

Outsourcing Medical Writing: The Evolution of a Niche Domain:

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Medical writing has been described as the art of producing scientific documentation by a specialized writer. Some have described it the art of telling a scientific story. Others have described it as the art of collecting, analyzing and presenting data using scientific method, supported by the use of scientific judgement. Bottom line - it is not just a technical skill, it is an art.

It involves a fine blend of writing capabilities, awareness and application of regulatory and scientific guidelines (such as ICH E3, CONSORT, ICMJE, etc.) templates, style guides (organization specific or the AMA style guide for example) and standards, a bent of scientific inquiry, the ability to define the best approach to present the data in the desired format, the ability to accurately analyze and interpret the data, and manage strategic communications with other partners such as clinicians, statisticians, regulators and even working with clients and outsourcing partners. A debate was held at the Drug Information Association (DIA) at Washington D.C. in June '10, on whether Medical Writer's should be scientists or not. Some of the key points that were highlighted were that though an advanced degree in science may not be a key requirement, having relevant therapeutic area knowledge, having an understanding of the safety and efficacy profiles of the molecule that one is working on, the clinical trial design and methodology, the significance of the design of product strategy, statistical concepts, data interpretation skills and so much more. On the other hand, owning a degree in advanced science or medicine does not necessarily mandate that the person would be a good medical writer¹.

Knowledge of document management systems, version controlling, editing and doing qc checks, attention to detail, the ability to manage the scientific information flow, to perform critical content review (To quote H.G. Wells, 'No passion in the world, no love or hate, is equal to the passion to change someone else's draft.') and finally manage project deliverables, all determine the capability of the writer to author quality documents. Thus document expertise, scientific expertise, writing skills and project leadership constitute the four pillars of medical writing.

To quote Dr. Stephen de Looze, Hoechst Marion Roussel, 'In many ways, medical writing is its own worst enemy. The reason is that better the writing, the more invisible it becomes'². Simplicity and conciseness are very important. In addition, medical writing is not only about verbose descriptions, considerable art and wisdom also goes into the effective tabular presentation of key data. One needs to be picky in identifying exactly what needs to go in there and what would be the best format for presenting the data in this table. Hence, the ability to focus upon significant findings, an effective presentation style and clarity of thought are very important skills. Else, one may reflect upon the remark that Sir F. M. R. Walshe made to a London physician on the publication of a somewhat obscure paper 'I see you have an interesting paper in the latest number of Brain. When is the English translation coming out?'

The ability to write a good discussion is possibly the indication of a good and an experienced writer. Some of the key elements of a good discussion are the ability to bring out patterns, establish relationships, explain conflicting results, present both sides of an argument, discuss unexpected findings, come out with key conclusions, identify potential limitations of the research process and their impact on the interpretation of the results and not only summarize the key implications of the findings, but make some recommendations based on the same as well³.

Medical writers primarily work on regulatory writing and marketing material writing.

Regulatory writing is an integral part of the drug development and approval process and includes protocols, Investigator's Brochures, interim and final clinical study

reports, annual safety reports and periodic safety update reports, safety narratives, Investigational New Drug applications⁴, Common technical documents, Food and Drug Administration (FDA) briefing documents, Integrated summaries of efficacy and safety, manuscripts, abstracts, posters and product labeling.

Medical Writers also work on package inserts, product literature, and continuing medical education initiatives to support medico-marketing activities to enhance brand awareness in consumers and physicians and also meet the growing need for healthcare information, safety alerts and evolving regulatory guidelines.

The challenges that a Medical Writer faces are unique. Firstly, while most medical writers do have some scientific degree and / or a language background, many of them are not necessarily graduates/post-graduates in medicine or Ph.Ds⁵. This thus necessitates taking inputs from medical experts, clinicians, and statisticians and the medical writer needs to present their thoughts in the most meaningful, logical and succinct manner. Secondly, writing the manuscript for medical experts is one thing, receiving no acknowledgement for the same is another. This is not a very rewarding experience and every effort should be made to recognize both the medical expert's contribution to content and the medical writer's writing skills as well. Thirdly, the medical writer often has to work across different document types, different therapeutic indications and different phases. This calls for the ability to quickly comprehend the varying requirements of each document type, phase and indication. It is also important to quickly develop an in-depth understanding of the subject matter to be able to present a meaningful

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discussion. Fourthly, the medical writer has to be able to deal with a continuous state of flux and rather challenging deadlines, as the data typically comes-in late, but submission timelines don't change. Further, the medical writer needs to be able to manage processes and documents in a very structured manner as the versions of the data-sets undergo multiple changes and corresponding changes would be required in the drafts of the clinical study report as well. In addition, the medical writer needs to shake himself out of his cozy nook, and if dealing with outsourcing partners, needs to manage cross-cultural communication and time zone differences as well.

Expiring patents and depleting pipelines create an urgent need to ensure the effective documentation of the safety and efficacy of new molecules and high-quality medical writing can contribute significantly to obtaining a speedy drug submission and approval.

Thus, in a recessionary economy, the ability to gain efficiencies at lower costs becomes a key driver for outsourcing. In addition, outsourcing also allows the Pharma to become leaner, reducing fixed costs, especially during lean periods of the product development cycle, as the bulk of medical writing activity occurs either towards the beginning or the end of the study. Outsourcing could constitute a mix of working with a dedicated team to manage the bulk of the work and working with freelancers to meet the need to quickly scale up as required to meet pressing timelines. Awareness of local regulatory requirements and other niche specializations could also favor working with freelancers.

Restructuring in organizations, resulting from mergers and acquisitions, retrenchment and the need to pace drug development programs are increasingly driving outsourcing to CROs, which provide a secure and steady supply of a team of trained medical writers, as against freelancers, which was the preferred model not so long ago. Dedicated FTE-FSP (Full Time Equivalent - Functional Service Provider) models are gaining increasing popularity. The advantages of this model include a team which is well versed with the sponsor's expectations, templates and style guides, SOPs, document management systems, and a team of writers that can specialize in working on particular therapeutic indications, or document types which are specific to the sponsor. In addition, as the team is dedicated to a particular sponsor, fluxes in work can be distributed across the team and thus peaks and troughs can be effectively buffered as required.

While there are many advantages to this model, this does require considerable investment from both the sponsor and the CRO in establishing well defined governance models, communication and issue escalation plans, and attrition management plans. Adequate training should be provided

by the sponsor so as to ensure that the team is suitably equipped to deliver per the sponsor's expectations. The governance model established should be such that communication of the right issues occurs at the right levels and senior level leadership and commitment is key to the success of such models. In addition, it is important to remember, that both the sponsor and the CRO need to invest in nurturing this relationship, through on-going trainings, face-to-face meetings, and need to ensure complete transparency in terms of managing various issues that may result during this period. Relationships often fail as the perceived productivity of the medical writers at the CRO's end is found to be significantly lower than that of in-house writers. It is important to remember however that this loss of productivity many a times results during the transaction of knowledge between the medical writer at the pharmaceutical company and at the CRO, as the medical writer at the CRO does not have the corresponding degree of direct access to internal company information and deliberations. Thus, providing direct access to sponsor's document management systems, erooms, etc, albeit after ensuring that the required security systems are in place, can significantly enhance productivity. The CRO also needs to partner with the sponsor, not just in terms of generating high quality deliverables, but also in terms of developing an in-depth understanding of the sponsor's processes, understanding the bottlenecks and contributing value by driving process improvement using Lean Six Sigma methodology. Both the CRO and sponsor teams also need to understand the dynamics of effective co-authoring, which is critical to the success of such a partnership. Dr. Steve Carr, Director Medical Writing, Janssen AI, stressing upon the human factor, has observed that "Spending time, developing one on one relationships with offshored colleagues improves the quality of documents, reduces the burden on the in-house writer, and makes the whole outsourcing endeavor more fun. Developing one on one relationships is the way to go!" The key elements of successful partnering were presented by SIRO Clinpharm at the DIA Annual Meeting, at San Diego, in 2009, as a case study based on the successful implementation of such a partnership⁶.

Lastly, sharing of the long-term vision and strategy by the sponsor, drives commitment from the CRO's end and helps both to work in a mutually beneficial manner towards a shared goal.

To quote Dr. Carolyn-Smith Barret, Global Head, Regulatory Medical Writing, JnJ PRD US, who has provided strategic direction resulting in the successful implementation of medical writing partnerships, "Outsourcing can be an extremely efficient and effective method of supporting the internal workload when done correctly. Close partnerships including up-front open discussions of assumptions and

expectations in both directions are critical, as are ongoing training and discussions of continued process improvement."

A basic element of success to such initiatives is to identify and recruit medical writers with the right skills sets, which map appropriately to the sponsor's requirement. A Medical Writing Competency Model⁷ has been developed by the Medical Writing special interest group to facilitate the same and was presented recently at the DIA in June 2010, at Washington D.C. When invited to comment upon the value of this model in establishing outsourced relationships, Dr. David Clemow, Scientific Communications Consultant Global Medical Communications, Eli Lilly and Co., who chaired this session at the DIA and presented on this model as well, commented, "The Medical Writing Competency Model is a valuable tool for medical writers, supervisors of writers, and those hiring medical writing services. The model provides the competencies and associated knowledge, skills, and behaviors believed by global industry experts to be needed to succeed as a medical writer in the pharmaceutical industry. Thus, the model can be used as the basis for a multitude of practical applications related to recruiting and hiring; onboarding and training; and employee performance evaluation, management, and retention. In regard to establishing long-term, sponsor-vendor relationships, the model can be used by the sponsor and the vendor to align on what competencies the vendor can provide in relationship to what the sponsor needs; performance score cards based upon the model could then be used to monitor the vendor's performance of those delivered competencies."

Medical Writing has been identified by CenterWatch⁸, in a vendor and outsourcing Survey, conducted in 2005, as the fourth most frequently outsourced function, after Monitoring, DM and Clinical Trials Supply Management in that order, with 41 % of the respondents confirming that they outsource their medical writing work. CenterWatch also reported that the medical writing market doubled in size from \$345 million in 2003 to \$694 million in 2008, growing 15% year on year.

India is serving as the key destination for the outsourcing of medical writing activities as not only does it have a vast number of highly qualified professionals, with many having a sound knowledge of good clinical practices, drug development, experience with basic and clinical sciences. English is the primary business language, thus strong writing skills, and a good command over the language, complemented with cost effectiveness increasingly make India a primary destination for the offshoring of medical writing services.

Medical writing, unlike data management or clinical monitoring is still a relatively niche domain in India, though it is growing very rapidly. To quote, Art Gertel, VP, Strategic Regulatory Consulting, Medical

with a number of people who represent the medical writing departments in major pharma companies. They were told by mandate that they had to go to India for medical writing and establish a medical writing presence in India."⁸

In a survey conducted by Cactus Communications in October 2008, out of 49 respondents (albeit a small sample size), about 30% of the medical writers were found to be from Mumbai and 25% from Bangalore. Over 60% had medical degrees, but only 21% had over ten years of experience in the field of medical writing, indicating that this is a field which is still in its nascent stage in India, though growing very rapidly⁹.

Not all medical writing outsourcing relationships succeed. There has been a mixed response, as at times considerable effort has to be invested in training and retraining resources, rewriting some sections of a document and ensuring that the required level of quality control is maintained - all of these at times tend to defeat the purpose of outsourcing. But whether a relationship succeeds or fails depend upon the amount of ongoing investment at both the pharma and the sponsors end in establishing this relationship. Signing a contract does not ensure results, nurturing the relationship however does bring long term dividends.

So should a medical writer work with a CRO or a pharmaceutical company? Medical writers from a CRO have the advantage of working across a wider variety of document types and therapeutic indications and need to handle pressing timelines and adapt to the expectations of different clients¹⁰. Writers working at a pharmaceutical company, may

work within a more limited area, and while they also have to deal with pressing timelines, they usually benefit from more prolonged, in-depth and thorough training, giving them more time to on-board and familiarize themselves with the document type or therapeutic indication, making it effectively less stressful. CROs often prefer to recruit medical writers from pharmaceutical companies, who would have acquired the required levels of training and expertise and often, those writers are also keen on moving into a CRO as a result of having worked too long in a particular area, having limited flexibility to move out of that domain and possibly, having limited growth paths as well.

To conclude, as companies go virtual and try to curtail costs, the outsourcing of medical writing is very much the future. These companies will certainly continue to control strategy and project leadership, but offshoring and FTE/FSP partnerships will lead the way. The effort invested on both sides in establishing effective partnering models and transitioning the relationship from a purely transactional one to a strategic partnership can make all the difference.

Acknowledgements

I would like to personally thank Dr. Carolyn-Smith Barret, Global Head, Regulatory Medical Writing, JnJ PRD US, Dr. Steve Carr, Director Medical Writing, Janssen AI and Dr. David Clemow, Scientific Communications Consultant Global Medical Communications, Eli Lilly and Co., for having contributed their opinions for this article.

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