

# Lost in PICO? A simulation of the EU HTA scoping process

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## OBJECTIVES

The joint clinical assessment (JCA) according to Regulation (EU) 2021/2282 will initially be implemented for oncology drugs and ATMPs from January 2025. All JCA procedures are commenced by the scoping process: The formulation of a member state-specific research question, represented as individual PICO schemes. Patient population, intervention, comparator, and study endpoints to measure the outcome are determined by the authorities as basis for clinical evaluation. Given the diversity of standards of care in Europe, multiple PICOs can be demanded. By simulating an EU HTA-like scoping process as of today, this analysis aims to assess the risk of receiving numerous PICOs.

## RESULTS

