
Brian Bass


Mark Bowlby


Gail Flores

Q How much clinical trial data do you typically include in sales training manuals? What are the key issues in clinical trials that require education for sales reps?

A I've been writing sales training materials, primarily for oncology agents, for 17 years. Most of my work involves writing print or e-learning modules that sales representatives read and study on their own. Oncology sales representatives need to understand the data from clinical trials of their company's agents as well as those of their competitors. For a given clinical trial, representatives need to be familiar with the same publicly available data that their customers—physicians—may see, which includes data presented in the primary manuscript for the trial, the agent package insert, and any data presented at meetings and congresses that have not been published elsewhere. The representatives have access to PDFs of these publications, so the purpose of training modules is to highlight the most important data and to provide definitions and explanations of the more complicated information.

In oncology clinical trial sales training modules, the content is typically divided into 3 parts: study design, efficacy, and safety. Regarding the study design, representatives need to know the inclusion/exclusion criteria, whether the study was randomized, and the number of patients and dose and schedule of treatment(s) in each arm. It is also critical that they know the trial's primary and secondary end points and the patient baseline characteristics.

The trial's efficacy section includes data related to the primary end point and some or all of the secondary end points. For oncology trials, this most often consists of survival outcomes and tumor response rates.

Safety data are usually presented as all-grade and grade 3-4 adverse event rates. The incidence of any serious adverse events and deaths due to adverse events are also provided. Finally, the safety section will include information about any drug discontinuations or dose interruptions, reductions, or other modifications due to adverse events.

In contrast to what some people may believe, the content in these modules is not promotional—sales representatives just need to have background knowledge about the disease, the agent, and the current treatment landscape so they can have intelligent conversations with their customers.

—Gail Flores

Every sales training manual is different, just as every client's sales training needs and expectations are different. In my experience, a typical module educating sales representatives about a product they are responsible for selling focuses on the pivotal clinical trials included in the product labeling. Of course, in a learning module, we go into much more detail about each clinical trial than is found in the labeling. So I usually work with the clinical study report (CSR) and sometimes also with the investigator's brochure (IB) and/or the study protocol to get all the information I need.

The sections of a clinical trial reported in a sales training manual typically include

- Study description—a brief statement of what the trial is (eg, phase 3, randomized, placebo-controlled, multicenter trial)
- Study design—a description of how the study was conducted (often including an algorithm) and study endpoints
- Materials and methods—a summary of inclusion and exclusion criteria for patient selection and the frequency and dosing of treatments
- Results—a review of the efficacy and safety of the product for all defined end points
- Conclusion—a brief statement of the key takeaway

Learning content typically also includes insights for sales representatives to help them understand and appreciate certain aspects of the trial. For example, perhaps the enrolled patient population had an especially serious disease or some unusual or specific characteristic that is relevant to the study outcome. Or perhaps the study used a unique biomarker that

the sales representatives need to learn more about so they can inform and educate their customers.

In most circumstances, sales representatives must be familiar with all aspects of the pivotal trials for their product. When they are speaking with health care professionals, having a thorough understanding of the trials and data translates into confidence, which is necessary for success.

Sales representatives should also have a solid understanding of the pivotal clinical trials for competing products. Products cannot be compared unless they have been studied in a head-to-head comparative trial, so sales training cannot compare clinical trial results. When writing sales training content on the clinical trials of competing products, medical writers will not have access to proprietary documents like CSRs, IBs, and protocols. For this content, we have to rely on published data from journal articles and the product prescribing information (PIs).

—Brian Bass

Whether freelancing or working in-house, medical writers often are asked to write the "medical backgrounders" included in sales training programs—for print media, videos/slides, and online learning. Content may include extensive educational material about the indication in question, an overview of the anatomy and physiology of the target body system, and reviews/interpretations of clinical trials that have taken place with the company's product(s). Regarding "how much" data from clinical trials to include, this decision will be made by the company's marketing and/or sales training department. At minimum, you must include succinct, simply written summaries of the pivotal phase 3 trials on which FDA approval was based. Also, of course, any studies that ended up published as journal articles and/or comparing the company product with competitive products should be included. Summaries of phase 4 studies are also necessary because they are pertinent to postmarketing information, and phase 1 and 2 study summaries are needed if clinical pharmacokinetics are a significant issue. Moreover, results from pivotal and other important clinical studies need to be put into perspective relative to the company's "competitive products" so that the sales reps can answer questions intelligently and handle objections from the physicians and health care providers they call on. Details on what specific information should be included is more a "how-to" question than a "freelance" question—but if you have more questions on this topic, please feel free to contact me personally at evanscathryn@aol.com.

—Cathryn Evans

Q How do you use the clinical study report (CSR) to develop an outline for a manuscript?

A As a freelance, you are likely to be "directed" by the client in this regard. However, according to AMWA's Code of Ethics, presumably you, as a medical writer, will not be developing the outline for a manuscript based on a CSR unless you are (1) in close collaboration with the named author and/or (2) going to be included as a co-author. That being said, the decision about how to carry forward information from a CSR to a journal article for publication depends on the study design and objectives as well as the Instructions for Authors provided by the target journal. Caveat: You do ***not*** just automatically outline the manuscript as "Introduction, Methods & Materials, Statistical Analysis, Results, Discussion, References, Tables/Figures"—rather, you must evaluate each individual study protocol relative to the client's intentions and, of course, to the target journal types of articles, styles, and author instructions.

In the past, companies could (and did) "cherry-pick" data from a CSR to include in a journal article; most of the time the investigators themselves were not even given a copy of the final CSR. And frequently the "authors" had little or no input to the paper (by choice, not because the company excluded them). Today, the ethical environment is quite different: companies are required to be far more transparent about all clinical-trial data. And most of the better medical journals have both print and online publication, which means you can include extended information about the methodology (and results/tables/figures) in a submission of supplemental material, which will not be printed in the journal but will be available to readers online. Hence, you can consider using a relatively large proportion of the CSR for the journal article. Again, there is more to be considered here than space allows in this column, and again, this is more a "how to" question than a "freelance" question—but if you have questions about a specific CSR/journal article, please feel free to contact me personally at evanscathryn@aol.com.

—Cathryn Evans

Q How can I best acquire familiarity with regulatory practices in pharma (or devices, or biologics, etc)?

A Like many aspects of life, your options depend on your circumstances. However, the first subtlety to understand is that regulatory practices applied in pharma are composed of (1) regulatory affairs and (2) regulatory writing, working in concert with a broader project team. Regulatory affairs professionals are responsible for learning the

regulations governing drug/biologic/device development and interpreting them for pharmaceutical and biotechnology companies, but it's not primarily a writing position. Regulatory writers, however, primarily report, summarize, and even interpret scientific results (usually clinical) in a format appropriate for regulatory agencies and clinical study sites. They are the primary writers of regulatory documents such as clinical protocols, investigator brochures, clinical study reports, and the many summary documents required for submission of new drug applications.

Aspiring regulatory writers coming out of college have several options for further education in medical writing, regulatory affairs, and other similar areas. These include formal graduate programs in medical or scientific writing (eg, University of the Sciences in Philadelphia) and education programs from professional organizations such as AMWA. A less well-recognized path for obtaining training, however, is to obtain a job in the pharmaceutical or biotechnology industry (including contract research organizations [CROs]) in a medical writing or regulatory affairs role. Even though it is rare to hear about this path, it is probably the dominant career path by which most current regulatory writers have gotten into the field, although many positions in industry that expose employees to project team clinical development activities can lead to regulatory and medical writing careers. Often the best teacher is experience with the team responsible for guiding a drug through the myriad of regulations governing its development.

This leads me to another large group of aspiring regulatory writers—those working in functions not associated with clinical development in pharmaceutical or biotechnology companies. Because most regulatory writing occurs during clinical development, exposure to this area is key to obtaining the experience that can lead to full-time opportunities. In these situations, you need to look for opportunities to work with a drug development team. Get in touch with others working in development in a therapeutic area that you have experience with, talk about opportunities to get involved, and add this onto your career development plan. You may be surprised at the support you receive as long as you continue to meet your main daily job expectations. It takes some perseverance and motivation, but it's a viable method for leveraging your current position to gain experience in this area.

Last, there's the direct route of entering a regulatory writing role at a pharma, biotech, or CRO without prior regulatory or pharma training. This is probably the most difficult path because it places the burden for training on the employer instead of the employee. As a result, many employers prefer not to hire regulatory writers without experience, so the challenge is to seek out companies willing to train new writers. These companies do exist in both the pharma and CRO spheres, but most don't advertise directly for writers without experience. However, if you have the right aptitude, work well in a team, and are serious about a career in regulatory or medical writing, entry-level positions do exist when the employee-employer match is right.

—Mark Bowlby

In this response, I am assuming a lack of any knowledge or experience with any aspect of pharma/biotech/device companies. I am also assuming that the readers are experienced medical writers in other areas of health care. For the purposes of this response, I will talk about the pharmaceutical industry, but the same principles apply to biotech/device companies.

The first requirement is that you understand the industry as a whole: What is it? How/why did it come into being? What is its purpose? How does it operate? For this intelligence gathering, there are many resources. Search the internet and/or libraries if you like. One initial source might be Eisai's "Understanding the Pharmaceutical Industry" (www.eisai.com/ir/individual/knowledge.html). It is especially important that you understand the entire process of drug development, from the bench, to animal studies, to phase 0-4 clinical trials, to mass marketing, even if you end up working only on clinical study documents.

Moreover, you must understand the industry not only as a developer and marketer of health care products but also as a business—because business (making money) is, in fact, the top priority for these companies. Nearly all major decisions made by upper management are made on the basis of profit/loss, and the prospective employee or vendor for a drug company must accept this philosophy. (Of course, this does not by any means negate the remarkable innovations and benefits to medicine and health care generated by industry; it is just a realistic understanding that I feel one needs when working for industry. About 75% of my career has been pharmaceutical-based, in both MedCom and regulatory affairs; if I did not like and respect this industry, I would not have given so much of my life to it.)

Next, read some of the regulations; the Code of Federal Regulations (CFR) is available online and can be searched by topic. Peruse the US Food and Drug Administration (FDA) websites, too—new/revised regulations, guidelines, commentaries, and examples of documents are freely available there. You can download extensively annotated outlines of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

documents such as a Protocol or Clinical Study Report (CSR). Complete New Drug Application (NDA) submission information (including structure and contents of the Common Technical Document [CTD]) are also easily accessed through the FDA website or via simple Google search. This is particularly important if your intention is to enter into a career in regulatory writing.

Another seriously important move would be to try to acquire and carefully read samples of specific documents that are generally written by medical writers—a few examples include (in no particular order)

- Investigational New Drug (IND) reports
- Preclinical and clinical study protocols
- Investigator Brochures (IBs)
- Clinical Study Reports (CSRs)
- Abbreviated CSRs
- Informed Consent Forms (ICFs)
- Interim reports
- Toxicology reports
- Pharmacology and/or pharmacokinetic reports
- Risk-management plans
- FDA Briefing Documents (for pre-Protocol/pre-NDA meetings and/or for pre-identified sensitive issues)
- CTD summaries (too numerous for this list but when you review the CTD outline, you will see how many types of documents need to be written for a CTD)
- Product labeling (package inserts)
- Responses to specific questions from the European Medicines Agency (EMA) and/or FDA
- Slide presentations for advisory boards (FDA and others)
- Advisory board meeting summaries

Please join the Drug Information Association (DIA)—so much can be learned about the industry from attending their meetings. Go to an annual meeting if budget permits (and it *should* permit, because this is an important part of your career development!); attend the larger seminars as well as the smaller breakout meetings as well as all meals and cocktail parties. Meet people in the industry—this is a critical thing to do, in my view. Equally important: pay attention to the people as individuals. Watch and listen. You can gain a lot of intelligence this way, especially a sense and feeling of what kind of people they are; do you identify with them psychologically/emotionally and do you wish to be around them every day? You should be quite certain that regulatory writing for industry is the niche you really seek. If budget permits, join the Regulatory Affairs Professional Society (RAPS) for at least a few years, as they offer meetings and educational programs of interest (they also have a RAPS educational certificate you may wish to look into, but it is not for "regulatory writing" in particular).

Of course, in my opinion, the best way to become intimately familiar with the industry is to immerse yourself in it by accepting a full-time job and staying for several years before going freelance. Do keep in mind that regulatory affairs is just one part of the arena for medical writers: MedCom, sales training, public relations (PR), marketing communications, and other departments offer scores of other interesting writing opportunities. Regardless of your choice, to work well in this industry you must understand it well—and a strong background in regulatory affairs is an excellent underpinning of a long career in this industry.

—Cathryn Evans

A Message From the Chapter Advisory Council Chair

It is my great honor to lead the efforts of the new Chapter Advisory Council as inaugural Chair. The new structure (see article on page 186) offers an opportunity for AMWA to be more strategic in its mission to its members. I look forward to working with the Chapter Advisory Council and appreciate the commitment of these chapter volunteers to advancing AMWA through their leadership.

—Katrina Burton