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Medical Writing — An Outsourcing Competency

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Abstract: The history of medical writing began with the rise of the modern clinical trial. A medical writer can be your most pivotal ally in a clinical trial. While clinic directors, data managers, and investigators in the pharmaceutical industry are required for clinical trials, medical writers are the glue that holds clinical trials together. The increase in volume of clinical trials has already put a tremendous strain on journal editors and reviewers. A medical writer can play a key role in accelerating the publication of clinical trials, by preparing manuscripts and their current format in accordance with journals' requirements. As a result, well-designed manuscripts can be published faster, and results can reach the public faster and more cost-effectively.

In 2009, 13% of all pharmaceutical expenditure worldwide was estimated to be spent on medical communication. Yet the role and the medical writer's impact on clinical trials is often misunderstood by sponsors, who don't realize how often they truly need medical writers. As pharmaceutical companies now look to outsourced medical writing service providers to augment their internal teams, the role and the agencies importance can no longer be underestimated.

Medical writing involves developing clinical data into structured review documents such as protocols and reports that inform a drug's development, status tracking, and crisis management. Ideally, medical writing is carried out by skilled writers who can elicit crucial scientific information from expert scientists and condense and format the collected data into review documents for submission to regulatory bodies.

Several challenges such as stringent timelines need for accuracy and cost requirements on medical writing necessitate that the qualified writers are accompanied by an array of project managers and other resources. From a financial standpoint, medical writing differs from other activities in the pharmaceutical industry in many respects. It is labor-intensive, and so, the cost of high-caliber writers is more.

Additionally, increased product types and complexity in the regulatory landscape means that medical writers have to be specialists in their content areas. As a result, companies are discovering that the supply of medical writers is lagging behind the demand.

There is also a supply and demand imbalance. Often, pharmaceutical companies hire a team of medical writers to handle a single project, resulting in writers on "bench" post the completion of the said project.

On the other hand, medical writers are frequently required to live up to weekend working requirements, even though approval agencies and pharmaceutical companies are behind in setting their deadlines.

Agencies continue to mandate that medical writers be required to work long hours to meet submission deadlines. This results in experienced writers and other staff with professional and personal commitments to deter from pursuing careers in medical writing.

Due to the reasons mentioned above, pharmaceutical firms have begun to look at outsourcing as an alternative. This can alleviate the demand disparity and supply bottlenecks, lower risks associated with staff turnover, and reduce overall cost and cycle time for medical writing.

Among the dispute resolution mechanisms that encourage such outsourcing are modern and global interpretations of site selection criteria, provisions that allow the use of a custom site or subcontractor model, and approved dictators on a case-by-case basis.

One of the main reasons the pharmaceutical industry outsources medical writing is limited access to clinical trial sites. There is a well-documented global shortage of clinical trial centers and qualified investigators, which hinders the timely implementation of clinical trial protocols. Lack of real-life clinical settings and a low number of trained investigators in those centers create a bottleneck in drug development.

Drug companies usually outsource any subsequent trials once a drug gets through the Phase I clinical trials, and there is no perceptible benefit to being innovative for a higher end-patient population.

For example, a National Cancer Institute can provide investigator-initiated Phase I cancer trials for approximately 0.2% of the probable twenty-five hundred (2,500) researchers registered with the organization. This means that more than ninety-nine percent (99%) of the researchers registered with the NCI cannot receive funding for a Phase I trial.

In 2006, there was a similar situation at another Southern-American National Cancer Institute (INCA), with an estimated 50 investigators competing for a limited number of Phase I clinical trials. The slow rate of site acquisition is further compounded by the additional complications introduced by local culture -– a counterpart to time and talent considerations. In several locations across Eastern Europe, some trials require multiple nurses, whereas, in other locations, it is acceptable to use graduate students instead.

For North American trials, there are often requirements so specific that they are written into the clinical protocols themselves. In Europe, the requirements lead to approval delays because of questions about feasibility. This is further complicated by a growing demand for international expansion, particularly into China and India. According to the publicly available data, nearly sixty percent (60%) of Phase II and III trials are now conducted in low or middle-income countries.

Nevertheless, cultural norms in countries like China, where the government is highly protective of intellectual property rights, may conflict with the Western rational trial designs. Specific centers like India only permit studies that treat pathological conditions present at a prevalence of thirteen percent (13%) or higher. These parameters present significant challenges from the point of view of writing tasks and timelines.

The authors of US drug development must submit their trial protocols and other reports to the Food and Drug Administration's Center for Drug Evaluation and Research (CDER) and are often required by non-US Regulatory Authorities to submit to their specific offices as well.

These submission requirements are determined by strict formatting regulations and face a high risk of errors. The FDA guidance document on Study Reports, Investigational New Drugs (INDs), New Drug Applications (NDAs), and Regulatory Submissions, indicate that one reason for rejecting a report is if "insufficient time was spent on the protocol."

Report corrections often lead to approval delays, which in turn cause a setback to the drug approval and time-to-market. Moreover, according to the publicly available data, one (01) out of three (03) drug candidates on the final stages of the Regulatory process has more than one "major milestone" and is delayed as a result. Such a lag happens once every three months.

Based on this, if every project that receives approval is delayed by 2.4 months, six hundred and eighteen (618) potential medical breakthroughs would not be available. They would lose the jobs of fifty-one thousand seven hundred (51,700) Americans.

Due to a low number of medical writers, this year's survey on Regionalized Deficiencies & Site Adequacy for Phase I Trials in the Region indicates that approximately forty (40) to fifty

percent (50%) of all the US/European international trials for oncology and/or CNS related compounds are being outsourced on a vendor/custom site model.

Further more, two-thirds of trials are outsourced on a subcontracting model. However, the timing of authors' submission requirements must be taken into consideration when analyzing outsourcing data.

In the US, most trial conditions begin in the spring, peak in the summer, and abate in the fall. In Germany, on the other hand, investigators have more options in the early part of the year than later in the year.

The data sources bring forth challenges that prove that specific government policies impede clinical trials and hinder the commercial approval of new drugs. These are mentioned below.

Personnel – In addition to a host of site location, funding, and high prioritization issues, a significant challenge for timely approval of trials is the lack of appropriately trained personnel such as clinical research assistants and medical writers.

Regulatory Agencies – As the Regulatory framework is increasingly varied in different countries, it is difficult to obtain timely regulatory approval. Examples include China challenging the United States Food and Drugs Administration (USFDA) and France challenging the European Medicines Agency (EMA).

Site Personnel – Capacity limitations, budget overruns, Service-level Agreements (SLAs), and local linguistic requirements are among the issues that affect site adherence.

Space – Outsourced trials have significant space requirements, including patient rooms for conducting trials and storage space for materials, drugs, and investigational products.

Global Subcontracting and Vendor Sites – In many cases, pharmaceutical companies do not have the resources to conduct trials at preferred sites or gain access to specialist medical writers. Because of this financially driven demand for specialized resources, some pharmaceutical companies have turned to third-party contractors to carry out higher-risk, non-core functions, including medical writing, primary research, and data entry to meet financial and geographical requirements.

As pharmaceutical companies transition from in-house to vendor and subcontractor models, they continue to use some of the resources from their own companies, including empty sites, to lower costs.

Methods to Improve Access to Sites – Since medical writing is considered a high-risk function, the determination of what extent it should be outsourced is predicated by a site selection process that meets business, quality, technical, and legal criteria.

Several imperatives need to be in place for outsourcing medical writing. These are as follows.

Economic calculations – Based on the current data, companies believe that using high-value enrolees in various settings would cost nearly five times more than using a credentialed facility, as opposed to a hospital trial. However, product managers estimate that some of these costs can be saved by allowing medical meetings to be held virtually.

Quality and safety – Effective communication between contracting companies and investigator sites and between research sites, Contract Research Organizations (CROs), sponsors and ethics committees are essential to ensure that all stakeholders are clear on what is required of them and their roles and responsibilities are well-defined.

Standard processes and contractual limitations – In terms of core competencies, outsourcing functions to temporary service providers such as CROs and corporate departments require complex SLAs, precise language, clear site selection guidelines, and simple terms of appointment. If not established at the onset, this puts the entire project at risk.

Robust data management systems – Typically, in handling clinical trial documentation, a meaningful site selection process and the subsequent output depend on the availability of high-quality clinical data capture and management systems. Offices utilizing such systems provide the means for real-time tracking of interactions and trials. As a result, site selection can often be fine-tuned as trials progress. Similarly, the rules for establishing a panel or a list of preferred investigational sites and/or subcontractors vary significantly by country and situation.

Legislative hurdles – Laws and regulations on clinical trials such as the EU Clinical Trial Directive have similar mandates, including criteria related to patient safety, legitimate commercial aims, and scientific validity.

While these Regulations encourage the development of new drugs, they are not always flexible enough to accommodate real-world conditions, which has resulted in an ongoing debate.

Global Regulations – While Regulator criteria may differ across countries, a trend towards creating global and uniform systems has begun. Since these sites will likely be used for trials in many countries, adopting an international body of standards for investigative and medical writing site selection and evaluate and monitor trial sites. Such rules will likely require inputs from multiple industry stakeholders to standardize the practices globally and implement a global payment system for services uniformly.

Based on the sheer complexity of the sources above, outsourcing medical writing activities to a single-window competent agency proves to be the utilitarian and preferred alternative to ensure constant compliance.

Author Bio

Manan A Pharmacist and MBA graduate from NMIMS Mumbai – Manan believes, that there is a place for innovation in the every-day lives of all stakeholders, internal as well as external. He holds experience across the Pharmaceutical and Healthcare value chain raging from Formulation development and R&D to Healthcare Advertising and Communications. A Senior Associate at Freyr, Manan drives innovation in processes and communication for the Medicinal Products Division with creative flair.