The EU JCA scoping process: a health technology developer perspective

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The PICO simulations were used to predict the scoping process outcome, and its implications on evidence generation & analysis

<table>
<thead>
<tr>
<th>HYPOTHETICAL SCENARIOS</th>
<th>1L NSCLC</th>
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</thead>
<tbody>
<tr>
<td>Country specific PICO</td>
<td>6+1</td>
</tr>
<tr>
<td>PICO¹ (direct comparison)</td>
<td>14 (6)</td>
</tr>
<tr>
<td>Unique population</td>
<td>11</td>
</tr>
<tr>
<td>Comparators</td>
<td>9</td>
</tr>
<tr>
<td>Outcomes</td>
<td>28</td>
</tr>
<tr>
<td>Proportion of analysis requiring indirect evidence²</td>
<td>57%</td>
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1 Includes NICE, as a proxy of remaining MS
2 Based on base case scenario (no additional outcome measure, subgroup or inclusion of safety analyses required in Germany). Requested analyses does not imply feasibility

What was learned from the simulations and case studies?

What are the implications of the process on HTDs and HTA bodies?

How could the process be built upon to increase the quality, efficiency and usage of the JCA?
The proposed process, high number of PICO$s and significant analysis burden has implications for HTDs and HTA bodies

**For HTDs...**
- Additive PICO$s will not change trial and evidence development
- Lack of evidence-based guidance and engagement reduces predictability, transparency and inclusivity
- Redundant and exponentially-growing analyses requests
- Majority of PICO$s require more complex indirect analyses

**For EU HTA assessors...**
- Significantly higher PICO count than was predicted by EUnetHTA
- Significant resource required to assess large & complex dossier
- Large proportion of ITCs will require substantial time for assessment and write-up vs direct comparisons

**For local HTA bodies...**
- MS have different approaches to PICO$s – no guidance creates increased variation
- Many safety & subgroups analyses not usable or not used by most Member States
- Size & complexity compromises utility at a local level
Addition of evidence-based medicine principles, building on the EUnetHTA process, would increase quality and value of EU HTA.

- **Evidence-based PICO**
  - Not all PICO or analyses should have the same weight

- **Clinically relevant**
  - Selection and prioritization of subpopulations

- **Used in practice**
  - Guidance for assessors and Member States on comparator selection

- **HTD engagement**
  - Increase HTD engagement

Ensuring a high quality, inclusive and transparent JCA relevant to Member States.
Addition of evidence-based medicine principles, building on the EUnetHTA process, would increase quality and value of EU HTA.

Increase HTD engagement

- Early engagement whilst retaining independence of final PICO.
- Use evidence HTDs have on the disease, clinical practice and endpoints to inform PICO.
- HTD to propose a base case PICO.
Addition of evidence-based medicine principles, building on the EUnetHTA process, would increase quality and value of EU HTA

Guidance for assessors and Member States on comparator selection

- Usage data to determine the “best available alternative”
- Robustness of effectiveness evidence supporting its use
- Requirement to treat a minimum proportion of the selected European (sub)population?
Addition of evidence-based medicine principles, building on the EUnetHTA process, would increase quality and value of EU HTA

Selection and prioritization of subpopulations

- Subpopulations (and subgroups) should be clinically relevant and actionable at a national MS decision-level
- Priority to pre-specified and clinical consensus
Addition of evidence-based medicine principles, building on the EUnetHTA process, would increase quality and value of EU HTA

Not all PICOs or analyses should have the same weight

- PICOs informed by evidence-based principles should have more weight
- Complementary clinical analyses were anticipated - and improve efficiencies
- MS PICOs are needed to ensure timely submissions at a national level