Too Many PICOS for Joint Clinical Assessments (JCA)? How To Adapt the Systematic Literature Reviews (SLRs) for Achieving Desired Outcomes

HTA52

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Background

- Effective 12 January 2025, new medicines for the treatment of cancer, and advanced therapy medicinal products are subject to Joint Clinical Assessments (JCA).
- There have been concerns regarding evidence generation needs due to high numbers of PICOS (Population, Intervention, Comparator(s), Outcomes) required in a short timeframe and simultaneously.
- On 28th November 2024, the European Member State Coordination Group on Health Technology Assessment (HTACG) released scoping guidance on how to seek, consolidate and finalize member state (MS) requirements in the context of PICOS.[1]
- On 3rd February 2025, the six PICO exercises that were carried out by the JCA subgroup for drafting the scoping guidance were also published at European Commission website.[2]
- The objective of this research was to evaluate the guidance and identify opportunities to operationalize the SLR to support the development of the JCA dossier

Methods

- We reviewed HTACG guidance on scoping for JCA and evaluated how SLRs may need to be adapted to meet JCA requirements including multiple PICOs and short turn around time.
- The HTACG guidance on scoping was accessed through the below link https://health.ec.europa.eu/publications/guidance-scoping-process_en

Results

- HTACG guidance on scoping provide details on how the assessment scope is prepared and finalized. In summary, following important points needs to be factored in while finalizing the assessment scope (PICO)
- The assessment scope should be inclusive to reflect Member States (MS) needs and at the same time it should capture the requirements through a minimum number of PICO parameters.
- Members states should specify their requirements (PICO)
  - P: Patient population (same as full claimed indication by Health Technology Developer or only subgroup population)
  - C: Comparators
    - Unique comparator
    - Multiple comparators
    - Individualized comparators
  - In case of multiple comparators, Member States should clearly state if comparison is required against "all comparators" or "at least one comparator".
  - During the consolidation phase of PICOs, comparators deemed desirable but not mandatory by the Member State can be dropped from final scope.

Conclusions

- HTASG guidance on the scoping process is a valuable tool for researchers to understand PICOs requirements for JCA. Currently guidance for assessment scope is at EU level requiring further adaptations at individual member state level to factor in the dynamically changing clinical practice. Adapted SLR's involving SMART strategy is a promising solution to complex evidence needs for JCA

- Due to the JCA requirements, Health Technology Developer (HTD) faces the **following challenges**:
  1. Consolidation of evidence across multiple PICOs
  2. Changes to assessment scope after CHMP opinion
  3. Focus of SLR and dossier on individual PICO scenarios rather than consolidated synthesis of PICOs for individual MS
  4. Reporting of comparative effectiveness across PICOs for MS
  5. Difficulties in drawing conclusions from studies with overlapping PICOs
  6. Short turnaround timelines for evidence submission
  7. Validation of assessment scope (PICO)
  8. Evidence gaps for some PICOs after assessment scope finalization

- SLRs form the building stone of the JCA dossier, so to circumvent these challenges, it is imperative to adapt SLRs to meet these requirements. Parexel proposes a SMART strategy for SLRs to achieve the desired outcome.
- **S: Search strategy adaptations:**
  - Comprehensive search strategies that can pick up all the evidence from multiple PICOs for each MS.
  - SMART approach preemptively considers assessment scope while allowing incorporation of modifications to PICOs once assessment scope is shared with the HTD
- **M: Managing multiple PICOs**
  - SMART SLR's involve exclusive extraction and reporting of studies with overlapping PICOs to avoid repetition while also allowing to drill down the evidence by individual PICO
- **A: Additional stakeholder inputs**
  - The SMART strategy includes additional relevant stakeholder involvement regulators, payers and patient groups) for validating the PICOs and providing further input to HTDs.
- **R: Reporting adaptations**
  - Traditional SLR's involve all evidence combined reporting approach which leads to difficulty in drawing insights for individual PICOs conclusion as well as maintaining insights from studies involving overlapping PICOs.
- **T: Technological adaptations**
  - SMART SLRs will adopt AI enabled tools to manage high amount of evidence efficiently while allowing quicker analysis and development of deliverables.

Parexel advice for ensuring JCA success

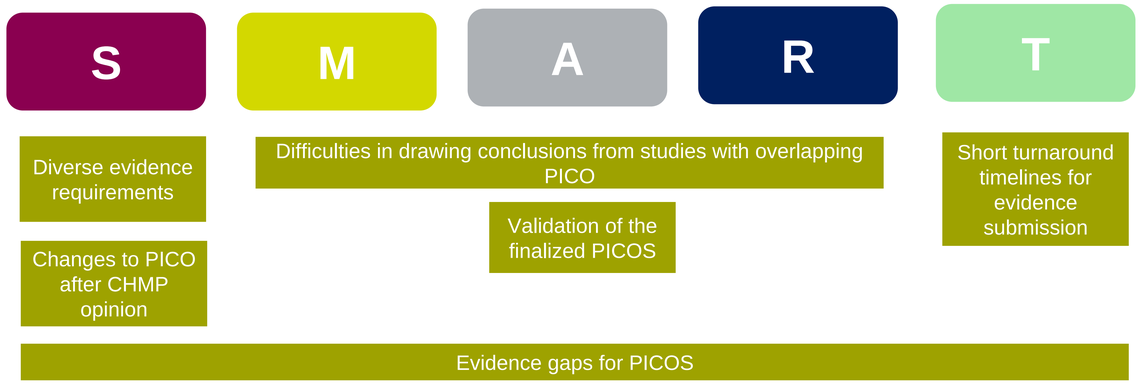
- **START early –ideally start planning when Phase III trial is initiated and initiate SMART with interim readout**
- **Evidence generation with SMART strategy**
- **Stakeholder involvement & validation**
- **Understanding market launch sequence**
- **HTD to be more involved in assessment scope discussion**

Figure 1: SMART strategy proposed for the SLR's for adapting to evolving JCA needs

HTA: Health Technology Assessment; JCA: Joint Clinical Assessment; MS: Member states of JCA subgroup; PICO: Patient population, Intervention, Comparator, Outcome; SOC: Standard of Care

SMART strategy is a solution for meeting JCA requirements. It can cover evidence more comprehensively and faster (3 months vs. 9 months compared to traditional SLR's)

Figure 2: How SMART SLR's can help Health Technology Developer to mitigate challenges due to multiple PICO



CHMP: Committee for Medicinal Products for Human Use; PICO: Patient population, Intervention, Comparator, Outcome; SOC: Standard of Care

REFERENCES

[1] https://health.ec.europa.eu/document/download/7be11d76-9a78-426c-8e32-79d30a115a64_en?filename=hta_jca_scoping-process_en.pdf&prefLang=de
[2]https://health.ec.europa.eu/publications/pico-exercises_en