EU HTA:
Communicating Statistics & Uncertainty
The Case of Health Technology Assessment

Brought to you by the HTA ESIG

Session Chair: Lara J. Wolfson, MSD

"We are a community dedicated to leading and promoting the use of statistics within the healthcare industry for the benefit of patients."

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Opening Remarks

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Session Overview

Introduction – An Overview of EU HTA & Communication
Lara Wolfson, MSD, HTA ESIG Co-Chair

Help your non-statistician audience make sense of risk
Maricarmen Climént, Sense about Science

Communicating statistical concepts to an HTA Audience
Professor Nick Latimer, University of Sheffield, Petauri Evidence

Using statistical communication to build trustworthy HTA (Discussion)
Anders Gorst-Rasmussen, NovoNordisk, Former HTA ESIG Co-Chair

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EFSPI EUROPEAN FEDERATION OF STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY
Representing Statistical Associations in Europe

An Overview of EU HTA & Communication

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The EU HTA Regulation

Passed into law in Q4 2021; effective January 2025

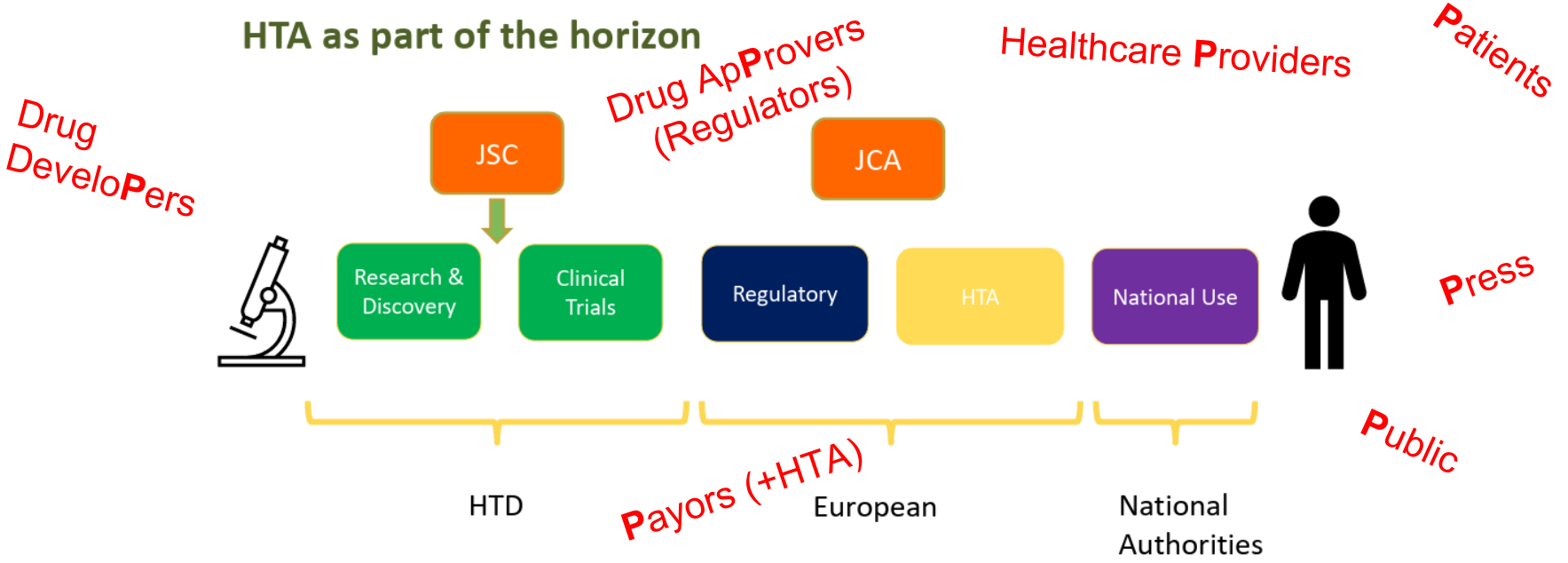
Accessible here

The **mandatory** requirement of **centralised clinical assessment** for patient access of new health technologies to MS of the EU

Joint Clinical Assessment (JCA)

EU, European Union; HTA, Health Technology Assessment; HTAR, Health Technology Assessment Regulation; MS, Member State.

HTA Assessments will be used in multiple ways by multiple **Players**



https://health.ec.europa.eu/document/download/40feaa77-58a6-4a4b-9a77-2fc032e284b3_en?filename=hta_20250516_co01_en.pdf

EU HTA: The Mandatory Requirement to Submit a JCA

What's a JCA?

Definition

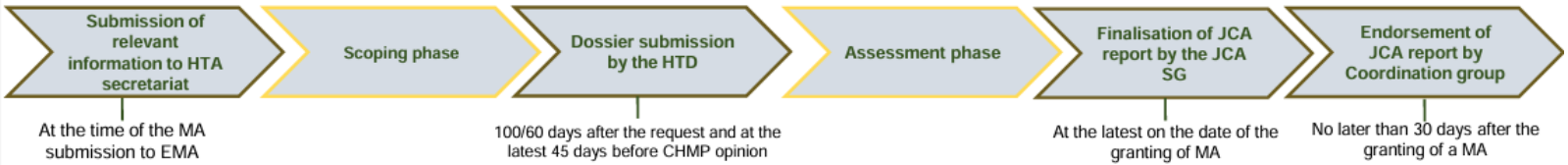
→ Compilation of comparative clinical evidence with an analysis of the degree of certainty of the available data
→ In accordance with an assessment scope (PICOs)
→ Based on the scientific aspects of the clinical domains of HTA

Relevant medicinal products and medical devices

2025: New oncology medicines and ATMPs + new indications for which a JCA report has been published
2028: New orphan medicinal product
2030: All new medicines authorized through a centralized procedure

From 2026: Class IIb and III medical devices + Class D in vitro diagnostic medical devices for which the EMA expert panels have provided a scientific opinion *(subject to selection by implementing decision)*

Timeline – Medicinal Products



HTA CG Subgroup for Joint Clinical Assessments

https://health.ec.europa.eu/document/download/40feaa77-58a6-4a4b-9a77-2fc032e284b3_en?filename=hta_20250516_co01_en.pdf

The Assessment Scope for JCA→ PICOs

The assessment scope should include all relevant parameters in terms of the PICO framework:

- **P**atient population
- **I**ntervention
- **C**omparator(s)
- **O**utcomes

PICO selection is **policy**-driven, not evidence-driven.

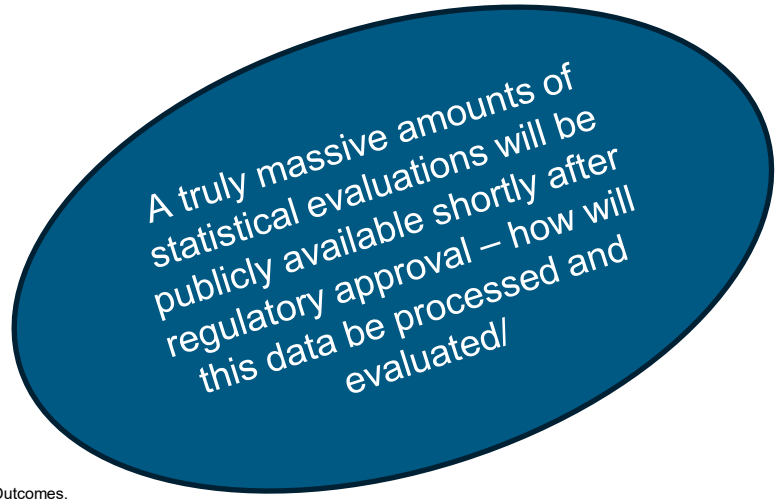
MS should determine their PICO needs and a consolidation of requirements should happen

- Timepoint: ~100 days after regulatory submission

All endpoints for all P/C combinations

Fixed templates

Delta Dossiers at the national level



EU, European Union; JCA, Joint Clinical Assessment; MS, Member State; PICO, Population, Intervention, Comparator(s), Outcomes.

How do we write a JCA, knowing multiple audiences will use it for multiple purposes?

Training Module	Learning Objectives	Course Summary (Exercise types)	Available session*
Clinical study evaluation	• Apply clinical study design principles to evaluate the external and internal validity of the study • Distinguish between different types of outcomes and critically assess the impact of outcomes on relative effectiveness • Gain an overview of statistical techniques in treatment effectiveness	It provides an overview of clinical study design components and method types. Participants can gain knowledge on types of biases and **how to assess the internal and external validity of studies, interpret treatment effect accuracy, and evaluate outcomes relevance**. EU HTAR experts will provide practical examples in JCA and JSCs on how to assess the robustness of clinical study design, covering cases from different study design types. During the course, there will be exercises with example clinical study evaluation sections in a JCA report, including completing gaps and finding the mistakes to improve.	Start as of September 20 until March 2026
Evidence Synthesis evaluation	• Understand the different evidence synthesis methods and their application • Interpret the application of evidence synthesis methods for PICO framework • Comprehend the uncertainty associated with evidence synthesis methods	It provides an overview of evidence synthesis methods and their application areas. Participants can gain knowledge on PICO framework, and its use in the context of evidence synthesis. There will be a focus on the application of **quantitative evidence synthesis methods**, both direct and indirect comparisons. EU HTAR experts will provide practical examples in JCA on how to assess the methodological quality of direct and indirect comparison studies. During the course, there will be exercises with example direct/indirect comparison sections in a JCA report, including completing gaps and finding the mistakes to improve.	Start as of September 20 until February 2026
Scoping process and PICO consolidation	• Formulate comprehensive PICO parameters, define PICO scenarios applying comparator scenarios (e.g. OR, AND) • Execute the scoping process steps including the design of PICO surveys, collecting PICO inputs and considerations • Demonstrate in-depth knowledge in when and how to gather expert inputs in different stages of the scoping process	This course provides a practical and **accessible introduction to the formulation and application of the scoping process** (PICO framework) within JCA context. Designed for HTAs staff who is involved in providing national PICO requirements . It guides participants through **the entire scoping process, from defining PICO parameters to gathering patients, clinical experts and other relevant expert input.** During the course, there will be a set of simulations to develop PICO requirements, gather expert inputs and finalise the consolidated assessment scope proposal.	Start as of June/July 202 until March 2026
HTAR Governance, JSC/JCA procedures (MPs)	• Comprehend the process and scope of JSC and JCA for MPs • Identify the roles and responsibilities of various actors in the delivery of JSC and JCA for MPs • Understand the detailed procedural steps and timelines for conducting JSCs and JCAs, including documentation and communication requirements	It covers HTAR governance, key stakeholders and their roles. Participants will learn steps of JSC (e.g. consolidation of List of issues, final recommendations) and JCA (e.g. scoping, JCA report writing) on MPs, **including specific time triggers, actor handovers, critical documents and how to fill them**. There will be a deep dive on how to collect expert inputs with different methods. Participants will have an introduction to key elements in the conflict of interest guidance and key communications with EMA. During the course, there will be a set of exercises to identify key steps, stakeholder interactions and attention points in each step.	Start as of July 2025 until April 2026
HTAR Governance & JSC/JCA procedures (MDs/IVDs)	• Comprehend the process and scope of JSC and JCA for MDs/IVDs • Identify the roles and responsibilities of various actors in the delivery of JSC and JCA for MDs/IVDs • Understand the detailed procedural steps and timelines for conducting JSCs and JCAs for MDs/IVDs, including documentation and communication requirements	It covers HTAR governance, key stakeholders and their roles. Participants will learn steps of JSC (e.g. consolidation of List of issues, final recommendations) and JCA (e.g. scoping, JCA report writing) on MDs/IVDs, **including specific time triggers, actor handovers, critical documents and how to fill them**. There will be a deep dive on how to collect expert inputs with different methods. Participants will have an introduction to key elements in the conflict of interest guidance and key communications with EMA. During the course, there will be a set of exercises to identify key steps, stakeholder interactions and attention points in each step.	Start as of November 20 until April 2026

European Commission | HADEA/2023/OP/0032: Building capacity and knowledge for the implementation of the EU Health Technology Assessment Regulation | Funded by EU4Health Programme

*Each module will be delivered multiple times during the indicated period

https://health.ec.europa.eu/health-technology-assessment/htar-capacity-building-programme_en

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Closing Remarks

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HTA ESIG

Want to get more involved in this discussion and help impact the future of EU HTA? Become a member of the HTA ESIG today – scan the QR code or email htasig@psiweb.org

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