HTA REGULATION

JOINT SCIENTIFIC CONSULTATIONS & JOINT CLINICAL ASSESSMENT

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Dichiarazione di trasparenza/interessi*

Le opinioni espresse in questa presentazione sono personali e non impegnano in alcun modo l'AIFA

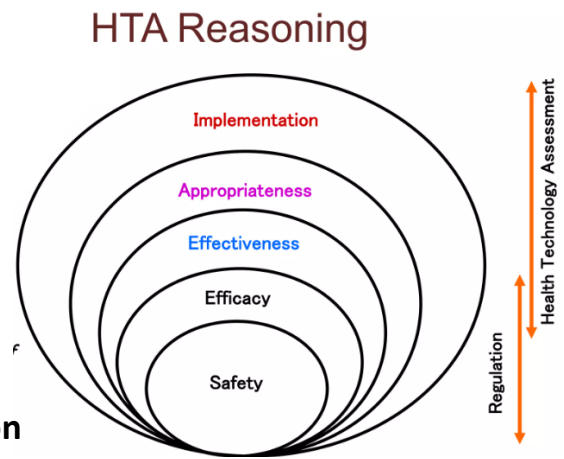
Interessi nell'industria farmaceutica	NO	Attualmente	Da 0 a 3 anni precedenti	oltre 3 anni precedenti
INTERESSI DIRETTI:				
1.1 Impiego per una società: Ruolo esecutivo in una società farmaceutica	☒	☐	☐	☐ obbligatorio
1.2 Impiego per una società: Ruolo guida nello sviluppo di un prodotto farmaceutico	☒	☐	☐	☐ obbligatorio
1.3 Impiego per una società: altre attività	☒	☐	☐	☐ facoltativo
2. Consulenza per una società	☒	☐	☐	☐ facoltativo
3. Consulente strategico per una società	☒	☐	☐	☐ facoltativo
4. Interessi finanziari	☒	☐	☐	☐ facoltativo
5. Titolarità di un brevetto	☒	☐	☐	☐ facoltativo
INTERESSI INDIRETTI:				
6. Sperimentatore principale	☒	☐	☐	☐ facoltativo
7. Sperimentatore	☒	☐	☐	☐ facoltativo
8. Sovvenzioni o altri fondi finanziari	☒	☐	☐	☐ facoltativo
9. Interessi Familiari	☒	☐	☐	☐ facoltativo

* Pia Rivetti di Val Cervo, secondo il Regolamento per la disciplina dei conflitti di interesse all'interno dell'Agenzia Italiana del Farmaco approvato dal CdA AIFA con Delibera n. 37 del 13 ottobre 2020.

N.B. Per questo intervento non ricevo nessun compenso.

Health Technology Assessment: HTA

Medicinal products
Medical devices
IVD devices and procedures
Measures for disease prevention
diagnosis
treatment



Non-clinical for HTA≠ Non-Clinical for regulators

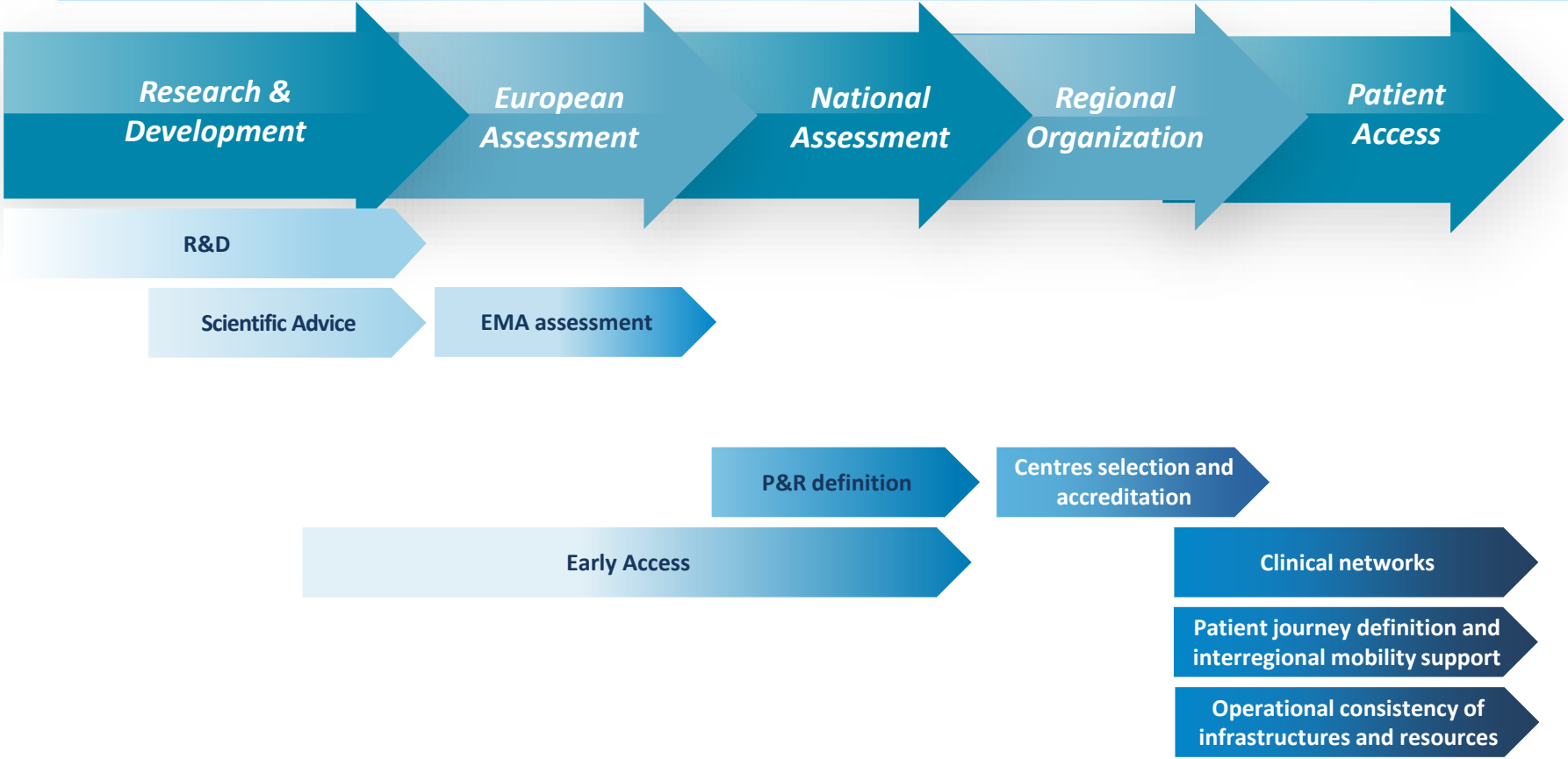
HTA DOMAINS	
CLINICAL DOMAINS	» Health problems and currently used health technologies (e.g. medicines, medical devices, surgical procedures). » Description of health technology under assessment. » Relative clinical effectiveness. » Relative safety.
NON-CLINICAL DOMAINS	» Economic evaluation. » Ethical aspects. » Organisational aspects. » Social aspects. » Legal aspects.

» Is a new medicine more effective in treating a certain disease?
» Do expected costs and benefits present sufficient value-for-money when compared to alternative healthcare interventions?

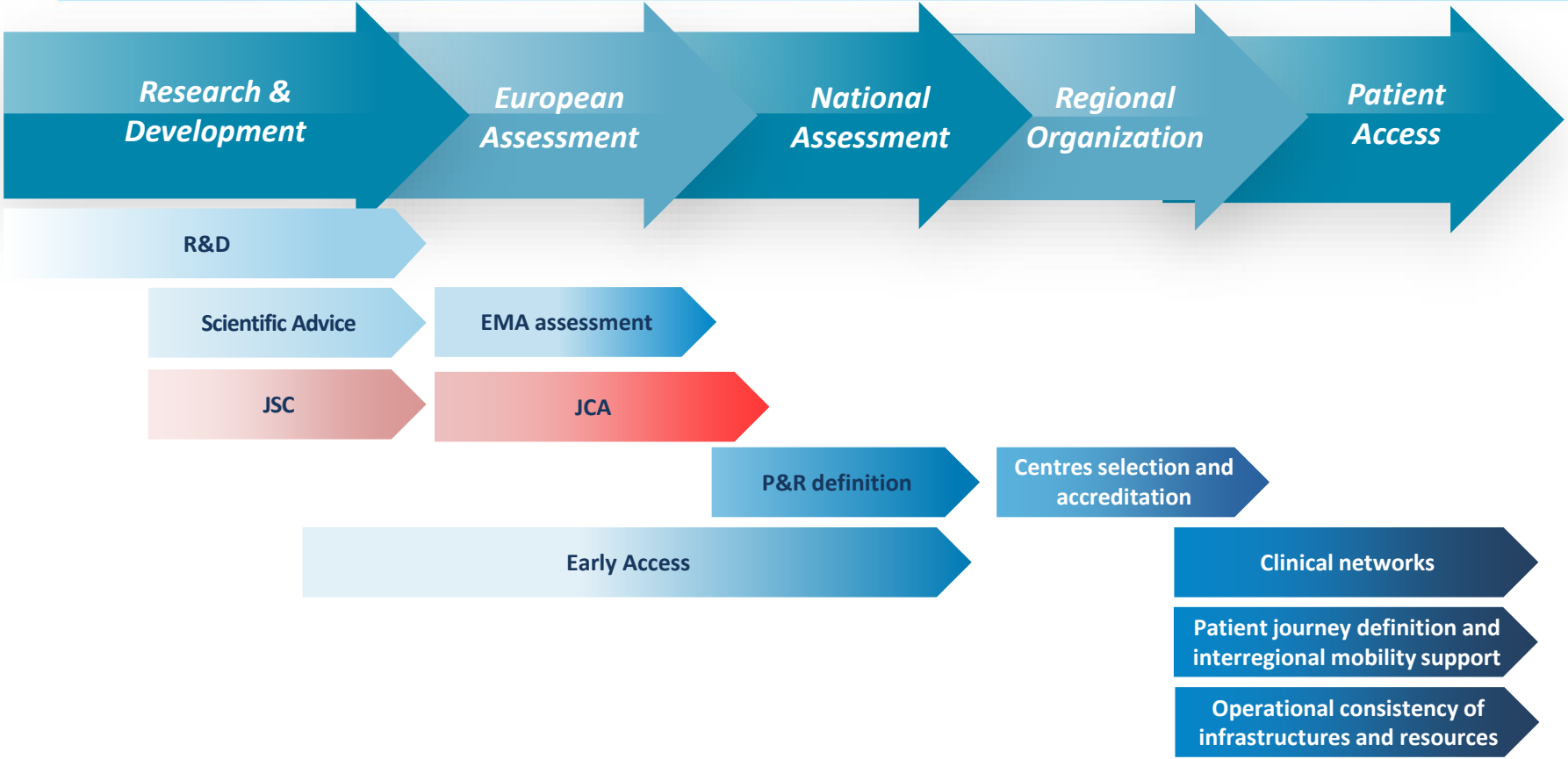
Quality
Accessibility
Sustainability

DO I NEED IT?
DO I BUY IT?

ACCESS PATHWAY



ACCESS PATHWAY



EUROPEAN HTA

Table 5. Obligatory HTA: Pharmaceuticals

Country	Reimbursment	Pricing
Austria	√	√
Belgium	√	√
Croatia	√	√
Czech Republic	√	√
France	√	√
Finland	√	√
Germany		√
Italy	√	√
Ireland	√	√
Latvia	√	√
Lithuania	√	
Poland	√	√
Sweden		√
UK	√	
Norway	√	

Table 6. Obligatory HTA: Medical Devices

Country	Reimbursement
Croatia	√
France	√
Germany	√
Latvia	√
Poland	√
Portugal	√
Sweden	

Mapping of HTA national organisations, programmes and processes in EU and Norway

- **Not all EU countries have HTA bodies**
- **HTA is not used in the same way in EU countries with HTA bodies**
- **Different technologies are evaluated differently (MD vs MP)**
- **Duplication of dossiers and evaluations**
- **Outcome variability**
- **Time to patient access variability**
- **Developers choose not to market in some countries**

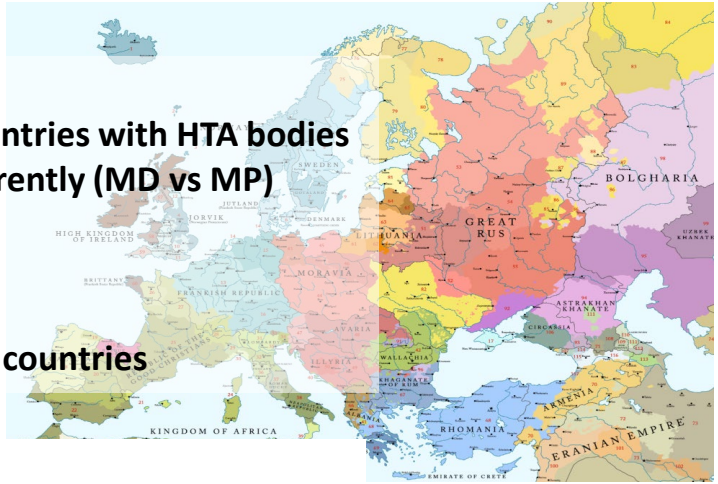
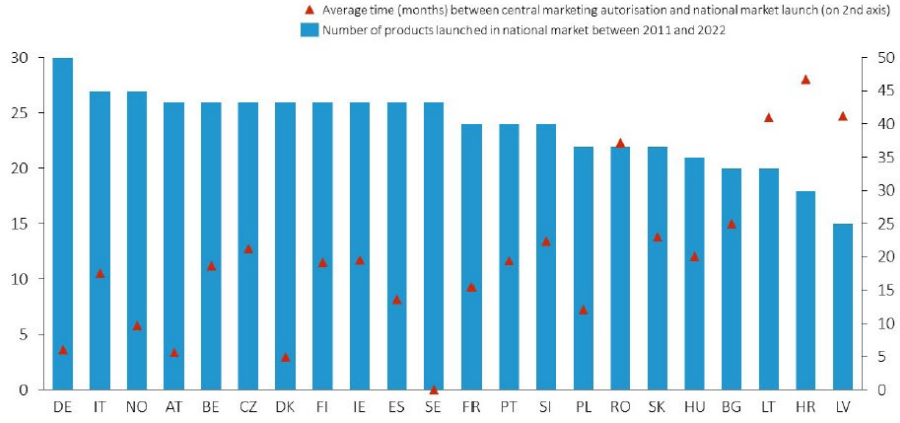


FIGURE 7

Wide differences in national market launches

Medicines for human use (excluding generics and biosimilars) with central marketing authorisation granted in 2011



In general, time to market is strongly (inversely) correlated to the size of Member States' healthcare budget per resident.

EUROPEAN HTA

the European Commission has supported Member States' cooperation on HTA since 2006 through the EUnetHTA initiative.

→ assessing the effectiveness of new therapies once and jointly

→ sharing expertise

→ avoiding duplication.

- EUnetHTA21
- JA3 Archive (2016-2021)
- JA2 Archive (2012 – 2015)
- JA1 Archive (2010 – 2012)
- EUnetHTA Collaboration (2009)
- EUnetHTA Project (2006-2008)

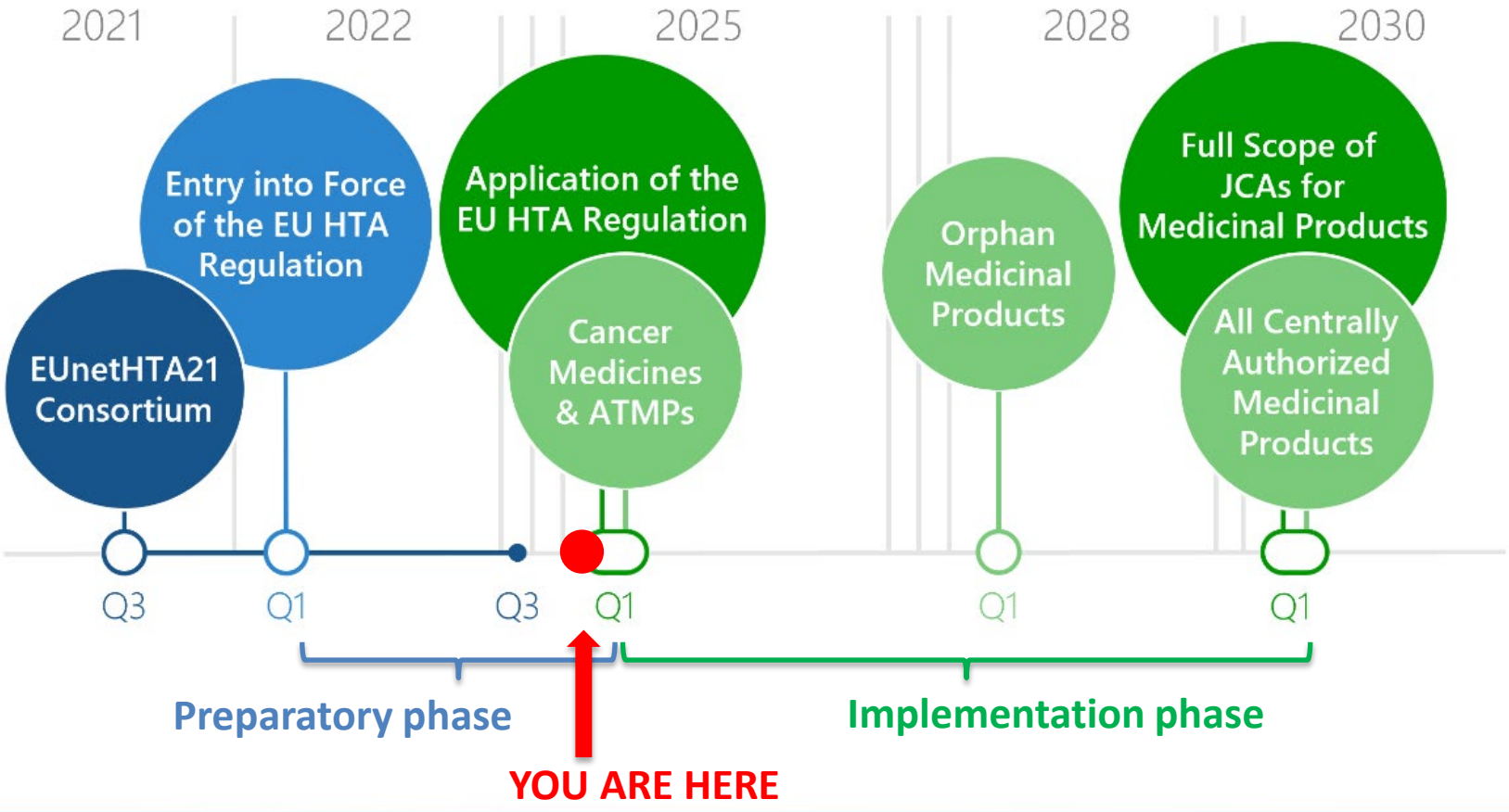
Framework for Joint HTA cooperation in collaboration with EMA

REGULATIONS

REGULATION (EU) 2021/2282 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 December 2021
on health technology assessment and amending Directive 2011/24/EU

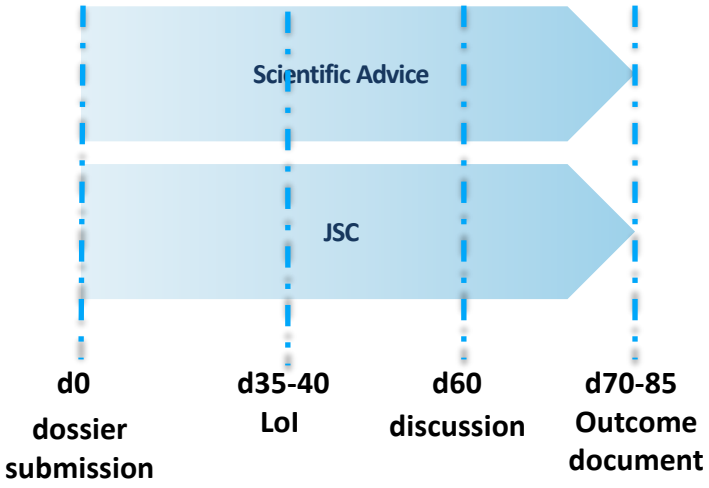
(Text with EEA relevance)

EUROPEAN HTA



JOINT SCIENTIFIC CONSULTATIONS

- JSCs to obtain **guidance on data, analyses**, etc. and **facilitate the generation of evidence** that meets the likely requirements of a JCA on that health technology.

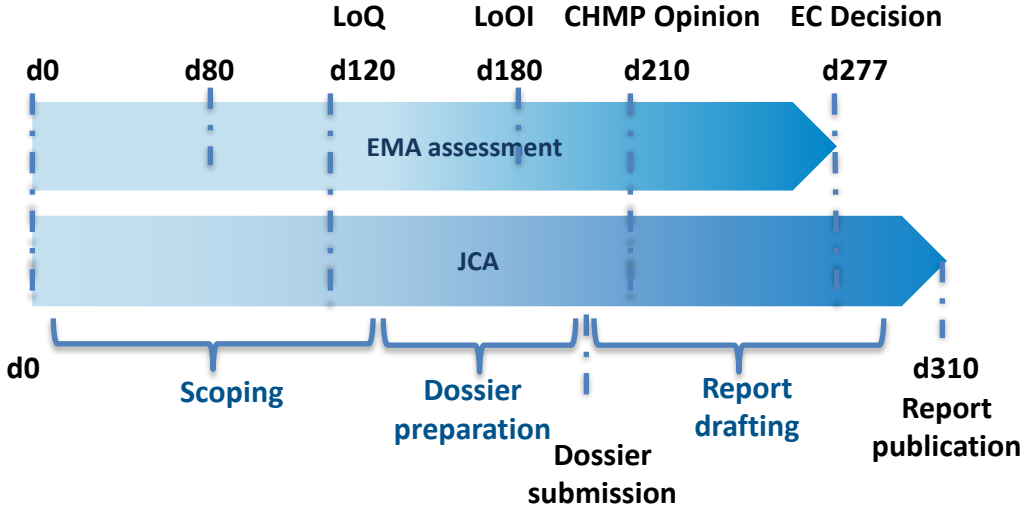


WHO?
Likely for JCA
Planning stage
Unmet medical need
First in class
Impact on patients/HC
EU relevant

WHAT?
Study design aspects
Optional:
Non-clinical aspects

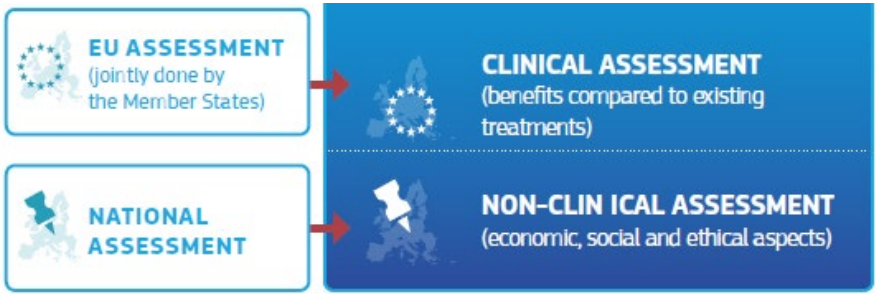
HOW?
Upon request
Multi HTA/Parallel to SA
Not legally binding

JOINT CLINICAL ASSESSMENT



EPAR

JCA report



Scientific analysis of an HT's
-Relative effects
-their degree of certainty
-evidence strengths and limitations

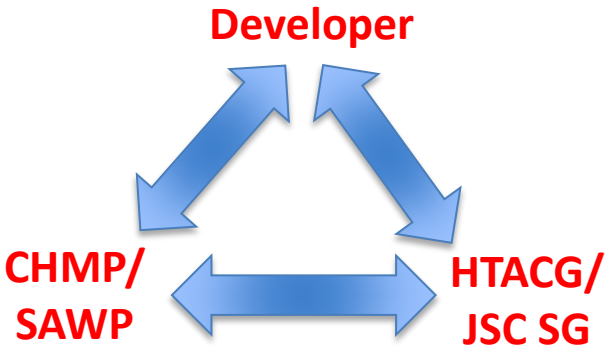
NO recommendations on the added benefit, place in therapy or reimbursability of a HT

→ remit of the National Competent Autorities

TAKE HOME MESSAGE

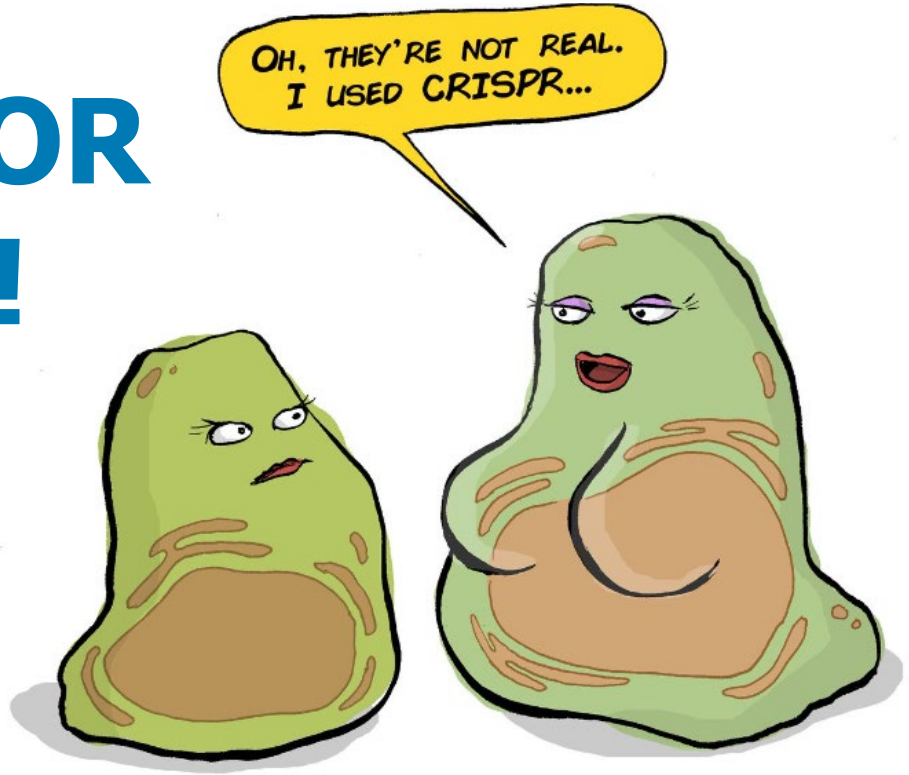
Single arm trials
Low patient numbers
Short follow-up
Surrogate endpoints

Difficulty in defining added value



-active interaction between developers, HTA and regulators
-increase in research plan acceptability
-increase in research quality
-evidence-based, timely decisions on new HTs
-benchmarking

THANK YOU FOR LISTENING !



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