Future model of HTA cooperation: Development of the White Paper

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Background

- Objective 1.2 in the EUnetHTA JA3 Grant Agreement is to support voluntary cooperation between HTA agencies by providing the scientific and technical mechanism of a permanent European cooperation on HTA.

- To meet this objective EUnetHTA WP1 initiated a piece of work to develop the underlying scientific and technical principles for a future model of HTA cooperation.

- Two key stages:

  - Production of a RoadMap that describes the elements of a model that have already been defined within JA3, the elements that could be improved or are missing and identifying next steps.

  - Production of a White Paper, defining the scientific and technical principles for future HTA cooperation, referring to the elements in the RoadMap.
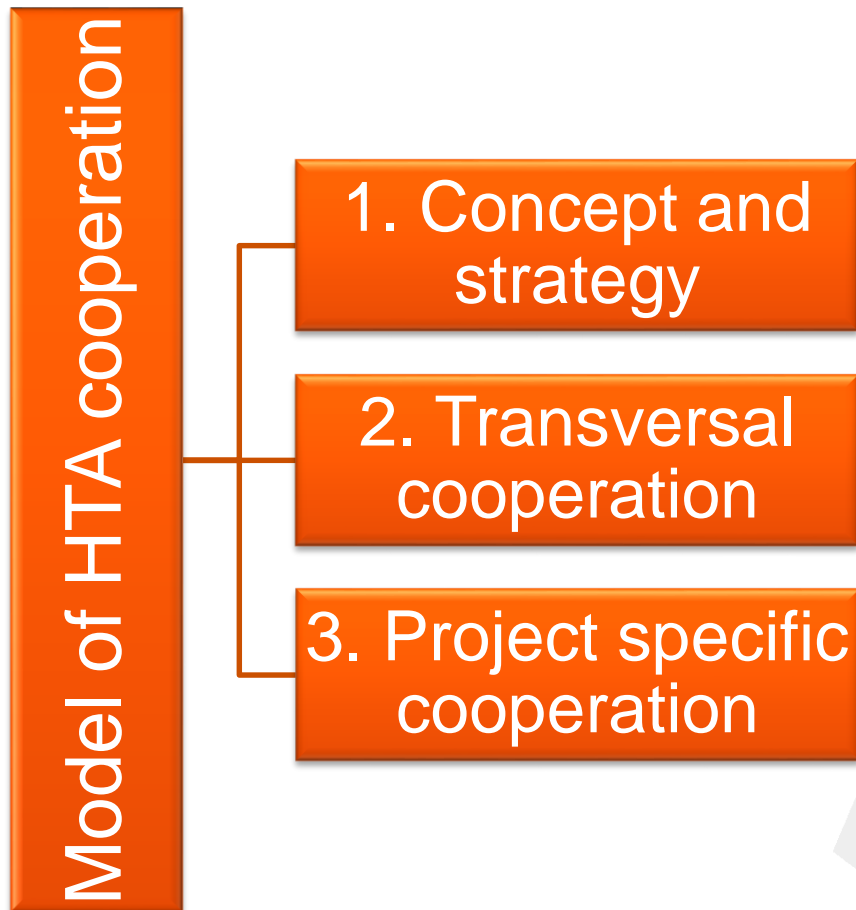
Status of the work

- Completed RoadMap

- Production of the RoadMap involved a 17 member task group with discussion groups in the Executive Board and Project Managers Group and consultation with EUnetHTA partners

- The RoadMap uses a simple thematic framework, to

    - list existing documents and tools,

    - identify missing elements, and

    - identify and prioritise areas for improvement.

- Final stage of the work is to transform the RoadMap into a White Paper.

- This final stage of the work has been taken into the Executive Board and the original task group has been stood down.

The White Paper

- The White Paper will be based on the Road Map and also incorporates findings from existing or in progress documents produced by EUnetHTA

- Aim to compile the outputs of EUnetHTA JA3 into a document that describes in a single framework the way we worked, what we have achieved, what we have learnt and what we recommend for the future

- Signposting for those taking HTA cooperation forward:

  - The most relevant documents and tools from JA3

  - The areas of alignment and agreement

  - The areas of disagreement and reasons why

  - The areas requiring further work

FMC White paper general structure

Model of HTA cooperation

- 1. Concept and strategy
- 2. Transversal cooperation
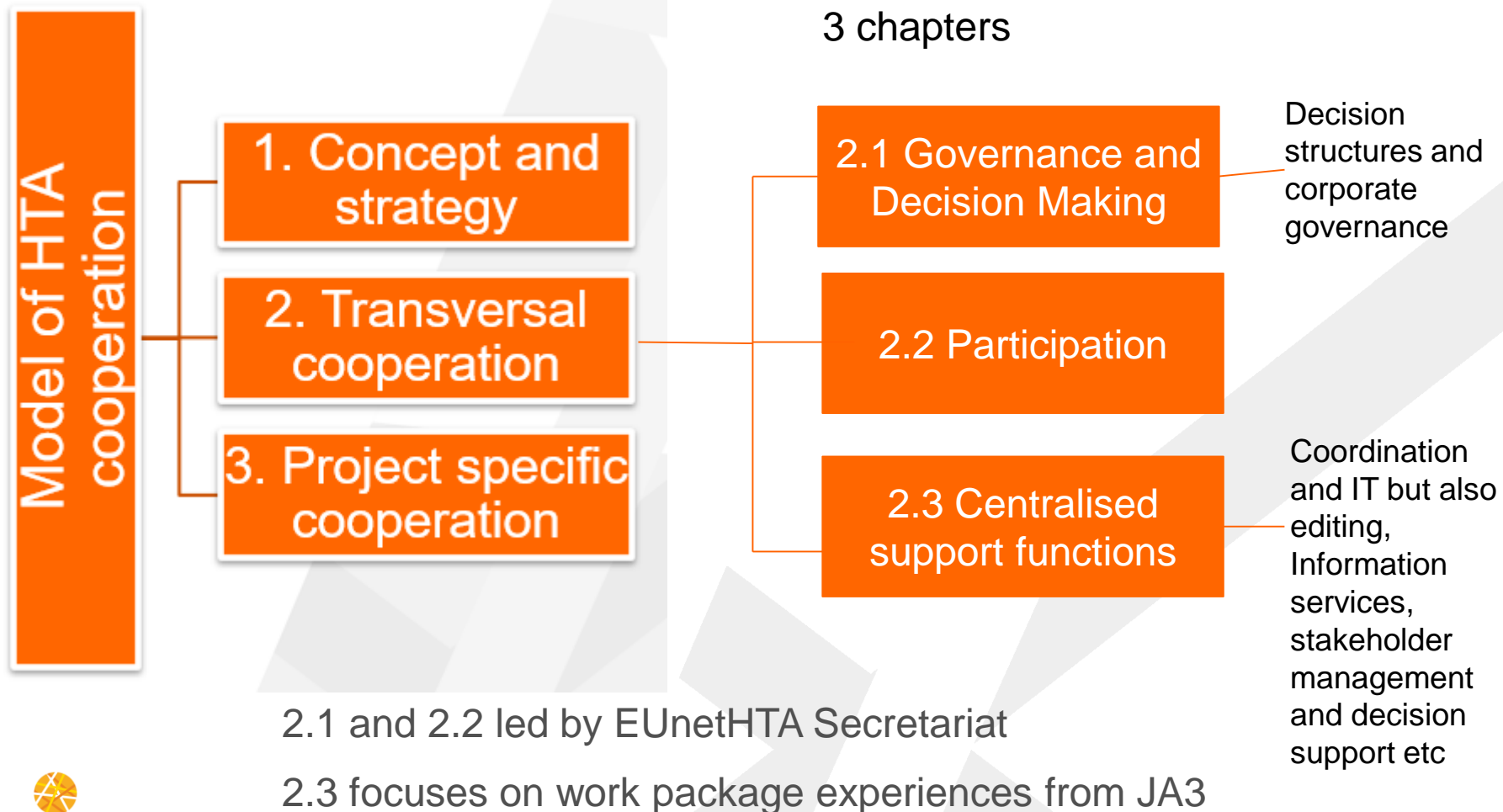- 3. Project specific cooperation

- Transversal cooperation = elements going across HTA activities

- Project specific cooperation = organised around core outputs ED, JA/CA and PLEG

- Explicit signposting of the inter-relationship between sections

  - Underlying rules and principles in section 1 should be reflected in cooperation structures in sections 2 and 3

  - Transversal elements (section 2) and project specific elements (section 3) should be mutually supportive

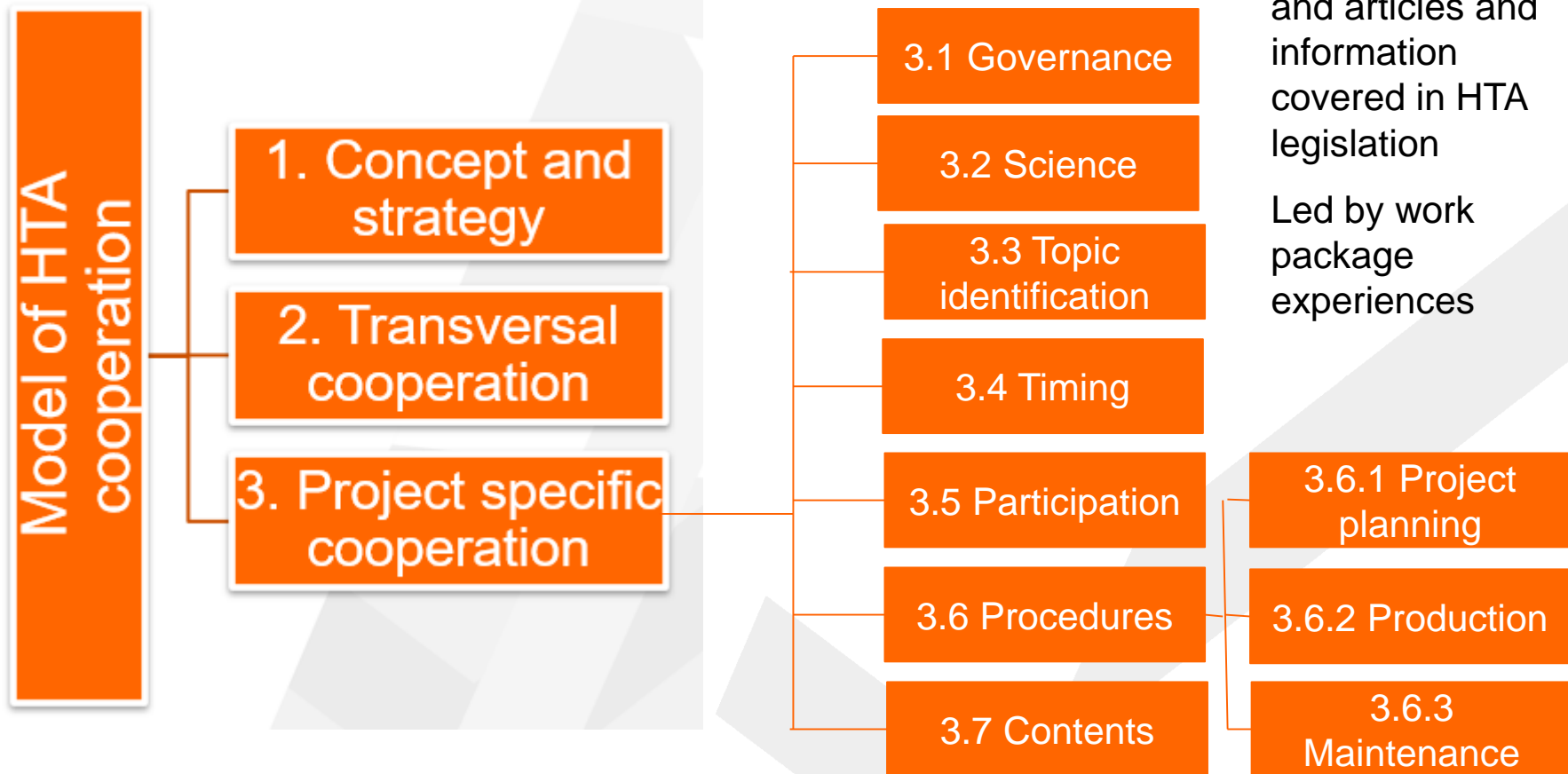# 1. Concept and Strategy

- One chapter, covering:

  1. Description of the core outputs: ED, JA, CA, PLEG

  2. Links between activities and rationale why these activities as a set are important in HTA cooperation

  3. Future expansion beyond core outputs to meet further needs

  4. General rules/principles underlying HTA cooperation

- Work included in this chapter has been led by the Executive Board

2. Transversal cooperation

3 chapters

Model of HTA cooperation

1. Concept and strategy

2. Transversal cooperation

3. Project specific cooperation

2.1 Governance and Decision Making — Decision structures and corporate governance

2.2 Participation

2.3 Centralised support functions — Coordination and IT but also editing, Information services, stakeholder management and decision support etc

2.1 and 2.2 led by EUnetHTA Secretariat

2.3 focuses on work package experiences from JA3

3. Project specific cooperation

7 chapters

Broadly map to RoadMap issues and articles and information covered in HTA legislation

Led by work package experiences

Model of HTA cooperation

- 1. Concept and strategy
- 2. Transversal cooperation
- 3. Project specific cooperation
  - 3.1 Governance
  - 3.2 Science
  - 3.3 Topic identification
  - 3.4 Timing
  - 3.5 Participation
  - 3.6 Procedures
    - 3.6.1 Project planning
    - 3.6.2 Production
    - 3.6.3 Maintenance
  - 3.7 Contents

Common structure for each cooperation chapter (sections 2 and 3)

1. Key documents EUnetHTA has produced

2. Summary of JA3 ways of working

3. Lessons learnt

4. Recommendations for a future model

5. Recommendations for future work

Development of general rules underlying HTA cooperation

Concept and Strategy prioritised further work

Background

- While the RoadMap was being prepared the Executive Board identified that further work was needed to define general rules underlying a future model of HTA cooperation, for example transparency, confidentiality etc

- General rules = Shared rules and principles that should guide the joint outputs created and/or how the network functions

- Provides an explicit reflection point and a guide to elaborating elements

  - when an element of a model is elaborated, the proposal can be checked against the extent to which it meets the shared rules and principles – adjustments made or reasons for different approach made explicit

Areas where general rules are being developed

Independence and Conflicts of interest
Transparency and Confidentiality
Communication
Evidence and Data inclusion in HTA
Involvement (internal, external, interactions between parties)
Relevance (topic identification) – what makes a project of value
Relevance (scope) – what makes a European scope
Use and Usability – how far should joint HTA go?
Quality systems approach
Timeliness
Review [up to date-ness]
Fairness of procedure

Developing the rules – ongoing work

1. The principles

   - For each area 1-3 fundamental principles that you would expect to see underpinning a model of HTA cooperation

2. Importance of these principles for HTA cooperation

3. Key learnings for developing a model of HTA cooperation

   - Any JA3 or personal learnings that should be highlighted in the White Paper

4. Recommendations to support implementation of these principles

   - Structures and processes to support implementation of the principle in a model of HTA cooperation

Hypothetical example 1: Elements should thread through the White Paper sections

Concept and strategy articulates the rule/principle underlying HTA cooperation

- HTA should be a participatory process

One aspect of implementing this in project specific cooperation is that:

- The procedures for producing all HTA outputs (ED, JA/CA, PLEG) should normally include an explicit patient and clinical expert contribution

The learning from JA3 is that to implement this at a project specific level requires transversal cooperation structures and processes:

- Personnel to support expert identification and engagement

- IT tools to manage stakeholder information

- Corporate governance policies: conflicts of interest and information governance

Importance for including these in a model - without these transversal cooperation elements, project specific cooperation is less successful meaning that HTA cooperation may not address the underlying participatory principle

Next steps

Timetable for the final White Paper

Stage	Timing
Executive Board carrying out some prioritised work from Road Map relating to strategy and governance	Sep – Dec 2020
WP final documents and deliverables	Mid Oct 2020
Drafting White Paper	Oct – Dec 2020
Executive Board January – Review of draft White Paper, discussion and decision on need for further additional work	Jan 2021
Partner and stakeholder consultation on White Paper	March 2021
Final White Paper	May 2021