# PriMHE
**Programme in the Methods of Health Economics**

# Real-word data and evidence in regulatory decision-making

## Associate Professor Joshua D. Wallach

The U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have traditionally relied on evidence from clinical trials to assess the efficacy of new medical products. Recently, both agencies have shown growing interest in incorporating real-world data—such as electronic health records and administrative claims data—to supplement clinical trials and generate real-world evidence on therapeutic use, benefits, and risks, particularly to accelerate access to treatments for serious conditions. However, concerns remain about the reliability of real-world data for regulatory purposes, including issues related to data quality, completeness, and relevance to specific regulatory questions. This talk will review current FDA and EMA frameworks for integrating real-world data and real-world evidence into regulatory decision-making, examine key methodological and practical challenges, and present recent research on how the FDA has already used real-world evidence to support decisions on the safety and effectiveness of all novel therapeutics approved between 2016 and 2024.

**Date: 12 June 2025 /12.00 – 13.00 CET (hybrid event – see page 2)**

## Summary

Dr. Joshua D. Wallach is an Associate Professor in the Department of Epidemiology at Emory University's Rollins School of Public Health. His research applies diverse methodologies and data sources to evaluate how evidence informs policy decision-making and the development, regulation, and use of medical products. He specializes in evidence synthesis and evaluation, including systematic reviews, meta-analyses, next-generation reviews, and meta-research. A central focus of his work is evaluating the quality of the evidence base for pharmaceutical and medical device regulation (i.e., regulatory science). Dr. Wallach is a core faculty member of the Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT), which conducts strategic research to inform policies to ensure robust evidentiary standards for U.S. FDA-regulated products, and the Yale Open Data Access (YODA) Project, which facilitates access to clinical trial from Johnson & Johnson. He also serves as an Associate Editor for the *Journal of the American College of Cardiology*.

***This lecture is accredited with 1 DFP-point for members of the Austrian Medical Chamber.***

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# Hybrid Event

## Location

**MedUni Vienna, Center for Public Health, Department of Health Economics (DHE)**
**Kinderspitalgasse 15**
**1090 Vienna**

**Seminar room 2, ground floor, courtyard building (entrance Zimmermangasse)**


## Join information webex meeting

**Meeting link**

https://meduniwien.webex.com/meduniwien/j.php?MTID=m5d09e47ed5d9aecb9ac9bdaf002c8948

**Meeting number**

2795 418 6493

**Password**

ciJtnHxB363 (24586492 when dialing from a video system)

**Join by video system**

Dial 27954186493@meduniwien.webex.com

You can also dial 62.109.219.4 and enter your meeting number.

**Join by phone**

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Global call-in numbers