

Readability testing of patient information leaflets

PIL of whom 90% can show they understand it". However, even if conflicting testing criteria can exist, low scores are rare given the procedure applied (revision, pilot-testing, first testing round, revision, second testing round) and, on average, most questions score above 92% during the first round of tests and are well above 95% once the leaflet is revised. MA holders are entitled to use any method which enables patients to identify, understand and act appropriately on the leaflet information. This is understandably a source of great debate.

After the second testing round, a qualified person checks all the data and statistical analysis is performed using macros. Two regulatory affairs officers validate and sign off all reports. The most important aspect of the final report is to demonstrate that improvements have been made. The European Medicines Agency (EMA) and MHRA validate the reporting criteria.

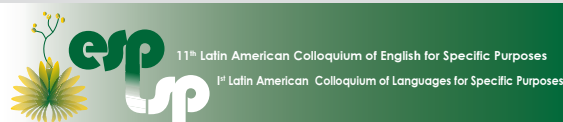
For MA holders of products aimed at the European market, there are a variety of different procedures an MA holder can apply for and depending on those, there is specific guidance about which language must be used. However, this also depends on the countries that a given product will be marketed in as well as the fact that individual healthcare authorities have differing rules on language requirements. It is therefore crucial to ensure that translations are performed by suitably qualified teams of medical translators who understand all the issues involved in processing PIL information. Thorough checking is recommended when national versions are validated by respective regulatory authorities.

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References:

1. Always read the leaflet, MHRA, 2005
www.mhra.gov.uk/home/groups/pl-a/documents/publication/con2018041.pdf
2. Guidance on the user testing of patient information leaflets, MHRA June 2005
www.mhra.gov.uk/home/groups/pl-a/documents/publication/con1004417.pdf



We have the pleasure to inform you that the 11th Latin American ESP Colloquium and 1st Latin American LSP Colloquium will be held at the University of The Andes (Mérida, Venezuela) from November 9th to 13th, 2009.

Françoise Salager-Meyer
Colloquium coordinators

José Villalobos

For more information, visit:
<http://eventos.saber.ula.ve/coloquiolfe2009>

That extra syllable really makes it sound impressive! Really?

The objective was to compare INR using the point-of-care method with the conventional laboratorial method.

Laboratorial? This really made me do a double-take. I have fought against the use of *lab* for years, because it is a casualism. But now that fancy *la-bo-ra-tor-i-al* has arrived, give me the casualism any time instead of pomposity! The next thing we'll see are *observatorial* fittings in the field of astronomy or *refectorial* facilities in the field of hospital gastronomy. I will always prefer *laboratory* used as a noun or adjectivally, but am beginning to wonder whether I should still insist on this in texts I edit. I will definitely insist that *laboratorial* be banned.

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Open Access not less prestigious

Nowick, Elaine A. Academic Rank of Authors Publishing in Open Access Journals. *Agricultural Information Worldwide*. 2008;1(2):45-51.

When deciding where to publish their research results, faculty take into consideration factors such as the prestige and readership of journals. The weight a journal article will carry is particularly a concern for pre-tenured faculty members. Previous research has indicated that some faculty members may have some concerns about publishing in Open Access journals because of a perceived lack of rigor and reputation of Open Access titles. In this study, the academic rank of authors publishing in Open Access and commercial scholarly journals was compared. Most authors in both Open Access and for-profit journals were full professors. There was no indication that pre-tenured faculty avoided Open Access titles. In fact, there was a slight but significant trend for pre-tenured faculty to publish in Open Access journals (<http://tinyurl.com/6txzyq>).

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Medical writing for early clinical development

by Bidy Schilizzi

How does one become a medical writer in early clinical drug development? Having recently taken the plunge from salaried employee to go freelance, I've become aware of an apparent need for writers with experience in this area, in particular in pharmacokinetic (PK) writing. Because the question has been asked as to how one gets started in this line of medical writing, I'll present my own observations and experience gained from working in a large Phase I/IIa CRO.

Early clinical drug development means Phase I and IIa trials, conducted in small groups of healthy volunteers or patients, respectively. For the medical writer there are a number of interesting and distinguishing features about Phase I/IIa work.

First, these trials are often 'first-in-man' studies, so safety is paramount; second, there may be an exploratory study of pharmacodynamic (PD) endpoints; and last but not least important PK data will be collected. This data will help determine the subsequent dosing level and frequency in the intended therapeutic population. Since many therapeutic agents are 'killed' in Phase I/IIa, the quality of work delivered in these early trials can sometimes make or break a particular drug.

The focus here will be on PK/PD reporting (as medical writers are generally better informed about safety writing) with a brief illustration of how regulations and guidelines are relevant to Phase I/IIa medical writing.

Becoming a Phase I medical writer

Medical writers who write for Phase I/IIa in my experience come from various backgrounds. Writers typically come from one of the biomedical sciences, clinical medicine or pharmacology, and usually have a PhD. To ease the transition from academia to industry, many universities now offer post-graduate courses comprising specialised training for careers in the pharmaceutical industry.

Writers are, however, often recruited at a junior level directly from university, with no prior experience in the pharmaceutical industry. More experienced individuals with several years in clinical or pre-clinical research may have a pure research, project management or regulatory background. In my case, I'd worked in clinical research (immunology) at a university hospital, followed by product management at a biotech company. Whatever the background, an interest in clinical research and affinity with the interpretation and

presentation of data is a prerequisite. Prior knowledge of the principles of Good Clinical Practice (GCP), is desirable.

Training

The skills and experience required for Phase I reporting are gained through a combination of on-the-job training, and specialised courses in PK.

The best form of training for any Phase I medical writer, regardless of background, is to work with a mentor, usually a senior colleague with PK and medical, or regulatory writing experience. In-house statistics and PK specialists, who, in larger organisations generally act as internal consultants, also play a valuable role in the learning process. In a reasonably sized pharmaceutical company or full-service CRO, there will be opportunities to work on a range of documents from pre-study (e.g. Protocol, Investigator Brochure [IB]), to final Clinical Study Report (CSR). CRO employees benefit from working for different sponsors, ranging from big pharmaceutical to small biotech companies. This provides exposure to a variety of therapeutic areas and study designs; drug products ranging from traditional chemical entities to recombinant proteins, and not least, working across national boundaries. These varying aspects broaden the range of skills and enrich the PK experience.

An understanding of PK is certainly required to interpret and describe the PK data in the CSR. This understanding is an advantage at an even earlier stage when writing or reviewing the Study Protocol or IB. Another pre-study document, the Investigational Medicinal Product Dossier (IMPD), contains summaries of information relating to the quality, manufacture and control of the Investigational Medicinal Product (IMP), and may be submitted as an addendum to the IB. A background in pharmacology or pre-clinical drug development is an added asset when it comes to preparing this rather technical document. When reviewing the Statistical Analysis Plan (SAP), a good understanding of PK enables you to contribute to discussions with the statistician and/or PK expert. All this contributes to the overall quality of the final CSR.

Completion of several CSR's containing a PK section gives a good idea of the desired structure and content of a Phase I/IIa CSR. Then follows the ideal moment to deepen or refresh PK and statistical know-how. Commercial courses (at commercial rates) are relatively easy sourced, however