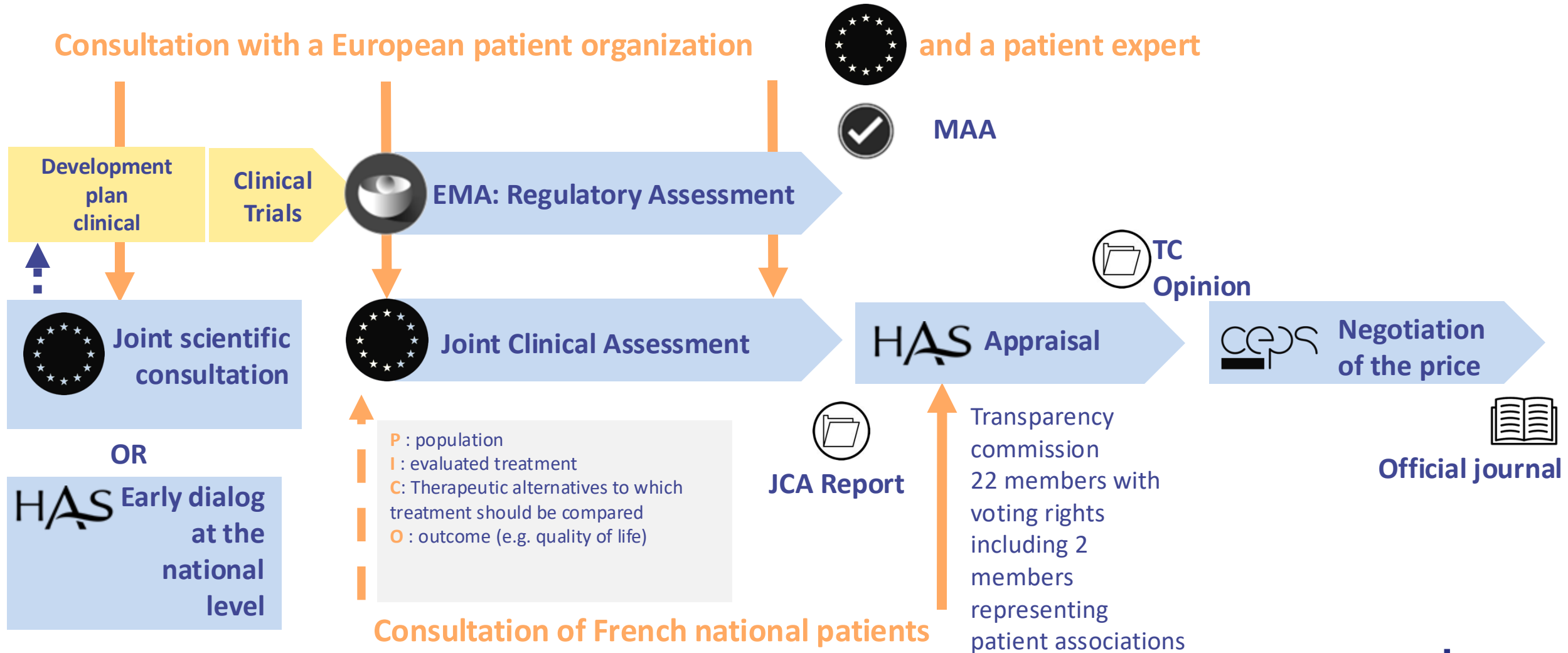


Involvement of patients in the French HTA process



Role of patients in the French HTA process



National Patient

- In the PICO survey

Possible request for input from national patients

The HAS is creating a pool of patients



National Patient Associations

- In the EAP process and the common clinical appraisal procedure for reimbursement:

Input from national patient advocacy groups

Questionnaire – Common procedure for reimbursement

- Impacts of the disease on quality of life (patients, relatives and caregivers)
- Currently available treatments (excluding the medicine under evaluation)
- The medicine under evaluation
 - Your comments on the indication requested by the laboratory
 - If you have experience with the medicine under study (otherwise, move to the next section), Advantages/ Disadvantages observed when using the medicine under study compared to other treatments currently used
 - If you have no experience with the medicine under evaluation: what are your expectations and concerns for the medicine under study?

Questionnaire – Early Access Program

- Your position regarding the criteria for early access authorisation
- Your position on the data to be collected by patients if early access to the medicine is granted
 - The data and information that are important to collect
 - Your opinion on the therapeutic use protocol – Data collection

Information available to PAG

Stage of the HTA evaluation procedure (National and European)	Type of PAG Contribution	Documents available for patient organizations
CSC & Early Dating	<ul style="list-style-type: none"> • Will French patients have the opportunity to take part in a JSC? 	No element planned at the national level
JCA & Early Access Pre-Marketing Authorization	<ul style="list-style-type: none"> • The HAS continues to take the opinion of French patient associations via: <ul style="list-style-type: none"> - Written contribution, - Audition possible - +/- comments on the therapeutic use protocol and data collection 	Nothing new
JCA & Early Access Post-Marketing Authorization	<ul style="list-style-type: none"> • The HAS continues to take the opinion of French patient associations via: <ul style="list-style-type: none"> - Written contribution - Audition possible 	Patient associations will eventually have the JCAR (in French?) and the file submitted by the company (in English)
JCA & Reimbursement Request (excluding EAP)	<ul style="list-style-type: none"> • The HAS continues to take the opinion of French patient associations via: <ul style="list-style-type: none"> - Written contribution 	Patient associations will eventually have the JCAR (in French?) and the file submitted by the company (in English)

French patients and medical experts are involved in the French HTA process

