

# “Follow the Sun” writing: A hybrid operating model to optimise collaboration and efficiency

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## Abstract

Time, quality, and accuracy are of the essence for expeditious global regulatory submissions. An around-the-clock, 24/7, global medical writing model has been developed that allows efficient development of high-quality documents with appreciable reduction in time to completion. Writers work across global time zones, relaying the work accomplished during their workday to the writer in the successive workday without interruption. This also enables “rolling” continuous quality control checks. Authors can focus on messaging and content with confidence as documents are developed. Best results are achieved by proactive alignment of content and messaging, strategic assignment of tasks to suitable talent, and fostering a culture of open communication founded on trust and mutual respect.

Medical writers are perpetually challenged to meet increasingly aggressive timelines for documents, whether they are stand-alone or part of a global regulatory submission. The 8-hour workday is often insufficient to meet the progress expected and this can be compounded by time limitations of working with subject matter experts who are in different time zones. Compressed timelines increase the potential for error, burden the team with unplanned extra review cycles, add stress for the writer(s), and can result in failure to meet corporate goals.

To address this challenge, we developed an operating model to optimise use of global resources and ensure continuous coverage around the clock: The “24/7 Follow the Sun” model. While 24-hour shift schedules have been successfully employed in other industries,<sup>1</sup> to our knowledge, they have not been used in the medical writing practice. Our Follow the Sun model was designed as a novel approach to ensure continuous authoring, collaboration across the globe, and maintenance of normality of the writing team’s working hours. The goals of the model are to:

- Decrease the number of days needed to develop a document, resulting in reduced resourcing costs and reduced down-time due to non-working hours and holidays

- Optimise and improve document development efficiency by leveraging global talent across diverse geographical regions
- Provide professional growth opportunities and enhanced work-life balance for the writing team

This article describes the creation, use, and outcomes of the Follow the Sun model as experienced by a global medical writing team of writers, quality control (QC) reviewers, and document specialists (together called MWs). Our experience is with clinical Common Technical Document (CTD) modules for a regulatory submission. However, this model can be applied to other types of projects, collaborations, and document types, such as risk management plans or protocols, which are time sensitive and involve diverse teams of contributors and stakeholders.

## Building the model

### What does the model look like?

The Follow the Sun model leverages global team talent across various geographical locations to facilitate continuous progress on the project. When facing particularly aggressive timelines, medical writers (MW) located in overlapping time zones (e.g., EU between India and/or the



Figure 1. Benefits of the Follow the Sun Model



US) can play a critical role in ensuring the Follow-the-Sun model has optimal resource utilisation. Each team member completes an agreed-upon set of tasks during their workday, relaying work accomplished to the team members who will work during the next successive workday (Figure 2). This approach also makes continuous quality checks possible as the document is developed.

**What is needed to enable the model?**

**Planning**

To enable optimum outcomes, the project's scope should be set forth prior to its initiation, including goals, medical writing deliverables,

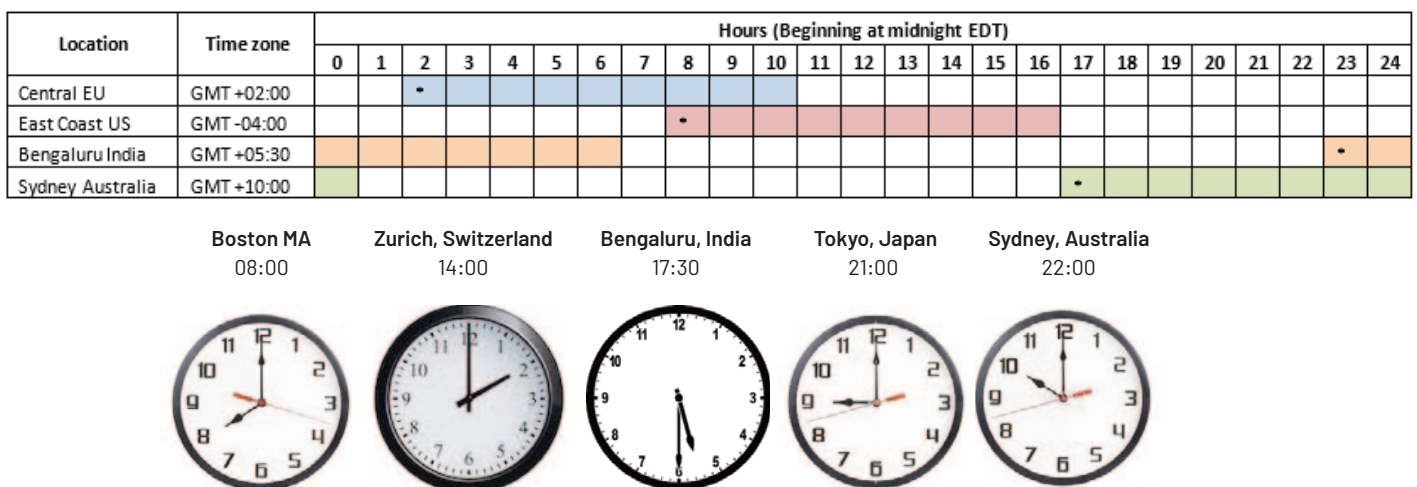
expectations, activities, tasks, and timelines. A granular timeline should be developed by the MW team to provide a detailed outline and inventory of the MW tasks required for the project, which may comprise a single document or an interrelated set of documents. This is used by the MW team to track progress of specific tasks related to the writing portion of the project and "nests" within the overall project timeline.

**Resourcing**

The MW team selected for each project should be based on their experience relative to the tasks required for document development. Document development tasks include, but are not limited

to: drafting content, creating in-text tables and figures, initiating review (peer review, subject matter expert review, or QC review), comment resolution, proof-reading and style guide checks, and formatting. Balancing skill sets relative to the timeline optimises work hours across time zones. Resourcing is scalable: depending on the status of the project, MW team members can be added or removed to ensure continuous support.

Choosing a strong leader is essential. The MW lead is responsible for coordinating all activities of the MW team. (In some cases, this role may be performed by a Project Manager. But for the purposes of this article, we will refer to the "MW lead"). The MW lead should have excellent



**Figure 2. Workday overlap across time zones**

NOTE: This example demonstrates workday overlap on a team with MW lead based on East Coast US.

diplomatic and communication skills, the ability to see the “big picture” and the finer details, and a broad understanding of the project content, strategic purpose of the document(s), and project deliverables. As the primary interface with the broader interdisciplinary project team, the MW lead should attend project team meetings, address, redirect, or delegate questions or concerns in the document that require team input, and manage the operational writing tasks. Ideally, the MW lead should be in the same time zone as the key project team members. It can also be valuable to have “local” MW sub-leads in each time zone who are empowered to address issues and questions that arise outside of the MW lead’s time zone.

**Tools**

Web-based applications (e.g., Microsoft Teams, Vault RIM, SharePoint) provide a secure, shared workspace to store documents and work collaboratively and simultaneously. This centralised repository also serves as a hub for the document’s current and previous versions, along with essential resources for its development, including reference materials, project timelines, team rosters, reviewer lists, and team calendars.

The tools used to draft the document must be accessible to all MWs, including templates and

toolbars that adhere to conventions and provide consistent, predefined styles for formatting text, headings, tables, and references. Styles can be preset within MS Word or as an integrated custom toolbar (e.g., StartingPoint eCTD submission authoring suite). Use of a spreadsheet or Smartsheet to track document development plans, progress, and action items ensures each deliverable is accounted for.

An important tool for document development is a conventions document (Table 1) that addresses project-specific considerations beyond those covered in a sponsor’s style manual. Developing this tool prior to document authoring is beneficial for the team and reviewers, saving time early on and reducing the risk of impact from late-breaking changes. The larger project team can proactively identify and agree upon terminology (e.g., subject vs patient vs participant, trial vs study), content/structure of page headers and footers, standardised text (e.g., treatment regimen and formulation descriptions), and key message wording prior to initiation of writing. The conventions document can also be used to identify and avoid use of terminology that may introduce confusion when its content is translated into another language. The conventions document serves as a “living document,” which can be further developed over

time as a resource as the product/project matures.

**Communication**

Proactive communication and responsiveness are key to developing trust and collaborating successfully. The MW team should agree on the communication method that is quickest and easiest during document development. While email is a useful global tool, other instant messaging tools (e.g., Slack and MS Teams) and within-document communication using comment bubbles with “@” mentions for targeted feedback can be helpful. For the Follow-the-Sun model, we developed a colour-coded highlighting system to indicate development stages, quality control status, and areas requiring attention which facilitated MW communication (see Table 2).

A global MW team should be able to work together remotely almost always; this warrants good teamwork. Basics for good teamwork include being reliable and showing up when required, showing respect for others’ work norms and cultures, responding promptly to questions or requests, and most importantly, being kind.<sup>2</sup> Expressing acknowledgement and appreciation is important for maintaining engagement.

Meetings for the MW team are vital for success.

- **Timing:** A day/time when all medical writers will be able to attend must be agreed upon; times should be rotated so that the inconvenience of early morning or late-night meetings is shared equally.

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**Table 1. Examples of terminology employed in conventions document**

Correct	Incorrect	Notes
Adverse events were reported in x of y (x.x%) patients.	Overall, a low incidence of AEs was observed.	Given the limited follow-up in the Phase 2 studies at the initial submission, avoid use of words such as “low” when describing safety that may only be a feature of the limited exposure.
AEs of special interest	Targeted AEs	For consistency across the programme, as agreed with Global Safety.
AE that occurred during study drug administration is an <i>infusion-related reaction</i>	Infusion reaction	Unless specifically identified as an anaphylactic or immune related reaction, refer to the event as having occurred during drug administration.
drug 100 mg IV q8w	100 mg of drug administered intravenously every 8 weeks	<treatment> <dose mg> <route> <dose frequency>

**Table 2. Example of colour-coding text for ease of communication**

Example of colour code	What it indicates
■ Green = question for reviewer	Text has a question for the team to address
■ Blue = note for MW	Text has been updated and requires additional action by MW, such as: <ul style="list-style-type: none"> <li>● Ready for Lead MW review</li> <li>● Pending question for Lead MW to address</li> <li>● MW note to self</li> </ul>
■ Yellow = ready for QC	Text is ready for QC
■ Pink = QC completed	Text has been drafted and QCed
■ Grey = text is ready for team review	Text has been updated, reviewed by Lead MW, and QCed, and is ready for team review

Abbreviations: MW, medical writer; QC, quality control

- Frequency: A pre-scheduled meeting series provides a time when MWs can ask questions and provide updates; meetings can be cancelled if not needed. Meetings conducted regularly, sometimes daily, assess progress, encourage collaboration, identify action items, and address issues or problems. For less experienced writers, participating in such discussions and receiving real-time feedback

from experienced writers offers a valuable growth opportunity: this enhances skills and helps build and retain talent. While complex high-level and high-visibility documents (e.g., Module 2 summaries, briefing books) are often assigned to senior writers, junior writers have much to gain by actively participating and contributing to their development.

- Agendas and minutes: A "standing" agenda for regular meetings will encourage MWs to be prepared to provide updates on their tasks. A tool such as OneNote can be used during the call to capture document status and decisions, creating an archive for reference and a place to record action items that require follow-up.

And finally, timely and open feedback is essential to prevent errors, improve productivity, ensure goals are clear, and boost the team's confidence. In some cultures, asking questions and providing critical observations are not encouraged, which can lead to misunderstanding as well as frustration, fear, and lack of self-worth. Everyone benefits when questions can be asked, differences can be resolved, and miscommunication minimised.

**Table 3. Benefits and challenges of the 24/7 Follow the Sun model**

**Benefits**

- Reduces stress and burnout by working within "normal" work hours, and encourages best efforts for superior work
- Creates a sustainable work-life balance, supporting employee retention and job satisfaction
- Encourages talent engagement by offering opportunities for professional growth, international collaboration, and challenging projects with highly skilled and qualified writers as well as with other subject matter experts
- Collaborative efforts to solve problems and challenges
- The model is scalable, allowing for teams to be efficiently increased or shifted as work needs demand
- Writing team's project knowledge enables successful post-submission filing activities, e.g., agency responses

**Challenges**

- Building trust and rapport across cross-cultural teams during the initial phase of engagement requires mutual time and effort
- Addressing time zone differences, vacations, holidays, etc.
- Providing continuous open feedback, which requires time and effort
- Keeping central calendar current
- Cultural differences to request assistance or clarifications, or providing feedback
- Ensuring documents read as if written by a single writer ("one voice")
- Difficult for some writers to work in collaborative fashion, prefer to have ownership/control over document

**Using the model**

With the elements for the model in place, the Follow-the-Sun model can be utilised for a single document (e.g., a clinical study report) or an interrelated set of documents (e.g., clinical overview, CTD Module 2 clinical summaries, risk management plan).

**Project kick-off meeting for the MW team**

This first meeting sets the tone and expectations for the project and aligns participants' understanding of the timeline, the deliverables, and the key stakeholders. The MW lead and, as appropriate, line function members, guide the presentations and discussion. Participants include all members of the global writing team, i.e., MWs, QC reviewers, and document specialists. A typical agenda includes, but is not limited to, the following:

- Background material to familiarise MWs with



the topic (training on disease or indication background, reference documents, source documents, journal articles, etc.); a clinical (or other) expert can be invited to present this information

- Confirm use of project tools and templates
- Identify and assign roles and responsibilities: MW lead, local sub-leads as appropriate, then by-writer responsibilities by subject or task
- Agree on writing best practices to be used: e.g., lean writing, conventions, template sentences for results, rolling QC and scope of QC (no formatting checks or no abbreviations checks), and standard email messaging to ensure the writing team has “one voice”

**Ready, set, write!**

The MW team now moves forward as one. They work rapidly and without pause across time zones in their assigned roles: writing, inserting tables and figures, performing rolling QC checks for accuracy and consistency, and applying formatting and other style needs. Tools such as the conventions document and use of the colour-coding system help the team to quickly understand what is needed and where, with consistent use of terminology. Writers add questions, assign tasks, and provide input to the other writing team members using pre-agreed communication methods. Optimum performance is achieved when responsibilities are very clear. Team members need to be willing to help each other as

needed as project needs may shift over time.

Meetings, scheduled or ad hoc, allow rapid problem solving and can pivot resource allocation to solve unforeseen difficulties during document development (e.g., ad hoc analyses, changes in strategy, table re-run/updates, etc.).

When a draft is available, reviewers can focus on the content relevant to their expertise, confident that the MW team has worked to identify and correct in data and formatting, which saves reviewer time and energy. In addition, a section-by-section “rolling QC” saves valuable time near document completion, resulting in reduced time for final QC.

**Project wrap-up**

Once the project is complete and the deliverables have been transferred to the publishing team, all elements of document development should be archived in the appropriate repository. Some or all documents may be required to address subsequent regulatory needs, such as regulatory inspections or questions from health authorities, inform journal publications, or other documents for communication about

the product or programme. The now-experienced global MW team is perfectly positioned for continued rapid responsiveness, saving time and resourcing energy when demands are received.

Finally, the global MW team should meet for an open discussion of plus/delta experiences and outcomes, summarised in a “lessons learned” format that can be applied to future projects (Table 3). Key metrics for performance should be summarised, and used as comparators with other projects to measure success or further needs for improvement. This is also a great time to have individuals and teams commended for the job well done and may even spark a virtual global celebration! Being a part of a successful team endeavour is invaluable for positive professional growth and sense of self-worth. This experience identifies and nurtures future leaders, and also encourages employee retention by fostering a sense of belonging and accomplishment.

**Best results are achieved by proactive planning, alignment of content and messaging, strategic assignment of tasks to suitable talent, and fostering a culture of open communication founded on trust and mutual respect.**

**Conclusions**

The 24/7 Follow the Sun model, a strategic initiative to improve performance, was successfully piloted and subsequently implemented as a “business as usual” practice for individual documents and inter-related documents included in regulatory submissions. The model offers a sustainable, scalable solution to the ever-increasing need for faster development of high-quality documents. During the pilot phase of model implementation, time to write (draft to final) was appreciably reduced by working across time zones with informed, engaged MW team members.

Building and implementing this model requires commitment across the global MW team, their leaders, and key stakeholders. Benefits gained from use of the model can be significant; for success, considerations must be granted to address individual and team needs, at both personal and corporate levels.

It should be noted that this model predates the availability of ChatGPT or other generative artificial intelligence tools and could be modified to incorporate these and other technological advances as they become available. As the model

**Lessons from the Follow the Sun pilot**

Our initial Follow the Sun pilot was for a new biologics license application that included four Phase 1, two Phase 1b/2, and two Phase 3 clinical studies. The lessons we have learned and subsequent evolution are summarised in the table below.

How we started and what went wrong	How we corrected
Prepared minutes from MW meetings and circulated them by email. Required too much time.	Used OneNote online for live minute-taking during meetings.
Drove MW meetings using list of deliverables and asking each writer for status update. Required too much time.	Asked if anyone was not tracking to timeline; used meeting time to problem solve.
Used complex Excel spreadsheet tracker that included granular list of tasks with instructions and assignments for each time zone. Tracker was not maintained, and inaccurate information created confusion.	Relied on verbal communication at daily meetings, group IMs, OneNote, and most importantly, communication within the document itself using comment bubbles and colour-coding.

is revised, refined, and improved over time with the experience gleaned from early projects, benefits have included: significant reduction in time from data to final document, decreased external resource spend, enhanced collaboration among both writers and subject matter experts, reduced reviewer workload, and streamlined publishing.

Opportunities for global collaboration, professional growth, and better work-life balance offer increased job satisfaction and a greater sense of empowerment for writers across the globe, which subsequently encourages talent development and retention. Use of the Follow the Sun model has created a lasting alliance, with improved working relationships among MW teams across geographical regions, contributing to a long-standing, respectful, productive partnership. Best results are achieved by proactive planning, alignment of content and messaging, strategic assignment of tasks to suitable talent, and fostering a culture of open communication founded on trust and mutual respect.

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The opinions expressed in this article are those of the authors and not necessarily shared by their employers or EMWA.

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For inquiries about data and other supplemental information, please contact the corresponding author.

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