>Investigator</th>
<th>Informatician</th>
<th>Reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project definition</td>
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<td></td>
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<td>Create a project</td>
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<td></td>
</tr>
<tr>
<td>Add members to a project, define roles</td>
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<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Edit project name</td>
<td>if unlocked</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Edit scope and metadata</td>
<td>if unlocked</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Protocol design</td>
<td>if unlocked + without results</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Evaluate assessment element relevance and formulate research questions of a particular domain</td>
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<td>x</td>
<td>If incomplete</td>
<td></td>
</tr>
<tr>
<td>Define framing of a particular domain</td>
<td>x</td>
<td>x</td>
<td>If incomplete</td>
<td></td>
</tr>
<tr>
<td>Rearrange the topics and issues</td>
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<td>x</td>
<td></td>
<td>?</td>
</tr>
<tr>
<td>Complete a particular domain by locking it</td>
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<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Unlock a particular domain</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>View the protocol and research questions</td>
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<td>x</td>
<td>x</td>
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</tr>
<tr>
<td>Research</td>
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<td></td>
</tr>
<tr>
<td>Download a template</td>
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<td>x</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

### Results for Core HTAs

<table>
<thead>
<tr>
<th>Leader</th>
<th>Primary investigator</th>
<th>Investigator</th>
<th>Informatician</th>
<th>Reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upload a domain-specific template</td>
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<tr>
<td>Enter general texts of a particular domain</td>
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<td>If incomplete</td>
<td></td>
</tr>
<tr>
<td>Enter answers of a particular domain</td>
<td>x</td>
<td>x</td>
<td>If incomplete</td>
<td></td>
</tr>
<tr>
<td>Mark (research question) answer of a particular domain complete</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mark results of a particular domain complete</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mark (research question) answer of a particular domain incomplete</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mark results of a particular domain incomplete</td>
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<td>x</td>
<td></td>
<td></td>
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<td>Enter the methods of a research question answer of a particular domain</td>
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<td>If incomplete</td>
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</tr>
<tr>
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<td>If incomplete</td>
<td></td>
</tr>
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<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Results for a rapid HTAs</td>
<td>Leader</td>
<td>Primary investigator</td>
<td>Investigator</td>
<td>Informatician</td>
</tr>
<tr>
<td>--------------------------</td>
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</tr>
<tr>
<td>Upload a template (rapid)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Enter the general texts of a rapid assessment</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enter results of a particular question</td>
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<td>x</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Mark results of a particular domain complete</td>
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<td></td>
<td>Yes</td>
</tr>
<tr>
<td>View and submit</td>
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<td></td>
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</tr>
<tr>
<td>View the collection</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Publish a draft</td>
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</table>