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Considerations on Medical Ghostwriting and Research Consultancy

WHAT IS A MEDICAL GHOSTWRITER?

At some stage of one's medical curriculum, most physicians have written a draft a text for their too busy superiors. By that doing, they have undertaken some medical writing personally. Maybe you did not recognise that, but you have already done some medical ghostwriting yourself. By definition, a professional **Medical Ghostwriter** writes medical texts on behalf of others as a full time profession. It is good to remember that whenever you were not among the authors in the research report that you drafted, you acted as a medical ghostwriter yourself.

HOW DO THEY OPERATE?

Basically, a medical ghostwriter operates in the same way as you did while drafting your text to your boss. How did it happen? You probably first agreed with the contents and the format of the text, but not infrequently, you had to find out yourself, how to structure the document. You made a literature search or collected other material to get updated with the recent developments on the topic. You also made the necessary contacts with the colleagues who were supposed to make their own contributions to the text. After having all material and all contributions at hand, you wrote the draft document. This was then circulated among the contributors for comments, including your superior and all others who were to agree upon it before sending to Journal. One round is not always enough, but you need to repeat it for the second draft, etc. This is very much the way how a professional medical ghostwriter does her/his daily work.

WHAT DOES MEDICAL RESEARCH ETHICS SAY ABOUT THIS APPROACH?

The good news is that the guidelines for the preparation of regulatory documents or the **Uniform Requirements for Manuscripts Submitted to Biomedical Journal**s do not state that the manuscript / report must be drafted by the Author. Accordingly, a medical ghostwriter is an established profession, and indeed, they make an important contribution to the published medical literature of today. As in many aspects of medicine, situation with medical ghostwriters is different in Europe and in the US.

In the United States, where the old principle: publish or perish, still holds true, many authors have started systematically using the services of medical ghostwriters to improve the efficiency of their scientific output. The American Medical Writers Association (AMWA) is huge, currently incorpo-

rating over 4.000 members. Even Universities have opened courses to educate graduates in Medical Writing, to meet the increasing demand for these professionals.

In Europe, the most frequent employers of medical writers are the pharmaceutical companies running the clinical trials with their new drugs. Clinicians controlling these trials are frequently offered access to ghostwriting services, because reluctant to devote their limited time to writing the scientific reports of these clinical trials. The subject was recently aroused as the topic of a debate by the Editors of European Journals in The Lancet (Sharp D. A ghostly crew. Lancet 1998;351:1076 and the replies by Wager E. and Grossman L. Lancet 1998; 351:1741).

As a result, a meeting was organised between representatives of pharmaceutical industry and medical editors. A document was drafted that sets the standards for **Good Publication Practice (GPP)**. The final version of the document was recently published in the Lancet: Sharp D. Drug Industry Code Proposed on "Ghost" Writing. Lancet 2000;355:1084.

This important document both accepts and regulates the activities of medical writers. Importantly, it also regulates the relationship between pharmaceutical industry and clinicians, regarding their sponsored biomedical publications.

The key points of the GPP document are the following:

1) The **authors** (signatories) are **responsible for the contents** of the text. They must be involved in the drafting of the article, starting from the working outline up to approval of the complete final version, including all figures and tables.
2) The **Medical Writer** should ensure that all requirements of the guidelines and/or instructions to Authors are complied with and **coordinate** the collection of contributions. Each Author must be given sufficient time to make meaningful comments.
3) Medical Writers **should not accept** to draft editorials or articles that reflect the personal opinion of an expert in some way. These articles should always be written directly by the expert. The only acceptable contribution of Medical Writers can be the review of the English style of texts drafted by Authors whose mother-tongue is not English.

MEDICAL GHOSTWRITER AND AUTHORSHIP?

A frequently asked question is, whether **medical ghostwriter** should be included among the authors of the Report? The answer is crystal-clear **no**, if the text is a manuscript to be submitted for publication in an international medical Journal. This position is based on the latest version of the **Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URMSBJ),** stating (..among other things..) that "the **authors** must have taken part in the study, so that they can take responsibility for its contents. In particular, they must have made a significant contribution to the following:

1) the conception and design of the study, as well as the analysis and interpretation of the data

2) the drafting or review of the contents of the manuscript
3) approval of the final version of the manuscript for publication."

Clearly the medical ghostwriter could easily meet the criteria 2) and 3), but not the most important of them, criterion 1). The key here is that we are speaking about traditional medical ghostwriters.

Following this reasoning, the situation should be different for the new group of **medical expert consultants**, i.e., professionals who offer services in medical writing, but also in subjects going far beyond the expertise of a traditional medical ghostwriter. From this point of view, the core services include a) participation in study design, and b) statistical analyses and interpretation of their results. These two activities certainly fulfil the above stipulated URMSBJ criteria of an authorship.

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According to the requirements of the **GPP Document,** the contribution of the medical writer in a regular Journal paper should be mentioned in the Acknowledgements. Concerning the regulatory documents on therapeutic products for different health authorities, this practice certainly depends on the internal operating procedures of the companies.

WHEN DO YOU NEED SERVICES OF A MEDICAL GHOSTWRITER?

Let's talk about the traditional medical ghostwriter first. There is no general rule when to consult a medical writer, but this decision completely depends on what you are doing. If you are able to write the document yourself without any major difficulty and only **want to save time**, hiring a medical ghostwriter is probably not worthwhile, unless you are a regular user of a personal ghostwriter, who is profoundly familiar with your research topic and the content of your manuscripts. Using someone who is unfamiliar, might face the risk that the time you have to invest in briefing the writer is longer than it would take you to write the document yourself.

Almost the only other occasion to hire a purely medical ghostwriter might be, if you feel uncomfortable to write in English, just because that is not your **native language**. Even in such a case, you do not probably need a writer to draft the document itself. Probably the best solution is to draft the text yourself and have it corrected by a ghostwriter who can also do the editing. If your English is really poor, you should write the text in your own language and have it translated to English, because traditional ghostwriters do not usually provide translation services.

WHEN DO YOU NEED AN EXPERT CONSULTANT OF MEDICAL RESEARCH?

Should you need instructions and assistance in any topics beyond these, you should seriously consider contacting an expert scientific consultant, who can guide you through **all the steps from the study design to the day when your research report appears in a peer-reviewed international Journal.**

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Once again, it is essential to make the different between a medical ghostwriter and a medical expert consultant offering services based on personal experience as an active scientist, with own record of original publications, abstracts, review articles, book chapters, etc. These people are experts in all aspects of medical research, starting from study design, raising the funding, running the study, analysing the data, interpreting the results, and writing the manuscript. In addition, they know, how to select the most appropriate Journal where to submit your report. They are also experts in responding the reviewers' criticism and making the necessary (but not the unnecessary) revisions to improve the quality of the manuscript, without compromising the original idea, if the reviewer's criticism was not justified.

There is a major difference between these two professionals,
as you can appreciate from the above.