Get Real

Real-Life Data in Drug Development

Real-world evidence (RWE) Navigator launch

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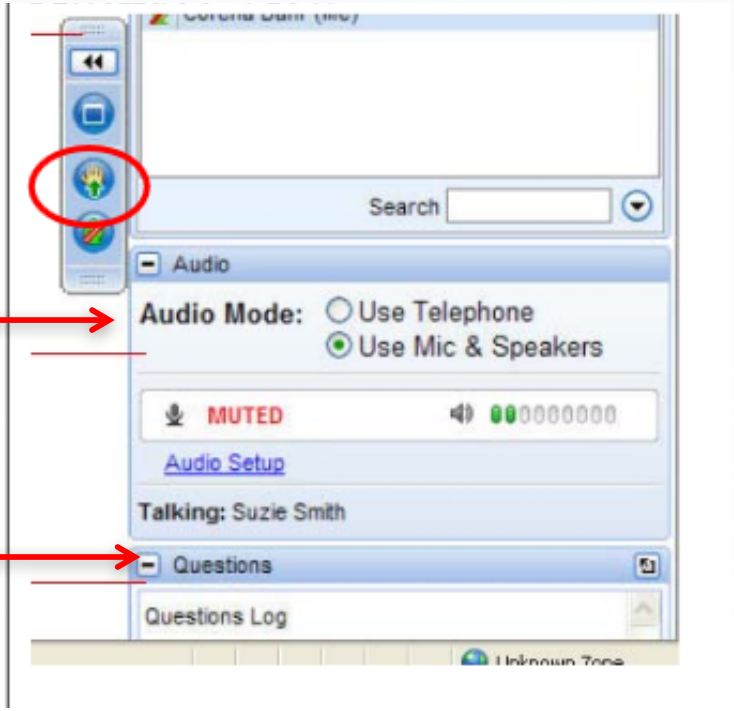
Raise your hand

Dial in or headphones

Ask a question



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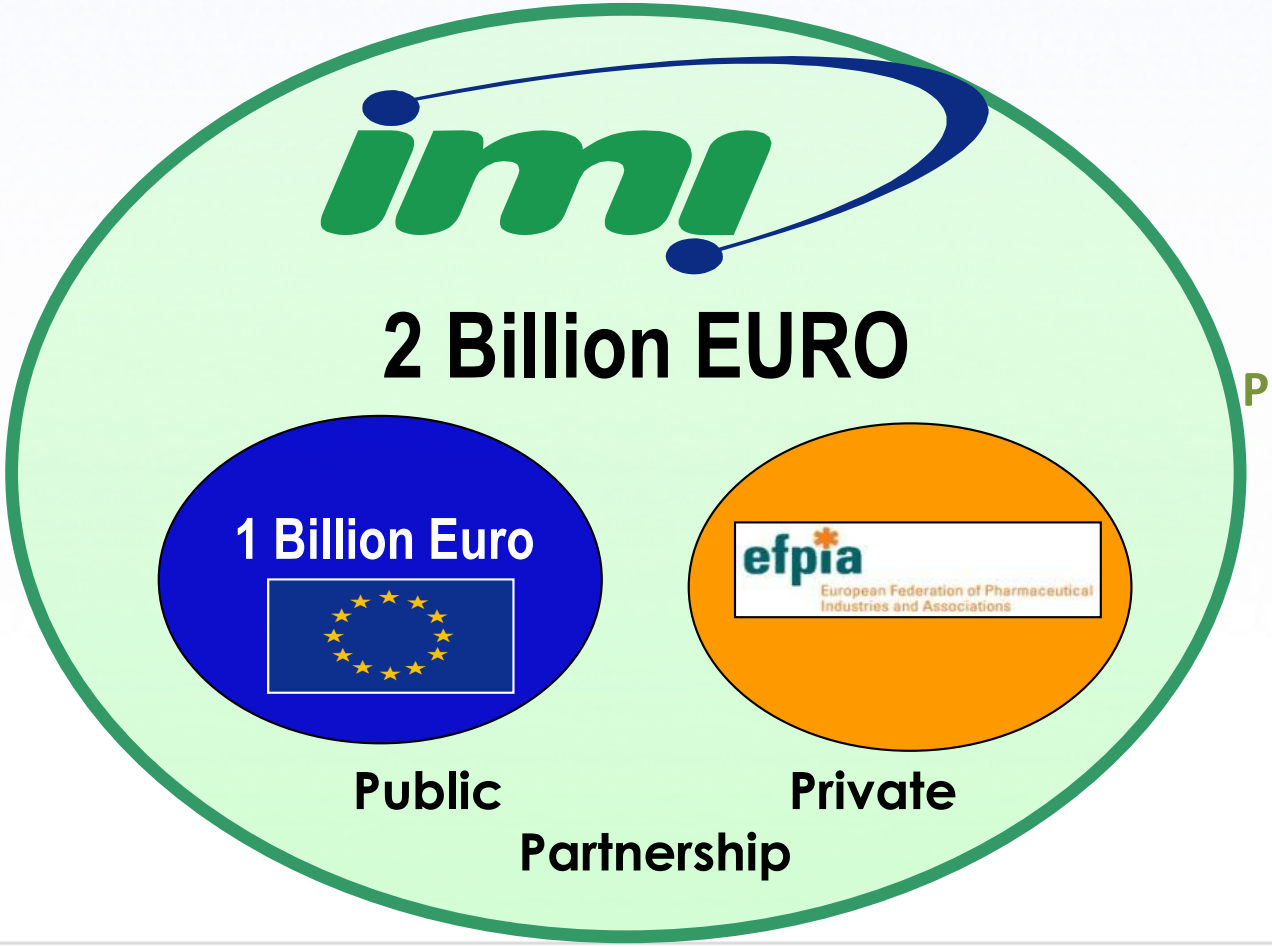
Innovative Medicines Initiative (IMI)

FP7 Funding

Cash payment to investigators in Europe: SME/public



European Federation of Pharma Industries & Assocs.

In kind contribution

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Why the need for change?

Environment

- Increasing strength and demands of **HTA/payers**
- Pressures for **earlier access** to new medicines of value
- Possibility of more flexible reimbursement and **access arrangements**
- **Rare disease** populations more prominent, hard to fit into trial paradigm
- Willingness of regulators to **engage**

Data and methods

- Recognition that data arriving at HTA are **sub-optimal**, especially the key data on relative effectiveness
- Growing **availability** (at least in principle) of RWD
- **New methods** to synthesize data and adjust for bias
- **IT infrastructure**: new possibilities for data collection and integration

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Mind the gap

Efficacy

Can it work?

Effectiveness

Does it work? (for my population)

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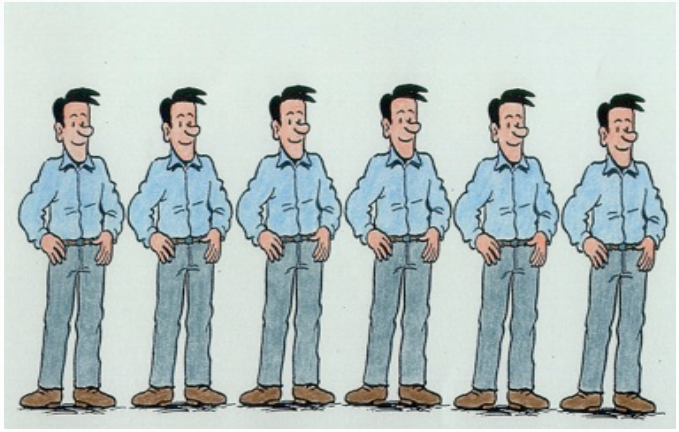
Efficacy *vs* effectiveness



- Benefit and harm in experimental and closely monitored research studies, normally RCTs
- RCTs minimise bias (high internal validity)
- Generalisable?

- Benefit and harm in everyday practice. (Pragmatic clinical trials, Observational studies, synthesis)
- 'Dirty' - variability and biases

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Three Years of a *Real* Public Private Partnership

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Wide range of outputs

Real-Life Data in Drug Development

Methods

- Detection of bias
- Adjustment of bias
- Aggregate RWD in NMAs
- Individual patient RWD in NMAs

Original research

- Drivers of effectiveness
- Analytical methods
- Prediction models
- Methodological guidance

Tools

- Software
- Checklists & templates
- Design options for pragmatic clinical trials

Summaries

- Study types
- Sources of data
- Methods
- Literature reviews

Case studies

- Retrospective analyses of relative effectiveness issues
- Disease area specific issues
- Stakeholder views

Illustrative examples – not a complete list of GetReal outputs

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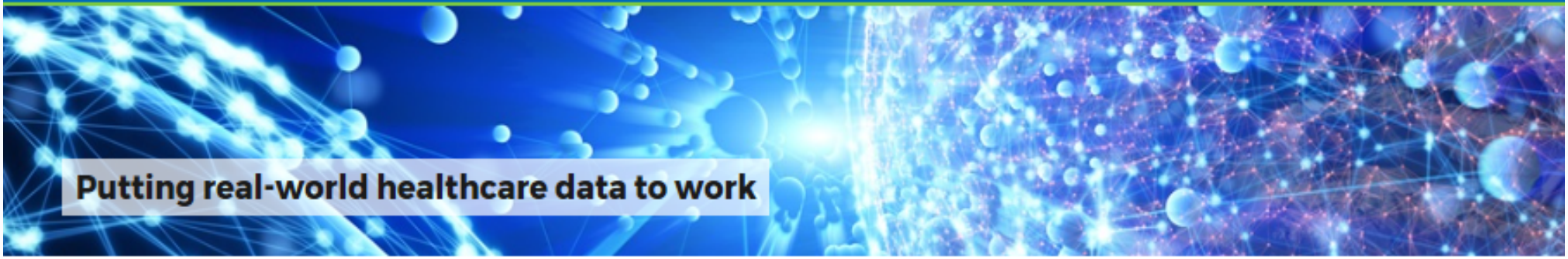

Real-world evidence (RWE) Navigator

The Real-world evidence (RWE) Navigator:

- **Is an educational resource**: helping users to find out more about the potential issues in demonstrating relative effectiveness of new medicines (referred to as 'effectiveness issues').
- **Provides guidance**: guiding users to specific types of analyses or study designs using RWE to support the development of medicines.
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The RWE Navigator has been designed for a wide variety of users. For example, pharmaceutical companies may find it useful to increase awareness about the use of RWE among their staff members, or patients may use it to understand concepts related to RWE and better understand challenges of using or generating RWE.

Understanding GetReal and the RWE Navigator

Step 1: Clarify the issues

Step 2: Find RWE options

Directory of resources

Using RWD is already part of evidence planning within pharma...

Real-Life Data in Drug Development

Development	File and launch	Post-marketing
Analyse RWD to assess effectiveness of existing medicines	Include evidence on use and effectiveness of existing medicines in registration package	Assess relative effectiveness of our new medicine in claims and EMR database analyses
Highlight shortcomings in existing treatments using RWE	Conduct network meta-analysis to estimate relative efficacy (or effectiveness) of new medicine	Synthesize studies on relative effectiveness vs competitor medicines
Incorporate RWD to estimate cost-effectiveness using economic models		

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...but evidence generation is evolving and GetReal is a key contributor – and resource

Real-Life Data in Drug Development

Development → **File and launch** → **Post-marketing**

- Plan early – consider adaptive pathways
- Use historical cohorts to provide context for single arm clinical studies
- Greater use of analytics to help design clinical trials
- Include trial designs that are more "pragmatic"
- Consider novel techniques to simulate relative effectiveness
- Seek greater dialogue with regulators & HTA agencies

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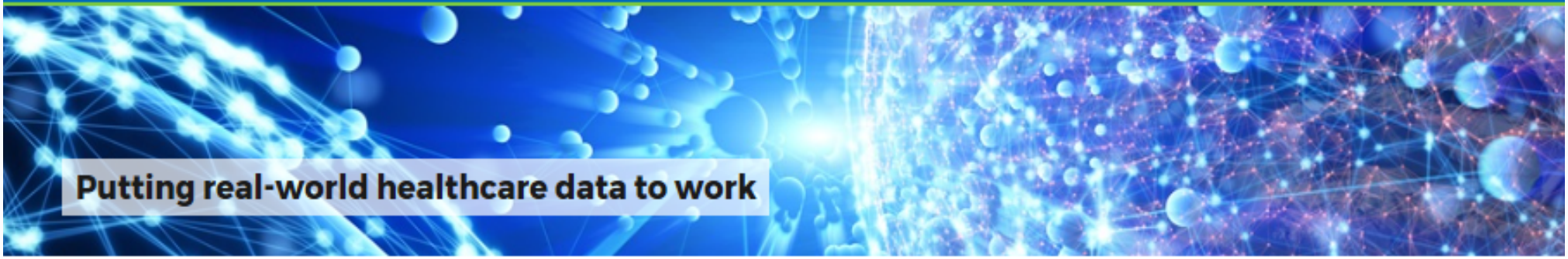

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Directory of resources

Main purposes of the RWE Navigator

- An **educational resource** to find out more about the potential issues in demonstrating relative effectiveness of new medicines ('effectiveness challenges').

Step 1
Clarify the Issues

- A **guide** to specific types of analyses or study designs using RWE to support development of medicines.

Step 2
Find the RWE Options

- A comprehensive **directory of resources** on the use of RWE in medicines, signposting to GetReal outputs and other authoritative sources.

Directory of Resources

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Who is it for ?

Clinicians

Patients

HTA agencies and payers

Shared platform for understanding and collaboration

Regulators

Researchers

Pharmaceutical companies

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What will I find?

- Sources of existing RWD
- Generate RWE (study designs)
- Summarise and synthesise evidence
- Assure quality and credibility of RWD/RWE
- Model effectiveness in real world setting
- Adjust for bias in non-randomised /obs studies
- Governance of RWD

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Organising principles

Effectiveness issues (challenges)

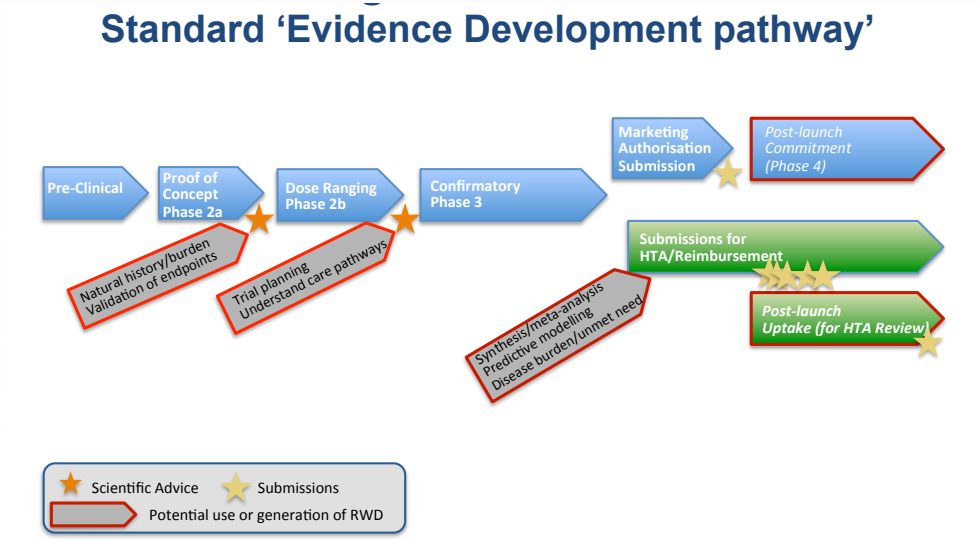
Examples

Population: Trial population mix differs from routine practice

Intervention: Adherence in study differs from usual practice

Comparators: Trial comparators do not include current usual care or standard of care

Evidence development pathways



Organised by: PICO-S & Development Phase

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RWE Navigator is…

an educational resource

a source of guidance

a directory of resources

a shared platform

NOT a decision-making/support tool

Does **NOT** replace formal scientific advice

Does **NOT** guarantee approval, access or funding

Methods tested still experimental

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RWE Navigator

rwe-navigator.eu

Get Real

About | Step 1: Clarify the issues | Step 2: Find RWE options | Use RWD | Case studies | Background | Glossary | Directory of resources

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Scenario 1: Clinician interested in learning about patient powered research networks

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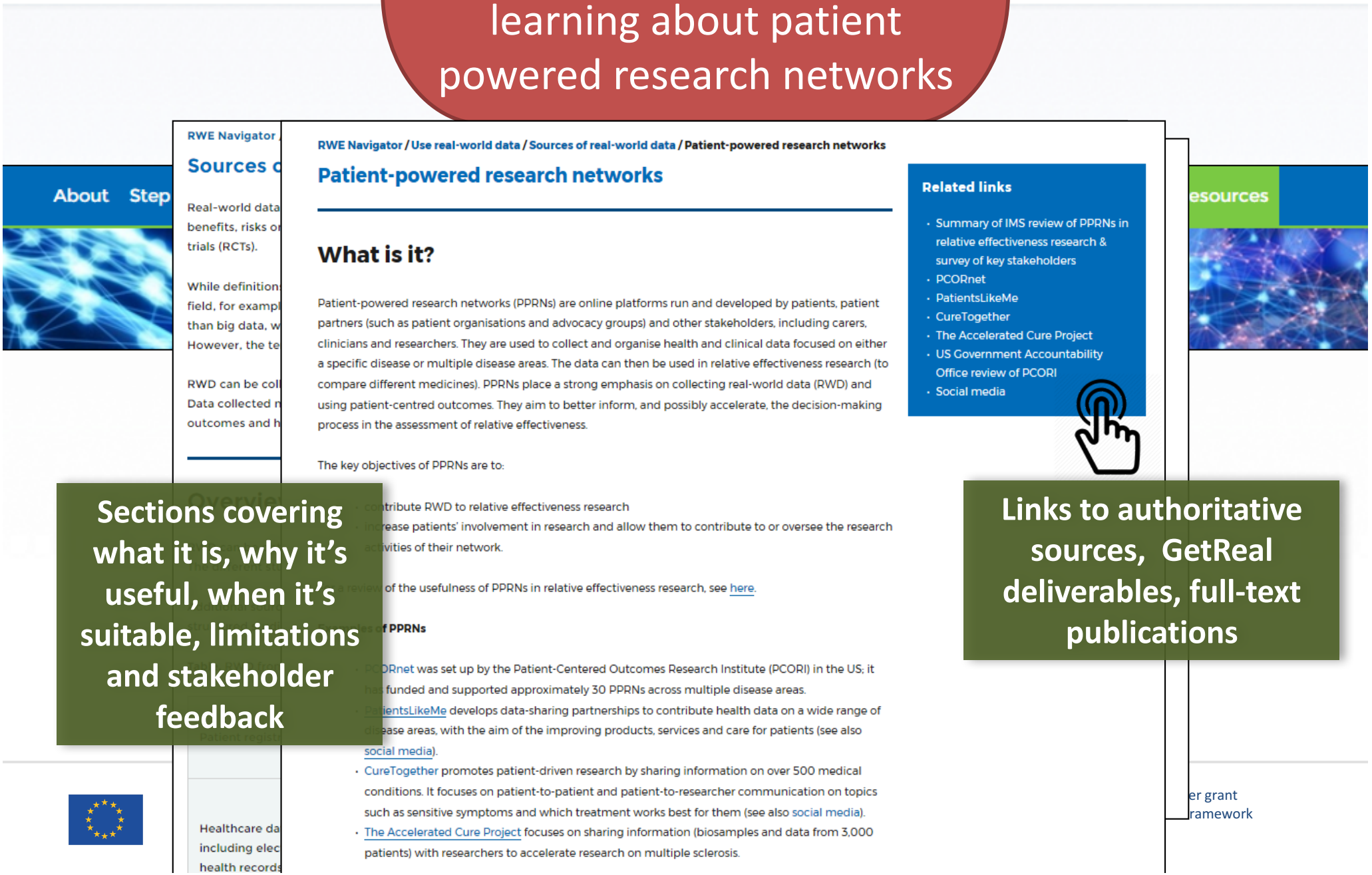

Scenario 2: pharmaceutical company preparing an evidence development plan for a new medicine

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- How & why effectiveness differs from efficacy (the 'gap') and 'drivers of effectiveness'
- Planning questions to consider for each aspect of PICO (population, intervention, etc)
- Methods to explore the gap
- Examples

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Scenario 2: pharmaceutical company looking for **options using RWE**

Find potential options using RWE to address the identified issues

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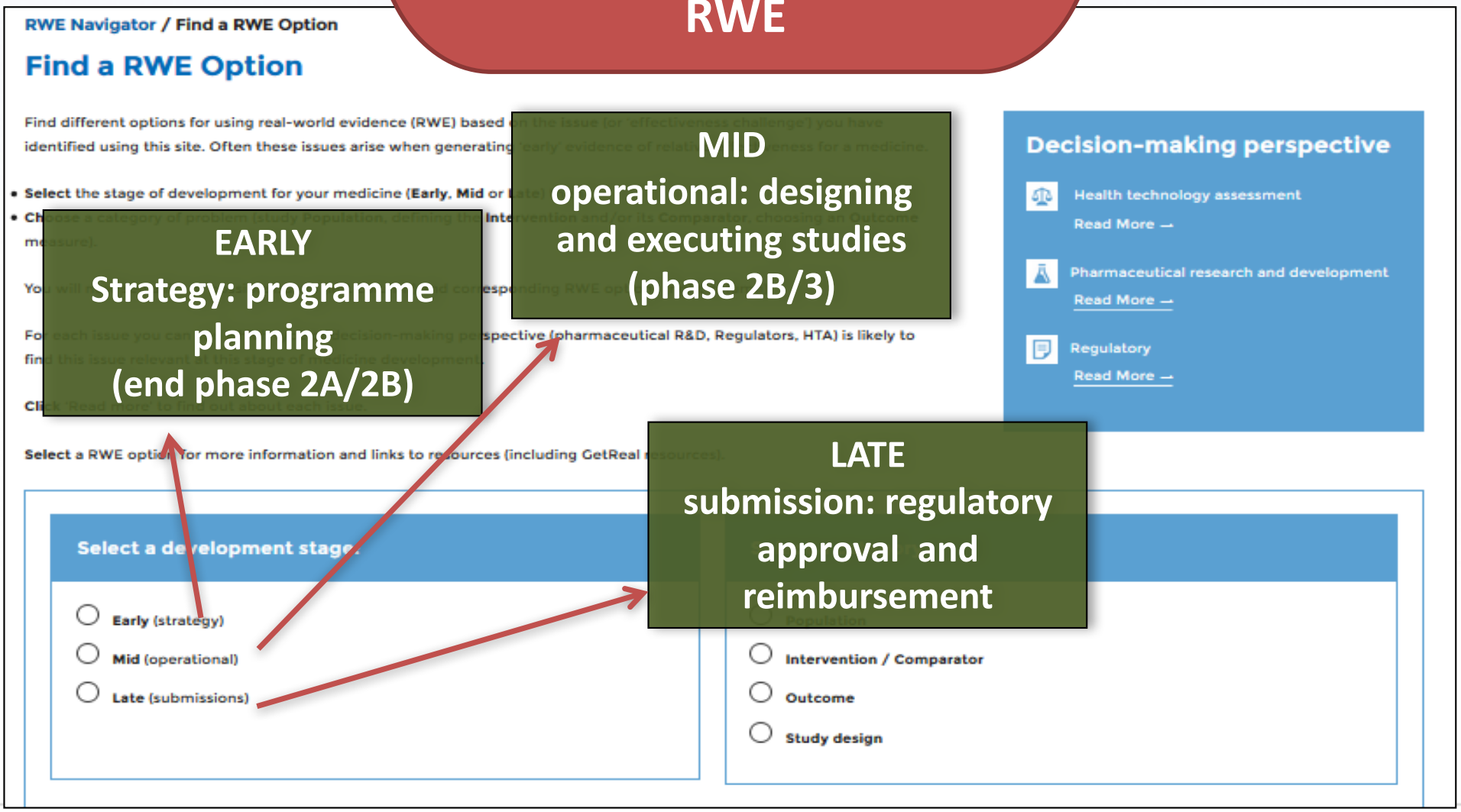

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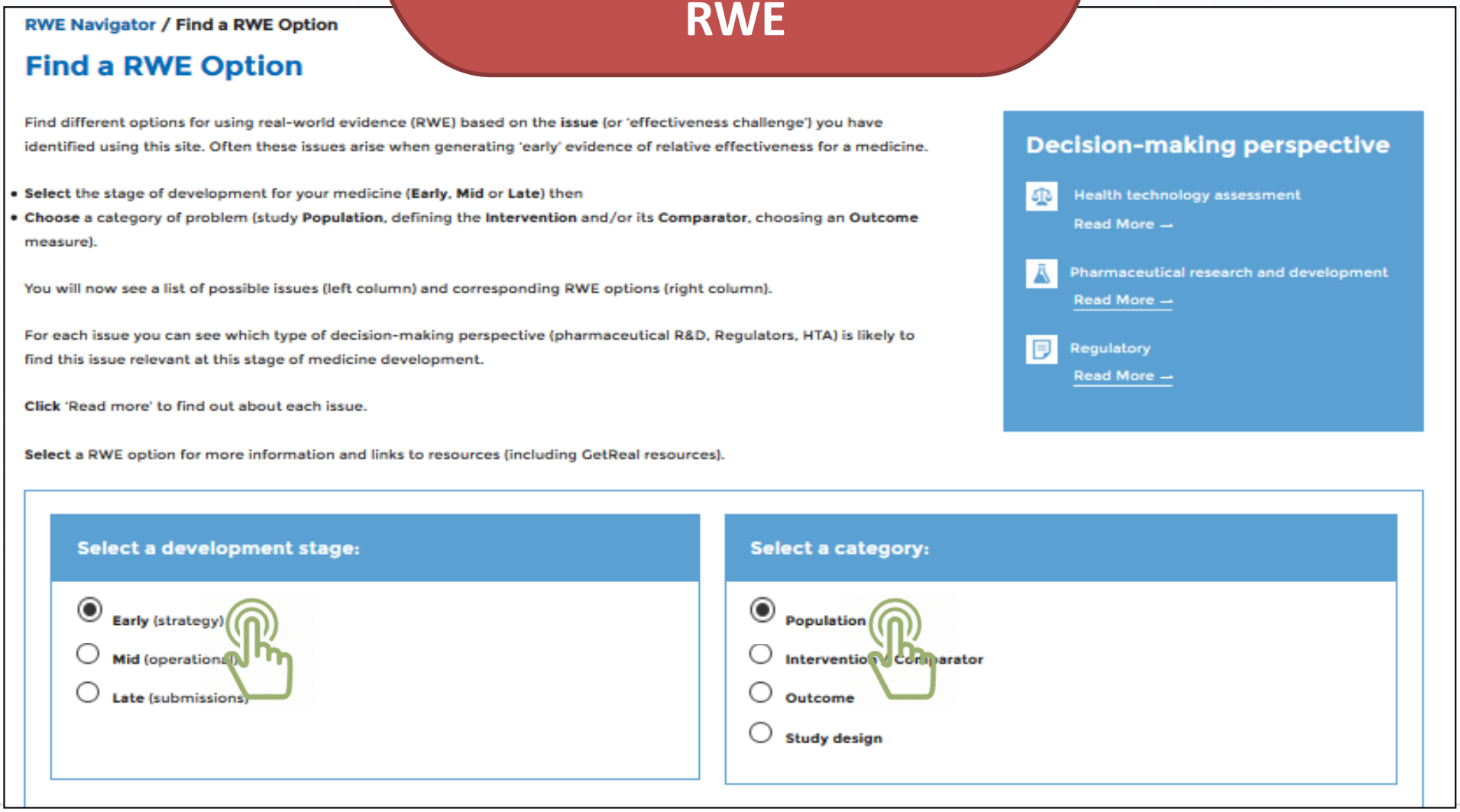

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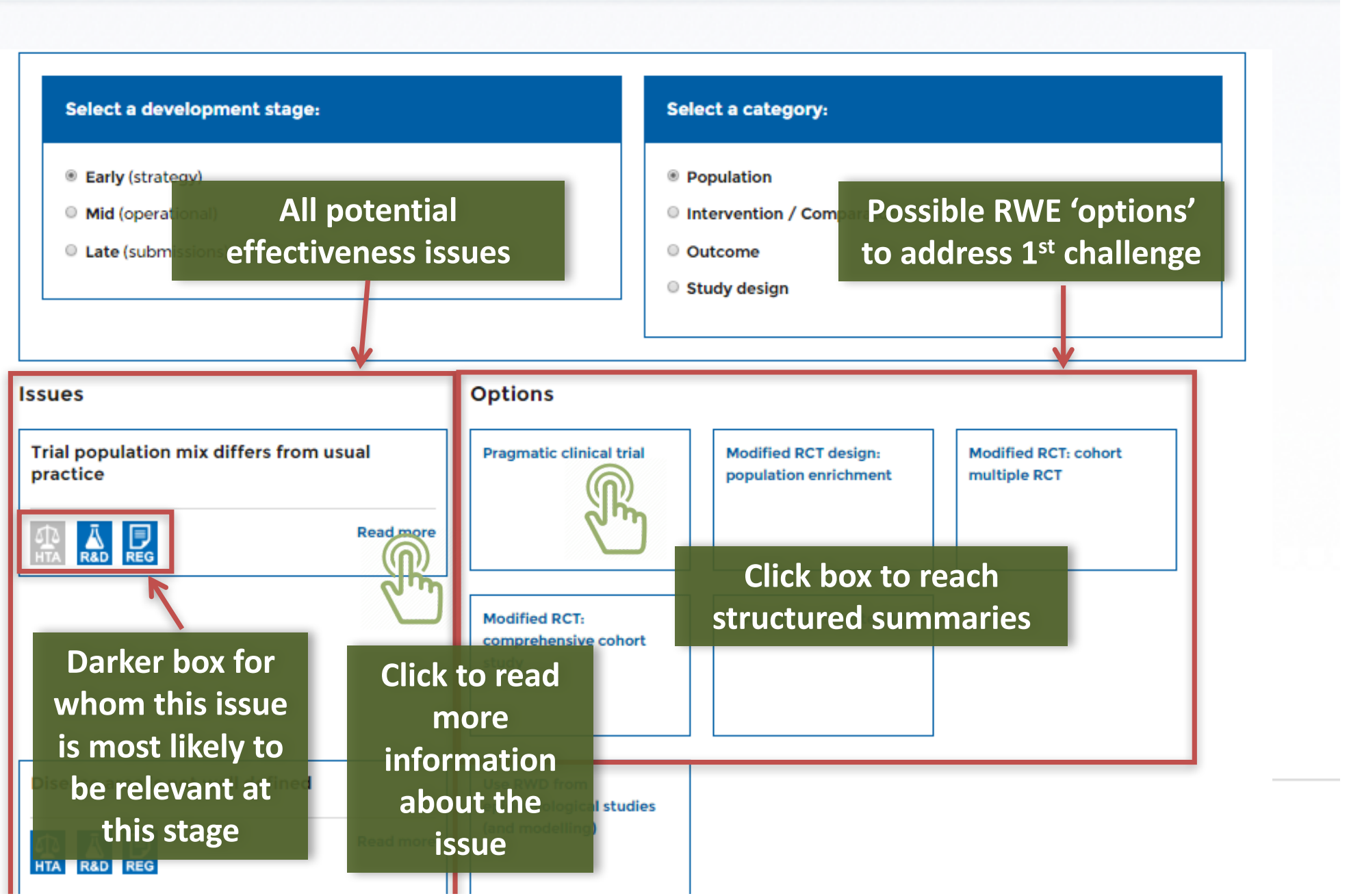
Issues and RWE options for early + population



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Structured summary

RWE Navigator / Use real-world data / Generate real-world evidence / Study design: Pragmatic trial

Study design: Pragmatic trial

What is it?

Pragmatic trials aim to measure the relative effectiveness of treatment strategies in real-world clinical practice, as first described by Schwartz and Lellouch in 1967. They provide evidence of the added value of a treatment strategy in routine clinical practice, while maintaining the strength of a randomised controlled trial.

This entails the comparison of randomised groups of patients that are similar to the target group in the characteristics that modify drug response, in the setting where they would be treated in real life. The treatment strategies for comparison and outcome measures should be relevant for routine clinical practice. The term 'pragmatic trial' is commonly used for trials that asses the difference between treatment strategies, including extraneous factors (for example, the effe to maximise generalisability to a broader setting or patient population.

For most new market-approved treatments, the c still insufficient to fully guide clinicians and policy makers in choosing the optimal treatment for their patients. Pragmatic trials can help supplement this data with real-world evidence (RWE).

Sections covering what it is, why it's useful, when it's suitable, limitations and stakeholder feedback

Related links

- Learn more about study design considerations in pragmatic trials
- Pragmagic tool
- Nieuwenhuis et al 2016 publication in J Clin Epidemiol on the affect of pragmatic trial design features on features affect validity, generalizability, precision, or feasibility
- Sackett 2013 Clinical Trials publication on pragmatic trials
- van Staa et al 2014 HTA publication on TwiCs using routine electronic records reviewing strengths and weaknesses of
- GetReal Stakeholder views on pragmatic trials
- Cohort multiple randomised controlled trials (cmRCTs) / trials within cohorts (TwiCs)

Links to authoritative sources, GetReal deliverables, full-text publications

Scenario 3:
HTA analyst wishing to understand how RWE/RWD can be incorporated in evidence synthesis

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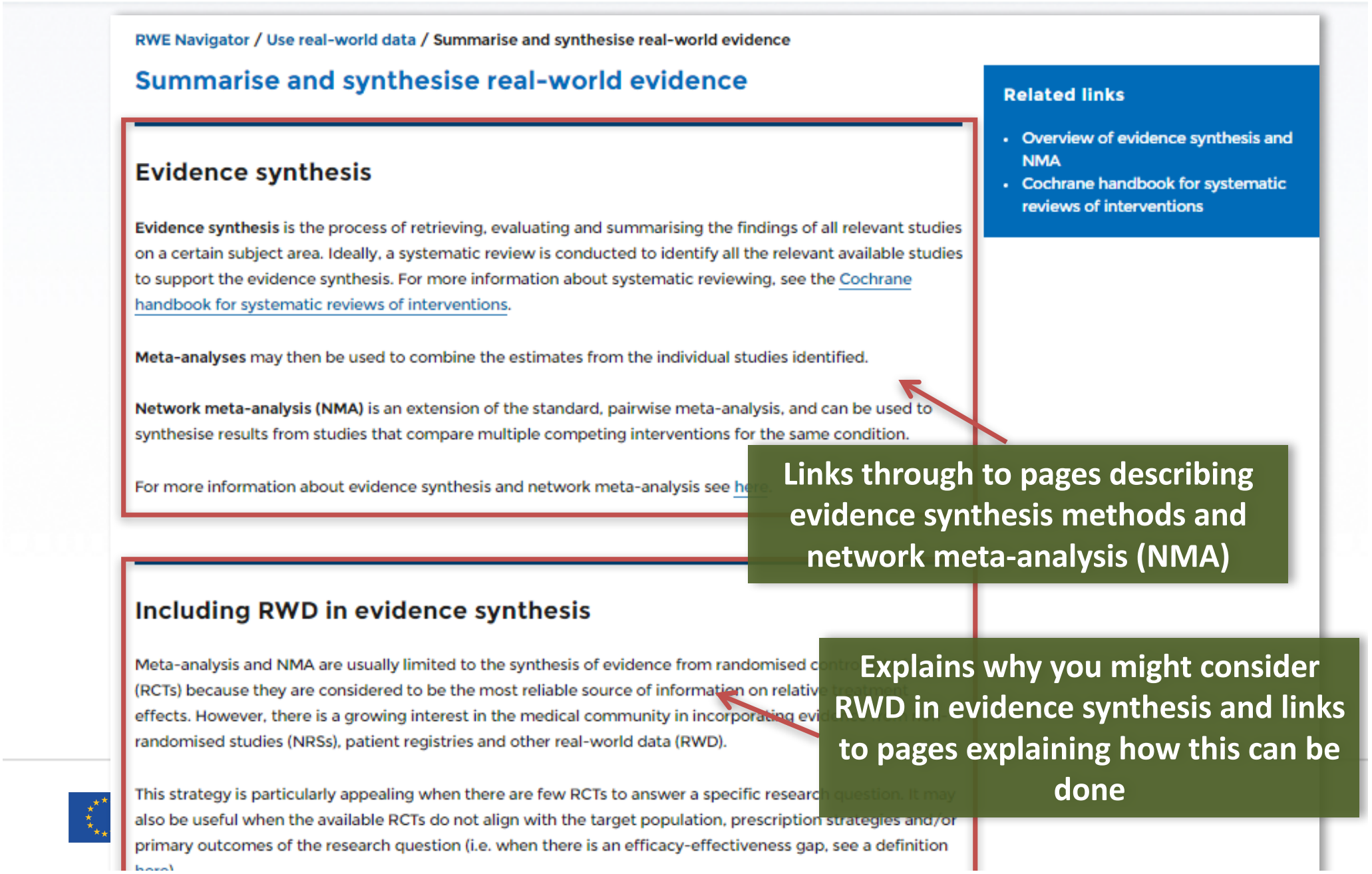

RWE Navigator / Use real-world data / Summarise and synthesise real-world evidence

Summarise and synthesise real-world evidence

Evidence synthesis

Evidence synthesis is the process of retrieving, evaluating and summarising the findings of all relevant studies on a certain subject area. Ideally, a systematic review is conducted to identify all the relevant available studies to support the evidence synthesis. For more information about systematic reviewing, see the Cochrane handbook for systematic reviews of interventions.

Meta-analyses may then be used to combine the estimates from the individual studies identified.

Network meta-analysis (NMA) is an extension of the standard, pairwise meta-analysis, and can be used to synthesise results from studies that compare multiple competing interventions for the same condition.

For more information about evidence synthesis and network meta-analysis see here.

Related links

- Overview of evidence synthesis and NMA
- Cochrane handbook for systematic reviews of interventions

Links through to pages describing evidence synthesis methods and network meta-analysis (NMA)

Including RWD in evidence synthesis

Meta-analysis and NMA are usually limited to the synthesis of evidence from randomised contro
(RCTs) because they are considered to be the most reliable source of information on relative treatment
effects. However, there is a growing interest in the medical community in incorporating evi
randomised studies (NRSs), patient registries and other real-world data (RWD).

This strategy is particularly appealing when there are few RCTs to answer a specific research question. It may also be useful when the available RCTs do not align with the target population, prescription strategies and/or primary outcomes of the research question (i.e. when there is an efficacy-effectiveness gap, see a definition here).

Explains why you might consider RWD in evidence synthesis and links to pages explaining how this can be done

What technique for evidence synthesis are available to use?

The specific technique or analytical method used for the synthesis of evidence will depend on the nature of the data available, please see the table below.

Links to relevant references on issues not covered by GetReal

Link to page describing method covered by GetReal work

		Aggregate	IPD	Aggregate + IPD
Source of data	RCT only	See references here.	See GetReal work and references here.	See references here.
	Real-world data (with or without RCT)	See references here.	See references here.	See GetReal work and references here.

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More information on evidence synthesis & NMA

Indirect treatment comparison and network meta-analysis

Meta-analysis is a widely accepted statistical tool, used for synthesising evidence on the relative effects of interventions obtained from multiple individual RCTs. However, the value of pairwise meta-analysis may be limited in real-world clinical

do not include some of the pairwise

by undertaking an NMA.

son, B vs. C, may be carried out

e carried out indirectly, by

diagram below, for B vs. C there is

o sources of evidence can be

arisons

nparisons

CTs may not cover all of the

reatments (A–F) and a set of

but not all of the pairwise

comparison there may be direct and

to synthesise all of the evidence

'Best practice' for conventional indirect comparisons/network meta-analysis using aggregate RCT data

Network meta-analysis (NMA)

Information on best practice for conventional indirect comparisons and network meta-analysis (NMA) is summarised on this page, with links to useful resources.

For more information describing NMA see here. The GetReal review on NMA methods can be found here and the articles identified in this review can be found here.

Assessing the assumptions of NMA

NMA adopts the same set of assumptions as a usual (pairwise) meta-analysis, but also uses an additional assumption that may be hard to assess, called transitivity (also called similarity or exchangeability) (Ades 2011, Salanti 2012, Efthimiou et al 2016).

- Transitivity assumes that information for the comparison between treatments B and C can be obtained via another treatment, A, using the comparisons A vs. B and A vs. C.
- Researchers can assess this assumption by checking the distribution of effect modifiers across comparisons (Jansen et al 2011).
- They can also use conceptual considerations, for example, checking whether the missing treatments in each trial are 'missing at random' or whether the choice of treatment comparisons in the trials is not associated either directly or indirectly with the relative effectiveness of the interventions and

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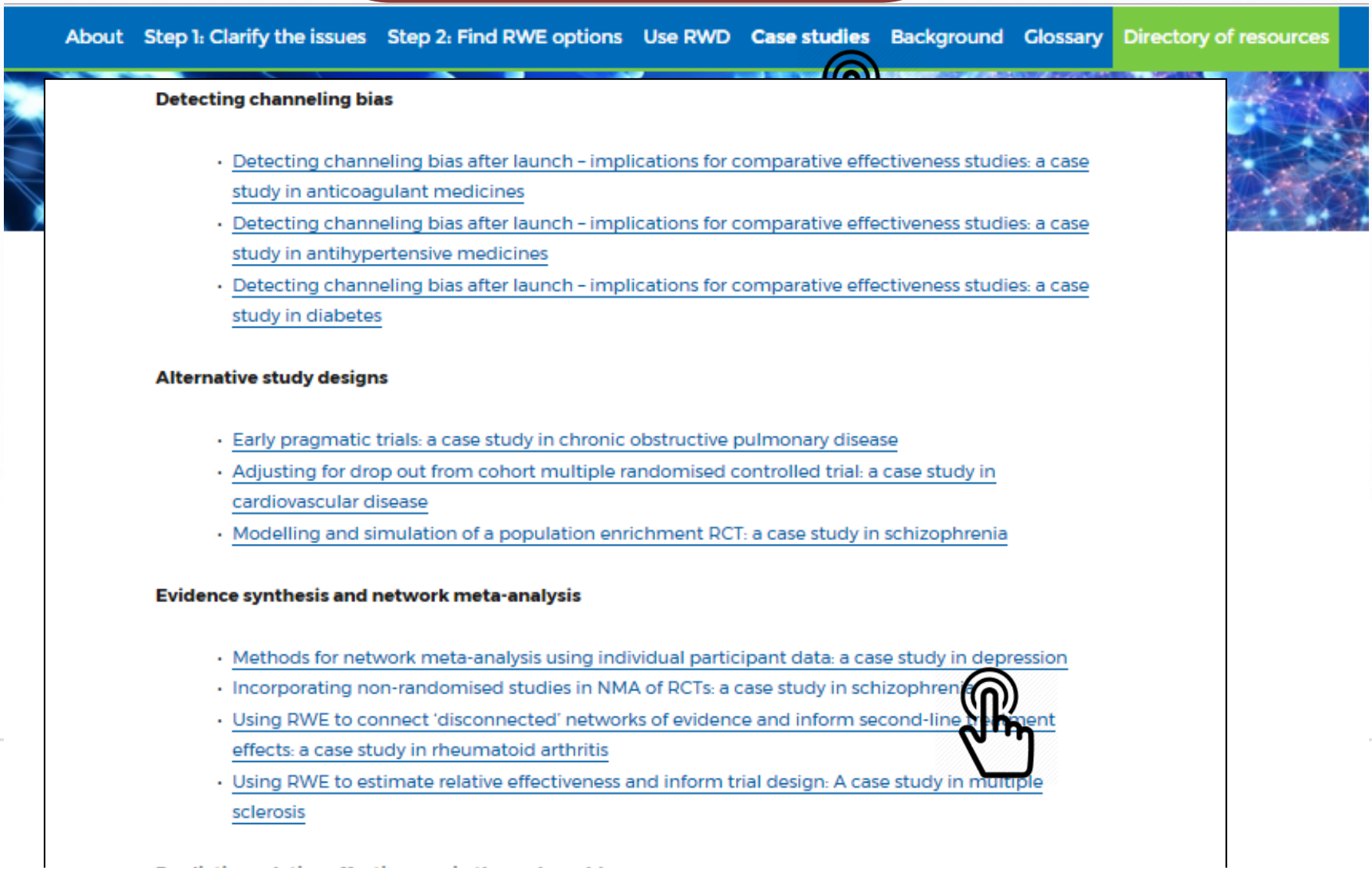
Scenario 4: Anyone looking to understand more about GetReal case studies



Incorporating non-randomised studies in NMA of RCTs: a case study in schizophrenia

Context

Schizophrenia is a mental disorder which affects the way a perso… by abnormal social behaviour and may lead to difficulties in distingu… what is real and what is imaginary. Schizophrenia has been ranked among the top causes … (Murray et al 1996, Tandon et al 2008).

There are a wide range of competing antipsychotic drugs available in the market and there have been many randomised controlled trials (RCTs) that assess most of the available treatment … cover a wide range of treatment comparisons, forming a network of evidence (see here for a description of network meta-analysis). In addition, there have been non-randomised studies (NRSs) measuring the effectiveness of drugs in real-world clinical settings. However, the two different types of evidence have not been jointly synthesised. The benefits of adding NRS, a type of real-world data (RWD), to the synthesis is explained here.

What was examined in this case study?

The aim of this case study was to assess existing methodology and develop new methods for combining evidence from RCTs and NRSs in a network meta-analysis (NMA). Specific issues examined were:

- How can inconsistencies between the different types of evidence (randomised and non-randomised) be assessed?
- What analytic methods can be used to incorporate RWE from NRSs into an NMA?

Related links

- Network meta-analysis incorporating RWE
- Efthimiou et al 2016 publication in StatMed on combining randomised and non-randomised evidence in an NMA [TO BE ADDED]

Headings give context, explain brief methods, findings/conclusions, limitations of case study, (any) stakeholder feedback

Link to publications and deliverables

Other useful content…

Generate RWE (study designs)

Assure quality and credibility of RWD/RWE

Key related initiatives

Adjust for bias in non-randomised / observational studies

Governance of RWD

Model effectiveness in real world setting

Policies & perspectives on RWD

Glossary

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Real-Life Data in Drug Development

WE NEED YOUR INPUT!

- You've seen a presentation of the tool, what specific recommendations or improvements would you like to see to use to tool to facilitate patient access?

- Please tell us using the question field on your webinar desktop

You can also ask your own questions too!

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