

HTA Core Model Training Course

Helsinki, 1 – 2 October 2015

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PLEASE NOTICE:

This presentation is a public version of the materials used within the HTA Core Model Training Course(s). The most recent course was organised in October 2015. Some important changes to themes relevant for modules 4 and 5 took place after the course. Relevant slides in this presentation have been updated to reflect the situation at the end of Joint Action 2. Changes are indicated with "Addition 2016".



Aim

- Focus on **using the HTA Core model Online to produce core HTA information.**
- Use of the resulting information for local HTA products and basics on the structure of the HTA Core Model will also be covered, but less extensively.
- Participants should bring with them an idea of a **real or simulated HTA project** for which a protocol will be designed and results entered during the course.
- During the course participants acquire knowledge that can be used to train further users of the Model in their respective organisations / countries.
- “Training the trainers”



Agenda

Thursday, June 5

12:00 – 13:00	Lunch
13:00 – 14:30	Session 1 (modules 1 & 2)
14:30 – 15:00	Coffee break
15:00 – 17:00	Session 2 (modules 2 & 3)
19:30 –	Dinner

Friday, June 6

09:00 – 12:00	Session 3 (modules 2 – 4)
12:00 – 13:00	Lunch
13:00 – 14:00	Session 4 (module 5)
14:00 – 15:00	Further focus on participants' needs identified during the course

Training modules

1. Theoretical background to the HTA Core Model
2. Producing HTA information using the HTA Core Model Online (main focus of this course)
3. Utilisation of existing core HTA information
4. Principles steering the utilization of the HTA Core Model and core HTA information
5. Terms of Use of the HTA Core Model



Module 1

Theoretical background to the HTA Core Model



Structure and Basic Concepts



EUnetHTA Joint Action 2

EUnetHTA was established to create an effective and sustainable network for HTA across Europe – we work together to help developing reliable, timely, transparent and transferable information to contribute to HTAs in European countries.

EUnetHTA supports collaboration between European HTA organisations that brings added value at the European, national and regional level through

- facilitating efficient use of resources available for HTA
- creating a sustainable system of HTA knowledge sharing
- promoting good practice in HTA methods and processes.

<http://www.eunetha.eu/about-us>

What is TA / HTA? – back to basics

“The Congress hereby finds and declares that:

(a) As technology continues to change and expand rapidly, its applications are

1. large and growing in scale; and

2. increasingly extensive, pervasive, and critical in their impact, beneficial and adverse, on the natural and social environment.

(b) Therefore, it is essential that, to the fullest extent possible, the consequences of technological applications be anticipated, understood, and considered in determination of public policy on existing and emerging national problems.”

Office of Technology Assessment Act, 1972

http://www.princeton.edu/~ota/ns20/act_f.html

THE HTA CORE MODEL

Key aims of the HTA Core Model

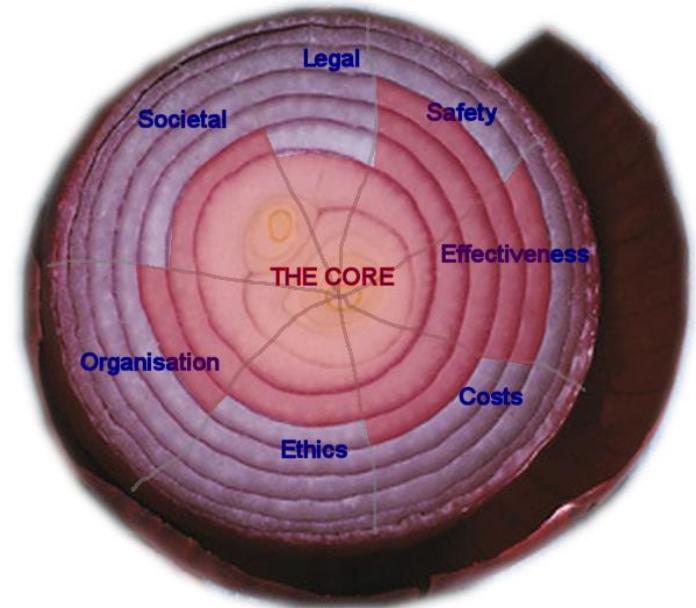
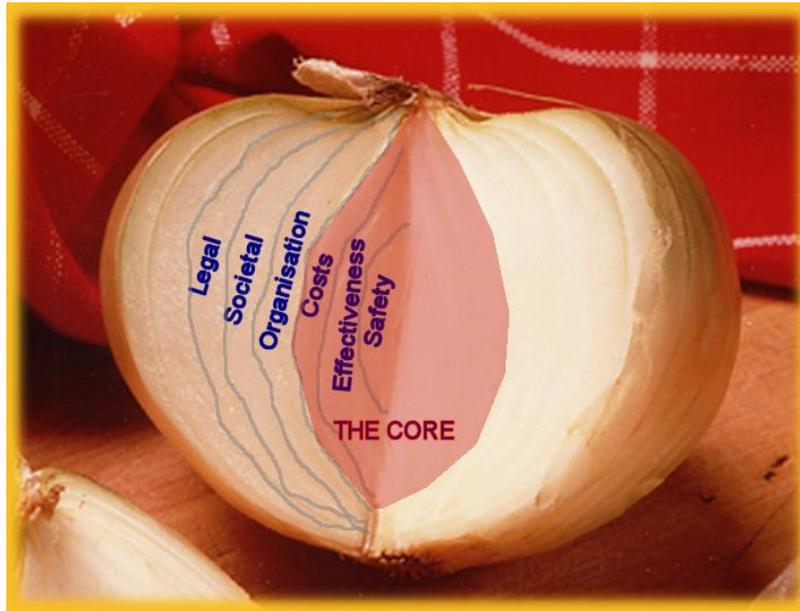
- To capture the shareable "core" of HTA
- To enable **production** of structured HTA information and **sharing** the acquired knowledge
- To support **joint HTA** production
- To support **local HTA** production

How do we perceive HTA, i.e. how to split the onion?



What is the Core?

- Two options for splitting the onion



Technology assessment in health care is a **multidisciplinary** field of policy analysis. It studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology.
(INAHTA 2005)

Starting points

Two problems acknowledged:

HTA implemented differently across Europe

-> Reduced applicability of foreign reports

Varying structure of reports

-> Extraction of data from reports is often difficult

Aim: Attempt to define and standardise elements of an HTA to facilitate shared understanding of HTA and promote the international use of HTA results

Heidi Anttila, Anne Kärki, Ulla-Maija Rautakorpi ja asiantuntijaryhmä

Pivohilan raportti 30 • 2007

Lymfaturvotuksen fysioterapia
rintasyöpöpotilailla

Vaikuttavuus, käytännöt ja kustannukset



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Vaikuttavuus, käytännöt ja kustannukset



Domains of HTA

- Identified in previous EU projects, particularly EUR-ASSESS and ECHTA/ECAHI
- Promote the multidisciplinary nature of HTA

Health problem and current use of technology

Technical characteristics

Safety

Clinical effectiveness

Costs and economic evaluation

Ethical analysis

Organisational aspects

Social aspects

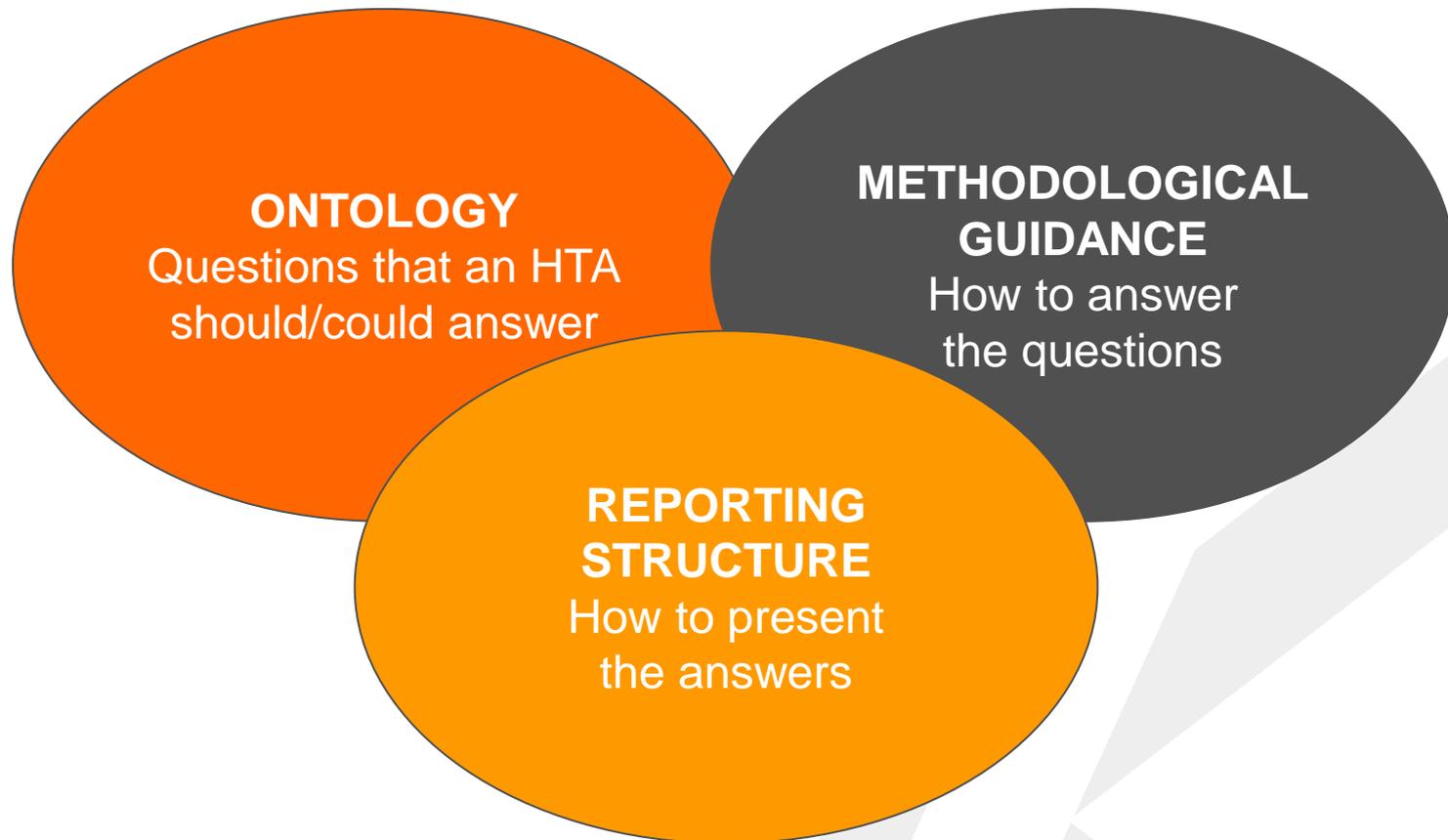
Legal aspects

Topics

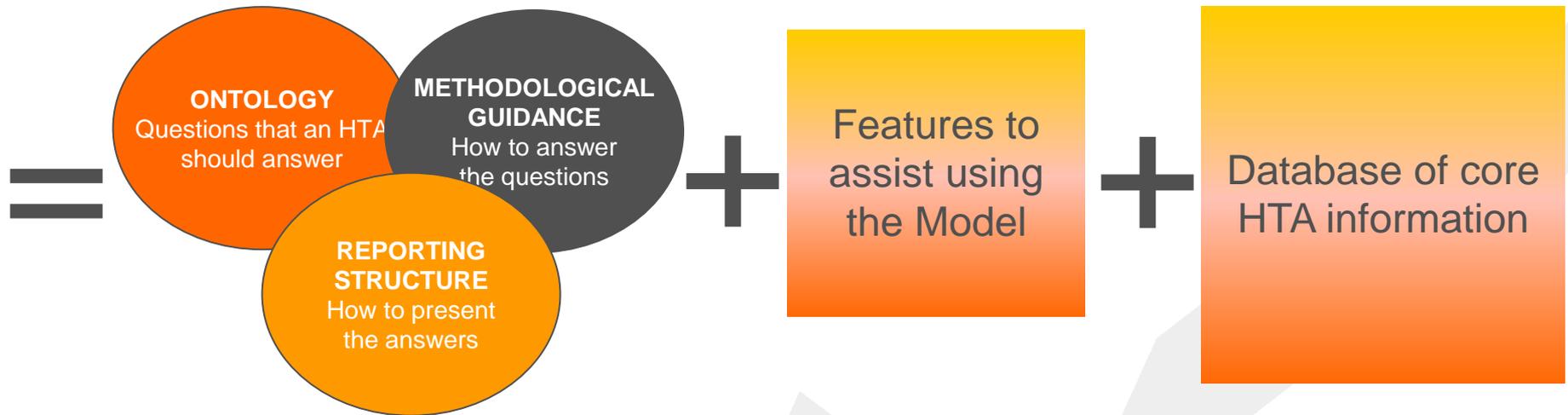
Clinical effectiveness
Topic 1: Mortality
Issue 1: What is the effect of the technology on overall mortality?
Issue 2: What is the effect of the technology on mortality caused by the target disease?
Issue 3: etc...

Health problem and current use of technology
Technical characteristics
Safety
Clinical effectiveness
Costs and economic evaluation
Ethical analysis
Organisational aspects
Social aspects
Legal aspects

Three components of the HTA Core Model



HTA Core Model Online – corehta.info



I. HTA Questions / Ontology

- A formal representation of the information **contents** of an HTA (e.g. "the effect of technology on reduction of symptoms") and **relationships** between various parts of the content
- Assessment elements as building blocks (each provides information on certain aspect of technology)
- Assessment elements are defined by
 - 9 domains (wider angle of viewing, e.g. clinical effectiveness),
 - topics within domains (more specific areas of investigation, and
 - issues within topics (practical questions)
 - EXAMPLE: Clinical effectiveness (Domain) / Function (Topic) / What is the effect of the technology on work ability (Issue)
- Until now divided into core and non-core elements. Core elements are mandatory to consider in core HTAs and rapid REAs. Terminology subject to further considerations.



Ontology - Assessment elements

- Combination of domain-topic-issue
- The basic unit of the model. Each element defines a piece of information that describes the technology or the consequences or implications of its use, or the patients and the disease for which it is applied.
- Nature of elements may vary across domains, since the consequences and implications are understood and studied differently
- The common denominator for all elements is that they outline a set of information that may be useful when deciding on the use or non-use of technology
- Divided into core and non-core elements based on their “importance” and “transferability”

CORE MATRIX		Importance		
		Optional	Important	Critical
Transferability	Complete	Not core	Core	Core
	Partially	Not core	Core	Core
	Not	Not core	Not core	Core

II. Methodological guidance

- Assists in finding answers to questions defined by the ontology
- Different levels: domains, assessment elements, whole model / whole HTA
- Domain-level guidance mostly as reviews of state-of-the-art methodology and links to detailed guidance (including EUnetHTA Guidelines)
- Different strengths of guidance: tips, recommendations, standards

III. Reporting structure

- Standardized format for output of HTA information production
- In the form of **collections** containing
 - General texts, e.g. introduction, summary
 - Domain-level content, e.g methodology, discussion
 - Result cards, each containing an answer to question (or answers to questions) defined by one assessment element (=combination domain-topic-issue)
 - Appendices
- **Core HTA information** = any HTA information produced using the HTA Core Model and published within the HTA Core Model Online
- Different types of collections (EUnetHTA/Other)
 - EUnetHTA Core HTA = Extensive assessment, all domains included
 - EUnetHTA Rapid HTA = Assessment done within some months, a selection of domains included
 - Other = Based on users needs, e.g. single AE, single domain
 - WP5 Rapid REAs can be called also “Reports”
- EUnetHTA collections do not contain recommendations



Applications of the HTA Core Model 1/2

- Model divided into "subsets", specific for different types of technologies.
- The majority of the content common for all applications.
- Shared ontology for all types of HTA (core HTAs and rapid HTAs)
- Each application contains
 - General content (introduction etc.)
 - Content for each domain
 - Domain description
 - Methodology
 - Appendices
 - Assessment elements (what to ask and how to answer etc.)

Applications of the HTA Core Model 2/2

Currently available applications:

- Medical and surgical interventions (WP8)
- Diagnostic technologies (WP8)
- Screening technologies (WP8)
- Pharmaceuticals
 - Rapid REA of pharmaceuticals (WP5)
 - Full assessment of pharmaceuticals (WP8)
- Rapid assesment of non-pharma (WP5), possibly split into same 3 as above

Elements cards (contain application-specific data)

- Each element card defines one assessment element in further detail
- Contains the following data:
 - Element basics, Id, D-T-I, which applications belongs to
 - Clarification = What this issue is about?
 - Information sources -> Methodology = How to find an answer (in addition to domain methodology)?
 - Importance = How important is this question from the viewpoint of HTA?
 - Transferability = How transferable is this information in general?
 - Content relations = Which other elements deal with relevant themes?
 - Sequential relations = Which other elements need to be answered before or after this one (after is automatic)?
 - References = Where does this question stem from?



Practical Utilisation



What can we do with the Model?

For example...

- Produce core HTA information (FOCUS of this presentation)
 - Information that is produced using the Model AND published through HTA Core Model Online
 - Core HTAs, Rapid HTAs
 - Can be a project within EUnetHTA JA2 or outside it
 - Currently limited to projects owned by EUnetHTA Partners and Associates
- Produce HTA information and reports to be published elsewhere
 - Using the HTA Core Model Online (non-commercial parties)
 - Using the PDF version of the Model (anyone with commercial or non-commercial license)
- Organise information in knowledge bases and processes



Information production process in brief

1. Select the assessment elements to be included in the collection.
2. Translate the included generic issues each into one or more practical research question(s).
3. Answer the questions using guidance within the Model.
4. Organise and present the answers according to the common reporting structure.
5. Result: a structured collection of HTA information in which information on a particular issue can be found at a standard location (whether in paper or electronic format).

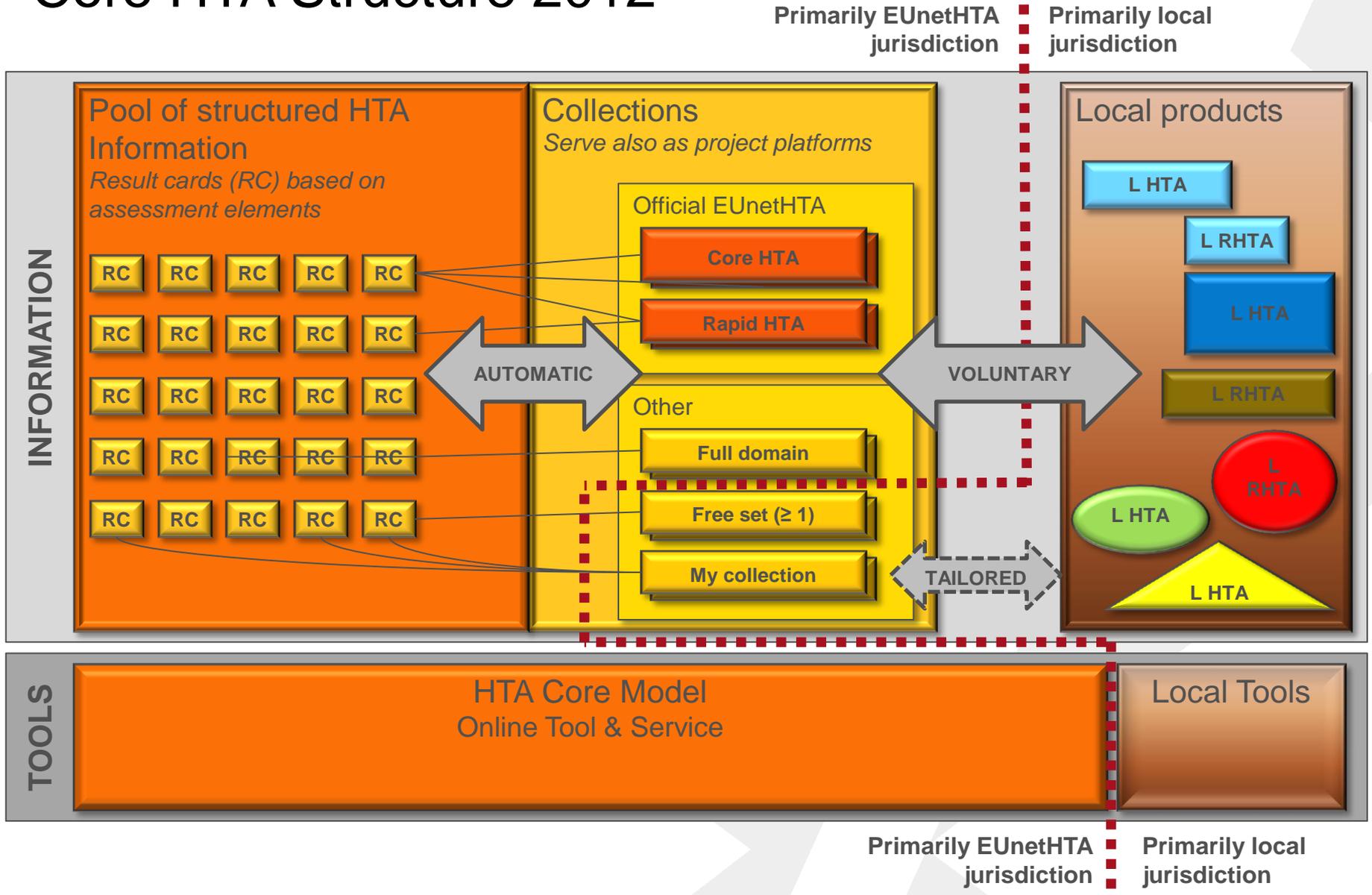
SIMILAR PROCESS APPLIES TO ALL COLLECTIONS:

Select elements – Formulate research questions – Answer questions

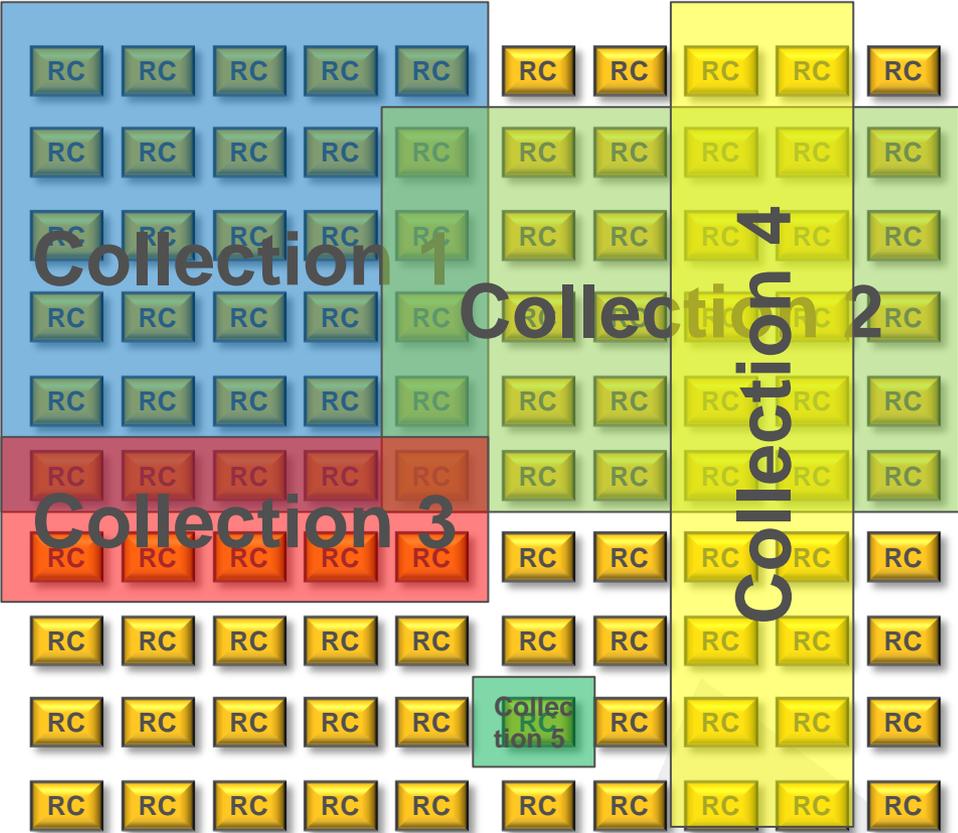
Core HTAs

- One type of core hta information collection
- Five pilot core HTAs produced until now within EunethHTA, Two further pilots will be ready by Nov 2015 (WP4).
- Intentionally built to “not look like a *European HTA report*”
- Serve primarily as a scientific basis for local (national, regional) reports
- Do not contain recommendations regarding the use (or non-use) of technologies
- Enable distributed production of HTA (e.g. different domains by separate research groups)
- Easy sharing of produced information

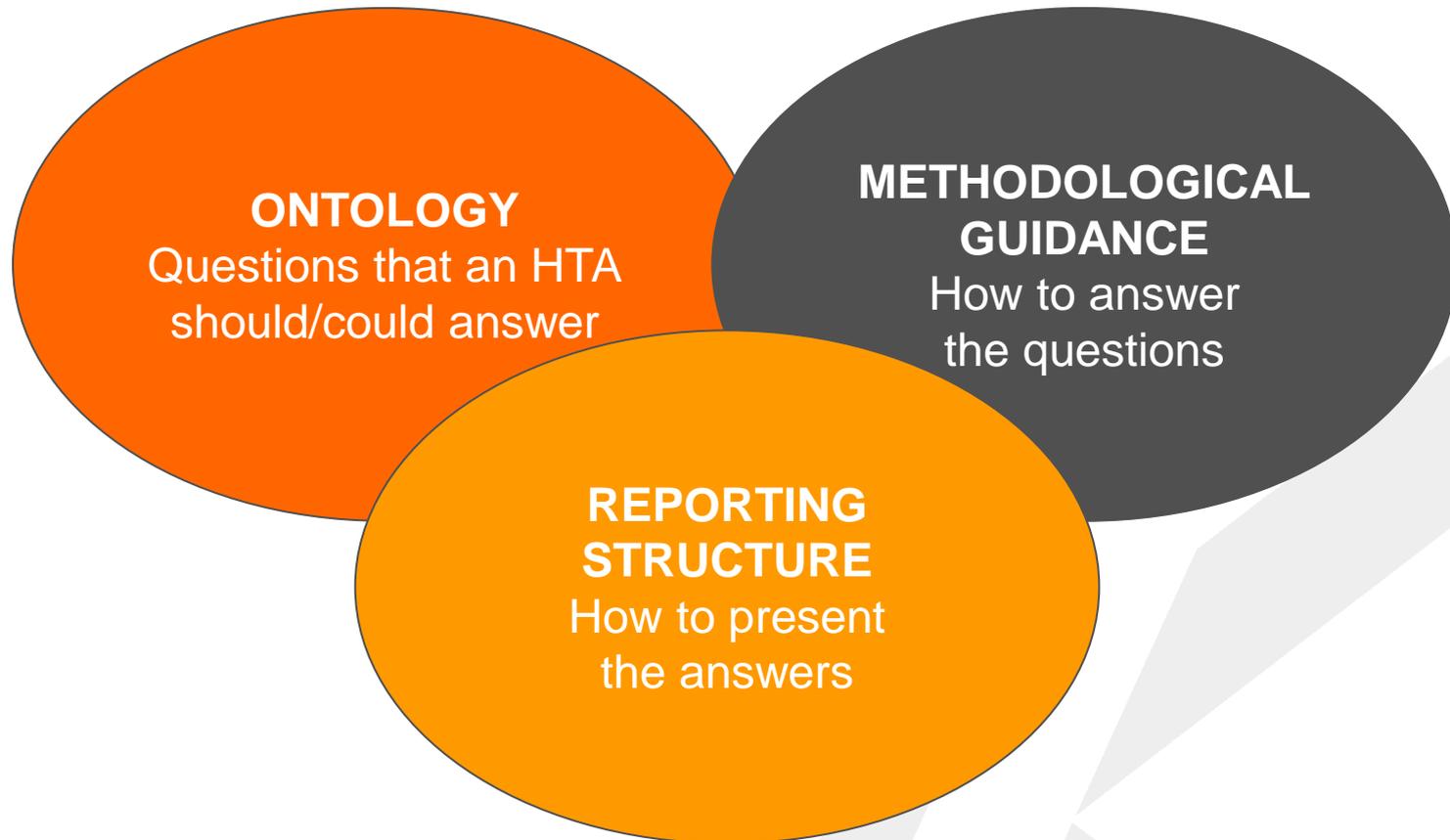
Core HTA Structure 2012



Result cards and collections



Three components of the HTA Core Model



Other relevant documentation for projects

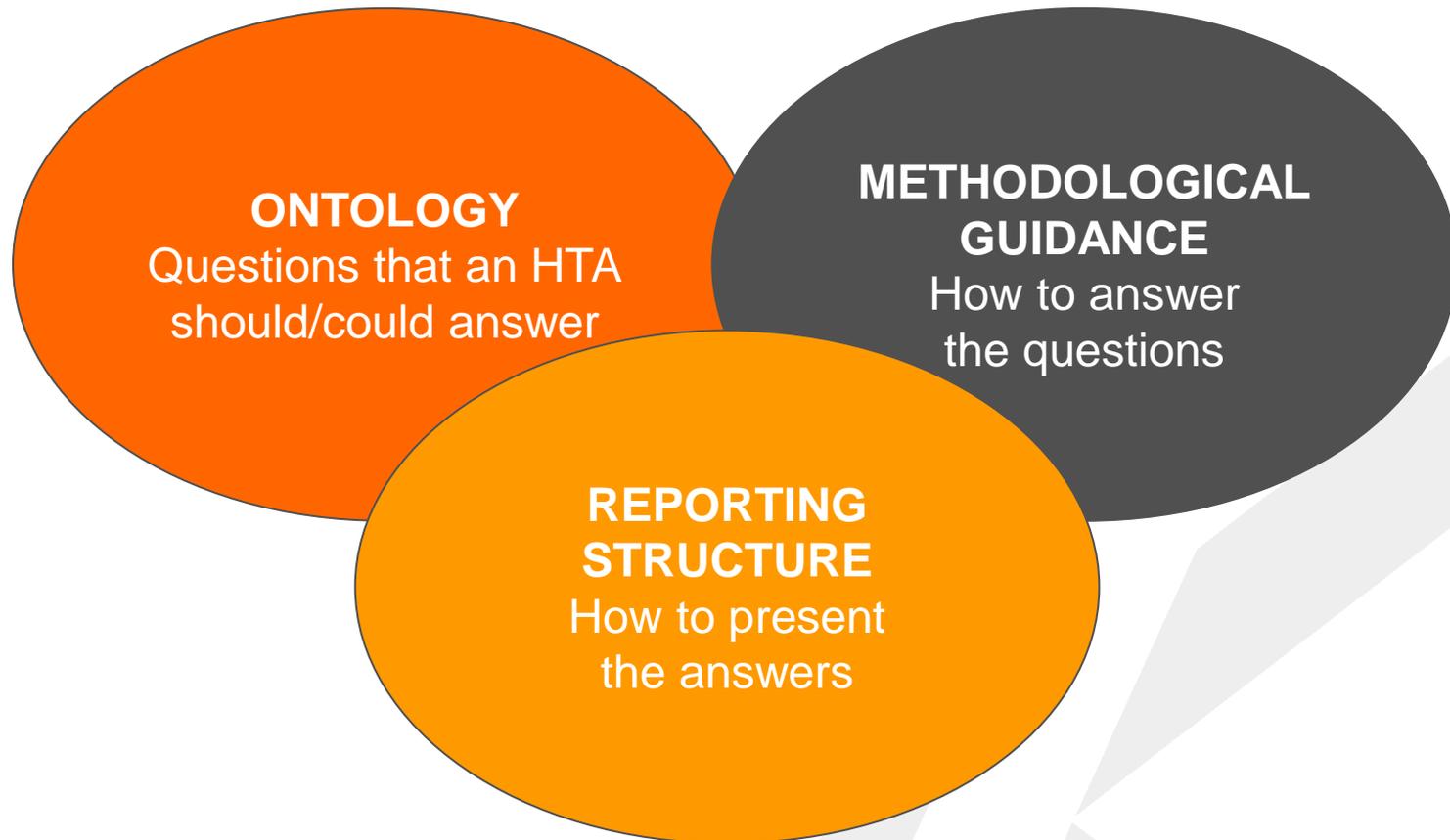
- HTA Core Model Handbook
- HTA Core Model - User Guide
- HTA Core Model Online - User Guide
- EUnetHTA Guidelines
 - JA1 / WP5
 - JA2 / WP7
- JA2 / WP4: Methodological Standards and Procedures (MSP)

Benefit-risk considerations within the HTA Core Model

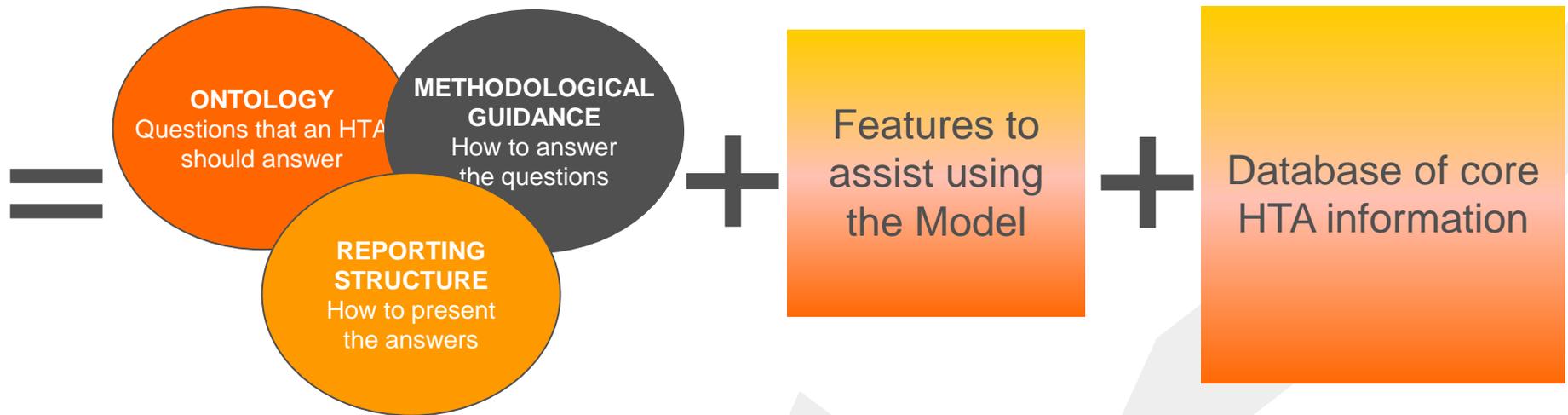
- Both benefits and risks included in several domains, but mostly as separate questions, not combined.
 - Safety domain topics:
 - Patient safety
 - Occupational safety
 - Environmental safety
 - Safety risk management
 - Clinical effectiveness domain topics, e.g.
 - Mortality
 - Morbidity
 - Function / HRQL
 - Patient satisfaction
- Ethical analysis domain (under construction):
 - *What are the benefits and harms for patients, and what is the balance between the benefits and harms when implementing and when not implementing the technology? Who will balance the risks and benefits in practice and how?*
 - *Can the technology harm any other stakeholders? What are the potential benefits and harms for other stakeholders, what is the balance between them? Who will balance the risks and benefits in practice and how?*
- Collection summary contains a standard table listing consequences of using or not using the technology
- More advanced analysis is a local responsibility -> Adaptation tools / Appraisal



Three components of the HTA Core Model



HTA Core Model Online – corehta.info



Some marketing

Why use the HTA Core Model?

Expected benefits...

1. for HTA agencies

- Core HTAs, rapid HTAs and other collections (including single result cards) to support local HTAs
- International collaboration within projects (exchange of expertise and methods)
- Greater variability of HTA information available (through reduction of overlapping work)
- Standardized information exchange with the industry?

2. for Health care decision-makers

- Better informed decisions through improved evidence-base
- Better understanding of the consequences and implications of technology use/nonuse
- Better ROI on HTA through reduced overlapping work in different countries

Why use the HTA Core Model? Expected benefits...

3. for Health professionals

- Integration of HTA information with decision support systems, clinical practice guidelines and electronic health records
- International evidence base for clinical practice guidelines

4. for Citizens, patients

- Better care through more robust evidence base
- Better use of tax money
- Better understanding of the consequences and implications of technology use/nonuse

5. for Commercial companies (e.g. technology manufacturers)

- Standardized information exchange with public bodies (regulatory, HTA)

"In today's environment, hoarding knowledge ultimately erodes your power. If you know something very important, the way to get power is by actually sharing it"

- Joseph Badaracco

*Professor of business ethics, Harvard Business School,
Contemporary -*

Module 2

Producing HTA information using the HTA Core Model Online (main focus of this course)



Process Overview



Project management and roles

- Strong coordination needed, "project owner", 1-3 persons
- Contents of each domain produced by domain teams, consisting of
 - Primary Investigator (1-2)
 - Investigators (1 or more)
 - Internal reviewers (minimum one from another organisation in another country, recommended 5 or more)
- Domain team overlap recommended to improve coordination
- Editorial team consisting of PIs coordinates work
- Different collaborative models have been tested and are tested still
- No need to have 9 domain teams outside the tool. There can also be one research group that works on all domains. The tool needs only to know what rights and responsibilities to allocate to each user.



Overall timeline and order of work

Light green indicates preparatory work, including preparation of relevant protocols and reading other teams' drafts.

Dark green indicates an active phase of research within the domain.

	Domain teams	Domain team work					
		1 st quarter	2 nd quarter	3 rd quarter	4 th quarter		
Topic selection	Editorial team	Finalize scope and protocol	Coordination	Coordination	Prepare for final editorial work	Final editorial work 2-3 months	Peer review and approval Process to be developed by WP4-5-8
	CUR	Dark green	Dark green				
	TEC	Dark green	Dark green				
	SAF	Light green	Dark green	Dark green			
	EFF	Light green	Dark green	Dark green			
	ECO	Light green	Light green	Dark green	Dark green		
	ETH	Light green	Light green	Dark green	Dark green		
	ORG	Dark green	Dark green	Dark green			
	SOC	Light green	Dark green	Dark green	Dark green		
	LEG	Light green	Dark green	Dark green			

From:
Methodological Standards and Procedures,
WP4/JA2 Draft work in progress

Production Phases



What do we need?

- HTA Core Model Online, corehta.info
- User account
 - EUnetHTA Id (preferably)
 - Alternative: local user name, e.g. for non-staff members
- Handbook
 - Available in the tool
 - Currently a mix of HTA Core Model and HTA Core Model Online
 - Major revision by the end of project
- User's guide (draft available)
- An idea of a project!



Project in 5 phases

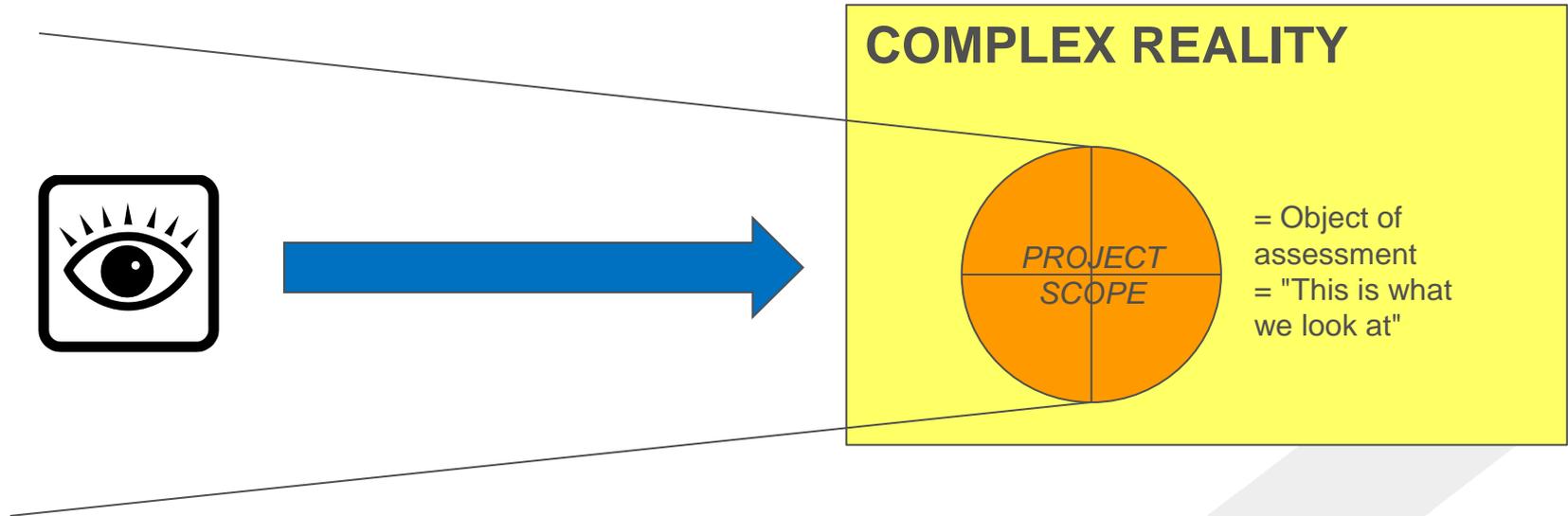
1. Project definition
2. Protocol design (define questions)
3. Research (find answers)
4. Upload results
5. View and submit for publication

Phase 1: Create project, define its scope and add participants

- Basic information on the project
- Project home page
- Add a few participants to your project and assign roles to them
 - Primary investigator (1-2 per domain)
 - Investigator
 - Reviewer
 - Informatician

Scoping of Collections

- Common scope for the whole project



- Extent of analysis may differ between domains through domain framing

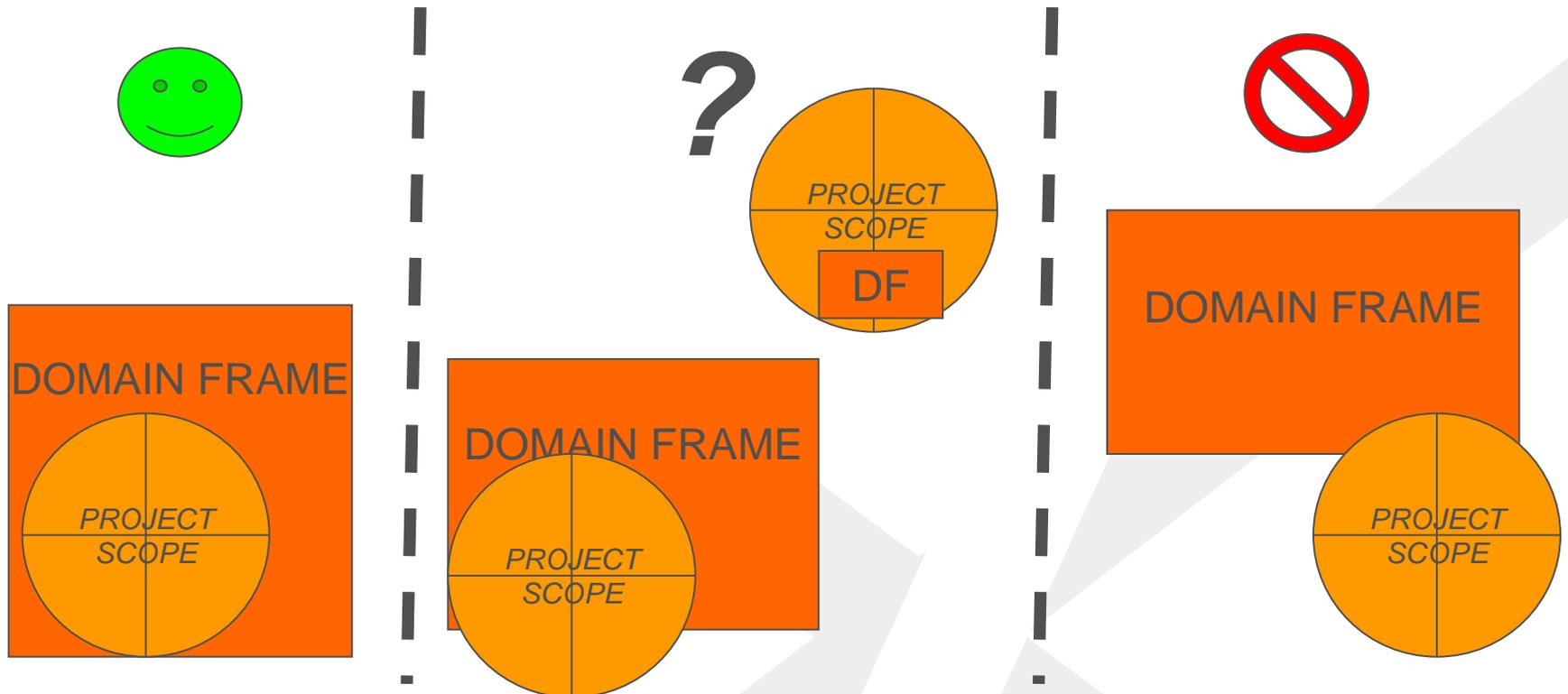
Phase 2 part 1/3: Select questions for your collection

- Consider the relevance for each assessment element
 - For official EUnetHTA collections: certain rules (e.g. for core HTAs each core element must be considered)
 - For other collections: free selection
- Translate generic issues into research questions you intend to answer
- Possible to change order of topics and issues

Phase 2 part 2/3: Frame your domains, lock and review protocol

Domain framing

- Project scope used as default for each domain
- Can be changed for any domain through domain framing
- Domain scope must fit into domain framing



Phase 2 part 3/3: Complete and review protocol

- Lock all domains
- Completed protocols have different status from non-completed
 - Allows proceeding to entering results
 - Core HTA information protocols will be made public automatically once completed (not implemented yet)
 - Ready for review
 - Can be unlocked by project leader
- Protocol template still needs refinement, notice the relations
- Questions, issues, clarification
- Methodological guidance (not actually protocol)

Phase 3: Answer the questions and produce other content

- Download MS Word template, use it for producing content for your collection
- Observe how to include references
- Possible to add internal links to other result cards and appendices within the same collection
- Internal links to other collections not possible yet, except as regular web links.

Common reporting structure for core HTAs

Collection-level information (applies to the whole collection)

- Introduction
- Methodology
- Summary of findings

Domain-level information

- Introduction
- Methodology (including automatic AE table)
- Discussion
- References
- Appendices

Individual assessment elements

- Methods (optional, if different from domain methodology)
- Result = Answer to the question (mandatory, 1-2 pages all the rest as appendices)
- Comment (optional, possibility to consider the result and its implications, "discussion")



References

- Each domain makes its own list of references.
- According to "Uniform requirements",
http://www.nlm.nih.gov/bsd/uniform_requirements.html
- Indicate references with numbers in curly brackets within the text {1}.
- Include references in the order of appearance under the domain references heading in the MS Word template and upload the list in phase 4 to the respective box.
- Multiple references can be included within same brackets {2, 5-7}.
- The system automatically lists the references at the end of domain contents and indicates in result cards the correct references too

Links to other result cards

Include in the text the code of the result card, three letters of the domain and element number, using the following abbreviations:

TEC

CUR

SAF

EFF

ECO

ETH

ORG

SOC

LEG

Examples: EFF4, ECO1

Appendices

1. Give each appendix a code name according to the following syntax: Domain abbreviation with three CAPITAL letters and a number starting from 1 onwards, separated with a single dash but no spaces. Use the following 3-letter codes: CUR, TEC, SAF, EFF, ECO, ETH, ORG, SOC, LEG.

Examples:

EFF-1 = the first appendix of effectiveness

ETH-3 = the third appendix of ethics

2. Give each appendix a title/name that is easy to understand (as if you do in any project). Write the word “Appendix”, the standard code and this title/name at the top of the first page of the respective appendix. Separate the different parts with a single space.

Examples:

Appendix EFF-1 Impact of acetosalicylic acid on the mortality of cardiac patients

Appendix ETH-3 Health professionals’ view on the acceptability of stem cell –based technologies

3. Upload the appendices to HTA Core Model Online. Instructions available there.

Whenever you want to refer to an appendix in the text, simply place the code in curly brackets.

You can for example write “More information is available in {EFF-1}. A link to the appendix will be made automatically.



Phase 4: Enter results into standard structure

- Upload MS Word to the system
- Pay attention: new file overwrites existing data!
- Possible to continue editing online
- Possible to work completely online, bypassing the MS Word phase

Experiment with the user interface

1. Write or copy-paste text into a result field (of a result card) and include some table and lists.
2. Include an image within the text.
3. Add citations to text and respective references to a domain.
4. Add links to other (existing) cards.
5. Upload and appendix and make a link to it in the result field of a card.



Phase 5: Review results and submit for publication

- All information of collection as one package
- Can be used for confidential review & peer-review
- Publication process still under construction, not used fully now
- Possible to publish drafts visible for those with EUnetHTA Id

Module 3

Utilisation of existing core HTA information



Adaptation and support for local reports

- Strongly related concepts
- Adaptation of information from one setting to another
 - EUnetHTA Adaptation Toolkit, by WP5 of EUnetHTA 2006-2008
 - Toolkit partly implemented in the HTA Core Model Online
 - Challenges:
 - Domain-focused approach
 - Initially designed for adapting information from "traditional" HTA reports, not core HTA information
- Support for local report
 - Initially not built into the HTA Core Model Online, not part of task
 - Increasingly interest in some form of support, now in JA2
 - How to efficiently utilize core HTA information as building material for local reports

Different types of adaptation

- From local (national/regional) reports to local reports in another country/region
 - Main setting in Adaptation Toolkit 2008
 - Not so relevant approach in JA2
- From core HTA information to local reports
 - Most important setting in JA2
- From local reports to core HTA information
 - Within any core HTA information project, when answering a question by using one or more local HTA reports
 - As "by-product" of local reports, filling information in result cards afterwards
- From one core HTA information collection to another



Support for local reports

- New feature of the HTA Core Model Online to assist utilisation of core HTA information, under construction
- Use on voluntary basis
- First implementation: select and download material to be used in your local system, will be done within JA2
- Future implementation (?):
 - Browse and select result cards relevant for your local report, even across collections
 - Compile the cards in your own collection using template "My collection"
 - Add new cards if not exist in the collections or ontology
 - Add text chapters based on your own needs and practices
 - Use original result cards as main building material or add them as appendices? Both options available?
 - How to deal with IPRs?



Module 4

Principles steering the utilization of the HTA Core Model and core HTA information



Guidance documents

- Policy for the HTA Core Model and core HTA information
 - Divided into 5 sections:
 - HTA Core Model
 - Production of core HTA information
 - Publishing of core HTA information
 - Storage and availability of core HTA information
 - Retrieval and utilization of core HTA information
 - **Addition 2016: A new set of "Guiding principles of use" were agreed on for the HTA Core Model. These are included in the policy and licence documents.**
- Terms of Use
 - Two licenses: non-commercial and commercial (**Addition 2016: The two licences were combined into a single licence at the end of Joint Action 2, and the document title is now "Licence" instead of "Terms of Use"**)
 - Certain uses require registration (**Addition 2016: Now all use requires registration**)
 - Limited to HTA Core Model (not core HTA information)
- HTA Core Model® is a registered trade mark (CTM, community trade mark)



Module 5

Terms of Use of the HTA Core Model



Terms of Use

- HTA Core Model ® is a registered trade mark (CTM, community trade mark)
- Terms of Use originally crafted in 2008
- All commercial use originally prohibited
- During JA ExCo outlined that commercial use should be allowed
- New version of ToU developed parallel to policy development within WP8 of JA2
- Two licenses: non-commercial and commercial
- Certain uses require registration
- Limited to HTA Core Model (not core HTA information)
- **Addition 2016: The non-commercial and commercial licences were combined into a single licence at the end of Joint Action 2. Also, now all use requires registration.**



Different use purposes/settings

Purpose/Setting	License	HTA Core Model Online – Production	HTA Core Model Online – Publication
EUnetHTA member agency produces HTA information	NC	Yes	Yes
HTA agency (not EUnetHTA member) produces HTA information	NC	Yes	No
More?			

Thank you

Any questions?

This presentation arises from the EUnetHTA Joint Action 2 which has received funding from the European Union, in the framework of the Health Programme

