

Managing protocol development with international teams:

Soft skill perspectives from a global team of protocol writers

Jonathan Mackinnon¹, Anuradha Alahari²,
Leo Daffue³, Wiebke Griemberg⁴,
Mati Kargren⁵, Chris Matthews⁶,
Kavita Muchandi⁷, Gunnar Schilling⁴

¹ Parexel International S.L., Madrid, Spain

² Parexel International, Paris, France

³ Parexel International (Pty) Ltd, Bloemfontein,
South Africa

⁴ Parexel International GmbH, Berlin, Germany

⁵ Parexel International Co., Ltd., Taipei, Taiwan

⁶ Parexel International, Durham, NC, USA

⁷ Parexel International, Bengaluru, India

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Correspondence to:

Jonathan Mackinnon

Jonathan.Mackinnon@parexel.com

Abstract

Clinical trial protocol development forms part of the critical path for launching a trial, which means timelines are tight and progress must be fast and sustained throughout the protocol's development. In order to be successful, medical writers require well-developed soft skills to meet the needs of the trial team and to produce a high-quality protocol. We focus on five critical soft skills that are essential for medical writers working with international teams: critical thinking, leadership, communication, teamwork, and adaptability. Based on our experience as a global team of protocol subject matter experts from Asia-Pacific, Europe, India, South Africa, and the US, we also discuss soft skills that are important for working with team members across different regions.

Like many professions, it is important for medical writers to have both hard and soft skills to be successful.¹ There are too many soft skills that are integral to medical writing to cover in one article so we will focus on standout skills needed for protocol development. Notable skills that we consider fundamental for professional development as a medical writer (and therefore are not covered in more detail here) include *work ethic*, *creativity*, and *time management*. Certainly, having a reliable and disciplined work ethic is crucial. Similarly, creativity and time management are important and defining characteristics of medical writers, each applied in their own way to the document at hand.

For protocol development, we consider five soft skills (Figure 1) that stand out as critical to meet the needs of the trial team and to produce a high-quality protocol; we also recognise that soft skills are not one-size-fits-all and cultural elements must be considered when approaching a multinational trial team.

To set the scene, protocol development forms part of the critical path for launching a trial, which means timelines are tight and progress must be fast and sustained throughout the protocol's development. A further challenge for contract research organisation (CRO) medical writers is that there are often at least two teams involved – the “product team” (usually the client team representing the trial sponsor) and the “operational team” (internal CRO team comprised of various functional area members). Combined, this means that our starting point for protocol development is a document that needs fast development with a trial team that has not yet fully established collaborative bonds.

Skills across borders – which skills help to engage multicultural teams

Critical thinking

Critical thinking is a central tenet of medical writing; core critical thinking skills include interpretation, analysis, evaluation, inference, explanation, and self-regulation.² Like other document types, critical thinking for protocol development includes tangible skills such as analysing relationships between content and expressing information in a way that is understandable to a diverse audience of protocol readers. By contrast, intangible skills are related to people- and project-management and are important as medical writers need to constantly seek relevant and precise information at a time where details may be limited, as well as discuss and reach agreement on outstanding issues within the team.

How tangible and intangible skills come together will depend on the protocol setting. Where medical writers can particularly provide benefit is to critically interpret information in the context of the whole protocol and make sure that the team members agree. For example, imagine a scenario in which the trial objectives have changed and a team member has chosen to “copy-paste” legacy content from a prior protocol. Upon inspection, the legacy content is on the right subject but the reasoning behind it is in conflict with the current scope of the trial. In such circumstances, the medical writer must work with the relevant team members to understand what is needed and how they can harmonise the content to all team members' satisfaction. In order to achieve this, the writer needs to understand how the content is linked and who needs to be involved in reaching a consensus.

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Leadership

In team-driven document development, leadership is a critical soft skill³ as it makes the difference between whether the team is steered towards completing the document on time vs. extended development time that absorbs significant effort from the team.

Leadership for a medical writer is a challenging skill as it requires the writer to establish a leadership role in an environment where there are already parallel formal leadership roles, such as project leaders or functional area leaders. For example, one common complication for protocols, in particular, is that document development often occurs in parallel to team formation, thus giving the medical writer two challenges in one – getting the team working together and developing the protocol. To overcome this, the medical writer must be able to coordinate input while simultaneously building trust with formal project leaders and key team members.

In our experience, leadership overlaps strongly with communication as initial engagement helps build trust in the team, confidence in approaching the task, and establishes communication lines. Once achieved, the medical writer needs to guide the team in identifying and



resolving obstacles so that progress momentum is maintained. Ultimately, these efforts coalesce into “managing expectations” – namely, if the reviewers are expecting a complete protocol at the first draft stage but are hesitant to provide

input or make decisions, the medical writer needs to communicate the risk of the team reviewing an incomplete protocol at Draft 1, thus risking additional review rounds and extending the development timelines.

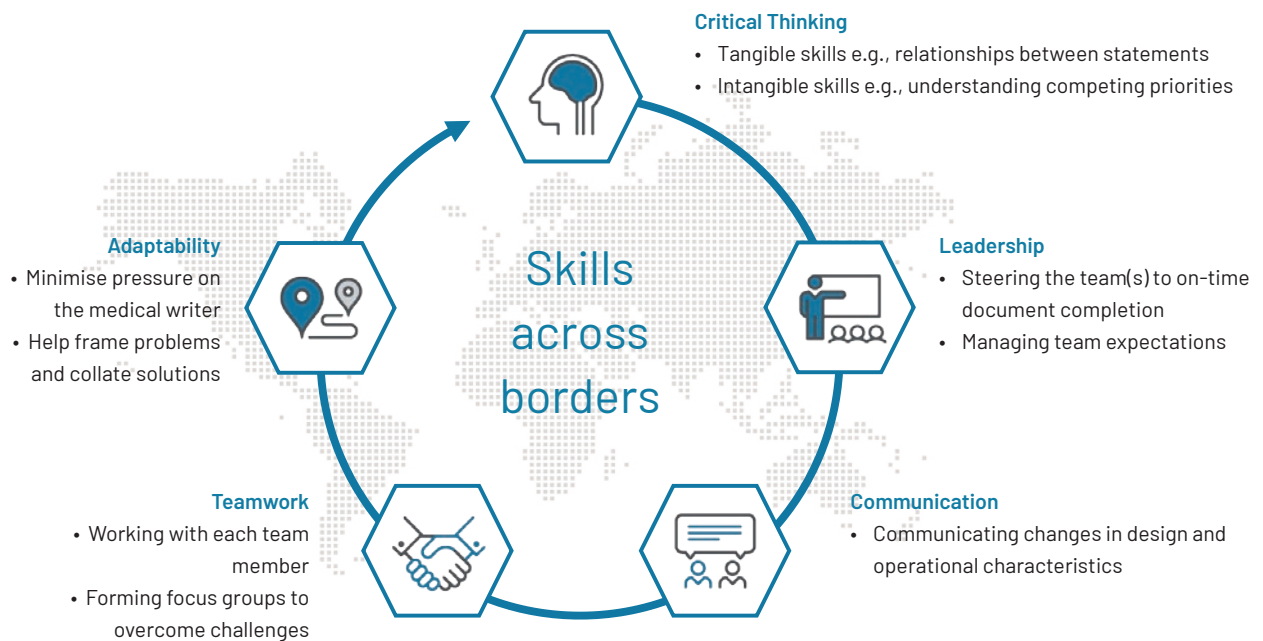


Figure 1: Essential soft skills for protocol development

Communication

Another hallmark of medical writing is strong communication skills,³ a competence that is often cited as critical for team satisfaction with the protocol development process. Building on the leadership soft skill above, managing expectations is a vital part of protocol development as the trial design matures and the team agrees on scientific and operating priorities. For example, it is not uncommon for teams to visit, and then revisit, key design and operational concepts. In extreme cases, entire designs can change during

the course of the protocol's development. Communicating these developments is key to avoiding misaligning expectations when it comes to the team's review. If done successfully, the medical writer can gain momentum with the team (e.g., flag in a timely manner that the draft cannot be completed without the required information, which will likely result in further downstream finalisation delays). If unsuccessful, the medical writer can damage their credibility in the eyes of the team members – further risking the timely completion of the protocol.

Teamwork

The number of team members required to be involved in protocol development continues to increase. New roles such as risk management, patient-reported outcome experts, patient representatives, diversity expertise, and data science join the well-established functional roles such as medical doctors, clinical operation leaders, biostatisticians, and data managers. Social interaction and awareness during development-related tasks such as demonstrating problem-solving or conflict resolution management in

Regional skills

Following our global skills above, some of the authors have provided perspectives on which skills they perceive as being important for the region they are based in. For those who are new to working with teams within these regions, taking note of some of these attributes may help you rapidly build trust and accelerate the start of your protocol development.

Asia-Pacific

Mati Kargren: Based on my experience working with clients in Asia-Pacific (APAC; e.g., Japan, mainland China, Hong Kong, Taiwan, Malaysia, or Singapore), *work ethic* is highly valued in the region. Asian colleagues and sponsors are particular about being on time. Optimally, when conducting a meeting with Asian colleagues or sponsors, you want to join the meeting a few minutes early to demonstrate that you are punctual and reliable. This is especially important when meeting sponsors for the first time, such as during a protocol kick off meeting.

On the contrary, even though you are expected to be punctual when interacting with Asian peers, you have to exert a greater degree of *flexibility* in terms of completing project work in the given timeframe. For example, when completing adjustments to country-level protocols (originating from global protocols), APAC clients more often than not expect you to put in extra hours to reach the deadline rather than extend the timelines.

Last but not least, clear *verbal and nonverbal communication*, and *cultural awareness* are important when facing APAC peers. Even though English is the modern-day lingua franca, not everyone has the same level of exposure or fluency in the language; accommodating for this through patience, repeating information to ensure correct understanding, and written

follow up can help ensure a productive working relationship.

Europe

Wiebke Griemberg: *Effective communication* plays an important role in Europe's diverse and multicultural work environment. Thinking ahead and understanding the needs of the team members, especially based on regional and cultural background, helps to drive good and effective communication. Not only in Europe, but generally in a global team setting, strong communication skills are particularly important to bridge cultural and language barriers.

However, the most significant soft skill is *adaptability*. Due to the diverse backgrounds in multicultural teams, adaptability is a great asset and enables you to navigate uncertainties, overcome setbacks, and effectively respond to evolving project requirements. Being open to new ideas and approaches, embracing change (e.g. from unexpected requests to timeline changes), recognising cultural awareness and sensitivities, or adjusting working styles to suit team members' needs all contribute to improved collaboration and engagement.

Gunnar Schilling: Working with a European client does not mean that all team members are located in Europe and even if they are from the same country, you can expect to encounter multicultural backgrounds from all over the

world. This European diversity has become more common over the past 25 years and at the same time has become less noticeable in the way we communicate, collaborate, and solve problems. In addition, there are certainly still country- and client-related differences in the way that people work and interact internally and with us as CRO medical writers, including the way they see us as an integral part of the team or more as contractors. It can be challenging to adapt our behaviour to the team's expectations right from the start of a protocol, but this is required if the protocol is to be completed successfully.

Anuradha Alahari: I agree that recognising cultural differences and *adapting* our working habits accordingly is important, especially in a service provider community like CROs. Medical writers should be cautious not to let the knowledge about a person's origin trigger stereotypical biases and prejudice. I try to avoid allowing my judgement to be clouded by such biases. To give an example of a cultural difference, after working in India and the US in academic fields, when I first started working in France as a medical writer, I used to be pleasantly surprised when people would thank me for what I considered was simply part of my job and sometimes just a minor task! Valuing each other's efforts and contributions helps team building.

relation to competing priorities or perspectives require strong teamwork skills.⁴ In our opinion, strong collaborative skills involve engaging each team member individually rather than coordinating activities through formal power structures led by project leaders. As team members work on multiple activities in parallel, it is often tempting to delay or attempt to defer decisions until a more opportune time – not necessarily considering the impact that this has on the overall protocol development timeline. Bringing together relevant team members

individually or in small focus groups to overcome challenges helps to make team work more dynamic and can further the protocol's development.

Adaptability

A key feature of protocol development is that it frequently brings unexpected challenges, thus requiring the medical writer to be adaptable to emerging situations.⁵ Being able to listen, understand issues, solve problems, and being resourceful when addressing challenges are ways the medical writer can demonstrate adaptability.

First and foremost, an adaptable mindset helps medical writers sustain a healthy working cadence, and secondly, helps diffuse the pressure and tension that can build up around project-related issues. For example, when a team gets stuck in decision loops with constant back-and-forth communication on outstanding items, trust in the team's perception of their ability to complete the task is eroded and introduces team fatigue. Medical writers who are confident in adapting to evolving situations can help teams stay on track by framing the challenge and collating solutions from collaborators.

Conclusions

In modern clinical trial protocol development, soft skills are an essential part of a medical writer's professional development. We consider *critical thinking*, *leadership*, *communication*, *teamwork*, and *adaptability* to be critical for modern protocol development. We also recognise that different regions have additional cultural values that enrich the collaborative task of protocol development. By highlighting some of the key skills we hope that this may help medical writers work with team members from the respective regions.

Disclaimers

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

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

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India

Kavita Muchandi: In my experience, *teamwork* and *adaptability* are two key soft skills in the context of authoring protocols for clients and teams in India. Protocol development timelines are generally short in this region, with the intent of speeding up the start of a trial. Many times, protocol development is expected to start based on available (and sometimes incomplete) sources, keeping placeholders for open items, and adjusting the content in light of new information or change in strategy. A medical writer's ability to collaborate with the team to obtain input and facilitate decision making to steer towards protocol timelines is important.

While *flexibility* is perceived as a positive attribute within the team, *problem-solving* helps medical writers to maintain composure under pressure. For medical writers from other regions who are to work with clients from India, cultural awareness is important. To avoid misunderstandings, it is advisable to summarise meeting decisions and action items in an email.

South Africa

Leo Daffue: South Africa has a rich history of multiculturalism, however, as a country we are not without challenges due to the many cultures, languages, and backgrounds of its citizens. South Africans as a whole need to be highly *adaptable* and *flexible*. There is rarely an answer of just "no", but rather one of "how we can make do with what we have at the moment" and then make a decision. We pride ourselves in the quality of our work, and to complete any task that is assigned. Using these traits can be extra beneficial in

almost any area of business, but especially when we are dealing with shifting timelines to name one example. As an extension of living in a multicultural country, South Africans are mostly sympathetic to how we interact with other cultures and people around the globe.

United States

Chris Matthews: US clients are typically native speakers of English, and misunderstandings, whether cultural or practical, are relatively uncommon when facing native English-speaking sponsors and colleagues. For protocol development, most communication is done via email, and US clients prefer emails that have an informal, friendly tone. For example, an email might start with "Hi" rather than an impersonal "Hello" or the very formal "Dear". For online meetings, chatting briefly with early attendees about personal topics (e.g. "How was your vacation?") or with the whole team (e.g. "Did everyone watch the Super Bowl?") demonstrates that you are interested in them, and fosters a sense of team togetherness. Whether in meetings or via email, it is important to pivot without too much delay to the outstanding issues in need of their help to be resolved.

A willingness to "go the extra mile" to complete drafts, including fulfilment of time-consuming last-minute requests, on time is expected among US clients. However, US clients recognise that you have obligations outside of work, and especially when unexpected and abstract issues arise close to a deadline, it is acceptable to let clients know that you may need more time to get them resolved.

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Author information

All authors are protocol subject matter experts within the Medical Writing Services department at Parexel International.



Leo Daffue is a Senior Medical Writer based in South Africa and supports early phase protocol development for studies conducted at Parexel's Early Phase

Clinical Units. In this role, he supports clients and other medical writers in overcoming challenges and provides targeted support for early phase protocols.



Chris Matthews is a Senior Medical Writer based in the US who mentors junior medical writers and works primarily with biotech clients.



Jonathan Mackinnon is an Associate Director based in Spain and leads a protocol specialist team within Medical

Writing Services. He regularly works with clients and other medical writers to support the development of protocols for drug development. He also teaches protocol development and trial design at the London School of Hygiene and Tropical Medicine.



Wiebke Griemberg is a Senior Medical Writer based in Germany who specialises in non-interventional study protocols and

regularly works with clients across the globe to develop trial protocols. She also provides support for a large multinational client.



Kavita Muchandi is a Senior Principal Medical Writer and a Capability Excellence Lead based in India. She

is responsible for mentoring and upskilling medical writers. She also routinely presents internally and externally on protocol development



Anuradha Alahari is a Principal Medical Writer based in France and is involved in creating job aids and best practices

for developing protocols for a major client partnership. She also mentors new joiners and medical writers for protocol development.



Mati Kargren is a Medical Writer based in Taiwan who works with clients in East Asia to develop country-specific protocols for

ethnobridging studies or to provide local requirement perspectives for global protocols.



Gunnar Schilling is a Clinical Trial Protocol Specialist and Senior Principal Medical Writer based in Germany.

He works with clients across the globe and acts as medical writing subject matter expert for a partnership with a large multinational client.