Review Article

Medical and scientific writing: Time to go lean and mean

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Abstract

The Lean Six Sigma methodology for process improvements and driving efficiency is old, but lean writing was adopted late by the pharmaceutical world in terms of size of the documents. The documents were lean earlier, and then became voluminous, and now we are about to complete a full circle in this regard, i.e., coming back to the lean documents again using e-formats and hyperlinking. Furthermore, writing has become more and more precise over time. The need for this lean and mean medical and scientific writing arose from voluminous research globally, both industry and academia which are abuzz with skyrocketing regulatory and scientific submission volumes. The quantum of literature is so much that reviewers or information seekers firmly believe that going through even selected and relevant literature has become highly challenging. Considering this, there has been much insistence on downsizing the medical writing documents, which could be tempting enough to be leveraged for scientific publications as well. Here, we present the need for lean and mean medical writing, discuss this concept in relation to the pharmaceutical industry, and how to apply this to key documents. Furthermore, presented is the proposed algorithm for lean and mean clinical study reports and manuscripts. These thoughts are aligned to the recently established concept of data transparency, and can be easily achieved by web links between the protocols and clinical trial results disclosed publicly, and the corresponding manuscripts.

Keywords: Lean, medical and scientific writing, process maps, recommendations

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INTRODUCTION

The competition in clinical research is increasing ever, with pharmaceutical industry and academia vying hard to secure a place for new and generic drugs, medical know-how and techniques, disease pathophysiological mechanisms, diagnostic and treatment techniques. Just to give the numbers, in the preceding 10 years, the Food and Drug Administration (FDA) witnessed filing of about 342 new molecular entities (NMEs) and 265 of these have been approved. In the year 2013, there were 36 NME applications filed and 27 were approved.[1] The volumes of these submissions have been enormous too, up to 10 GB for an electronic common technical document (eCTD) and multiple files in this range. The scenario for scientific writing is no different. Data published in the year 2009 show that over 2,000,000 papers were published annually in some 20,000 journals.[2] Data for the publications in cardiovascular research show that these numbers increased by up to 14% annually, and if this concept is applied to all research areas, it can be assumed that these could have doubled since 2009.[3] Publications too reach around 2500–5000 words, and significant time is required to go through full publications.

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This clearly reflects the huge load on both pharmaceutical industry and academia in terms of data and information that is circulated through documents such as study protocols, reports, investigator brochures, manuscripts, and several other regulatory and marketing publications. Both writers and reviewers of these documents are overwhelmed with data and information overload, more so while adhering to guidelines/recommendations, which inadvertently increases the volume of the documents. Keeping in view the limited writing/reviewing resources with required expertise at regulatory agencies, research organizations, and scientific journals, it becomes important to reduce this excess load, particularly the volumes. This would also reduce the turnaround time for these documents, accelerate research and knowledge dispersal, and would also benefit the end users of this information. This is pertinent as controlling the load of new drugs and research ideas is an out-of-scope activity, however leaning the volume of these documents seems a worthwhile exercise. This idea of shedding the volumes brings with it the concept called "lean and mean writing." This would increase the efficiency, utility, and practicality, while retaining the absolute essentials, which is the call of the time.

Whatsoever innovative it seems, the idea of getting lean and mean in processes is in fact not new. Lean is almost a century-old practice, and various industries have evolved and benefited over the years using the lean and mean concepts. Lean works by eliminating the futile processes or components in any setup, thereby bringing innovation and improvement at the microlevel and then call it the best practice before it becomes a routine practice. The concept of lean is now percolating fast into clinical research with significant impact on all activities associated with it, including medical writing, that is, right from automating protocol authoring, digital patient recruitment, electronic data capture, reporting to publishing the study in public domain, use of eCTD rather than paper CTD, and so on. This means that lean encompasses data interpretation as well, which is more clear and precise making it to the point or "mean." Regulatory agencies still need to harmonize themselves to this concept. While the Food and Drug Administration is more focused on "lean and mean" data, the European Medicines Agency is elaborate in their mode. This difference is comparable to the difference between industry and academia. In the past few years, the idea has moved into scientific publications where often there is limit to words, though it is not very stringently followed, especially in case of e-publications. Scientific papers are often too elaborate and descriptive, bringing in different perspectives such as those from exploratory or *post hoc* analysis, which fails the purpose of the communication. On the other hand, readers are prone to bias at times and might give up on reading the whole content due to several pages in the document.

This paper focuses on the lean and mean writing in both industry and academia and will bring about the scope, the challenges, and the solutions for the key documents written.

EMERGING NEED FOR WEIGHT (VOLUME) LOSS

The need for volume reduction by eliminating the futile content from the documents is a highly emergent need of the pharmaceutical industry as well as academics as evident by the popularity of quality-by-design concept. Managing large volumes of documents is a double-edged sword and adversely affects both the writer and the reader/reviewer in terms of investment of time, resources, funds, storage of data, and archiving.

Of these, time is the most precious and important aspect. There is a race to finish everything on time (or before time), yet it is difficult and challenging to meet the timelines. Meeting global deadlines such as disclosure of trial results, Para IV filings, meeting the submission dates for clinical study reports (CSRs), and publishing of high-priority manuscripts and abstracts to the congresses are a few examples where medical writers and clinical teams struggle and juggle to make ends meet. Therefore, cutting off the futile processes that increase the authoring and reviewing timelines has been always welcome. Reducing the weight (volume) of documents/data would also reduce the time for quality check, and the resources can be utilized for other critical tasks. Elaborating unnecessarily on data that can be otherwise presented in a straightforward manner needs to be addressed.

Although one may wonder if we really need to worry in an era of clouds for storage, and the answer is yes. Everyone will agree that use of cloud allows faster deployment of resources and capabilities, has global reach and management, and has a low-risk. However, at the same time, it is associated with threat to the data since it moves out of a secured environment. Besides this, there are other technical glitches that can make one feel dicey such as connectivity and access issues, when people move in and out of the environment.

WHAT IS LEAN AND HOW FASHIONABLE IT IS?

The "lean" approach includes developing problem-solving skills, refining processes, and driving for excellence, and one needs to work on both the process and the content of the documents. The term "Lean" was first used by a

group of researchers at Toyota where they tried to improve processes. The lean process includes five steps, which are cyclical in nature and can continue till the purpose is achieved [Figure 1]. The first step is the identification of deliverable, for example, for CSR, or manuscript, as specified by customers. The next step would be to have a look at the process and mark the steps to be eliminated which would not affect the quality of the deliverable. Once a work flow is in place, the documents must be developed according to this new flow, and the quality and performance should be evaluated based on the feedback from the customer. Following this, one should aim to seek perfection using this new lean process. Based on the feedback, the process can be updated and evaluated again after a time period.

An important feature of lean is A3 problem-solving, an 8-point format, which was also introduced by Toyota [Figure 2]. Combining these two concepts efficiently is one of the effective ways to achieve lean medical writing.

The concept of lean has now found a place in health and pharmaceutical industry, and organizations are working toward leaning several age-old set processes. Clinics and hospitals work on improving the outcome where the customer is patient while they aim to reduce the waiting time for reports, or say appointments.[4-6] For example, an eye surgeon can lean the process by having patients ready in adjoining rooms with complete papers, and the surgeon would just then have to move from room to room performing the surgery, ensuring minimal time lags between the ocular surgeries planned for the day. In industry, the focus may be toward timely submission of regulatory documents or may be reducing turnaround time for a manuscript, and so on.

BEING MEAN - WHEN IT IS REALLY APPRECIATED?

The concept of mean is equally important and fully complements the concept of lean. Large data sets, and an equally elaborate analysis, encompassing all the aspects of possible analyses, and the multiple publications of data including repetition of study methods pay a toll on authors, reviewers, publishers, and the readers. Keeping these challenges in view, it will be good if the key, exploratory, and *post hoc* analysis is clearly demarcated and overlapping publications are discouraged. For exploratory and *post hoc* analyses, the authors should be motivated to provide short reports that supplement/complement the publications from the main study. It should be possible to completely skip the methods that have already been published, and then just hyperlink it to CSR or the main publication. Statistical analysis that is not preplanned should be scrutinized and labeled clearly. A complete abolishing of such analysis is not a good practice as this not only precludes the subgroup efficacy or selectivity, but would also hamper the decision on inclusion and exclusion criteria.[7] Therefore, there is a need to lean toward mean, but with a pinch of salt.

EVOLVING CONCEPT IN PHARMACEUTICAL INDUSTRY AND ACADEMICS

The voluminous documents make the information retrieval move at a snail's pace and often tedious despite a nanolevel tracking available. The sites and servers respond and perform at a lower speed when these carry large volumes.

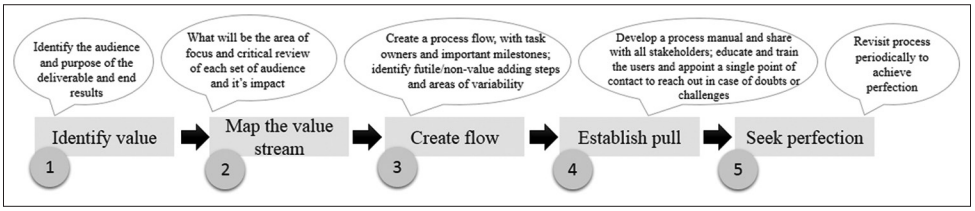

Figure 1: Leaning the process

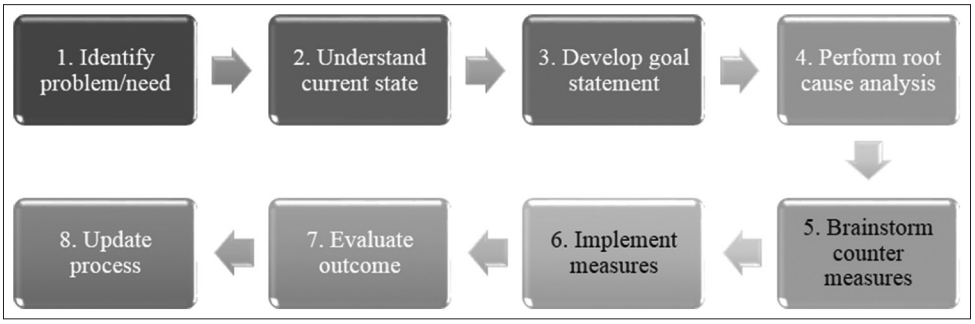

Figure 2: Problem-solving – the A3 format

Therefore, lean and mean writing would have a double benefit. First, a reduced load on the reviewers, and second, lesser challenges while managing, accessing, and archiving these data. This clearly underlines the need of lean CSRs and dossiers with lots of external hyperlinking so as to avoid repetition or duplication of information and data.

The trend continues to grow in academics. Right from writing a thesis to writing the manuscripts, everyone is talking about a lean writing. The theses have gone "slimmer" so that not only it takes less time to write, but also to review and archival. The scientific papers have a limitation, and publishing additional pages often incur an additional cost. Furthermore, additional tables or supporting data can be published as "online" only. These trends are being globally appreciated, and are taken positively, with several pharmaceutical companies and journals putting up initiatives in place for the same.

ACCEPTANCE OF LEAN AND MEAN IN MEDICAL WRITING

The concept of lean and mean medical writing is yet evolving and is yet to be globally accepted by the pharmaceutical companies, academics, and scientific communities. The lean and mean medical writing involves a lot of precision around presentation of huge data in a limited volume, with focused data analysis and presentation. This shall be possible with targeted efforts and would require unison between pharmaceutical companies, regulatory authorities, academia, and scientific communities. A detailed guideline on the lean and mean medical writing, by document type, is highly warranted and is the need of time. Once this is set forth, the acceptance will surely increase considering especially the benefits of lean and mean medical and scientific writing.

HOW TO GO ABOUT IT WITHOUT COMPROMISING THE SANITY OF IT?

The basic concept is to cut down on "creative language" and write straightforward and precise. This can be easily done using short sentences, text bullets, creating short summary highlights, and tabulating the data. While writing, writers can attempt to limit themselves to 75% on an otherwise normal length document. Once it is complete, one can always go back and further cut down on words. It is easily possible by restructuring complex sentences and cutting off those extra "showy" words because this is where science differs from art. It is a good practice to create a shared library of documents, guidelines, and templates at product level, project level, or company level for reference to ensure all stakeholders are aligned. The library should be revisited periodically for any variations to streamline the things that have achieved standardization due to process improvements and best practices. The focus should be on the art of writing, and it has to be short, sweet, and smart. Presented in this paper are a few algorithms for lean and mean medical writing.

Considering the other side of coin, the data analysis and interpretation and streamlining the processes and guidelines for exploratory analysis also need to be in place. The relevance and importance of extra analysis should be carefully considered and should not be vaguely performed just for increased number of publications as it tarnishes the very aim of scientific publications. To align, there is also a need to discourage publishing the data broken into multiple small pieces or multiple analyses.

ROAD AHEAD: SMART AND CORRECT MOVES AND PROPOSED ALGORITHMS

The road ahead should be clear and uncluttered, cutting off the redundant data such as repeating the information in CSR that is already available in protocol, data tables, listings, figures, etc. An algorithm for the same is suggested in Table 1. The idea is to add a mandatory checklist that ensures that there is conformance with the components of good clinical practices. To enhance this feature, a comprehensive checklist such as Consolidated Standards of Reporting Trials can be developed for CSR, and the items in the checklist can be appropriately hyperlinked. This would reduce the volumes of the CSR by up to one-third.

Similarly, the manuscripts can be condensed, and a pattern such as hypothesis, key studies in the past 5 years, results, and summary and conclusion can be followed. The aim of creating a high-quality publication is to present all the data so that it is easy to comprehend, significantly reduce redundancies, and present reproducible data through facts/figures/tables/graphs to explain the progress stage wise in reaching the results for the scientific study undertaken. An algorithm for the same is suggested in Table 2. Similarly, meta-analysis can be presented in a lean way. To cover up for the deficit in understanding and details, narrative reviews can be published in full so that budding researchers, scientists, students, and other pharmaceutical industry professionals have an opportunity to note the developments in the field.

Going forward, when the practice of data transparency is followed globally, it would be only enough to publish the results of clinical trials, and possibly the key highlights of

Table 1: An algorithm for the lean clinical study report

Report section	Current practice	Proposed
Section 4, ethics	A detailed description on ethical practice during trial includes ethics committees, ethical conduct, and informed consent process	Hyperlink to protocol, do not repeat details that are available in protocol, and add address tables only, hyperlink for detailed information and mention only deviations, if any
Section 5, investigators and study administrative structure	The details are tabulated/presented in text	Present tabulated information only, for details hyperlink to master documents
Section 6, introduction	The data and information are copied from protocol	Hyperlink to protocol, do not repeat details that are available in protocol, and mention only newly emerged information or changes, if any
Section 7, objectives	The data and information are copied from protocol	Hyperlink to protocol, do not repeat details that are available in protocol, and mention only changes, if any
Section 8, investigational plan	The data and information are copied from protocol and are updated for changes and/or deviations	Hyperlink to protocol, do not repeat details that are available in protocol, and mention only changes, if any. For example, amendments to trial design or changes to inclusion/exclusion criteria, efficacy or safety variables, or statistics in the study protocol
Section 9 through 11	The data are presented in text and in-text tables with reference to EOT tables	Add only relevant in-text tables, do not repeat data in text and tables. Tabulate a list of EOT, and hyperlink
Section 12, discussion	The results are discussed, as appropriate	Limit the section to a maximum of one page

EOT = End-of-text

Table 2: An algorithm for the lean manuscript

Manuscript sections	Current practice	Proposed
Introduction	The pace is set for the current study	Replace with hypothesis and research in the past 5 years
Methods	Methods are described in detail	Replace with an elaborate study design, and minimum text, tabulate inclusion/exclusion criteria, and study end points and their analysis
Results	Text, tables, and illustrations are included	Focus more on tables and illustrations
Discussion	Results are discussed in detail, also versus other studies, and study limitations are provided	Replace with summary and conclusion that focus on what was different and what was similar to studies in the past 5 years, or novel findings

study for patients and medical professionals, eliminating the need for research articles, but that would be a blue sky.

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Conflicts of interest

There are no conflicts of interest.

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