



# 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

HYPOTHETICAL SCENARIOS	1L NSCLC
Country specific PICO	6+1
PICO <sup>1</sup> (direct comparison)	14 (6)
Unique population	11
Comparators	9
Outcomes	28
Proportion of analysis requiring indirect evidence <sup>2</sup>	57%

<sup>1</sup> Includes NICE, as a proxy of remaining MS  
<sup>2</sup> Based on base case scenario (no additional outcome measure, subgroup or inclusion of safety analyses required in Germany). Requested analyses does not imply feasibility

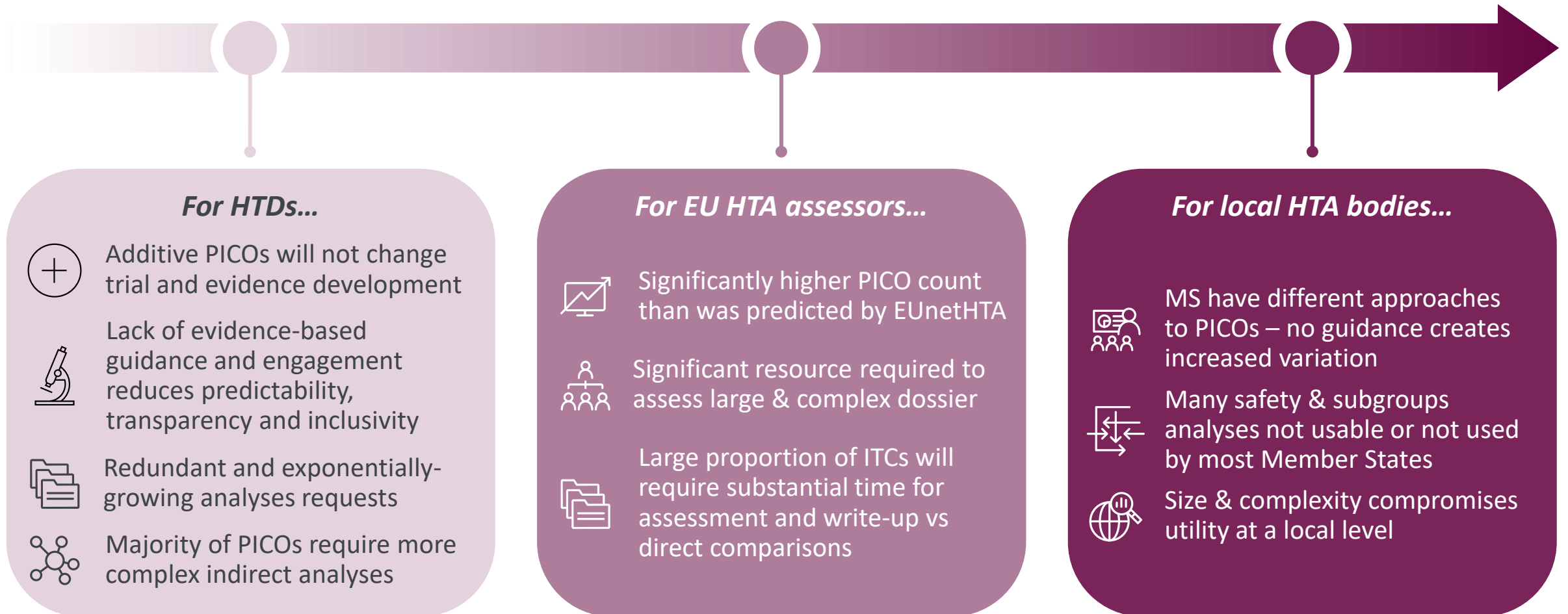
*What was learned from the simulations and case studies?*

*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 PICOs and significant analysis burden has implications for HTDs and HTA bodies



# Addition of evidence-based medicine principles, building on the EUnetHTA process, would increase quality and value of EU HTA

## Evidence-based PICOs

Not all PICOs or analyses should have the same weight



## HTD engagement

Increase HTD engagement



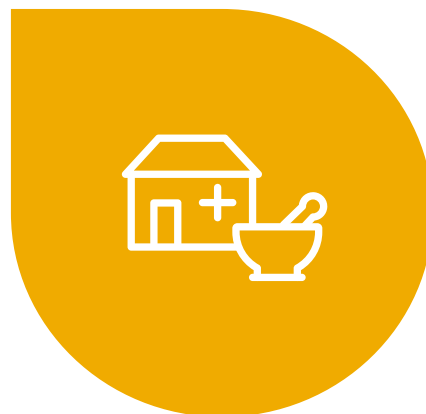
## Clinically relevant

Selection and prioritization of subpopulations



## Used in practice

Guidance for assessors and Member States on comparator selection



Ensuring a high quality, inclusive and transparent JCA relevant to Member States



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## Increase HTD engagement

- Early engagement whilst retaining independence of final PICOs
- Use evidence HTDs have on the disease, clinical practice and endpoints to inform PICOs
- HTD to propose a base case PICO

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## 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?

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## **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

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## **Not all PICO or analyses should have the same weight**

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