THANK YOU FOR JOINING ISMPP U TODAY!

The program will begin promptly at 11:00 am EDT

July 22, 2015

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- ISMPP is pleased to announce our first Asia Pacific meeting – registration is now open!

2015 ASIA PACIFIC MEETING OF ISMPP

REGISTRATION IS OPEN!

COLLABORATING FOR ETHICAL & EFFECTIVE MEDICAL PUBLICATIONS

Beijing, China • August 30, 2015

Tokyo, Japan • September 2, 2015

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ISMPP International Society for Medical Publication Professionals™

2015 ASIA PACIFIC MEETING OF ISMPP

COLLABORATING ON: ETHICAL & EFFECTIVE MEDICAL PUBLICATIONS

BEIJING AUGUST 30 ♦ TOKYO SEPTEMBER 2

PROGRAMME HIGHLIGHTS

- GPP3 (latest update, ***GPP3 for Authors*** checklist)
- **Four plenary sessions** exploring aspects of successful publication planning in AP
- Expert-moderated **roundtable sessions**
- Outstanding faculty from academia, industry, government, medical affairs, clinical research, medical journals

- **Keynote Speaker:** Professor Ana Marušić
  - President Elect, European Association of Science Editors (EASE), EQUATOR Network Steering Group member
  - Leadership experience at many influential organizations
  - Research on how industry sponsors work with investigators to ensure best authorship practice

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To optimize your webinar experience today:

- Use a hardwired connection if available
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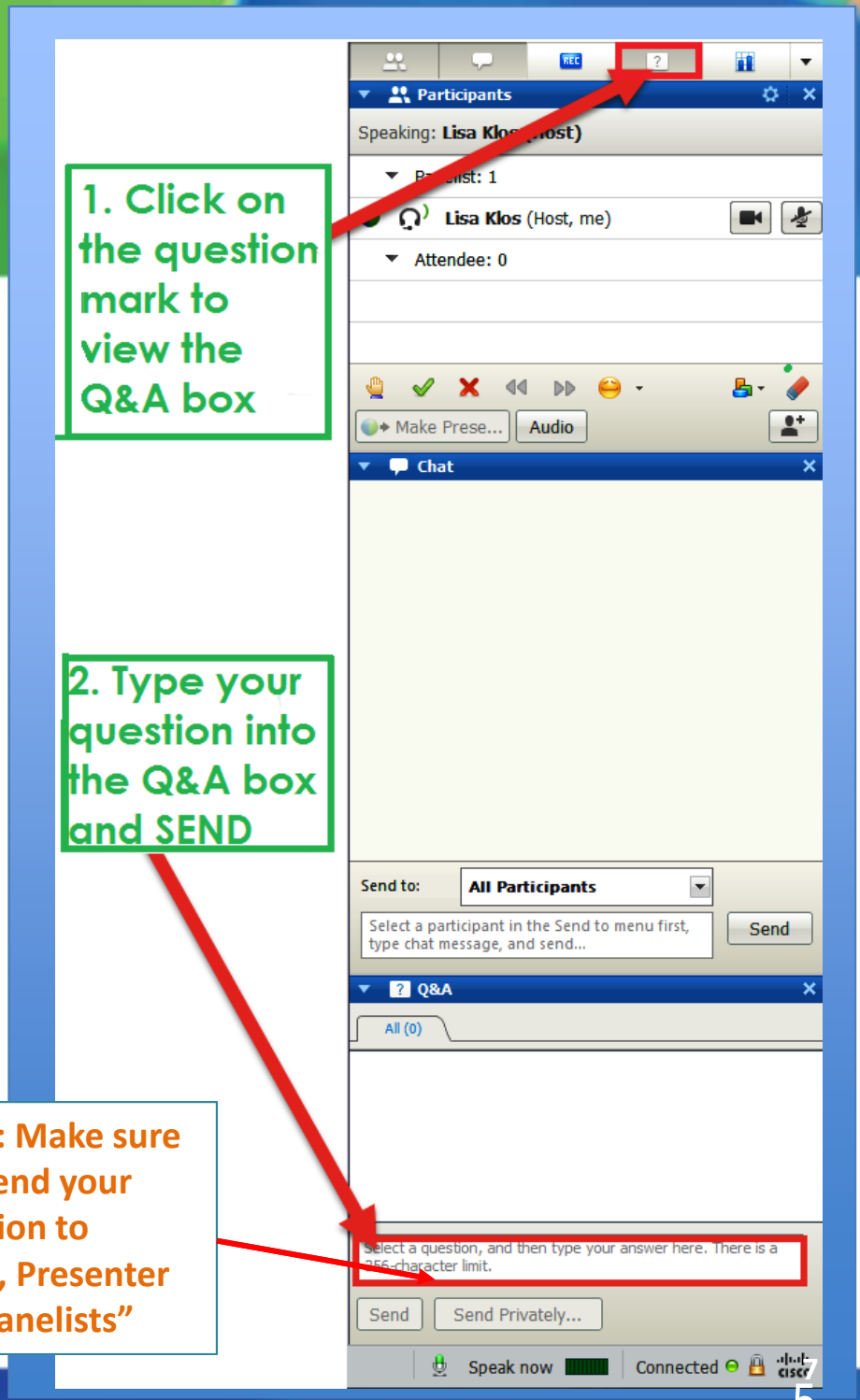
QUESTIONS…

- To ask a question, please type your query into the Q&A box
  - To ensure anonymity and that all panelists receive your question, please choose the drop down box option, "Hosts, Presenters and Panelists." Otherwise, all audience members will be able to see your submitted question
- We will make every effort to respond to all questions



NOTE: Make sure you send your question to "Host, Presenter and Panelists"

REAL WORLD EVIDENCE (RWE) AND COMPARATIVE EFFECTIVENESS RESEARCH

RICHARD WHITE MA PHD
… A BIT ABOUT HIM

- Background
  - MA, PhD and Research Fellowship in Pharmacology, University of Cambridge, UK
  - International Marketing Programme, INSEAD
  - Advanced Health Economic Modelling Programme, University of Oxford
  - Honorary Research Fellow, Oxford Brookes University
- Oxford PharmaGenesis
  - Publication planning for major brand launches
  - Founder of the Value Demonstration Practice

TIM KODER PHD
… AND A BIT ABOUT HIM

- Background
  - MSc, PhD and postdoctorate in the neuropharmacology of recognition memory, University of Bristol, UK
  - 10 years of experience in medical communications and publishing as an editor, writer and in client services
- Oxford PharmaGenesis
  - Building an internal client company RWE network
  - Planning publications and communications for a pioneering global observational study in diabetes

DONNA SIMCOE, MS, MS, MBA, ISMPP CMPP™ … AND A BIT ABOUT ME

- Background
  - Certified Medical Publication Professional
  - 3 Master degrees in Biomedical Writing, Biotechnology and an MBA
  - Former Chair of the ISMPP U Committee (2013-2014)
  - Recently elected to ISMPP's Nominating Committee
  - Current AMWA Pacific Southwest Chapter President (2014-2016)
  - Medical Publication consultant with 20 years of experience in publication management at Cephalon, Wyeth, AstraZeneca and Cadence

DISCLAIMER

- Information presented reflects the personal knowledge and opinion of the presenters and does not represent the position of their current or past employers or the position of ISMPP

OBJECTIVES

At the end of this presentation, attendees should be able to:

- Understand the specific issues associated with the publication and communication of RWE studies
- Understand how internal policies for publishing RWE studies can adopt the same level of rigor as those for RCTs

REAL-WORLD EVIDENCE (RWE) AND COMPARATIVE EFFECTIVENESS RESEARCH

Meeting the challenges of publication and communications planning

Richard White MA PhD
Commercial Director, Oxford PharmaGenesis
Honorary Research Fellow, Oxford Brookes University

Tim Koder PhD
Account Director, Oxford PharmaGenesis

WHAT IS RWE AND WHY IS IT IMPORTANT?

AUDIENCE QUESTION

How do you feel about RWE?

A. Love it

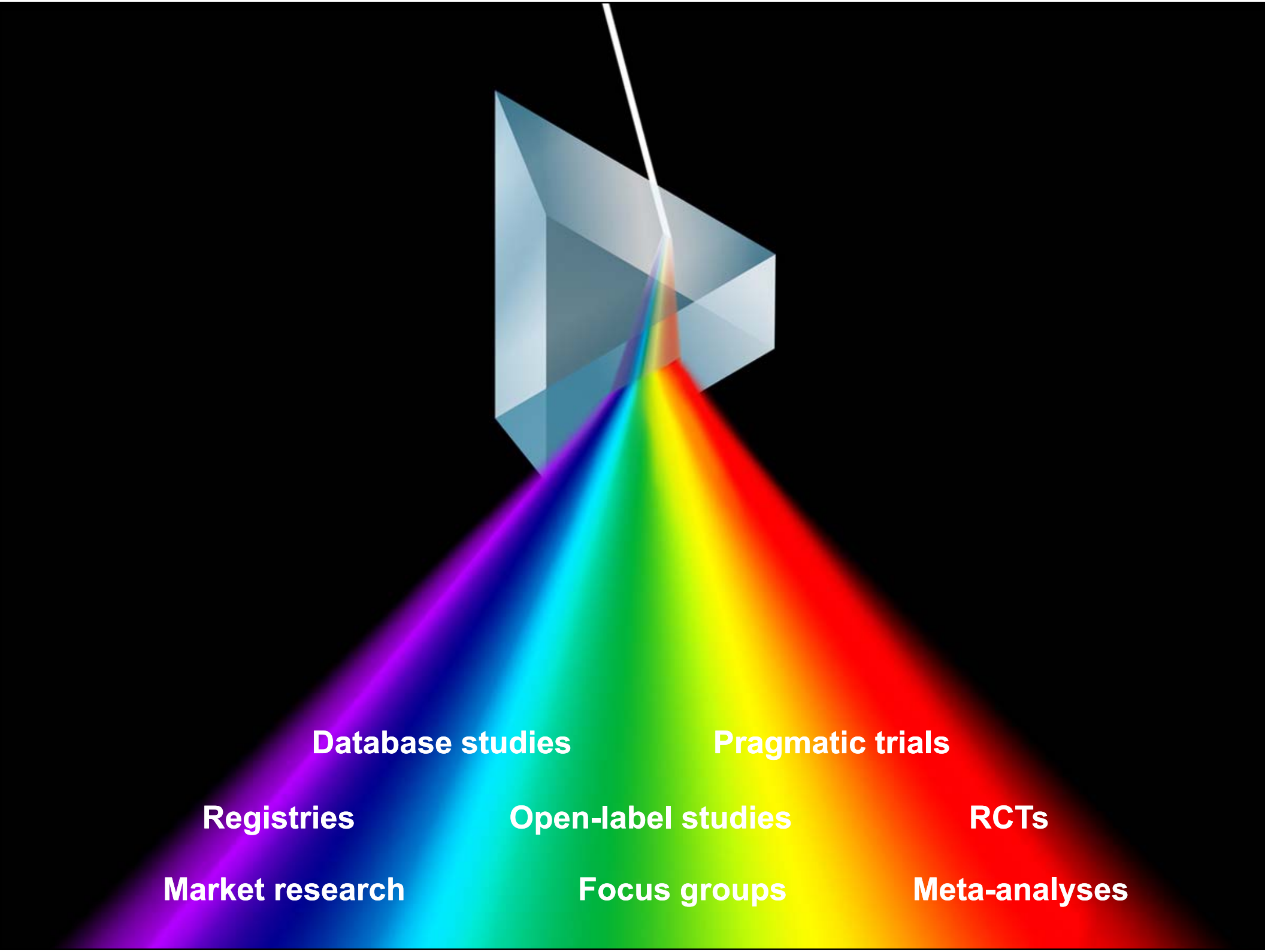
B. Like it

C. Don't care

D. Hate it

E. No idea – what's real world evidence?


Meta-analyses
RCTs
Open-label studies
Observational studies (RWE)


Database studies
Pragmatic trials
Registries
Open-label studies
RCTs
Market research
Focus groups
Meta-analyses

WHY DOES THIS MATTER TO US AS INDIVIDUALS?

WHY DOES THIS MATTER TO US AS INDIVIDUALS?

WHY DOES THIS MATTER TO US IN OUR ROLES IN THE PHARMA INDUSTRY?

RWE demonstrates

↓

Unmet needs | Effectiveness | Safety

in patients in the **real world**

↓

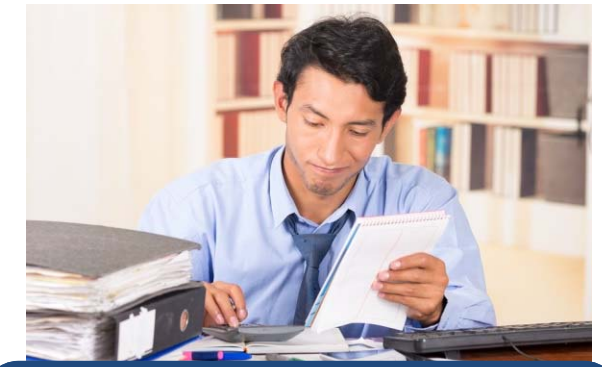
Payers	Regulators	Patients
Politicians	Clinicians	Industry

↓

Patient access

WHY DOES THIS MATTER TO US IN OUR ROLES IN THE PHARMA INDUSTRY?

- Several important developments are increasing the demand for continuous RWE generation



Regulators are demanding RWE safety studies as a condition of approval

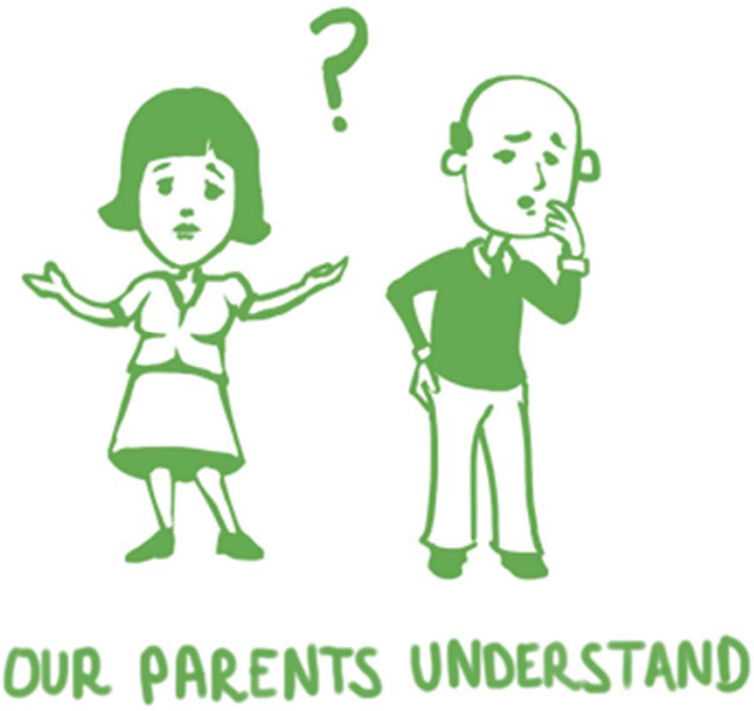
Payers are re-evaluating products post-launch by using comparative RWE

Physicians are using RWE to inform guidelines that influence clinical practice

- Value demonstration is now required **throughout the product life-cycle**, not just at launch

CLEAR AND EFFECTIVE COMMUNICATIONS ARE ESSENTIAL FOR RWE STUDIES

- Research question



CLEAR AND EFFECTIVE COMMUNICATIONS ARE ESSENTIAL FOR RWE STUDIES

- Research question
- Explore in the real world

CLEAR AND EFFECTIVE COMMUNICATIONS ARE ESSENTIAL FOR RWE STUDIES

- Research question
- Explore in the real world
- Understand the data sources

CLEAR AND EFFECTIVE COMMUNICATIONS ARE ESSENTIAL FOR RWE STUDIES

- Research question
- Explore in the real world
- Understand the data sources
- How many patients

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- Research question
- Explore in the real world
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- How many patients
- Followed for how long

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- Research question
- Explore in the real world
- Understand the data sources
- How many patients
- Followed for how long
- Results

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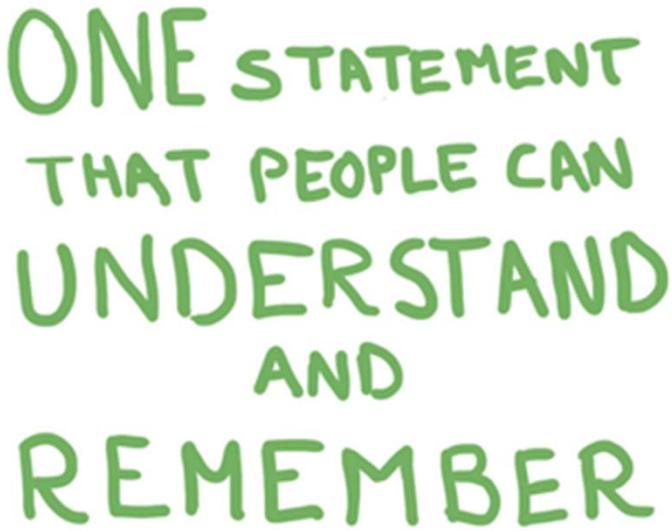
- Research question
- Explore in the real world
- Understand the data sources
- How many patients
- Followed for how long
- Results
- Conclusion



WHAT IS RWE?

- The ISPOR task force's definition of RWE

> Data used for clinical, coverage and payment decision-making that are not collected in conventional RCTs[1]

- Real-world data are observations of treatment effects where the researcher has no control over the subsequent medical management of the patient beyond observing the outcomes

HOW DOES RWE DIFFER FROM RCT EVIDENCE?

- **Efficacy** is the intrinsic effect of an intervention measured under pre-specified conditions (RCT), while **effectiveness** measures the beneficial effect in routine clinical practice (RWE)

HOW DOES RWE DIFFER FROM RCT EVIDENCE?

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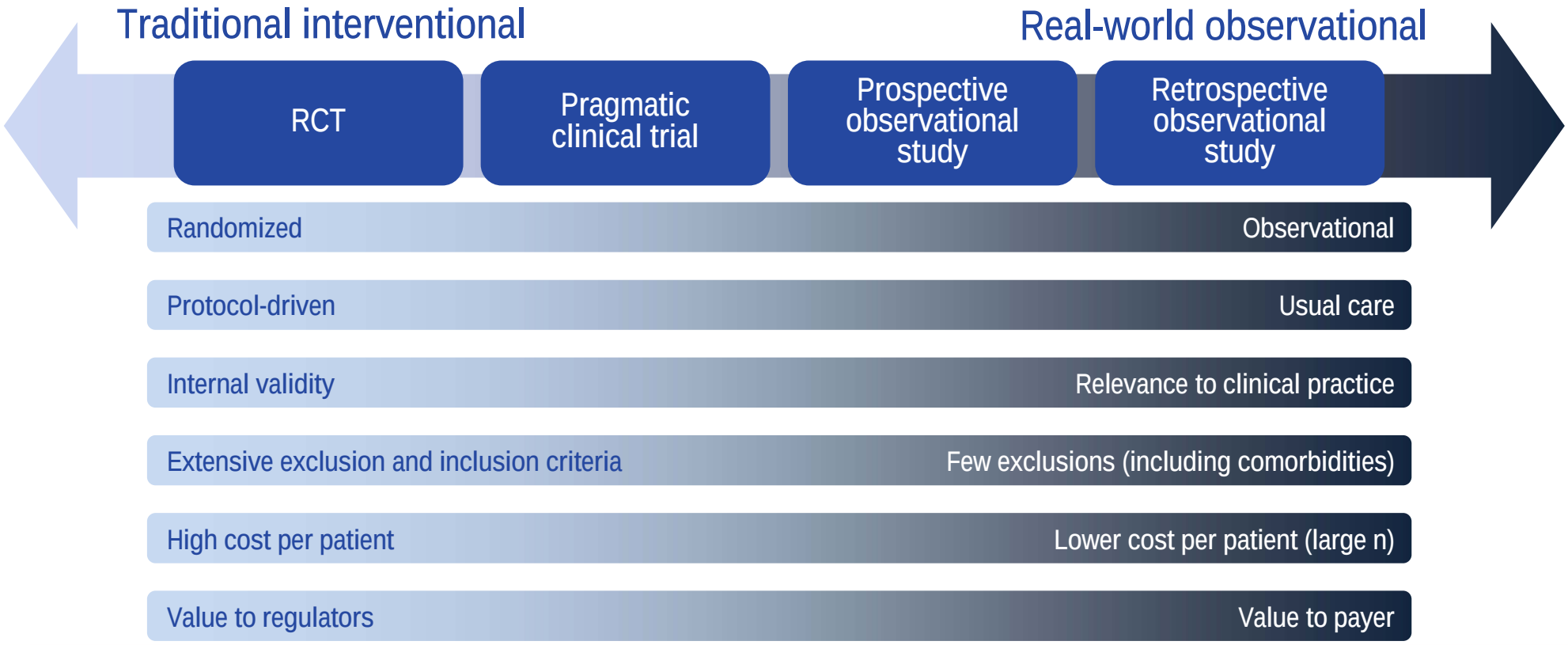


EFFICACY VS EFFECTIVENESS: AN ANALOGY

Standing quarter mile:
12.5 seconds

EFFICACY VS EFFECTIVENESS: AN ANALOGY

Standing quarter mile:
12.5 seconds

Standing quarter mile:
> 12.5 seconds!

RWE COMPLEMENTS RCT RESULTS

Assessment of effectiveness in a real-world setting

- In a diverse patient population reflective of clinical practice
- Provides a description of real-world physician/patient characteristics (e.g. guideline use, non-adherence, off-label use, comorbidities)

Comparative evidence against **multiple realistic comparators**

- Comparison is ideally with current standard treatment (which differs by patient segment and country), not placebo

Improved **understanding of benefit–risk profile**

- Assesses long-term clinical benefits and rare adverse events

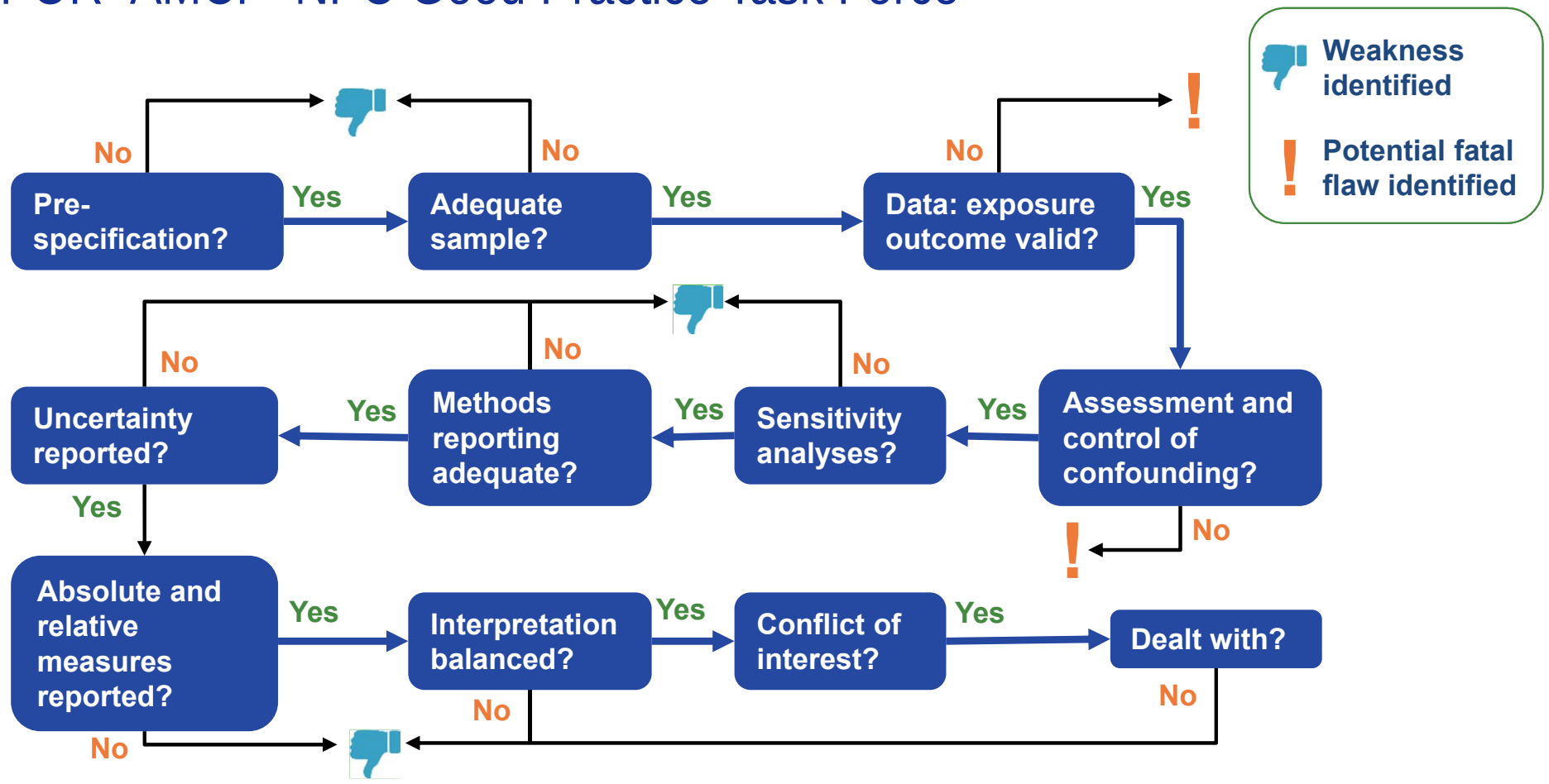
Broader range of outcomes than are measured in RCTs

- Patient experience, patient-reported outcomes (PROs) and costs to support economic evaluations

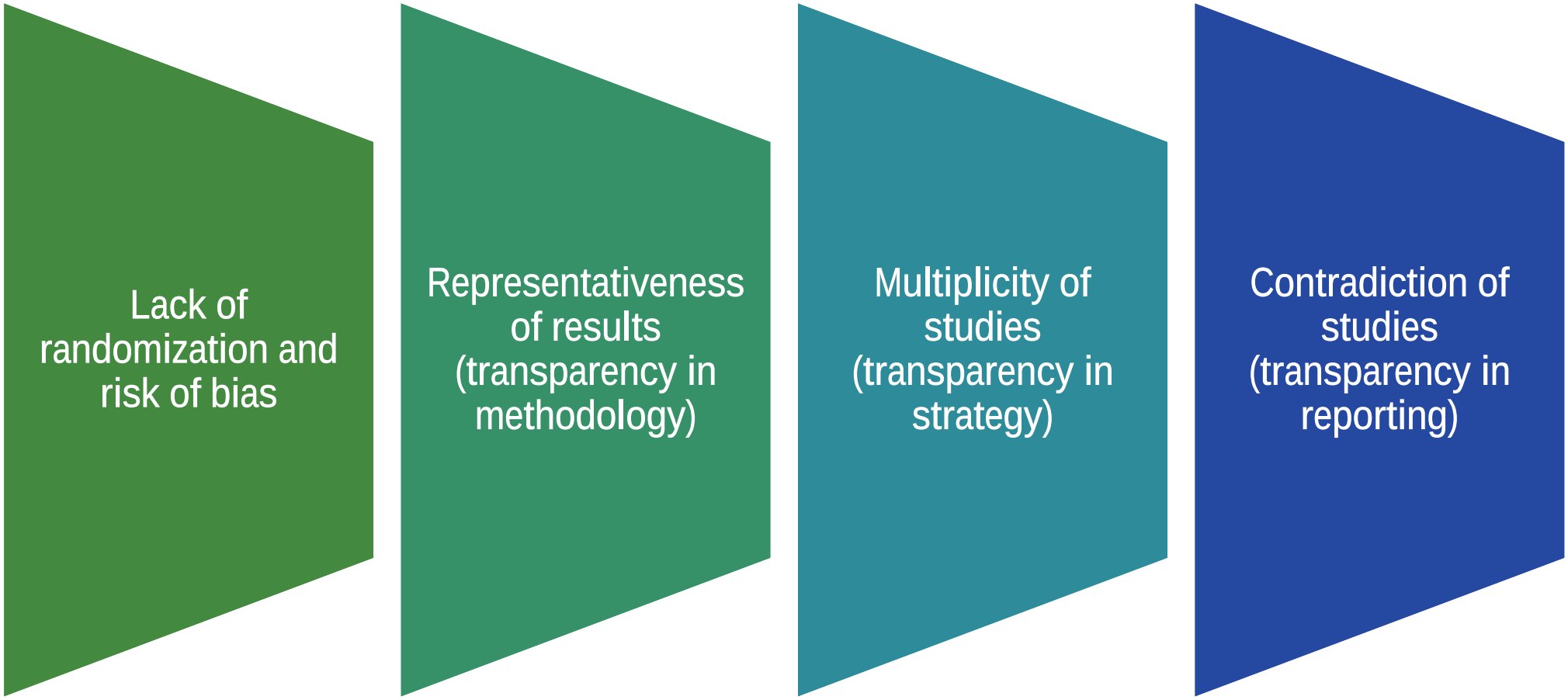
WHAT ARE THE SPECIFIC ISSUES FOR RWE STUDY PUBLICATIONS?

GUIDANCE FOR REPORTING A RWE STUDY

- ISPOR–AMCP–NPC Good Practice Task Force



MAJOR BARRIERS TO CREDIBILITY OF RWE



RWE ISSUE 1: LACK OF RANDOMIZATION AND RISK OF BIAS

Standing quarter mile:
16.2 seconds

Standing quarter mile:
21.6 seconds

RWE ISSUE 1: LACK OF RANDOMIZATION AND RISK OF BIAS

Standing quarter mile:
16.2 seconds

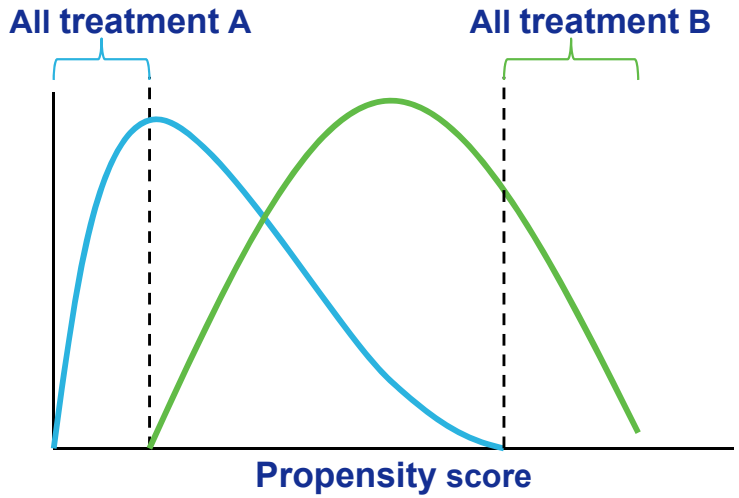
Standing quarter mile:
21.6 seconds

Standing quarter mile:
12.5 seconds

RWE PUBLICATIONS MUST EXPLAIN THE METHODS USED TO MINIMIZE BIAS/CONFOUNDING

- Simple comparison of real-world outcomes for patients on drug A vs patients on drug B risks bias – because treatment allocation in clinical practice depends on patient characteristics
- Statistical methods (e.g. propensity score matching) allow the creation of comparable cohorts of patients from a heterogeneous RWE dataset

Regression analysis is used to determine the likelihood of patients receiving a particular therapy as a function of characteristics such as age, sex, and disease duration and severity



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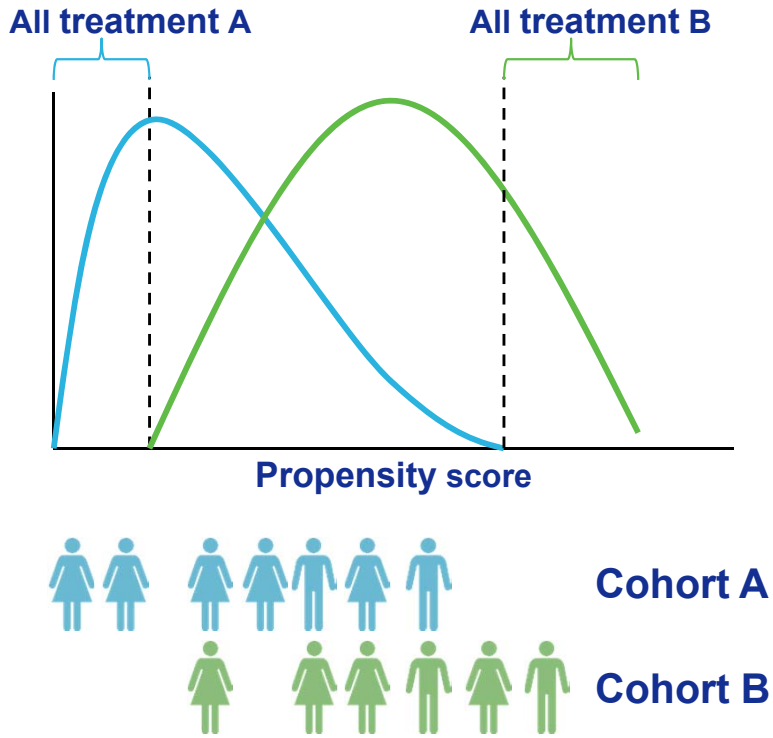
Patients in different treatment groups are matched according to their propensity score



Rosenbaum and Rubin. *Biometrika* 1983;70:41–55

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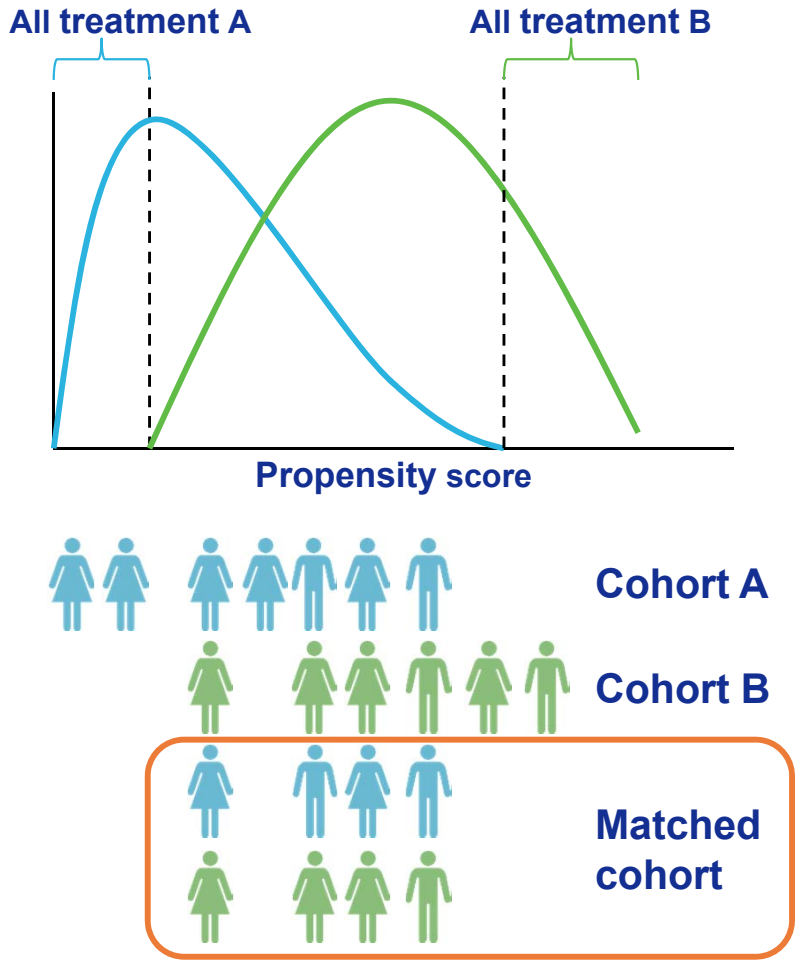
Regression analysis is used to determine the likelihood of patients receiving a particular therapy as a function of characteristics such as age, sex, and disease duration and severity

Patients in different treatment groups are matched according to their propensity score

The resulting matched cohort is balanced with regard to patient characteristics that influence treatment allocation



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RWE ISSUE 2: REPRESENTATIVENESS OF RESULTS (TRANSPARENCY IN METHODOLOGY)

Standing quarter mile:
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RWE ISSUE 2: REPRESENTATIVENESS OF RESULTS (TRANSPARENCY IN METHODOLOGY)

Standing quarter mile:
19.5 seconds

Standing quarter mile:
21.6 seconds

FINDING THE RIGHT RWE DATA SOURCES, RATHER THAN ANY AVAILABLE DATA SOURCE

- RWE studies commonly face one of two major issues

'Data deluge'

- Often encountered for common therapeutic areas (e.g. diabetes, cardiovascular diseases)

'Data desert'

- Often encountered for orphan indications, specialized information (e.g. laboratory data) or rare events

DIFFERENT TYPES OF RWE DATA SOURCE PROVIDE DIFFERENT INFORMATION

Claims databases

Population

Healthy and sick individuals

What is being collected

Longitudinal collection of resource use and associated payments

Outpatient | Inpatient | Pharmacy | Demographics | Costs | Treatments

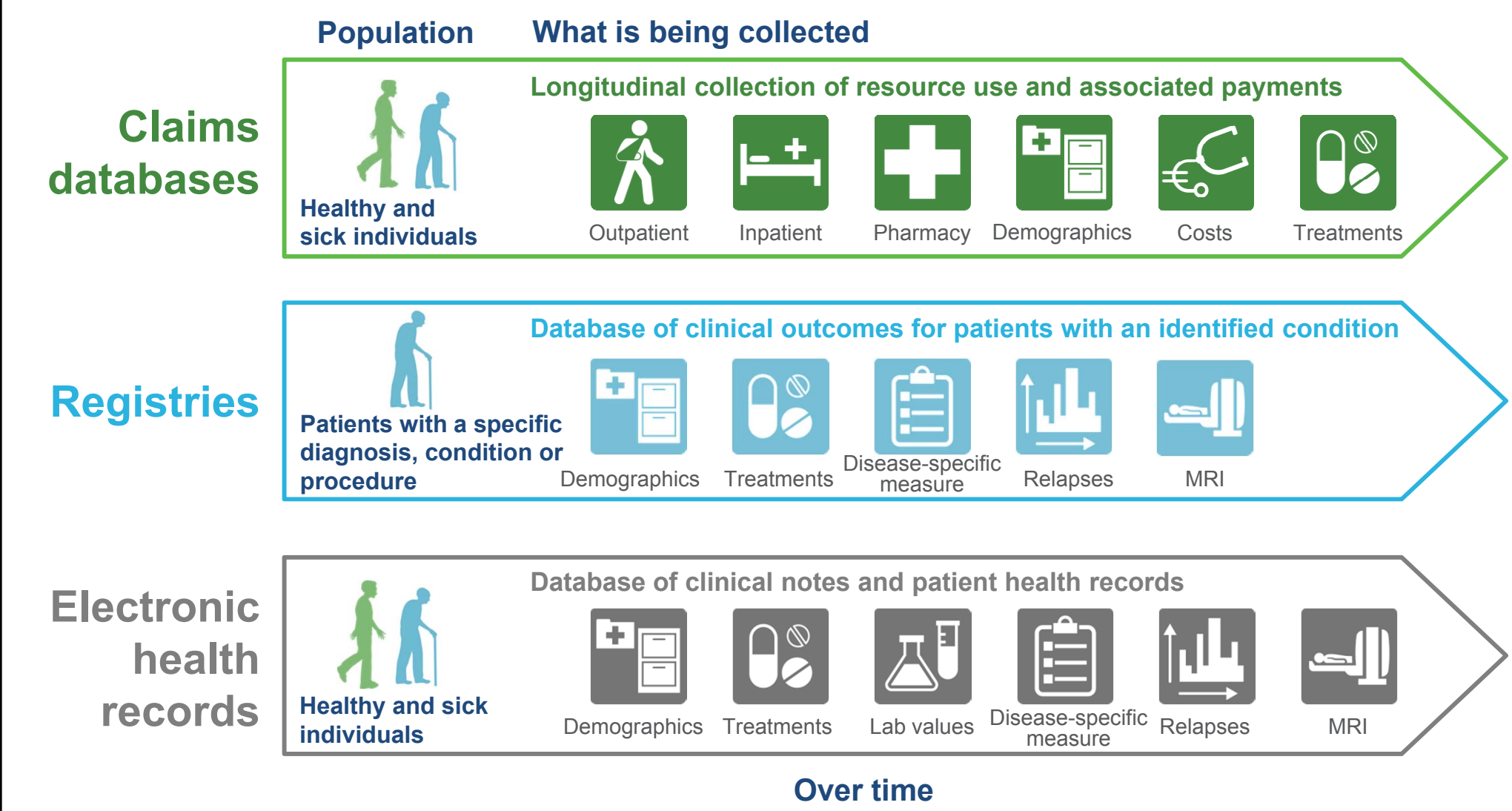
Over time

DIFFERENT TYPES OF RWE DATA SOURCE PROVIDE DIFFERENT INFORMATION

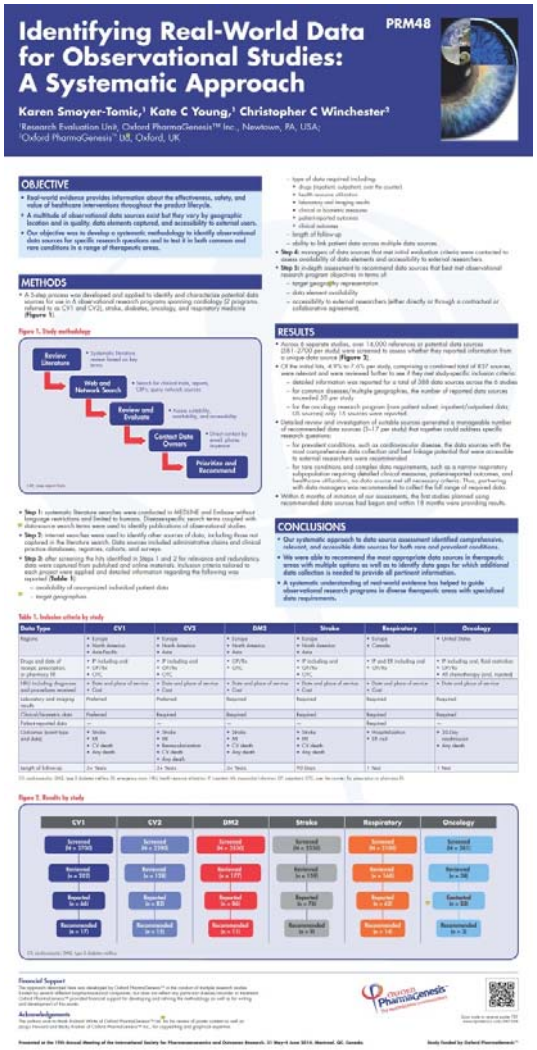
	Population	What is being collected
Claims databases	 Healthy and sick individuals	Longitudinal collection of resource use and associated payments: Outpatient, Inpatient, Pharmacy, Demographics, Costs, Treatments
Registries	 Patients with a specific diagnosis, condition or procedure	Database of clinical outcomes for patients with an identified condition: Demographics, Treatments, Disease-specific measure, Relapses, MRI

Over time

DIFFERENT TYPES OF RWE DATA SOURCE PROVIDE DIFFERENT INFORMATION



SYSTEMATIC ASSESSMENT OF RWE SOURCES PROVIDES FOUNDATION FOR RESEARCH


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

PRM48

Karen Smoyer-Tomic,[1] Kate C Young,[1] Christopher C Winchester[2]

[1]Research Evaluation Unit, Oxford PharmaGenesis™ Inc., Newtown, PA, USA; [2]Oxford PharmaGenesis™ Ltd, Oxford, UK

OBJECTIVE

METHODS

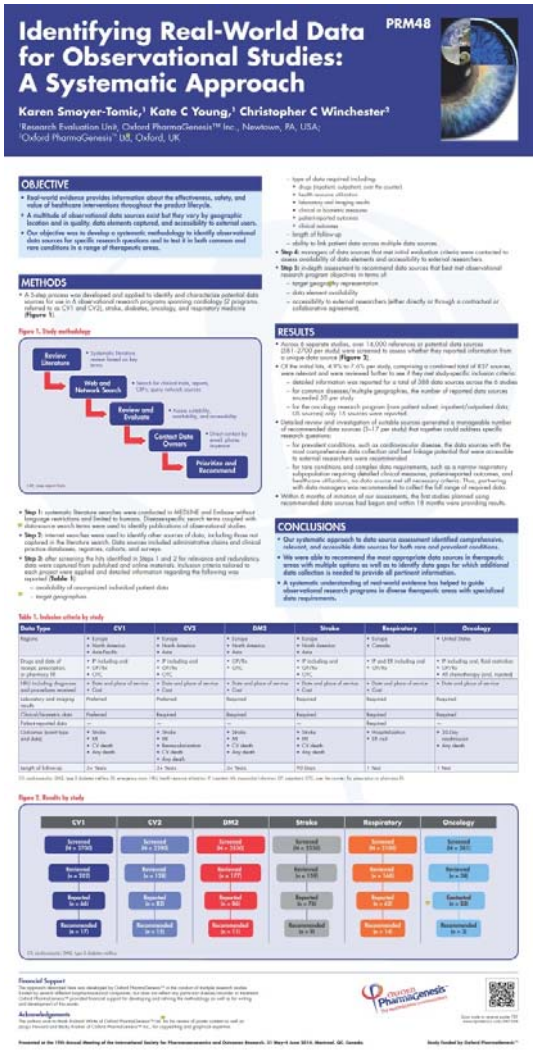
RESULTS

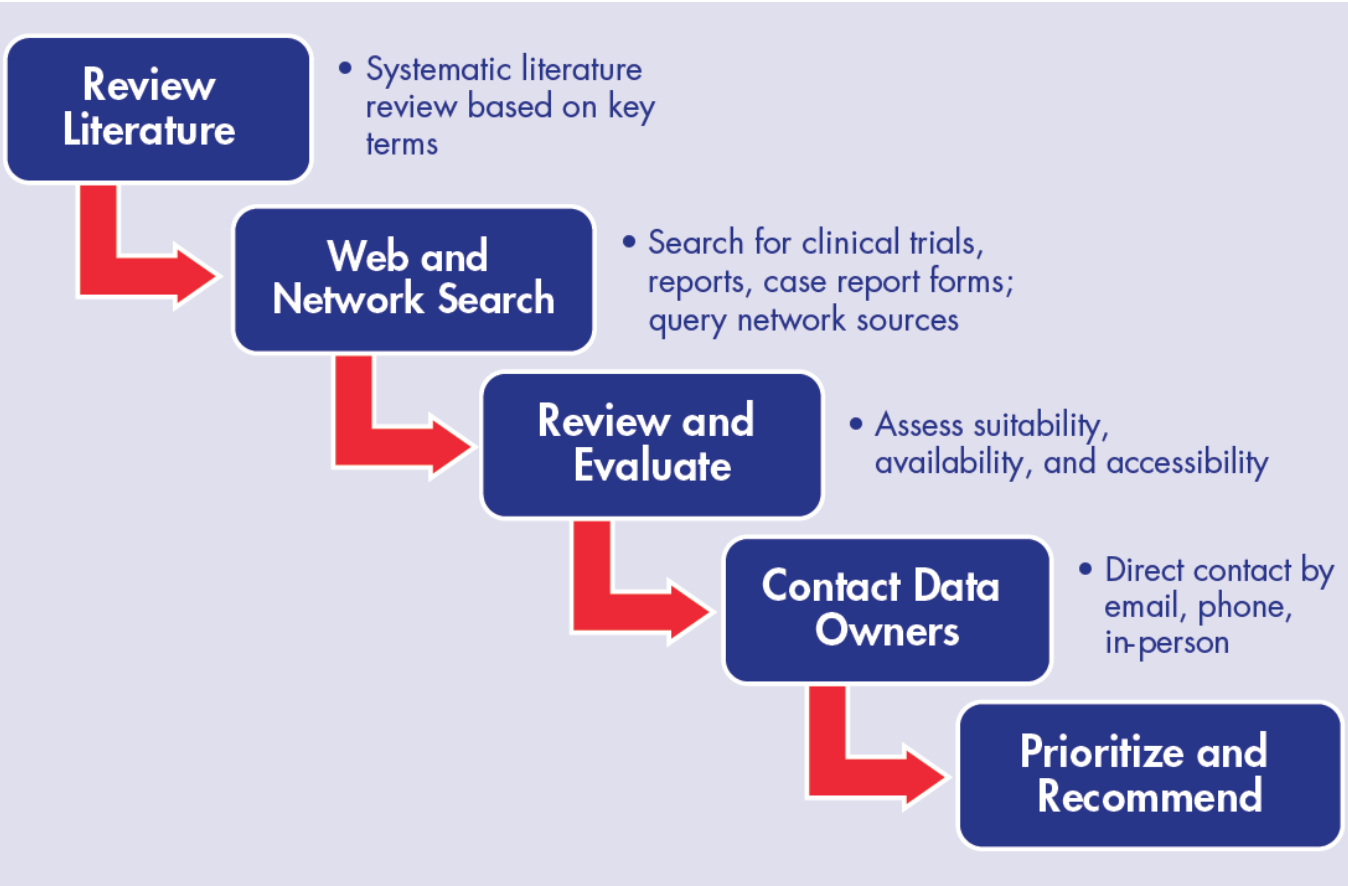
CONCLUSIONS

OBJECTIVE

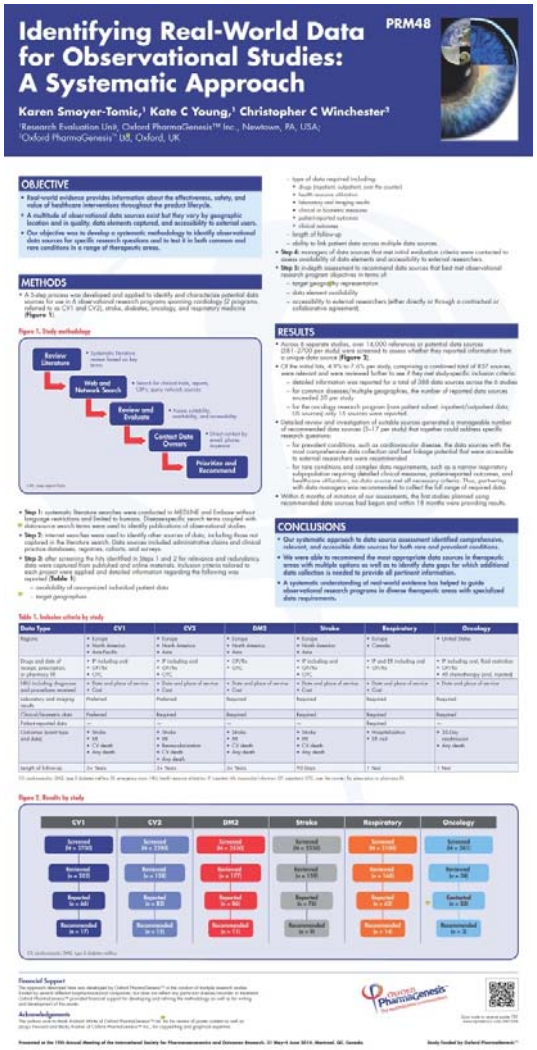
- Real-world evidence provides information about the effectiveness, safety, and value of healthcare interventions throughout the product lifecycle.
- A multitude of observational data sources exist but they vary by geographic location and in quality, data elements captured, and accessibility to external 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.

SYSTEMATIC ASSESSMENT OF RWE SOURCES PROVIDES FOUNDATION FOR RESEARCH





SYSTEMATIC ASSESSMENT OF RWE SOURCES PROVIDES FOUNDATION FOR RESEARCH



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OBJECTIVE

METHODS

RESULTS

CONCLUSIONS

CONCLUSIONS

- Our systematic approach to data-source assessment identified comprehensive, relevant, and accessible data sources for both rare and prevalent conditions.
- We recommended the most appropriate data sources in therapeutic areas with multiple options as well as identified data gaps for which additional data collection was needed to provide all pertinent information.
- A systematic understanding of real-world evidence has helped to guide observational research programs in diverse therapeutic areas with specialized data requirements.

RWE ISSUE 3: MULTIPLICITY OF STUDIES (TRANSPARENCY IN STRATEGY)

RWE ISSUE 3: MULTIPLICITY OF STUDIES (TRANSPARENCY IN STRATEGY)

MULTIPLICITY OF STUDIES: ISSUES FOR INTERNAL RWE PUBLICATIONS POLICY (1/2)

- Need clear internal RWE study and publications policies – adopt the same rigour as for RCTs

AHRQ, Agency for Healthcare Research and Quality; EMA, European Medicines Agency; GRACE, Good Research for Comparative Effectiveness; ISPE, International Society for Pharmacoepidemiology

MULTIPLICITY OF STUDIES: ISSUES FOR INTERNAL RWE PUBLICATIONS POLICY (1/2)

- Need clear internal RWE study and publications policies – adopt the same rigour as for RCTs
- Commit to publishing protocol
  - RWE study protocols can be posted on the Internet (e.g. www.clinicaltrials.gov)
  - Predefine outcomes and analyses
- Follow guidance on the design and validation of RWE studies
  - GRACE, AHRQ, EMA, ISPE

AHRQ, Agency for Healthcare Research and Quality; EMA, European Medicines Agency; GRACE, Good Research for Comparative Effectiveness; ISPE, International Society for Pharmacoepidemiology

MULTIPLICITY OF STUDIES: ISSUES FOR INTERNAL RWE PUBLICATIONS POLICY (2/2)

- Clarity on data ownership and access
  - Pharmaceutical sponsor, expert clinician, data vendor or shared?
  - Who makes decision over third-party access to data (e.g. external investigators)?

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- Commitment to publishing results
  - Same approach as for RCT data?
  - Results to be posted/published within 12 months of study completion, positive or negative?

MULTIPLICITY OF STUDIES: ISSUES FOR INTERNAL RWE PUBLICATIONS POLICY (2/2)

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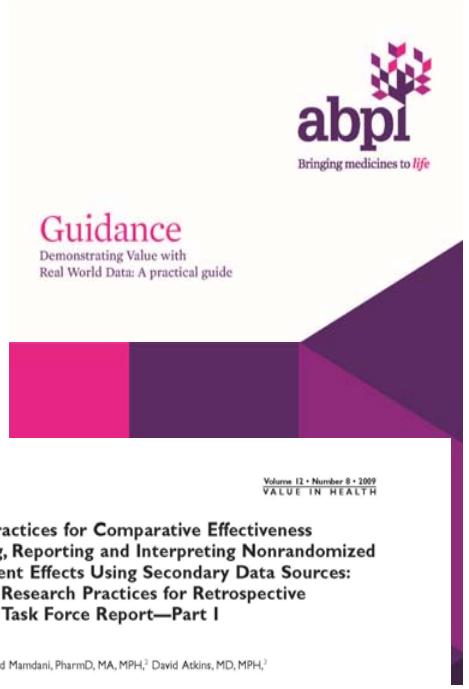
  - Pharmaceutical sponsor, expert clinician, data vendor or shared?
  - Who makes decision over third-party access to data (e.g. external investigators)?
- Commitment to publishing results
  - Same approach as for RCT data?
  - Results to be posted/published within 12 months of study completion, positive or negative?
- Transparency of publication policies
  - Predefined vs *post hoc* analyses (primary vs secondary publications)?
  - Interim analyses and periodic assessments (e.g. 12-monthly reviews of registry/database)?



RWE ISSUE 4: CONTRADICTION OF STUDIES (TRANSPARENCY IN REPORTING)

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RWE ISSUE 4: CONTRADICTION OF STUDIES (TRANSPARENCY IN REPORTING)

Standing quarter mile:
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WRITING UP THE STUDIES – STROBE

STROBE Statement

Strengthening the reporting of observational studies in epidemiology

- Guidance for the reporting of observational studies in epidemiology (cohort studies, case–control studies, cross-sectional studies)
- Specialized versions
  - STROBE for conference abstracts
  - STROME-ID – molecular epidemiology in infectious diseases
  - STROBE – EULAR version for biologics RWE studies
  - STROBE-ME – epidemiology/molecular epidemiology studies
  - STREGA – genetic association studies

STROBE GUIDANCE CAN BE AT LEAST AS CHALLENGING AS CONSORT

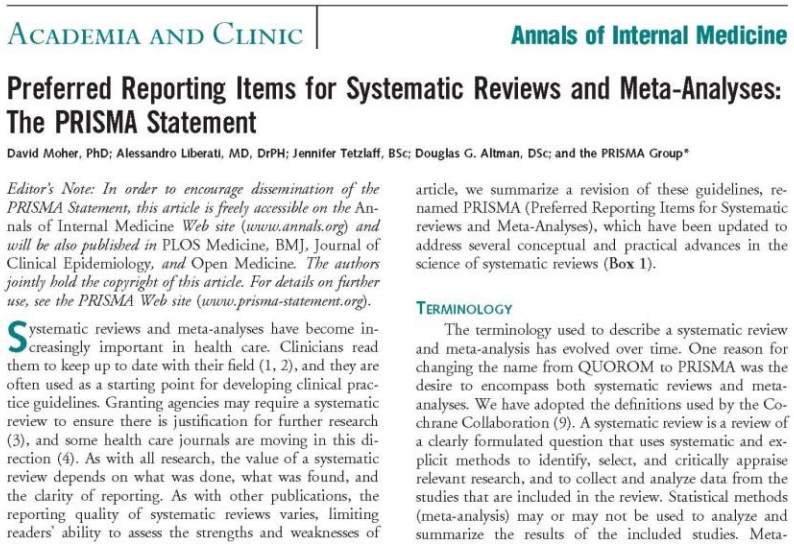
- How can I address all 22 points of the STROBE core checklist within a 3000-word manuscript?
  - **Publish in advance** as much of the RWE study methodology as you can (e.g. data source characterization, algorithms to identify patient populations and outcomes)
  - Make use of **supplementary tables/figures/methods**

- How can I convey the meaning to a non-RWE specialist among all this technical detail?
  - **Use the abstract** to place the study in a clinical context
  - **Preface each section** with one sentence that tells the non-specialist what it means (e.g. what is propensity scoring)
  - **Use the conclusion** to convey how the results might affect healthcare decision-making

WRITING UP THE STUDIES – OTHER GUIDELINES

- **PRISMA:** Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) and for study protocols (PRISMA-P)
- **MOOSE:** Meta-analysis Of Observational Studies in Epidemiology
- **The CARE Guidelines:** Consensus-based Clinical Case Reporting Guideline Development

equator network



ACADEMIA AND CLINIC | Annals of Internal Medicine

Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement

David Moher, PhD; Alessandro Liberati, MD, DrPH; Jennifer Tetzlaff, BSc; Douglas G. Altman, DSc; and the PRISMA Group*

Editor's Note: In order to encourage dissemination of the PRISMA Statement, this article is freely accessible on the Annals of Internal Medicine *Web site (www.annals.org) and will be also published in* PLOS Medicine, BMJ, Journal of Clinical Epidemiology, *and* Open Medicine. *The authors jointly hold the copyright of this article. For details on further use, see the PRISMA Web site (www.prisma-statement.org).*

Systematic reviews and meta-analyses have become increasingly important in health care. Clinicians read them to keep up to date with their field (1, 2), and they are often used as a starting point for developing clinical practice guidelines. Granting agencies may require a systematic review to ensure there is justification for further research (3), and some health care journals are moving in this direction (4). As with all research, the value of a systematic review depends on what was done, what was found, and the clarity of reporting. As with other publications, the reporting quality of systematic reviews varies, limiting readers' ability to assess the strengths and weaknesses of article, we summarize a revision of these guidelines, renamed PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses), which have been updated to address several conceptual and practical advances in the science of systematic reviews (**Box 1**).

TERMINOLOGY

The terminology used to describe a systematic review and meta-analysis has evolved over time. One reason for changing the name from QUOROM to PRISMA was the desire to encompass both systematic reviews and meta-analyses. We have adopted the definitions used by the Cochrane Collaboration (9). A systematic review is a review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyze data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyze and summarize the results of the included studies. Meta-

WHEN TO TARGET MAINSTREAM CLINICAL VS SPECIALIST JOURNALS AND MEETINGS

- Specialist journals and meetings for RWE studies exist
  - But most of your key audiences are not outcomes research specialists
- Effective publication planning is essential

Mainstream clinical journals and meetings

- Core RWE outcomes papers – can be top-tier journals (*BMJ*, *Circulation*…)

Specialist journals and meetings

- Technical and methodology papers (e.g. disease and outcome algorithms)

COMMUNICATING QUALITY OF METHODOLOGY IS ESSENTIAL FOR CREDIBILITY AND SUCCESS

- Easy to **conduct** poor-quality observational research
  - Fails to correct for important confounders, leading to bias

COMMUNICATING QUALITY OF METHODOLOGY IS ESSENTIAL FOR CREDIBILITY AND SUCCESS

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- Important to **communicate effectively and transparently** on RWE methodology
  - **Understand** potential sources of bias
  - **Design** studies that will minimize bias
  - **Clarify** methodology and be transparent about assumptions
  - **Acknowledge** limitations and draw meaningful conclusions


EFFECTIVE RWE
COMMUNICATIONS:
BRINGING IT ALL TOGETHER

AUDIENCE QUESTION

- You have just completed an RCT that will provide important data to support your product
  - A robust and timely publication in a high-quality, peer-reviewed journal is essential

Would you choose the contract research organization who ran the study to develop the journal publication by themselves?

A. Yes

B. No

C. Don't know

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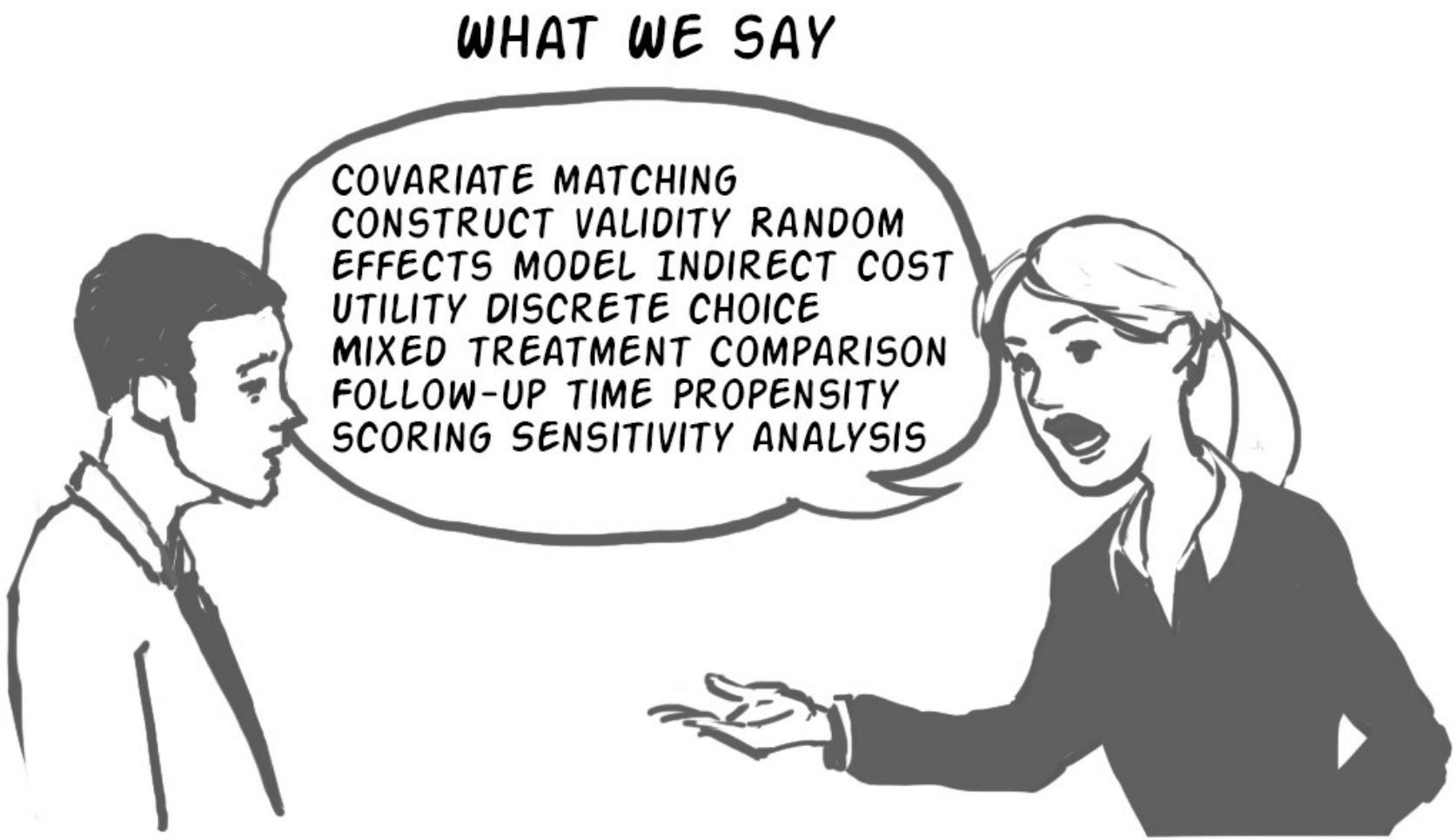
- Acknowledged, transparent, specialist **medical-writing support**

COMMUNICATING EFFECTIVELY MEANS CUTTING OUT THE TECHNICAL JARGON



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HELP YOUR AUDIENCES – BEYOND PUBLICATION

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

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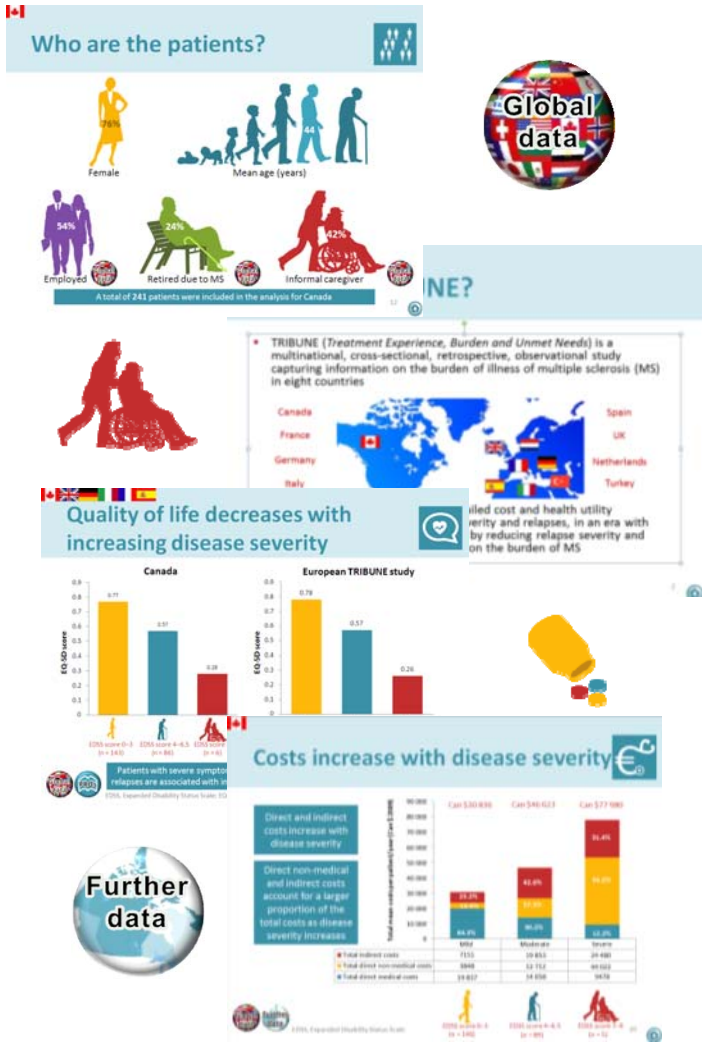
- Most of your internal and external audiences for RWE publications will **not understand the technical details of RWE**

- 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



AUDIENCE QUESTION

Does your organization or client have a clear RWE publication policy?

A Yes

B There is a policy, but it isn't clear

C No

D Don't know

RWE STUDY PUBLICATION POLICIES NEED TO BE CLEAR IN REMIT AND REACH

- What is the **definition** of an RWE study covered by the policy?
  - Does it include safety studies (e.g. PASS)? PRO and utility studies? Pragmatic (or 'large simple trials')?

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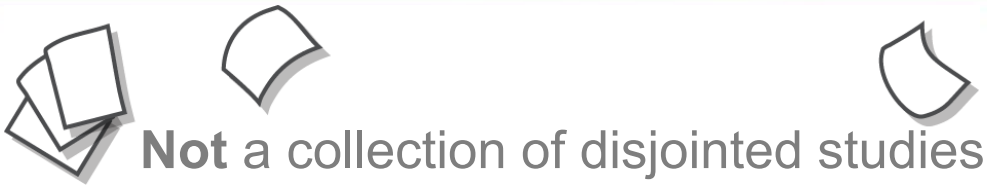
- Will the policy **assure compliance** with standard publication plan requirements?
  - Disclosure of author affiliations and financial relationships, acknowledgement of non-author contributions, documentation of payments and TOV

HOW SHOULD AN RWE STUDY PLAN BE DEVELOPED AND COMMUNICATED?



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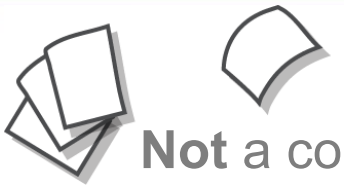

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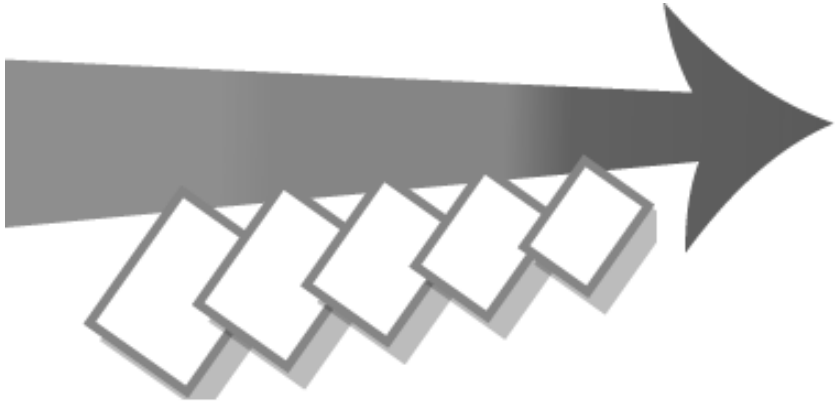
Comprehensive
plan across life cycle



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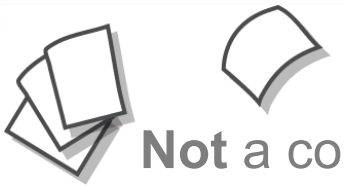

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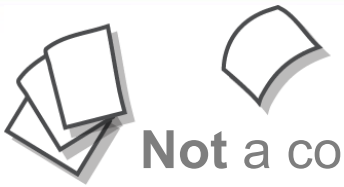

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Internal awareness and communication

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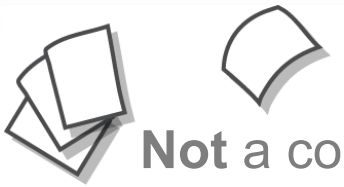

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Comprehensive
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Evidence from
multiple sources

External awareness and education

Internal awareness and communication

Global and local collaboration

External participation

True strategic planning

Excellent quality to ensure credibility

CONCLUSION

For best impact and value:

RWE as you would RCT evidence


THANK YOU!

QUESTIONS . . .

- To ask a question, please type your query into the Q&A box
- To ensure anonymity, before sending please choose the drop-down box option, "Hosts, Presenters and Panelists." Otherwise, ALL audience members will be able to see your submitted question

UPCOMING ISMPP U'S

- September 23, 2015
  - Topic: Predatory Journals and the Threat to Scholarly Publication: Impact on Medical Publications
  - Presenter:
    - Jeffrey Beall, MA, MSLS, Scholarly Communications Librarian/ Associate Professor, Auraria Library, University of Colorado Denver, Denver, Colorado

- October 21, 2015
  - Topic: Biostatistics in medical writing and publication planning
  - Presenter (additional presenter to be announced):
    - Meg Franklin, PharmD, PhD, President, Franklin Pharmaceutical Consulting, LLC

THANK YOU FOR ATTENDING!

- We hope you enjoyed today's presentation. Please take a few moments to **complete the survey that will appear on your screen** immediately after the presentation. We depend on your valuable feedback and take it into account as we develop future educational offerings