



Real-world data and real-world evidence: A new ethics of knowing

The field of medicine stands at a critical juncture. In the ever-evolving journey from evidence to action, from clinic to community, and from regulation to lived experience, real-world data (RWD) and real-world evidence (RWE) are no longer auxiliary concepts – they are becoming central to how we understand health, disease, and care. This special issue of EMWA's *Medical Writing* journal is dedicated to exploring the technical and practical dimensions of RWD/RWE, recognising it as a powerful

doi: 10.56012/rfcq2943

conduit for patient-centered insight and innovation grounded in reality, responsive to needs, and driven by practicality.

We are no longer satisfied with understanding health solely through the lens of randomised controlled trials (RCTs), valuable though they are. While RCTs answer the “does it work” question, RWD/RWE tell us how it works in real-

life. Thus, now we now ask ourselves: How do patients experience treatment in the everyday world? What happens between visits, outside hospitals, beyond clinical endpoints? RWD/RWE shifts our focus from the controlled to the lived, from the prescriptive to the observed, and perhaps most importantly, from the theoretical to the ethical. It draws us into the reality of care – messy, complex, and often unmeasured – and forces us to confront whether our systems reflect the needs of the people they serve.

GUEST EDITORS



Laura C. Collada Ali

laura.collada@trilogywritings.com



Maria Kołowska-Häggström

maria.koltowska-haggstrom@propermedicalwriting.com

Ethics: Who owns the evidence?

At the heart of RWD/RWE lies a fundamental ethical question: Whose knowledge counts? When we speak of patient-generated data – whether from electronic health records, mobile health devices, or social determinants of health – we are not merely gathering statistics. We are witnessing people's lives in data form. And with that comes the imperative to respect privacy, autonomy, and agency.

RWE gives rise to a new ethics of knowing, which rethinks the principles, responsibilities and power structures involved in the creation and dissemination of knowledge. It challenges us to recognise that evidence is not neutral – it is shaped by who collects it, how it is interpreted, and for what purpose. As one of our feature articles explores from a European regulatory perspective, the development of guidance around RWD/RWE is not just about technical rigour; it's about safeguarding trust. Transparency, inclusivity, and participatory design must become ethical cornerstones of how we integrate RWE into health systems – not only to reflect scientific rigor, but also the realities of care delivery and decision-making.

Patient-centeredness: Evidence that feels real

Patient-centered care is often defined in philosophical terms. RWD/RWE makes it tangible. We see this in our contributors' work on chronic disease management, digital therapeutics, and community health analytics. By incorporating diverse data sources – wearables, patient-reported outcomes, behavioural data – we begin to understand not just how treatments work, but how they work for real people in real contexts.

What emerges is a more holistic picture of health. Lifestyle factors, social environments, and personal goals – all too often left out of traditional clinical data – are captured in ways that illuminate the true burden and benefits of care. Several articles in this issue address the intersection of RWD with lifestyle medicine, showing how real-world insights can lead to proactive, preventive strategies that align with patients' needs – and not just clinical endpoints.

Crucially, RWD/RWE allows us to hear from populations often excluded from clinical trials: older adults, people with comorbidities, rural communities, and ethnically diverse groups. Patient-centeredness means acknowledging these voices not as exceptions, but as essential to understanding effectiveness in the real world. The data must reflect the lived realities of those whose health and outcomes depend on our systems.

Opportunity: From observation to transformation

The promise of RWD/RWE is immense — but so is the responsibility. We have the tools to detect patterns across vast datasets, to tailor interventions to specific populations, and to predict outcomes with increasing precision. But will we use this opportunity to reinforce equity, or will we widen gaps?

Image: Freepik



EUROPEAN
MEDICAL
WRITERS
ASSOCIATION

Submissions:

For instructions to authors, go to the journal section of EMWA's website (www.journal.emwa.org). All manuscripts should be submitted to mew@emwa.org.

Editor-in-Chief

Raquel Billiones

Co-Editors

Evguenia Alechine Jonathan Pitt

Associate Editors

Anuradha Alahari Sarah Milner
Jennifer Bell John Plant
Nicole Bezuidenhout Sampoorna Rappaz
Barbara Grossman Amy Whereat

Visual Communications SIG Lead

Judit Mészáros

Section Editors

Daniela Kamir **AI/Automation**
Jennifer Bell **Biotechnology**
Nicole Bezuidenhout **Digital Communication**
Somsuvro Basu **EMWA News**
Adriana Rocha **Freelancing**
Ana Sofia Correia **Gained in Translation**
Ivana Turek **Getting Your Foot in the Door**
Wendy Kingdom / Amy Whereat **Good Writing Practice**
Alison McIntosh / Pablo Izquierdo **In the Bookstores**
Maria Kołowska-Häggström **Lingua Franca and Beyond**
Lisa Chamberlain James **Medical Communications/**

Writing for Patients

Payal Bhatia **Medical Devices**
Evguenia Alechine **My First Medical Writing**
Anuradha Alahari **News from the EMA**
Tiziana von Bruchhausen **Pharmacovigilance**
Maddy Dyer **Publications**
Clare Chang / Zuo Yen Lee **Regulatory Matters**
Sam Hamilton **Regulatory Public Disclosure**
Louisa Ludwig-Begall / Sarah Kabani **The Crofter:**

Sustainable Communications

Jeff Blair/Luiza Ventura **Veterinary Writing**

Senior Editor

Victoria White

Managing Editor

Alicia Brooks Waltman

Layout Design

Chris Monk

Editors Emeritus

Elise Langdon-Neuner
Phil Leventhal



One of the most compelling aspects of this issue is how it spans the full ecosystem – from the regulator’s office to the patient’s kitchen table. We see articles addressing how the industry is embracing RWD and its potential, the future of drug safety, statistical and reporting challenges, AI-driven insights, medical device surveillance, language and evidence in a polarised era, and the practical relevance of lifestyle medicine. Together, they illustrate that RWD/RWE is not just a technical evolution; it’s a cultural shift in how we think about evidence – one that emphasises practicality, responsiveness, and accountability.

In health economics, RWE is helping systems allocate resources based on actual utilisation patterns. In rare diseases, RWD offers the only practical route to understanding natural history and treatment response. In pharmacovigilance, RWE captures safety signals that would be missed in trials. In each case, the opportunity is

not just to observe, but to act – to refine policy, improve practice, and empower patients.

The role of the medical writer

Amid all this, medical communicators have a vital role to play. We are not merely translators of data – we are stewards of meaning. In the RWD/RWE landscape, clarity, relevance, and practical insight matter more than ever. It is up to us to help stakeholders – clinicians, patients, payers, regulators – understand what this data means and what it does not. We must advocate for ethical reporting, resist oversimplification, and emphasise the needs and narratives behind the statistics.

Moreover, we must be champions of inclusivity in how evidence is communicated. As more patient-generated data enters the evidence base, we must ensure that patients are not just sources of information, but co-authors of understanding. Their lived realities must shape

not just the data we collect, but the decisions we make and the words we choose.

Looking ahead

This issue reflects a collective recognition: that evidence must meet life where it happens. As we move forward, let us centre our work on a simple, radical idea – that real-world evidence is not just about what works, but about what matters. It must address real needs, reflect lived realities, and be applied with practical wisdom.

To all our readers – medical writers and science communicators in Europe and beyond – we invite you to consider how RWD/RWE can be a tool not only for insight but for integrity. Let us use this moment to reimagine evidence as not just a pathway to approval, but a commitment to accountability and care.

Let the real world speak – and let us listen, wisely and well.

Author information

Laura C. Collada Ali is a Senior Medical Writing Manager at Trilogy Writing & Consulting. She has over 25 years of experience writing, editing, and managing medical and scientific documentation for diverse clients and audiences worldwide. She is a member of EMWA’s Executive Committee and a workshop leader and holds multiple certificates in linguistics, pharmacology, medical devices, clinical research, and regulatory writing.



Maria Kołowska-Häggström, MD, PhD, runs Proper Medical Writing, the first Polish medical writing agency. She has 30 years of experience in the pharmaceutical industry, primarily in clinical research, including real-world data (RWD) and real-world evidence (RWE).

Maria has authored over 80 peer-reviewed publications, many focused on RWE and patient-reported outcomes. She is a member of EMWA, EASE, ESE, and GRS; serves as a journal reviewer and Associate Editor for BMC Endocrine Disorders; and is an EMWA workshop leader, and a section editor for *Medical Writing*. She was EMWA president in 2023–2024.

