How should an RWE study plan be developed and communicated?

Tim Koder
A question for you

What involvement have you had in RWE planning?

1. Gap analysis and strategy
2. Methodology and analysis
3. Publication support only

Please use the app to respond!
How should an RWE study plan be developed?

Not a collection of disjointed studies, *but rather* ...
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**Not** a collection of disjointed studies, *but rather* ...

- Comprehensive plan across life cycle
- Evidence from multiple sources
Study planning considerations

What are our objectives?

What type of study are we going to do?

Who is the target audience for the study?

How will we carry out the study?

What resources are required?

When do we need the study results?

Where will the study be carried out?

Who is needed to carry out the study?

How will the study be communicated?
Research question

- Address the evidence need by formulating the scientific objective and hypothesis (if appropriate)
  - This should be determined before the study starts
  - Do not start a study hoping an interesting question will emerge

A good research question is:

- Feasible to answer
- Interesting
- Novel
- Ethical
- Relevant
- **PICO framework** is useful for structuring and focusing the research question.

<table>
<thead>
<tr>
<th>Patients</th>
<th>Intervention (or exposure)</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Patients? Disease? Care setting?  
(e.g. adults with type 2 diabetes in primary care) | Treatment? Delivery? Purpose?  
(e.g. a self-administered medicine to prevent long-term complications) | Alternative treatment or no treatment?  
(e.g. current standard of care) | Symptoms? Side effects? Surrogate endpoint? Quality of life?  
Economic endpoint?  
(e.g. glycated haemoglobin level) |
Deciding how the evidence need will be met

- Can existing data be analysed?
- Do we need to generate new data?
- RCT data?
- Electronic medical records?
- Registry study?
- Literature review?
- Prospective non-interventional study?
Systematic assessment of RWE sources provides foundation for research

OBJECTIVE

- Real-world evidence provides information about the effectiveness, safety, and value of healthcare interventions throughout the product lifecycle.
- A multitude of observational data sources exist but they vary by geographic location and in quality, data elements captured, and accessibility to external users.
- Our objective was to develop a systematic methodology to identify observational data sources for specific research questions and to test it in both common and rare conditions in a range of therapeutic areas.
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Comprehensive plan across life cycle

Evidence from multiple sources

Global and local collaboration

External participation
Collaborating with external experts

- External partners can:
  - advise on the study design and methodology
  - provide access to data
  - use contemporary statistical approaches to analyse data
Global and local collaboration

- Understanding the perspectives of local healthcare decision-makers is crucial for ensuring that the right evidence is generated.

- I'm interested in new treatments for patients who have switched treatment.

- How effective is this treatment in patients at high risk?

- Is this treatment safe for our population?
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Comprehensive plan across life cycle

Internal awareness and communication

Global and local collaboration

External awareness and education

External participation

Evidence from multiple sources
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- Comprehensive plan across life cycle
- Evidence from multiple sources
- External awareness and education
- Internal awareness and communication
- Global and local collaboration
- External participation
- True strategic planning
- Excellent quality to ensure credibility
A question for you

How confident are you in communicating RWE?
1. I’m very experienced and I know what I’m doing
2. I do work with RWE but I’m still learning
3. I’m completely bamboozled

Please use the app to respond!
Question for the panel

What are the challenges you face?
A core methodology of EBM is the systematic review
- All relevant published evidence relating to the indication is identified and evaluated

Publications evaluated in the EBM process will inform decision-making
- Relevant publications identified by the systematic review will have to be considered
- A publication by clinical experts in a high-quality, peer-reviewed journal lends credibility and weight to your data
Communicating effectively means cutting out the technical jargon

WHAT WE SAY

COVARIATE MATCHING
CONSTRUCT VALIDITY RANDOM EFFECTS MODEL INDIRECT COST
UTILITY DISCRETE CHOICE
MIXED TREATMENT COMPARISON
FOLLOW-UP TIME PROPENSITY
SCORING SENSITIVITY ANALYSIS
Communicating effectively means cutting out the technical jargon.
Help your audiences: beyond publication

- Most of your internal and external audiences for RWE publications will not understand the technical details of RWE

- Develop simple, non-technical tools to accompany publications
  - One-page ‘Evidence Summaries’ of key RWE study publications
  - Infographics-driven, visually stimulating, interactive slide decks
  - Usable by field force in discussions with payers, prescribers and other decision-makers
Conclusion

For best impact and value:

Plan → Perform → Publish...

...RWE as you would RCT evidence