

## How should an RWE study plan be developed and communicated?

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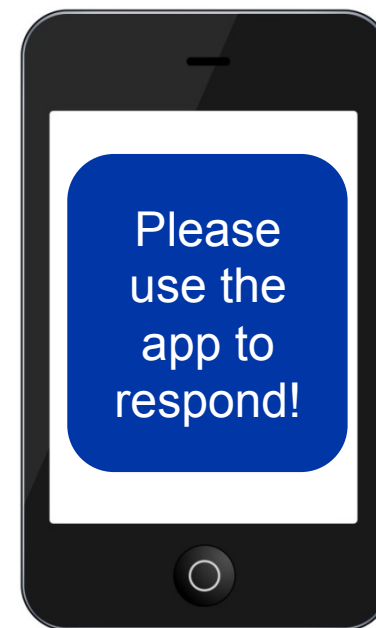
Tim Koder



## A question for you

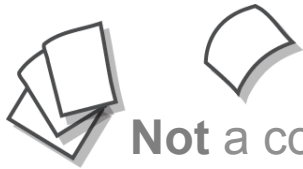
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- What involvement have you had in RWE planning?
  1. Gap analysis and strategy
  2. Methodology and analysis
  3. Publication support only



# How should an RWE study plan be developed?

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



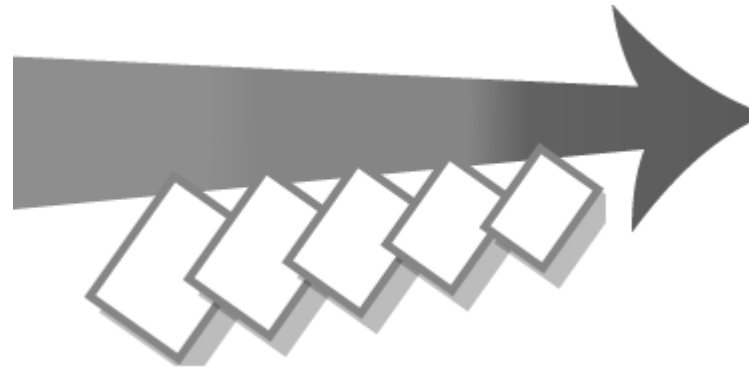
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Not a collection of disjointed studies, *but rather ...*

**Comprehensive**  
plan across life cycle



Evidence from  
**multiple**  
**sources**

# Study planning considerations

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# Research question

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- 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**

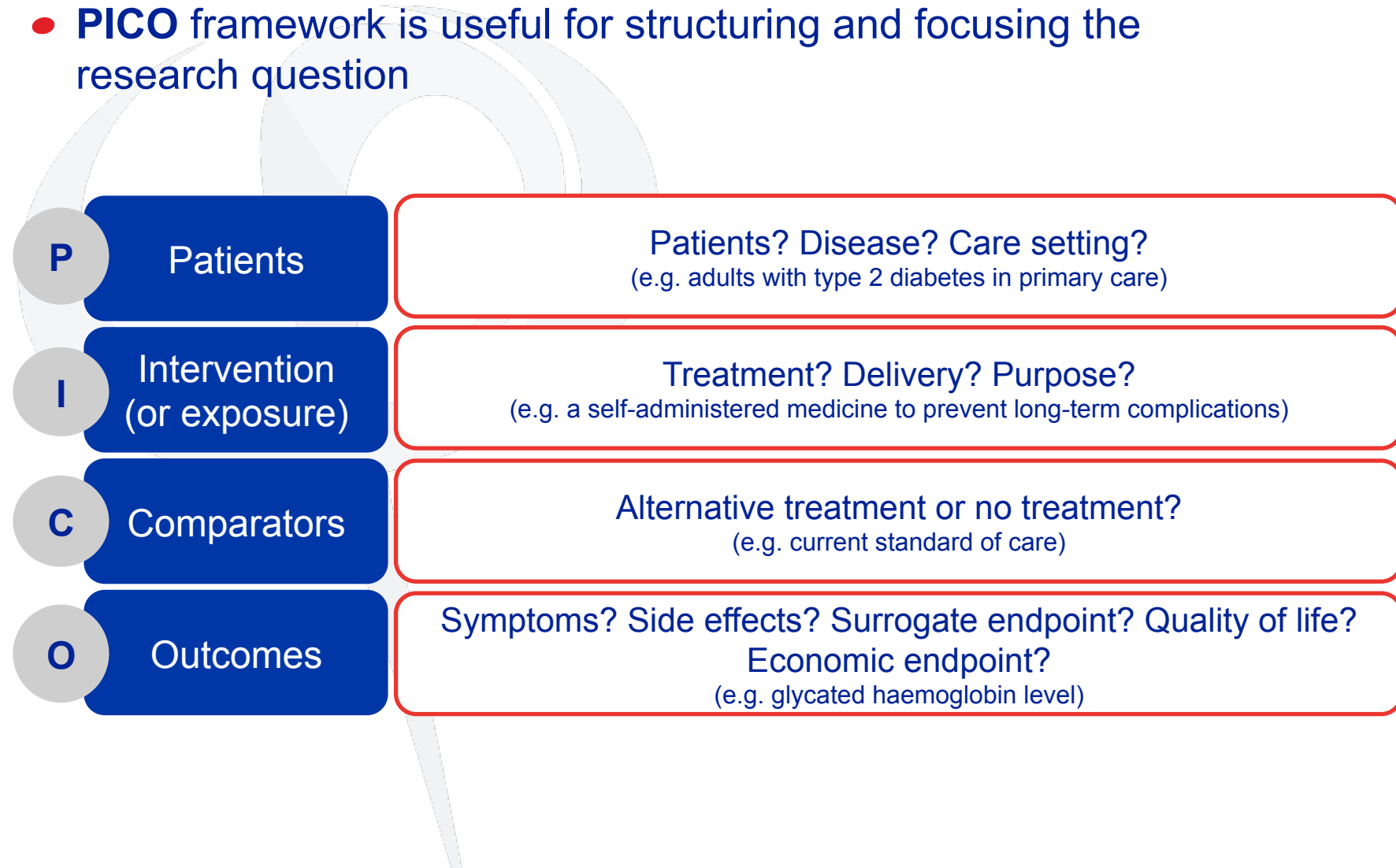
**Novel**

**Ethical**

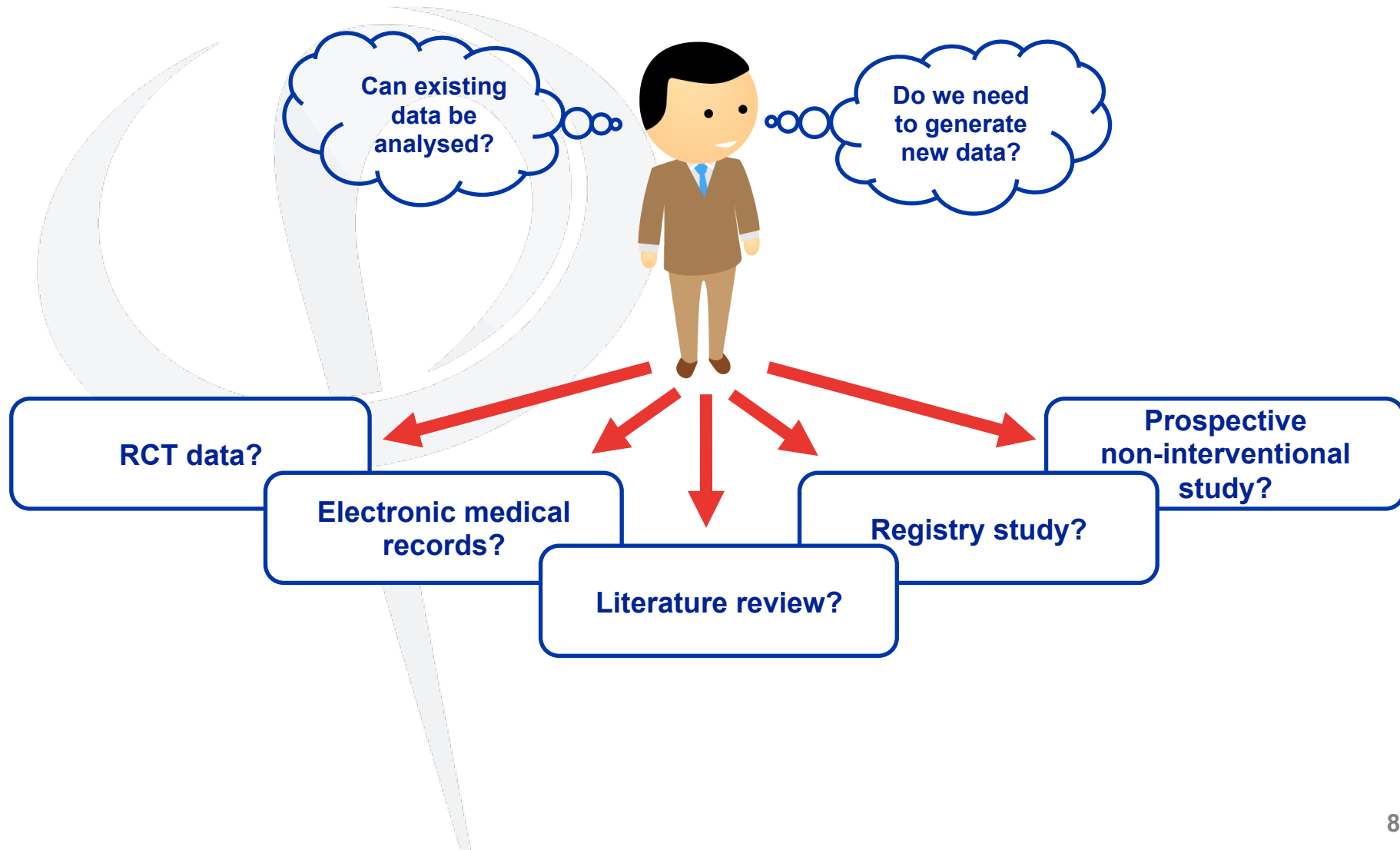
**Relevant**

# Deciding what will be studied

- **PICO** framework is useful for structuring and focusing the research question



# Deciding how the evidence need will be met





# 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.

## Identifying Real-World Data for Observational Studies: A Systematic Approach

PRM48

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**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.
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**METHODS**

A 3-step process was developed and applied to identify and characterize potential data sources for use in observational research programs spanning cardiology (2 programs), internal medicine (CVI, DM2, stroke, diabetes, oncology, and respiratory medicine).

**RESULTS**

Approximately 14,000 references were screened to identify potential data sources. 181 (1.3%) were identified as relevant to the research question. 181 (1.3%) were identified as relevant to the research question. 181 (1.3%) were identified as relevant to the research question.

**CONCLUSIONS**

A systematic understanding of real-world evidence has helped to guide observational research programs in diverse therapeutic areas with specialized data requirements.

**Table 1. Include criteria by study**

Study Type	CVI	CV2	DM2	Stroke	Respiratory	Oncology
Study	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence
Study and date of report, publication or reference ID	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence
IRB including description and approval/ethical approval	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence
Study and analysis	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence
Observational study	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence
Reported data	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence
Observational study and data	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence
Length of follow-up	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence	1. Evidence 2. Evidence 3. Evidence

**Table 2. Results by study**

Study Type	CVI	CV2	DM2	Stroke	Respiratory	Oncology
Screened	Screened n=2700	Screened n=2700	Screened n=2700	Screened n=2700	Screened n=2700	Screened n=2700
Excluded	Excluded n=265	Excluded n=265	Excluded n=265	Excluded n=265	Excluded n=265	Excluded n=265
Reported	Reported n=117	Reported n=117	Reported n=117	Reported n=117	Reported n=117	Reported n=117
Screened	Screened n=117	Screened n=117	Screened n=117	Screened n=117	Screened n=117	Screened n=117

**Financial Support**



The research was funded by Oxford PharmaGenesis™. The number of white space cells in the table represents the number of studies that were included in the final analysis. The number of studies that were excluded from the final analysis is shown in the 'Excluded' column. The number of studies that were reported in the final analysis is shown in the 'Reported' column. The number of studies that were screened in the final analysis is shown in the 'Screened' column.

**Acknowledgements**

We thank the members of the Research Evaluation Unit at Oxford PharmaGenesis™ for their support and assistance in the development of this research. We also thank the members of the Research Evaluation Unit at Oxford PharmaGenesis™ for their support and assistance in the development of this research.

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PRM48

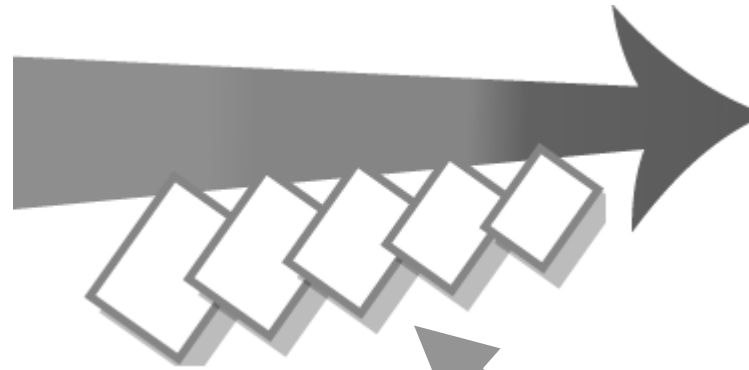



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**Global and local**  
**collaboration**

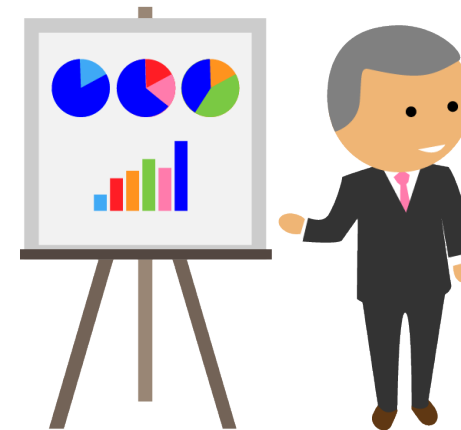


**External**  
**participation**

# Collaborating with external experts

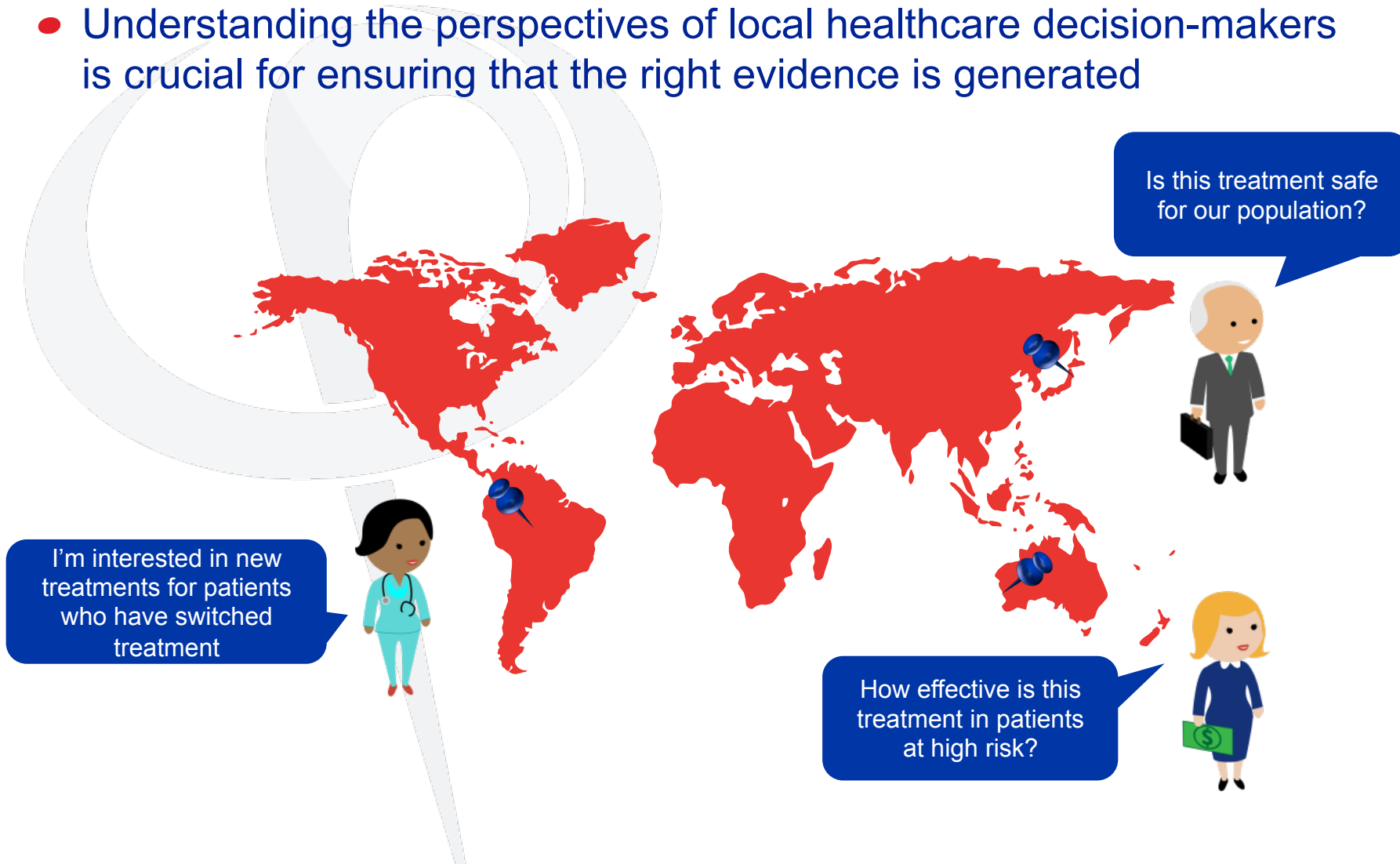
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- External partners can:
  - advise on the study design and methodology
  - provide access to data
  - use contemporary statistical approaches to analyse data



# Global and local collaboration

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

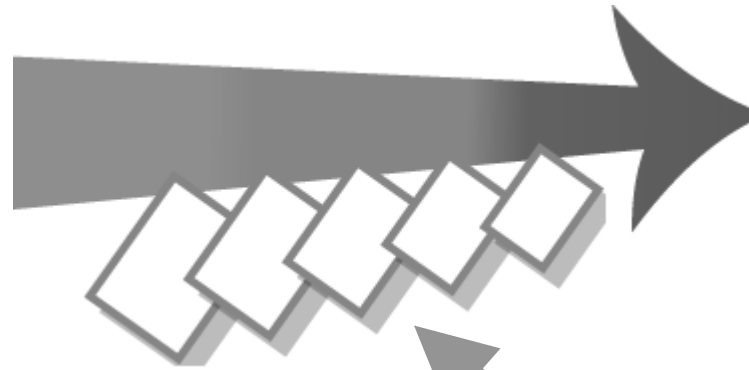


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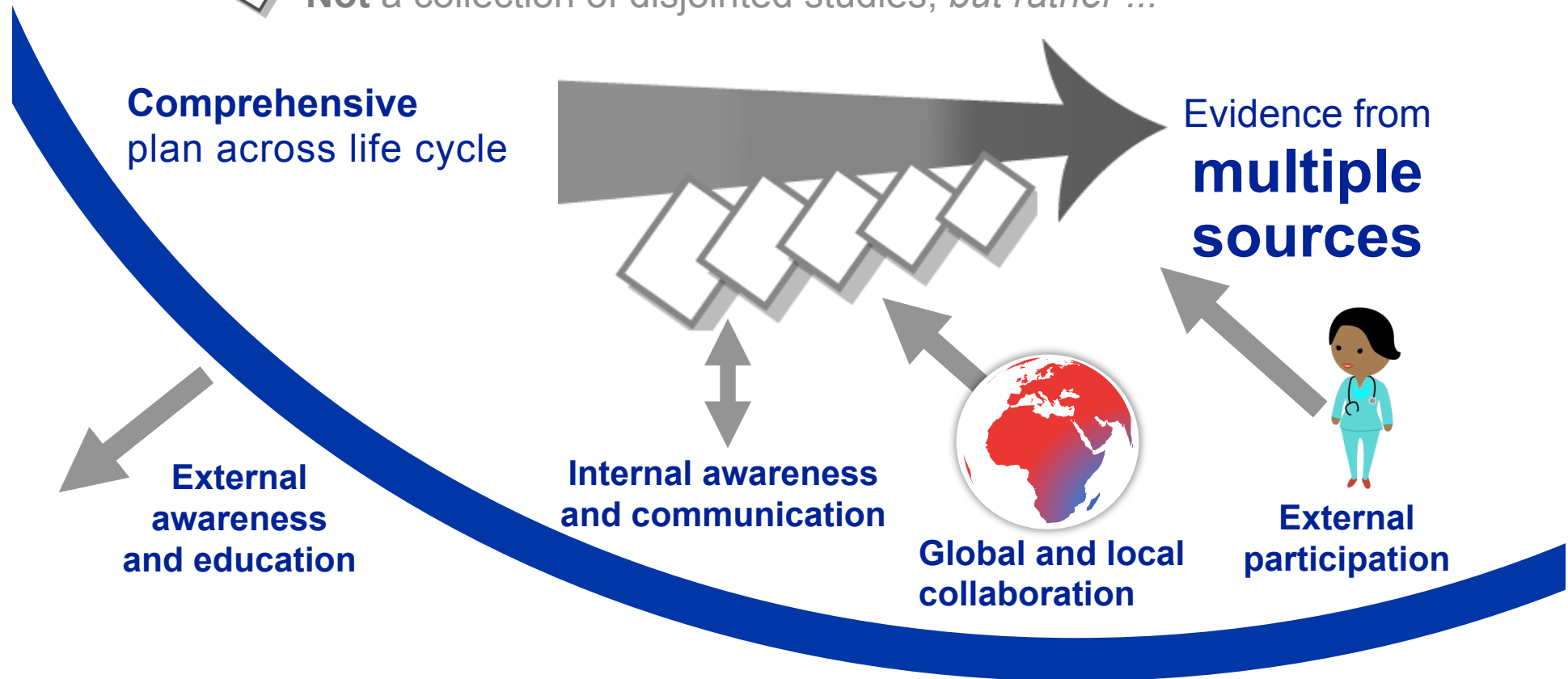


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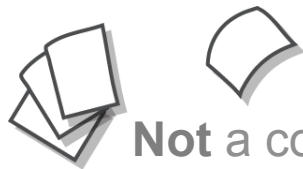
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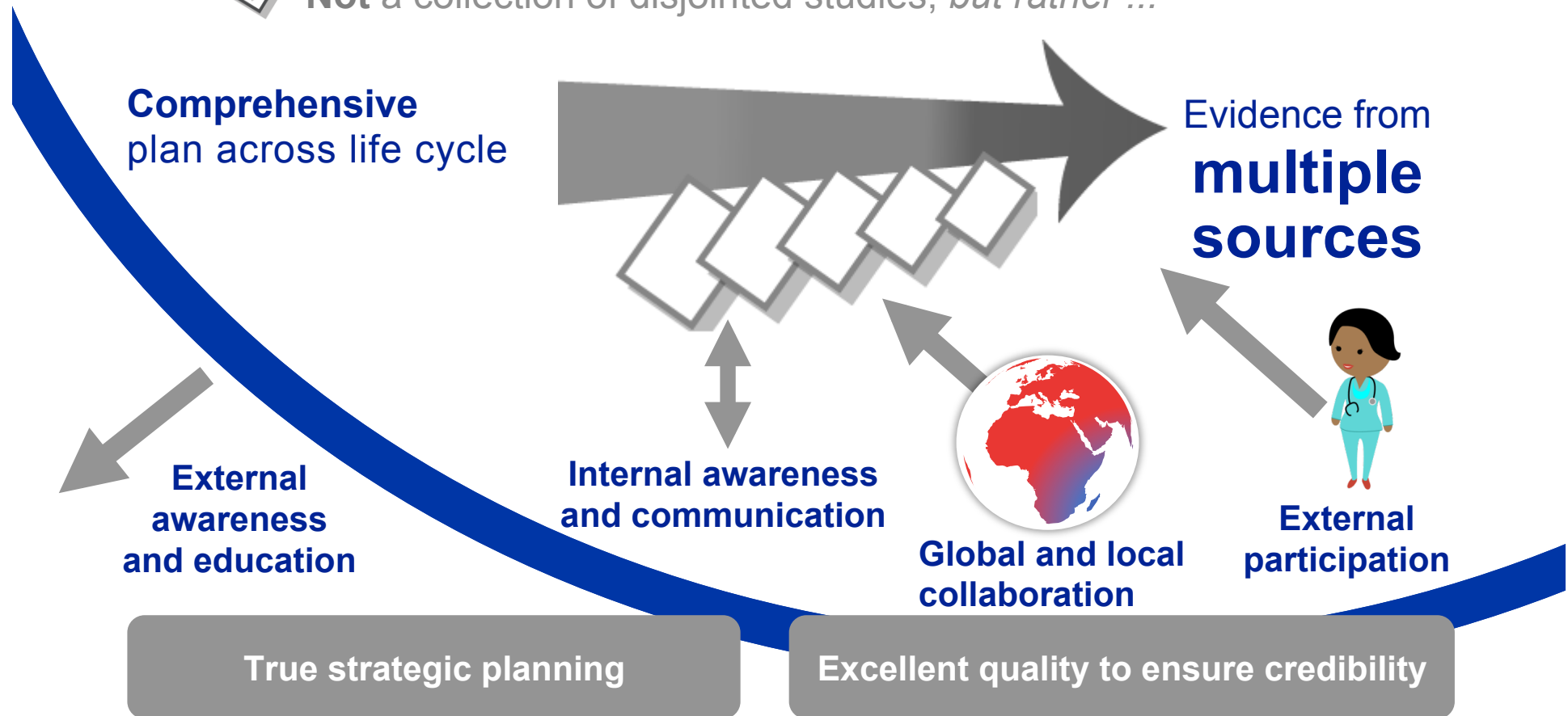
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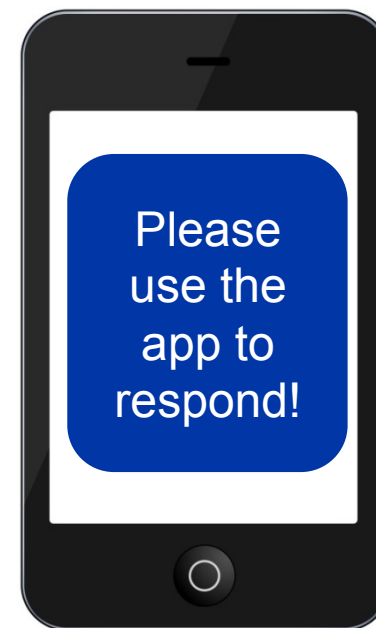
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## A question for you

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- 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





## Question for the panel

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A large, light gray microphone icon is positioned on the left side of the slide. A blue speech bubble is overlaid on the microphone's head, containing the text 'What are the challenges you face?'.

What are the challenges  
you face?



# Publications matter ... because EBM relies on systematic literature reviews

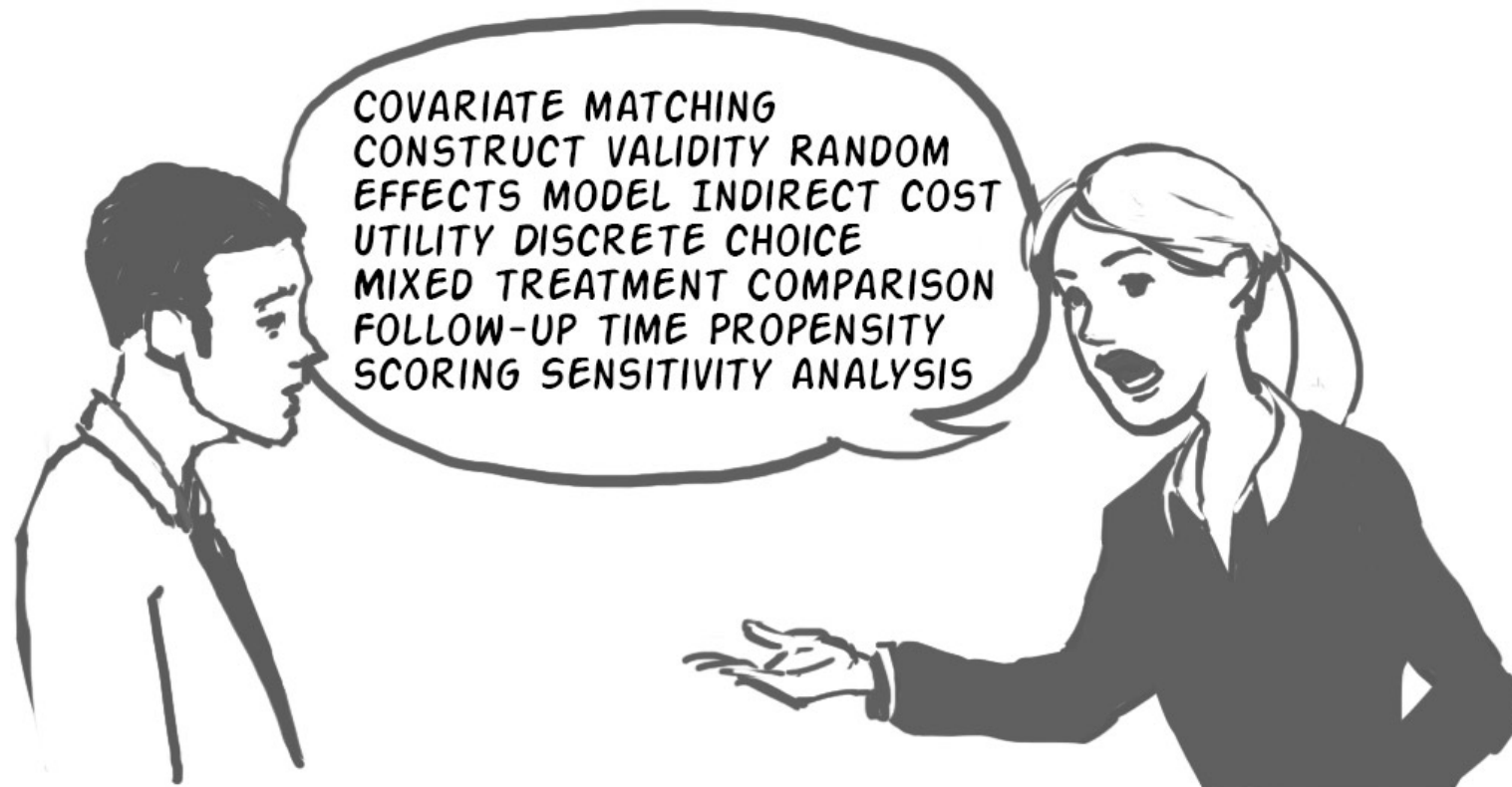
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- A **core methodology** of EBM is the systematic review
  - **All relevant published evidence** relating to the indication is identified and evaluated
- Publications evaluated in the EBM process will **inform decision-making**
  - Relevant publications 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

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## WHAT WE SAY



# Communicating effectively means cutting out the technical jargon

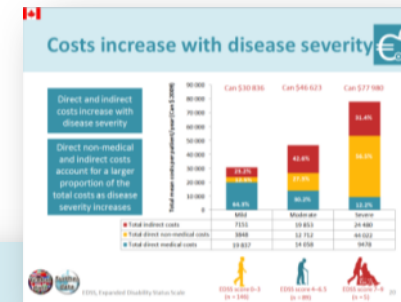
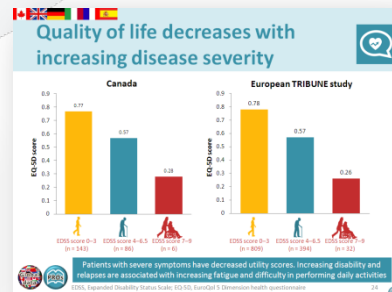
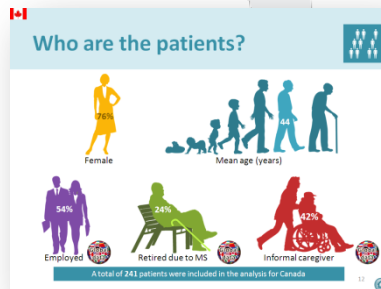
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## WHAT THEY HEAR



# 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

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**For best impact and value:**

**Plan**



**Perform**



**Publish...**

**...RWE as you would RCT evidence**