



European HTA: Clinician Perspective



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Disclosures

- No COI with pharma industry
- Receive payments from the Haute Autorité de Santé
- <https://www.transparence.sante.gouv.fr/>
- <https://dpi.sante.gouv.fr/>

What do clinicians need from HTA?



Timely access to
effective and less toxic
therapies



Recognition of patient
heterogeneity and
subgroups



Continuity of access to
essential medicines



HTA aligned with real
clinical practice

Access depends on three pillars

Evidence generation

HTA process (Assessment – JCA / Appraisal – national)

Pricing and reimbursement decisions

EU-HTA harmonizes assessment, not access

What evidence do clinicians need?

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- Robust level of evidence (RCT + complementary data)
 - Comparative data (head-to-head or robust indirect)
 - Relevant populations and subgroups
 - Up-to-date comparators reflecting real practice
 - Patient-relevant outcomes (OS, QoL, function)

Comparative evidence challenges

Limited availability of head-to-head trials



Increasing reliance on indirect comparisons

Need for high-quality external cohorts

A priori identification of external dataset

Critical importance of confounders and t0 definition



Need for European shared and generated datasets (IPD)

EU-HTA: Key levers for clinicians

- **JSC**: essential to influence trial design early
- **JCA**: based on pre-existing trials → limited flexibility
 - Multiple PICOs → complex and less interpretable results
 - Need for harmonization of methods
 - Roles of various stakeholders input
 - Most critical methods identification
- Appraisal and access remain national

Risks of EU-HTA

- PICO multiplicity leading to unclear conclusions
- Mismatch between comparators and real practice
- Heavy reliance on post hoc analyses
- Limited clinician involvement (COI constraints)
- Persistent access inequalities across countries

Mains messages



EU-HTA is a major step forward but not sufficient



JSC should be strengthened to shape evidence early



PICO must reflect real clinical decision-making



Better integration of RWE and patient-reported outcomes



HTA should answer: how do I treat my patient tomorrow?