CDDF SPRING CONFERENCE 2021
08 - 10 February 2021
Virtual Conference
Current and future challenges of innovative oncology drug development

EUnetHTA as a possible avenue to speed up patient access

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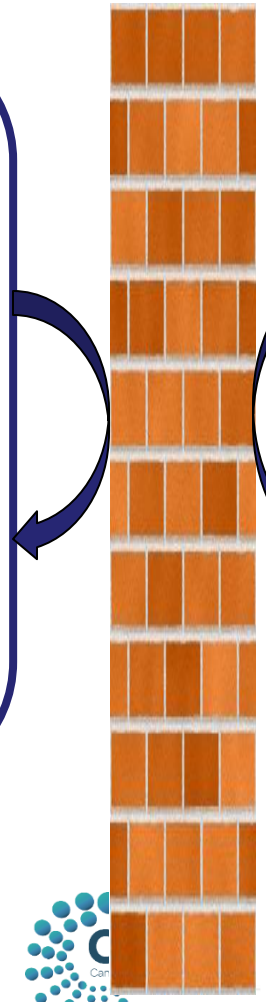
27 Member States – 27 Pharma Systems

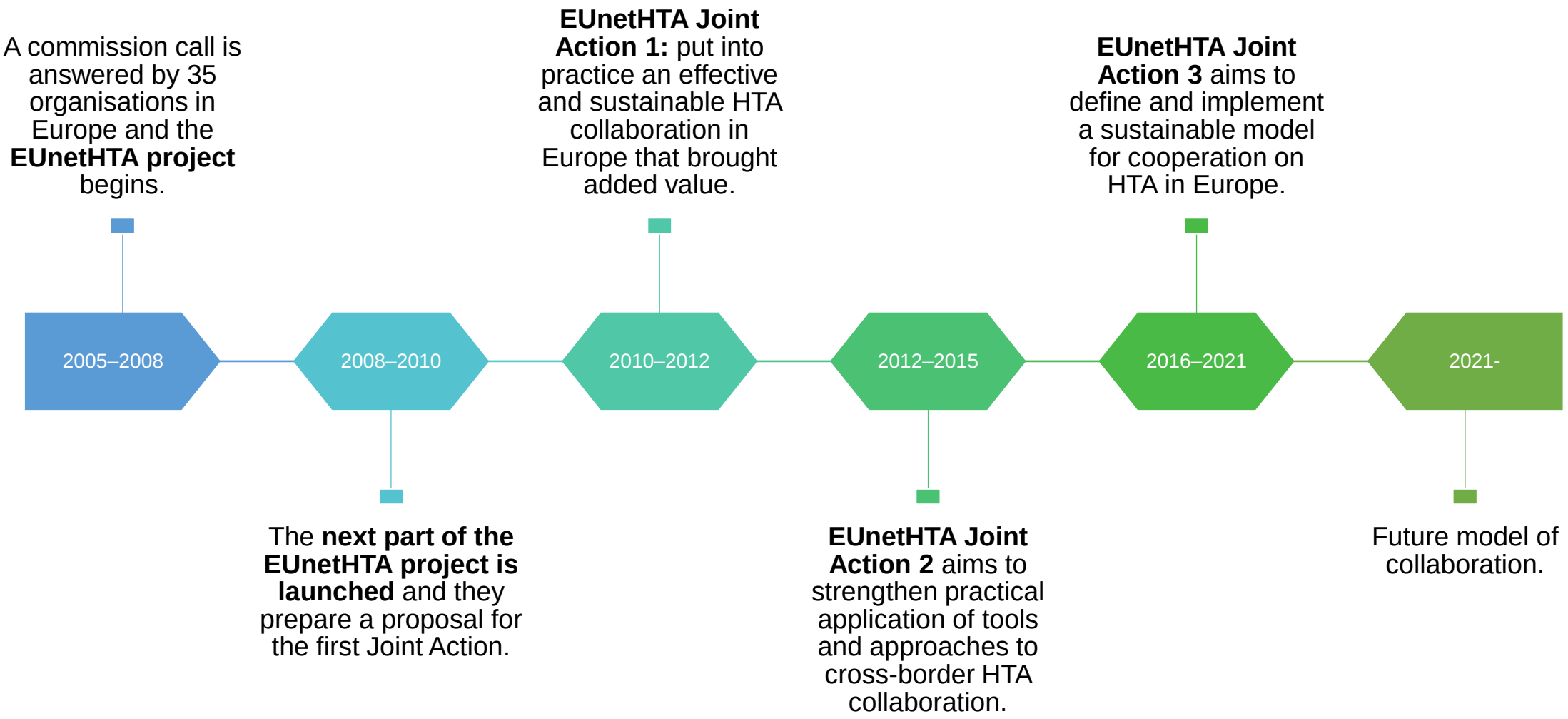
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- Single licensing system
- Single EU legislation
- Well defined and agreed assessment criteria



- 27 different HTA and Pricing&Reimbursement systems
- National legislations
- Different methodologies and assessment criteria

The history of EUnetHTA



Legal basis for EUnetHTA

Directive 2011/24/EU on cross-border healthcare

The Directive provides a detailed legal framework focused on:

Rules concerning the reimbursement of cross-border healthcare costs.

Cross-border healthcare responsibilities of Member States.

Cooperation between healthcare systems.

EU objectives in HTA Article 15, Directive 2011/24:

Support cooperation between national HTA authorities.

Support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information […] to enable effective exchange of information.

Avoid duplication of assessments.

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How can HTA bodies balance the need to ensure timely access to new drugs with uncertainties and high costs?

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Key products of EUnetHTA

EARLY DIALOGUES	JOINT ASSESSMENTS	POST LAUNCH EVIDENCE GENERATION
DEFINITION		
Scientific advice provided by HTA bodies to manufacturers on the clinical development.	Joint HTA reports produced by multiple European Member States (at least four).	Common definition of evidence gaps and uncertainties among different Member States for specific pharmaceuticals.
AIM		
To generate evidence that satisfies the needs of HTA bodies during their assessment and ultimately facilitates patient access	To improve European cooperation on HTA, avoiding duplications of work at the national level	To define a common dataset for generation of post launch evidence and possibly pan-European registries.

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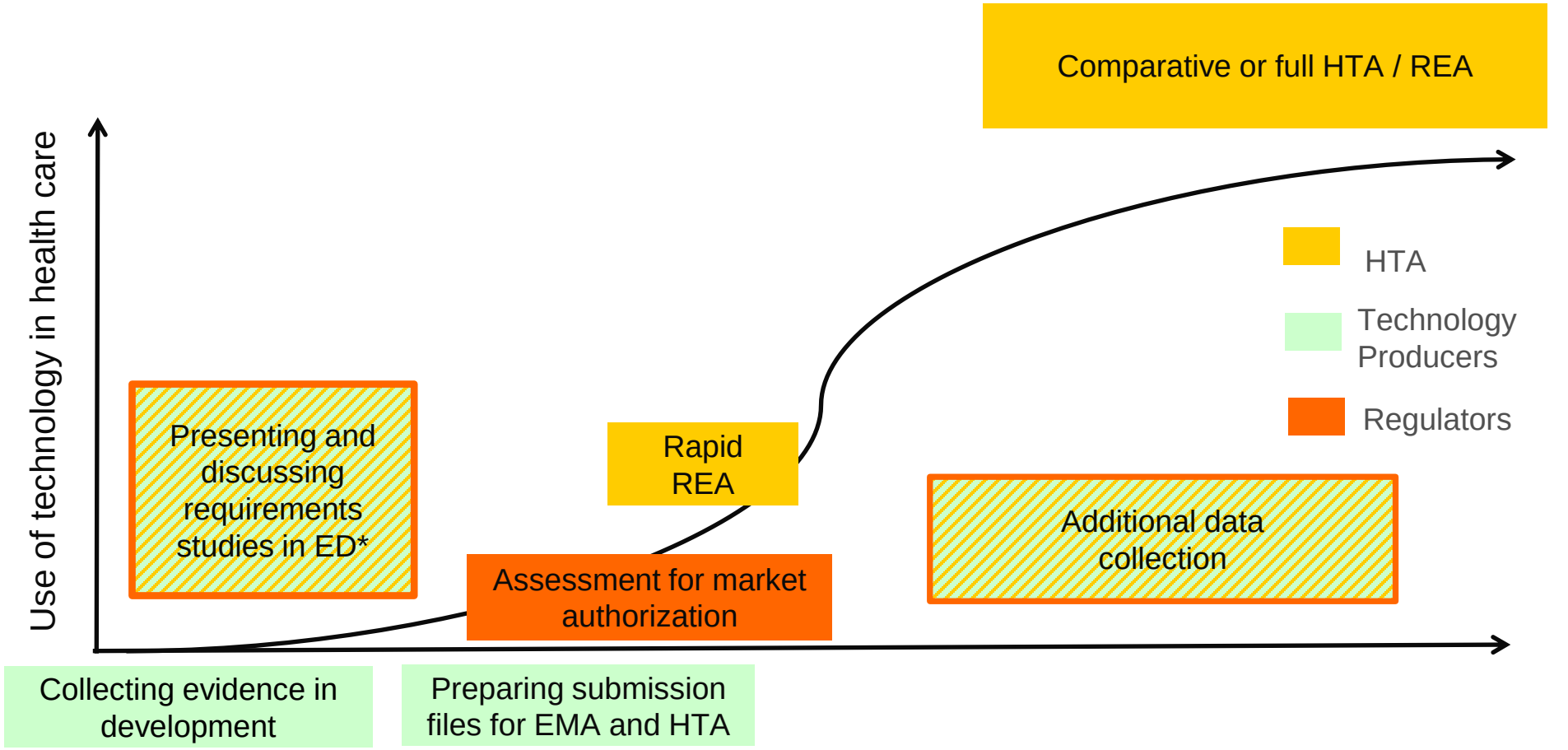
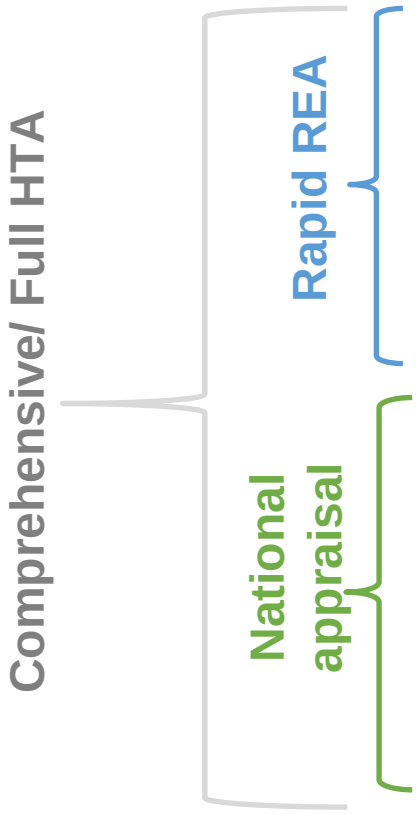


**Early dialogue*

EUnetHTA HTA Core Model®



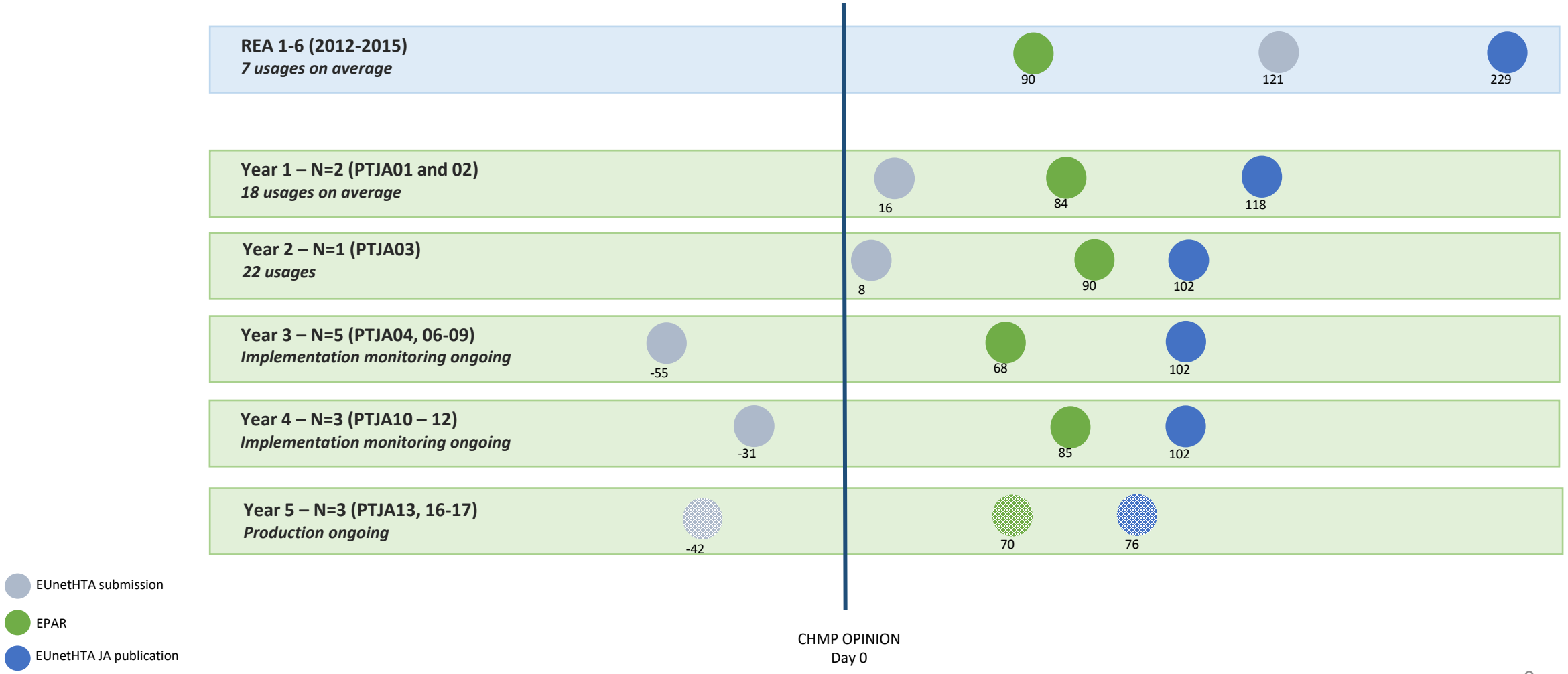
HTA Core Model DOMAINS
1. Health problem and current use of technology
2. Description and technical characteristics
3. Safety
4. Clinical effectiveness

EUnetHTA does not give recommendations on added value or reimbursement

*** the numbering does not show importance of the topics**

Pharma REA production

Experiences so far



How do we ensure implementation?

- EUnetHTA prioritisation List
- PICO survey for EUnetHTA scope REA
- Focus on clinical domains
  - Reimbursement decions remains in national autonomy
- Use of EUnetHTA guidelines and SOPs
- REA available close after Market Authorisation
  - National assessment/appraisal often starts after EPAR
  - REA in JA3 published within 2-3 weeks after EPAR
  - Aim: publish even closer after EPAR

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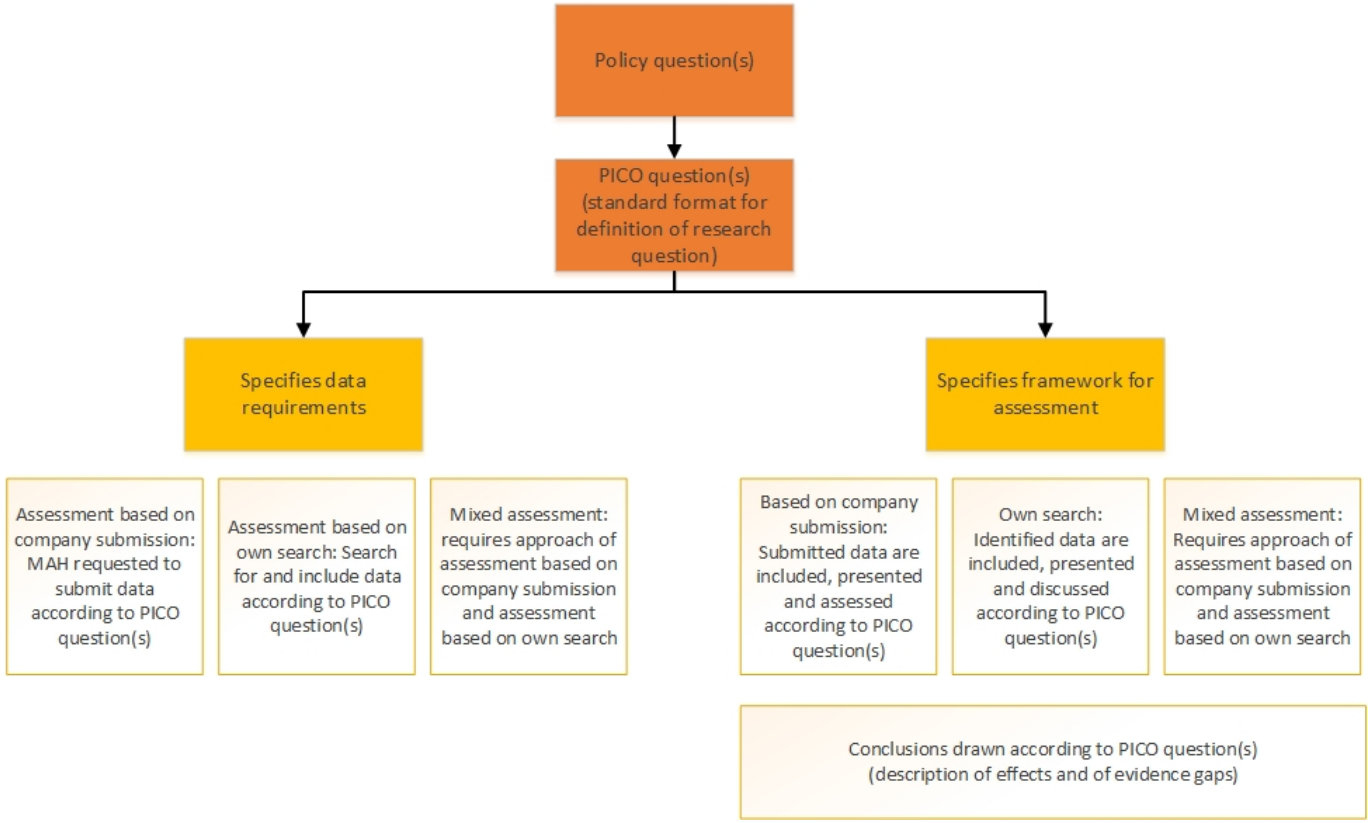
How to reach consensus on PICO for a REA?

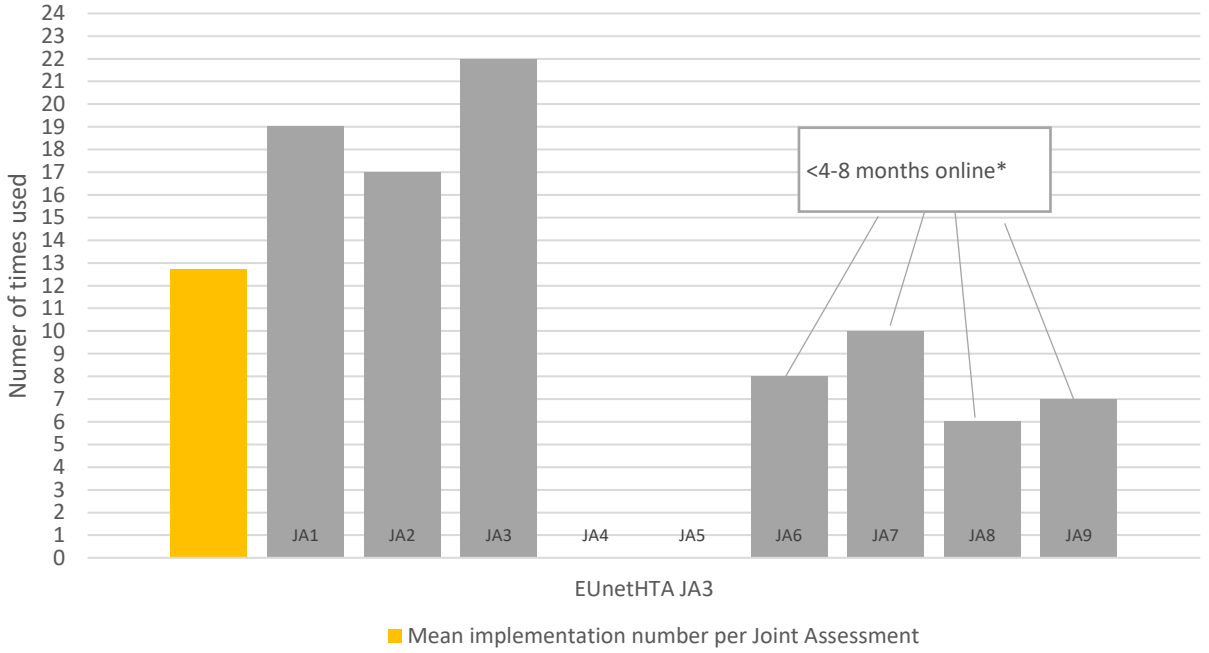
- PICO = policy question
  - Not data driven
- If different national policy questions:
  - >1 PICO to be answered
- PICO survey as tool



https://eunethta.eu/PICO

Implementation pharma REA
Based on PTJA01 - 09

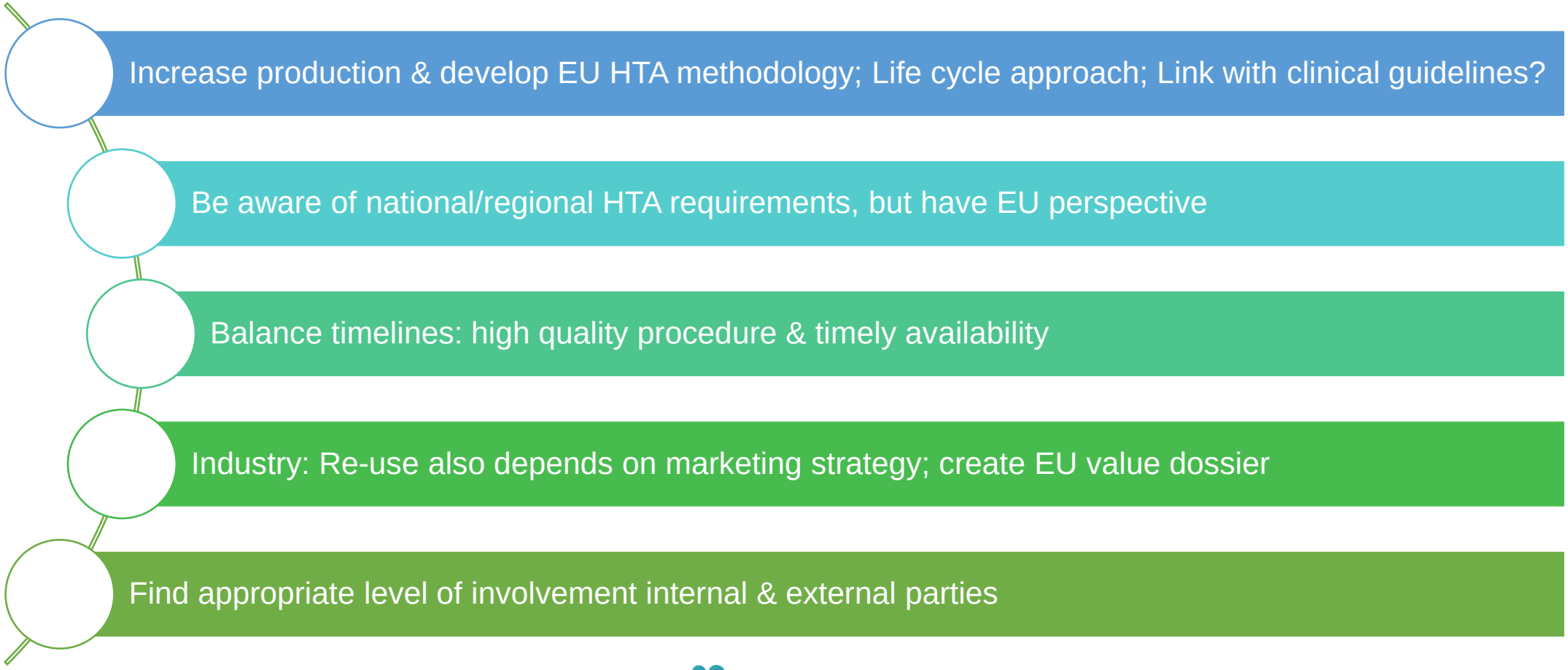
- National appraisal often starts after EPAR
- Authors/Co-authors of PTJA01-03
  - their national appraisals were on average 3 weeks quicker
  - due to the EUnetHTA report
- Same if they were not author?



**To accurately capture the implementation of JA/CA a follow up period of approximately 18-24 months is needed*
Data cut-off point: June 29, 2020

[July final implementation report]

Lessons learnt



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Thank you!

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