

Session 1: Implementation of the HMA/EMA Big Data Task Force priority recommendations

An academic perspective

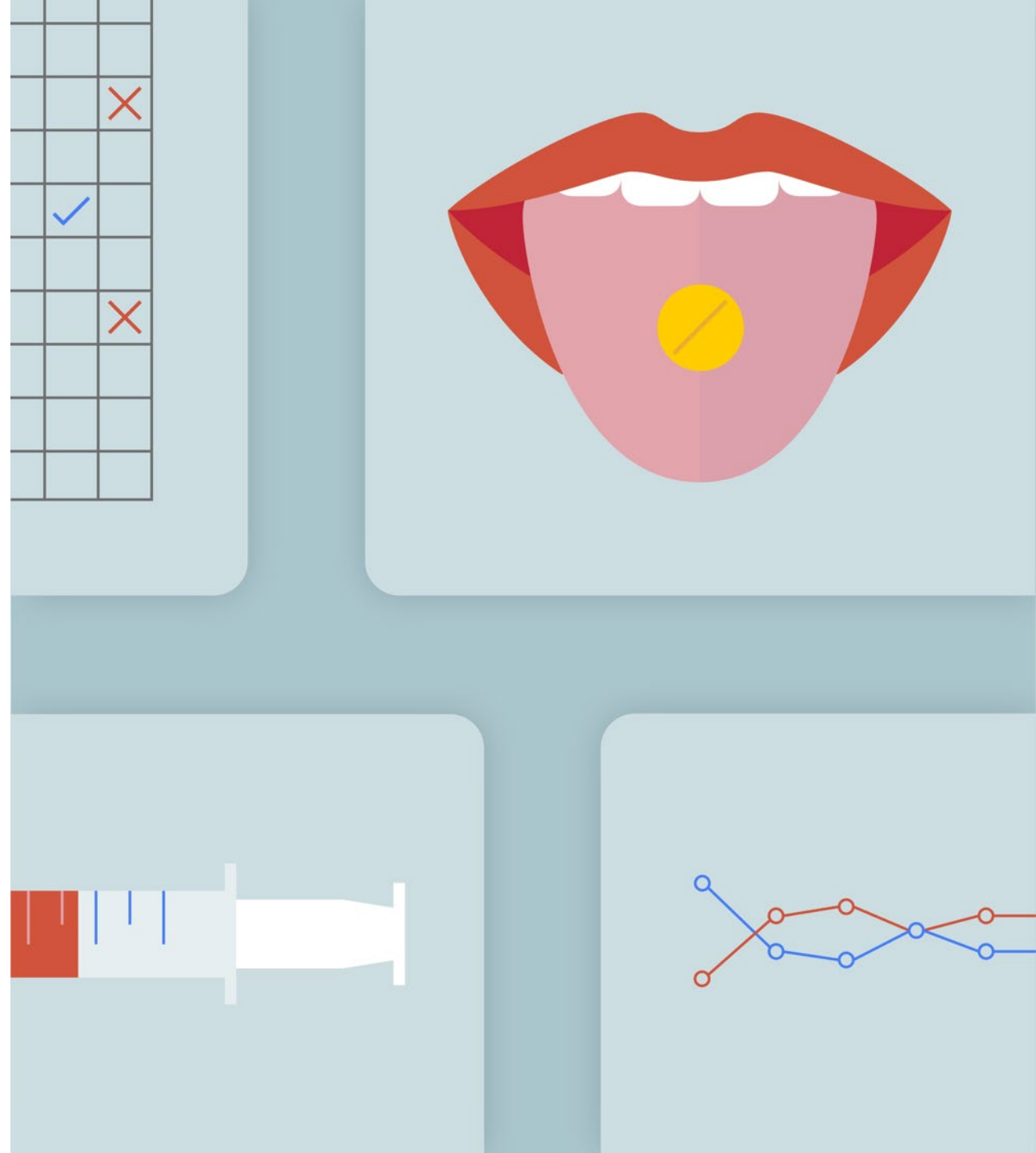
Prof.dr. Helga Gardarsdottir

HMA/EMA Big Data Stakeholder Forum 2024
27th of November

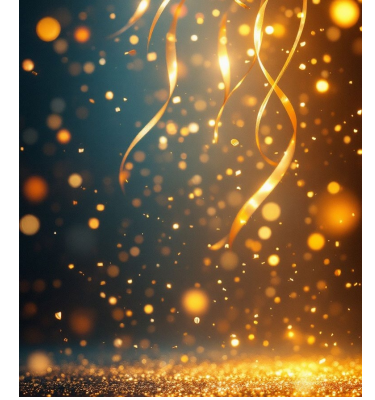


Utrecht University

Pharmacoepidemiology
and Clinical Pharmacology



Recognising what has been achieved



Establishment of DARWIN EU

Publication of Guidelines

- Enhanced data discoverability (Minerva & EMA's List of Metadata).
- Introduction of a Data Quality Framework
- Development of a reflection paper on leveraging Real-World Data (RWD) for non-interventional studies.

Academic Collaborations

- Active involvement in Working Groups (WGs) and the European Specialized Expert community.
- Educational partnerships, including the creation of the Big Data Curriculum.
- Execution of tendered studies

Transparency

- Commitment to openness and clear communication in all processes and findings.



The road ahead



Key areas for the future

Address challenges related to **future data needs** and usage.

Continuing advancements and learning **AI**

Sustaining **academic collaborations** to:

- Develop and test methodologies, incl. for DARWIN EU.
- Build capacity for future research and innovation.

Enhancing **specificity of guidelines**, such as the Data Quality Framework for Real-World Data (RWD) usage.

How to address these

Link with the European Platform for Regulatory Science Research & EMAN 2028 (network led partnerships)

