Organising the review process in Microsoft Word®

Alexander Nürnberg

CRS Clinical Research Services Mannheim GmbH, Grünstadt, Germany

Correspondence to:

Alexander Nürnberg
CRS Clinical Research Services
Mannheim GmbH, Richard-
Wagner-Strasse 20, 67269
Grünstadt, Germany
alexander.nuernberg@crs-group.de

Abstract

Regulatory documents are prepared in a highly collaborative process within tight timelines. The time and the resources required for collecting input, organising document review, and processing the reviewers' responses often dwarf those invested in the actual writing. In our company, I have developed Microsoft Word® macros to manage and document the review process. This solution, combined with the modifications of the review workflow, is efficient and, as it relies on the features already contained within Microsoft Word, does not require additional software.

Keywords: Macros, Document review, Microsoft Word

Review is the key process in document development, which ensures the quality and the credibility of the document.[1] It is also one of the most time-consuming steps for medical writers,[2,3] which has, if poorly organised, a high potential for introducing errors and inconsistencies into the document. Software tools can speed up and greatly assist in the organisation and the conduct of document review;[2] yet, software solutions that meet the medical writers' expectations are remarkably scarce.

Usually, documents are distributed in Microsoft Word format and reviewed by using tools available in Microsoft Word. These review tools, e.g. tracked changes and comments, are not only widespread and broadly accepted; they are also easily customisable with macros. We, therefore, decided to adapt them to our needs, aiming at a solution that:

- Is intuitively clear and does not need initial (or worse, on-going) training;
- Promotes a strict separation between the review itself and its implementation, with the reviewers concentrating on the content and the medical writers caring for the implementation, proper wording, and consistency check;
- Guides the reviewers through the document, focusing them on relevant issues;
- Allows a parallel review and an unproblematic consolidation of the reviewers' responses;
- Provides a clear documentation of the review process, discussions, and resulting decisions;
- Facilitates review organisation and processing by the medical writers;
- Leaves the ultimate control over the document in the hands of the medical writers.

Our solution consists of changes in the review practice and the programming adaptations of the commenting functionality in Microsoft Word, involving rules for tagging comments and a set of macros.

Changes in review practice

We have abandoned the 'track changes' mode, which is an excellent tool for indicating changes in a single distributed copy, but is not practical if several reviewers are involved in the review. Instead, we distribute document copies that permit commenting only and ask the reviewers to provide their opinions as comments in the document. This way, the medical writer retains ownership of the document.

Upon review completion, comments from the returned copies are automatically transferred into the master document without producing conflicting insertions and deletions. The resulting master document containing all the comments represents a clear record of the review process. This document can then be conveniently processed by using dedicated macros.

Tagging a comment

A comment in Microsoft Word conveys three major pieces of information: the comment itself, the author, and the scope (i.e. the marked text to which the comment is attached). For an efficient processing, we additionally specify the addressee, the relevance, and the status of a comment by

introducing standard descriptive phrases (tags) into the comment's body.

Addressee

The addressee of a comment is given by a boldfaced upper case expression like '@SOMEBODY:' (Figure 1A and B). By using this tag, we provide guidance for the reviewers, denoting the comments that need special attention. As the tags are in bold uppercase, we reduce the risk of the comments or the questions being missed. Unified abbreviations implemented in the macro, e.g. @ALL, @INVESTIGATOR, or @STAT, contribute additionally to the clarity. In the end, this approach saves the reviewers' time, especially when the documents contain numerous comments (a typical situation in the early stages of document development).

Relevance

The relevance (in our parlance 'rating') is shown in the first line of a comment as boldfaced 'Rating:' followed by one of the five categories (in descending order): critical, major, minor, note, or editing (Figure 1B and C). Assigning relevance to the comments and the questions allows us to prioritise their processing and to quantify document quality. In addition, we introduced escalation rules, e.g. the critical comments must be immediately clarified with the team, the major comments need to be confirmed and followed up, the minor comments require confirmation only if declined, and the notes can be implemented or rejected at the medical writer's discretion.

Status

We specify the processing state of a comment by assigning the 'status' using four categories: done,

pending, declined (rejected), and confirmed (Figure 1B and C). Similar to the rating, this tag can be smoothly added or changed by a macro.

Replies

Although Microsoft Word provides functionality for replying to a comment, such replies appear as normal comments, with the only visible difference being an 'R' added to the author's initials (It has been changed in the newest version, Microsoft Word 2013, where the replies are displayed as a discussion tree. Comments can be also marked as 'done' in this version.). Often, however, people add replies as a new comment, sometimes at a rather arbitrary location. In either case, the original comment and several replies form a bewildering array, which becomes even more disorganised if several unrelated issues are discussed within one page.

Our strategy is therefore to discuss each issue within one comment, keeping the discussion thread together. For this, we place a new reply directly at the end of the initial comment and any previous replies therein. Each reply starts with a boldfaced expression 'REPLY(Initials):' (added automatically) and is followed by the actual reply (Figure 1B and C). Of note, our macro prevents addition of the eighth reply, notifying the user that a telephonic conference may be a better solution.

Managing comments

Although it is already a great improvement when a comment clearly states what has to be done and who has to do it, the full effect of these ideas is only seen on a document-wide macro solution. Such a macro analyses the comments within the document,
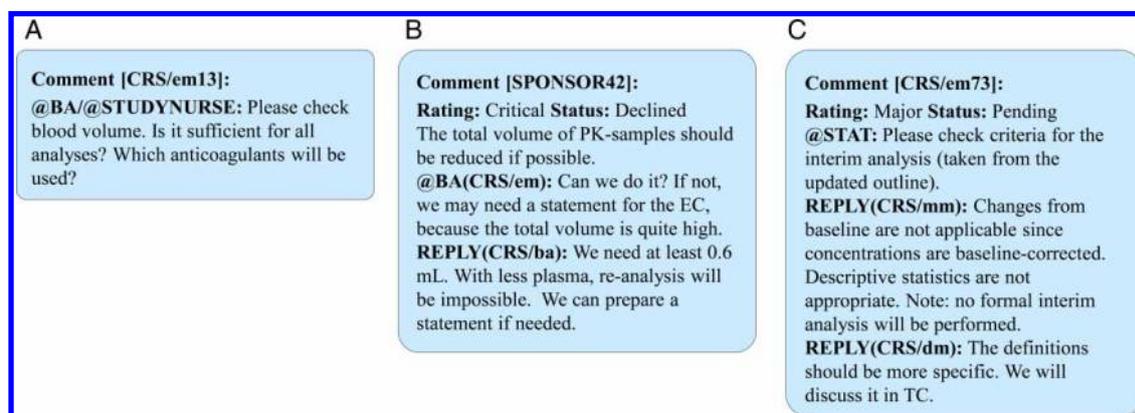

Figure 1: Examples of Microsoft Word comments in our format. (A) A comment addressed to a bioanalyst and a study nurse during an internal review. (B) A comment from a sponsor that we rated as 'critical' and redirected to the bioanalyst. The bioanalyst replied, declining the proposal. Hence, the status of the comment is 'declined'. (C) A comment to the statisticians during an internal review. There are two replies from the statisticians. Note that we set the user initials in Microsoft Word to 'company name/initials' to distinguish in a better manner between the internal and the external comments and to provide clarity for our customers.

extracting information on the addressees, the ratings, the status, and the replies. The extracted information can be used in several ways.

Comments can be selected on the basis of their tags (Figure 2). The macro allows a flexible combination of tags, e.g. selection of all the comments to the investigator that are pending and critical, and do not contain replies. The selected comments can then be exported into a Microsoft Word or Excel® file, with the tags and the replies displayed in separate columns (Figure 3). We use these lists for documentation of the review process, for overviews, for preparing telephonic conferences and meetings, and as supportive documents for the reviewers.

Alternatively, the comments can be selectively deleted from the document. We routinely remove unrelated comments from the distributed copies, leaving the complete set of comments in the master document only. This approach is especially useful for an interim clarification of a single issue: in this case, we can easily create an ad hoc copy of the document that contains only issue-specific comments.

Other applications of the macro include quality metrics, with the overall number and relevance of the comments being measures of document quality, estimation of the remaining work load using the status tag, and work allocation. The macro can also control the proper implementation of the reviewers' comments, e.g. requiring that all the declined comments are replied or that all the critical and major comments are processed. Finally, small and handy tools incorporated into the macro, e.g. predefined replies or copy/paste of the entire comment, provide good assistance and enhance productivity.

Summary

Certainly, the presented approach requires accustoming and some tuning of the review workflow, but its benefits clearly stand out: document development becomes more standardised and efficient. Although we mostly use these tools internally (external reviewers are invited but not required to mark comments in our way), this approach has been already accepted by several sponsors due to its obvious benefits. Other companies also use macro-assisted approaches in a similar manner with a noticeable increase in the productivity and the streamlining of the review process (Gwyn Hopkins, personal communication). One macro of particular interest in this context extends the compare/combine functionality of Microsoft Word to be able to combine the comments of several documents in one go, again demonstrating the power of macro programming and its opportunities.
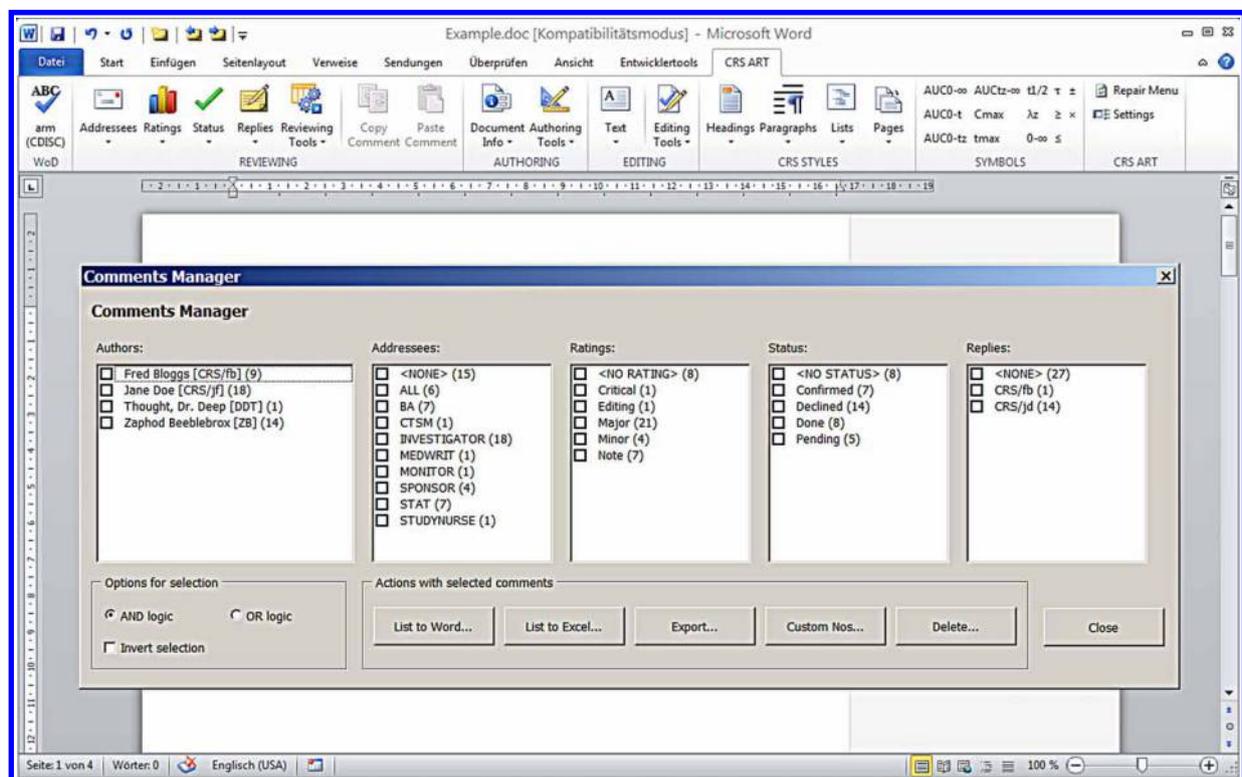

Figure 2: 'Comments manager' used for selection of comments on the basis of five attributes.

Figure 3: An example of an exported comment. For clarity, the macro exports the whole paragraph surrounding the comment's scope. The scope (i.e. the marked text to which the comment is attached) is then automatically highlighted.

In conclusion, the author wants to encourage medical writers to use macros in their daily work and to invite them to discussions and exchange of ideas. Macros are useful for a variety of tasks performed by medical writers, saving time, resources, and improving document quality. They can also promote new ideas: forcing people to manually add predefined text expressions in a specific format most probably would have failed, whereas the same ideas provided as easy-to-use menu buttons were highly appreciated.

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Conflicts of interest and disclaimers

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The screenshot of Microsoft Word shown in Figure 2 is used with permission from Microsoft.

Supplementary material

Online supplementary material 1 of a demonstration file, containing the simplified macros described above, is available.

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Author information

Alexander Nürnberg is a medical writer at CRS Clinical Research Services Mannheim GmbH.