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Current Trends in Clinical Endpoint Evaluation Used for Relative Effectiveness Assessments of Pharmaceuticals in Context with EUnetHTA

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The HTA perspective

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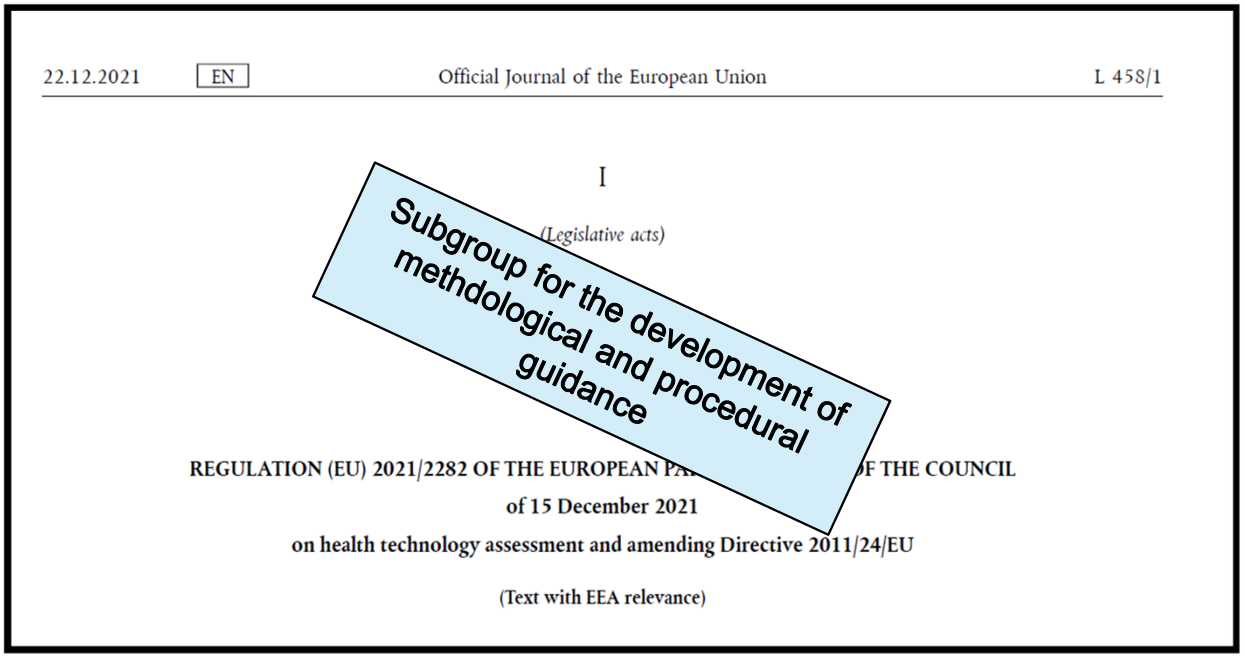
Disclosure:

No interests to disclose

Agenda

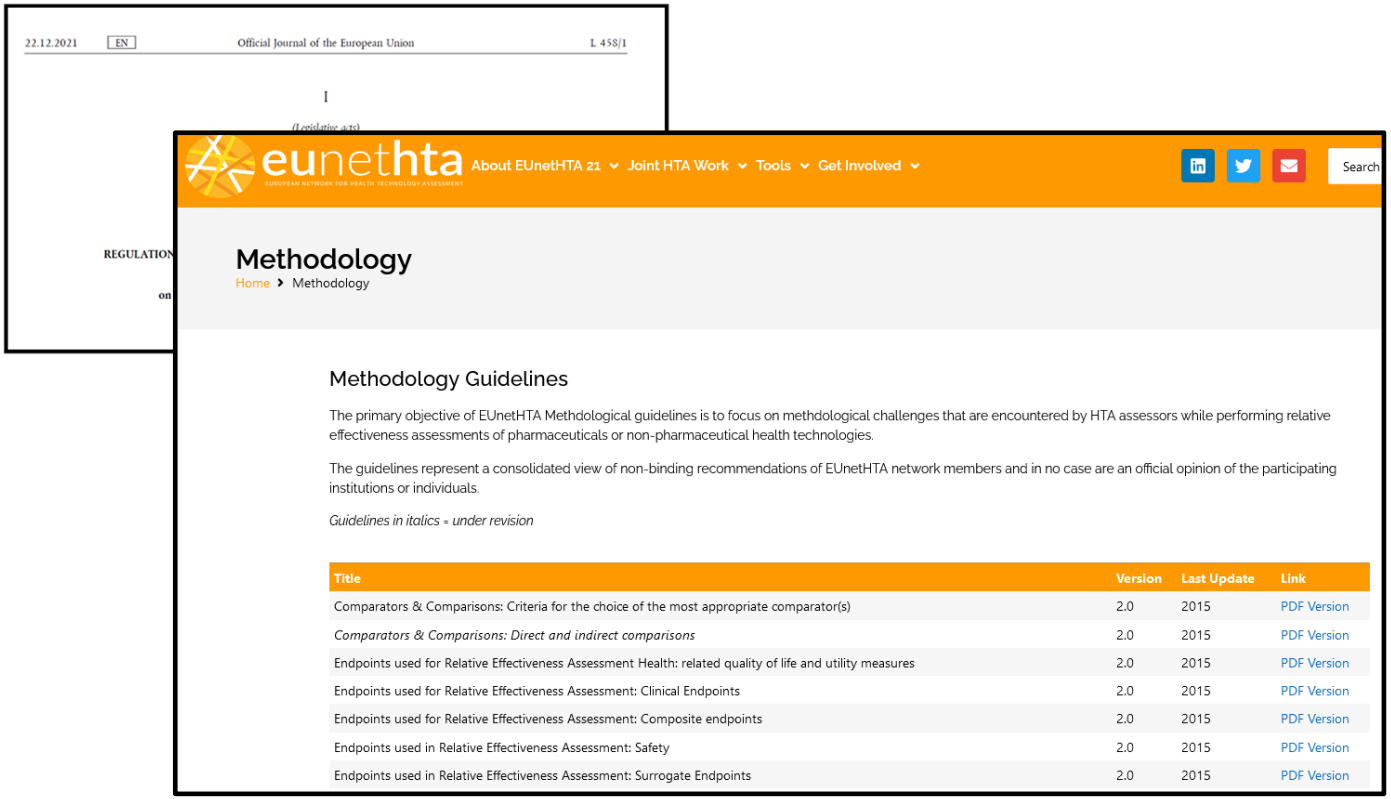
- Types of endpoint guidance for European HTA
- Requirements of the HTA Regulation concerning endpoints
- Methods guidance on endpoints

Endpoint guidance for the European HTA (1)



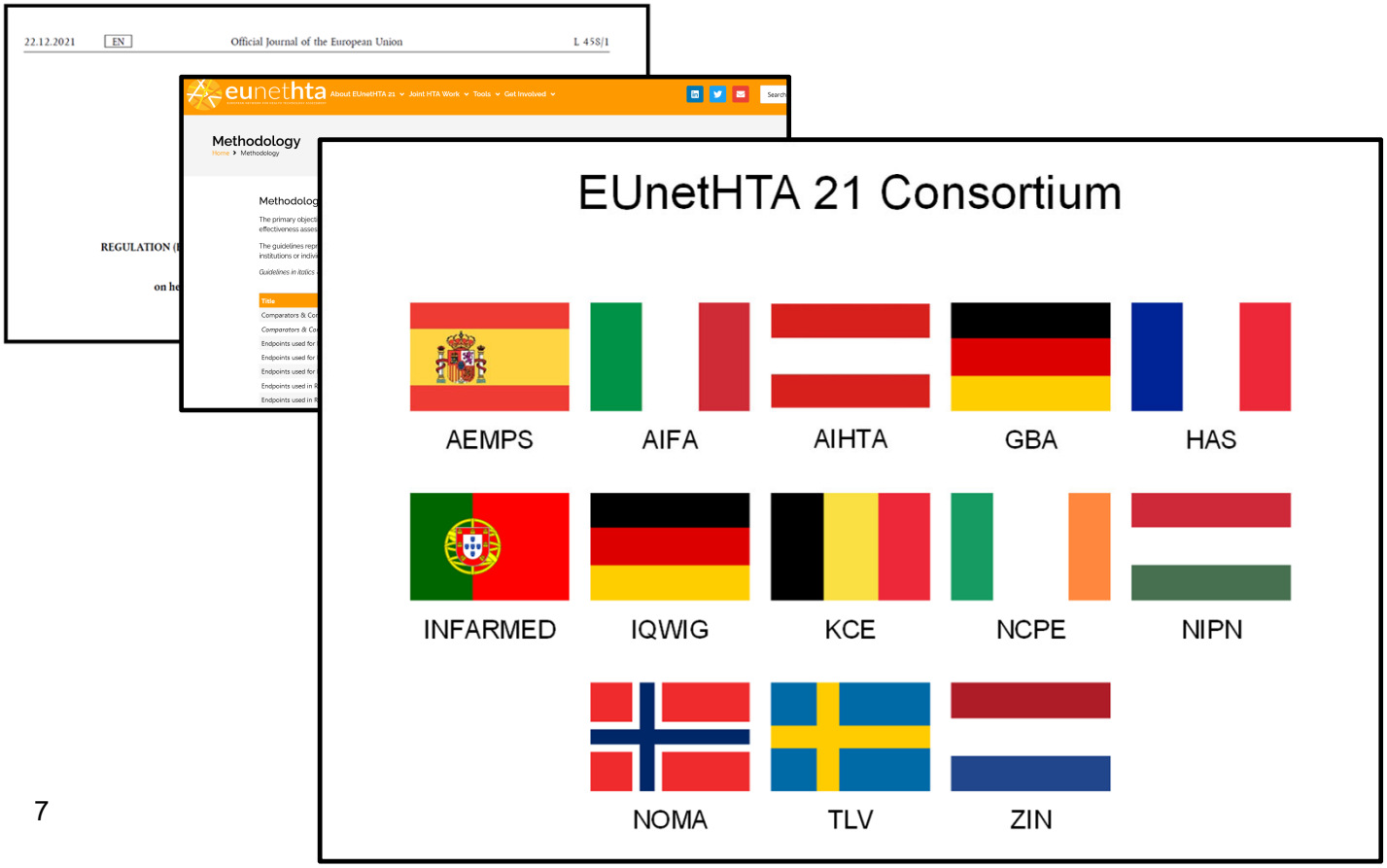
- The HTA Regulation
  (Regulation (EU) 2021/2282)

Endpoint guidance for the European HTA (2)



- The HTA Regulation
  (Regulation (EU) 2021/2282)
- Methodological Guidelines from Joint Actions

Endpoint guidance for the European HTA (3)



- The HTA Regulation (Regulation (EU) 2021/2282)
- Methodological Guidelines from Joint Actions
- Methodological Guidelines from EUnetHTA 21

Endpoint guidance for the European HTA (3)

- The HTA Regulation
  (Regulation (EU) 2021/2282)
- Methodological Guidelines from Joint Actions
- Methodological Guidelines from EUnetHTA 21

Requirements from the HTA Regulation

- The Joint Clinical Assessment (JCA) should address relative effectiveness and relative safety
- The JCA shall not contain any value judgement or conclusion on the overall clinical added value of the technology under assessment
- The assessment scope shall be inclusive and reflect Member States‘ needs in terms of the P(opulation) I(ntervention) C(comparator) O(utcomes)
- The JCA report should be factual and should not contain any value judgement, ranking of health outcomes …
- Member States shall give due consideration to the JCA report …, this shall not affect MSs competence to draw their conclusions on the overall clinical added value in the context of their specific healthcare system

Methodological guidance from Joint Actions

Endpoints used for Relative Effectiveness Assessment Health: related quality of life and utility measures	2.0	2015	PDF Version
Endpoints used for Relative Effectiveness Assessment: Clinical Endpoints	2.0	2015	PDF Version
Endpoints used for Relative Effectiveness Assessment: Composite endpoints	2.0	2015	PDF Version
Endpoints used in Relative Effectiveness Assessment: Safety	2.0	2015	PDF Version
Endpoints used in Relative Effectiveness Assessment: Surrogate Endpoints	2.0	2015	PDF Version

https://www.eunethta.eu/methodology-guidelines/

Methodological guidance from Joint Actions

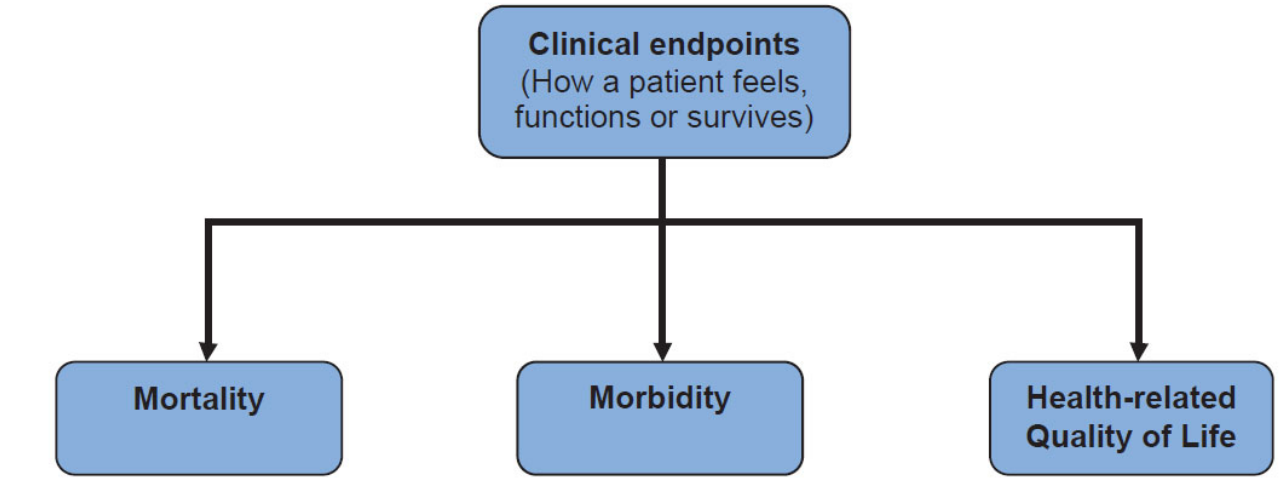
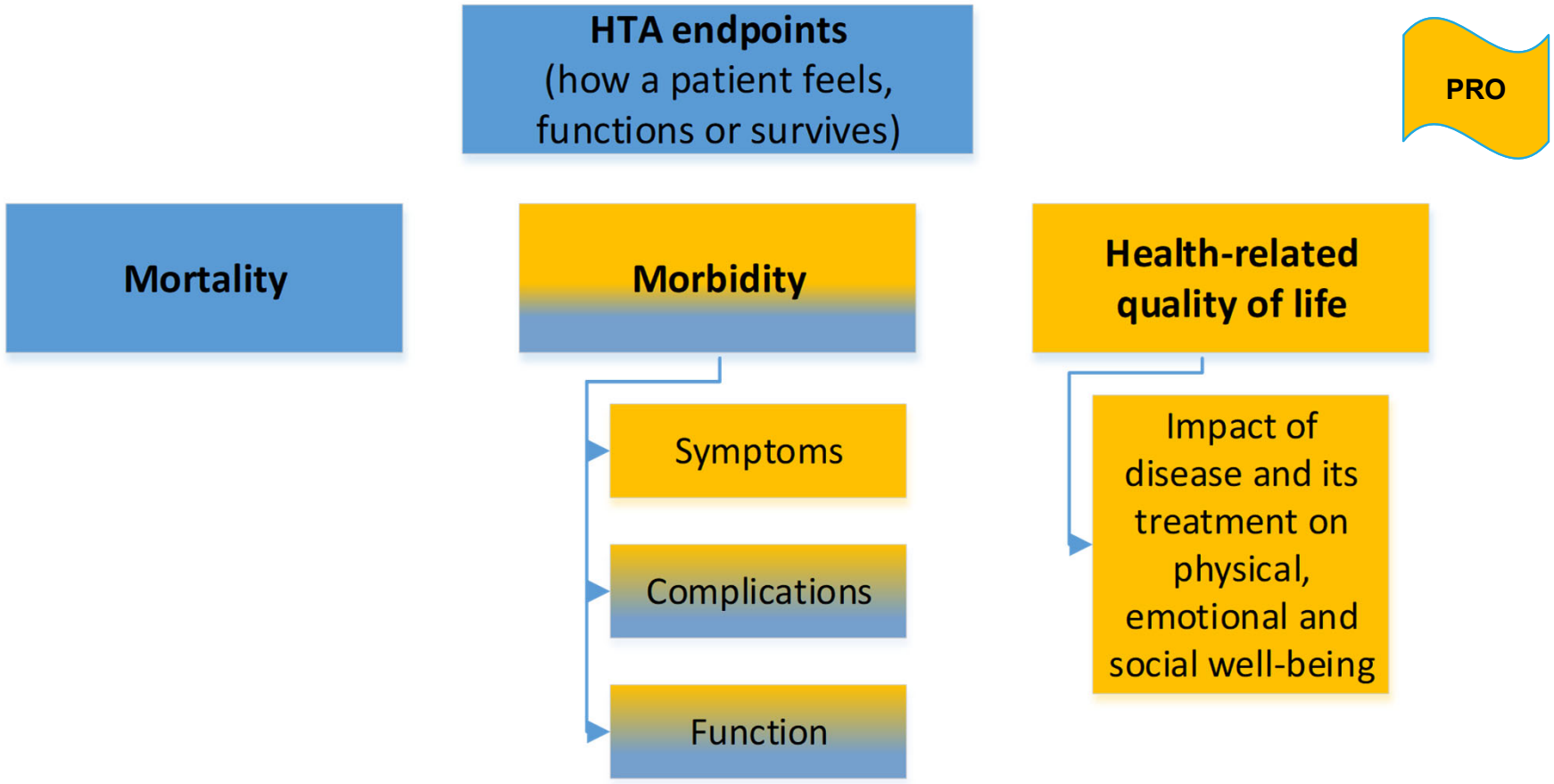


Figure 1. Endpoint domains.

EUnetHTA: Endpoints for relative effectiveness assessment: clinical endpoints (2015)


HTA endpoints
(how a patient feels, functions or survives)
PRO
Mortality
Morbidity
Health-related quality of life
Symptoms
Complications
Function
Impact of disease and its treatment on physical, emotional and social well-being

EUnetHTA 21 Endpoint Practical Guideline

- Aims to support endpoint definition by Member States within the scoping process

- Aims to support endpoint reporting in the Joint Clinical Assessment

EUnetHTA 21 Endpoint Practical Guideline

- Definitions of types of outcomes
  - patient-reported outcomes vs. clinician-reported outcomes vs. performance outcomes
- Aspects of clinical relevance of outcomes
  - concept of patient-centered outcomes
  - concept of core outcomes sets
  - need for validation of surrogate outcomes
- Endpoints to assess relative safety
  - description of relevant safety outcomes (overall rates and specific AEs)
- Specific requirements concerning outcomes measured via scales
  - validity and reliability
  - interpretability

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