

# Comparison of EUnetHTA core model, 82304-2, DiGA, PECAN and more

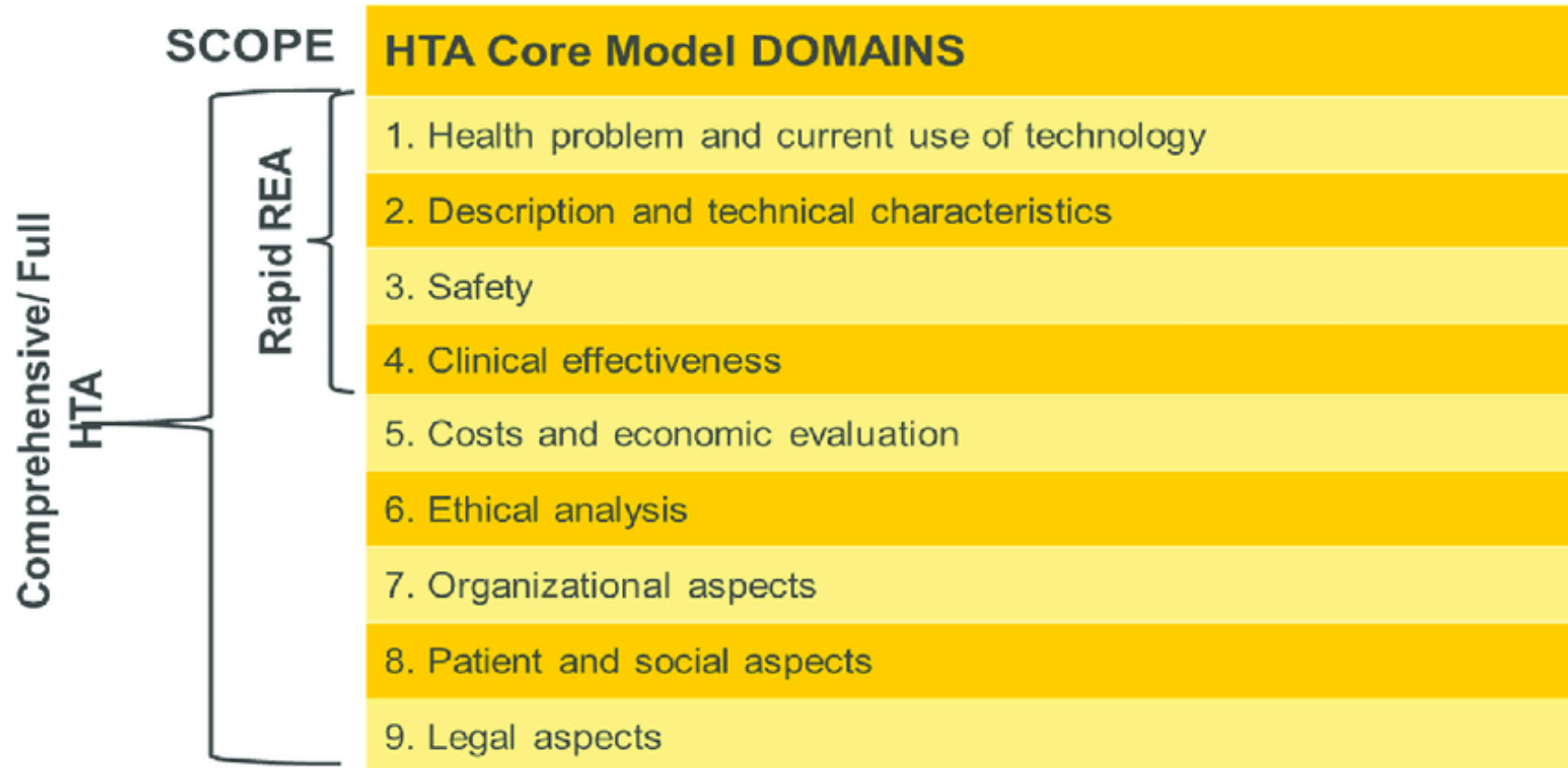
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# EUnetHTA Core Model (EU)



# Approach

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Comparison based on the principles of  
**EUnetHTA Core Model & CEN-ISO 82304/2**

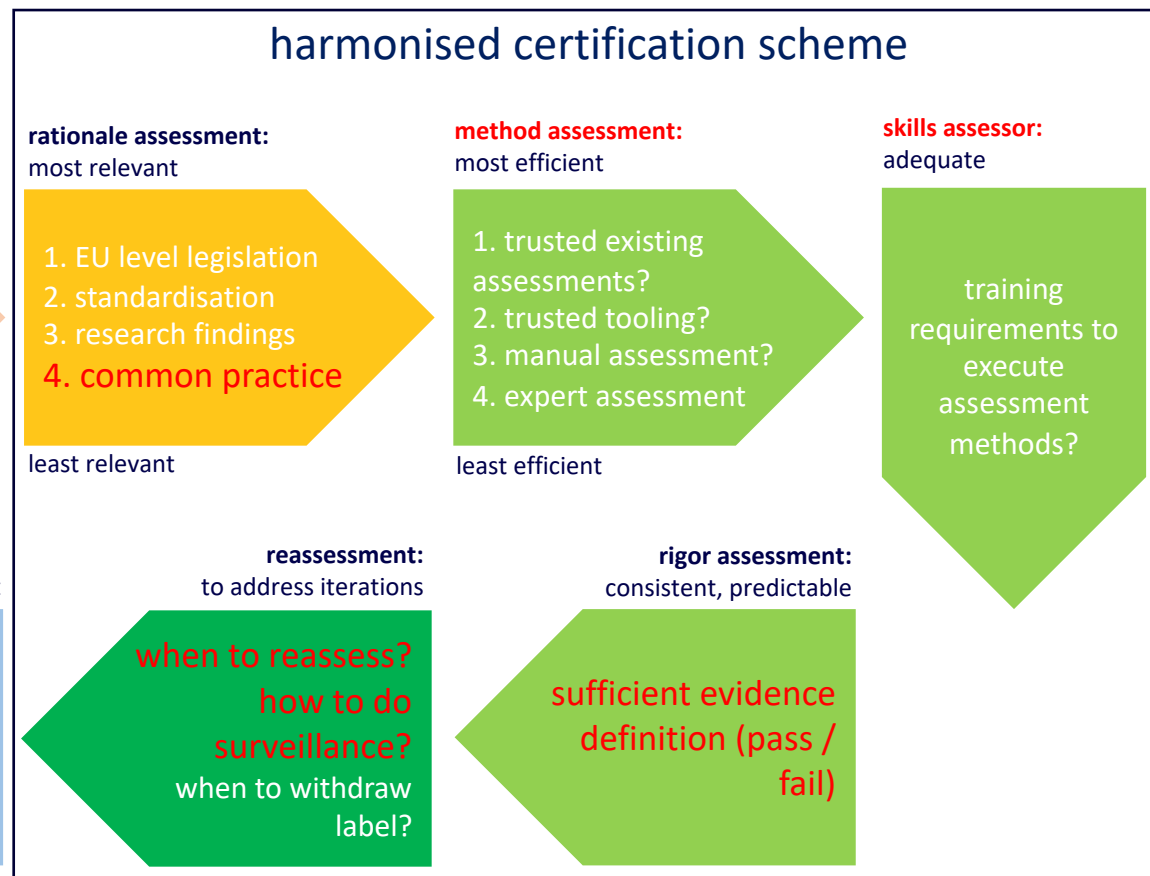
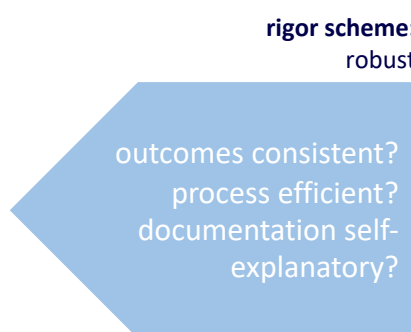
This led to **4 82304-2 requirements that are key:**

- **5.2.4.5** Is evidence available to support the **health benefit** of using the app?
- **5.2.5.1** Is evidence available of a **societal benefit** of using the app?
- **5.2.2.1** Are the **health risks** of the health app analysed?
- **5.2.3.1** Are **ethical challenges** of the health app assessed and documented with intended users and health professionals?

**to attain trust and impact:**  
for each 82304-2 requirement



**subject matter expert:**  
to evolve the scheme



# Common Practice: DiGA (GE) and PECAN (FR)

## Health Benefit:

- **Similar methodologies (PECAN & DiGA)**
  - RCTs as preferred methodology
  - Preferred **blinding** and active **comparator**
- **DiGA (4):**
  - 1) improvement of the state of health,
  - 2) reduction of the duration of a disease,
  - 3) the prolongation of survival or,
  - 4) an improvement in the quality of life

## Societal Benefit:

- **DiGA (9):**
  - 1) coordination of treatment procedures,
  - 2) alignment of treatment with guidelines and recognized standards,
  - 3) adherence,
  - 4) facilitating access to care,
  - 5) patient safety,
  - 6) health literacy,
  - 7) patient autonomy,
  - 8) coping with illness-related difficulties in everyday life, or
  - 9) reduction of therapy-related efforts and strains for patients and their relatives

## Health Risks:

- **DiGA:** Manufacturers assess for adverse events
- **Health risks** also assessed through the MDR post-market surveillances (risk class **Ila/I Ib/III**)

## Ethics:

- **DiGA:** consultation with at least one ethical committee that is outside of the BfArM procedure is required.

## Other (Non-Clinical):

- **International standards** widely used (ISO 27000 (GE), 11073 (GE), 10781 (FR)) to build on
- **Interoperability & Security** of high relevance, being covered in both countries
- **DiGA** having rather **broad requirements**, with multiple ways of proving compliance
- **PECAN** having more context-specific and stricter requirements, building further on **national initiatives** (e.g., EHR, INS, PSC)

# In practice: assessment 53 DiGAs (DiGA 06-2023)

- Provisional listing (29), Final listing (18), Canceled (6)
- All studies conducted (or proposed) **RCTs**
- Relatively **smaller population samples** compared to regular clinical trials
  - Lowest: 56, Highest: 1442, Average: 300
- **High dropout rates** in some of the studies
- **Limited follow-up** (8 weeks to maximum of 12 months)
- Almost **no blinded** RCTs, due to **difference** in defining **standard of care**
  - No treatment: 44 (83%), treatment without a DiGA: 9 (17%)
- **50/53** DiGAs are MDD/MDR risk class I (**30/53** are **MDD I**, **20/53** are **MDR I**), where **3/53** is MDR risk class IIa
- Only **1/53** DiGAs solely applied to **Societal Benefit**, **52/53** DiGAs had at least one **Health Benefit**
- Total of **75 positive healthcare effects** over **53 DiGAs** (**1,4** on average)
- **60/75** of the positive healthcare effects were **Health Benefits**
  - 47/60 applied to the medical benefit “improvement of the state of health”
- **15/75** were **Societal Benefits**
  - (5/15 patient autonomy, 4/15 health literacy, 3/15 coping with illness-related difficulties, 1/15 reduction of therapy-related efforts and strains, 1/15 alignment of treatment with guidelines, 1/15 adherence)

## Next steps

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- Interview **EUnetHTA** (EU), **PECAN** (FR)
- Check comparisons with **DiGA** (DE) and **PECAN** (FR)
- Comparison with **Digi-HTA** (FI), **DAQ/DTAC** (GB) and potentially **Validation pyramid** (BE)

# Thank you for your attention

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**Disclaimer**