



The HTA Core Model ® Licence

Terms and conditions for using the HTA Core Model

Last Updated 12 January 2016

1. Introduction and definitions

The HTA Core Model ® (later also "The Model") is a methodological framework for production and sharing of HTA information. The Model enables effective collaboration and sharing of information.

The HTA Core Model ® is a registered trademark.

This licence applies to all applications and versions of the Model. The name and version of applications are available in the relevant documents to be found at www.htacoremodel.info and www.eunetha.eu.

This Licence covers any use of the Model including, but not limited to,

- a) reproduction and distribution of the Model
- b) production and publishing of HTA information and
- c) use of the Model and its information structure in other tools.

“Licence” shall mean the terms and conditions for use, reproduction, and distribution as defined herein.

”User” shall mean an individual or Legal Entity exercising permissions granted by this Licence.

“Legal entity” shall mean the union of the acting entity and all other entities that control, are controlled by, or are under common control with that entity. For the purposes of this definition, "control" means (i) the power, direct or indirect, to cause the direction or management of such entity, whether by contract or otherwise, or (ii) ownership of fifty percent (50%) or more of the outstanding shares, or (iii) beneficial ownership of such entity.

“Work” shall mean the original work of authorship irrespective of form and medium of its presentation.

“Derivative Works” refers in this Licence to any Work that is based on (or derived from) the use of the Model and for which any modifications represent, as a whole, an original work of authorship.

“HTA” refers to Health Technology Assessment.

“EUnetHTA” refers to the European network for Health Technology Assessment.

“THL” refers to the Finnish National Institute for Health and Welfare.

Following its initial development in the EUnetHTA Project 2006-2008, EUnetHTA Joint Action 2010-2012 and EUnetHTA Joint Action 2 2012-2015, the Model is subject to further development by EUnetHTA. Interested parties are encouraged to participate in the development of the Model, adhering to this licence.

2. Use, reproduction and distribution of the HTA Core Model

The Model can be used in two different settings:

- Within the EUnetHTA joint activities
- Outside of the EUnetHTA joint activities

Use within the EUnetHTA joint activities setting is governed by this licence and steered in further detail by the “Policy for the HTA Core Model and core HTA information”, available at www.htacoremodel.info.

Use outside of the EUnetHTA joint activities setting is governed by this licence. Users of the Model who aim at producing core HTA information (a specific type of HTA information) are encouraged to read the aforementioned policy.

The HTA Core Model® is **free for use** by any party provided that the User adheres to this licence.

Any use of the Model **must be registered** at www.htacoremodel.info. Users are encouraged to provide feedback on their experience with using the Model.

The Model must be used following the *Guiding Principles on Use* contained herein. The most recent version of the Model available through www.htacoremodel.info should be used. If the Model is updated during on-going work, Users of the Model may choose to finalize their work using the version they started with, or to adjust their work to the updated version

The User may make copies of the Model without modifications for own use, provided that the following conditions are adhered to:

- a) User must give any other recipients of the Model a copy of this Licence;
- b) User must retain in readable format all copyright, patent, trademark, and attribution notices pertaining to the Model.

The User must not distribute the Model to any third parties. Distribution of the Model to third parties is permitted only for parties and sites defined by EUnetHTA. These are disclosed at www.htacoremodel.info.

Use of the Model, including information on its version, must be disclosed in any Derivative Works by including the following text in their description

"The HTA Core Model ®, developed within EUnetHTA (www.eunethta.eu), has been utilised when producing the contents and/or structure of this work. The following version of the Model was used: [include name and version here]. Use of the HTA Core Model does not guarantee the accuracy, completeness, quality or usefulness of any information or service produced or provided by using the Model."

When using the Model for non-commercial purposes, any information produced using the Model should be made publicly available either on the Internet or in printed format, unless local legal requirements on confidentiality prevent this.

All materials, documents, data, software, information and inventions supplied to the User of the HTA Core Model by or on behalf of EUnetHTA and/or the Finnish National Institute for Health and Welfare (THL) shall be and remain the sole and exclusive property of EUnetHTA and/or THL. The User shall use such property only for the purposes described by this Licence and shall not use such property for, or disseminate such property to, any third parties.

EUnetHTA and/or THL shall retain exclusive ownership to all materials included in the HTA Core Model and hereby grants the User and its affiliates a nonexclusive, perpetual, worldwide, royalty-free, licence to use the materials.

Any information or other types of Derivative Works produced by the User by using the HTA Core Model is the property of the User. User must give any recipients of the Derivative Works a copy of this Licence.

This Licence does not grant permission to use the trademarks, service marks, or product names of EUnetHTA/ THL, except as required for reasonable and customary use in describing the origin of the Model.

User must not use the terms EUnetHTA, THL or HTA Core Model for any kind of marketing purposes

EUnetHTA or THL will not be liable for any loss, damage or inconvenience arising as a consequence of any use of the HTA Core Model. Users of the HTA Core Model and users of any information or product made using the Model do so at their own risk.

Production and publishing of HTA information using the Model

You are allowed to

- Produce information on health technologies using the Model.
- Publish, copy, distribute and transmit information you produced.
- Exploit the information you produced commercially for example by combining it with other information, or by including it in your own product or application

You may not

- Place advertisement(s) in the final product (e.g. a research report) on the page or double-page (spread) showing information produced using the HTA Core Model, if the advertisement(s) deal(s) with the health technology or technologies considered in the product.
- Claim or even indirectly imply that the use of the HTA Core Model or EUnetHTA methodologies would guarantee the quality of your information.

Use of the Model within information systems (including computer software and online services, databases and web sites)

You are allowed to

- Use the whole HTA Core Model, or parts of it (e.g. the HTA ontology) as part of your information system. When building your system, you should preferably use the most recent version as defined in general terms (see above).
- Exploit commercially the information system you produced using the Model.

You may not

- Place advertisement(s) in any contents of the final product too close to information you produced using the HTA Core Model, if the advertisement(s) deal with the health technology or technologies considered in the product. The design of your product should make it easy for users to distinguish between scientific, professional and other non-promotional material from advertising and other promotional material.
- Claim or even indirectly imply that the use of the HTA Core Model or EUnetHTA methodologies would guarantee the quality of your product.

3. Guiding Principles on Use

Purpose of the Guiding Principles

To outline fundamental principles for the utilisation of the *HTA Core Model*® (the Model)¹ in various settings contributing to Health Technology Assessments (HTAs)², and to the production and use of a reliable, timely, transparent and transferable knowledge in healthcare supporting patients' access to effective health technologies³.

Definition and purpose of the Model

- The HTA Core Model is a *methodological framework* for production and sharing of HTA information. The HTA Core Model® is a registered trademark.
- The Model consists of the following three components, each with a specific purpose:
 1. A standardised set of *HTA questions (the ontology)* allows users to define their specific research questions within a hierarchical structure (see below)
 2. *Methodological guidance* to assist in answering the research questions that
 - Recommends use of already existing, generally recognised guidance and guidelines (e.g. EUnetHTA methodological guidelines, Cochrane Handbook⁴, EQUATOR network⁵), along with other methodological recommendations
 - Requires transparency on the methods used when applying the HTA Core Model.
 3. A *common reporting structure* for presenting findings in a standardised “question-answer pair” format
- HTA information produced by using the Model following the ontology and the common reporting structure can be designated as *core HTA information*, with high potential for being shareable and transferable knowledge. In order to facilitate re-use of information, registered users (see below) of the HTA Core Model should facilitate the traceability of the core HTA information they produce.

¹ The HTA Core Model® and the Online Tool and Service (also known as the HTA Core Model Online) are two related but separate products of EUnetHTA. This document refers only to the HTA Core Model®. The HTA Core Model Online contains features that assist in using the Model in certain settings, but should not be viewed as part of the Model.

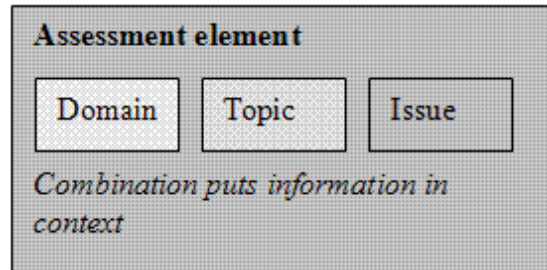
² **Health technology assessment (HTA)** is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Despite its policy goals, HTA must always be firmly rooted in research and the scientific method.

³ **Health technology** is the application of scientific knowledge in health care and prevention. Examples of Health Technology: Diagnostic and treatment methods, Medical equipment, Pharmaceuticals, Rehabilitation and prevention methods, Organisational and supportive systems within which health care is provided

⁴ Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

⁵ The EQUATOR (Enhancing the QUALity and Transparency Of health Research) Network is an international initiative that seeks to improve the reliability and value of published health research literature by promoting transparent and accurate reporting and wider use of robust reporting guidelines. <http://www.equator-network.org/>

- The assessment elements are units of the structure of the Model, which consists of *domain, topic* and *issue* (translated further into one or more specific research questions in concrete projects) that are used to assess a health technology. In this way, within a hierarchy, all research questions relate to a specific domain and subordinate topic.



- Flexibility in the choice and combination of these structural elements is an important characteristic of the Model and its utilisation. It means that to produce and to present core HTA information, users can choose from an overall set of assessment elements those relevant for their project and use them in their own order and combination. This flexibility in choice and order allows collecting assessment elements (i.e. question-answer pairs) and building them into a structure of reporting, tailored to the needs of the user and a specific health technology assessment
- The Model does not mandate either a certain order or hierarchy (apart from the Domain, Topic, Issue hierarchy presented above) of its structural units or any specific process of producing the information.
Any further structuring of core HTA information is done at the discretion of the Model users.

Open access and collaboration values

- The design of the Model is and will remain publicly accessible
- EUnetHTA's objective is and has always been to deliver a model that can be shared and its use customised to the needs and objectives of the users, provided that the defining characteristics of the model described in this document are respected
- The "open" approach to developing and welcoming wide use of the EUnetHTA outputs – among which the HTA Core Model is one - designates a set of values and refers to something that can be further developed by EUnetHTA and others because its design is publicly accessible. The HTA Core Model is intended for general use, and all stakeholders in HTA and health research and policy are welcome not only to use it as a final and complete tool, but also to build upon it and develop their own products, tools and systems by using the defined and standardised framework of the Model. Those who utilise the HTA Core Model in derivative products (e.g. information systems) should clearly disclose to users whether they have used the Model as it is made available by EUnetHTA or whether some parts have been modified/revised.
- The standardised "question-answer" format and open access to the Model explicitly support users to produce, share, access and re-use HTA information in a reliable, timely, transparent and transferable manner

Intended use

- The HTA Core Model is free of charge provided that its use is registered by using the registration form and providing information about the user (including but not limited to contact details) and intended use of the Model. The registration is performed at www.htacoremodel.info.
- The Model offers a common ground to various stakeholders at any and all stages of the development of health technologies and their application by facilitating a common HTA language worldwide and through offering a standard structure and a transparent set of proposed HTA questions for consideration by health technology assessors and stakeholders
- The Model can be used at any and all stages and for any purpose in a technology's life cycle and in the systems within which health technologies are applied, e.g. (but not limited to):
 - In agreeing on the scope of an HTA, selecting relevant assessments elements in the early phases of an assessment
 - In agreeing on the content of submission files/dossiers, according to relevant assessment elements
 - In providing structure to early scientific advice /early dialogues between HTA entities and health technology developers, in early and later stages of development and evidence generation
 - In identifying evidence gaps and in generating further evidence for technologies that are already introduced to healthcare
 - In providing a framework from which further recommendations and other steps in informing decision-making on health technology reimbursement or policy can be derived
- EUnetHTA welcomes any legitimate use of the HTA Core Model and any efforts to ensure compatibility between derivative works and the HTA Core Model and efforts to facilitate a consistent experience with using the Model and core HTA information
- Transparency of the methods used to answer the research questions derived from the ontology is mandatory when using the HTA Core Model.

Availability and versions

- The HTA Core Model is available on the EUnetHTA website (www.eunetha.eu) and www.htacoremodel.info in pdf and MS Word formats.

Intellectual property rights

- Use of the HTA Core Model, including information on its version, must be disclosed in the final product(s) as indicated in the HTA Core Model® License.

4. Changes in the Terms of Use prior to 2016

The use of the HTA Core Model was limited to non-commercial purposes until the end of 2012.

From July 2013 until December 2015, the use of the HTA Core Model was subject to either a non-commercial or commercial licence, depending on the nature of the use. *Commercial use* in this context was defined as any use intended for or directed toward commercial advantage or private monetary compensation, while anything else was regarded as *non-commercial use*. Users of the HTA Core Model were required to select the appropriate licence and agree to the terms defined in the selected licence. The old Terms of Use which were applicable between July 2013 and December 2015 can be accessed at www.htacoremodel.info.