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 regulatory medical writing community

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Abstract

CORE Reference offers globally applicable resources for clinical study reporting, including a user manual and a mapping tool, and continuous professional development (CPD) resources. This report presents the results of the 2023 Utility Survey conducted by the CORE Reference Project Team to measure the awareness and perceived usefulness of these resources by the regulatory medical writing community. The survey found an increased use of the CORE Reference open-access manual, compared to results of the 2017 survey. Most respondents found the resources extremely, or somewhat, useful for preparing disclosure-ready clinical study reports. Over half of the respondents were aware of the CORE Reference CPD resources. Most respondents found the bi-monthly news summary extremely, or somewhat, useful. One-third of the respondents required knowledge of the reporting and public disclosure landscape in Asia and found the updates of Asia extremely, or somewhat, useful. The survey results indicate a positive reception of the CORE Reference Project amongst regulatory medical writers.

Introduction

CORE Reference (https://www.core-reference.org/core-reference/) was developed between May 2014 and May 2016 by the European Medical Writers Association (EMWA)/American Medical Writers Association (AMWA) Budapest Working Group (BWG), which comprised a group of experts from the regulatory medical writing community. Developed based on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E3 guidance and USA and EU regional guidance, CORE Reference integrates options to allow for the reporting of design elements common to today's complex clinical studies, as well as ensuring that public disclosure considerations are taken into account. Thus, it serves as a best practice tool for medical writers and regulatory professionals in developing globally applicable clinical study reports (CSRs) in the current regulatory reporting environment.[1]

The first CORE Reference Utility Survey was conducted in 2017 – one year after its launch – with a target audience of medical writing and regulatory communities. The 2017 questionnaire contained six questions that focused on utility of the user manual and its value to users; the results were presented at two conference meetings.[2,3] Since then, the CORE Reference website has evolved to not only house the established resources – the CORE Reference user manual, mapping tool, and related publications – but also provides self-directed continuing professional development (CPD) learning resources that support CSR authoring. CPD resources include an archive of monthly summaries of clinical study reporting and disclosure-related news and updates, as well as external links to public disclosure regulations, and portals of participating regulatory authorities.

The CORE Reference Project Team conducted a brief 2023 utility survey to rate both awareness of the 2016 original open-access resources and the perceived usefulness of the CORE Reference 2022 extended continuous professional development initiative.

In April 2022, the EMWA Special Project designation was conferred, with the aim of expanding the CPD offering to the medical writing community. Under the original Chair, the CORE Reference Project Team evolved and expanded to support the increased workload necessary for global surveillance of the regulatory reporting and public disclosure landscapes. The current CORE Reference Project Team provides subscribers with a free bi-monthly email in the form of a

news summary that includes updates on major changes in regulatory reporting and public disclosure requirements from around the world including the EU, Canada, USA, and Asia. In late 2023, the CORE Reference Project Team conducted a brief utility survey to rate both awareness of the 2016 original open-access resources, and the perceived usefulness of the CORE Reference 2022 extended CPD initiative. This article reports the results of this survey.

Methods

Questionnaire design and distribution

The CORE Reference 2023 Utility Survey contained 13 questions, building on the 2017 Utility Survey questionnaire. All questions were multiple-choice, fixed responses, with half of the questions containing an "other" response that provided a free-text option. The questionnaire was produced on Survey Monkey and was open for 6 weeks from October 25, 2023, to December 5, 2023. The questionnaire was designed to take less than 5 minutes to complete, and data were collected anonymously.

EMWA distributed the survey questionnaire with the access link to all its members via email and announced the survey on its social media platforms via newsletters and discussion groups. In addition, the CORE Reference Project Team distributed the survey to its subscribers via emails and announced it on the CORE Reference website. All announcements of the survey clearly outlined the survey's intention to collect information on the awareness and perceived usefulness of CORE Reference. The survey was open to all members of the medical writing community and was not restricted to EMWA or AMWA members or CORE Reference subscribers.

Data analysis

All responses were collected automatically and analysed on the Survey Monkey platform. The raw data and the survey results were exported into a Microsoft Excel spreadsheet and PDF documents. All results were presented using descriptive statistics only. For questions that allowed multiple responses, percentages of the different answers did not always add up to 100%. All percentages were rounded to full integers.

Results

Respondents

There were 154 respondents who participated in the 2023 survey, which was an increase of 75% compared with the 2017 survey (which had 88 respondents). Not all respondents in the 2023 survey answered all the questions in the survey.

The highest proportions of respondents worked in mid-sized contract research organisations (CROs) (19%; 29/154) and as freelancers (18%; 27/154). Ten percent (15/154) of the respondents worked in small CROs and 12% (18/154) worked in large CROs. Similarly, 10% (16/154) of the respondents represented small pharmaceutical companies, another 10% (16/154) represented mid-sized pharmaceutical companies, and 12% (19/154) represented large pharmaceutical companies. Among the 9 respondents who responded "other", 2 worked in the medical devices industry and 2 others in medical communications/writing agencies. Three respondents identified as writing medical devices documentation or worked for a medical device manufacturer. The overall distribution of the respondents' affiliations in the 2023 survey (41% CROs and 32% pharmaceutical companies) was similar to that of the 2017 survey (42% CROs and 38% pharmaceutical companies).

Just over half of the respondents were regulatory medical writers (52%; 79/153); 23% (35/153) of the respondents were in managerial roles; and < 10% were medical writers in medical communications (8%; 12/153) or transparency and disclosure (T&D) specialists (5%; 7/153). Of the 13% (20/153) of respondents who responded "other", most had cross-functional roles in clinical trial quality assurance (QA), project management, clinical operations, pharmacovigilance (PV), and T&D, as well as roles in medical communications.

Most respondents prepared documents for clients based in Europe (93%; 143/153) and the US (77%; 118/153), 34% (52/153) for Canada, 27% (42/153) for Asia-Pacific, and 8% (12/153) for clients based in other locations including

Latin America, South Africa, and the Middle East.

Utility of CORE Reference open-access manual

In the 2023 survey, most respondents found value in the CORE Reference open-access manual as an unofficial reference tool (52%; 78/150) and in authoring CSRs (47%; 71/150). Approximately one-third of the respondents used it to train others and had incorporated it into standard operating procedures, policies, or templates (Figure 1). Five of 8 respondents who responded "other" had never used the CORE Reference manual, and one respondent used it for CSR appendices collation for the European and USA regions. Compared with the 2017 survey in which 38% of the respondents used it as an unofficial reference tool and 28% used it to author CSRs, there was a notable increase in the use of the manual.

The CORE Reference mapping tool is a 4-page overview of the granularity within each main section in the CORE Reference manual, compared with the sections in the ICH E3 guideline. Users may download it to keep as a sectional reference while the manual itself contains a complete content description of these sections and subsections. Almost half of the respondents (45%; 63/139) had only downloaded the CORE Reference mapping tool. There were nevertheless respondents who found value in this overview document in that 41% (57/139) of the respondents had used it as an unofficial reference tool, and approximately one-fifth had used it to author CSRs and to train others (Figure 2), most likely as a supplementary tool to the manual. Of the 14 respondents who responded "other", 12 had not used or heard about the mapping tool.

When asked about the usefulness of the CORE Reference resources for preparing disclosure-ready CSRs, the majority of the respondents found it either extremely useful (50%; 74/148), or somewhat useful (21%; 31/148), most of the remaining respondents did

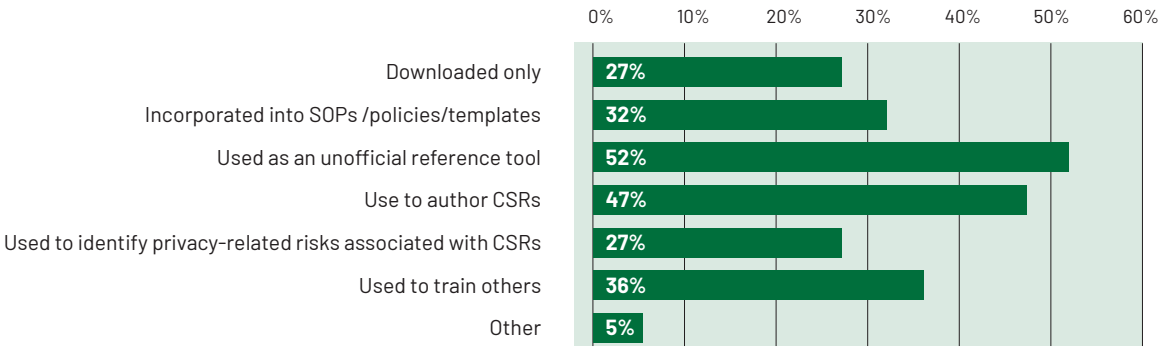

Figure 1. Use of the CORE Reference open-access manual

Abbreviations: SOPs, standard operating procedures; CSRs, clinical study reports

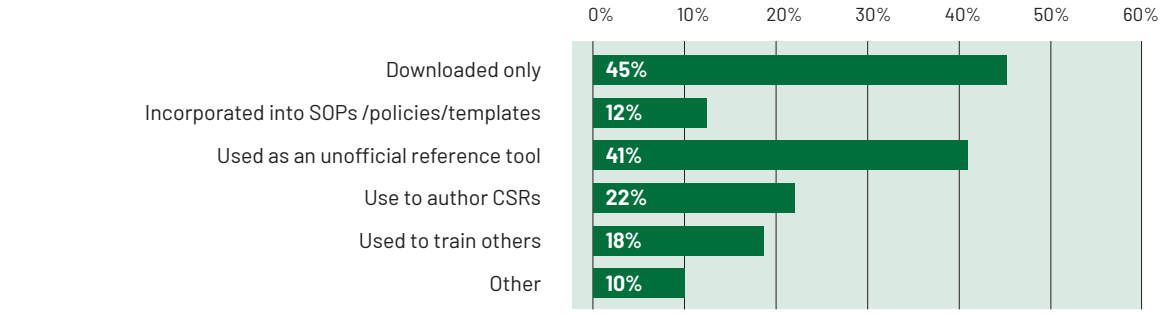

Figure 2. Use of the CORE Reference mapping tool

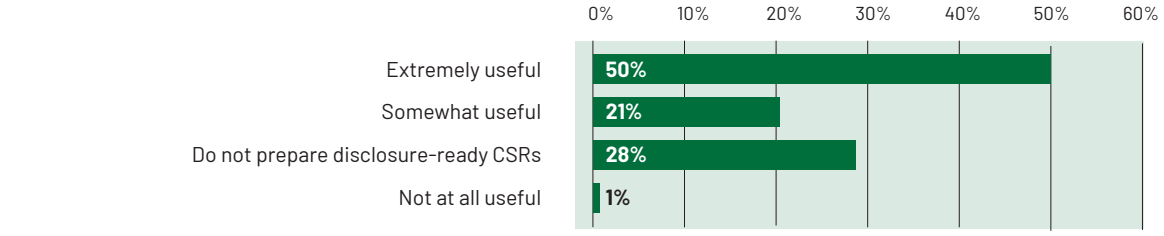

Figure 3. Usefulness of the CORE Reference resources for preparing disclosure-ready clinical study reports

not prepare disclosure-ready CSRs (28%; 41/148) (Figure 3). Notably, two respondents commented that they did not find the CORE Reference resources useful. One respondent – employed in a medical writing managerial role at a writing agency – commented on the redundancy of the CORE Reference resources with the availability of other open-access resources such as those from TransCelerate. This same respondent confirmed they used/had used CORE Reference open-access manual as both an unofficial reference tool and to train others. The second respondent was a freelance regulatory medical writer who prepared documents for medical devices and confirmed that they had only downloaded both the CORE Reference open-access manual and the mapping tool.

Utility of continuous professional development resources

Over half of the respondents (55%; 84/152) were aware that the CORE Reference Project also provides regulatory reporting and public disclosure updates as CPD. Interestingly, 73% (112/153) of the respondents had subscribed to the free CORE Reference bi-monthly news summary, which was not in line with the lower proportion of respondents who indicated their awareness of the CPD resources. The majority of the respondents found the news summary either extremely useful (47%; 69/148), or somewhat useful (32%; 47/148) (Figure 4).

Only 28% (43/152) of the respondents had accessed the archive of news summaries on the CORE Reference website (https://www.core-reference.org/news-summaries/). Respondents might find the "real-time" bi-monthly news summary sufficient to keep abreast of the fast-evolving regulatory reporting and public disclosure landscapes. Importantly, the bi-monthly news summary is shared with all EMWA members and the wider medical writing community via social media platforms and discussion groups. Once deposited in the archive it is a one-stop portal to view all updates within any given month.

With increasing demands of cross-regional regulatory submissions of clinical and regulatory documents, since mid-2022, the CORE Reference Project provides CPD on the T&D landscape in Asia to provide relevant information and updates to medical writers who may need to prepare clinical and regulatory documents for Asian health authorities. Approximately one-third of the respondents (35%; 54/153) confirmed that their roles required them to know about the regulatory reporting and public disclosure landscapes in Asia. However, only 27% (42/153) of the respondents had previously confirmed that they prepared documents for clients based in Asia-Pacific. Of the 20 respondents who did not confirm they prepared documents for clients based in Asia-Pacific, but did confirm that their roles required them to know about the regulatory reporting landscapes in Asia-Pacific, 4 respondents confirmed their role as T&D specialists who did not prepare disclosure-ready CSRs; 10 as regulatory medical writers; 3 as having a regulatory medical writing managerial role; and 3 as having "other" roles (namely: medical writer – clinical documents; scientist, also running clinical trials; and clinical trials project management).

Of the 10% (15/148) of respondents who found the regulatory public disclosure (RPD) updates from Asia extremely useful (Figure 5), 11 respondents reported preparing documents for the Asia-Pacific region; of the 29% (43/148) of respondents who reported the updates somewhat useful (Figure 5), 21 respondents were preparing documents for Asia-Pacific. The respondents who replied "Not at all useful" (5%; 7/148) were either not aware of the resources, did not need the resources, or did not currently find them useful, but may need them in the future.

Overall, there were positive responses about the usefulness of the CORE Reference Project amongst regulatory medical writers – 63% (95/151) of the respondents found the CORE Reference Project extremely useful and 24% (36/151) found it somewhat useful (Figure 6). Among the 11% (17/151) of the respondents who confirmed that they were not a regulatory medical writer (Figure 6), 4 were T&D specialists, 6 were medical communications

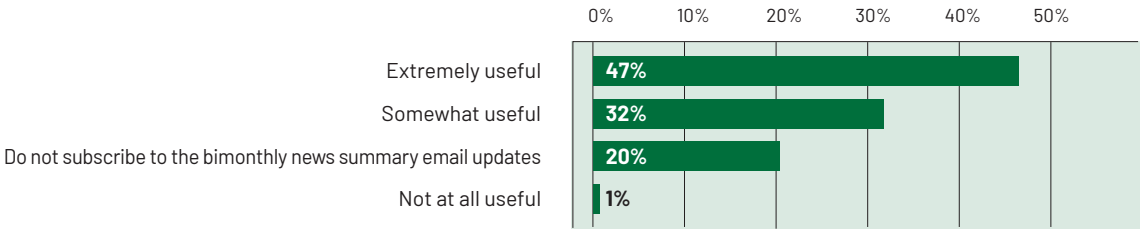

Figure 4. Usefulness of real-time CORE Reference bi-monthly news summary email updates for continuous professional development

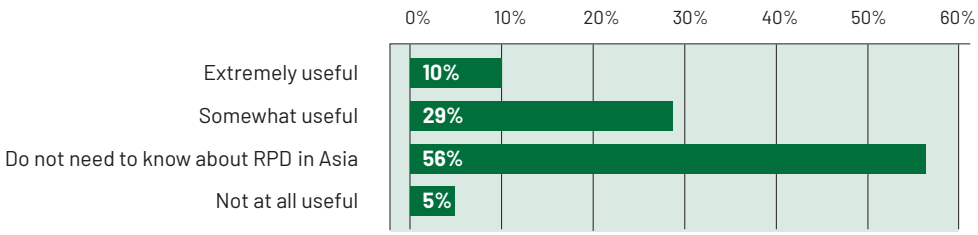

Figure 5. Usefulness of regulatory public disclosure updates from Asia

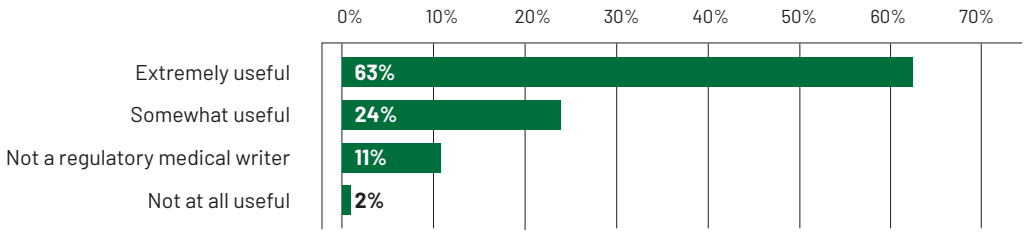

Figure 6. Overall usefulness of the CORE Reference Project to regulatory medical writers

medical writers, 7 were "other" – namely teacher, QA and GCP auditor, vice president of global clinical operations, PV writing managerial role, clinical trials project manager, clinical documents medical writer, and clinical QA senior manager.

Discussion

Uniqueness of CORE Reference among available resources

Integrated CSRs and their appendices are not necessarily destined for a CTD-compliant regulatory drug submission dossier, which will be reviewed by a regulatory authority before a decision on granting the product license is made. This is because many drugs involved in clinical studies eventually fail during clinical development. The development of these products may be terminated, and these clinical studies never progress to a product submission. A CSR written for each clinical study must stand alone for review by regulators, sponsors, investigators, investors, and other interested parties. A standalone CSR contains full description of the study and includes source tables, figures, listings, and all appendices necessary to understand the study context with minimal cross-references to other external documents. In the EU, certain clinical study documents, including the CSRs, are now required to be publicly disclosed. When the CSR stands alone and is not part of a drug submission dossier (and any EU participants are included), public disclosure takes place through the Clinical Trial Information System portal of the EU Clinical Trial Regulation; if the CSR eventually forms part of a European drug submission dossier, its public disclosure will take place through the EU Policy 0070 portal. Canada has a similar system to publicly disclose standalone and dossier submission CSRs through their equivalent portal. CORE Reference provides clarifications on how to interpret verbiage within ICH and regional guidance that is difficult to understand or is ambiguous, guiding writers in making informed choices to produce a CSR fit for reporting their study. The overwhelming majority of respondents in the 2023 survey found the CORE Reference resources extremely or somewhat useful in preparing disclosure-ready CSRs.

> There were positive responses about the usefulness of the CORE Reference Project amongst regulatory medical writers – 63% of the respondents found the CORE Reference Project extremely useful.

CORE Reference pre-dates the TransCelerate CSR template by 2.5 years, and is cited as a source for its development.[4] As well as supporting the standalone and publicly disclosable CSR need, CORE Reference is the only resource that incorporates clarifications on particular regulatory guidance or legislation applied to granular CSR content requirements. Key to understanding the value of CORE Reference to the community is that large pharmaceutical companies, which house their CSRs within complex, closed document management systems, are not the only clinical study sponsors – and they do not own all products from inception right through to licensing. Sponsors also include biotech developers, investigators, and charities, whose less elegant and agile systems may inadequately support content reuse and document linkage within the closed system and externally, for example, if the product changes hands. In the preparation of full submission dossiers, TransCelerate templates for protocols and CSRs, their content reuse solutions, and cross-talk among different documents within the submission are undoubtedly useful to the sponsor and regulator. When CSRs need to stand alone – which at some point in the product's development, they all must – extensive content reuse and hyperlinking cannot always adequately serve the needs of the mixed audience. In particular, the TransCelerate CSR template may not serve the needs of sponsors outside of large pharmaceutical companies well, including even the larger CROs who need flexibility in their reporting template to service a wide range of client types.

Value of CORE Reference in the age of artificial intelligence

The value of CORE Reference as a training tool is confirmed from the survey with more than a third of users using it to train others. With the increasing rise of artificial intelligence (AI) tools and platforms to generate CSR data and texts, AI tool developers rely on the expertise of knowledgeable medical writers who understand the content requirements of disclosure-ready CSRs and must use that knowledge to prompt the AI tools to output the correct content. Concerns around safe and effective T&D will only increase as AI tools are fed more clinical data. The role of the medical writer will evolve from de novo content creator to preparing expert-led prompts and critical review in the process of developing AI-generated CSR texts. Medical writers owning these parts of the process will reduce the potential for AI hallucination and ensure continued trust in regulatory documentation. CORE Reference stands apart from other open-access resources – including guidance and templates – with its unique clarifications that aid interpretation and understanding of reporting and public disclosure requirements, which help medical writers to confidently evolve their skillset to support innovation, which includes an onslaught of AI tools used to create texts.

CORE Reference as self-directed learning resource

Awareness of new clinical study reporting requirements since May 2016 is necessary to ensure current reporting keeps pace with regulatory developments. CORE Reference was designated an EMWA Special Project in 2022 to support expansion of CPD for medical writers through ongoing surveillance of the rapidly evolving regulatory reporting and public disclosure landscapes. To this end, CORE Reference regularly distributes a distillation of recently released new information to regulatory medical writers and other interested parties. This open-access, bi-monthly news content dissemination within the community is also unique to the CORE Reference Project, and this level of CPD for regulatory medical writers engaged in clinical study reporting, to our knowledge, is not provided, globally, by any other project. In the feedback, more than three quarters of respondents found the bi-monthly news summary either extremely, or somewhat, useful. Interestingly, although 45% of the respondents declared they were unaware that the CORE Reference Project provides regulatory reporting and public disclosure updates as CPD, 73% of the respondents were already subcribers to the bi-monthly news summary. We recognise that information overload is a common problem in today's workplace. Therefore, the discrepancy in the number of subscribers who are aware of their subscriptions could be indicative of the current high-speed and demanding work environment. However, the CORE Reference Project Team would like to emphasise that regulatory medical writing professionals who review, appraise, and evaluate the information provided in the bi-monthly news summary will keep up to date with the latest industry-specific developments and in doing so will be undertaking self-directed CPD learning, which is part of a medical writer's holistic training to enhance skills and knowledge of new developments.

With fewer than 10% of the respondents identifying as working in the T&D space, there is scope to better target and reach this group of professionals for whom both the user manual and the CPD have direct relevance. As the T&D sector grows, professional networking with T&D experts should increase to allow for the exchange of insights regarding what this group finds beneficial, while concurrently spreading knowledge about the CORE Reference Project. Sponsors outside of "big pharma" have wide-ranging regulatory knowledge in preparing disclosure-ready documents. T&D consultants will find value in the CORE Reference manual and CPD materials in providing the full spectrum of public disclosure-related insights to such clients. As multi-regional clinical trials increase, clinical data are shared among regions with differing regulations, increasing the need for an expanded knowledge base for T&D specialists. The CORE Reference CPD T&D offering supports the needs of T&D experts in this respect.

> CORE Reference stands apart from other open-access resources … with its unique clarifications that help medical writers to evolve their skillset, especially in the face of AI.

Limitation of the 2023 survey

Limitations of the survey include the absence of question(s) about the usefulness of the medical devices information included in the bi-monthly news summary. At the time of the 2023 survey development, the CORE Reference Project Team concentrated their efforts on interrogating the usefulness of the established CORE Reference resources including the user manual, mapping tool, and the CPD resources. From the survey responses, we found only 3 respondents who identified as writing medical devices documentation or worked for a medical device manufacturer. Prior to March 2024, the accelerating developments in the regulation of medical devices were captured more broadly. This extensive archive of regulatory information for medical devices writing professionals is available to that point in time. Since March 2024, more nuanced medical devices content is presented in the news summary to better align with the CORE Reference Project's aim to provide CPD in the T&D space. This ensures that developments in medical devices regulations that impact reporting in drug-device studies, including those with in vitro devices, are not missed by professionals in the medicines and devices fields. To achieve this, the "Medical Devices" subsection of the news summary has been honed to focus on transparency concerning medical devices and the emerging intersection of the medical devices and drugs spaces.

Conclusion

The results of the CORE Reference 2023 Utility Survey show the CORE Reference open-access manual continues to be perceived by the regulatory medical writing community as a useful tool when preparing disclosure-ready CSRs. It is encouraging to see that since the 2017 survey more medical writers are using the CORE Reference manual as an unofficial reference tool and to author CSRs, and that there is a slight increase in its usage to prepare CSRs submitted to Asian health authorities. The majority of respondents are subscribers of the CORE Reference bi-monthly news summary who find this useful.

The CORE Reference Team hopes the 2023 Utility Survey results allow readers to find out about how the CORE Reference manual and CPD resources have been used and perceived so far, and to increase the awareness for the regulatory medical writing and transparency and disclosure communities about the availability of the CORE Reference resources as valuable tools for their work and professional development.

Acknowledgements

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Disclosures and conflicts of interest

The authors declare no conflicts of interest.

Data availability statement

The 2023 Utility Survey questionnaire is appended at the end of the article. Raw data are available to download from the CORE Reference website (https://core-reference.org/core-reference-2023-utility-survey-all-responses/). Researchers who plan to reuse these data should email contact@core-reference.org and provide a concept for data reuse and make reference to this article in any publication in which these data are used. Re-use of these data is by a priori written permission from CORE Reference.

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Google Scholar profile Alison McIntosh: https://scholar.google.com/citations? user=4LBUEQ8AAAAJ&hl=en&oi=sra

Vivien Fagan has 28 years' of experience in a global CRO of which 25 have been in regulatory medical writing. In her current position, Vivien manages a team of UK/European Medical Writers and a group of Disclosure Specialists based out of India. Vivien was a member of the EMWA-AMWA group who delivered the open-access www.core-reference.org in May 2016. On the topic of CORE Reference, Vivien is an EMWA Workshop Leader, DIA panellist and a member of The CORE Reference Project committee. In more recent years, Vivien has been an Expert Seminar Series presenter on the topic of the EU CTR/CTIS.

Sam Hamilton, PhD, is a postdoctoral virologist, pharmaceutical industry professional since 1994, and a regulatory medical writer since 1998. She has supported pharmaceutical, CRO, and biotech clients through her writing activities and CRO leadership. Sam is currently consulting, with a special focus on regulatory MW strategy and education. Sam is an EMWA Past President, EMWA Fellow, and Chair of the EMWA-AMWA CORE Reference Project (www.core-reference.org; an open access resource to support authoring of disclosure-ready CSRs).
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Appendix. CORE Reference 2023 Utility Survey – Questionnaire

1. What type of organisation do you work for?
- ☐ Large Pharma
- ☐ Mid-size Pharma
- ☐ Small Pharma/Biotech
- ☐ Contract research organisation – Large
- ☐ Contract research organisation – Mid-sized
- ☐ Contract research organisation – Small CRO
- ☐ Freelance
- ☐ Government/Regulatory Authority or Agency
- ☐ Academia
- ☐ Charity organisation
- ☐ Other (please specify)

2. What is your role?
- ☐ Regulatory Medical Writer
- ☐ Medical Writer – medical communications
- ☐ Regulatory Affairs Specialist
- ☐ Transparency and Disclosure Specialist
- ☐ Medical Writing Managerial Role (for example Manager, Associate Director, Director, Senior Director or above)
- ☐ Other (please specify)

3. What region do you prepare documents for? Select all that apply.
- ☐ USA
- ☐ Canada
- ☐ Europe
- ☐ Asia-Pacific
- ☐ Other (please specify)

4. How have you used the CORE Reference open access manual? Select all that apply.
- ☐ Downloaded only
- ☐ Incorporated into SOPs/policies/templates
- ☐ Used as an unofficial reference tool
- ☐ Used to author CSRs
- ☐ Used to identify privacy-related risks associated with CSRs
- ☐ Used to train others
- ☐ Other (please specify)

5. How have you used the CORE Reference mapping tool? Select all that apply.
- ☐ Downloaded only
- ☐ Incorporated into SOPs/policies/templates
- ☐ Used as an unofficial reference tool
- ☐ Used to author CSRs
- ☐ Used to train others
- ☐ Other (please specify)

6. How useful do you consider the CORE Reference resources when preparing disclosure-ready CSRs?
- ☐ Extremely useful
- ☐ Somewhat useful
- ☐ Do not prepare disclosure-ready CSRs
- ☐ Not at all useful - please specify and explain why

7. Are you aware that the CORE Reference Project also provides Continuous Professional Development (CPD) for medical writers by surveillance of regulatory reporting and public disclosure landscapes?
- ☐ Yes
- ☐ No

8. Have you subscribed (https://www.core-reference.org/subscribe) to receive the free CORE Reference CPD news summary email updates in real time on www.core-reference.org?
- ☐ Yes
- ☐ No

9. How useful are the real time CORE Reference bimonthly free email news summary updates for your CPD?
- ☐ Extremely useful
- ☐ Somewhat useful
- ☐ Do not subscribe to the free bimonthly news summary email updates
- ☐ Not at all useful - please specify and explain why

10. Have you accessed the archive of CORE Reference news summaries and news items on https://www.core-reference.org/news-summaries/ that support the CPD needs of regulatory medical writers?
- ☐ Yes
- ☐ No

11. In your role do you need to know about the regulatory reporting and public disclosure landscapes in Asia?
- ☐ Yes
- ☐ No

12. Overall how useful are the regulatory public disclosure (RPD) updates from Asia to you in your role?
- ☐ Extremely useful
- ☐ Somewhat useful
- ☐ Do not need to know about RPD in Asia
- ☐ Not at all useful - please specify and explain why

13. Overall how useful is the CORE Reference Project to you as a regulatory medical writer?
- ☐ Extremely useful
- ☐ Somewhat useful
- ☐ Not a regulatory medical writer
- ☐ Not at all useful - please specify and explain why