

## 4 WAYS TOWARD A SUCCESSFUL

# EUROPEAN COOPERATION ON HTA

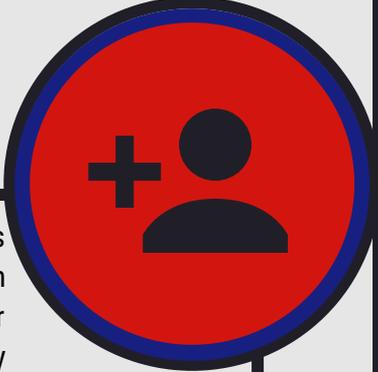
AN IMPORTANT STEP TOWARD EQUAL ACCESS TO HIGH-QUALITY  
MEDICINES FOR EUROPEAN PATIENTS



## 1. USE HIGH STANDARDS

Given that the uptake of the joint clinical assessment decisions will be mandatory, there is a clear need for high standard assessment with high quality endpoints. Hence, EU Member States would not feel the need to re-assess decisions met by the Coordination Group.

## 2. MEASURE PROs & RWE



In order to measure the quality of medicines, looking at patient reported outcomes (PROs) and real world evidence (RWE, if available during primary assessment, always in re-assessment phase) should be mandatory in order to recommend the treatment for reimbursement. Clinical outcomes assessed should include both survival, morbidity and PROs reflecting the quality of life.

It is essential that industry (i) collects PROs as early as possible in clinical trials, not only in Phase III; (ii) delivers its promises to collect RWE after the market approval; and (iii) discloses all available data to the HTA authority, including unpublished data from failed trials, to enable full high quality assessment.



## 3. INVOLVE PATIENTS

Involving patients in all activities of the EU HTA, including horizon scanning, development of guidelines, joint scientific advice and clinical assessment is key to accurately capture patients' needs while assessing the added value of all treatments.

## 4. BE TRANSPARENT & INDEPENDENT



It is crucial to act in a transparent manner with no or minimal confidentiality connected to stakeholder meetings. Strong conflict of interest rules should apply for members of the Coordination Group and its subgroups (i.e. experts) and the relationship with all stakeholders should be clearly defined.

Given the narrative of the HTA and its aim to objectively assess the value of new treatments, it is necessary to keep all HTA personnel independent from the industry's influence.