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TOPICAL FEATURE

Celebrating 10 Years of the CORE Reference Project

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INTRODUCTION

This article was originally published in the journal of the European Medical Writers Association (EMWA): McIntosh A, Lee ZY, Fagan V, Hamilton S. Celebrating 10 years of the CORE Reference Project. *MEW*. 2026;35(1):71-77. doi: 10.56012/lxmo4674.

Minor adaptations to contextualize the original article for readers of *AMWA Journal*, including this introduction, have been made in this version.

Two AMWA members, Dr Aaron Bernstein and Dr Art Gertel, were on the original Clarity and Openness in Reporting: E3-based (CORE) Reference development team, The Budapest Working Group (BWG). Both served from project inception in May 2014 to resource publication in May 2016. Dr Gertel continues to act as strategic advisor on an as-needed basis for the ongoing project. AMWA's Brian Bass kindly liaised between the CORE team and AMWA to ensure that the open-access 2016 resources reached the widest possible audience in the American medical writing community.

I am periodically asked if the 2016 CORE Reference resources will be updated. I can confirm that there is no current plan to do so and with good reason.

Anyone who uses CORE Reference in their daily work knows that the resources are "evergreen" if used in the correct way. They are region-agnostic, globally applicable, and usable by all types of sponsors from big pharmaceutical companies to contract research organizations (CROs) to biotechnology companies, academicians, and charities. Use of the May 2016 published CORE resources, combined with an understanding of downstream changes in the clinical trials ecosystem, will continue to serve medical writers (MWs) well in production of fit-for-purpose clinical study reports (CSRs).

CORE Reference—like any other best practice document—is a reflection of a point in time (May 2016). The myriad regulatory and public disclosure requirements and guidelines introduced thereafter contribute to an ever-changing clinical study–reporting ecosystem. An update of the original resource would therefore be outdated immediately upon publication.

We have therefore taken a practical and pragmatic approach to keeping our outputs alive and current.

The main ongoing endeavor of the CORE Reference Team is to survey the clinical study–reporting and public disclosure landscape and distill the information into concise monthly updates released via our LinkedIn page. This material is available for self-led continuing professional development (CPD) that requires your engagement. I invite you to access it and put aside time to read and understand what is going on in the space. Apply your evolving knowledge intelligently as you develop your CSRs.

In 2026, The CORE Reference Project collaborated with Jonathan Mackinnon's Protocol Development LinkedIn endeavor to create a joint summary of what MWs need to know to align their clinical study protocol (CSP) and report writing activities with the most current requirements. These are the "need-to-knows" for creating fit-for-purpose individual study-level documents and will particularly resonate if you are new to the industry and have not followed the CSP and CSR development stories over the past decade or so. Our joint summary is available here: https://emwa.org/wp-content/uploads/2026/08/CORE-PROT-Joint-Summary-Final_28Jul26.pdf.

For more about the original resources and the CPD at your fingertips, read on.

You should not overlook The CORE Reference Project if you write or review CSRs.

—**Dr Sam Hamilton**, Chair

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Dr. Sam Hamilton
Original Author and Chair
2014 - ongoing

In 2014, I became EMWA's VP, knowing my main aim was to tackle the ambiguity inherent in ICH-E3 that often left CSR authors confounded. Working with knowledgeable colleagues, a vision for approaching the problem emerged quickly. We worked for 2 years to create CORE Reference – the user guide plus all the accompanying materials needed to understand and navigate it. The team grew in confidence; we engaged with industry partners; and navigated a complex and sometimes hostile micro-political environment because back then, industry did not much engage or question the wisdom of the regulators. I am glad I held steady - because the original outputs and current CPD offerings are invaluable in educating regulatory medical writers. I rank this pro-bono work firmly alongside the many medicines and vaccines that I have helped on their approvals journeys in my long scientific career, and I am proud of its standing in the industry.

Vivien Fagan
Original Author and Committee
2014 - ongoing

I was absolutely thrilled when Sam Hamilton approached me to join a working group she was forming – right in the middle of an inspiring session at the 2014 EMWA Conference in Budapest, where the EMA was discussing Pharma's growing responsibilities in making clinical trial data publicly available. Being invited to contribute to something so timely and important felt incredibly special. We called ourselves the Budapest Working Group. Over two years, under Sam's leadership, the group seized every opportunity to collaborate and develop what has become a cornerstone resource for educating regulatory MWs. Contributing to CORE Reference has been a highlight of my career, and I'm proud to continue supporting its mission as an EMWA Workshop Leader, and current committee member, sharing its principles and practices with the wider community, while enriching both my own and our readers' continuing professional development through the monthly News Summaries.

Debbie Jordan
Original Author & EMWA Trainer on CORE Reference
2016 - 2020

I joined the CORE Reference project at the 2014 EMWA Conference in Budapest, and was very excited to be joining a group of experienced and knowledgeable colleagues (and friends!) in looking at ways the ICH CSR guidelines could be updated and improved. Having had my own frustrations with the ICH guidelines over the years, I was pleased to be able to provide input into the CORE Reference document and greatly enjoyed the many discussions we had on what we liked and what we wanted to change. I was instrumental in the actual writing of the CORE Reference document and I feel immensely proud of what we achieved and the legacy we have left to help other medical writers, as well as the numerous clients over the last 10 years that I have helped transition to using the CORE Reference document as the basis for their CSRs.

Anna Shannon
Original Contributor

I was contacted by Sam Hamilton in 2014 inviting me to join the CORE Reference initiative and provide input from the perspective of a project statistician. With many years of experience collaborating with Medical Writers, Sam included, on CSRs I was familiar with the processes and ICH E3 but this was a unique opportunity to contribute to a comprehensive review. The initiative was launched at a time of increased industry awareness of the need for disclosure alongside data protection considerations and this led to thought-provoking discussions across the expert, multi-disciplinary team I joined. It was a fantastic opportunity for me personally and I was honoured to be able to contribute to the early days of a guidance document which continues to support the Medical Writing community 10 years on.

Dr. Graham Blakey
Original Author and Member
2014

I am a clinical pharmacologist by trade so my involvement with the CORE Reference Project was not anticipated. Nonetheless, having worked with Sam providing pharmacokinetic input into clinical study reports I was invited to present at several EMWA conferences. An invite onto the steering group for The CORE Reference Project followed which I was delighted to accept. Two years later, after many enthusiastic and thought-provoking meetings CORE Reference was ready for launch. I thoroughly enjoyed the collaboration and was glad I could fight for the often overlooked clinical pharmacology corner. It is pleasing to know that 10 years after going live CORE Reference is now an invaluable resource for medical writers.

The authors of the 2016 CORE Reference manual worked in 2 consecutive phases on the project. Phase 1 involved the De Novo Review Team comprising Sam Hamilton, Vivien Fagan, and Debbie Jordan, who provided regulatory medical writing and public disclosure know-how to forensically analyze working practices and existing guidelines. Sam, Vivien, and Debbie worked closely with statistical experts Anna Shannon (biostatistician) and Graham Blakey (pharmacometrician), who focused on statistical reporting considerations.

The Oversight Review Team was involved in Phase 2, reviewing the first-phase outputs, each team member with a special focus: Aaron Bernstein's was regulatory medical writing, Tracy Farrow's was public disclosure, Art Gertel's was regulatory and project strategy, and Walther Seiler's was content-versus-template considerations.

Quality control (QC) of outputs, mapping tool creation, and website design were all considerable tasks. We were lucky to have external volunteers who kindly supported us. Tania Kotsokechagia provided QC expertise and contributed to the design of the CORE Reference website. Katie Brooks and Linda J. Fraser created the E3-CORE Reference sectional mapping tool. Katie Brooks, Amy Myers, and Anna Ramirez-Soriano provided supporting QC reviews and comments on CORE Reference. From February 2024 until June 2025, Raquel Billiones generously supported the project with medical device considerations for the monthly News Summaries.

Dr. Aaron B. Bernstein
Original Author and Promoter

Like many medical writers in pharma, I relied on the ICH E3 guideline as my go-to resource for writing CSRs. Yet I often questioned parts of its guidance. So, when Sam Hamilton invited me to join a taskforce of seasoned writers to represent the United States perspective in clarifying ICH E3 and adapting it for a new era of transparency, I leapt at the chance. It was clearly important for the final resource to resonate globally and be applicable across jurisdictions. I quickly discovered that my colleagues had wrestled with the same issues no matter where they were located or which agencies they wrote CSRs for. With support from an international network of medical writing and regulatory experts, we tackled these questions and provided practical guidance for safely increasing CSR transparency. Seeing CORE Reference embraced so widely after publication was deeply rewarding—a rare chance to make a lasting professional impact.

Tracy Farrow
Original Author and Committee
2014 - 2023

Sam and I had collaborated for several years, including presenting EMWA workshops together. Naturally, our conversations often revolved around medical writing trends and potential improvements. My background in clinical study reporting and the evolving field of regulatory public disclosure and data privacy made it a perfect match when Sam invited me to join the Budapest Working Group in 2014. I learned so much from being part of the group and felt proud to share my knowledge in return. Giving back to the medical writing community through the CORE Reference initiative is a definite highlight of my career and an achievement I am still very proud of.

Dr. Art Gertel
Strategic Regulatory Advisor

I have always been an advocate for a unified theory of medical writing – encouraging standards which provide guidance to interpretation, rationale, and best practices in complying with expectations of regulatory authorities, worldwide.

The CORE Reference serves such a purpose, as an accessible, clear resource for medical writers and others who have responsibilities for the preparation of clinical study reports. The 2-year effort, like all collaborative exercises, was one which challenged us to think hard about how to best provide a practical tool which could be applied to an important work product – one which would serve to best communicate the therapeutic and safety profile of new drugs. We argued (gently), changed hearts and minds, and did our best to achieve consensus. All-in-all, a rewarding experience which resulted in a legacy that will, hopefully, serve as a living resource as we continue to shepherd the clinical study report through its evolutionary pathway.

Dr. Walther Seiler
Original Contributor

It is hard to believe that more than 10 years elapsed since I was approached to join what rapidly evolved into one of the most impressive initiatives I have encountered during my long life as a Regulatory Medical Writer. In rainy Budapest of May 2014, Sam Hamilton sketched out her vision of what was later coined CORE Reference to a handful of attendees of the EMWA spring conference. While we soon decided for good reasons to deprioritize the aspect I was initially recruited to cover (the clinical study protocol) it was my great pleasure and a valuable source of learning to contribute to CORE's exegetic re-interpretation of ICH E3, one of the longest-living rocks in the ever-changing regulatory environment. In particular, I remember conceptualising the graphs and ensuring that we kept the "template" aspect separate from guidance on populating the CSR document, having CORE's global applicability in mind.

Dr. Zuo Yen Lee
Committee
2022 - ongoing

I first encountered CORE Reference when I joined EMWA in 2016, the same year it was launched. Fresh out from academia, CORE Reference is an important source I used in my initial training as a new regulatory medical writer. In 2022, I was given the opportunity to become a committee member of CORE Reference, which I unhesitatingly accepted. My involvement within CORE Reference has broadened my perspective in the areas of transparency and disclosure in regulatory writing. With my experience in Asia, I am also contributing towards closing the intelligence gathering gap by bringing regulatory transparency and disclosure perspectives and guidance from Asia. We now have a subsection "News from Asia Regulators" in the monthly News Summary; I have also written about the regulatory transparency landscape in Asia in MEW. It has truly been fulfilling working alongside the CORE Reference team who are experts with decades of knowledge in the medical writing industry. I hope to continue to contribute to CORE to the best of my ability.

Dr. Alison McIntosh
Committee
2022 - ongoing

Sam asked me to join the CORE Reference project team when it was designated as an EMWA Special Project in Summer 2022. My main role is to sift through the avalanche of new regulatory information that we are bombarded with, and identify any that might impact the documents written in support of the licensing of medicines. Coming from diverse medical writing backgrounds our small team has a wide-ranging awareness of the regulatory environment which we put to good use when populating the monthly News Summaries. In the spirit of sharing knowledge, I have also co-presented several webinars covering different aspects of EMA Policy 0070 and contributed to our Regulatory Public Disclosure section in the EMWA journal MEW. Since joining the committee, I have thoroughly enjoyed collaborating with like-minded colleagues to help CORE Reference achieve its expanded aim of delivering timely, self-led continuing professional development to fellow regulatory medical writers.

SIX QUESTIONS TO SAM HAMILTON AND VIVIEN FAGAN

CORE Reference is a user manual developed from 2014 to 2016 to help MWs navigate relevant guidelines as they create CSR content relevant for today's studies.

During the CORE Reference 10th anniversary year, Alison and Zuo Yen—current CORE Reference team members who joined in 2022—posed 6 questions to Sam and Vivien, members of the current team who were also integral to the successful realization of the CORE Reference Project in 2016.

Sam and Vivien were asked to reflect on the past, present, and future of CORE Reference as it moves forward into a second decade.

Q1. ***What is the BWG, and how is it related to CORE Reference?***

Sam and Vivien: Let us attempt to answer this question together. First, a bit of background. Since 1995, there have been incomplete attempts to clarify reporting guidance for CSRs, both regionally and globally, but to date, there has been no formal revision and reissue of the original International Council for Harmonisation (ICH) E3 guidance documents.

This left individual MWs to interpret the guidance subjectively, so there was a need to address ambiguities in ICH E3 and the 2012 question and answer (E3[R1]) CSR guidance text and reconcile these with European Union and US regional CSR guidance and, by doing so, present practical suggestions for developing CSRs, incorporating clarifications of the numerous CSR guidances. Any such effort would essentially take the form of a user manual for CSR authors.

A very timely European Medical Writers Association (EMWA) symposium took place titled "Transparency of clinical trial data: where do MWs fit in?" at the 38th Conference in Budapest, the same conference at which the idea of a best practice user manual took hold. The European Medicines Agency (EMA) speaker outlined impending EMA transparency requirements, including mandatory results posting, along with the plan to make CSRs public under EMA Policy 0070. It was immediately apparent that any user manual had to take this into account.

So, at the 38th Conference in May 2014, Sam, as EMWA Vice President, assembled a group of experts, dubbed the BWG, to address these issues. The aim was also to provide interpretational guidance and highlight privacy-related risks associated with published CSRs.

Q2. ***What was your role within the BWG?***

Sam: I stood for election to the 2014 EMWA Executive Committee because I had been mulling the idea of creating a resource to address ICH E3 inconsistencies for a while. I knew that something this ambitious could only be approached with an association "hat" on. Luckily, I was elected, and the first thing that I did at the 2014 Spring Conference after taking office was to invite long-standing colleagues and friends who were also experts in ICH E3, CSR templates, CSR authoring, statistics, pharmacokinetics, and public disclosure of clinical-regulatory documents to form the BWG. As well as being the founding member of the de novo review team, I was also Chair of the BWG and the CORE Reference Project.

Vivien: I was part of the de novo review team. As an end-user, my role was to provide recommendations to minimize ambiguity in existing CSR-reporting guidance. As ICH E3 links to many other guidance documents, including ICH E6, E8, E9, and other industry processes and procedures, our recommendations had to anticipate any possible "domino effect."

Q3. ***What challenges did you meet along the 2-year development pathway of the CORE Reference user manual?***

Sam: The micropolitical environment in clinical trials at that time was challenging for those placed outside big pharmaceutical companies and the regulators. The regulator-industry collaborations prevalent today were simply

not in place back then, and there was a definite hierarchy from which even the largest CROs were excluded. Persuading those in positions of power to engage was difficult. Although we were often told privately that it was a great idea, few were willing to publicly back the initiative for fear of upsetting ICH and regional regulators. Art Gertel—our strategist—and I navigated the complex environment together. An industry veteran of decades, Art was, and still is, very well-connected. His tenacity proved invaluable in securing credible stakeholder engagement, enabling us to bring the industry along on the journey with us, rather than delivering a "fait accompli" in 2016. The aim was to publish the resource exactly 2 years from the start of the work, at the 40th EMWA Conference when I stood down as EMWA President in May 2016. That meant that the work could not slow at all over the 2 years of development because of the sheer scale of the project, so we all just found ways to incorporate the considerable additional workload on top of our day jobs and into our otherwise busy lives.

Vivien: Developing CORE Reference over a 2-year period while working at one of the largest CROs presented its own set of challenges. One of the most significant was maintaining engagement and momentum while balancing ongoing responsibilities to my employer. Flexibility was essential—we had to continuously adapt while keeping the end goal in sight. Much of the work took place outside regular hours, which added complexity to the process. A particularly memorable milestone occurred in summer 2015, when the draft was shared with the Drug Information Association MW Community. The team received 70 pages of comments, which were carefully reviewed and addressed by Sam and I to ensure that CORE Reference reflected the needs and insights of the wider community. What kept me motivated was the belief in CORE's potential to make a real difference. Seeing early signs of support from colleagues and stakeholders helped fuel my commitment. I also found energy in the collaboration—working with passionate people who shared the vision made even the toughest days feel worthwhile.

Q4. ***What were the outputs from the BWG efforts?***
Sam: After a 2-year pro bono effort, the BWG produced a single text document, and the beauty of this was that everything was now in that document, namely CORE Reference. Separately, we also produced a mapping tool comparing ICH E3 and the CORE Reference sectional structure.

CORE Reference (with its Preface) and the mapping tool constitute the user manual. Jointly, they provide detailed content and practical suggestions for developing CSRs that will require minimum redaction and modification before public disclosure. We also published a peer-reviewed publication in the Biomed Central journal *Research Integrity and Peer Review* dubbed "the launch paper" that explained the background to CORE Reference and how to best use it.

CORE Reference was also registered as a reporting guideline with the Enhancing the Quality and Transparency of Health Research (EQUATOR) Network.

Close to the 2016 publication deadline, the need to house CORE Reference and the other outputs on a website where users could download them became apparent. To facilitate this, EMWA bought the CORE Reference domain name. With the help of Head Office, we built and loaded the website ready for the May 2016 launch in 6 weeks flat! Quite a task.

In 2026, we launched our new website, which now sits under the EMWA domain name as https://emwa.org/resources/the-core-reference-project/. The new website is complemented by The CORE Reference Project on LinkedIn, which we set up in January 2025.

Vivien: It is also important to remember that CORE Reference is not a template for CSRs but rather focuses on content guidance. The comprehensive information helps MWs create a CSR that is fit for reporting a particular study. It has become a vitally important resource to MWs searching for information and clarification about the structure and content of CSRs.

Q5. ***How is CORE Reference received after 10 years, and how do you keep CORE Reference relevant?***
Sam: Ten years on, the CORE Reference user manual is still relevant and stands the test of time. In a utility survey that we conducted in 2023, we received positive responses about the usefulness of CORE Reference—respondents are using it as an unofficial reference tool to author the CSR, to train others, and also to incorporate it into standard operating procedures and templates; the majority of the respondents find CORE Reference either extremely or somewhat useful to prepare disclosure-ready CSRs. CORE Reference is also cited as a source for the TransCelerate CSR template.

We should remember that any guidance or best practice document is only a reflection of a point in time. The reporting and disclosure environments do not stand still, so anything relevant and emerging in these areas needed to be tracked beyond May 2016 and included in CSR development. Tracking these developments is a large task in itself; to begin with, we were only able to publish periodic updates on the website, and as the work required to do the surveillance just kept increasing, it became unmanageable for the now pared-down team. The CORE Reference Project was designated an EMWA Special Project in 2022, and this allowed its expansion to support the increased workload necessary for global surveillance of the regulatory reporting and public disclosure landscapes. A small team of experts (including

you both, Alison and Zuo Yen) was assembled to survey the literature and identify relevant and useful information for our updates. The team's current aim is to provide a self-directed CPD offering to the regulatory medical writing community. We also occasionally produce stand-alone resources to support MWs as the environment requires.

The current relevance of CORE Reference was echoed in presentations at the 10-year celebration during the 61st EMWA Conference in Barcelona (May 2026). External speakers—Rona Vasey of Trilogy Writing and Consulting (an Indegene Company) and Philip Burridge of Morula Health—spoke eloquently about the continued value of CORE Reference. Rona illustrated how CORE Reference supports the deep foundational knowledge that MWs need to train artificial intelligence (AI) and then critically evaluate and refine AI-generated outputs. Phillip demonstrated a tried and tested process and workflow for creating CSRs within the biotechnology environment using the CORE Reference user manual to deliver high-quality, standardized reports.

Vivien: The current CORE Reference Project Team provides subscribers with a free monthly News Summary that includes updates on major developments in regulatory reporting and public disclosure requirements from around the world including the European Union, United Kingdom, Canada, United States, and Asia. We also aim to provide 2 online sessions per year, often featuring an external expert as our guest speaker.

Q6. *What is the future for CORE Reference as it moves into a second decade, especially amid the emerging AI technologies?*

Sam: The CORE Reference Project has moved away from delivering the monthly News Summary by email. Using LinkedIn, we have streamlined our distribution of educational materials, including our monthly News Summaries. Followers receive notifications of our postings, including the monthly News Summaries and other resources to support self-led CPD. We are seeing paced and organic growth of our LinkedIn followers, and, although it sometimes feels slow, we do seem to be reaching the right professionals. What I would really like to see is new entrants to our industry understanding that there is already a freely available and invaluable resource to help them author their CSRs. The standard we have created presents a unified approach to writing CSRs, and of course, the more common ground, the better for all concerned. I would very much like for this new tech-enabled cohort to help grow our network.

Our 2026 revamped CORE Reference website was made integral to the EMWA website and is our new and stable home for all our resources, alongside real-time releases being made on LinkedIn.

Vivien: We hold regular online webinars and have held "Learn and Share" face-to-face sessions at EMWA Spring conferences. All these opportunities are aimed at providing self-directed CPD. These offerings are set to continue.

With the growing presence of AI tools in our field, many are questioning the continued relevance of CORE Reference. However, I see AI not as a replacement for human intelligence but as a powerful complement that supports and enhances the work that we do. At this stage, AI tools do not represent a standalone and self-sufficient path to compliant CSR preparation. The technology still depends heavily on the expertise of MWs, particularly our deep understanding of the evolving regulatory landscape and the increasing emphasis on data transparency and reporting standards.

The user manual and the CPD offerings from CORE Reference are designed to help MWs build and maintain the critical knowledge and skills needed to navigate this complex environment effectively.

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Useful Resources

CORE Reference Manual 2016: https://emwa.org/?sawtd_download=11353

CORE Reference Mapping tool 2016: https://emwa.org/?sawtd_download=11356

CORE Reference Launch Paper 2016: http://dx.doi.org/10.1186/s41073-016-0009-4

EQUATOR Network registration 2016: http://www.equator-network.org/reporting-guidelines/core-reference/

CORE Reference review of the TransCelerate CSR template 2019: http://dx.doi.org/10.1186/s41073-019-0075-5

CORE Reference Utility Survey 2024: https://emwa.org/journal/clinical-trial-transparency-and-disclosure/the-2023-core-reference-utility-survey-perceptions-on-a-best-practice-tool-for-globally-applicable-clinical-study-reporting-and-provision-of-continuing-professional-development-resources-for-the-regu/

CORE Reference Website: https://emwa.org/resources/the-core-reference-project/ (includes all the above and further publications)

CORE Reference Video 2025: https://emwa.org/wp-content/uploads/2026/07/CORE-Reference-EMWA.mp4

The CORE Reference project on LinkedIn (updates on regulatory reporting and public disclosure): https://www.linkedin.com/company/the-core-reference-project

Webinar: CORE -Value for the Global Regulatory MW Community: An Evergreen User Manual & CPD for Self-led Learning, 28 Jul 26: https://vimeo.com/1217585263?fl=pl&fe=cm