RWD in the context of clinical trials – from pilots to practice

Where are we now?

"there has been no request for certain use case categories (notably representativeness and validity of clinical trials, as well as effectiveness). Further efforts will need to be made to help the identification of potential research topics in areas for which RWE is less established"

Source: Real-world evidence framework to support EU regulatory decision-making EMA/289699/2023

- RWD to inform the set-up of CTs
- Some pilots on EMR/RWD for data collection in CTs
- Increasing use of at-home data collection in CTs

Many remaining challenges for utilizing potential of RWD in CTs (with more pragmatic approaches)

- Access to & utilization of EMR/RWD for data collection
- Methodological/operational challenges
- (Perceived) acceptability of approaches
- Conservative ICH GCP interpretation

Where do we need to go?

Integration of clinical research and clinical practice, with EMR/RWD routinely used for data collection in CTs

What do we need for that?

- Improved access to EMR/RWD (patient-at-the-centre & federated approaches)
- Regulatory guidance on pragmatic approaches
- Clear role and guidance for use of AI in trial activities
- Easier involvement of local HCPs in clinical trials
- Combining innovations: EMR-based trials, complemented by at-home data collection

How? Sandbox environment & funding for proof-of-concept studies to advance the field together towards EMR-based patient-centric trials.

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