Adigens Health

ISSUE PANEL · ISPOR EUROPE 2026 · VIENNA

The Future of Causal Inference: How Large (or Small) Role Will AI Play?

MODERATOR

Radek Wasiak

Monday 9 November 2026 · 13:45 CET

TODAY'S QUESTION

AI will play a part in causal inference. The question is *how large* a part.

A useful assistant or a system that takes on much of the work, including the reasoning itself?



The AI landscape in health research

EMA & HMA	AI workplan to 2028; reflection paper on AI across the medicine lifecycle
EMA & FDA	Ten jointly agreed principles for good AI practice in the medicines lifecycle
FDA	Draft guidance: risk-based credibility framework for AI in regulatory decisions
NICE	Position statement on AI in evidence generation
ISPOR	Working Group on Generative AI; ELEVATE-GenAI reporting guideline
Reporting standards	TRIPOD+AI, PALISADE and others
Governance	Dozens of frameworks for clinical AI governance and evaluation



Much activity, little proof

77

AI governance frameworks for healthcare organisations. **None** found evaluated for effectiveness.

2 of 46

Clinical AI evaluation frameworks that underwent empirical validation (4.3%).

Limited

Use of AI within HTA evidence reviews, despite agencies acknowledging its potential.

None of these initiatives addresses **causal inference** directly.

Sources: Wang et al, npj Digit Med 2026; Lopez Medina et al J Med Internet Res 2026; Gautam et al ISPOR 2026 poster on AI/ML in HTA evidence synthesis

Two traditions, one causal question

Epidemiological causal inference

STARTS FROM

The question: target trial, estimand and causal assumptions, set before analysis

STRENGTH

Transparent, prespecified, familiar to regulators and HTA bodies

CHALLENGES

Manual and slow to scale; depends on expert knowledge of confounders

Data science causal inference

STARTS FROM

The data: flexible algorithms that learn structure and effects at scale

STRENGTH

Handles high-dimensional data and treatment-effect heterogeneity

CHALLENGES

Assumptions often implicit; data alone cannot establish causation

Where should these traditions meet?

Hernán, Hsu & Healy, Chance 2019; Hernán & Robins, Am J Epidemiol 2016



A small role, a large role

SMALL — LARGE

01

AI assists experts

Extracts confounders from notes, harmonises sources, flags whether a protocol can be mapped to the data

02

AI takes on stages

Automated endpoint derivation; longitudinal patient histories built from fragmented records

03

AI runs analyses

Growing autonomy; dynamic protocol emulation updated as data arrive; "decision-grade" RWE systems

The non-negotiables

01

Scalability

Emulations struggle as data complexity grows, potential for AI's role

02

Transparency and reproducibility

Each step handed to AI must still meet reporting standards such as TARGET

03

Regulatory trust

FDA's framework links required rigour to how much a model's output influences a decision

Our Panelists

Gorana Capkun

VP, Global Head of Patient Focused RWE, Merck Healthcare

Michael Haft

CEO, Xplain Data

Miguel Hernán

Director, CAUSALab & Professor, Harvard University

AUDIENCE POLL

AI's future role: an assistant to experts OR an autonomous causal analyst

Adigens Health