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Metrics and Medical Writing – We Don't Just Count Words

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ABSTRACT

This presentation introduces the use of various document-specific metrics in support of business objectives and productivity. Topics address within-document metrics as well as group and departmental approaches to quantifying the value added to the drug development process through medical writing expertise.

The manuscript provided here is the corrected version.

INTRODUCTION

We have all written something at one time or another.

Thus, regardless of length, subject, audience, or complexity each of us has labored through the solitary process that is writing. Writing takes intellectual momentum, concentration, and time for thought, analysis, and data presentation. For medical writers, these projects are our professional responsibility and are both complex and time-consuming.

For anyone in the 21st Century workplace it is not unusual to be faced with limited time for one's work. When time is of the essence, individuals need ways to accelerate their work while maintaining the expected level of quality. Medical writers and editors are no different. For all of us, time is a most precious commodity that is a key driver of business activities.

In the following text we will present our view on how tracking one's work – developing metrics – can support complex writing projects in a variety of ways. We will employ basic but powerful concepts that reinforce the importance of metrics and illustrate the value these data provide to the medical writer and to the project.

HOW DO METRICS HELP WRITERS?

There are many different types of medical writing, which take place in both independent (ie, the freelance) and corporate (ie, in-house) settings. Regardless of the type of writing and the structure of the business environment, metrics are essential tools alongside laptop computers and software platforms. Although not always evident to the writer, and even sometimes feared for what may result from their use (ie, low efficiency), metrics do matter.

Without stereotyping anyone or making sweeping generalizations, the separation between words (for writers) and numbers (for the more mathematically oriented persons) is obvious. Each has its own purpose. However, what if we were to combine these 2 broad concepts and say that numbers can be used to support words? This supporting aspect is what we refer to as metrics, or ways to quantify the business process – in this case, medical writing.

The relationship between words and numbers can be self-evident, ie, count the words in this sentence, or vague, ie, how much time does it take to write a document? It is this overlap that presents an opportunity to bring analytical clarity to the writing that occurs in a professional workplace. And, because productivity and efficiency are universal expectations

for business, having a way to show that efficiency in writing projects translates into real productivity is a powerful tool.

Aside from the written documents themselves, without data-driven tools that can make the intellectual expertise of writers evident, writers are faced with the daunting challenge of demonstrating their value on a project via subjective assessments and general perceptions of what others believe writers provide. It is not enough to have an extensive writing background or highly advanced training in complex clinical or analytical subjects. Today's workplace demands high value from each person, writers included. Moreover, because writing is a solitary task, the behind-the-scenes focus and grit needed to develop well written scientific reports is not self-evident. And because project teams are focused on their deliverables and deadlines, the final product becomes all-consuming. It is for these reasons that medical writing groups tend to rely on specific metrics to demonstrate their valued-added work.

WHY USE METRICS FOR WRITING?

The beginning of any writing project is where the constituent needs are assessed. To effectively do this, some basic data are needed. These data are gathered by asking questions, by comparing the current project to prior experience, and by carefully considering the time and effort spent on each individual task within the larger work package.

NECESSARY SKILLSETS

No matter the size or complexity of writing projects, writers must possess certain skillsets. Aside from expert writing and communication skill, writers must be superb project managers, timeline moderators, and efficient budget-conscious team members. Writers focus their attention on the project milestones and writing. This is not surprising; recall the words vs. numbers dichotomy above. If you have ever been asked to create a project plan you likely realize that not only must the actual writing time be included but depending upon the business needs, writing time may be further subdivided to include formatting work, quality control checks, writing of any unique/specialized sections, and any number of technical and content-heavy components.

For the preparation of a "typical" manuscript it is reasonable to expect the writer to possess the following project-oriented abilities or competencies: negotiation skills, focused questioning, contingency planning, timeline development, and ultimately time and cost analysis coupled with metrics generation to support project decisions and timelines.

Let's briefly examine these competencies in turn:

- *Negotiation Skills* – the ability to achieve consensus and agreement on project needs while focusing the team on the project objectives.
- *Focused Questioning* – the ability to look ahead and anticipate challenges through careful discussion and questions asked of the team. As the discussion evolves the project details become clear.
- *Contingency Planning* – the act of always having a back-up plan…always. This type of advance planning could be crucial should the work be redirected or if the team encounters unforeseen difficulties with data collection or other details.
- *Timeline Development* – the planning of project milestones, managing the review of drafts, and managing the team within key dates and actions. Such an ability is an essential skill for medical writers.

- *Resource Allocation* – the effective use of personnel and resources, which is a highly scrutinized aspect of any project. Complex clinical document development requires careful review of all available resources.

Identifying and tracking the necessary tasks

For illustrative purposes we will use a "standard" scientific manuscript format as the basis from which metrics can be developed and analyzed.

As with the manuscript you are reading, published journal articles must follow a specific layout style, presentation format, and heading structure. The general structure typically follows the "Introduction – Methods – Results – Conclusions" order and is familiar to many across myriad disciplines (Sollaci and Pereira, 2004).

Although this section-based description is commonly used for journal manuscripts, parallel sections and a similar approach can also be applied to regulatory clinical documentation. The challenge, regardless of document type, is to clearly delineate the tasks involved in a given writing project and then to quantify the time and cost associated with the tasks.

Key details to be considered when assessing writing projects include but are not limited to the following list (Table 1). From these details one can derive the component tasks to be accomplished and their place in resource allocation.

Question	Information Gained
What is the document type?	Journal article, CSR, Narrative, Module 2
What is the "Due Date"?	Calendar date for final submission; needed for timeline development
Who is the target audience?	Scientists, clinicians, the public
What is the complexity of the topic?	High, Medium, Low
What guidelines/guidance documents are to be followed?	AMA Style, in-house style, journal-specific, other
How many interim drafts are being requested?	Typical process specifies 2 drafts and 1 final document (also a draft)
How many collaborating team members will be involved?	Medical Writing is a collaborative activity that can involve large authoring teams and reviewer groups
What is the anticipated medium for the work (print, electronic, other)?	Printed journal, Web page, Video, other
How will source information/data be provided?	Do the authors identify and provide all sources or will a supporting staff assist with this?
What contingency plans are to be considered?	Handling late reviews, requests for changes in scope, technical problems, other

AMA, American Medical Association; CSR, Clinical Study Report

Table 1. Focused questions help identify project complexity, scope, and underlying tasks.

These questions are, in general, the types of questions discussed at the outset of most medical writing projects. By probing the requestor for this information, the following more specific tasks and expectations become evident:

- Overlapping tasks and challenging timelines (eg, rapid response to regulatory requests)
- The document type (eg, journal article or CSR) and study design
- The complexity of the subject matter (as well as the size of the data set[s] to be analyzed)
- The number of drafts to be reviewed
- Who the audience will be – a key part of preparing an appropriately written document
- How to style the draft (ie, format, presentation, word limits, submission requirements)
- With whom will the lead writer be collaborating and what are their roles/areas of expertise
- The guidance documents and/or regulations that govern the document being prepared
- The printed or electronic format used – a key aspect needed to guide the writing for the correct medium
- How to address unexpected delays, added reviews, etc.

These expectations and tasks comprise the fundamental parts of the writing project, each of which are then assessed separately for resourcing needs. Although the tasks can be grouped into 4 general categories, the completion of each task relies on more than 1 member of the authoring team.

Four example categories of writing project tasks are as follows:

- The reading, reviewing, and studying of source documents
- The writing and revising of each section (Intro-Methods-Results-Discussion)
- The data analysis, usually done per section (eg, efficacy, safety, discussion) and then synthesized for the Summary and Conclusions sections.
- The review, fact-checking, and quality control (QC) of the final draft

Due to the collaborative nature of writing and developing large complex regulatory documents, the efficient management of the people and process remains essential.

APPLYING NUMBERS TO TASKS

Now that we have an understanding of how to derive the basic parameters for this example project, how can we apply simple metrics to these data?

As with any business project, cost-effective work and a good return on one's investment are required elements of success. For writing projects, it is necessary to break down the various categories of activities so that detailed resource utilization can be implemented.

Such derivations are most easily achieved when a writer can use past experience from similar projects as information to build from. However, for first-time activities, past experience is only generally applicable. As such, a reasonable starting point for a project's needs musts be decided upon; thereafter, future projects will contribute to the knowledge base thereby allowing more accurate metric generation.

Because journal manuscripts tend to follow a set structure, this document type serves as an excellent example to build on. Following is a step-wise list that illustrates how multiple

manuscript projects of similar structure can be used for metrics generation. This is a common-sense approach but a meaningful one at the same time.

The writer is to monitor the components by…

1. Tracking the time needed to read and understand all source materials and data listings
2. Tracking the time spent for writing an Introduction section
3. Individually tracking the time spent on writing the Methods and Results sections; this also includes Table and Figure generation even if done with automated tools
4. Tracking the time spent writing the Discussion section
5. Tracking the time spent on creating and proofreading the Reference list

Once these section-specific times are known, averaging each section's time (rounded to the nearest quarter hour) provides totals that can be extrapolated to future similar projects. By doing this simple but focused time tracking for multiple projects, the amount of time needed to complete a new project can be accurately estimated.

These aggregate time estimates provide solid data upon which resource utilization can be estimated. Project-based time estimates are also used for budgeting and cost projections. And, in addition to resource allocation, this approach can be used to develop practical timelines to avoid inappropriate planning and unrealistic resource allotments.

The time tracking described above also allows for assessing shorter time intervals. Although the per-project time is composed of hourly averages, varied types of editorial work may be better suited to an hourly basis. Further, hourly tracking can also be part of an agreement as a way to cap "scope creep" should more work be requested beyond the original project specifications.

The counting of words and pages as part of developing metrics can also be a useful approach; however, for the typical regulatory document or journal manuscript project, these intervals are not useful or realistic. These more granular counts are typically used for the different types of editing or proofreading because these specialized tasks are not based on entire document development but are focused on the fine details relating to the words and sentences.

APPLYING METRICS TO WRITING PROJECTS

Document development – the writing, reviewing, checking, and finalizing – takes time to yield high-quality work that is reviewer appropriate. The time between any of these primary functions can shift loosely forward or backward for many reasons not discussed here. However, the disciplined medical writer will remain aware of this potential and strive to maintain timelines, quality, and accuracy.

Yet, how can this vigilance be quantified to clearly show the **value** added by the medical writer? How can these "cycle times" be improved (ie, shortened) while keeping all other project goals intact?

The answer is simple – Metrics. Not any metrics, but those that provide useful feedback on the constituent parts of a writing project.

MEANINGFUL METRICS

Writing is clearly a task that can be quantified. And, within a writing project, flexibility of time and talent also remains a key necessity. In scientific endeavors the work is neither predictable nor locked into specific time-bound activities. This is yet another reason why

metrics are needed – to support dynamic staffing and resource allocation in ways that yield a successful project.

Generally, in-house writing staff and external contract staff compose the 2 resourcing models used in corporate medical writing departments. This provides the flexibility for the ebb and flow of work while also allowing for sufficient staffing for larger projects.

Due to this multi-faceted resourcing approach the challenge of monitoring productivity and efficiency becomes more difficult. Each writer has unique skills and experience that may influence the time needed or the document's quality, hopefully for the better in both cases. Measuring productivity within writing projects is not as simple as our manuscript example may seem.

Documents and people differ, and no two projects are alike. Thus, there remains the need to standardize the work as best as possible. By doing this, the derivation of metrics that can champion high efficiency and superb document quality becomes more evident, demonstrating the value of metrics in today's business environment.

This demonstrated value translates into a type of competitive advantage. Accurate tracking of project and document work leads to improved performance, improved (ie, faster) cycle time, and improved efficiency for the writer and the team, while providing insight into where potential project gaps or process shortcomings lie. Together, these aspects further reinforce the importance of focused metrics for medical writing work.

WHERE CAN THESES APPROACHES TAKE US?

Data are an essential part of Clinical studies, and by using the correct information companies can develop various regulatory deliverables that lead to drug approvals and improve and save lives of many. Medical Writing uses a majority of the data gathered in these studies to develop the Patient Safety Narratives, which are required for all phases of clinical studies. The narratives are an essential appendix within the Clinical Study Report, which describes a subject´s experience in the trial. These in-depth narratives are not always needed for all the subjects enrolled in the study, and the number of required narratives is evaluated by the stakeholders assigned to the study.

Just as the information gathered from a clinical study is used in the production of the narratives, Medical Writers need to gather additional data regarding the writing process to allocate resources, develop timelines, identify areas of improvement, and to analyze new tools and applications that create efficiencies in the writing process. Collecting the "right" data will result in the ability to drill down through the information to analyze trends for cycle times, production time, document quality, and writer performance, to better understand the operation. These simple analyses can lead to a number of improvements in the writing process such as the standardization of how the study data are presented in the narrative, the use of dynamic writing templates that "pull" the study data into the corresponding fields, and the ability to cross-reference patient information across files. These advances will allow the writer, and the reviewer as well, to more easily confirm the information presented. Further, such reviewer-friendly documents will allow for a review process that lets the reviewer's expertise guide the assessment.

THE PATIENT NARRATIVES CASE STUDY

To further understand how metrics can improve the writing process, our department decided to make various business decisions by using data for support. These decisions were based on investigations of data collected by individuals within our team. The results have allowed the ongoing use of a mix of business analytics and business intelligence to identify where we could establish efficiencies that would allow us to:

- Improve timelines – so that deadlines are met even when taking on multiple studies with overlapping timelines.

- Allocate resources accordingly – in order to allocate based on the needed skillset as well as to drive the completion of projects ahead of planned times.
- Implement new tools and processes – to test new tools and improve current processes through innovation, allowing writers to focus on the data and create efficiencies.

Our initial approach centered around using different tools and in-house applications to centralize the writing process. Such centralization allowed for the development of applicable Key Performance Indicators (KPIs) and helped set the baseline for our new metrics. (McKenna and Horowitz, 2017).

At the project outset it was apparent that it was essential to capture project-specific information based on the narrative writing stages established by the ICH E3 Guidelines for Structure and Content of Clinical Study Report. This initial understanding supported the conceptualization of project details and downstream processes. The narrative writing stages are:

- Initial Draft – The initial draft of the narrative that includes a thorough discussion of adverse events, blood tests, physical exam findings, and other serious or fatal safety-related events.
- Peer Review – The editorial review of the narrative for clear writing and to ensure that all narratives for the given study use a consistent data presentation and format as governed by applicable guidelines and quality standards.
- Clinical Review – The review of the draft narrative after the peer review to ensure clinically accurate data and a clear description of the findings being reported.
- Second Draft – The resulting draft after the medical writer addresses all feedback from the prior clinical review.
- Quality Control – The review of the narrative to ensure quality, align to the project requirements, and comply with the ICH E3 guidelines. This includes full data verification and checks for clear and consistent language, formatting, and typographical/technical checks.
- Final Version – The completed narrative that has all quality control process findings addressed. At this stage the medical writer ensures that the document is ready to be included with the complete set of narratives to be placed in the appendix section of the Clinical Study Report.

Over an approximate 8-month period, during which we determined our baseline data, we were able to identify parts of the existing writing process that had room for improvement. As a result of these findings it was decided that standardized study data and document templates would improve the narrative writing process.

Following is a discussion of the type of outcome that can be realized when the described process changes are put in place. The data illustrated represent the initial approach employed by our colleagues.

By using templates along with uniform data formats, meeting project timelines became more achievable and appropriate resources were better fit to each project (Table 2). These innovations led to the creation of company data collection standards, standards for data structure, and governance for identifying and managing relevant information. The addition of in-house automation systems further enhanced the writing process, which decreased end-to-end project time and resource utilization while increasing the narrative document quality.

Topic/Subject Complexity*	Hours to Author (prior to automation)	Hours to Author (after automation)	Hours to QC (prior to automation)	Hours to QC (after automation)
Low complexity	4	2.25	1.7	1.0
Medium complexity	5	2.50	1.7	1.2
High complexity	10	4.00	2.3	1.3

QC = Quality Check

*Subject complexity was based on the total amount of hours needed to author narratives in different therapeutic areas such as Infections Diseases, Oncology, Primary Care, and Vaccines.

(McKenna and Horowitz, 2017)

Table 2. Process efficiencies through automation

The initial automation and standardization allowed for timelines to be completed, but when new studies with increased complexity and an increased number of narratives were being assigned, the need for further enhancements became clear.

Initially, the writers were navigating through large Study Data Tabulation Model (SDTM) files to find relevant clinical information. With further assessment we decided to enhance the writing template while also implementing a new macro-based tool. These improvements resulted in a semi-automated approach to visualize the SDTM clinical data and allowed writers to:

- View only the relevant data for a study participant across multiple domains.
- Generate a report of new and changed data points between the data cut-offs of a project. (Salazar, 2019)

These improvements lead to robust data integrity while maintaining any needed data protections. And, an average of 38% improvement in efficiency was achieved for the initial draft writing stage of the process (Table 3).

Overall, by focusing on the most appropriate data to collect, we demonstrated that specific technology enhancements in our process resulted in increased efficiencies, which culminated in the project being completed ahead of the planned time.

Topic/Subject Complexity	Hours to Author (with automation)	Hours to Author (after enhancements)*	Total Percentage of Increased Process Efficiency
Low	2.25	1.87	16.8%
Medium	2.50	1.08	56.8%
High	4.02	2.32	42.2%

McKenna and Horowitz, 2017.

*The following data were based on separate narrative projects finalized throughout 2019.

Table 3. Process efficiencies through enhancements

We have seen how focused data collection resulted in process improvements. Yet, we often face the challenge of handling multiple overlapping writing projects (Figure 1). Could such an approach also improve the resourcing challenges when faced with many tight deadlines?

Over time, with the accumulation of multiple data sets from ongoing projects, we then averaged the time needed for the integral steps to be performed. These averages, which resulted from the data handling and template improvements, yielded a more accurate assessment of required time/resources per project. When applied to overlapping projects of differing complexity, the results indicated that a greater number of writers required far fewer work days to meet the deadline. And, the overall attainment of the project timeline included the time needed to complete the other 5 stages of the narrative process. Management teams can then use these data to refine project resourcing needs for narrative projects (Table 4).

Each narrative project is different, but by understanding the complexity and the priority of each, overlapping resources can be assigned to complete the work; creating efficiencies in one segment of the work will result in improved productivity in the other stages.

One example of these further enhancements is Project C, below, which was a time-sensitive project that required more resources to meet the demand for a high number of narratives due within a short time (Table 4).

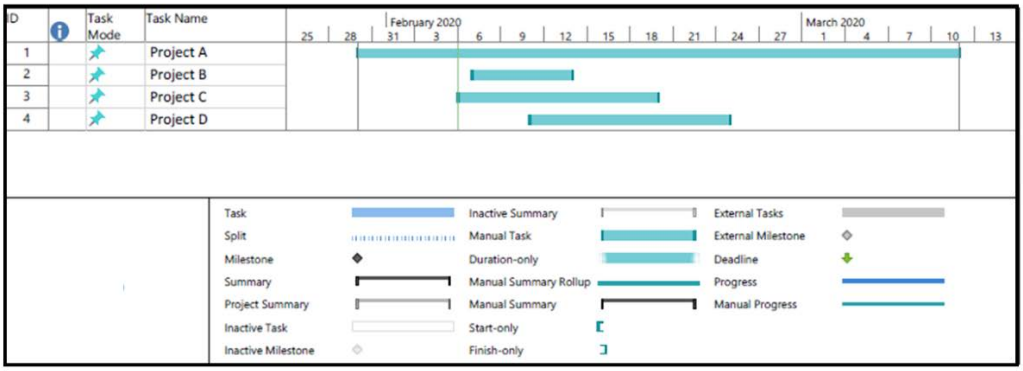

Figure 1.

Example Narrative Project Timelines

These data are only for illustrative purposes and do not represent actual results; however, the indicated trends align with past findings.

Project Name	Days from writing start to first complete draft*	Number of Narratives Required	Total Business Days to Complete by One Writer (8-hour business day)	Number of Resources Assigned	Total Business Days to Complete Initial draft with Assigned Resources
Project A	30	52	15	1	15

Project Name	Days from writing start to first complete draft*	Number of Narratives Required	Total Business Days to Complete by One Writer (8-hour business day)	Number of Resources Assigned	Total Business Days to Complete Initial draft with Assigned Resources
Project B	5	29	8	9	1
Project C	10	214	62	11	6
Project D	10	151	44	10	4

*These time intervals represent the writing/drafting portion of the overall project work.
These data are only for illustrative purposes and do not represent actual results; however, the indicated trends align with past findings.

Table 4. Resource allocation for Initial Draft

These are only a few examples of how numbers can support words, ie, writing projects. However, medical writing is not done in isolation and the integration of the writer within the authoring team remains a key success factor. Moreover, it is important to use these basic data collected with each project to help identify the problem areas and turn them into opportunities. Being able to use the right data in the writing process can lead to unexpected benefits that can firmly support the overall business model.

WHERE DO WE GO FROM HERE?

In today's highly technical and computer-oriented workplace it is no surprise that many industries are adapting to the new Industry 4.0. This new industrial revolution started to emerge after the adoption of the computer into routine business and continued to yield new innovations not only in the manufacturing, but also in facilitating everyday tasks. With the unexpected advances in technology we have seen how technology has paved the way for new strategies, algorithms, and improved Artificial Intelligence (AI) and machine learning. These successes resulted in new innovations across diverse industries. As such, pharmaceutical companies have developed AI algorithms to help diagnose clinical study participants at a faster rate by identifying patterns in disease progression through biopsy images, magnetic resonance imaging, and electrocardiography – examples of how businesses are adapting to the digital era.

But, how can Industry 4.0 adapt to Medical Writing? Technology and the authoring process need to work together for innovation to support the delivery of high-quality documents. By understanding our tools and applications, with our work alongside cross-function teams, this collective knowledge yields new perspective on the information being studied.

Extending these partnerships with teams and technology is now leading to platforms that can semi-automate or even fully automate regulatory document preparation. The benefit is that authoring teams can focus on how to interpret and present the data. However, before any tool can be used, writers need to evaluate if this tool can increase efficiency (eg, shorten timelines) in the document development process. These increases in overall efficiency hopefully translate into improved health and quality of life for patients.

The team-based nature of medical writing also reinforces the importance of working with our technical and statistical colleagues, not only to develop sound analysis plans but to also implement tools that improve how clinical data are structured. For the clinical authoring

team, having properly formatted data sets is a requirement for health authority review and must be standardized per existing guidelines. These intricate aspects are the purview of our colleagues who bring their perspective to the team.

Technology is a powerful tool and requires careful assessment, especially when applying the systems to the clinical study of human disease. As such, there are additional questions that we need to keep in mind when looking into tools that will manipulate these data:

- How will this new tool help our team analyze the data more clearly and better understand the relationships between different sets of clinical data?
- Will this tool help us create efficiencies, reduce timelines, improve document quality, and produce well thought-out documents?
- Will this tool help present the data in a standardize format that is required by the different regulatory agencies?

There are many possible outcomes of how Industry 4.0 can benefit medical writing. Whether if to develop more accurate resourcing models or identify process efficiencies that integrate data interpretation and machine learning, the intersection of technology with writing is upon us. Given this, applying these digital tools takes responsibility and care, especially when the lives of others are at stake.

CONCLUSION

When we add numbers to words, we have the ability to track various components of our work to quantify our value. By taking on a metrics-oriented point of view, writers can take a step forward by identifying tasks and asking additional questions based on the data. Metrics are now playing an important role in the writing process allowing us to find new ways to improve timelines and allocate resources, while always maintaining high quality. Data collection can be used in various ways and when used responsibly, we become pioneers in our industry.

By understanding the importance of numbers, we can do much more than write words. We have always had access to these numbers, but it is time to broaden our perspective to pave the way for a new era of medical writing. The combination of technology with the collective expertise of the team can then elicit breakthroughs to help patients and as writers we have the power to tell this story. Numbers and words really do need each other.

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RECOMMENDED READING

- *Base SAS® Procedures Guide*
- *SAS® For Dummies®*

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