THANK YOU FOR JOINING ISMPP U TODAY!

The program will begin promptly at 11:00 am EDT

July 22, 2015
ISMPP WOULD LIKE TO THANK . . .

. . . the following Titanium and Platinum Corporate Sponsors for their ongoing support of the Society:

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ISMPP ANNOUNCEMENTS

• Did you earn your ISMPP CMPP certification in 2010? Find out what you need to do to recertify (www.ismpp.org/recertification)

• Presentations from the 11th Annual Meeting are now available in the Archives (www.ismpp.org/annual-meeting-archive)

• Watch interviews with key presenters and stakeholders from the 11th Annual Meeting on our YouTube channel

• ISMPP is pleased to announce our first Asia Pacific meeting – registration is now open!
REGISTRATION IS OPEN!

COLLABORATING FOR ETHICAL & EFFECTIVE MEDICAL PUBLICATIONS

Beijing, China • August 30, 2015
Tokyo, Japan • September 2, 2015

http://www.ismpp.org/asia-pacific-meetings
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
To optimize your webinar experience today:

• Use a hardwired connection if available

• Use the fastest internet connection available to you

• If you are accessing the presentation over your computer, please be sure to increase the volume of your computer speakers
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
• **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
• **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?
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?
Database studies
Pragmatic trials
Registries
Open-label studies
RCTs
Focus groups
Market research
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

SO OUR PARENTS UNDERSTAND
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
CLEAR AND EFFECTIVE COMMUNICATIONS ARE ESSENTIAL FOR RWE STUDIES

- Research question
- Explore in the real world
- Understand the data sources
- How many patients
- Followed for how long
CLEAR AND EFFECTIVE COMMUNICATIONS ARE ESSENTIAL FOR RWE STUDIES

• Research question
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• Results
CLEAR AND EFFECTIVE COMMUNICATIONS ARE ESSENTIAL FOR RWE STUDIES

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

ONE STATEMENT THAT PEOPLE CAN UNDERSTAND AND REMEMBER
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 RCTs¹

• 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

¹ISPOR, International Society for Pharmacoeconomics and Outcomes Research; Garrison et al. Value Health 2007;10:326–35
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).
**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).
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

Diagram:

- Pre-specification? Yes → Adequate sample? Yes → Data: exposure outcome valid? Yes
- Uncertainty reported? Yes → Methods reporting adequate? Yes → Sensitivity analyses? Yes → Assessment and control of confounding? Yes
- Absolute and relative measures reported? Yes → Interpretation balanced? Yes → Conflict of interest? Yes → Dealt with?
- Pre-specification? No → Adequate sample? No → Data: exposure outcome valid? No → ! Weakness identified
- Uncertainty reported? No → Methods reporting adequate? No
- Absolute and relative measures reported? No → ! Potential fatal flaw identified

Adequate sample? No → Data: exposure outcome valid? No → ! Potential fatal flaw identified

Pre-specification? No → Uncertainty reported? Yes → Methods reporting adequate? No

Notes:

- Berger et al. Value Health 2014;17:143–56

- AMCP, Academy of Managed Care Physicians; NPC, National Pharmaceutical Council
MAJOR BARRIERS TO CREDIBILITY OF RWE

Lack of randomization and risk of bias

Representativeness of results (transparency in methodology)

Multiplicity of studies (transparency in strategy)

Contradiction of studies (transparency in reporting)
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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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

Standing quarter mile:
19.5 seconds
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.

<table>
<thead>
<tr>
<th>Population</th>
<th>What is being collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy and sick individuals</td>
<td>Longitudinal collection of resource use and associated payments</td>
</tr>
<tr>
<td>Outpatient</td>
<td>Inpatient</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>Demographics</td>
</tr>
<tr>
<td>Costs</td>
<td>Treatments</td>
</tr>
</tbody>
</table>

Over time
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

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

<table>
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<tr>
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<tbody>
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<td>Healthy and sick individuals</td>
<td>Longitudinal collection of resource use and associated payments</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Outpatient, Inpatient, Pharmacy, Demographics, Costs, Treatments</td>
</tr>
<tr>
<td><strong>Registries</strong></td>
<td>Patients with a specific diagnosis, condition or procedure</td>
<td>Database of clinical outcomes for patients with an identified condition</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Demographics, Treatments, Disease-specific measure, Relapses, MRI</td>
</tr>
<tr>
<td><strong>Electronic health records</strong></td>
<td>Healthy and sick individuals</td>
<td>Database of clinical notes and patient health records</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Demographics, Treatments, Lab values, Disease-specific measure, Relapses, MRI</td>
</tr>
</tbody>
</table>

Over time
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.
SYSTEMATIC ASSESSMENT OF RWE SOURCES PROVIDES FOUNDATION FOR RESEARCH

Identifying Real-World Data for Observational Studies: A Systematic Approach
Karen Smeyer-Tenick, Kate C Young, Christopher C Winchester

OBJECTIVE

• Systematic literature review based on key terms
• Search for clinical trials, reports, case report forms; query network sources
• Assess suitability, availability, and accessibility
• Direct contact by email, phone, in-person

Review Literature

Web and Network Search

Review and Evaluate

Contact Data Owners

Prioritize and Recommend
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
MULTIPICLITY 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
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)?
MULTIPLOCITY 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)?

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

• 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)

Standing quarter mile: 12.5 seconds

Standing quarter mile: 16.2 seconds
RWE ISSUE 4: CONTRADICTION OF STUDIES
(TRANSPARENCY IN REPORTING)

Standing quarter mile:  
12.5 seconds

Standing quarter mile:  
16.2 seconds

Standing quarter mile:  
19.5 seconds

Standing quarter mile:  
21.6 seconds
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

EULAR, European League Against Rheumatism; EQUATOR, Enhancing the QUAlity and Transparency Of health Research
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
• **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
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

- Easy to **conduct** poor-quality observational research
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  - Reinforces prejudices that RWE is ‘lower quality’ evidence than RCT data
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- Easy to **publish** poor-quality observational research
  - Reinforces prejudices that RWE is ‘lower quality’ evidence than RCT data
- 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
• 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
EXTERNAL EXPERT INPUT IS NEEDED TO GAIN MAXIMUM VALUE FROM RWE PUBLICATIONS

RWE studies involve only the data vendor and industry
EXTERNAL EXPERT INPUT IS NEEDED TO GAIN MAXIMUM VALUE FROM RWE PUBLICATIONS

RWE studies involve only the data vendor and industry

Involve external experts in concept, design, analysis and communication

- **Improve design** – clearly identify confounders/biases
- **Break down clinicians’ scepticism** of RWE studies
- Bring RWE studies into **mainstream clinical meetings/literature**
- **Enhance credibility** among payers and decision-makers
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Involve a Steering Committee in RWE plans throughout the life cycle

- Clinical experts, statisticians and database experts
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  - Enhance credibility among payers and decision-makers
- Involve a Steering Committee in RWE plans throughout the life cycle
  - Clinical experts, statisticians and database experts
- Acknowledged, transparent, specialist medical-writing support
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

WHAT THEY HEAR

BLAH BLAH BLAH
BLAH BLAH BLAH BLAH BLAH
BLAH BLAH BLAH BLAH BLAH BLAH
BLAH BLAH BLAH BLAH BLAH
BLAH BLAH BLAH BLAH BLAH BLAH
BLAH BLAH COST
BLAH BLAH TIME BLAH BLAH
BLAH BLAH BLAHBLAH BLAH BLAH
Most of your internal and external audiences for RWE publications will **not** understand the technical details of RWE.
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
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 **commit to publication** of data regardless of findings?
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Does the policy differentiate terms according to study leadership?
- Pharma-initiated vs investigator-initiated studies
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• Will the policy **commit to publication** of data regardless of findings?

• Does the policy differentiate terms according to **study leadership**?
  – Pharma-initiated vs investigator-initiated studies

• 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?

Not a collection of disjointed studies, *but rather* ...
HOW SHOULD AN RWE STUDY PLAN BE DEVELOPED AND COMMUNICATED?

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

**Comprehensive plan across life cycle**

Evidence from **multiple sources**
How should an RWE study plan be developed and communicated?

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

**Comprehensive plan across life cycle**

**Evidence from multiple sources**

- Global and local collaboration
- External participation
HOW SHOULD AN RWE STUDY PLAN BE DEVELOPED AND COMMUNICATED?

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

Comprehensive plan across life cycle

Evidence from multiple sources

External awareness and education

Internal awareness and communication

Global and local collaboration

External participation
How should an RWE study plan be developed and communicated?

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

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
CONCLUSION

For best impact and value:

Plan ➔ Perform ➔ Publish

RWE as you would RCT evidence
THANK YOU!
QUESTIONS . . .

- To ask a question, please type your query into the Q&A box
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UPCOMING ISMPP U'S

• September 23, 2015
  • Topic: Predatory Journals and the Threat to Scholarly Publication: Impact on Medical Publications
  • Presenter:
    • Jeffrey Beall, MA, MLS, 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.