Digital Communication

SECTION EDITOR

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Digital communication – bringing us closer

Digital or online communication is second nature to us all – with more than half of the global population active on the internet, a world without it seems unimaginable. In recent years, digital communication has increased in popularity for, among other things, the efficiency and convenience it lends to personal as well as business undertakings. In 2020, we relied on digital communication even more, with activities like virtual conferences, video meetings, and even telehealth becoming the norm. Furthermore, digital communication tools have proved useful in facilitating collaborative authoring and learning, particularly in remote work situations. Growing use of the internet and our swift adaptation to using digital communication tools show great potential for further development in online communication and distance working moving forward. In fact, a *Forbes* article estimated that 70% of the workforce will be working remotely at least five days per month by 2025.[1] In this section, you can expect to read more about digital communication in general, as well as relevant tools and applications in medical communication and healthcare.

To launch this new Digital Communication section of *Medical Writing*, we illustrate an overview of the evolution of digital communication, the most commonly used tools, and some of their applications (Figure 1).

References

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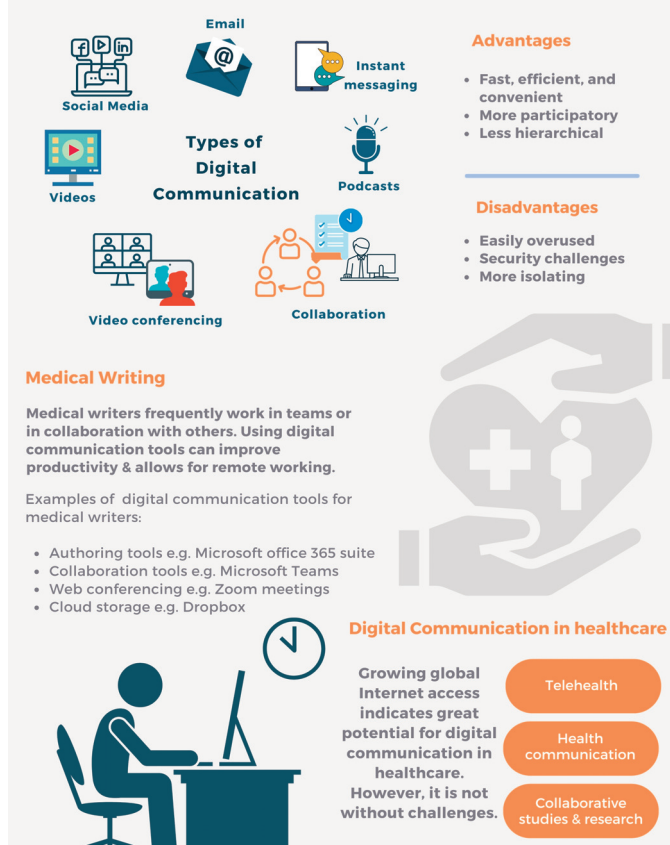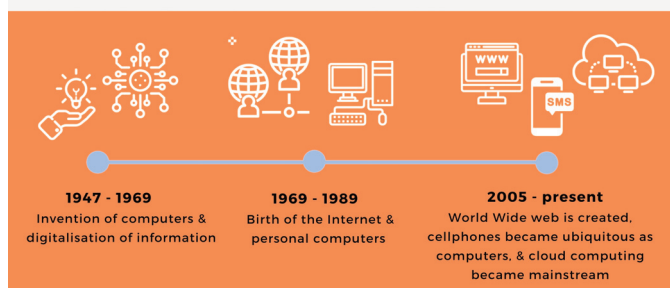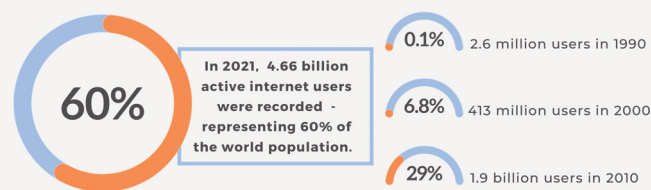
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Figure 1. A snapshot of digital communication
Global active internet users over the last four decades:
1990 – 2.6 million users per 5.28 billion people globally (0.05%)[2,3]
2000 – 412.8 million users per 6.114 billion people globally (6.8%)[2,3]
2010 – 1.992 billion users per 6.922 billion people globally (28.8%)[2,3]
2020 – 4.66 billion users per 7.9 billion people globally (60%)[4,5]

Collaborative authoring – an interactive and dynamic opportunity for acceleration

Cloud-based content collaboration platforms, including Microsoft's Office 365 suite as the most widespread solution, have become standard in the industry. The main characteristics of this type of platform include collaboration workspaces, simple workflow capabilities, and more granular security features that enable team-restricted access to the workspace and documents. The cloud-based location of these authoring suites and collaboration tools enable new ways of working, and its potential is increasingly recognised and utilised. The conventional sequential way of document development, with distinct cycles of authoring, review, and revision, is evolving towards a collaborative, highly interactive, and dynamic development process. This approach is more efficient and allows expedited execution. In this way, document development timelines can be met that are hardly feasible if based on solitary authorship.

The collaborative approach

Using Office 365 as an example, the interplay of MS OneDrive, MS Teams, and SharePoint (all of which are bundled within the Office 365 Suite), allows remote collaborative authoring to be conducted in a sequential, parallel, or simultaneous manner. Authors, other stakeholders, and reviewers may work on separate sections or on a single section of the document under preparation. A sequential collaborative approach

is applied, for example, when document development follows-the-sun, i.e., if the writing is done across distinct time-zones. Most often, collaborative authoring proceeds in a parallel-working fashion where a team of writers, coordinated by a lead author, works on separate sections of the document or fulfils distinct individual tasks – a kind of coordinated piecing-together of a puzzle – by multiple players. The collaborating authoring team can be permanently or transiently expanded to allow contributions, reviews, and revisions by subject matter experts (SMEs), experts performing quality control (QC), the client team, or the business partner. The exact touchpoints or collaborative phases can be handled flexibly as mutually agreed upon and adapted at any time during the development process. As for the clarification of very specific questions, a synchronised approach is recommended where the collaboration occurs during a conference call with the work-in-progress document shared online.

Employing these collaborative authoring tools allows the authoring or document development to become agile and responsive during the writing process, rather than only at distinct stages, where there is a "handover" between authors, other SMEs, or the external business partner (e.g., the client's expert team) via a predefined schedule.

The collaborative options

OneDrive utilises an individualised workspace and can be seen as a personal filing repository. A single SharePoint page is enabled for the document owner and document provision is based on a *SharePoint Document Library*.[1] Access control at the document level is managed by the document owner. OneDrive is optimally used for limited internal collaborative tasks, like the management of QCs by multiple quality reviewers or as a review tool for alignment among a smaller group of stakeholders.

MS Teams has proved to be a very powerful tool to accommodate all needs of an internal team of authors (medical writers), functional experts, and SMEs to drive collaborative document development efficiently and, if needed, in an accelerated fashion. Access control is at the team level and the document also resides within a *SharePoint Document Library* embedded in the team's SharePoint page. Similar to OneDrive, versioning is enabled and the central filing repository allows all information and source documents to be available within the team's SharePoint area. As a unified communication platform and in contrast to OneDrive, MS Teams allows communication by various means within the designated team space. Instant messaging can be restricted to team members, and when combined with task management, significantly promotes communication, interaction, and

alignment between all team members. Conveniently, the complete chat history is automatically stored and centrally shared with all team members. However, careful consideration should be given regarding whether to include external partners and clients in the team, because not all communication within the internal team might be appropriate for public sharing, e.g., internal alignment activities or certain decision-making.

SharePoint is also intended to be used by internal teams in addition to a wider audience. While the specific support capabilities for efficient team interactions are not as advanced as in MS Teams, as it is not designed for unified team communication, it allows stringent and secure access control of the central filing repository. Access is usually granted at the SharePoint page or folder level by a non-team member, such as an administrator who follows corporate security rules. Therefore, SharePoint is better for focused and controlled usage of the collaboration tools and is preferentially used when external stakeholders need to participate, e.g., clients or business partners, for collaborative editing or review of the document. These features of SharePoint are also integrated into the **Veeva Vault (VV) platform**, which combines effective and auditable document management with collaborative authoring, review, and approval capabilities. A document in progress is checked out from VV and a specific VV workflow is set up for edit/review collaboration using a specific VV workflow with a *SharePoint Shared Document Library*. The workflow allows edit permissions to be granted to internal as well as external users (e.g., the client team) via sharing settings.

All the above collaborative options support a browser-based and work with the desktop Word application respectively. The latter supports an expanded set of features and functionality and is therefore the preferred option for many collaborative authoring teams. This is relevant for using the comments and track-changes functionalities. Furthermore, if multiple authors work simultaneously in one document, it is important to see the others' changes, which happens dynamically if the auto-save functionality is on. Although this collaborative functionality enables provision of review comments and edits in a consolidated manner, there are other specifically designed collaborative review tools, like *PleaseReview*, which offer enhanced control over the entire review workflow and advanced clarity regarding review comments.

Planning, strategy, and rules

This new way of writing requires adaption at various levels – it affects resource management (>1 medical writer (MW) needs to be assigned) and requires both a conceptual framework defining how a team should work (e.g., an upfront agreement on rules and on best-practice prior to start) and a defined project-specific strategy for collaborative authoring depending on the document type or the project state. For example, if a team develops a clinical study protocol, it is relevant whether the process starts from a comprehensive synopsis, which defines the study design fully, or from a study outline where some decisions about essential study design elements are still pending when the protocol authoring work starts. In the latter case, collaboration of and decision making by functional experts takes place in parallel to authoring of the protocol. This scenario is initially more demanding in terms of the necessary alignment of all internal and external stakeholders, and the ambiguities that accompany the initial authoring phase.

The intensity of a collaborative authoring process can be significantly higher compared to the conventional sequential preparation of a document. Multilateral communication, a pronounced need for ongoing communication and adjustment across all team members are requirements that play less of a role in solitary authoring. Therefore, an enhanced commitment by all team members is necessary to ensure that reviews, comment provisions, and responses are coordinated in time.

Medical writing management also needs to promote this different setting and line-up for successful collaborative authoring, by training and cultivating an appropriate mind-set among the team of medical writers. Some writers, especially among those who are very experienced, have reached this level by focusing on details and being able to control every aspect of the authoring process and content. However, successful collaboration requires teamwork that is based on trust in the competency of co-authors and the ability to delegate tasks.

From a learning perspective, the collaborative authoring approach also allows delegation of less critical tasks to writers who benefit from the experience of a senior writer who leads the

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authoring team and coordinates the individual activities. In fact, depending on the document type (e.g., a clinical study protocol or a clinical study report), certain sections in these documents are less dependent on other sections and content can be broken down into separate entities. For example, the *Introduction* (rationale, background, benefit/risk assessment, etc.) can be written relatively independently from the remainder of a protocol. The three main clinical study report result sections: *Study Participants* (Disposition, Demographic/Baseline Characteristics, etc.), *Efficacy,* and *Safety* also lend themselves to division of labour. However, regardless of the respective collaboration strategy, it is crucial that one author leads the team through the document development process, to ensure consistency of content and messaging. The demands on the team leader in terms of administrative tasks and project management are higher than when with a single authorship project. Here it is the lead author who ensures that there is a common understanding of the content and the general objective(s) by the authoring team. When used effectively, the collaborative authoring process ensures there is a continuous parallel peer review of content by the other writers or SMEs involved.

Opportunities

For scenarios under constricted timelines, collaborative authoring might be the only way to meet aggressive deadlines. Under such circumstances, it is not only the team of authors and internal experts who need to adapt to this highly interactive approach. Rapid decision making, last-minute calls for resolution of conflicting perspectives, and quick resolution of queries require increased availability and flexibility from an external client or stakeholder team too. Their corresponding expectations and involvement are often dictated by specific situational business needs or exceptional circumstances (see *Case Study* below).

As business partners might become more closely involved in the drafting of a document, e.g., in that the work-in-progress document is more or less continuously accessible to them and edits and comments can be provided any time along the process, the classical sequential approach for document development (Figure 1A) may take a back seat. This might apply in particular to cases where there is an overlap between client expert contributors working directly in the document and the client reviewers. Conventionally, the writing approach is characterised by distinct pre-defined touchpoints that dictate a sequence of drafting, QC, client review, and

comment incorporation. In a collaborative process (Figure 1B), these touchpoints shift in favour of a process of reacting and responding (i.e., continuous review and revision). As a result, QC activities might shift towards an agreed time point shortly before finalisation of the document, with a more holistic focus. In fact, some business partners may welcome this option as they prefer to follow the developing status at any time rather than waiting for the traditional defined deliverable.

Case study – protocol development

With the advent of the COVID-19 pandemic, an immediate need for therapeutic measures became prevalent and respective clinical trials demanded accelerated start-up. Thus, the development and finalisation of respective protocols were expedited. The first COVID-19 protocol, prepared by Medical Writing Services, was finalised within approximately 2 weeks, and required a collaborative approach by a team of medical writers with full utilisation of collaborative authoring tools.

In this case, a lead author coordinated a team of three supportive writers. The team agreed upfront on the conceptual framework of their collaboration, with the lead author responsible for task allocation and management; they were also the primary contact for other stakeholders, including the client. Additional lead author responsibilities included version control of the in-progress master document, work-in-progress status updates for the internal team and the client, and authoring the critical study design elements of the protocol.

The collaboration mode of this authoring team entailed:
- Daily alignment on task completion and task allocation
- Parallel peer review of completed sections

Protocol writing commenced while other functional leads (statistics, medical, regulatory, data management) in liaison with the medical writing team worked out essential study design elements that flowed into a robust study synopsis.

The technical aspects of collaborative authoring for this protocol entailed:
- A master work-in-progress document that was maintained in **OneDrive** and was accessible to the medical writing team and quality reviewers for QC.
- At the end of each workday, a copy of the work-in-progress document was updated in the collaborative work space on **MS Teams** and made accessible to all members of the internal team to provide their contributions, review and revise drafted sections, and address queries raised by the Medical Writing team.
- The lead author directed specific tasks or questions to respective internal team members on a daily basis, using the task management functionality of MS Teams.
- Revisions and contributions made by the internal team (functional leads) in the MS Teams version were transferred to the master work-in-progress document in OneDrive.

Note: external (client) access to a common collaborative workspace at the time of protocol preparation was not yet available, but going forward, *the Collaborative Authoring module within Veeva Vault will allow the team to benefit from the full potency of this approach.*

Final remarks

Although not previously mentioned, all these collaborative authoring activities are available under remote working conditions. While pandemic conditions have driven us to this mode of working, collaborative authoring also underscores the great potential of being able to pull together the contributions of appropriate experts at a global level.

Disclaimers

The opinions expressed in this article are the author's own and not necessarily shared by his employer or EMWA.

Conflicts of interest

The author declares no conflicts of interest.

References

1. A *SharePoint Document Library* is a "place" to store, organise, and control files of various formats (e.g., Word-, Excel-, PowerPoint, Outlook-files, pictures, etc.). This "place" is an element (a library app) included in and associated with the distinct SharePoint page.

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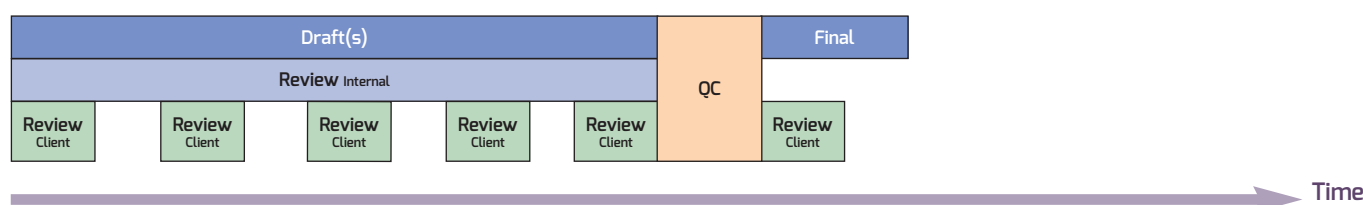**A. Sequential approach**

B. Collaborative approach

Time

Figure 1. Document development models

The sequential approach (A) requires some interaction between stakeholders but is characterised by phases where the work-in-progress document is primarily allocated to a certain party, while the others are excluded. Communication and decision-making proceeds preferentially in a staggered fashion, although common touchpoints (e.g., comment resolution meetings) are interspersed as needed. Central to the collaborative approach (B), the work-in-progress document is almost continuously accessible by all stakeholders, who are all engaged throughout the development of the document. The team works in a highly dynamic, interactive, and reactive mode leading to joint development.