The regulatory medical writer: More than a writer, an expert

by Mary Jane Lunsford

In response to the article entitled, 'Broad spectrum medical writer; Nature or nurture?' I intend to offer a different perspective as the Director of a global medical writing department at a clinical research organisation (CRO). I agree that medical writers with sufficient training and experience can generate and produce regulatory and medical communication documents. I further agree that regulatory medical writing is not suited for everyone's temperament and a broad spectrum medical writer might be exposed to more creative writing assignments including web site writing, slide deck creation, abstracts, or posters. The broad-spectrum medical writer may be able to identify the tone and style to allow them to be a good regulatory medical writer; however, I have found that a good regulatory medical writer is involved in a broad spectrum of tasks. Regulatory medical writers are trained on the latest global regulatory requirements, review other documents as part of the overall clinical research process (i.e. statistical analysis plans [SAPs]), summarise highly complex data, and are part of an internal and external team. Regulatory medical writers are familiar with International Conference on Harmonization (ICH) guidelines, regulatory style requirements, tone, and preferred terminology. Therefore, regulatory medical writers can easily meet the sponsor's needs without the additional start-up time it may take for broad spectrum medical writers who are likely to perform these tasks less frequently.

The function of a regulatory medical writer is to provide the highest quality scientific documents to satisfy the needs of the targeted audience. Regulatory medical writing has become more complex with the introduction of new requirements to secure drug approval. Since 2007, pharmaceutical companies that submit products containing a new active substance for regulatory approval to the European Medicines Agency are required to produce a Risk Management Plan. As of 2008, regulatory submissions to the Food and Drug Administration in the United States now require Risk Evaluation and Mitigation Strategy (REMS) documentation to support the approval of some classes of drugs (i.e., analgesic products that may be abused). In the global CRO environment, regulatory medical writers are trained in new global regulatory requirements and are prepared to meet the demands of each local regulatory body.

Pharmaceutical companies realise that speed-to-market is paramount to gain an advantage over their competitors. Regulatory medical writers are an integral part of the clinical research process. The regulatory medical writer must understand the data to interpret it correctly as well as have the ability to summarise the statistical findings. Those tasks, previously the responsibility of clinical researchers or biostatisticians, are now frequently performed by regulatory medical writers. Moreover, regulatory medical writers may be expected to summarise complex pharmacokinetic data to support early drug development for 'first in man' studies. These complex and highly scientific documents need to convey a story in an understandable and transparent manner to enhance the drug submission process.

The regulatory medical writers at many pharmaceutical companies and CROs are part of a team of individuals and typically work closely with data management, clinical trial management, biostatistics, regulatory affairs, and therapeutic or scientific experts. During protocol development, the regulatory medical writer works with the internal team and the sponsor to develop a protocol that is easily executed in the clinical setting. After the protocol is implemented at the clinical site(s), the regulatory medical writer continues to be part of the process. The regulatory medical writer reviews the SAP and upon finalisation of the SAP, constructs a clinical study report (CSR) shell that includes sample text. The regulatory medical writer participates in the review of blinded listings before database lock to ensure data quality. Upon database lock, the regulatory medical writer reviews draft tables and listings before the final tables and listings are produced. The tables and listings provide the scientific data to generate the CSR. As a member of the internal team, the regulatory medical writer has the ability to complete a clear and concise CSR that reflects the results of the clinical trial. The results of each CSR ultimately become a piece of the drug submission documentation. The regulatory medical writer's participation on the team ensures streamlining of the entire medical writing process, from protocol development through the drug submission process.

Many small to mid size pharmaceutical companies seek to outsource their regulatory medical writing when internal resources are not available. Our sponsors expect that the regulatory medical writers will expertly guide them through the process to tell an effective story about the study drug for the intended audience. Dedicated regulatory medical writers provide candid feedback and suggestions for process improvements back to our sponsors. On the rare occasion that our organisation experiences an unex-

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pected increase in workload, I employ freelance medical writers who are experienced in regulatory medical writing and who are trained in our standard operating procedures. Each freelance medical writer has experience in working with our data management and biostatistics departments to resolve any data issues and has experience in analysing and summarising clinical data. Also, each freelance medical writer is managed by an internal full-time regulatory medical writer. Just as I seek to employ strong full-time regulatory medical writers, I also seek to employ contract freelancers who can contribute to our internal team as an expert, not just as a medical writer.

Pharmaceutical companies and CROs are constantly challenged to identify process improvements to get the information to the appropriate regulatory agency as soon as possible. Experienced regulatory medical writers understand the requirements and expectations of the regulatory agencies. These dedicated regulatory medical writers have been part of the internal team and have had direct access to each of the team members. Regulatory medical writers are exposed to a variety of tasks and can offer insight in protocol design so that the data generated from the clinical trial will reflect the intended information needed for product labelling, assist in data interpretations, provide summaries of statistical data, provide summaries of highly complex data, and offer suggestions for process improvements to our sponsors. Based on the broad spectrum of tasks, I conclude that a regulatory medical writer can experience the same kind of job satisfaction that may be derived from broad-spectrum medical writing. If given the opportunity, try both to make your choice.

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Non-financial competing interests

Whether journals should pay more attention to non-financial competing interests is currently a hot topic of discussion among biomedical journal editors. One of the problems of course is where to draw the line between what is and what is not appropriate for declaration. If an author's membership of a political or other activist group or if he/she is a campaigner for a particular cause that could potential pose a competing interest declaration would seem appropriate. But there are plenty of other non-financial potential conflicts. An interesting editorial entitled "Making Sense of Non-Financial Competing Interests" has recently been published by *PLoS Medicine*. Available at http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0050199

A has-been that shouldn't have been

If you are talking in English about an event in the past that is finished, to use the *present perfect* (tense constructed with the auxiliary verb *to have* and the *past participle*) is wrong:

Copeptin, also known as the AVP-associated glycopeptide, has been described for the first time by Smith in the year 1972 [2].

This should read (note that I also jettisoned *for the first time* in favour of *first* and *in the year* because it is superfluous):

Copeptin, also known as the AVP-associated glycopeptide, was first described by Smith in 1972 [2].

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Definitions box

Incidence and prevalence

Incidence describes the number of times a condition or event happens in a given time period in the population at risk. Incidence describes a changing situation, whereas prevalence (see below) describes a static situation. The *Incidence rate* is therefore the number of persons developing a condition within a population over a set time period. This is usually expressed as the number of cases per 100,000 people in the population per year.

Prevalence, however, is an indication of the number of individuals in a population at risk who currently have (or in some cases who have had) a condition or event. *Lifetime prevalence* is thus the proportion of persons manifesting the condition during the period of their life up to the survey date. It is usually expressed as the number per 1,000 of the population at risk.

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