



A New European access pathway

How the EU JCA can deliver?



Ordem de Farmacêuticos
26.06.2025



European Cooperation: born to find a common ground

EUnetHTA pilots : harmonizing HTA practices



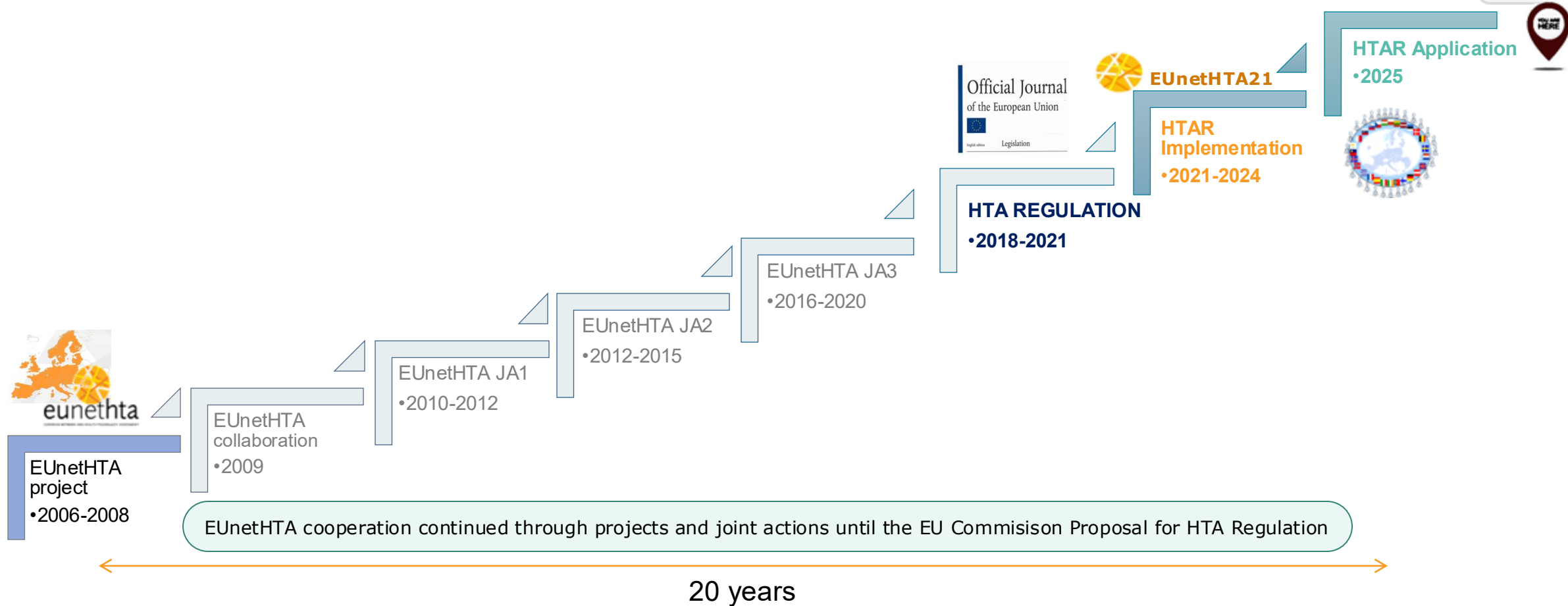
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EU Commission funded the European HTA bodies to engage under the EUnetHTA cooperation, to find common standards and incentivize harmonisation

A long history of European initiatives in HTA

>20 years of cooperation projects from a voluntary to a permanent framework



Today and Tomorrow

HTA Regulation is re-designing the road to patient access

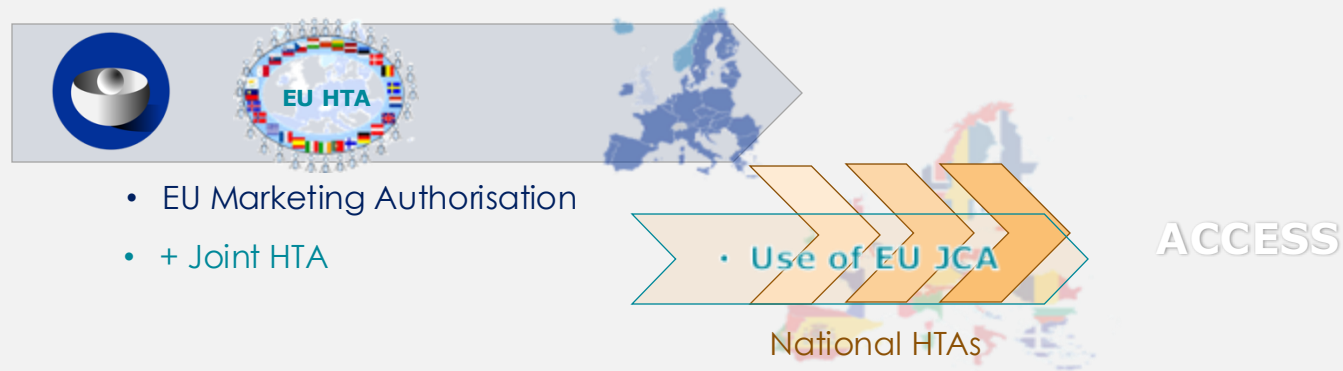
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EU license and **National HTA**:

- Two independent levels
- Different pathways

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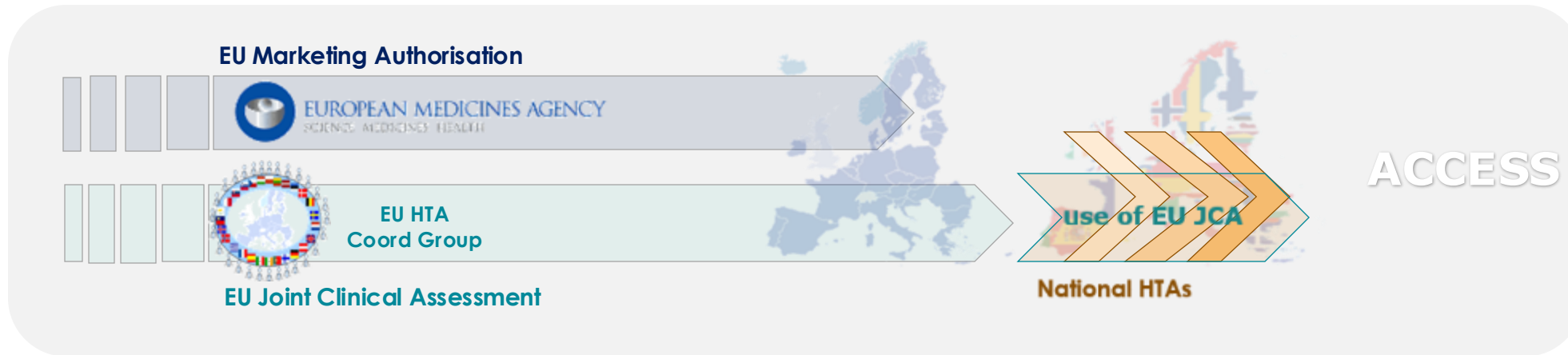


New entry and access pathway

- Pharmaceuticals applying to EMA will also undergo EU HTA
- EU HTA mandatory step ahead of national HTA

Today and Tomorrow

HTA Regulation is re-designing the road to patient access



Two parallel assessment processes

- Benefit-risk and clinical value running at the same time

Expected benefit

- Companies to experience streamlined route to access



EU and National HTA interplay

- National authorities are free to build their HTA on the EU JCA work

Expected benefit

- Better informing national decisions on access

After preparatory phase, the system is now set to run ?

Working to deliver on a new process : we expect challenges



- Preparation to EU joint work

- Time to deliver

- National adaptation

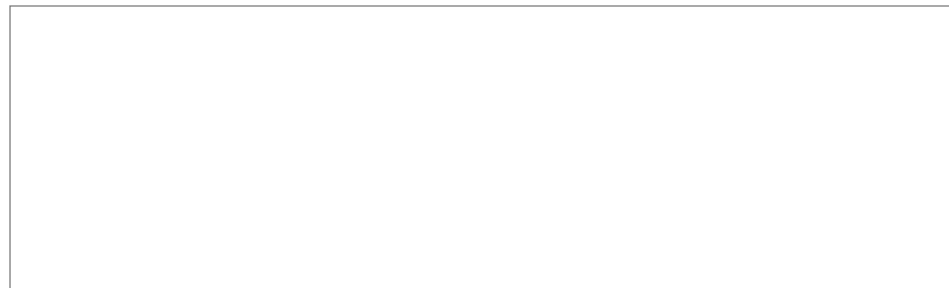
- Preparatory work lasted until the very end of 2024
- Companies had to prepare at risk with little visibility

- Challenges to be expected for a new untested process

- National adaptation is a work in progress for most countries

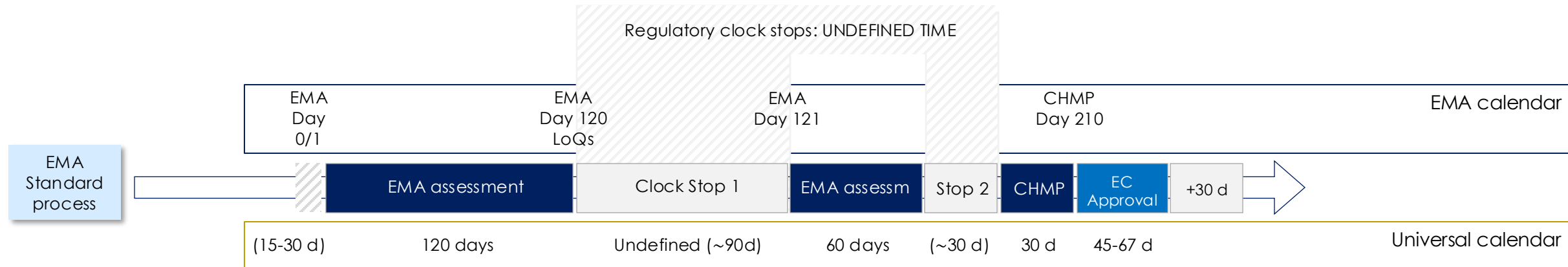


1. A new interplay with the EU Regulatory framework



Regulatory and EU HTA interplay

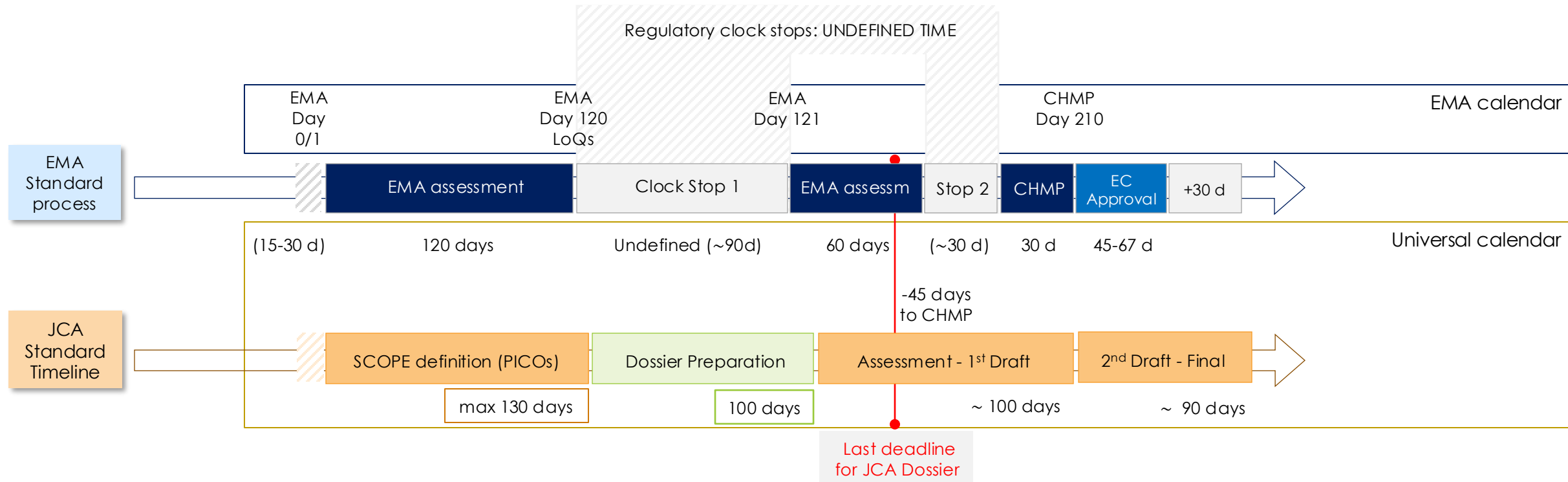
Regulatory and JCA processes have contact points, but on different timelines



- Be aware of the Regulatory background
- EMA process runs on a special timeline
- Time-points are moving targets

Regulatory and EU HTA interplay

Regulatory and JCA processes are anchored, but on different timelines

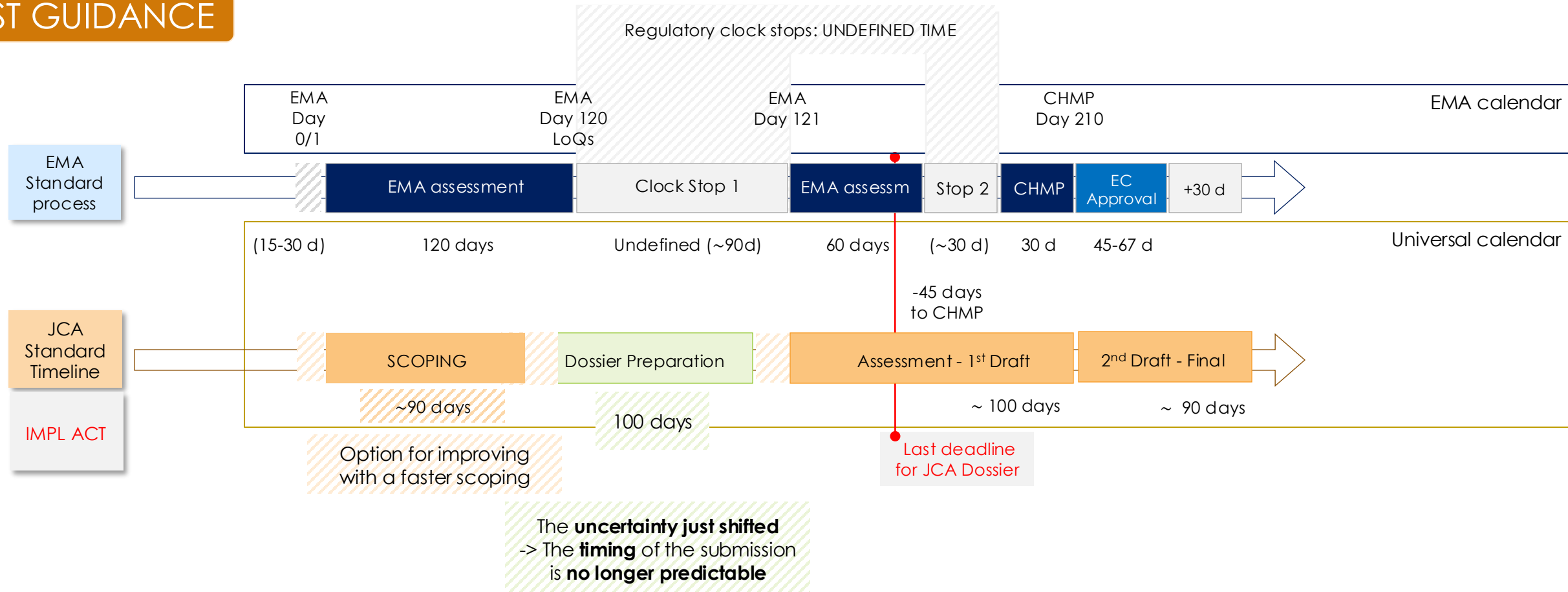


Regulatory and EU HTA interplay

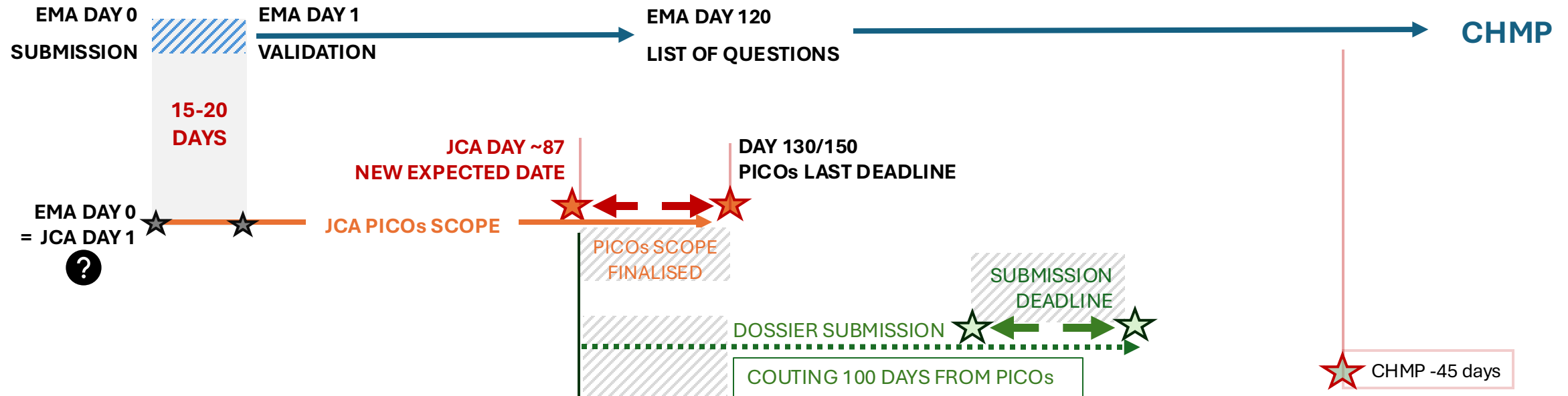
The EU JCA is still looking for pragmatic solutions for its own process



LAST GUIDANCE



JCA timeline. Persistent elements of unpredictability



UNEXPECTED SCENARIO

- The start of the JCA is not clearly set

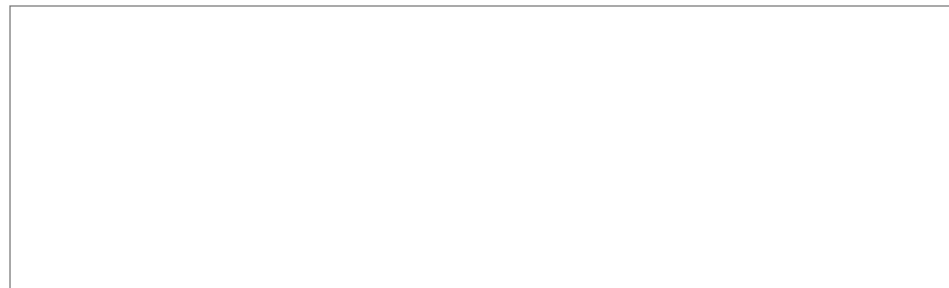
- Challenging to plan for key submission steps

* Increased unpredictability on companies' side

* Coordination Group provided a (not final but) workable answer



2. Key elements for a successful EU HTA



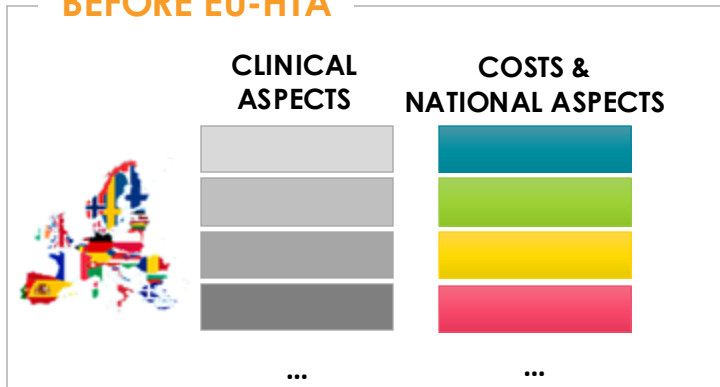
EU JCA : expectations and scenarios

European PICO or countries cumulative PICOs

SCOPE OF A JCA

P.	I.	C.	O.
Population	Intervention	Comparator	Outcome

BEFORE EU-HTA



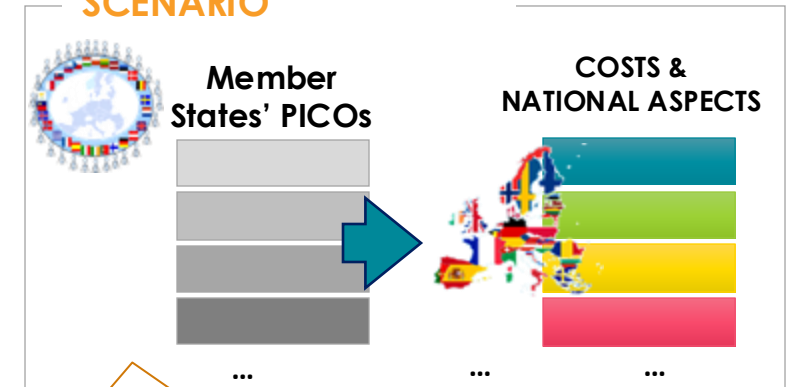
EXPECTATIONS



Common to EU 27

Impacting global clinical trials

SCENARIO



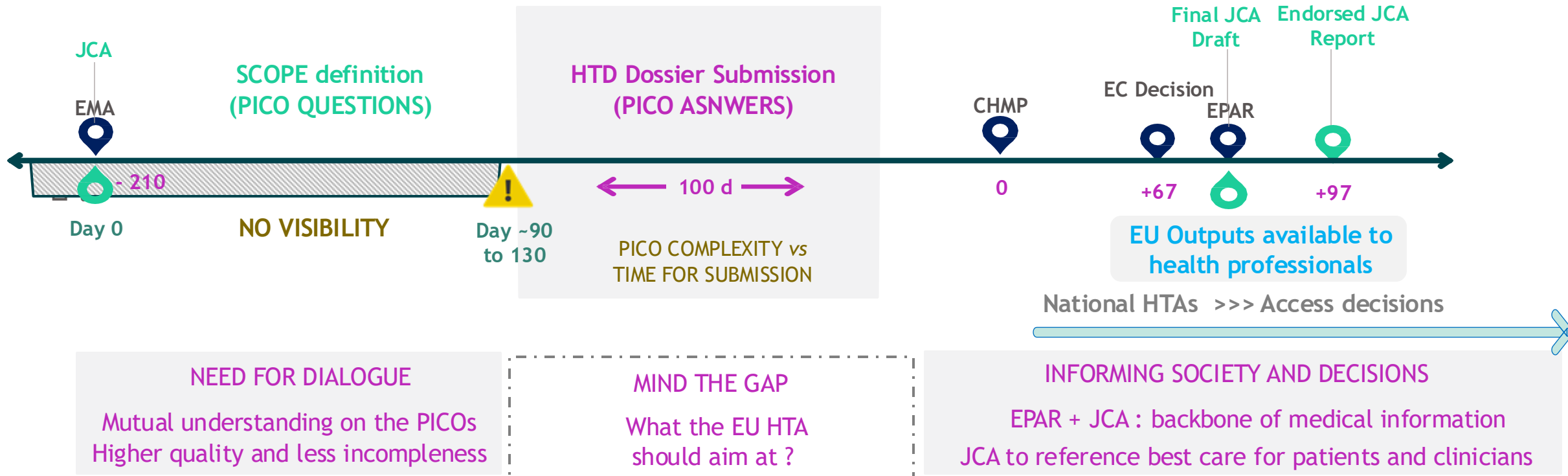
Risk of status quo:
No EU added value

With additional complex steps

- Europe can be more HTA-competitive worldwide
- Harmonization and divergence : stakeholders' expectations

EU JCA process : the challenge and the aim

Current solution puts quality and time of JCA at risk



Joint Scientific Consultation : key enabler

Evidence generation alignment will determine the future JCAs fitness



2025: ONGOING DEVELOPMENTS

2028: COMPANY SUBMITTING JCA DOSSIER

- **Evidence is generated now** for JCA in the new years
- **Dialogue** increases the chances of meeting **expectations**
- June 2024 : 10 CHMP positive opinions : 8 scientific advice



- EU HTA work programme **2025: only 7 JSCs for the year**
- No **capacity** to meet the **demand** for consultations
- **Selection process** still reflects Member States divergences




EFPIA SURVEY 1ST APPLICATION PERIOD 16 / 22 companies

- Not enough **time to prepare** for application (selection step add two months to EMA advice)
- **Offer of slots** so limited : did not match development and advice-engagement plan
- Uncertainty on **value** : cumulative vs consolidated advice

Methodologies and evidence

All evidence should be considered

INDUSTRY VISION

-  PLURALISM OF METHODOLOGIES
 - All methods to generate evidence shall be fairly considered
-  CONSIDERATION OF MOST ADVANCED MODELS
 - Not creating contradictions between JCA and national decisions
-  REALISTIC APPROACH
 - Multiple PICOs need indirect comparisons. One PICO is the only other way

e.g. surrogate endpoints

e.g. single arm trials

e.g. indirect comparisons



Conflict of interest rules

External experts are needed



Approved implementing act

Advising developer on unmet needs

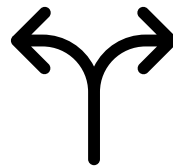
PATIENTS

Exclusion

Running therapeutic pathways study

CLINICIANS

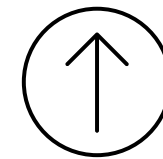
Exclusion



- Creating binary choice and silos
 - Expertise at risk either for research or for HTA

Industry Vision

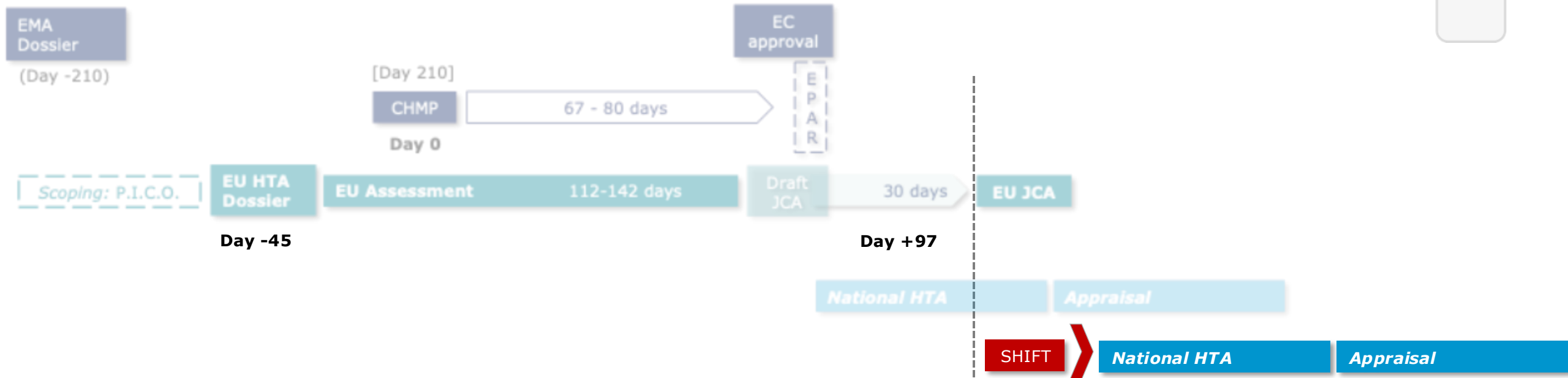
- Transparency over exclusion
- EMA as a model
- Learning from experience



- Clear frameworks for working relationships
- Awareness and education

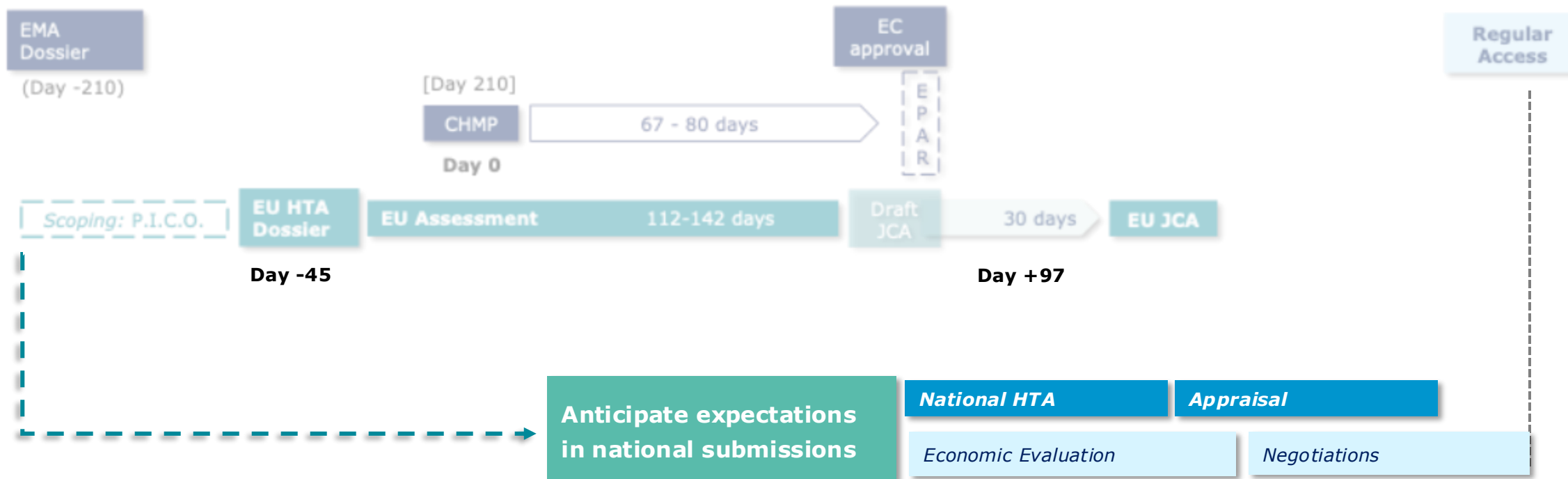
Key EU HTA objective: enabling faster access

Risk of producing a shift in national HTA



Key EU HTA objective: enabling faster access

Maintaining the benefit of early EU HTA : visibility on national submission



- 1. Engagement of HTD in scoping(PICOs)
- 2. Visibility on PICO requests from Member States

- 3. Countries to be ready to receive complementary info
- 4. Using JCA to streamline and accelerate national decision

MAKING THE MOST TO AVOID ACCESS DELAY

TO MAINTAIN THE ADVANTAGE GENERATED BY EU JCA FOR GIVEN COUNTRIES

Anticipating national changes

Preparing adaptations of national HTA frameworks



National Implementation EFPIA platform

Mapping the changes in national HTA frameworks

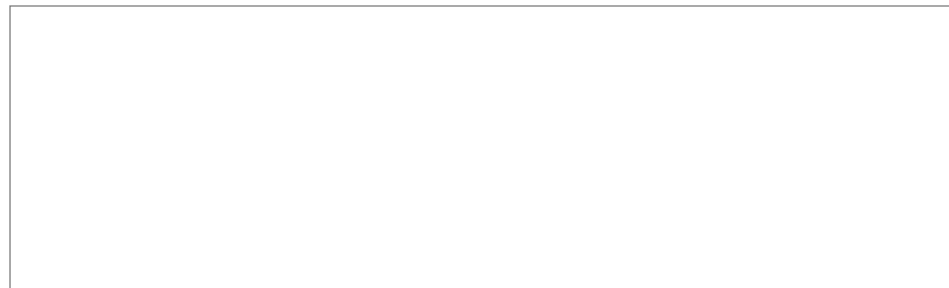
Templates, timepoints and decisions process will be impacted

Changes, e.g.	Impact
JCA report: timeline and availability	Time of submission and process unfolding
	Time of national reimbursement decision
Evidence package	Conditioned to EU JCA scope
Evidence consideration	Acceptance of JCA methodologies in appraisal
Potential parallel processes	Preparing national submission while JCA ongoing

All countries will experience some change !

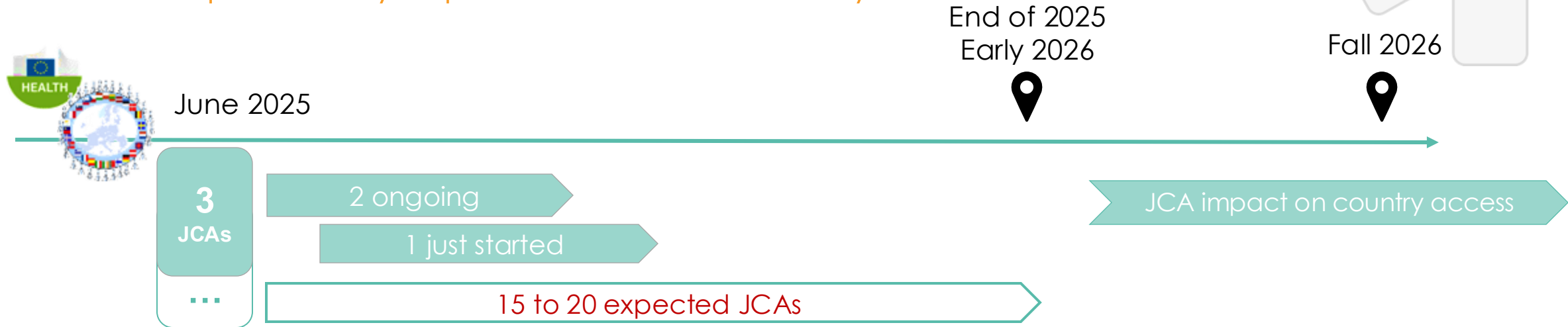


3. Building progresses on real world experience



The new system is now starting to deliver

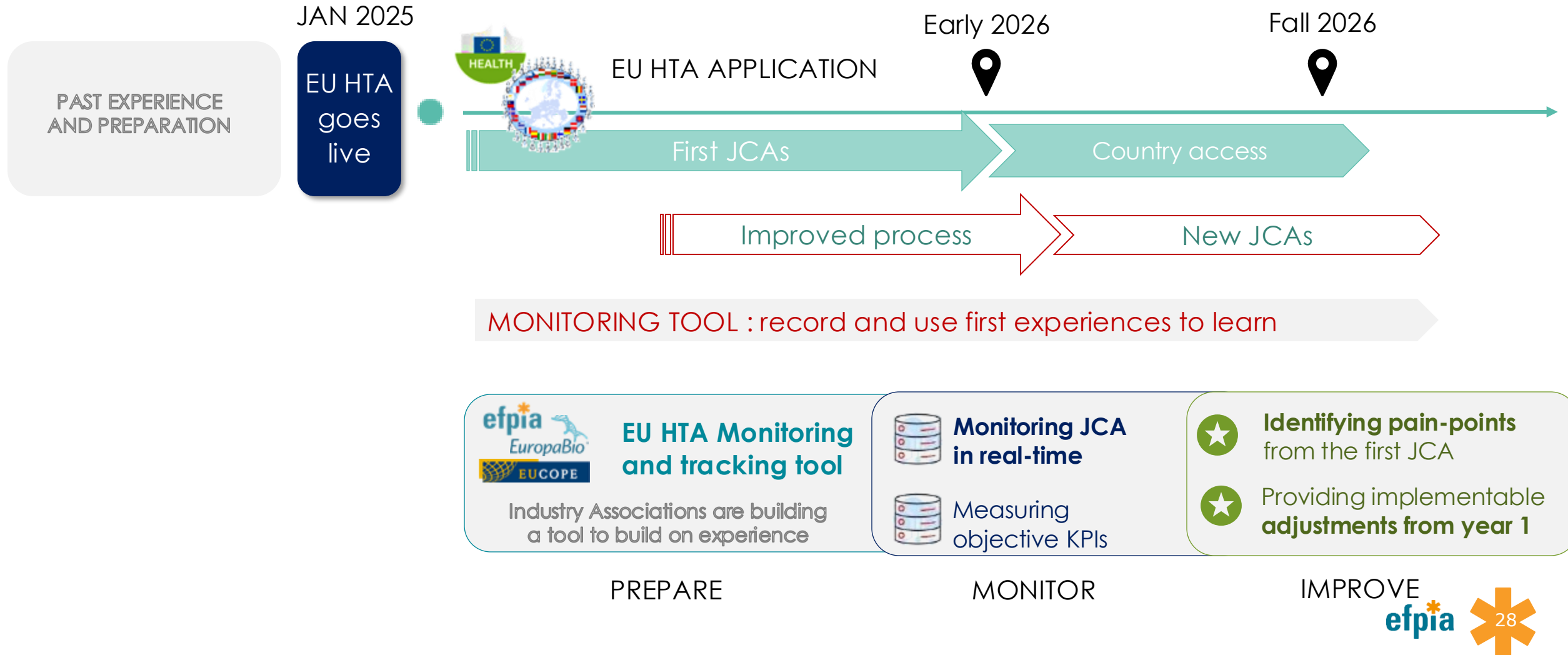
First JCAs: preliminary experience with the new system



1. **Little experience** so far :
feedback to be consolidated
2. **New** process is experiencing
some **unpredictability**
3. **Process** gaps should be enhanced
by proper **communication**
4. **System need to scale up**
to reach full capacity

Learning by doing. Monitoring to improve

New system not perfect : need to learn and improve from very first JCAs and JSCs



With the JCA Monitoring Tool, 7 key policy objectives will be covered



Policy objectives covered by the JCA Monitoring Tool

The Monitoring tool frame is the HTA-R objective: enabling faster access and better-informed decisions

01

JCA **timeline adherence** with HTA regulations

02

Encourage active **participation of Member States**

03

Ensuring **predictable process** for HTDs

04

Enhancing **stakeholders' involvement** in EU-level JCA process

05

Ensuring JCA **methodology** is comprehensive for innovation

06

Ensuring effective **integration of JCA in national HTA** reports

07

Minimizing **gap** between **JCA and national evidence**

Learnings from early experience of the EU HTA system



Predictability

Procedural uncertainties remain as potential painpoints

Dialogue

Alignment on PICO with developers is key for JCA dossier quality

Problem Solving

Platform with developers – chairs – secretariat to fix emerging shortcomings

Scalability

From few JCAs to full capacity: we need a scalable model to sustain the EU HTA system

Trust building

Creating mutual trust should be a top priority of this first phase of implementation

Key takeaways

1. **No more pilots**, the first JCAs will have **real consequences** on patient care
2. The JCA process : **enabler or barrier** for national access decisions
3. **Geopolitical context**: need to make Europe attractive and competitive
4. **From 27 to 1** European HTA framework: keep on the EU HTA promise
5. Monitoring the new process to **build on the learnings and improve** the system

Call for collaboration to leverage stakeholders' expertise and capacity: **help us to help you!**