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MEDICAL INFORMATION LETTERS IN THE 21ST CENTURY AN INNOVATIVE APPROACH TO UNSOLICITED QUESTIONS

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WHITE PAPER

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Introduction

The delivery of medical information in response to unsolicited requests is a mainstay of medical information departments within the drug, device, and biotechnology industries (companies). However, the formats for delivery have evolved little over the years. Newer technologies such as blogs, networking sites, and video-conferencing-based solutions have seen limited success due to budget constraints and implementation challenges. Further, there has been low adoption by healthcare practitioners (HCPs), who continue to prefer verbal phone responses and medical information letters delivered by email. The success of mobile applications (apps) for delivery of medical information is currently unclear. The need for HCPs to use a different proprietary app for each product or company, the time and costs for their development and maintenance, and the potential for this to be seen as promotion and raise concerns by regulatory and/or government agencies, may limit their uptake.

Responding to Unsolicited Requests for Information

Companies respond to non-public unsolicited requests via phone, in person, mail, fax, or email. It is important that such responses are focused, have a fair balance of efficacy and safety information, and are not promotional in nature. Information for such responses is taken from both internal company data (data on file) and peer-reviewed published literature, the latter of which is the preferred source. Analysis of unsolicited queries helps companies identify frequently asked questions (FAQs) for which standard responses are developed to ensure consistent responses.

Medical Information Letters

Companies often develop medical information letters that are designed to address the most common questions they either anticipate or receive. The queries often focus on off-label use (ie, unapproved indications) and, in these instances, must follow the requirements mandated by regulatory authorities regarding communication of off-label promotion (Figure 1).[1,2] The medical information letter usually includes a brief background on the topic, followed by a summary of the clinical and relevant safety information, with or without tables and graphs. The FDA also suggests that complete copies of all reference material be provided along with the response. Most companies, however, provide only a bibliography

▼ ***Figure 1****. US FDA Requirements for Responses to Unsolicited Requests for Off-label Information*[2]

of cited references, accompanied by abstracts and/or hyperlinks to online sources. This may be due to the inclusion of reprints as a reportable transfer of value based on the requirements of the US Federal Open Payments (or Sunshine Act).[3] Some companies add hyperlinks to the pivotal trial publications or the company's medical information website.

Also required is a list of approved indications, important safety information, and warnings, including boxed warnings, which are usually taken verbatim from the prescribing information (PI). This information may be included in a cover letter or directly within the medical information letter. A copy of the full PI, or an accompanying hyperlink, must also be included. If the response is for a consumer, then regulatory-approved patient labeling must be included.

Creating Medical Information Letters

Most large pharmaceutical companies have a global medical information function that is responsible for the development of medical information letters, which are usually housed in a central medical information repository. Regional medical information teams may customize this information to local labeling requirements before dissemination to HCPs. Some companies will utilize the services of a medical writing or publications agency. It is often practical to engage the same agency that creates a company's publications, as the company has already invested in educating the agency on its products, and the agency is intimately familiar with the products' data.

In order to minimize the time spent on medical information letters while maintaining quality and meeting requirements, there are a number of steps that should be considered. At CACTUS, we follow a "Best Practice SOP" to ensure production of high-quality, accurate, and compliant medical information letters (Figure 2).

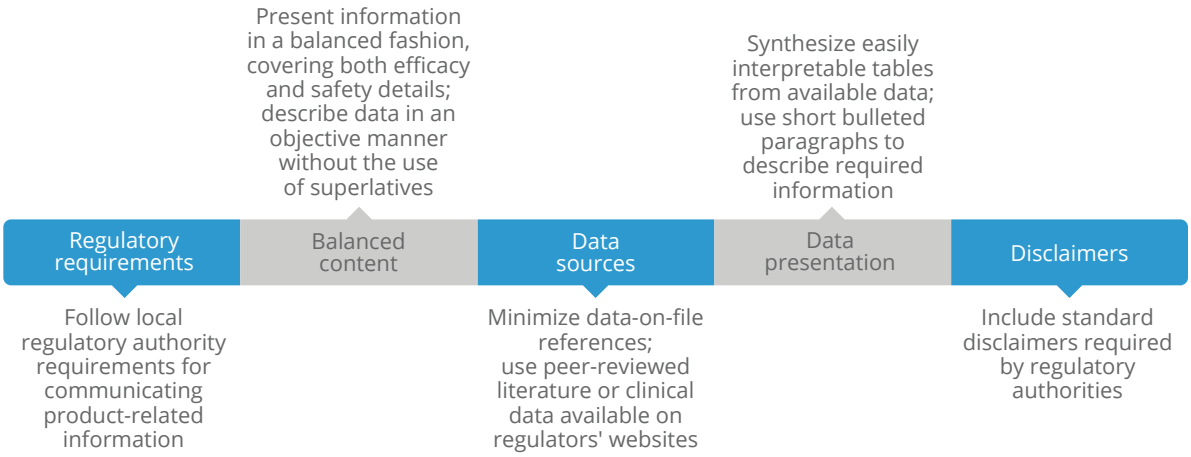
Consider Your Audience

HCPs most commonly request medical information to aid in their clinical decision-making related to the treatment of specific patients, and occasionally for their own edification. HCPs submit their enquiries via email, fax, telephone, medical information booths at scientific meetings, medical science liaisons or sales representatives, and more recently through medical information websites.

When creating medical information letters, it is important to consider the time constraints faced by HCPs. Thus addressing the HCP's question in a succinct and easily read document, yet covering all requirements, is critical to providing an answer that can be applied in clinical practice.

A recent global survey to clarify HCP preferences for receipt of medical information showed a preference for a 1- to 5-page clinical data summary with or without reprints, and that HCPs consider the primary study objectives, specific endpoints of interest, and all safety information important for making clinical decisions.[4] HCPs access medical information via desktop and/or laptop computers and handheld devices, and appear to prefer

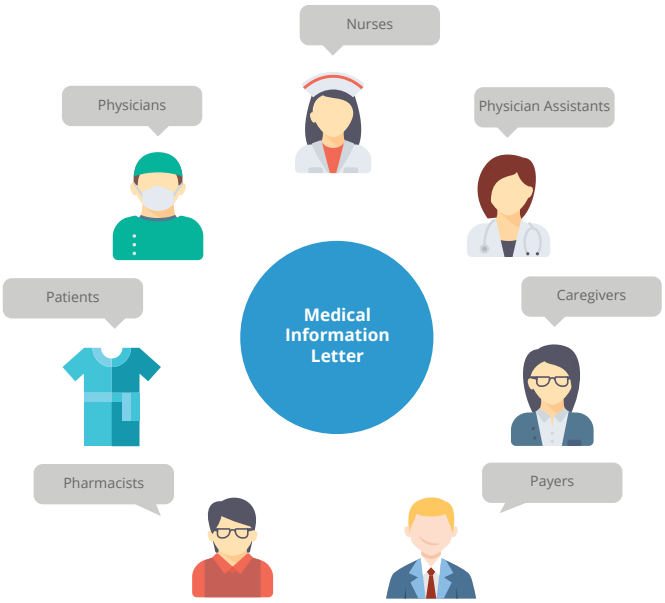
▼ ***Figure 2**. Best Practice SOP for Medical Information Letters*



the search results to show titles with bulleted summaries that can be accessed as PDFs or webpages.

Medical information letters also reach beyond physicians. Other audiences that may submit unsolicited requests for information include pharmacists, nurses, payers, patients, caregivers, and patient advocates (Figure 3).

▼ ***Figure 3**. The Reach of Medical Information Letters*



Considerations for the Medical Information Department

Medical information teams are typically understaffed compared to medical affairs or clinical development teams and may support 5-50 products. Busy teams may handle several thousand unsolicited queries per month. In addition to identifying frequent queries to develop into medical information letters, medical information departments also have to update an ever-increasing pool of letters at least annually based on emerging clinical data and product label changes. Most organizations have a mandate to provide standard responses within 2-6 weeks of receiving an unsolicited query. Companies with global medical information repositories face the additional challenge of maintaining consistency of response across regions.

Medical Information Letters in the 21st Century

Conventional medical information letters present information in a linear fashion. The letter may have a cover page with basic information on the drug, including its approved indications, any black-box warnings, and important safety information. This is followed by a short background on the topic; then the main textual summary supplemented by tabular or graphic presentation of the data; and ending with a bibliography (with or without the full reprints). The order of the information and the length of the letters vary widely based on topic and company policies and preferences. This lack of uniformity places additional burden on busy HCPs who need quick answers to help inform their clinical decisions.

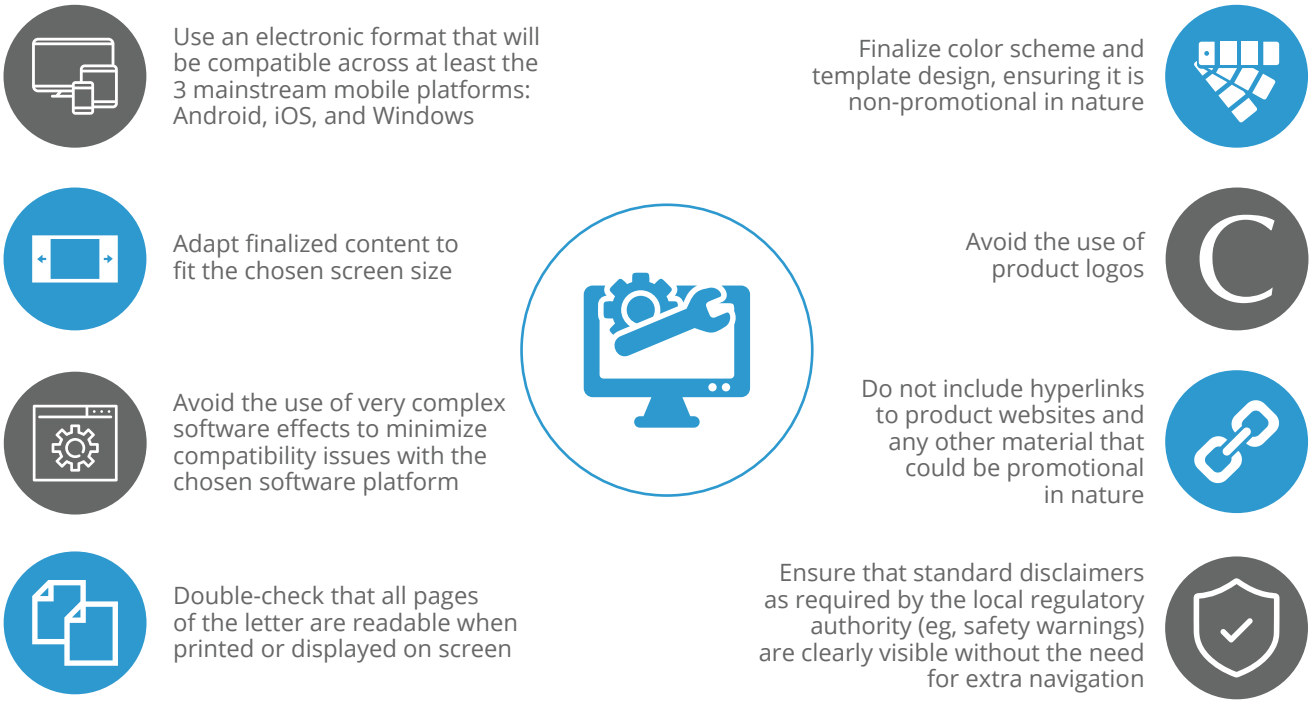
The technological advances in information access, increasing awareness about changing HCP preferences for medical information, and availability of cost-effective medical communications agency support should make it possible to update existing medical information letters to a more contemporary format, while retaining the spirit of FDA guidance on responding to unsolicited queries. At Cactus Communications, we believe that legacy medical information letters can be modernized with the use of more attractive templates with easy-to-read text, incorporation of simple animations for mechanism of disease or mechanism of action of a drug, and the use of hyperlinked elements that allow quick access to information of interest.

Our innovative, interactive medical information letter platform embraces simple technology that shifts the medical information letter paradigm—from a static document to one that allows immediate access to the area of interest for the end user (Figure 4).

Our enhanced medical information letter uses an easy-to-navigate tabbed interface with hyperlinks for rapid connection between the various content sections. The cover, or homepage, includes the topic of the letter in the header, and all required regulatory language or product disclaimers are prominently displayed. The cover page also displays the approved indications and important safety information along with a concise summary of key

***Figure 4**. Format of Medical Information Letters: Old vs New*

▼ ***Figure 5**. Practical Tips for Interactive Electronic Medical Information Letters*



data, and a brief direct response to the unsolicited query. Most companies also include a section with pertinent prescribing information. A brief summary of literature search results may also be added. Summaries of published and unpublished data can be distinct sections of the letter, supplemented with tables and graphs that can pop out for closer study. In-text citations can either be linked to the bibliography or the individual references can be displayed as popups; both can be hyperlinked to articles on PubMed or a journal website. Compression technology allows simple audiovisual animations such as treatment algorithms or the mechanism of action of a drug to be embedded in the letter. The current version of the PI is also included in the letter.

Finally, a printable version can also be embedded for HCPs who prefer to have a paper copy. HCPs can use freely available software tools to highlight data of interest or add comments or notes to the letter, thereby allowing users to personalize them for their own needs. Figure 5 shows some practical tips for developing interactive electronic medical information letters.

Summary

Technologies that both improve and simplify the communication of complex information have been adopted by a number of professions, including those in healthcare communications. This is evidenced by the numerous interactive opportunities utilized by the industry, such as websites, webinars, medical journals, and audiovisual materials that demonstrate the mechanisms of action of pharmaceutical agents and devices. That said, the application of technology to medical information letters has, in large part, been slow to occur. This is likely due to a company's desire to ensure that medical information letters retain their scientific nature, not only in content but also in look and tone, so as to avoid any possible negative scrutiny by regulatory authorities. At CACTUS, we believe that medical information letters can be developed with technologic features that make them more user-friendly, meet the needs of busy end users that want information "in the moment," and still retain their scientific look and feel. For more information, or for a demonstration of how our medical information letters can help enhance your medical communications with your customers, please contact us.

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About the Authors...

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Sandeep is a medical doctor by training and has over 10 years of experience in medical writing and editing. As the VP Medical Affairs at CACTUS, Sandeep is involved in recruitment, on-boarding training, mentoring and on-going training, and quality control. In addition to designing and implementing the stringent selection process at CACTUS, he has developed an intensive training program to help medical and life science post-graduates transition from a clinical or laboratory environment into a career in medical writing.

Sandeep has been a part of the publications team in a global top 10 pharma company. He has both publications and regulatory writing experience and has worked in several therapeutic areas, including ophthalmology, orthopedics, hematology, and hypertension. Sandeep is a member of ISMPP and has been on a panel reviewing the CMPP examination questions.

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As a scientific director at CACTUS, Kim is responsible for providing scientific direction and oversight for medical publications and communications projects. Kim also provides professional training for CACTUS staff worldwide to ensure currency with all professional standards and guidelines regarding medical publication practices. She also holds the position of Adjunct Assistant Professor, University of the Sciences in Philadelphia, where she teaches a graduate level course on publication planning. Kim has authored articles on medical publications and the Sunshine Act, and has presented at the annual meetings of ISMPP, the American Medical Writers Association, The International Publication Planning Association, and the Drug Information Association. She is also a peer reviewer for professional medical journals.

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