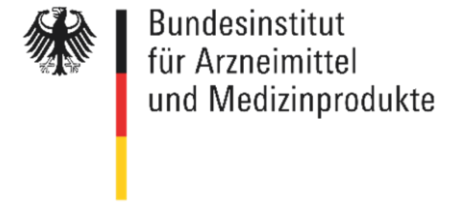




Unlocking Real-World Data with AI



# Real4Reg survey results

Lucas Depner, German Centre for Neurodegenerative Diseases (DZNE)

Real4Reg RWD Workshop | 14 October 2024



# Aims and Methods

## Aims:

- Exploring key stakeholders' views and needs about RWE
- Overview of RWD usage

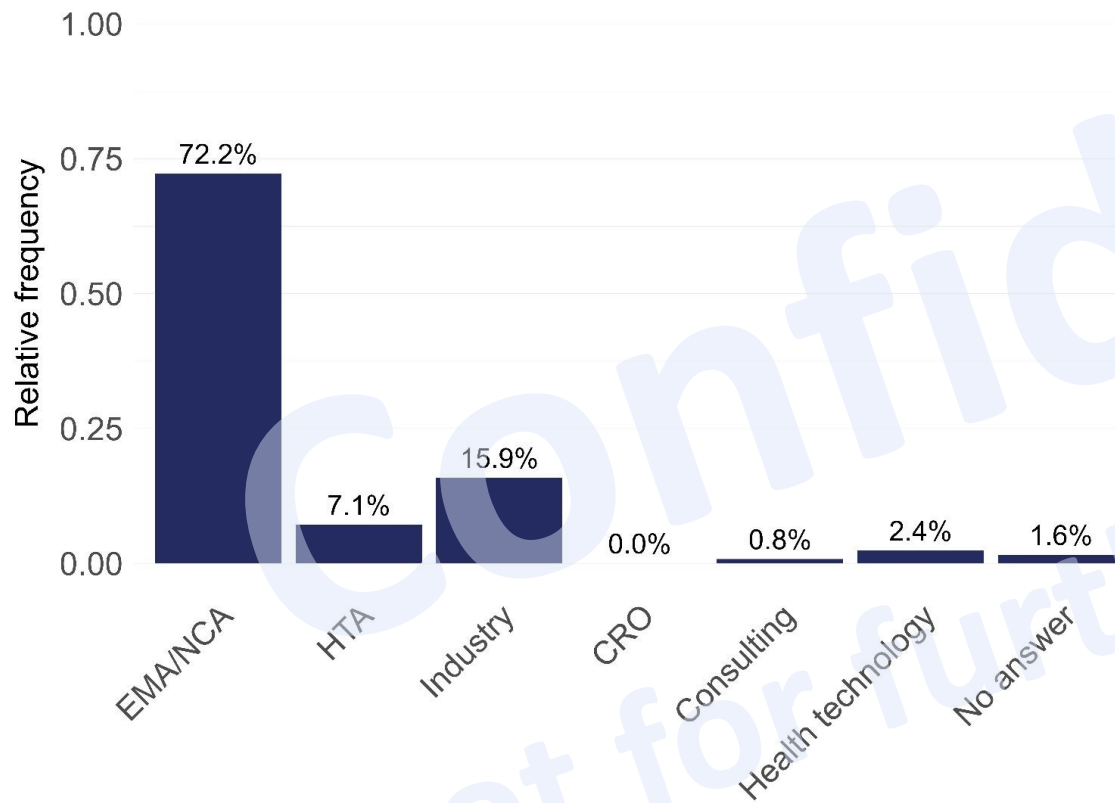
## Methods:

- Identification of key stakeholders via stakeholder analysis
  - Survey 1: Regulatory, health technology assessment (HTA), pharmaceutical industry
  - Survey 2: Academia
  - Survey 3: Payers
  - Survey 4: Patients and Physicians
- Recruitment by contacting stakeholders via e-mail
- Additional dissemination via social media
- Survey open for 2 months

Total respondents: 221 (126 | 36 | 6 | 53)

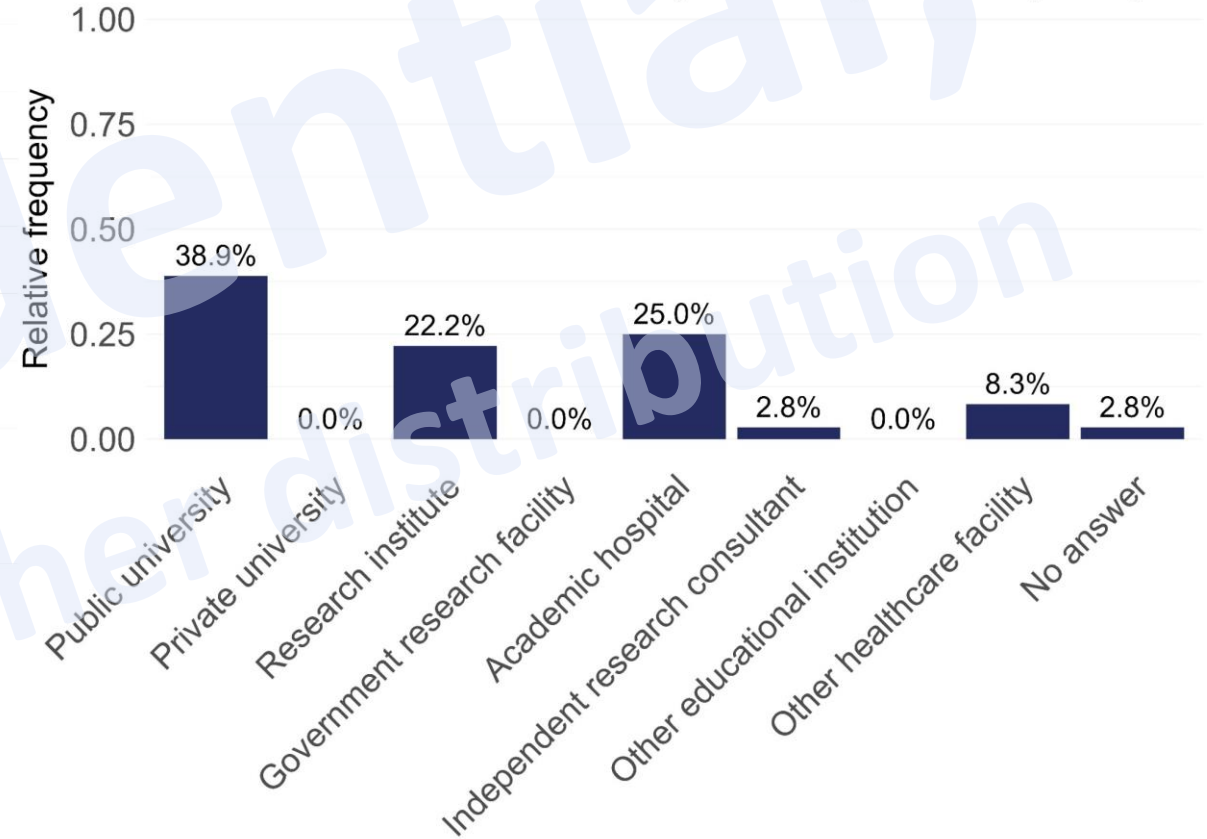
# Demographics

Which of the following best describes your employer? (n = 126)



Questionnaire for industry, regulators and HTA

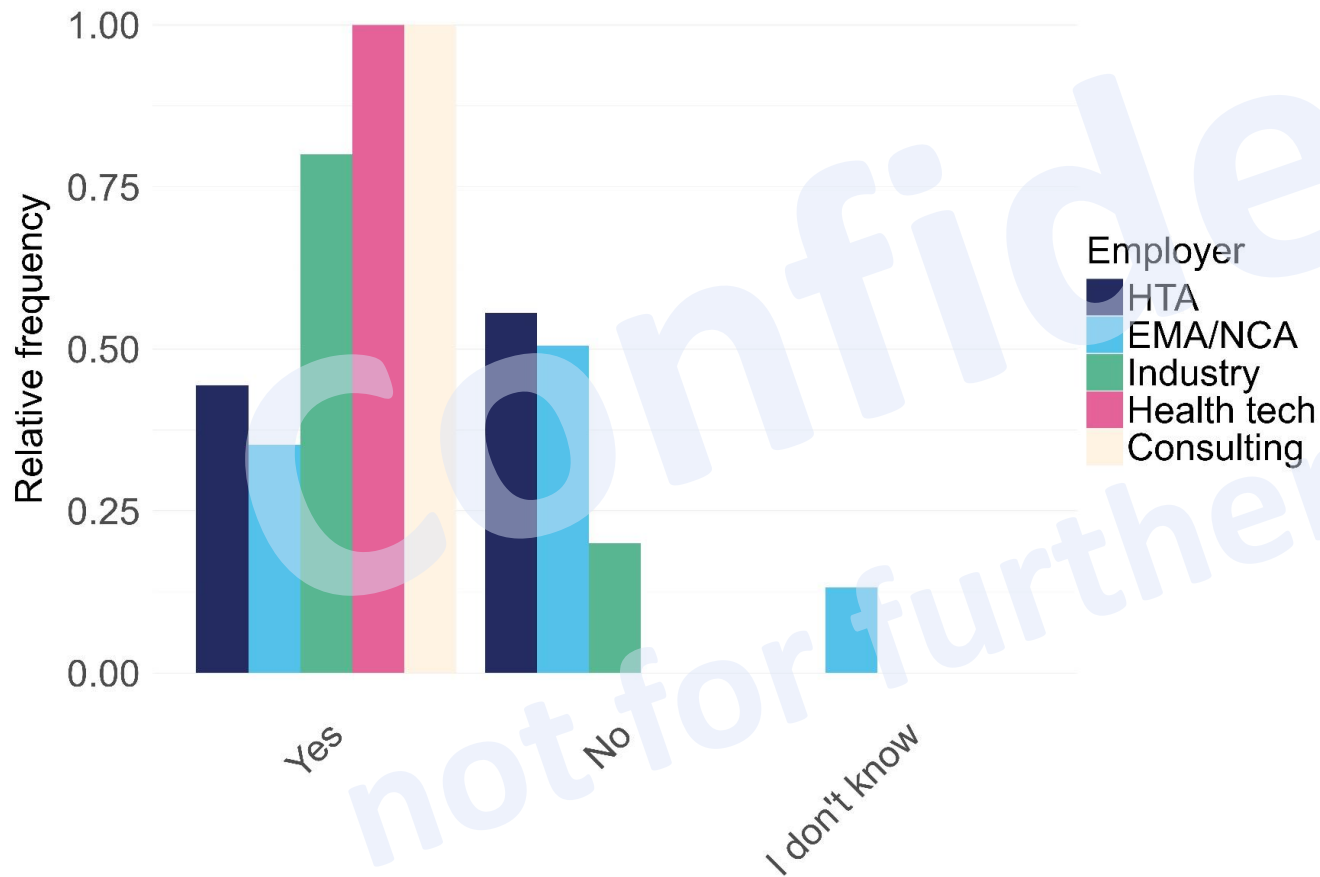
What best describes the institution you currently work for? (n = 36)



Questionnaire for academia

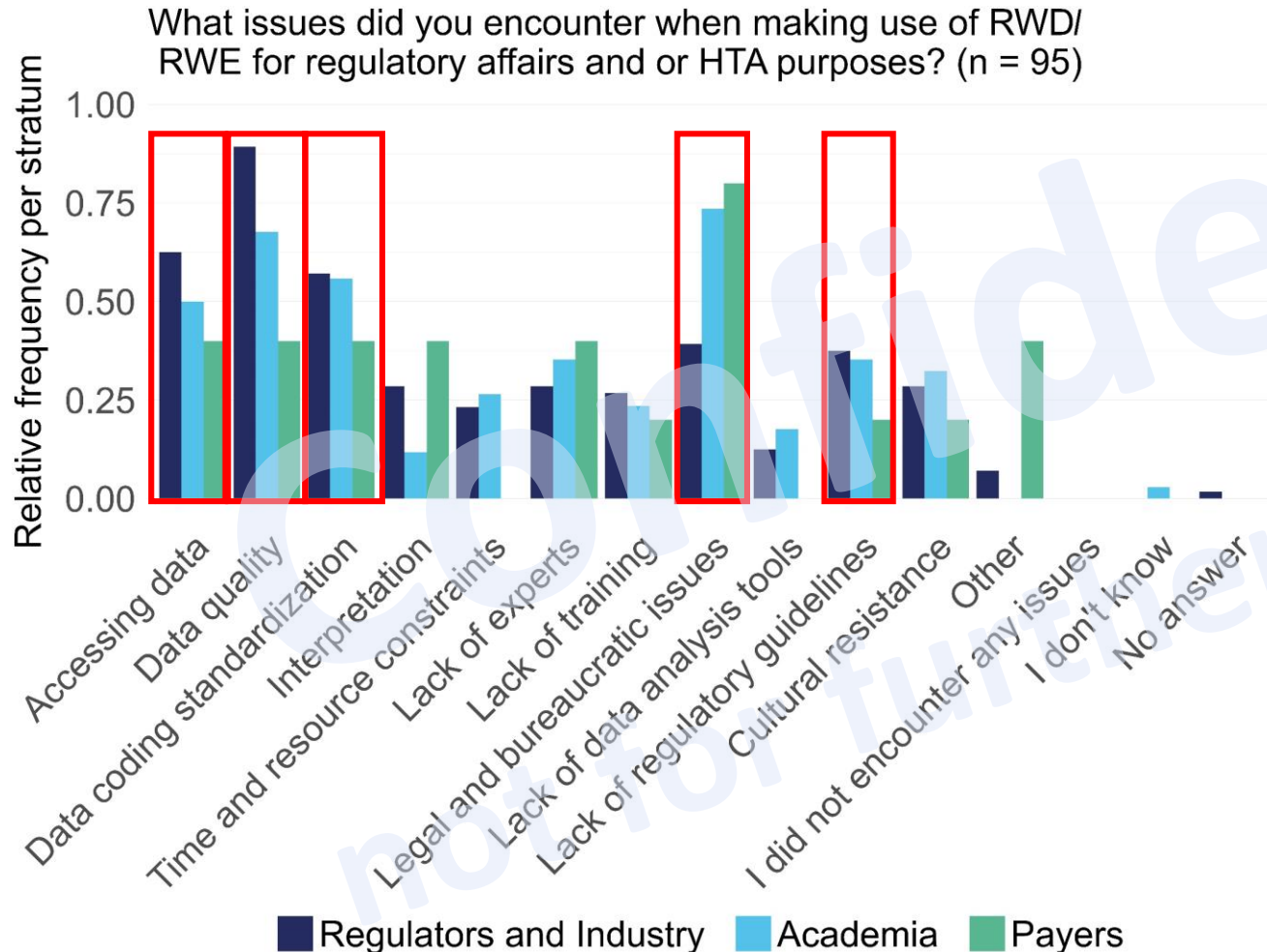
# Regulation, HTA, Industry: RWD usage

Do you already use RWD/RWE for regulatory affairs and/ or HTA purposes? (n = 124)



- Higher frequency of use by private stakeholders compared to public organizations
- Mainly used for „traditional“ applications: Contextualization, post-authorization studies
  - Still: Moderate use for „novel“ applications: Pre-authorization studies, indirect treatment comparisons, assessment of unmet medical need, etc.

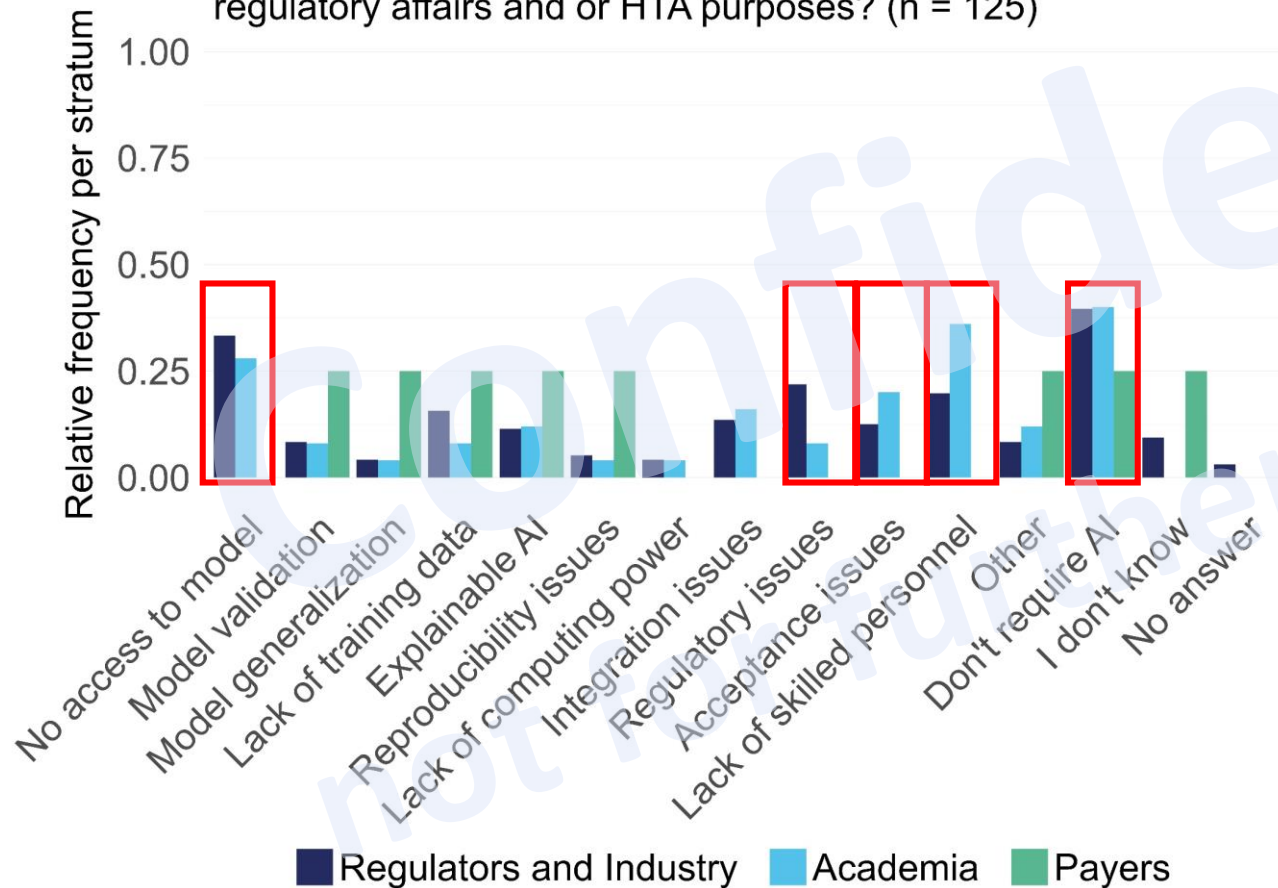
# RWD usage: Current issues



- Most frequently reported issues:
  - Data quality (fit-for-purpose)
  - Data access
  - Standardization (Data coding, data collection, quality requirements)
  - Legal and bureaucratic issues
  - Regulatory and guidance issues
- → Issues are both technical and systemic

# AI/ML (non-)usage

What are the reasons due to which you are currently not employing AI/ML based algorithms for RWD analysis for regulatory affairs and or HTA purposes? (n = 125)

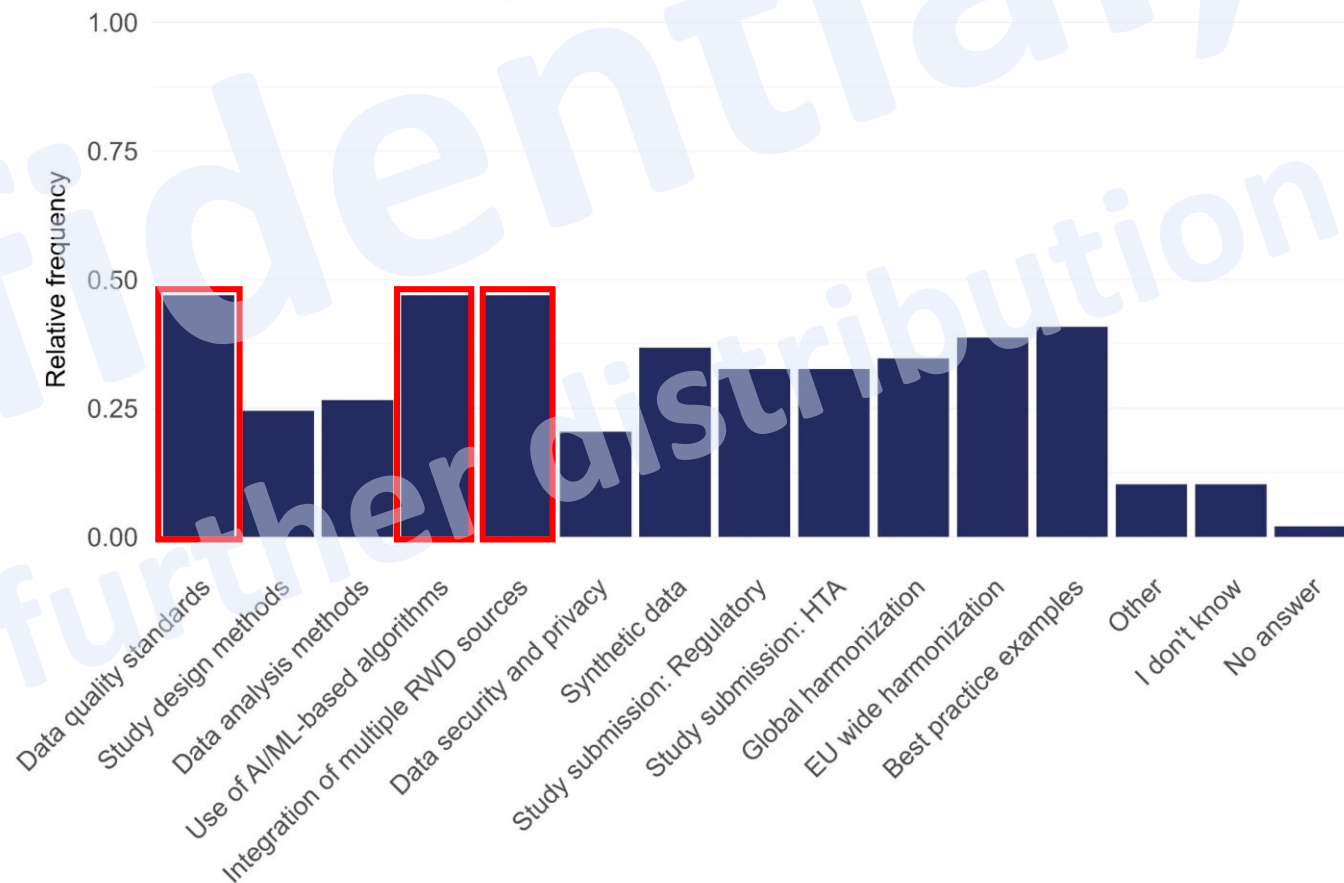


- AI/ML use is in its infancy
- Obstacles preventing AI/ML use (at this point) are mainly organizational and not technical

# Regulation, HTA, Industry: Guidance use

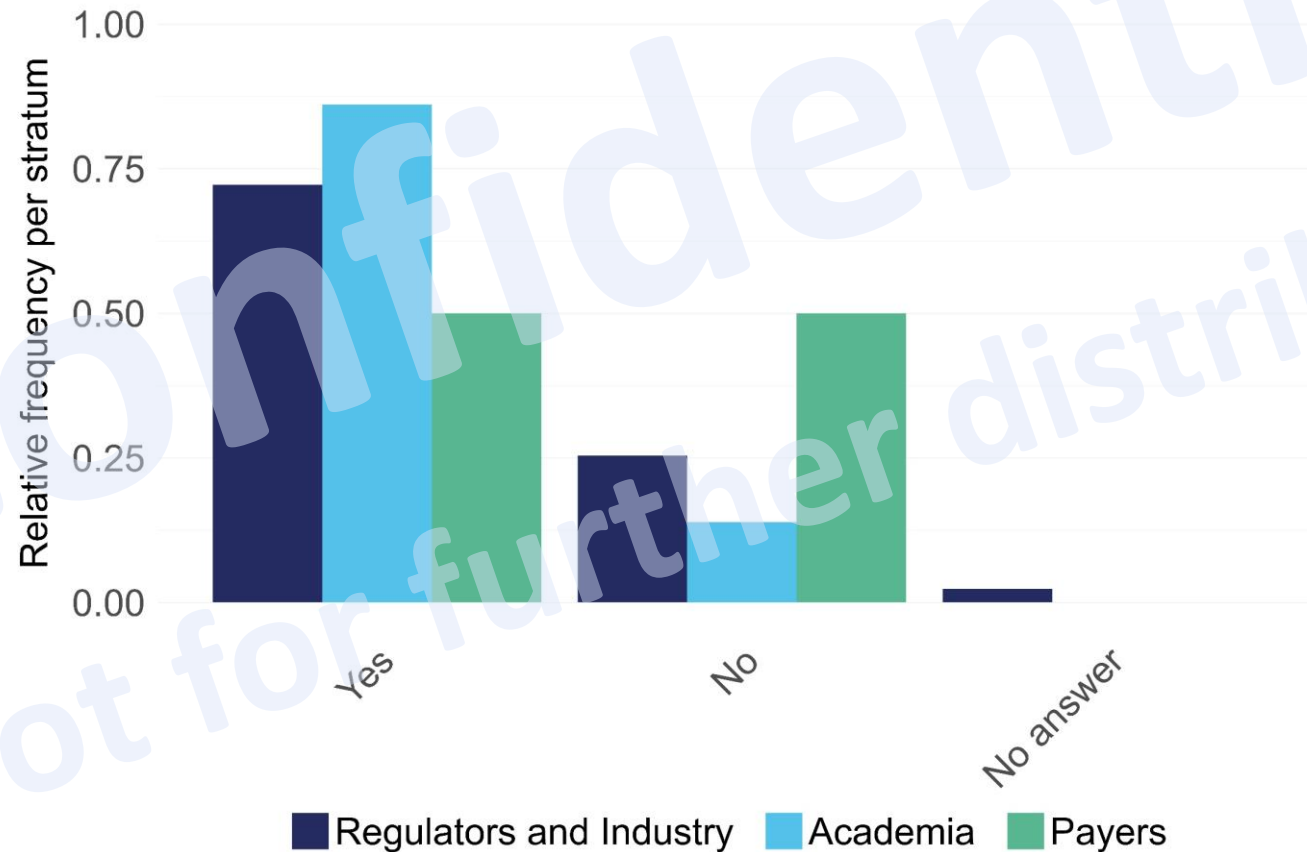
RWD/RWE guidelines/frameworks were **currently used by 38.9% of respondents**; limitations in usability were identified:

In your opinion in which aspects do the currently available guidelines have gaps? (n = 49)

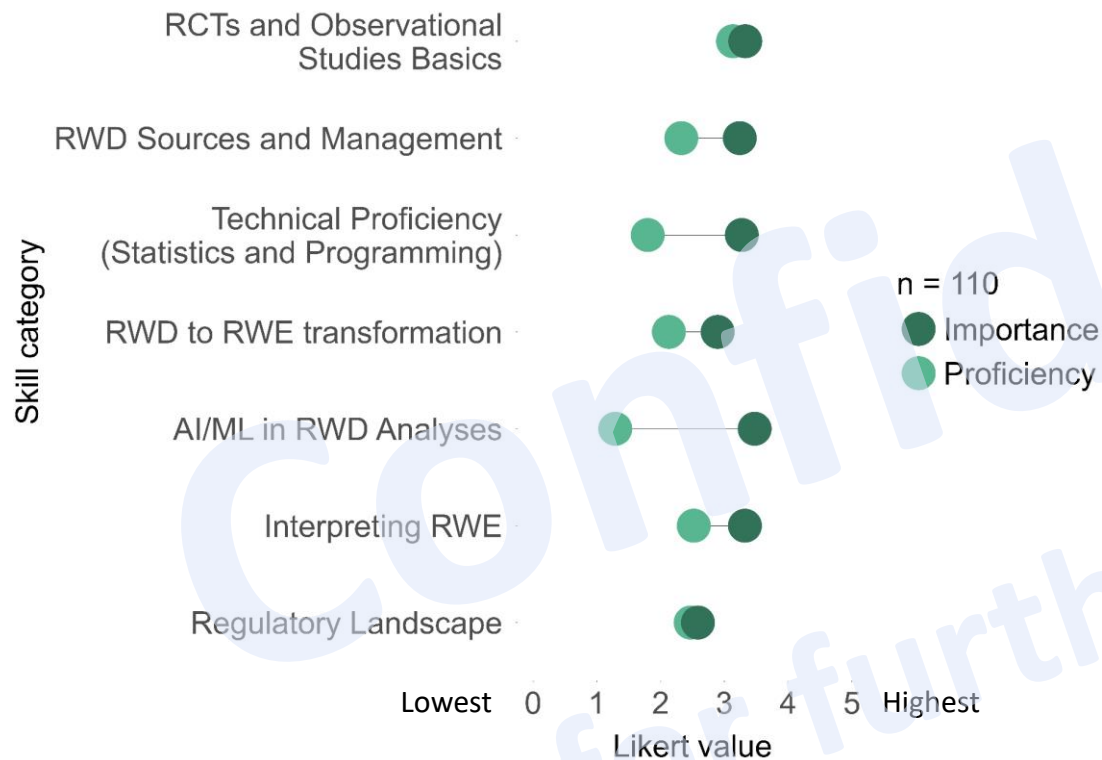


# Interest in training

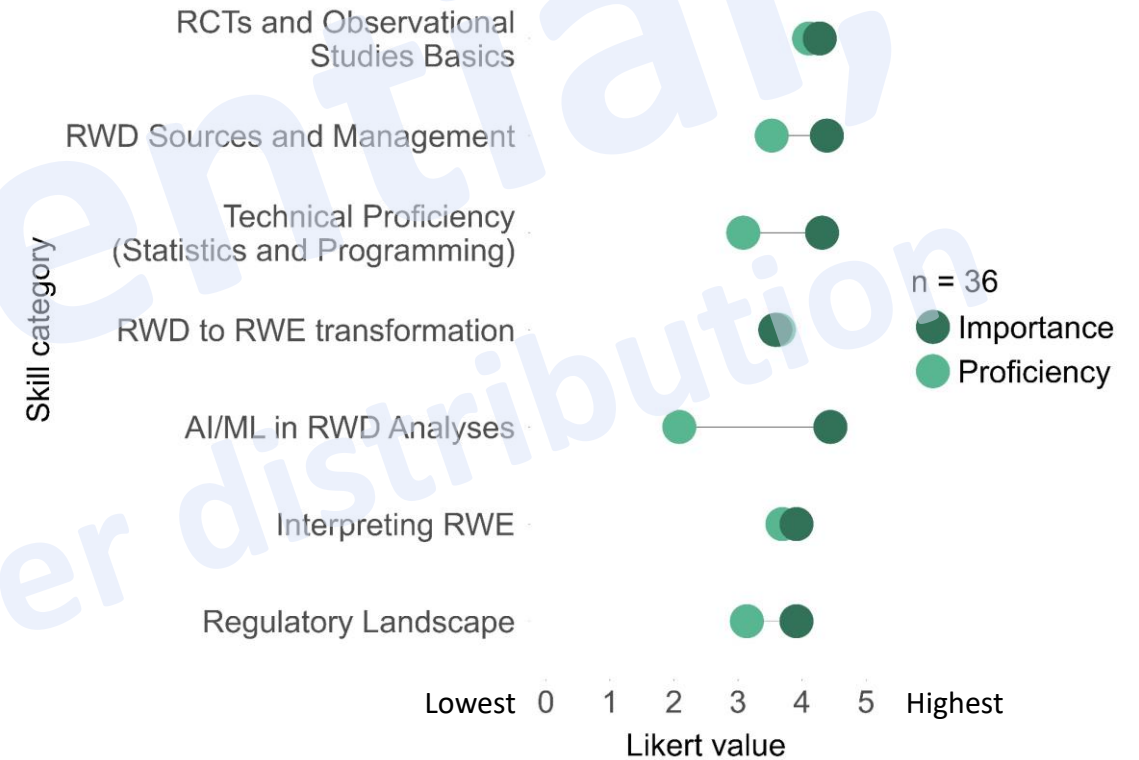
Are you interested in participating in training sessions or educational programs to learn more about the use RWD/RWE for regulatory affairs and or HTA? (n = 168)



# Training needs: Topics



Questionnaire for industry, regulators and HTA



Questionnaire for academia

# Summary

- Issues reported during RWE/RWE use are both technical (data quality) but also systematic (data access, regulatory and guidance)
- Issues preventing application of AI/ML algorithms are mainly organizational (lack of skilled personnel, model access)
- Interest in training is high, especially for technical aspects
- Different stakeholders have (partially) different training needs

# Thank you!

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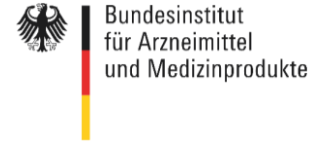
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