ISMPP U
Optimizing Development and Communication of Real World Evidence (RWE)
Strategies for Success

Wednesday, May 13, 2026; 11:00 am EDT

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One Region, Many Voices: Publication Equity in APAC

Save the Date for the 2026 Asia Pacific Meeting of ISMPP
September 17th, 2026 in Hong Kong. More details coming soon!

Save the Date! New Venue!
Leonardo Royal London Hotel Tower Bridge
European Meeting of ISMPP
January 25-27, 2027
London, UK

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September 29-30, 2026
Philadelphia, PA

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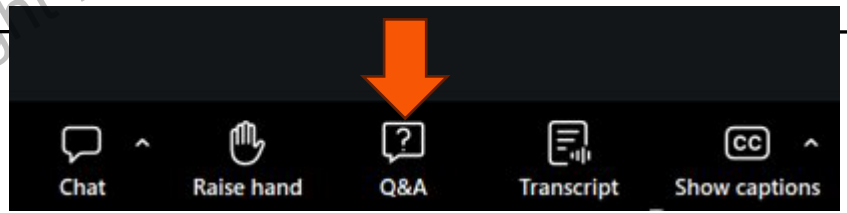
How to ask questions

Feel free to ask a question at any time; however, all questions will be held until the end of the presentation

To ask a question, open the Q&A window and type your question into the Q&A box. **Click "Send"**

Note: Check "**Send Anonymously**" if you do not want your name attached to your question in the Q&A

We will make every effort to respond to all questions live (out loud)



Disclaimer

Information presented today reflects the personal knowledge and opinions of the faculty and does not necessarily represent the position of their current or past employers or clients.

Today's Moderator and Presenters

Moderator:
Robert Marlowe,
President, Spencer-Fontayne Corporation

Presenter:
Tom Drake, MA, ISMPP CMPP,
Director, Global Outcomes Group, Inc.

Presenter:
Dr. Mike Holmes,
Independent Consultant and Founder, Holmes Darcy Pharma Consulting

Presenter:
Sharon F. Terry,
President and CEO of Genetic Alliance

Overall goal of today's webinar:

Equip medical communications professionals with an understanding of current challenges and best practices in developing and effectively communicating Real World Evidence (RWE).

Learning objectives

- Describe current regulatory and client perspectives regarding RWE, as well as recent developments in the field (e.g., HARPER protocol template, new RWE/RWD registry).
- Explain common challenges in developing publications for RWE studies and review important compliance considerations.
- Identify practical solutions for streamlining the RWE publication process, and for engaging with internal/external stakeholders, including KOLs and patients/care partners.
- Identify strategies to improve the dissemination and interpretation, and broaden understanding of RWD.

Agenda

Time	Topic
5 min.	Introduction
10 min.	Initiating Publication Development for RWE Studies
10 min.	Data Finalization and Publication Timelines
10 min.	Involving Patients/Caregivers as Stakeholders
10 min	Improving RWE Dissemination and Acceptance
15 min	Q&A

Audience Question (please choose 1 response)

What have been your experiences with RWE-related projects?

- Highly Successful
- Somewhat Successful
- Works-in-progress
- Not applicable

Topic 1

Initiating Publication Development for RWE Studies

Tom Drake, Mike Holmes

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Real-world data (RWD) are data regarding patient health status and/or healthcare delivery routinely collected from various sources in everyday practice

- Electronic health records (EHRs)
- Insurance claims/hospital billing data
- Registries
- Non-Interventional/Observational Studies
- Surveys
- Wearables
- Medical devices

Initiating Publication Development for RWE Studies

- Plan for high-quality data from the outset
  - Absolute clarity about study objectives & design (stats plan etc.)
  - Close cross-functional collaboration for internal alignment
  - Timelines & budget (Gantt chart or similar)
- Involve external KOLs early in RWE study design and conduct
- Stay updated with FDA/NICE/EU guidelines on RWE development and utilization

HARPER (HARmonized Protocol Template to Enhance Reproducibility) Guidelines

Created by an ISPE/ISPOR joint task force,
HARPER improves:

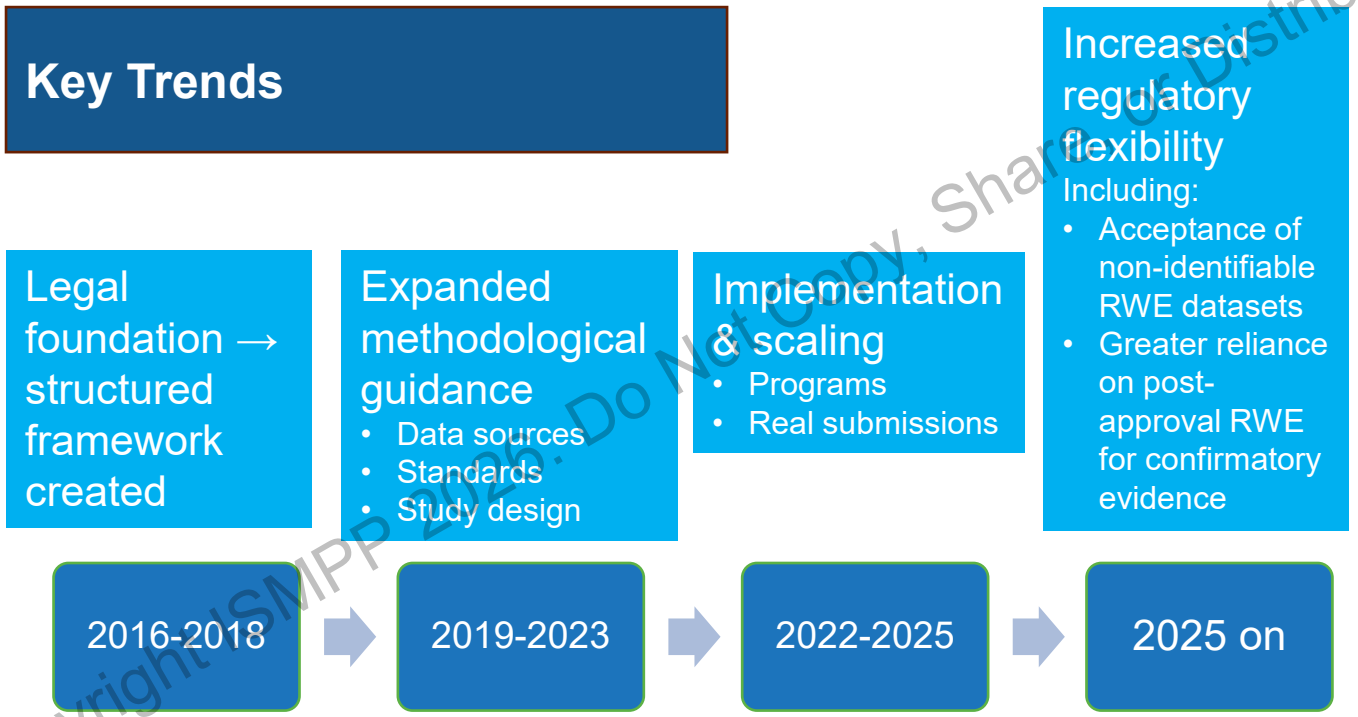
- transparency
- reproducibility
- evaluation of potential bias

Wang SV, Pottegård A, Crown W, et al. HARmonized Protocol Template to Enhance Reproducibility of hypothesis evaluating real-world evidence studies on treatment effects: A good practices report of a joint ISPE/ISPOR task force. Pharmacoepidemiol Drug Saf. 2023 Jan;32(1):44-55.

Supporting Development of High-Quality RWE

- FDA encourages sponsors to engage with agency early in evidence development process
- Supports sponsors to identify potential data or study design challenges
- FDA utilizes RWE to support regulatory decision-making

FDA RWE Milestones



Expanding FDA RWE Guidelines

FDA Eliminates Major Barrier to Using RWE in Drug/ Device Application Reviews – December 2025

- FDA removes a key limitation on RWE use in drug/device applications.
- Per new guidance for certain types of device submissions, the agency **will accept RWE** without requiring **identifiable** individual patient data collected from RWD sources in marketing submissions.
- FDA intends to consider similarly updating guidance for drugs and biologics.

https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence

Audience Question (Please choose 1 response)

Rate your internal collaboration with the cross-functional team, including PV, Regulatory, Clinical Development, and RWE:

- Seamless/successful
- Mostly successful
- Sometimes successful
- Needs work

Topic 2

Data Finalization and Publication Timelines

Mike Holmes, Tom Drake

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Audience Question (please choose 1 response)

Are your RWE communication/publication plans completely integrated with the overall clinical communication/publication plan?

- Always
- Sometimes
- Never

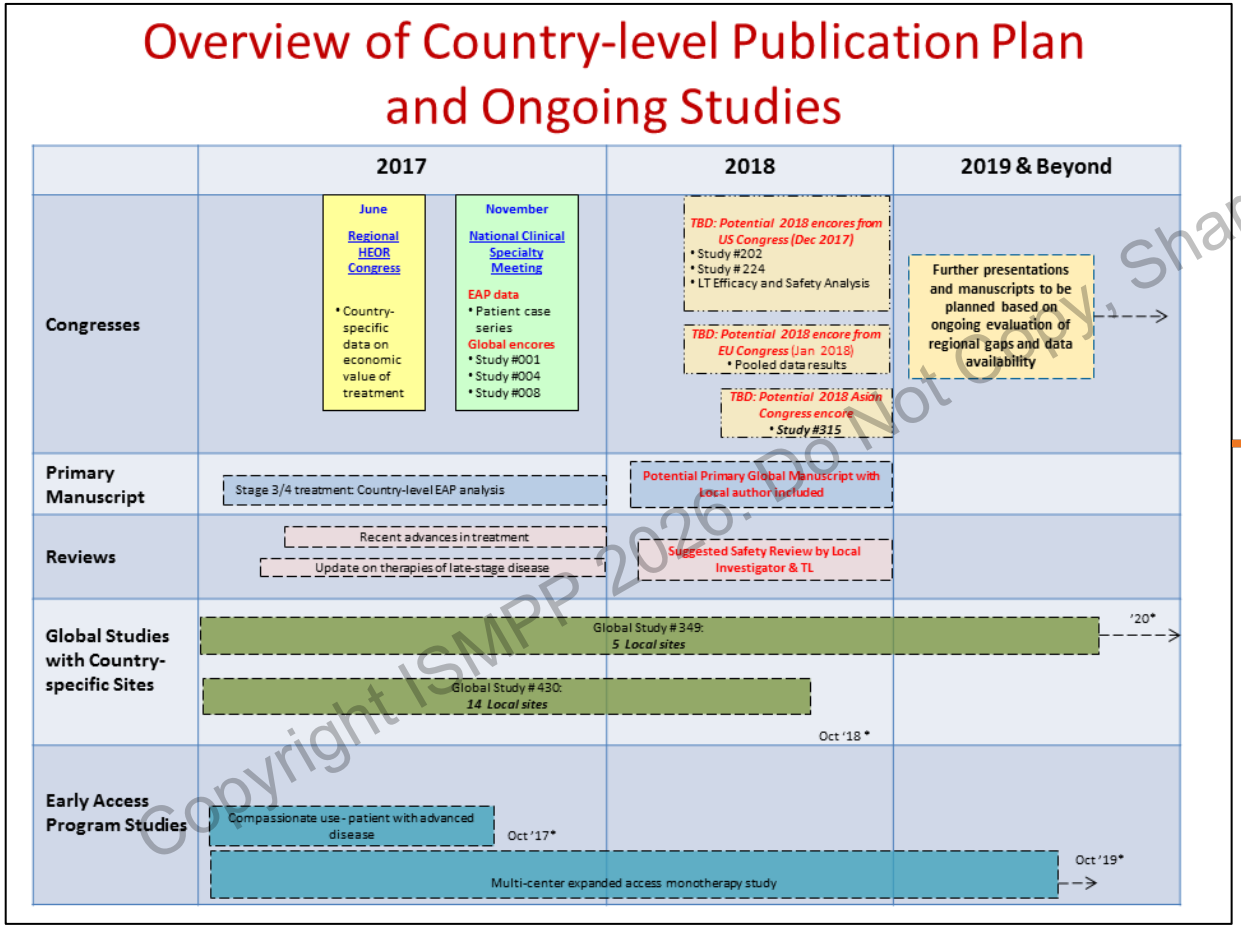
Data Finalization and Publication Timelines

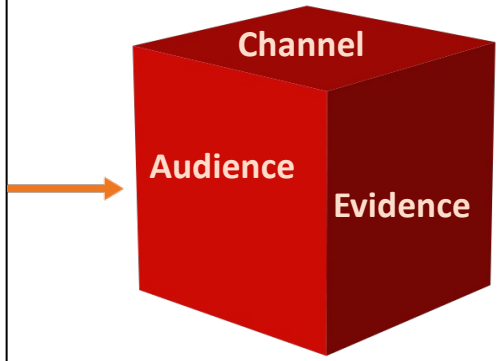
- Challenge of starting publication drafts before final dataset available
- Inefficiencies of starting publication development before data/ study report are finalized
- Potential helpfulness of AI
- Management of expectations

Working Across Multiple Agencies

- Potential lack of coordination across key stakeholders including vendors
- Early coordination, clear roles, consistent communication
- Importance of publication planning not happening in isolation

Modern Publication Plans are Multi-dimensional





All of these have EXPANDED

Source: ISMPP U RWE Communication Challenges (December 2021)

Potential lack of coordination across key stakeholders including vendors

MedComms agencies not coordinating towards a common goal for a pharmaceutical client leads to a fragmented strategy that:

- reduces impact
- wastes resources
- risks regulatory non-compliance.

Topic 3

Involving Patients/Caregivers as Stakeholders

Sharon Terry

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Involving Patients/Caregivers as Stakeholders

- Challenges engaging patients/care partners in RWE/HEOR publications
- Early involvement of Patient Advocacy Groups (PAGs)
- Strategies to improve accessibility of technical content

Challenges

- Engagement often happens too late
- Technical language and publication timelines make meaningful review difficult
- Patient and carer priorities don't align with sponsor, academic, or payer priorities
- No system is in place for compensation, training, and support
- Data may fail to reflect lived experience, burden, access barriers, or outcomes that matter
- Systems and actors appear untrustworthy
- Publication norms undervalue patient-authored or community-informed interpretation
- Tokenism risk: patients are asked to “react” rather than shape the work

Early and Often - Patient Advocacy Groups (PAG)

- Partners from start to finish
  - Use PAG input to identify outcomes that matter to patients and care partners
  - Involve PAGs in protocol design, plain-language materials, recruitment strategy, and interpretation of findings
  - Clarify roles, expectations, decision rights, compensation, and timelines up front
- Build long-term relationships rather than one-off consultation
- Include diverse PAGs and community voices to avoid over-representing the most resourced groups
- Share results back with the community before or alongside publication
- Recognize PAG contributions through appropriate mechanisms

Strategies to improve accessibility of technical content

- Create plain-language summaries alongside technical manuscripts
- Define acronyms and avoid unexplained jargon
- Use visuals, examples, and patient-centered framing to explain methods and findings
  - Explain why the study matters: what question it answers and how it may affect care, access, or policy
  - Separate key takeaways from methodological detail
  - Use layered communication: short summary, expanded explanation, full technical paper
- Test materials with patients, care partners, and PAG reviewers before release
- Translate findings into formats people can use: FAQs, infographics, webinars, short videos, and community briefings
- Be transparent about limitations, uncertainty, and what the study does not prove

Example: PXE International

- Built the longest-running patient-led data resources, 3 decades of participant-reported outcomes, clinical histories, molecular data, and participant-contributed records.
- Collected longitudinal data across approximately 1,700 individuals with PXE
- Led decentralized, participant-centered research using registries, biobanks, remote data collection, participant-mediated records, and patient-controlled data governance. Community Driven Innovation.
- Supported interventional trial execution, including recruitment, screening, enrollment, participant follow-up, and protocol implementation for PXE trials; in a recent Phase 2 TNAP inhibitor trial, PXE International enrolled 65 participants in under four weeks, with all completing the 12-week protocol.
- Collects and uses RWD in conjunction with the trial to supplement interventional trial data

Topic 4

Improving RWE Dissemination and Acceptance

Tom Drake, Mike Holmes

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Improving RWE Dissemination and Acceptance

- Recognition of challenges in publishing RWE studies due to limitations in journal selection
- Discussion with journal editorial boards
- Approaches to broaden reach of RWE

Challenges in Publishing RWE Studies

Are major medical journals publishing RWE manuscripts?

- Yes, major medical journals are increasingly doing so.
- As RWE's importance grows in healthcare decision-making, regulatory bodies and academic journals are focusing on its application
- High-impact journals (e.g. *NEJM, BMJ, JAMA*) are publishing studies that utilize electronic health records, claims data, and patient registries.

The NEW ENGLAND JOURNAL of MEDICINE

thebmj

Dang A. Real-World Evidence: A Primer. Pharmaceut Med. 2023 Jan;37(1):25-36. doi: 10.1007/s40290-022-00456-6. Epub 2023 Jan 5. PMID: 36604368; PMCID: PMC9815890.

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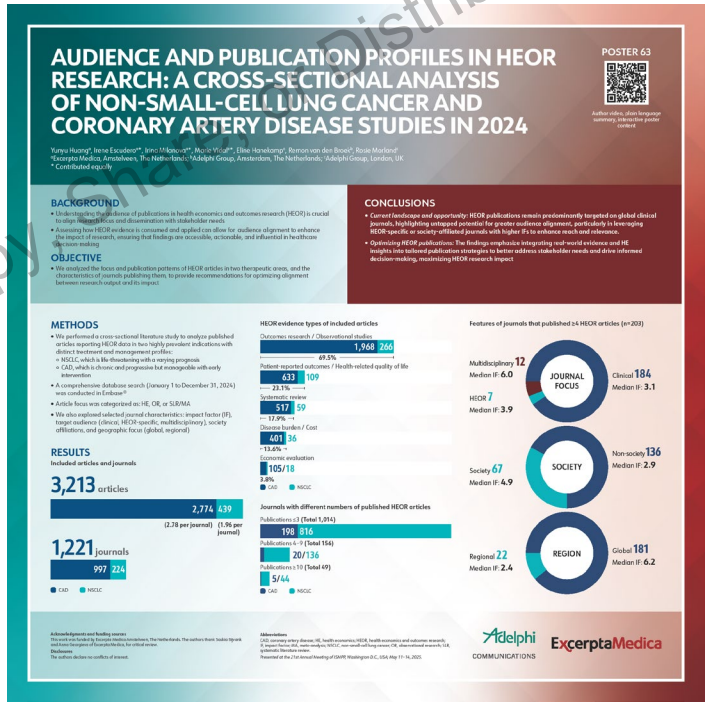
Challenges in Publishing RWE Studies

Poster #63 – ISMPP 2025 Annual Meeting

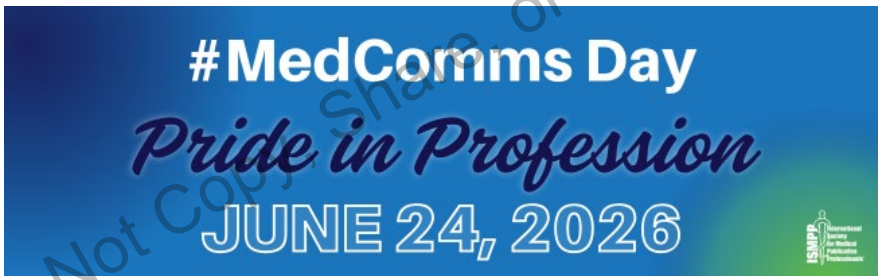


CONCLUSIONS

- **Current landscape and opportunity:** HEOR publications remain predominantly targeted on global clinical journals, highlighting untapped potential for greater audience alignment, particularly in leveraging HEOR-specific or society-affiliated journals with higher IFs to enhance reach and relevance.
- **Optimizing HEOR publications:** The findings emphasize integrating real-world evidence and HE insights into tailored publication strategies to better address stakeholder needs and drive informed decision-making, maximizing HEOR research impact

Q&A

Check out Podcasts and MedComms Day Programs!



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Thank you for attending!

We hope you enjoyed today's presentation.

After closing out of Zoom, please click the CONTINUE button on your screen to take our short survey. Thank you!