

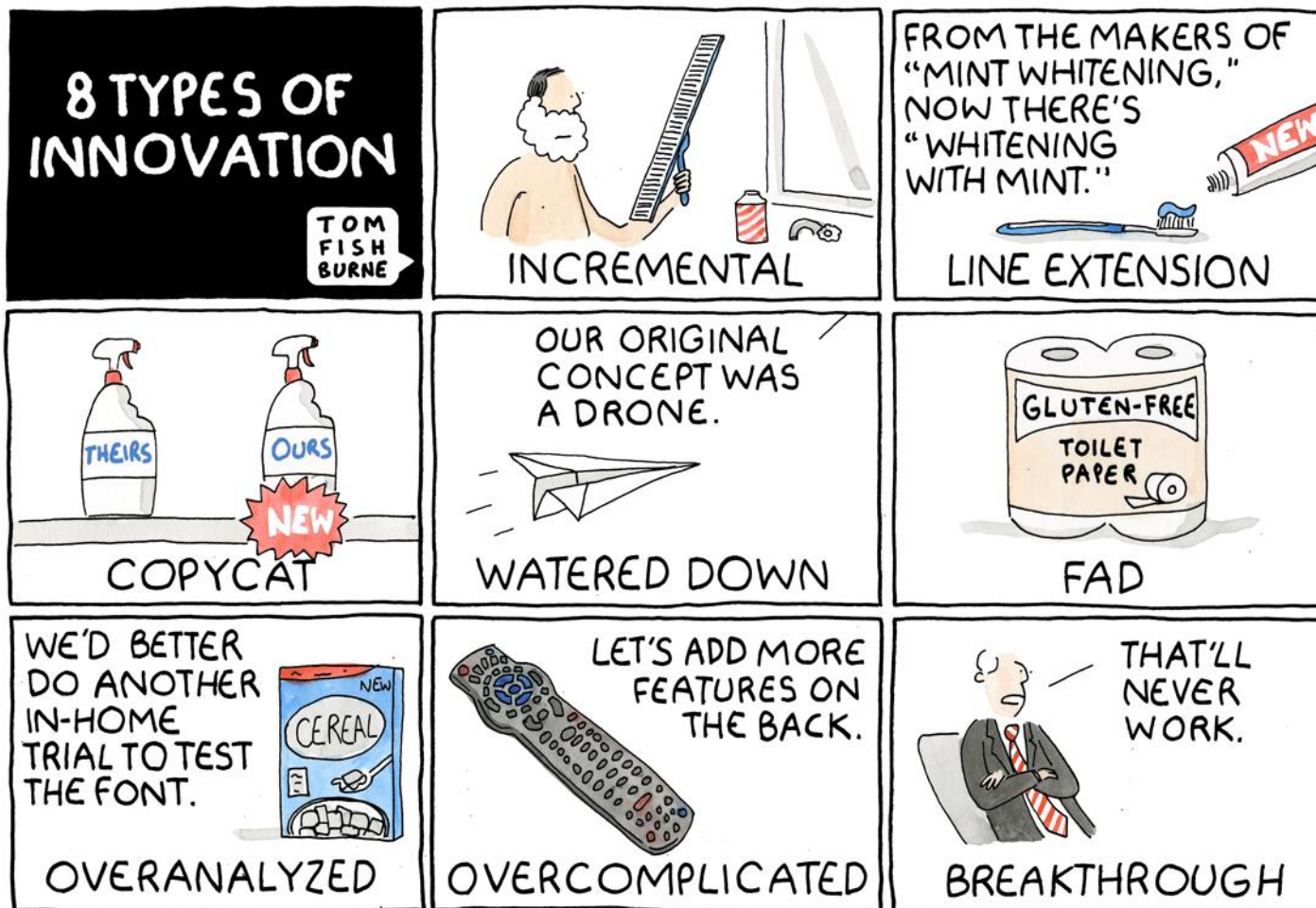
JAZMP in EUnetHTA

8. STRATEŠKA KONFERENCA VREDNOST INOVACIJ

Dr. Andrej Janžič, JAZMP



Inovacije in njihova vrednost

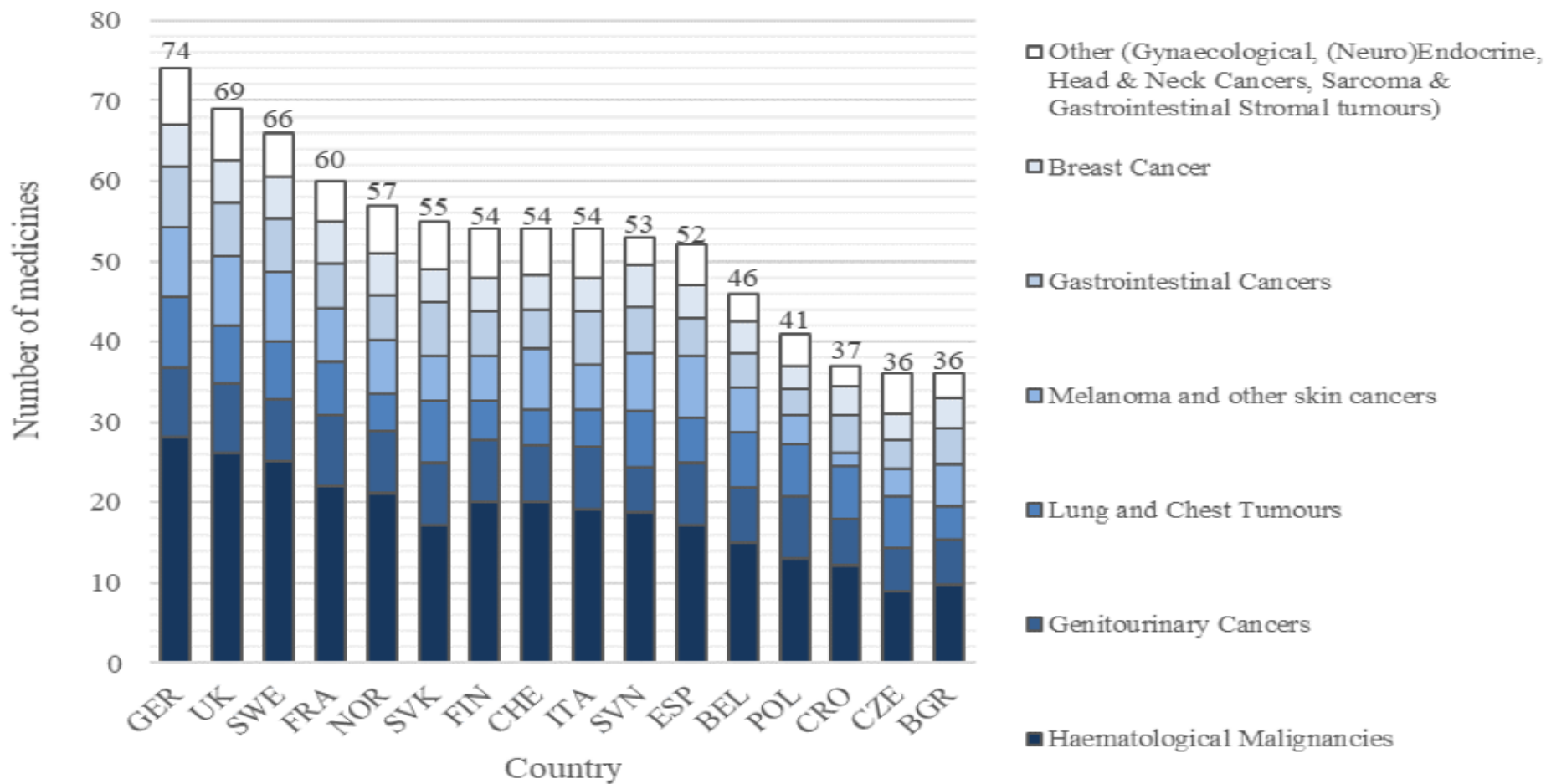


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Dostop do zdravil

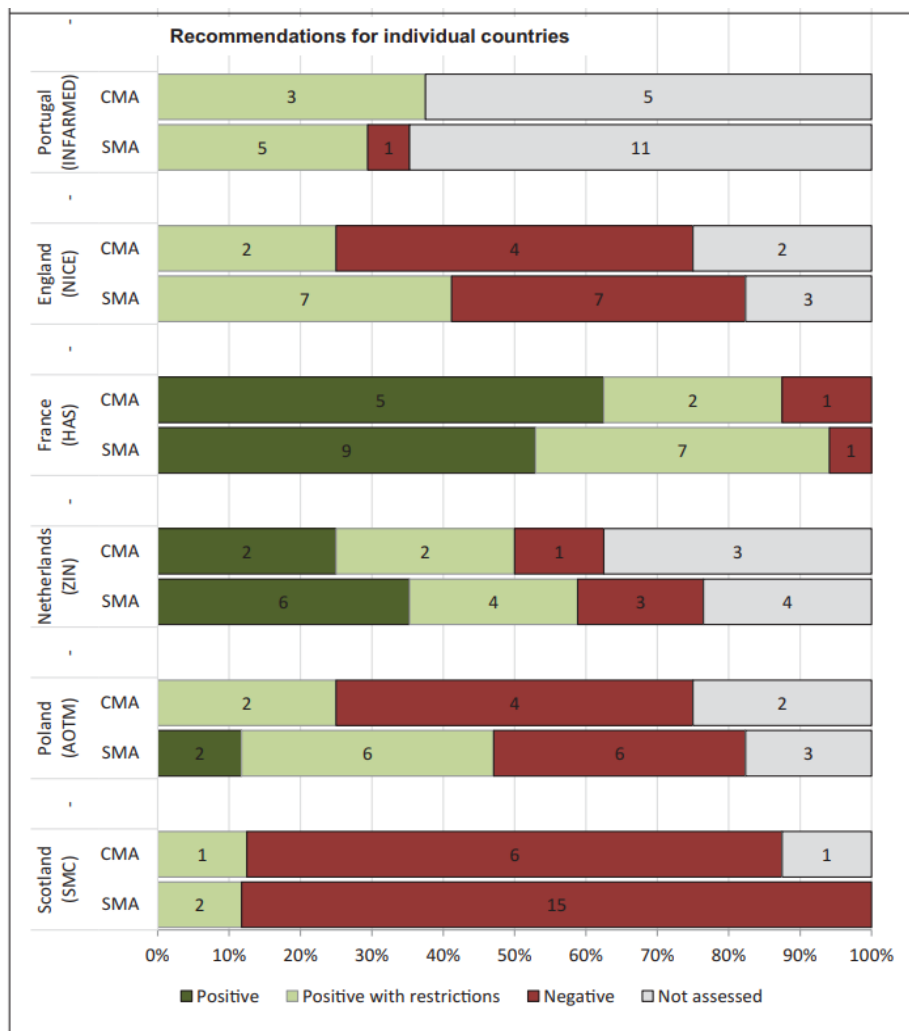


Število zdravil v kontinuirani uporabi



VIR: Detiček A. Umeščanje in dostop pacientov do inovativnih zdravil za zdravljenje redkih bolezni v Sloveniji, doktorska disertacija, 2019.

Odločitve NCA



Health technology assessment outcomes for conditional marketing authorization (CMA) vs. standard marketing authorization (SMA) for all jurisdictions included in the study.

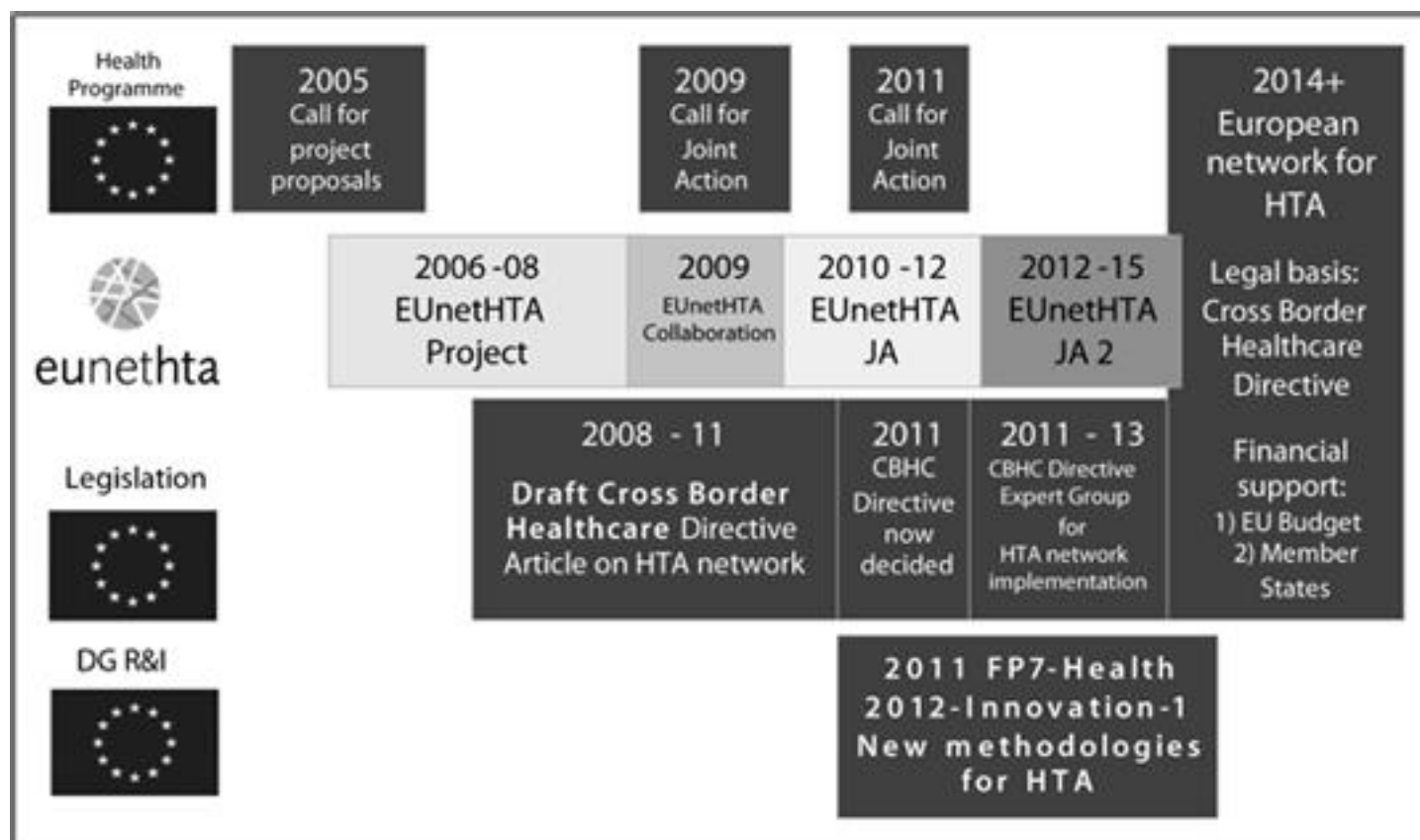
VIR: I Lipska et al. Does conditional approval for new oncology drugs in Europe lead to differences in health technology assessment decisions? Clin Pharmacol Ther. 2015 Nov;98(5):489-91.



- 2004 - Evropska Komisija in Svet ministrov opredelijo HTA kot „politično prioriteto“ s prepoznanjem o „nujno potrebnem trajnostnem evropskem omrežju HTA“.



- Shema iz leta 2012:



VIR (I.2012): Development of European HTA: from Vision to EUnetHTA" (Michael 2012;9: 147–156).



- Evropska mreža organizacij na področju HTA
- **Osnovni namen projekta JA3 je definirati in implementirati vzdržen model za znanstveno in tehnično sodelovanje na področju HTA v Evropi**
- Temelji na prostovoljnem sodelovanju nacionalnih in regionalnih organizacij, ki so tako ali drugače povezane z HTA
- Deluje v okviru „Zdravstveni program EU“ (Health Programme), s tem je delno financiran iz EU sredstev
- Osnova za vzpostavitev mreže: Direktiva 2011/24/EU (o uveljavljanju pravic pacientov pri čezmejnem zdravstvenem varstvu) → **Sodelovanje pri ocenjevanju zdravstvenih tehnologij** (15. člen)
- Mreža HTA gradi na izkušnjah iz prejšnjih ukrepov na področju ocenjevanja zdravstvenih tehnologij, ki jih podpira Unija, in skrbi za ustrezne sinergije s sedanjimi ukrepi.



- Trajanje: 2016-2020 (→ 2021)
- Sodelujoč institucije:

EUnetHTA JA3 Participants

81 partners consisting of national, regional and non-for-profit agencies that produce or contribute to HTA

Project Coordinator:
Dutch National Health Care Institute (ZIN)



European network for Health Technology Assessment | JA3 2016-2020 | www.eunetha.eu

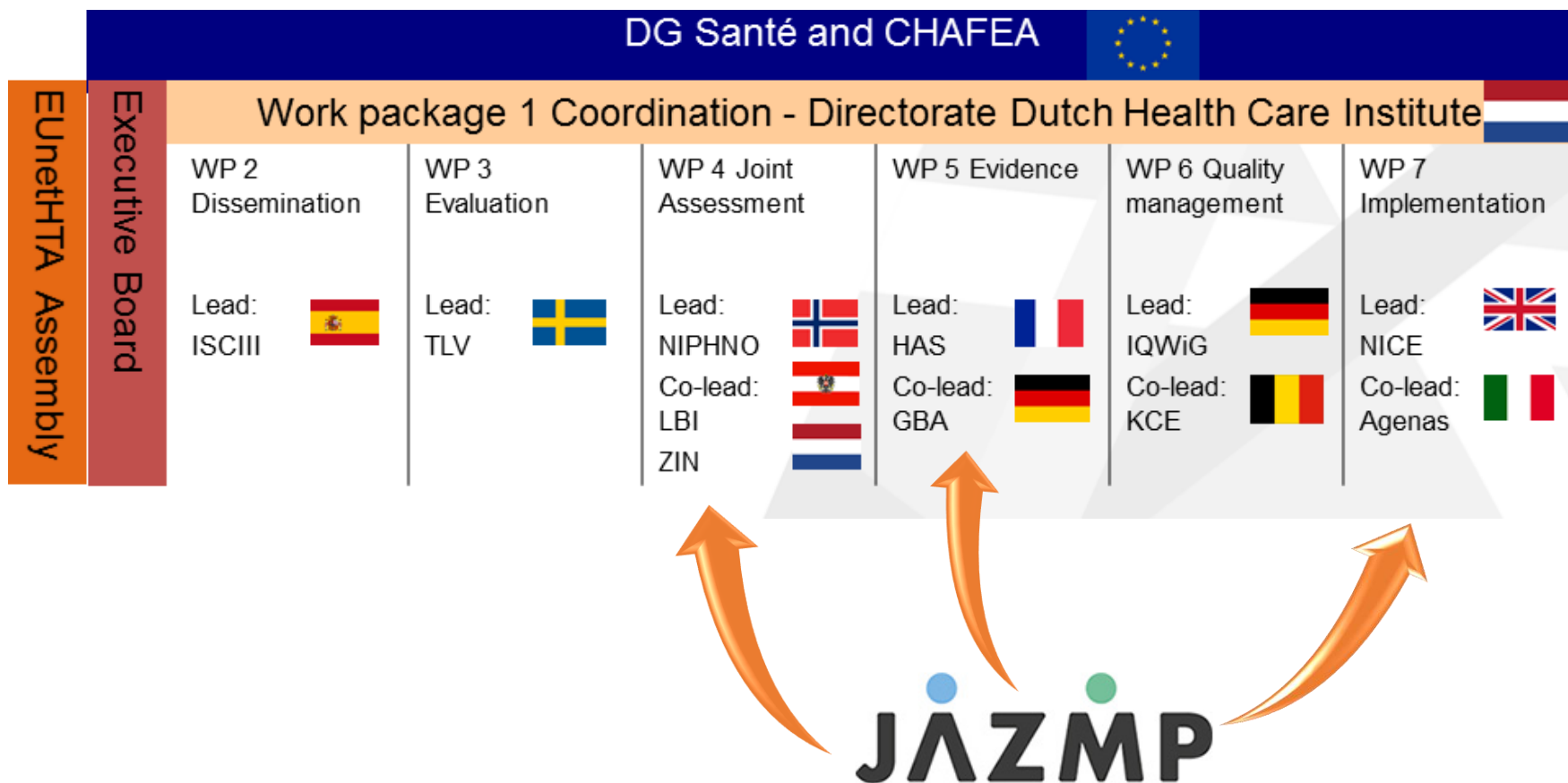


Ministrstvo za zdravje

JAZMP

NIJZ

Struktura EUnetHTA JA3



Work Package 5 – Evidence



Lifecycle Approach to improve Evidence Generation

Strand A – Early Dialogues (ED)

- Znanstveno svetovanje o načrtu kliničnih raziskav in njihovi relevantnosti v postopkih HTA/ocenah koristi/odločitvah o financiranju
- Paralelno svetovanje (EMA in EUnetHTA)
- EUnetHTA multi-HTA Early Dialogue (samo področje HTA)

Strand B – Post-Launch Evidence Generation (PLEG) and Registries

- Uporaba registrov v HTA postopkih
- Identifikacija potrebnih dodatnih raziskav oz. dokazov v HTA postopkih
- Zahteve po dodatnem spremljanju zdravila za namen HTA (registri)
- The Registry Evaluation and Quality Standards Tool (REQueST®)
- V pripravi: EVIDENT Database

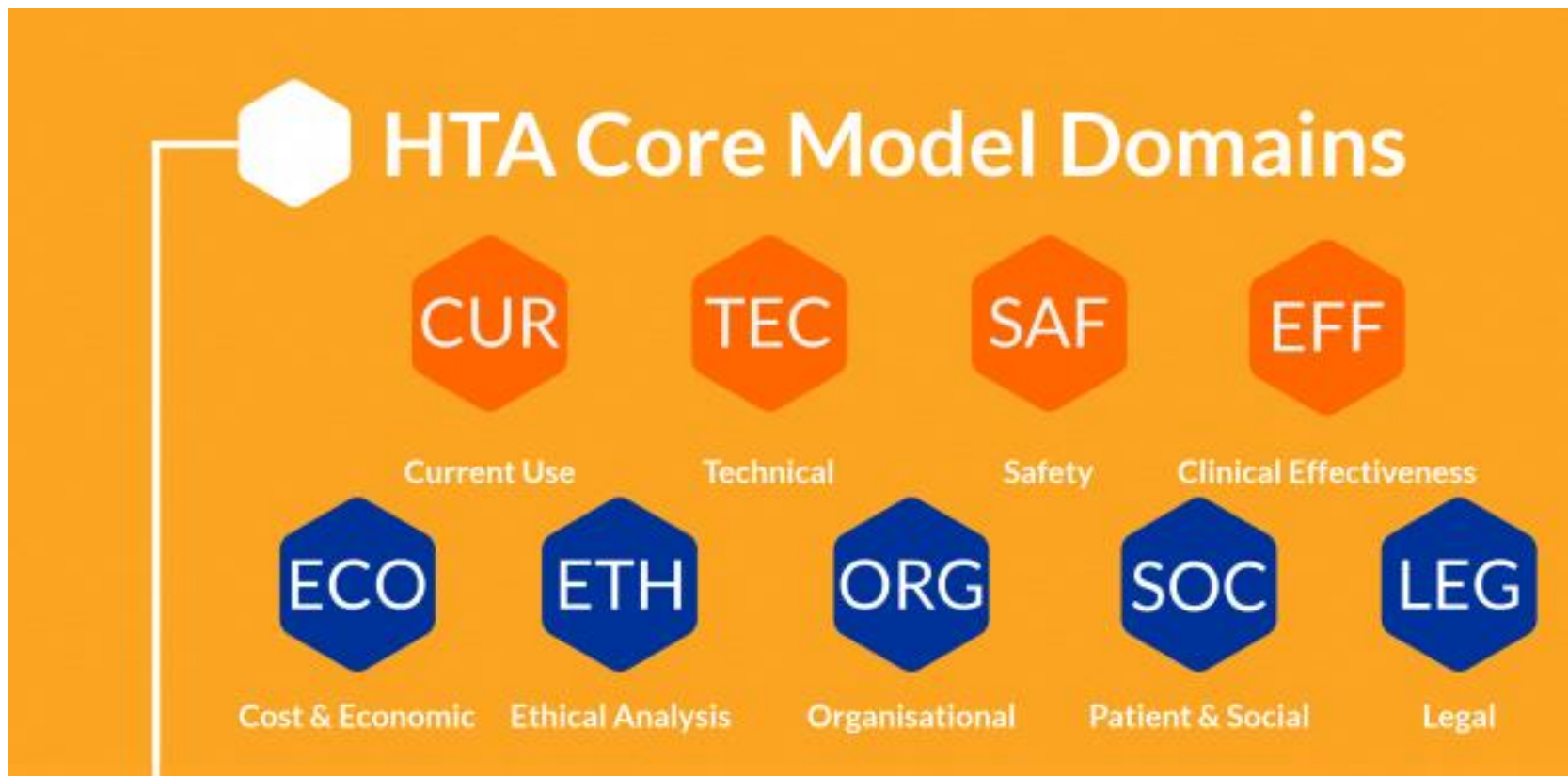


- Že razvito:
 - Metodološka navodila, postopki in časovnice
- Zahtev > kapacitet
 - Prvotna ocena cca 35 ED
 - Trenutno izvedenih ali v teku > 60 ED
 - Trije različni tipi ED (Večina kot PCC)
- EDWP – izbira glede na prioritete
- Vključitev pacientov
- **JAZMP** – v letu 2019 sodelovala v 2 ED (PCC)



- **Skupne ocene (JA) in Ocene s sodelovanjem (CA)**
 - Zdravila (PT)
 - Ostale tehnologije(OT)
- Uporaba
 - „HTA Core Model“
 - Metodološke EUnetHTA smernice
 - Definirani EUnetHTA postopki (manuals)
 - Upoštevanja upravljanja kakovosti
 - Definirani obrazci in predloge
- Seznam EPL (EUnetHTA Prioritisation List)

„HTA Core Model“





- 13 začetnih **skupnih ocen**
 - 2016: 1
 - 2017: 2
 - 2018: 4 (1 EPL)
 - 2019: 6 (5 EPL)
- 4 ocene končane (2 v letu 2017 in 2 v letu 2019)
- 9 ocen v postopku
 - **JAZMP** sodeluje pri vrednotenju 2 zdravil (PTJA)
- <https://eunethta.eu/rapid-reas/>

Skupne ocene ostalih tehnologij



- 16 končnih ocen (od tega 2 „Skupni oceni“, ostalo „Ocene s sodelovanjem“)
 - 6 diagnostics/screening
 - 10 medical/surgical interventions
- 8 ocen v postopku
 - 2 diagnostics/screening
 - 6 medical/surgicalintervention
- 2 oceni v pripravi
- **JAZMP** soavtor pri eni oceni
 - Stool DNA testing for early detection of colorectal cancer
- <https://eunethta.eu/rapid-reas/>



- POP database (Planned and Ongoing Projects)
 - Omogoča izmenjavo informacij o potekajočih in planiranih postopkih med agencijami v okviru EUnetHTA JA3

EUnetHTA POP Database

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The EUnetHTA Planned and Ongoing Projects (POP) database allows EUnetHTA partners to share information on planned, ongoing or recently published projects of participating agencies. The aim is to facilitate collaboration among European HTA agencies and reduce duplication of work.

[Read more about the objectives and history of POP Database.](#)

The EUnetHTA POP database currently stores 847 planned, ongoing and recently published projects from 40 EUnetHTA partners from 22 countries.

EUnetHTA ID

Password

[Login >](#)

Your session will time out after 30 minutes of inactivity, you will need to log in again. Potential downtime on Tuesdays & Thursdays, 08:30-09:30 due to maintenance.

[See FAQ #3 & #4 if you have no EUnetHTA ID or have login problems \(invalid access or forgotten password\).](#)

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Uporaba Skupne ocene



EUnetHTA
Skupna ocena

Informiranje na
nacionalnem nivoju

HTA agencije:
Priprava nacionalne
ocene

Nacionalni postopki,
zahteve, merila, lastnosti
zdravstvenega sistema,
prioritete, plan
zdravstvenega varstva,
neizpolnjene zdravstvene
potrebe, itd.

Odločitev o
financiranju/pogajanja

Definira obliko
in vsebino HTA
poročila



Q&A: Commission proposal on Health Technology Assessment

Brussels, 31 January 2018

What is Health Technology Assessment?

Health Technology Assessment (HTA) is a **multidisciplinary** process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner. It answers clinical questions like: How well does a new technology work compared with existing alternative health technologies? For which patients does it work best? HTA can also answer economic questions like: What costs are entailed for the health system?

It is therefore **a key tool for Member States** to ensure the accessibility, quality and sustainability of healthcare. The Commission proposal focuses on clinical aspects of HTA, i.e. problem definition, and the relative safety and clinical effectiveness of a health technology as compared with existing technologies.

HTA definicija



O&A: Commission proposal on Health Technology Assessment

HTA = ovrednotenje posledic uvedbe tehnologije (klinične, finančne, organizacijske...)

Health Technology Assessment (HTA) is a **multidisciplinary** process that

HTA = pomoč za odločevalce o financiranju in porabi sredstev v sistemu zdravstvenega varstva

It is therefore a **key tool for Member States** to ensure the accessibility, quality and sustainability of healthcare. The Commission proposal focuses on clinical aspects.

HTA poročilo odgovarja potrebam odločevalcev, naslavlja njihova vprašanja in kriterije odločanja



