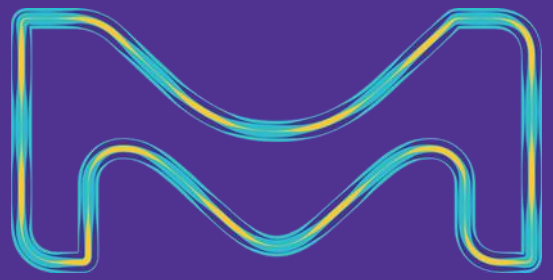
JCA insights unleashed

What can we learn from the first JCA procedures?

Panel Discussion with:
David McConnell, NCPE
Sarah Böhme, Pfizer
Thomas Ecker, Ecker & Ecker



MERCK

European collaboration on clinical aspects of HTA

EU HTA

Joint Scientific Consultation (JSC)

Clinical development

- HTD can obtain guidance on the evidence generation (in planning phase of pivotal studies)
- This advice may take place in parallel with **EMA scientific advice**

Joint Clinical Assessment (JCA)

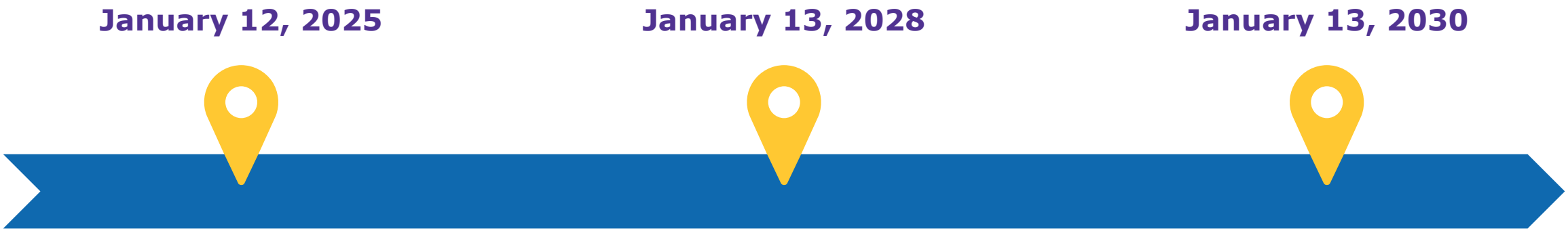
European clinical assessment

- Clinical Assessment of relative effectiveness and safety (no value judgements!)
- JCA process runs parallel **to EMA marketing authorisation procedure**

National HTA

Appraisal
Pricing & Reimbursement remains a national decision

The JCA is gradually introduced, with oncology products and ATMPs being in scope since January 2025



JCA **mandatory for oncology drugs, ATMPs** and implementation of JSC

JCA **mandatory for orphan drugs**

JCA **mandatory for all drugs (incl. vaccines)** registered centrally by the EMA

As the JCA is the basis for national procedures, the MS needs need to be well reflected in the process by the following requirements:

Assessment scope

The assessment scope for JCA should be **inclusive** and should **reflect all Member States' needs** in terms of data and analyses to be submitted by the HTD.

JCA dossier

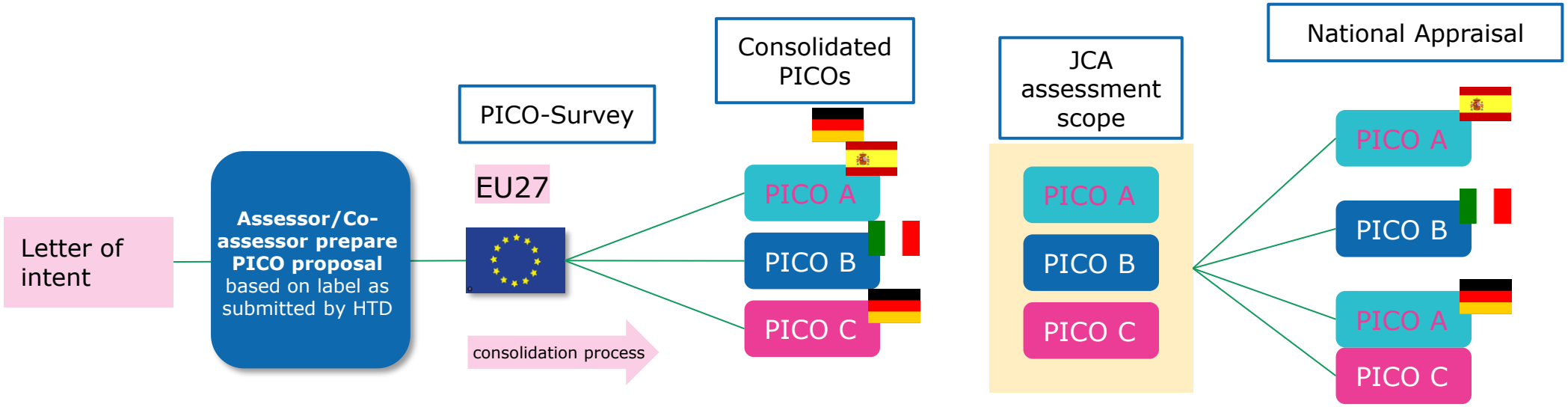
- the submitted evidence is **complete**
- the data has been analysed using **appropriate methods**
- adequate **presentation** of the data
- HTD shall **not submit** evidence at the national level that has been submitted at Union level.

JCA report

A JCA shall result in a JCA report. Those reports shall **not contain any value judgement** or **conclusions on the overall clinical added value** and shall be limited to a description:

- of the **relative effects**
- of the **degree of certainty** of the relative effects

A survey is sent to the 27 Member States to identify the assessment scope that fulfills all member state needs



Objectives

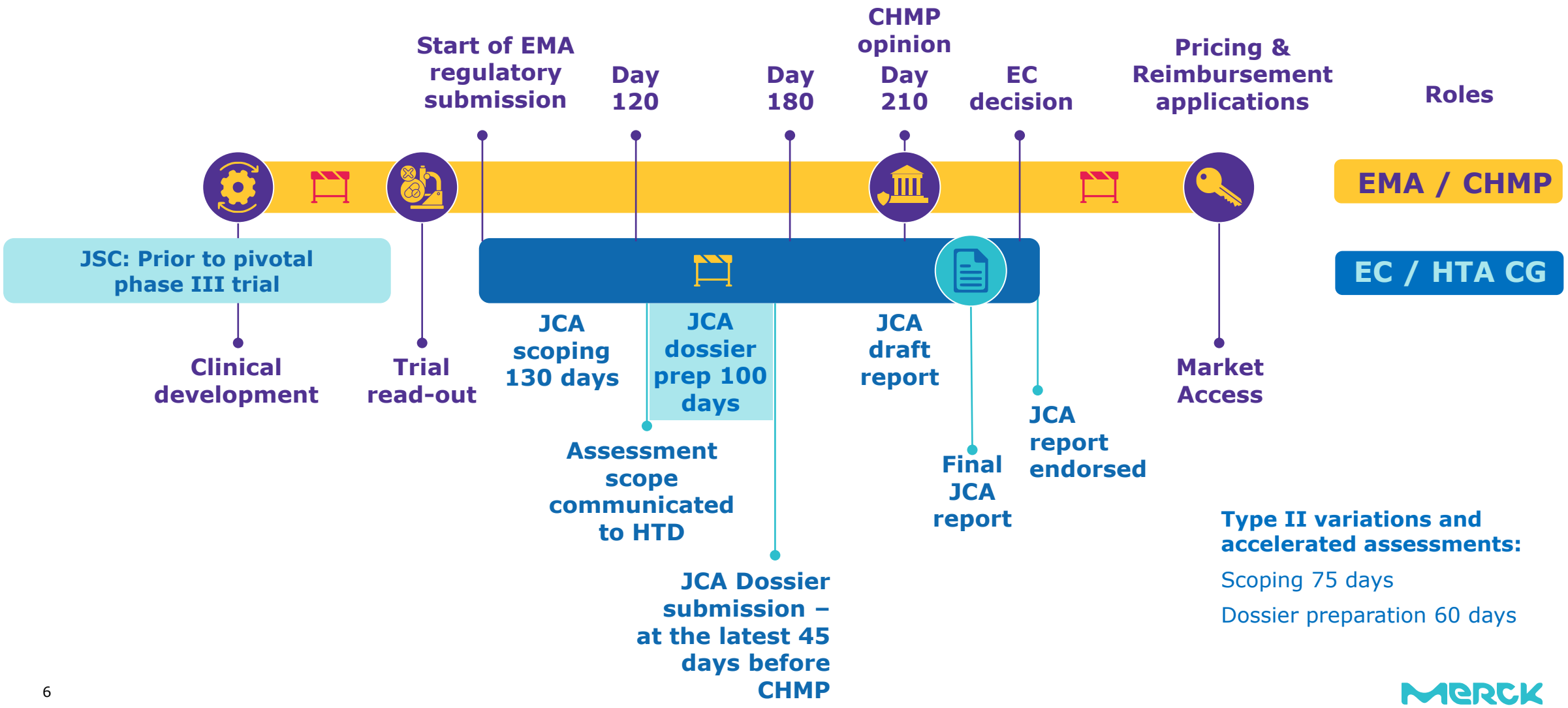
- The assessment scope shall be **inclusive and reflect Member States' needs.**
- To ensure that MS needs are translated in the lowest possible number of PICOs (consolidated assessment scope proposal)
- The consolidated assessment scope proposal will be shared with the subgroup asking MS for confirmation that their needs were met or if they require adaptations.

Implications

- National PICO is not known
- Number of PICOs is not limited
- Each PICO needs to be addressed with direct or indirect evidence (justification needed if no evidence is available)

Guidance on the scoping process: LINK

EMA regulatory procedure and JCA timelines are in parallel



Type II variations and accelerated assessments:

Scoping 75 days

Dossier preparation 60 days