



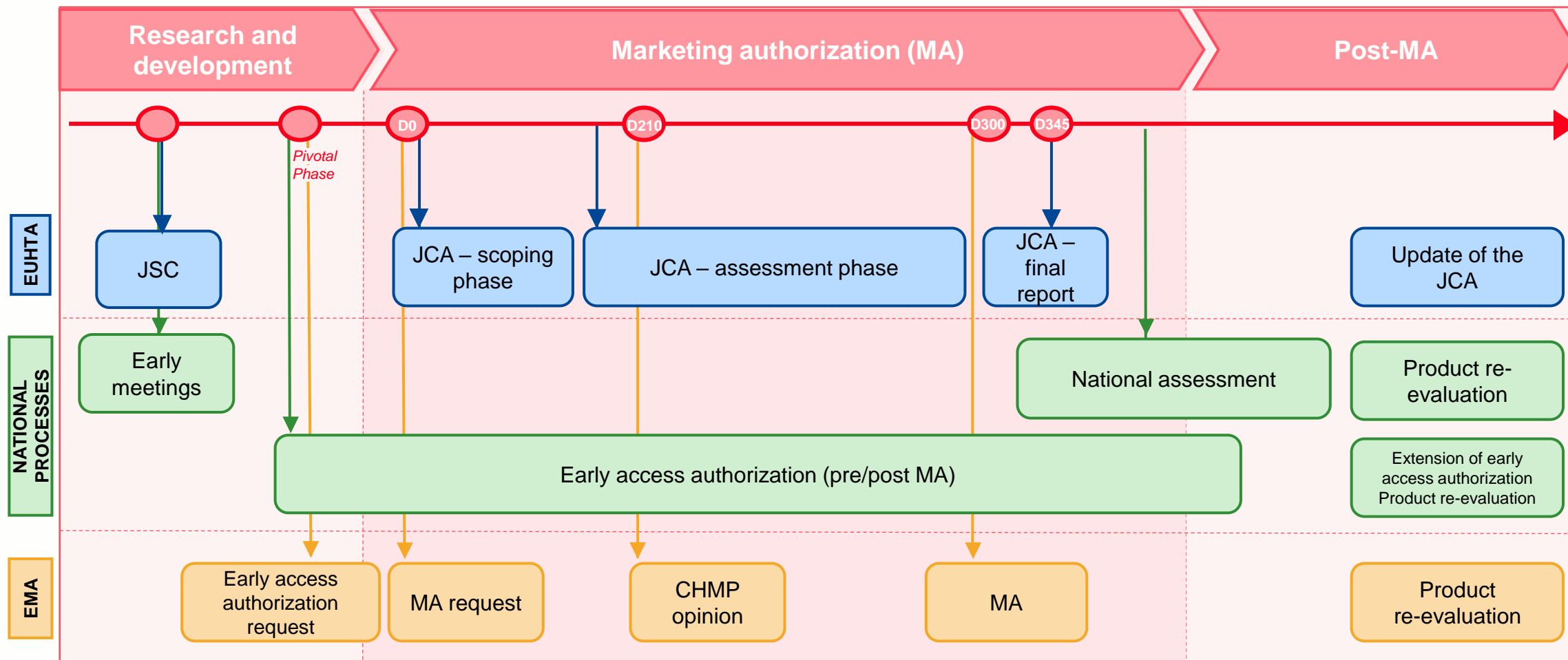
4th GIRF National Congress

HTAR - Sharing experience: France

Pierre Cochat – Haute Autorité de santé (HAS), France



Different procedures throughout the lifecycle of a medicinal product



JSC: Joint Scientific Consultation – JCA: Joint Clinical Assessment

What are the principles and expectations of a JCA?

The French and European responsibilities in the development of a JCA are organized as follows:



Scientific assessment

The clinical assessment of health products is centralized at the EU level, specifically:

- ▶ **Single dossier:** resubmitting data at the national level that has already been submitted at the European level is prohibited
- ▶ **Defining the assessment scope** (scoping phase - PICO)
- ▶ **Summary of comparative clinical evidence**
- ▶ Analysis of the **certainty** of the available data



National appraisal

The assessment of the value of a health technology, **pricing**, and **reimbursement** remain the competence of the Member States:

- ▶ **HTDs must still submit a reimbursement request**
- ▶ **HAS staff and Commission members will have access to the clinical data provided at the European level (JCA)**
- ▶ **The Commissions will continue to evaluate health technologies according to their doctrines**
- ▶ **The ministry continues to make reimbursement decisions**

Position of individual nations: 2 steps

1. Role of each individual nation in the HTAR assessment process
2. Impact of HTAR on each individual appraisal national process

Position of individual nations: 2 steps

1. **Role of France in the HTAR assessment process**
2. Impact of HTAR on each individual appraisal national process

Background

The National French Authority for Health (HAS) has been a founding member of EUnetHTA

Key persons

1. Pr Lionel Collet, co-chair, Heads HTAR
2. Paul De Boissieu, JCA subgroup chair (resigned)
3. Judith Fernandez, D-Director, HTA Department in charge of international affairs

Preliminary measures

1. Creation of an adequate committee within HAS (weekly meeting)
2. Information and training of HAS members
3. Information and training of Transparency Committee experts
4. Information and training of French representative of HTD
5. Online information at www.has-sante.fr
6. Publication of a special issue in *Quart Med Rev* (French journal in English)

Staff and experts: global action

1. Involvement of the whole Medicinal Product Assessment Office

2 delegates for JSC + 2 delegates for JCA

Coordination, regulation and information

2. Involvement of the board of the Transparency Committee

Search for PICO experts

Opinion on PICO French label

PICO methodology

Definition of the PICO method

P

Population: the patients or population for whom the intervention being evaluated is intended

I

Intervention: the therapeutic, diagnostic, or preventive intervention being evaluated

C

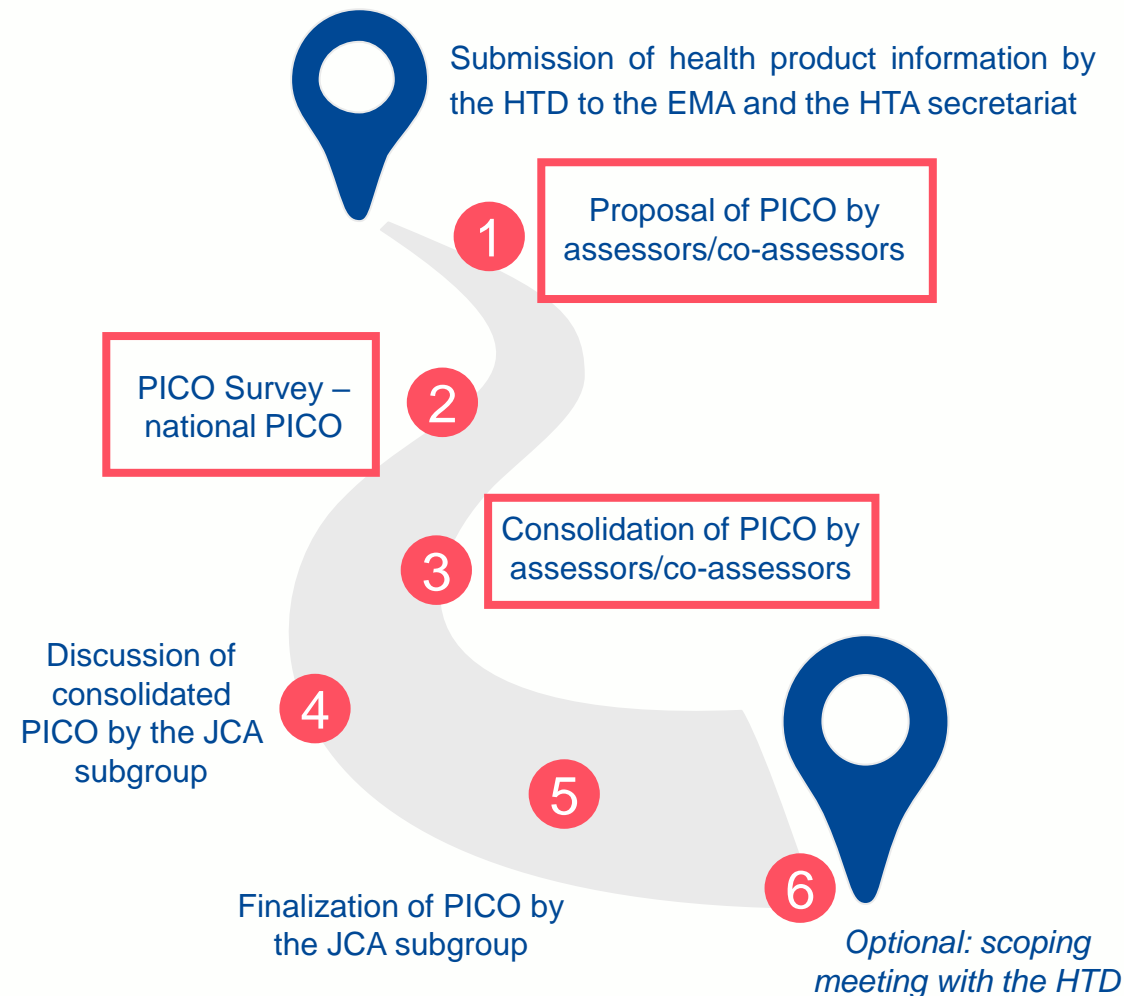
Comparators: the alternative intervention(s) to which the intervention being evaluated should be compared

O

Outcome: the relevant efficacy and safety outcome measures

The starting point of a JCA is the formulation of the PICO defining the framework and scope of the assessment. These PICOs are prepared before the submission of clinical data by the HTD and must reflect the expectations of the HTA agencies. They help guide and structure the dossier that the company must submit and the final JCA report. The PICO framework provides a standard format for researching this question.

Procedure for developing PICO



Position of individual nations: 2 steps

1. Role of each individual nation in the HTAR assessment process
2. **Impact of HTAR on the French appraisal process**

Evaluation of medicinal products in France

1. **Assessment Phase** - Medicinal Product Assessment Office (SEM):

40 project leaders

Pharmacists and MD

2. **Appraisal Phase** - Transparency Committee (CT):

29 experts

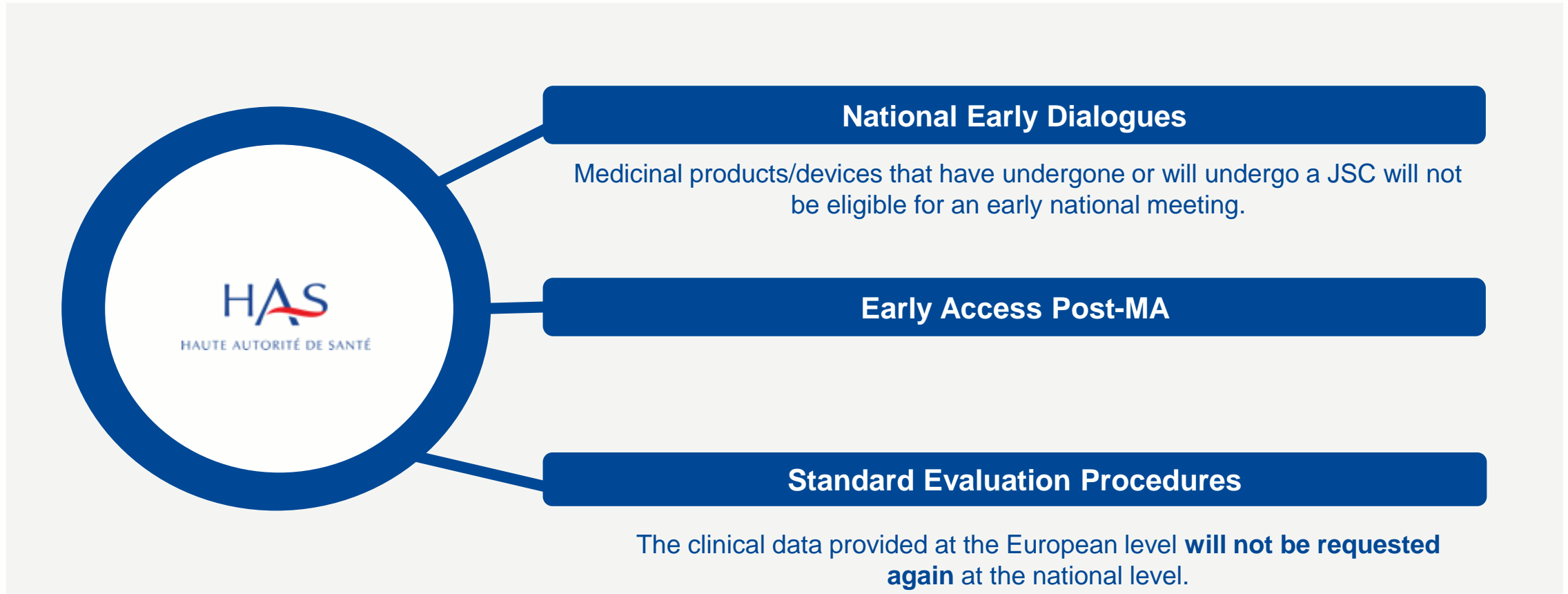
MD, pharmacists, methodologists, patient representatives

No economic mission : different adequate committee

Which procedures are unchanged at the national level?



Which procedures are affected at the national level?

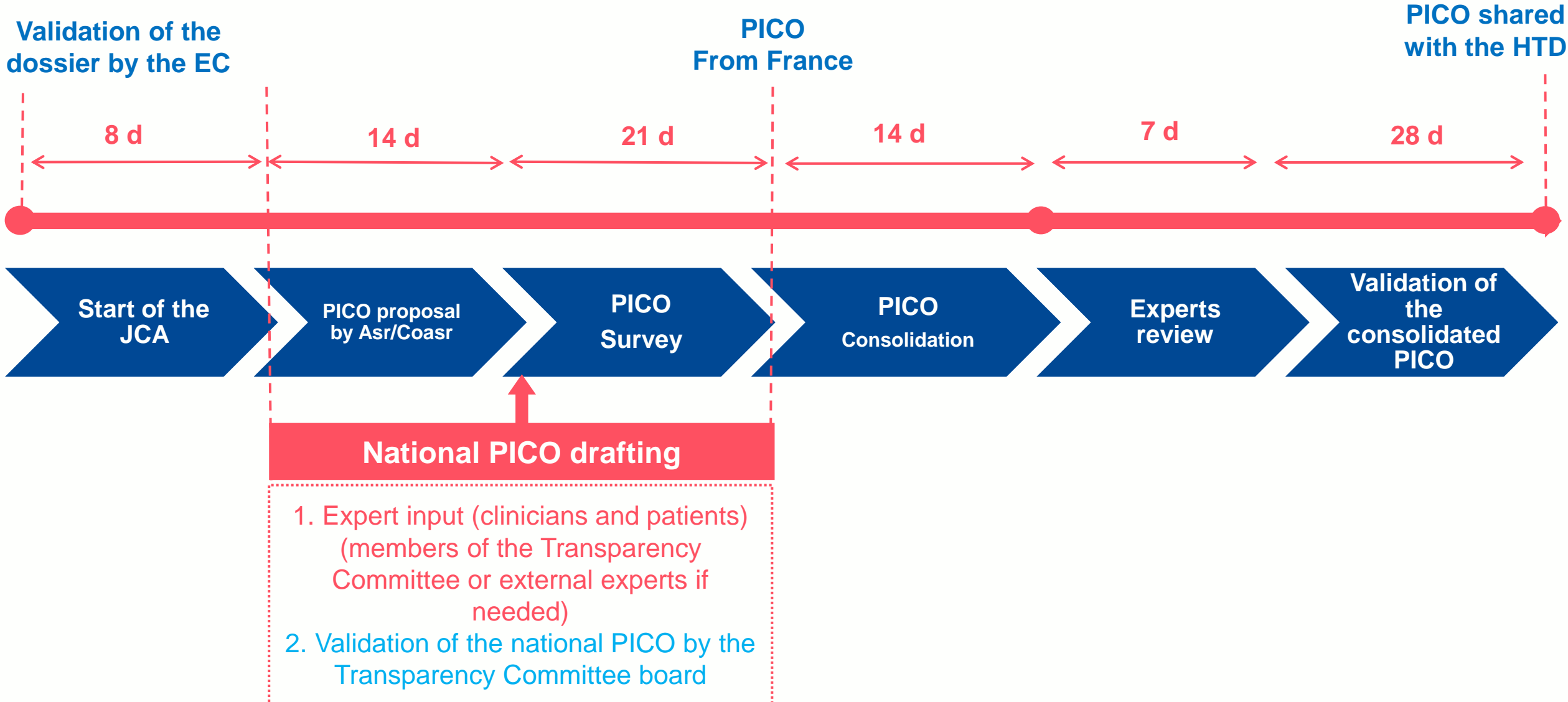


Ongoing JCAs



JCA	01	02	03	04
	Oncology	Oncology / ATMP	Oncology	Oncology
Therapeutic area	Glioma	Melanoma	Bladder cancer	Small cell lung cancer
Start	March	March	May	June

SCOPING PHASE : National implementation



Feedback on the first JCA experience

General Challenges

- Implementation of new processes that necessitate refinement and optimisation.
- Coordination and harmonisation between the two first JCA

Challenges as Assessor

- Complex JCA: PICO requiring numerous sub-populations
- Complex PICO consolidation across 27 Member States

Challenges as reviewer of other JCAs

- National procedures enabling to adequately address the national PICO:
 - Involvement of clinician and patient experts
 - Validation by the transparency committee board
- Implement this process and make it sustainable throughout the year

Acknowledgements

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www.has-sante.fr

