Regulatory perspectives on TTE for pharmacovigilance

Structured approach with explicit consideration of bias and relevant estimand has potential to optimise post-authorisation safety studies.

Principles are of value for assessment of RWE.[1]

Aspects to consider:

- Eligibility criteria may limit generalisability.[2,3]
- TTE may not be feasible.[2,4-6]
- Dataset remains observational.[2,3,7]
- More advanced statistical methods may be required.[8]
- Target trial against which to validate approach may not be available.

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