Global and multidisciplinary perspectives on collaboration with medical writers

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Abstract
Medical writers, document quality reviewers, and document specialists work together to produce high-quality clinical and regulatory documents. Cross-functional collaboration with other functional leads like biostatisticians, medical monitors, and project leaders is also crucial for timely project delivery. We interviewed people in these roles who emphasised that clear communication, setting clear expectations, addressing challenges proactively, and leveraging digital tools are all needed for successful cross-functional and cross-regional collaboration. Understanding different perspectives and roles, practicing active listening, and being mindful of time zones and cultural differences are also important when working in multidisciplinary and global teams. Overall, effective collaboration leads to better outcomes and competitive advantage in medical writing.

Cross-functional and cross-regional collaborations bring together diverse skills and perspectives across multiple fields of expertise. They foster innovation, enhance problem-solving, and promote groups to work towards a common goal, leading to better outcomes and competitive advantage. In this article, we explore diverse outlooks from some of the most common roles who work with medical writers as well as medical writers themselves for a wholesome perspective on strong and sustainable collaborations.

Collaboration within the medical writing sphere
In this section, we provide insights into some of the different roles within medical writing, their main responsibilities, and how they collaborate with others. These roles may be termed differently and may have slightly varying responsibilities across organisations.

Medical writer
Medical writers develop a variety of regulatory documents throughout the lifecycle of a product (e.g., clinical study protocols [CSP], informed consent forms [ICF], and clinical study reports [CSR]), including after a product is on the market (e.g., post-marketing surveillance or safety aggregate reports). Besides the main responsibility of authoring, medical writers employ a variety of hard and soft skills, including project management, communication, collaboration, and time management.[1] Moreover, they possess an in-depth knowledge of medical concepts, therapeutic areas, industry best practices, and attention to detail, and ensure the accuracy of data and compliance with quality and regulatory requirements. Medical writers generally use a combination of collaborative authoring strategies during document development with internal and external cross-functional teams for inputs and review of clinical and regulatory deliverables.[2]

Document quality reviewer
Document quality reviewers primarily collaborate with and act as a strong support to medical writers towards ensuring first-time quality in each stage of clinical and regulatory document review. The main role of document quality reviewers is to facilitate the timely delivery of error-free, high-quality medical writing documents by identifying errors in grammar, style, syntax, and format according to applicable style guides and conventions. They also ensure the accuracy, logic, and overall flow of the clinical data and content presented. Performing a high-quality review necessitates knowledge of regulatory requirements and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (GCP), as well as a deep understanding of the clinical research and drug development processes.

Document specialist
Document specialists work closely with medical writers to ensure that clinical and regulatory documents are ready for submission. The prime task of the document specialist is to guarantee consistent formatting and styles across templates. Moreover, they ensure that documents adhere to international regulatory document standards (e.g., ICH Electronic Common Technical Document [eCTD] specifications) and are easy to read and navigate. Document specialists assist in the accurate documentation of references and citations and may utilise reference management software to streamline the citation process. Normally, document specialists enable effective collaboration among cross-functional teams involved in compiling appendices/documents by coordinating timelines, milestones, and deliverables to ensure efficient workflows and timely completion of document-related tasks. They also ensure compliance with applicable client policies, company procedures for publication, and regulatory submission.

Mastering the art of internal collaboration
We reached out to our colleagues in different medical writing roles at Parexel about their take on internal and cross-functional collaboration, as well as collaboration across geographical borders and cultural barriers. Their unique answers and perspectives are presented in Box 1.

Communication is key
While document quality reviewers and document specialists primarily collaborate within the medical writing sphere, medical writers act as a bridge between the medical writing unit and

Figure 1. Common roles within the medical writing sphere and functional leads medical writers frequently collaborate with

other functional leads. (See Figure 1.) No matter the role, establishing transparent communication and addressing project risks up front are the keys to success. Furthermore, as our interviewees stressed, practicing active listening, clarifying uncertainties, and learning from one another are of the utmost importance to successfully managing your medical writing project.

Cooperation across a functional spectrum

Medical writers often need to cooperate with other functional leads such as biostatisticians, medical monitors, or project leaders (a.k.a clinical project managers). This cooperation can take place within the same company or, in the case of medical writers working at a contract research organisation, with the functional leads of the sponsor. In this section, we describe some of the most common cross-functional roles that medical writers interact with. These roles may be termed differently and may have slightly varying responsibilities across organisations.

Biostatistician

Biostatisticians play a significant role in all stages of clinical research, from designing robust studies, monitoring data integrity, and performing statistical analyses that are crucial for making informed decisions (e.g., about the effectiveness and safety profile of the study intervention) and advancing the field of clinical research.[3] One of their primary responsibilities is contributing to study design. Biostatisticians help determine appropriate sample sizes, develop randomisation techniques, and establish control groups, ensuring that the study will generate reliable and valid results. During a clinical study, biostatisticians monitor data management processes to ensure data integrity. They review data quality, identify anomalies, and address missing data issues. Additionally, they assist in detecting safety signals and evaluating the efficacy of the intervention. Biostatisticians are also responsible for selecting and performing statistical analyses to draw meaningful conclusions from the clinical study data. They utilise various statistical methods such as hypothesis testing, regression analysis, and survival analysis to analyse the data and determine the statistical significance of the study findings. This analysis helps make evidence-based decisions about the safety and effectiveness of the interventions being studied.

> Adopt an open mindset and try to learn from each other as much as possible.

Medical monitor

Medical monitors are responsible for ensuring participant safety and well-being throughout the duration of a clinical study.[4] Their primary role involves overseeing the proper implementation of the CSP and ensuring compliance with regulatory guidelines. Medical monitors closely monitor participants, evaluate adverse events, and recommend CSP modifications if necessary. With their extensive medical and therapeutic knowledge, medical monitors provide expertise in study design, patient eligibility, and risk management. They collaborate with various stakeholders, including investigators and project leaders, to ensure the smooth execution of clinical studies. Medical monitors also play a significant role in data review and analysis, ensuring data integrity and supporting the interpretation of study results. They actively contribute to the safety and success of clinical studies, bringing potential life-saving treatments to patients while adhering to ethical and regulatory standards.

Project leader

Project leaders are essential in clinical research as they oversee and manage all aspects of a clinical study.[5] Their primary responsibilities include coordinating and managing various stakeholders involved in the study (such as the study sponsor, investigator[s], internal team members, and external vendors) and ensuring adherence to CSP and regulatory guidelines. Project leaders play a crucial role in project planning, establishing timelines, and allocating resources. They are responsible for monitoring study progress, managing budgets, and addressing any

issues that may arise during the study.

Additionally, project leaders are responsible for maintaining quality standards, ensuring data accuracy, and upholding ethical considerations in clinical research.

Navigating success in global and cross-functional teams

We also reached out to collaborators from other functions at Parexel and sought their input on working with medical writers. Unique answers and perspectives from representatives in different roles outside of medical writing at Parexel are presented in Boxes 2 and 3.

Maximising synergy in global teams

In general, biostatisticians, medical monitors, and project leaders cooperate with medical writers during the development or review of the study synopsis, CSP, ICFs, CSR, or other clinical and regulatory deliverables. As mentioned by the interviewed functional leads, to increase project success, medical writers should go through therapeutic area training in advance (which is commonly conducted for product- and client-specific projects at contract research organisations), clarify the purpose of the deliverable, and ensure team members have the correct link to work on the latest draft of a document. Although time zone differences may pose challenges at times, global teams can also use them as an advantage during document review cycles when possible.

Box 1. Medical writing perspectives on successful cooperation

Question 1: When and with which roles do you normally collaborate?

Mary Burder, Principal Medical Writer, USA:
"Internal collaborations are with other medical writers on my team. External collaborations within the company are with clinical, safety, regulatory, clinical pharmacology, and statistical team leads."

Sneha Salgar, Principal Medical Writer, India:
"As a medical writer for pharmacovigilance authoring, I typically collaborate with safety experts, regulatory specialists, scientists, project leaders, and other medical writers and document quality reviewers."

Martina Grigat, Senior Medical Writer (currently a member of the document quality review group), Germany:
"For every quality check (QC) task, the main point of contact is the lead medical writer. If it is a collaborative QC (involving several medical writers), coordination between the quality reviewers is essential. Additionally, depending on the QC and its scope, I sometimes need to interact with drug safety physicians, medical monitors, and biostatisticians."

Pieter Visser, Lead Document Specialist, South Africa:
"As a document specialist team, we have a dynamic and adaptable collaboration with various roles throughout the document lifecycle. These include medical writers for ensuring proper formatting and the availability of internal and external links for document navigation; cross-functional teams from clinical operations, data management, biostatistics, pharmacokinetics, regulatory affairs, and safety/pharmacovigilance for review and input on appendices for various document types; project leads for project timelines and tracking; and sponsors of clinical studies and regulatory authorities for document formatting and submission requirements, respectively."

Question 2: What is your best tip for collaborating internally within medical writing and with external stakeholders/teams?

James Wolfe, Vice President of Medical Writing Services, France:
"In my experience with medical writers, most have been more introverted in their approach to leading their projects. Good medical writers need to marshal and guide their team of stakeholders. As everyone is different, it is essential to understand what is needed to develop writers to become good leaders."

Alexandra Wal, Medical Writer, Germany:
"Good and concise communication; emails should be as short as possible and clearly point out the most important aspects to consider without any room for mis-interpretation."

Karina Kordalewska, Associate Medical Writer, Poland:
"For internal collaborations, I recommend adopting an open mindset and trying to learn from each other as much as possible to gain a fresh perspective on writing and project handling styles."

Kavita Muchandi, Senior Principal Medical Writer, India:
"Setting clear expectations, monitoring, and patience are key to a successful collaboration. For example, if we need input from stake-holders, then the background, the parameters for which feedback is solicited, the timeline by which the feedback is required, and the format or collaborating platform, if applicable, need to be clearly communicated."

Christin Benjamin-Philander, Medical Writer, South Africa:
"Do not be afraid to ask as many follow-up questions as you need to get clarity on instructions or information. This approach prevents a lot of confusion during authoring."

Helen Wiggett, Senior Document Quality Reviewer, United Kingdom:
"Make use of available digital collaboration tools to make working collaboratively on a document easier and make sure you set up clear communication channels (e.g., Microsoft Teams) to ensure everyone is on the same page and kept informed throughout the process."

Pieter Visser, Lead Document Specialist, South Africa:
"My best tips for collaboration include practicing active listening and asking to clarify questions. Be mindful of language barriers and use clear, simple language to ensure everyone is on the same page."

Question 3: Any advice for working in cross-functional and cross-regional teams?

James Wolfe, Vice President of Medical Writing Services, France:
"The ability to understand writers across regions and functions is crucial as we expand our horizons. Never assume and break away from the 'group think' mentality; stop and reflect on someone else's approach, motivation, and probable next steps."

Ashwini Somayaji, Senior Principal Medical Writer, India:
"Be cognizant of time zones while setting up meetings, share an agenda ahead of time, and document the understanding and action items after calls. Follow through on the action items and involve subject matter experts where specific input is required."

Yogeeta Surinderkumar, Senior Document Quality Reviewer, India:
"I believe a 'Go the extra mile' mindset of setting clear expectations through transparent communication and proactively identifying and addressing potential challenges before they become significant issues helps deliver effectively as a team."

Beate Gerstbrein, Senior Principal Medical Writer, France:
"Peers from other functions may not be as tech-savvy as medical writers are with specific tools. Reviewers may require instructions on how to open a shared Word document so that the full Word functionalities are displayed and they are able to review and comment efficiently. Where needed, explain why shared documents should not be downloaded for offline review. Moreover, set up calendar placeholders for review periods, meetings, specific deadlines, and check up front for any potential time constraints from team members."

Pieter Visser, Lead Document Specialist, South Africa:
"To facilitate learning across regions and functions, organise cross-functional training sessions or workshops and create a mentorship program."

Box 2. Cross-functional insights on effective teamwork with medical writers

Question 1: When do you normally collaborate with medical writers?

Jagrutibahen Desai, Manager Biostatistics, India:
"Generally, I collaborate with medical writers at the time of project discussions, such as when developing the study synopsis, CSP, CSR, or reviewing CSR tables/figures/ listings. I also coordinate with medical writers at the time of internal or client partnership process revision."

Zuzana Traugottova, Medical Director, Czechia:
"The most usual occasions during which I collaborate with medical writers are the development and review of protocols, ICFs, CSRs, CSR addendums, and development safety update reports."

Marque Venter, Associate Director of Project Management, South Africa:
"I primarily work with medical writers to develop master or global ICFs and at the end of a study to compile CSR appendices."

Lucy Yim, Project Leader, Hong Kong:
"Normally, I collaborate with medical writers when an ICF needs to be drafted."

Question 2: What is your best tip for collaborating with medical writing colleagues?

Amy Pace, VP Biostatistics, USA, and Angela Hu, VP Biostatistics, Taiwan:
"Effective collaboration between biostatisticians and medical writers can enhance the quality of clinical documents and should be facilitated by:

- Clear communication when reviewing documents, i.e., employ a structured review process, use consistent terminology, and tag someone using the "@" sign when requesting specific input.
- Resolution meetings if documents in development need significant revision.
- Keeping the study team informed of any changes or new information, no matter how minor."

Marque Venter, Associate Director of Project Management, South Africa:
"My advice is to engage with the medical writers as soon as possible on project scope and expected timelines and provide as much detailed information about the project and CSP as possible. Ensure that requests from the medical writer are followed up on in a timely manner or establish a direct line of communication between the medical writer and other stakeholders to easily resolve more complex questions about the CSP, disease indication, or therapeutic area."

Lucy Yim, Project Leader, Hong Kong:
"My best tip is to provide the medical writer with all the study information and details they need."

Janos Antal, VP Global Head Neurology, Hungary:
"From my point of view, it is important for medical writing colleagues to go through therapeutic area training. Furthermore, email correspondences and track changes in documents may not always resolve an outstanding issue. Therefore, it is important to remain flexible and have the option for online discussions outside of regular team meetings."

Zuzana Traugottova, Medical Director, Czechia:
"For me, the most important aspect of cross-functional collaboration is the project kick-off meeting. Medical writers should clarify the purpose of a deliverable (e.g., the study drug, which study phase, study population, etc.) and the expected timelines."

Abbreviations: CSP, clinical study protocol; ICF, informed consent form; CSR, clinical study report.

Question 3: Any advice for working in cross-regional teams?

Denis Gungor, Associate Director of Biostatistics, Germany:
"Often, there is immense pressure at the end of clinical studies where we have no options to adjust timelines without impacting final delivery. From my experience, any neglected or uncommunicated detail comes back at a later time with a much bigger overhead and magnified impact. Hence, team members must stay in close touch to ensure project quality and timely delivery of clinical documents. Efficient communication without any gaps is of utmost importance when working in cross-regional teams."

Zuzana Traugottova, Medical Director, Czechia:
"Collaboration on a shared clinical document is crucial. Medical writers need to ensure team members have the correct link to work on the latest draft and that comments clearly demarcate the text they are referring to."

Marque Venter, Associate Director of Project Management, South Africa:
"When working in global teams, use time zone difference as an advantage during document review cycles when possible."

Lucy Yim, Project Leader, Hong Kong:
"Regarding collaboration across regions, respect time zone differences and set a reasonable timeline. To speed things up, call your colleague directly instead of emails."

Abbreviations: CSP, clinical study protocol; ICF, informed consent form; CSR, clinical study report.

Box 3. Practical tips on collaborating across roles and functions in international teams

Box 3a: Insights from medical writing peers

Document specialist
Practice active listening and clarify uncertainties up front. Be mindful of language barriers and use clear, simple language to ensure everyone is on the same page.

Document quality reviewer
Use digital tools to enhance collaborative document authoring and make sure you establish clear communication channels.

Medical writer
Know your remit and set clear expectations, anticipate risks, and prepare mitigation plans. Be mindful of time zones and cultural sensitivities for cross-regional collaborations.

Box 3b: Thoughts from frequent collaborators of medical writers

Biostatistician
Keep the study team informed of any changes or new information, no matter how minor.

Medical monitor
Medical writers should clarify the purpose of a deliverable (e.g., what the study drug is, which study phase, study population, etc.) and what the expected timelines are.

Project leader
When working in global teams, use time zone difference as an advantage during document review cycles when possible.

Conclusions

Based on the answers we received from internal medical writing colleagues as well as peers from other functions, successful collaboration requires a combination of supportive leadership, clear communication channels, shared goals, and cultural sensitivity. While challenges such as time zone differences and diverse work styles may arise, medical writers who foster a collaborative environment and maintain cooperative relationships are better positioned to succeed with projects requiring global teamwork. Ultimately, embracing cross-functional and cross-regional collaboration is not just a strategy but a necessity for long-term success in the medical writing field.

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The opinions expressed in this article are the authors' and interviewees' own and not necessarily shared by their employer or EMWA.

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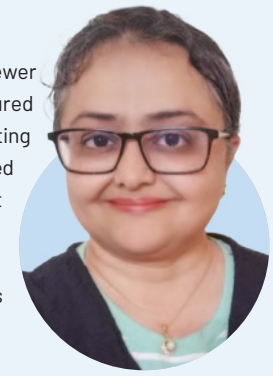

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