EUnetHTA Output

EUnetHTA Tools

EUnetHTA **HTA Core Model Online**

EUnetHTA **Planned and Ongoing Projects Database (POP)**

EUnetHTA **Evidence database on new technologies (EVIDENT)**

EUnetHTA **Adaptation Glossary & Toolkit**

EUnetHTA **Contact Database**

EUnetHTA **Intranet Groups**

EUnetHTA **E-meeting facility**

EUnetHTA **News Aggregator**

The POP Database

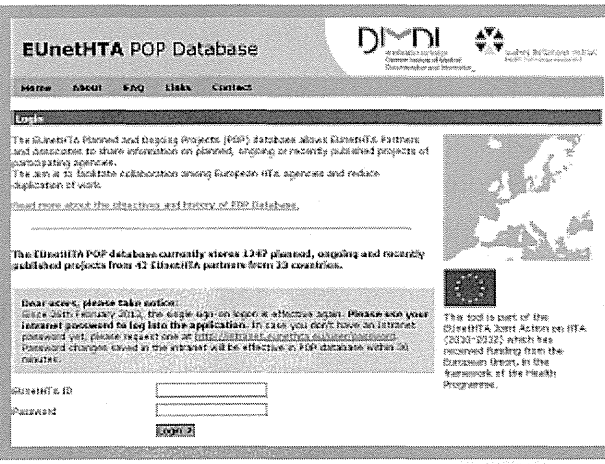
Description

The EUnetHTA Planned and Ongoing Projects (POP) database allows EUnetHTA Partners and Associates to share information on planned, ongoing or recently published projects of participating agencies and identify similar projects through a matching system provided by the online database.

Purpose

To facilitate collaboration among European HTA agencies and reduce duplication of work.

The POP Database Online



Access to the POP Database : http://eunethta.dimdi.de/PopDB/

POP Statistics: Quarterly Updates

In Spring 2014, POP Database contained: 1,230 planned, ongoing and recently published projects from 44 EUnetHTA JA partners and 24 countries

(Jan/March 2014) POP Request

Out of 63 EUnetHTA JA partners:

- 28 responded and entered/updated projects in the database
- 11 responded but DID NOT feed the database
- 24 did not respond at all (38%)
- Total number of projects: 1,219
- Alert (SAME) topics: 101 (8%)
- Similar projects (within alert topics): 249
- Access-rights: 41 partners

(Jan/March 2014) POP Request

Out of 68 EUnetHTA JA partners:

- 35 responded and entered/updated projects in the database
- 8 responded but DID NOT feed the database (no current changes in the projects)
- 25 did not respond at all (37 %)
- Total number of projects: 1,216
- Alert (SAME) topics: 103 (8 %)
- Similar projects (within alert topics): 247
- Access-rights: 46 partners

The EVIDENT Database

Description

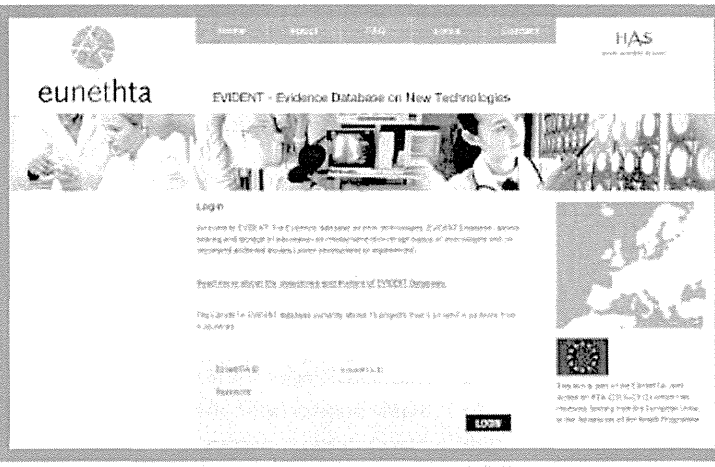
The EVIDENT Database enables sharing early information on evidence gaps identified during the production of HTA reports and consequent recommendations / requests for additional data collection.

It also contains information on reimbursement / coverage and assessment status of promising technologies in Europe.

Purpose

To reduce redundancy, promote generation of further evidence and facilitate European collaboration in the domain.

The EVIDENT Database Online



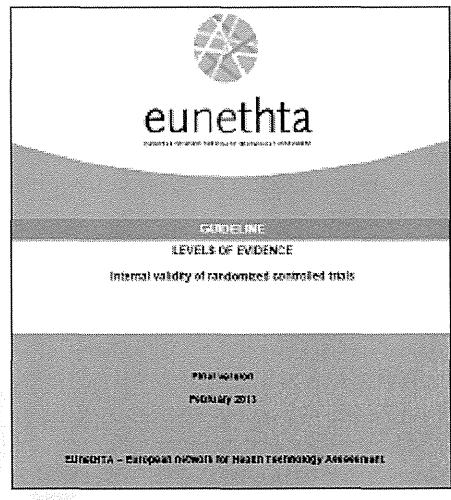
Access to the EVIDENT Database: https://evident.has-sante.fr/has/login.xhtml

9 Methodological Guidelines for Rapid REA

Development
9 Methodological Guidelines for Rapid REA of Pharmaceuticals developed in JA1 by WP5.

Content
Guidelines on methodological challenges that are encountered by health technology assessors while performing a rapid relative effectiveness assessment of pharmaceuticals.

Primary Aim
To help the assessors of evidence interpret and process the data that are presented to them as part of a REA.



9 Methodological Guidelines for Rapid REA

Endpoints used for REA of pharmaceuticals

1. Clinical endpoints
2. Composite endpoints
3. Surrogate endpoints
4. Safety
5. Health-related quality of life

Comparators and comparisons

6. Criteria for the choice of the most appropriate comparator(s)
7. Direct and indirect comparison

Levels of evidence

8. Internal validity
9. Applicability of evidence in the context of a relative effectiveness assessment

Link to the guidelines

http://www.eunethta.eu/eunethta-guidelines

External Collaboration

EUnetHTA-EMA Collaboration

- To identify opportunities for and undertake specific steps to improve the efficiency of the process and conditions for patients' timely access to an effective medicine.

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EUnetHTA-EMA Collaboration

- Scientific advice/early dialogues involving regulators and HTAs
- Scientific and methodological guideline development
- Post-licensing (post-authorisation) data generation
- Availability of clinical study data
- Orphan medicinal products
- Cooperation in specific pilot projects of EUnetHTA JA2
- Conferences, workshops and seminars/meetings

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Conflict of Interest and Confidentiality handling

Background:

- Necessity to standardise across JA2 WPs managing pilots on specific technologies
- No information on the presence of formal policies and procedures in a substantial number of EUnetHTA organisations
  - Diversity of the extent, thoroughness and specific practice of implementation in various organisations – need for a standard policy and procedures for a European level activity
- Concrete experience in JA2 pilots indicated the necessity to have a standard EUnetHTA CoI and Confidentiality handling procedures

Conflict of Interest and Confidentiality handling

Specific procedures proposal:

- Obligation to inform on the availability of the CoI and confidentiality policies and procedures in the partner/associate institutions once they apply for joining EUnetHTA
  - LPs and Co-LPs informed on the availability
  - Status of availability publicly announced on the EUnetHTA website
- DOICU form to be completed by each individual participating in JA2 prior to commencing any work in WP4 and 5 pilots
- DOICU form to be provided to the individuals by the WP4 and 5
  - Completed form to be returned to the respective WP LPs/Co-LPs AND the EUnetHTA Secretariat
  - Info valid until the individual's Conflict of Interest situation changes
  - EUnetHTA secretariat sets up a database for the DOICU issues. LPs and Co-LPs are to consult the database prior to requesting completion of the form by individuals (to avoid multiple declarations)

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

HTA 2.0 Europe

4）pCODE（カナダ）

< Questionnaire to Health Technology Assessment (HTA) Agencies>

カナダでは抗癌剤をどこが funding するかは下記のように州によって異なっている。

	病院	Cancer Agency	Drug plan
ブリティッシュ・コロンビア		○	
アルバータ		○	
サスカチュワン		○	
マニトバ		○	○
オンタリオ	○	○	○
ニューブランズウィック	○		○
プリンスエドワードアイランド	○		○
ノバスコシア	○		○
ニューファンドランド・ラブラドール	○		○

1 Please describe the annual budget in your organization, department and division of economic evaluation.

1.1 How much amount of the annual budgets do you set up for pCODR?

年間 200 万カナダドル(約 1.9 億円)、CADTH 全体では 3500 万カナダドル(約 33 億円)である。

1.2 Does funding come from the central/local government, pharmaceutical companies (or industry groups) and/or others?

・ According to your web site, pCODR is funded by provinces and territories. Do you have other funding sources?

財源は州(province)からのみ。CADTH は連邦政府からの資金も含まれる。

1.3 Who will cover the cost incurred for a review process (e.g. pharmaceutical companies pay for the cost)

財源 2015 年 4 月より、レビュー1 件あたり 72,000 カナダドル(約 700 万円)、適応拡大等の場合は 57,000 カナダドル(約 550 万円)を企業が支払う。ただし、cancer agency 等が提出する場合は、費用は免除されている。
レビュー1 件あたりにかかる費用はおよそ 10 万~14 万カナダドル程度。

2 Please describe the number of stuff of your organization, department and the division of economic evaluation.

2.1 How many health economists and other experts work for pCODR as staff?

職員としては 11 人、医療経済学を専門としているものはいないが、臨床疫学者が 3 名いる。ただし、医療経済学者は 20 名、臨床家/臨床疫学者は 50 名からなる外部の専門家パネル(Economic Guidance Panel, Clinical Guidance Panel)を持っている。

3 Please describe an economic evaluation method of healthcare technologies that are utilized in your country.

3.1 Please describe the scope of the technologies to be assessed.

- Are all anti-cancer (inpatient and/or outpatient) drugs assessed by pCODR?
- Do you re-evaluate of drugs in post-marketing phase?

外来薬と病院薬をともに評価する。市販後の再評価(複数の薬剤の同時評価)について、現在は実施していないが、将来は検討している。
ただし、支持療法の評価は CADTH で実施している。

3.2 When performing an economic evaluation, who is responsible for analyzing data and developing the models? (e.g. manufactures, independent academic groups, pCODR)

pCODR には、製薬企業、tumor group(医師のグループ)、各州の cancer agency が提出できる。提出者がレビュープロセスに必要な情報を提供する。