Narratives for a clinical study report: The evolution of automation and artificial intelligence

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Abstract
Automation and artificial intelligence (AI) are useful tools that are rapidly progressing in many fields within the clinical trial landscape, and their use in the production of narratives for clinical study reports is no exception. Technology and processes for efficient narrative production have evolved – but what may the future hold now that we are in the era of AI?

The generation of narratives for clinical study reports (CSRs) can be a complex, time-consuming, and costly task. The International Council for Harmonisation (ICH) E3 guidance indicates individual patient narratives should be included in Section 14 of a CSR for patients "describing each death, each other serious adverse event, and those of the other significant adverse events that are judged to be of special interest because of clinical importance".[1] The number of narratives required for an individual CSR can be as high as 1000 or more, depending on the phase of the clinical trial, and the work required to generate a narrative for each participant can necessitate a large team of dedicated medical writers (MWs).

> Best practices for creating CSR narratives have evolved over time, and continue to do so, with processes becoming increasingly efficient.

The majority of the work involved in generating CSR narratives needs to occur when final data for the trial are available (after database lock and when the tables, figures, and listings have been generated for the CSR); the narratives must be final and ready for inclusion in the final CSR. To perform this work efficiently and within the required timelines, strategies have to be employed to reduce time and effort and increase efficiency, which we will discuss in this article.

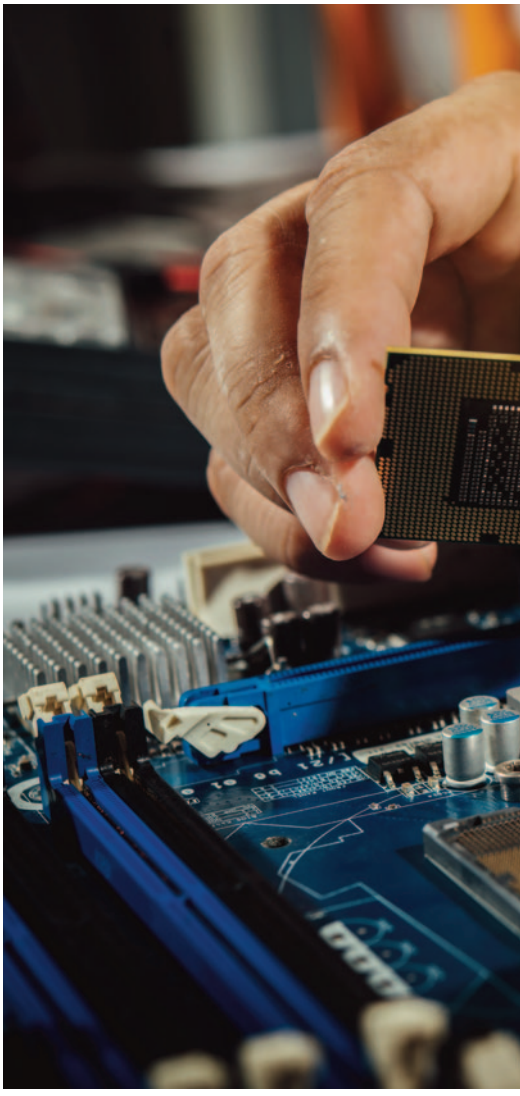
Where we have come from – a time-consuming and tedious manual approach

Best practices for creating CSR narratives have evolved over time, and continue to do so, with processes becoming increasingly efficient. Many of us will be familiar with a more manual approach to medical writing; whether preparing narratives, CSRs, or other regulatory documents, MWs used to spend a huge amount of time simply copying and pasting data from multiple sources.

Before any form of automation, narratives were created manually, in that MWs started from a template and populated it with data from various listings provided for the CSR. The complexity of a narrative can increase significantly in cases where the trial participant has a complex disease status, with a large amount of information needed to describe the disease or clinical status, concomitant medications, and the course of events that fully describe the event(s). Manually retrieving data from each listing for each narrative was a time-consuming task and increased the chance of human error. This, in turn, required a full, thorough quality control (QC) check of all data within the narrative to catch errors. When a CSR required the inclusion of hundreds of narratives, the manual process was a huge undertaking, and hence created the need for a more streamlined approach.

Where we are now – various tools for more efficient narrative production

Moving on from manual production of narratives, the process-driven automation approach is currently widely adopted and involves populating a narrative template containing placeholders or fields where data from



the clinical database can be inserted programmatically. As MWs are not trained programmers, we do not write the programming code ourselves – rather, we can use software or employ the assistance of trained programmers to perform the task. In large, multi-service organisations, where there is a department of programmers, the MW assigned to the narratives can work with a programmer to tailor the narrative template to the specific requirements for the trial. Essentially, we set the rules within the template for what actions follow: an automated trigger or a manual intervention, and the programmer can run narratives with text-based sentences populated with the data points required using the trial data captured in the case report form (CRF) fields. The programmer can generate as many narratives as needed for a CSR, producing consistent and accurate outputs. With the data having been inserted into the narrative programmatically, the QC check of each item of data by the MW is not necessary.

Alternatively, software can be purchased and installed on the MW's computer and used to generate narratives, using data from the clinical database. The MW can load the clinical data into the software package, and set the criteria for the narratives: which narratives should be run, which data should be included, and hence, how they will look. At the click of a button, the software will generate the required narratives.

Manual intervention by MWs in these narratives (either produced with a programmer or by using software) is, however, still required. The primary data source for drafting narratives is the clinical database, but supplementary data sources include data from the safety database (including the Council for International Organizations of Medical Sciences [CIOMS] forms or MedWatch forms), which still need to be inserted manually.[2] These secondary sources aid in providing additional details for building the story of the events being described. This, in turn, then merits a QC check of the manually incorporated text to the programmed output. That aside, it is clearly a benefit to writers to use automation to save time and effort in generating large numbers of narratives.

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The future of automation – AI

We say *the future*, but we are already in the era of artificial intelligence (AI). The use of AI is a phenomenon that is an ever-growing reality and many healthcare companies are now employing AI.

AI is defined as the ability of a digital computer or computer-controlled robot (or *bot*) to perform tasks commonly requiring human intelligence. Popularity of free-to-access AI tools like ChatGPT is growing and the use of AI tools to generate text within our industry is developing rapidly. AI can save MWs more than 30% of their time spent on QC processes and up to 80% of their time overall.[3,4]

AI is a promising tool to automate the narrative writing process beyond the programmed approach.

So where does AI come into play when generating CSR narratives? AI devices mainly fall into two major categories: the first being machine learning techniques that analyse structured data and select the desired information, and the second being natural language processing methods (of which ChatGPT is a form) that extract and analyse information from unstructured data such as clinical notes, to enrich structured data.[5] When we look at these two methods in the context of patient narrative preparation, AI is a promising tool to automate the narrative writing process beyond the programmed approach. An AI tool can automatically interpret the type of input data (CRFs, clinical database listings, CIOMS and MedWatch forms) and self-generate a full narrative output.[6]

Table 1. What are the benefits and potential challenges of AI in narrative production?

Benefits	Potential Challenges
✓ Increases efficiency of MWs	• AI detects and analyses patterns, so needs to be trained on large volumes of content to generate human-like text
✓ Raises the overall quality of the documents	• Adherence to laws and regulations, particularly privacy laws such as GDPR
✓ Re-use of tool to generate narratives after the first project can reduce overall costs	• Adherence to AI-specific laws in the process of being enacted such as the EU AI Act
✓ Reduces risk of errors	• Ethical issues remain largely unaddressed – such as biases in algorithms and protection of patient privacy[8,9]
✓ Reduces the number of reviews required	• Accuracy of output generated – AI tools used to generate text are based on patterns rather than facts, often resulting in factual errors[10]
✓ Maintains consistency between narratives	• Requirement of new skill set for MW using AI tool
✓ AI tool can be tailored closely to project-specific requirements	• Selecting only the relevant data may be a challenge – may include all data rather than just relevant data
✓ Allows MW to focus on data interpretation and messaging	• The narrative cannot be fully automated – MW input still required to ensure highest quality narratives • No efficiencies in medical review of the narratives

Abbreviations: AI, artificial intelligence; GDPR, General Data Protection Regulation; MW, medical writer

Production of narratives using AI still relies on a template being used as a starting point, with the MW adapting the template to meet the needs of the particular trial. This step is an early investment in time that subsequently saves time when the narratives are generated using the AI tool. If narratives are required for more than one trial, but following similar client or product specifications, generation of narratives for subsequent trials is even more efficient as less work is required in the initial template generation step.

The concept of using AI to generate narratives is still emerging, however, and there are a number of restrictions to consider when using AI tools (Table 1). For now, the programmed approach is still well-suited for generating standardised, repetitive documents such as patient narratives.

Will using AI replace MWs in narrative generation?

It is understandable that people feel anxious about the future of their careers when AI tools have quickly become more accessible and especially when a news outlet releases an article titled "Which Jobs will AI Replace?" stating that around 300 million jobs could be affected by generative AI.[7]

As with the introduction of any new process or tool, employing the use of AI will inevitably cause a change in the role of the MW. It will require learning a new skill set to be able to understand and use AI. As much as AI can collect large amounts of data and generate *human-like* text, it can't generate outputs or documents that don't need a human's input, at least to some degree. When preparing CSR narratives, MWs would be alleviated of the repetitive tasks required to manually incorporate data into each narrative and perform a full QC check for errors, and would instead be able to focus on the flow of the story of events for each participant and to use their scientific expertise. With each narrative project being less labour-intensive, MWs would also have the capacity to work on more projects concurrently, meaning refining skills in prioritisation and management of multiple projects at the same time. A medical review of the narrative, and incorporation of any comments, would still be necessary – AI could not replace this valuable part of the work.

> Rather than fearing that AI will replace MWs, we can use AI to our advantage to replace some of our most tedious tasks.

We have discussed the use of AI in the generation of narratives for CSRs, but what uses might it have beyond generation of narratives? In this rapidly evolving area, might we see its evolution heading towards AI tools creating the template used for the narratives by taking the structure of the clinical database and converting it into paragraphs with fields for the data to be inserted? Or further down the line, when narratives are final, could we see AI performing redaction or anonymisation of narratives to maintain patient confidentiality?

AI is quickly becoming a useful tool for MWs

but, at least for the foreseeable future, any output produced using AI tools would still be an initial draft that pulls together content from a variety of sources. As MWs, we need to adapt to using AI tools, just as we often have to adapt to working with updated processes or working to new regulatory guidelines. Rather than fearing that AI will replace MWs, we can use AI to our advantage to replace some of our most tedious tasks.

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Disclosures and conflicts of interest

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