

Synergies between ENCePP and Health Technology Assessment

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Joint Action

A total of 34 government appointed organisations from 23 EU Member States, Croatia and Norway and a large number of relevant non-for-profit organisations that produce or contribute to HTA

Main objective

to put into practice an **effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level**



EUnetHTA 2010-12: Work Packages

1. Coordination
2. Dissemination
3. Evaluation
4. Core HTA including adaptation
5. Relative Effectiveness Assessment (REA) of Pharmaceuticals
6. Information management system
- 7. New Technologies. Facilitating Evidence Generation and Collaboration on (Pre-coverage) Assessments**
8. Strategy development (Business model for sustainability including capacity building to do HTA)

Current situation

- Some new technologies (medicines, other HT)
 - Identified evidence gaps and need (common for several HTA bodies) for **additional evidence**
 - Data requirements: not clearly specified, not coordinated, not harmonised
 - **Multiple studies** with heterogeneous designs performed to answer similar requests
 - **Inconsistent results**
- Lack of critical mass of robust data to reduce uncertainty
- **Waste of time and money**



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Expected benefit from WP7

- **Update** information on new technologies and identify evidence gaps
- Update information on additional data requirements in the countries where the technology was assessed
- Possibility for **collaboration** to harmonise data requirements
- Studies (multinational or not) with **comparable** designs and outcomes
- Better **quality** information provided to decision makers at the time of the re-assessment



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Action Plan - Objectives

- Define **criteria** for selection of technologies that need additional evidence generation
- **Share** information (database) on new technologies
 - Evidence gaps
 - recommendation for additional data collection (research question, type of study),
 - HTA guidance and coverage and reimbursement status
- **Registry** of planned or ongoing clinical studies
 - PICO structure
 - **Minimum dataset development**



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Deliverables

- **Criteria**

- to select, among new technologies, the ones for which additional data collection will be useful and efficient

- **Database**

- User friendly IT functionalities
- Visual structure with rapid information access



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Perspectives

- Standardisation of further **research recommendations** in HTA reports
- **Facilitating** collaboration between sponsors/funders on agreed core protocols for a technology of interest
- Effective collaboration to set up **policy relevant studies**
 - Individual studies based on common core protocols
 - Multinational studies



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EVIDENT Database

- content: **information on**
 - health technologies (assessment status, evidence gaps, research questions, required additional studies, coverage decision status)
 - **planned studies** (a minimum information necessary for establishing collaboration: **PICO, protocols, results of studies, etc;**)
- scope:
 - **all** types of **technologies** (drugs, devices, procedures)
 - studies **requested by European HTA bodies** following a HTA,
 - studies still in the development phase
- goal: **support European collaboration and help avoiding duplication of studies, promote global analysis of results (critical mass of consistent data)**



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EVIDENT

vs.

ENCePP

(register of studies)

Scope

- all types of **technologies** (drugs, devices, procedures)
- studies **requested by European HTA bodies** following a HTA,
- studies still in the development phase
- Restricted access
- **Only** drugs
- **Any** pharmacoepidemiology and pharmacovigilance studies
- **Any** phase of the study
- **Public** access

Partial overlap of studies intended to be registered



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EVIDENT vs. ENCePP

content

- **information on**
 - health technologies (assessment status, evidence gaps, research questions, required additional studies, coverage decision status)
 - **planned studies** (a minimum information necessary for establishing collaboration: **PICO, protocols, results of studies, etc;**)
- **information on**
 - planned **and ongoing** studies
 - **identification of the drug, the sponsor, the investigator, etc...**
 - **description of the study design, the study progress and the results**



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Collaboration EVIDENT/ENCePP

- **First steps:**
 - Participation of ENCePP Public consultation on Evident
 - ENCePP representative attending the next WP7 Face to Face meeting next september
- **Further development:**
 - Encapsulated search on ENCePP through EVIDENT
 - Alert in EVIDENT on new studies being entered in ENCePP
 - Access to EVIDENT for ENCePP members to be discussed



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