In this issue of Medical Writing

Phillip Leventhal

Editor-in-Chief, Medical Writing

Correspondence to:

editor@emwa.org



Some of you might remember the old days when writing was done with a typewriter, spreadsheets were big pieces of paper, and slides were printed on film. Thanks to computers, these are old memories, and we can all be much

more productive. Software and operating systems continue to advance rapidly, supposedly making our lives as writers easier, but we often do not have time to keep up with the changes and learn all the ins and outs of new software or the most recent versions.

This issue starts with several articles on the Microsoft Office® suite. Some may use alternative software, but in our business, Office is the standard. Office has many quirks and secret functions, and learning about them can help simplify tasks and avoid problems. Therefore, we begin with several articles on Office software. Peter Aitken and Maxine Okazakion, Alistair Reeves, Alexander Nürnberg describe quirks and secrets of Word®, and Raquel Billiones discusses using templates in Word. Diarmuid De Faoite follows with an article describing the efficient and correct use of the oft-maligned PowerPoint®. Also, Daniel Kraus describes his excellent - and free! - add-in for Excel called Daniel's XL Toolbox, which enables medical writers to store data in one place, eliminating the need to use separate tools for the analysis and presentation of data.

More and more, pharmaceutical companies are going to specialised software to share and track documents. The most common of these is DatavisionTM. We therefore asked **Russell Traynor** and **Thomas Gegeny** to describe Datavision, what it can do, and what medical writers need to know.

Several following articles summarise different software tools. The first of these, by Laura Collada Ali, focuses on software for translators. Jesslynn Ooi and colleagues then describe graphing software, and Shirin Ghodke provides a list of software tools that have proven to be useful to medical writers. Finally, Julie Courraud explains the features and advantages of Zotero, an open-source reference manager.

Also in this issue...

Françoise Salager-Meyer presents the first in a twopart series on English for Medical Purposes, in which she summarises the research conducted on English-medium written medical discourse. Laura Collada Ali continues her Profile series by recounting her interview with Karina Ruth Tabacinic on some fundamental concerns of medical translation. Finally, Derek Ho tells about his experience as a first-timer at the 2013 EMWA conference in Barcelona.

New regular feature – News from the EMA

This issue of *Medical Writing* includes a new regular feature, **News from the EMA**, which is the result of EMWA's first steps towards establishing a collaboration with the EMA. This new section will initially include reprints of key press releases and communications with the EMA, but we hope that it will eventually become a mechanism for the EMA to communicate directly with EMWA members.

Your editorial team

Medical Writing has evolved into a collaborative team project. Stephen Gilliver has been promoted to Co-editor, and we now have five Associate Editors: Joselita Salita, Raquel Billiones, Anuradha Alahari, Shirin Ghodke, and Barbara Grossman. I would like to take this opportunity to thank the editorial staff for their excellent work and enthusiasm. Putting this journal together would definitely not be possible without their contributions. If you are interested in becoming a member of the editorial staff or contributing to the journal in any way, write to me at editor@emwa.org.

Happy reading!

Medical Writing

Contents

Software for Medical Writers

Volume 23 Number 1 March 2014

In this issue	1
Message from the President	4
EMWA's social media team	5
News from the EMA	5
Feature Articles	
Taming Microsoft Word® Peter G Aitken and Maxine M Okazaki	6
The secrets of Microsoft Word®. Part I – 'Find and Replace' and en-dashes Alistair Reeves	10
Organising the review process in Microsoft Word® Alexander Nürnberg	13
Document templates for medical writers Raquel Billiones	17
Getting more out of PowerPoint® Diarmuid De Faoite	22
Consolidated data analysis and presentation using an open-source add-in for the Microsoft Excel® spreadsheet software Daniel Kraus	25
Datavision™ – What do medical writers need to know? Russell Traynor and Thomas Gegeny	29
Software for translators Laura Carolina Collada Ali and Laurence Auffret	36
Graphing software for medical writers Jesslynn Ooi, Daniela Traini, and Paul M Young	41
A medical writer's must-have software Shirin Ghodke	45
Zotero: A free and open-source reference manager Julie Courraud	46
Origin and development of English for Medical Purposes. Part I: Research on written medical discourse Françoise Salager-Meyer	49
Profile: An interview with Karina Ruth Tabacinic on some fundamental concerns of medical translation Laura Carolina Collada Ali	52

A first-timer's perspective on the 2013 EMWA conference in Barcelona Derek K Ho	54
Regular Features	
English Grammar and Style Good writing practice The trouble with apostrophes (1) 'Ups' and 'downs' in (medical) writing (1)	55
Regulatory Writing Document authoring and review cycles: Harnessing technological advances Document management and publishing systems	58
The Webscout Software – What will help me?	60
Medical Communications Editorial How important is vocabulary in healthcare communication?	62
In the Bookstores Statistics: A Very Short Introduction Epidemiology: A Very Short Introduction Microsoft Word 2010 for Medical and Technical Writers	66
Manuscript Writing A guideline for manuscript flow. Part 3 – The results	69
Out On Our Own Editorial A writer's 'best friends' – Recommended language resources for (medical) writers – The basics Online freelance networks in the DACH region – Real job opportunities or just waste of time? The power of the collective voice The social web is your oyster	71

Themes of upcoming issues of Medical Writing

September 2014: The title for this issue will be 'Non-clinical health writing'. It will include articles on regulatory documents that medical writers might not be familiar with but can easily work on, such as documents for veterinary medicine, food and nutritional supplements, cosmetics, and environmental toxicology. The deadline for feature articles is 9 May 2014.

December 2014: The theme will be 'Post-approval Regulatory Writing'. This issue will include articles on post-approval documents and pharmacovigilance. The deadline for feature articles is 8 September 2014.

If you have ideas for themes or would like to discuss any other issues, please write to editor@emwa.org.



Message from the President

Andrea Rossi

EMWA President

Correspondence to:

president@emwa.org

Dear colleagues



As my 1-year term as the EMWA president is ending, I would like to say that it has been a great year! Manchester and Barcelona were incredible successes. The Executive Committee is working hard to improve all aspects of the EMWA, and, thanks to the

excellent partnership with Kingston Smith Association Management (EMWA's Head Office), we have mostly exceeded the more optimistic plans. My work has been greatly simplified because everyone has worked together and had a lot of fun.

There have been many positives this year:

- The quality, reputation, and visibility of the journal continue to increase.
- The number of followers and 'likes' for EMWA's social networking continues to grow.
- EMWA's financial situation has never been so healthy.
- EMWA's conferences continue to be well-recognised and appreciated as good value, due to the many workshops, addition of e-learning tools in 2014, and networking opportunities.
- Redesign of the EMWA's website, which should come online in early 2014.

Furthermore, the EMWA has started partnering consistently with local professional organisations from several countries and with software providers, and the number of professional partners supporting the EMWA has continuously increased.

Looking forward to the Budapest conference in May

Looking forward to the Budapest conference in May, the programme includes a full day's

symposium on the new European Medical Agency (EMA) Transparency Act. The symposium will include plenary sessions led by international experts. These will provide insight into the effects of the Transparency Act on medical writing from industry, regulatory, and other points of view. The EMA, who sent members to an EMWA conference for the first time in November (Barcelona) have confirmed that they will again participate: An EMA Transparency Act expert will attend the meeting in Budapest, ensuring that they will play an important role in the discussions. The symposium will include panel discussions and plenty of opportunities to ask questions and interact with the speakers.

Of course, in addition to the symposium, EMWA will be offering over 50 workshops covering a wide range of medical writing topics, as well as lots of interesting and entertaining social events. The full programme can be accessed at http://www.emwa.org. Do not miss this opportunity to visit wonderful Budapest and to network with professional colleagues. Early registration for the conference is strongly suggested, as the popular workshops tend to fill up very quickly!

Interested in joining EMWA's Executive Committee?

Just a final reminder for any member who would like to join the Executive Committee: Check out the job descriptions at http://www.emwa.org/EMWA-Officers.html. Online voting for Executive Committee positions will be before the May conference. We look forward to your vote. Furthermore, if you are interested, be sure to submit your candidature soon.

Ciao Andrea

EMWA social media team

Laura Carolina Collada Ali

Correspondence to:

Laura Carolina Collada Ali laura.collada@ontranslation.it

Social media are instruments of two-way communication. Social media are not just sources of information but also ways of interacting. EMWA is currently using social media to interact with its members on a daily basis, to promote discussions, and share information.

Changes to the EMWA social media team

First, we would like to thank *Leynna Prince*, who has managed the EMWA LinkedIn discussion group for many years and has recently decided to step down. She has done a great job and we have all very much appreciated her commitment.

We also would like to welcome two new members of the team:



Maria Kołtowska-Häggström has recently taken over responsibility for the EMWA LinkedIn discussion group. Maria is a paediatrician and independent consultant affiliated with the Department of Women's and Children's Health at Uppsala University, Uppsala,

Sweden and is the Medical Director at Proper Medical Writing, Warsaw, Poland. She has 22 years of experience at global senior positions in the pharmaceutical industry, both on the medical and marketing sides of the business. Maria has been a leading member of numerous research groups, which have produced more than 60 peer-reviewed publications.



Julianne Chaccour will be in charge of the EMWA Twitter account. Julie is a freelance medical writer currently based in Pamplona, Spain. She previously worked as a cell biologist and immunologist in Germany, the UK, and Venezuela.

We also want to thank Karin

Eichele, who is in charge of the EMWA Facebook account. The Facebook page has gone from 300 followers in early May 2013 to almost 600 in November.

Finally, if you are not following EMWA on social media, we would like to invite you to join in, as it is a great way of staying in contact with EMWA colleagues, follow-up on interesting discussions, and staying up to date with EMWA news.

News from the EMA

Update from the European Medicines Agency on development of its policy on publication and access to clinical-trial data

From the European Medicines Agency, 13 November 2013 – The European Medicines Agency is currently reviewing and analysing more than 1000 comments received during the public consultation on its draft policy on publication and access to clinical-trial data, which ran from June to end of September 2013.

The public consultation on the policy has generated input from an unprecedented range of stakeholders. Patients, healthcare professionals, pharmaceutical industry representatives, researchers, transparency campaigners, academic and public institutions, health technology assessment bodies, and a range of others sent their comments to the Agency. Many of the contributors provided detailed in-depth comments, some of them substantial, some of them technical, including suggestions relating to methodological and technical aspects of the implementation of the policy.

The Agency is grateful for this exceptional contribution from its stakeholders. As part of its collaborative

Correspondence to:

Monika Benstetter or Martin Harvey press@ema.europa.eu

approach to developing a methodology for the release of clinical-trial data with its stakeholders, the Agency is currently devoting attention to all comments received and reaffirms its commitment to transparency and the principles of publication and access to clinical-trial data.

In order to conduct the appropriate in-depth analysis required, the Agency will spend additional time in this reviewing phase which may therefore delay the finalisation of the policy initially planned for the end of 2013. An update on timelines will be provided at the latest following the EMA Management Board meeting on 11–12 December 2013.

The Agency has embarked on the development of a policy on publication and access to clinical-trial data, because it believes that the release of data is about establishing trust and confidence in the system. The Agency is also firmly of the opinion that the availability of data broadens the scientific knowledge base, fosters innovation, and encourages investment in the development of medicines and ultimately benefits public health.

More information on the work of the European Medicines Agency can be found on its website: http://www.ema.europa.eu.

5

Taming Microsoft Word®

Peter G Aitken, Maxine M Okazaki

Piedmont Medical Writers LLC, NC, USA

Correspondence to:

Peter Aitken Piedmont Medical Writers LLC 35 Wedgewood Road, Chapel Hill NC 27514, USA p.aitken@piedmontmedicalwriters.com

Abstract

The long, complex documents that medical writers often work with can place unusual demands on a word processing program. Microsoft Word[®] is a powerful program, but that does not mean using it properly is always easy or intuitive. Many problems that writers encounter are the result of not knowing exactly how Word works, what unintended effects its options may have, or the best practices for performing certain writing and editing tasks. This article explains some of Word's more troublesome quirks and shows you how to avoid them.

Keywords: Microsoft Word, Word processing

If you are a medical writer, there are pretty good chances that you use Microsoft Word® to create and edit your documents. For better or worse, it is the *de facto* standard in the pharmaceutical industry. It is a powerful and flexible program, to be sure, but as such it offers pitfalls and traps to the unwary user. Many of these potential problems are not bugs but are actually features of the program, features that may have their uses in certain circumstances, but which can also cause problems when the user is not aware of how they work. In this article, we explain some of these potentially problematic 'features' and tell you how to deal with them. We deal specifically with Word 2010, but the information is generally relevant to earlier versions of the program.

Keeping track of formatting

As you probably know, a style is a defined set of formatting rules that can quickly be applied to the text in your document and that can be easily modified. Styles are certainly an important and useful feature. However, some users find their list of styles becoming cluttered up with seemingly extraneous styles, styles that you do not remember being there when you started the document, and it can become difficult and time-consuming to locate and apply the styles you actually need. What gives

this unwanted proliferation of styles is what a medical person might call a *style malignancy*.

The culprit is a Word option named **Keep track of formatting**. When this option is turned on, Word keeps a watch on what you are doing and automatically defines a new style for formatting that you apply to the existing styles. Let us see how this works

Suppose that your document's base style for text is called Body Text and it is defined as Arial font, 12 points. As you edit the document, you select a paragraph formatted as Body Text and make it boldface. Word notes your action and creates a new style called Body Text + Bold. Then, you change another section of the Body Text from 12 points to 10 points – a new style called Body Text + 10 pt is created. This goes on and on until your style list is a metre long. It is easy to prevent Word from creating new styles by turning off a particular program option as follows:

- 1. Display the **File** tab.
- 2. Click the **Options** command.
- 3. Choose the **Advanced** category.
- 4. Turn off (remove the check from) the **Keep track of formatting** option, as shown in Figure 1.

Easy enough – but what if you have inherited a document that is already loaded down with these unnecessary styles from a previous user? You could delete them all, but it would be easier just to hide the style names so they do not clutter up the style list.

- If the style list is not already displayed on the right side of your screen, show it by clicking the diagonal down arrow at the lower right corner of the Styles group on the Home tab.
- 2. A dialogue box containing the style list will appear and at the bottom is the **Options** link. Select this link to open the dialogue box **Style Pane Options** (Figure 2).

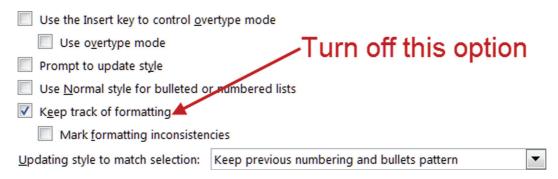


Figure 1: Telling Word not to create new styles based on the formatting changes.

3. Turn off the three options that are indicated in the figure and then close the dialogue box.

Now, your style list will not show the names of any styles that were created by the **Keep track of formatting** feature.

Prompt to update style

Have you ever had formatting in a document change, seemingly for no reason at all? You could think that there is a poltergeist in the computer! It is more likely, however, that the Prompt to update style option is turned on. This option tells Word to watch what you are doing and update the style definitions to match the manual formatting changes that you apply. For example, suppose your document has a style named Body Text that is defined as Times New Roman font, 12 points. If you select a single paragraph that is assigned this style and change the font size to 10 points, Word updates the style definition to match the previous command, with the result that all the current and future Body Text paragraphs will be formatted as a 10 point font. This is probably not what you want, and it can be

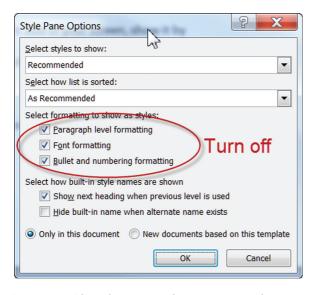


Figure 2: Hiding the names of unnecessary styles.

particularly problematic when you are working in a client's template and inadvertently change one of their carefully planned styles. We recommend that you turn this option off and leave it that way. It is located in the same dialogue box as the **Keep track of formatting** option (see Figure 1).

'Paste as Unformatted Text' – A writer's best friend

As medical writers, we are often required to copy text from a source document and paste it into our own document. Depending on where you are copying from, the copied text may be accompanied by its original formatting – that is, the formatting it had in the source document. Sometimes you may want this, but more often it creates problems because you want to apply formatting from the destination document to the copied text. In some cases, it can also bring one or more style definitions from the source document and these can conflict with your own document styles.

Here's where 'Paste as Unformatted Text' comes to the rescue. This command pastes just the text that you have copied, as if you had typed it in yourself, and ignores any and all formatting that may be attached to the text. By default, the formatting that is in effect where you paste the text is applied, but you can also format the text differently as desired. Here's how:

- 1. In the source document, copy the text to the clipboard.
- 2. Switch to the destination document and click the arrow at the bottom of the **Paste** command on the Home tab. This displays the **Paste Options** (Figure 3).
- 3. Click the button indicated in the figure to paste the clipboard contents without formatting.

There is a shortcoming with this technique, namely that non-standard text symbols such as \leq and \otimes are lost, as are non-breaking spaces and hyphens, and these will typically be replaced by small boxes in



Figure 3: Pasting text without formatting.

the pasted text, so you will have to put them back in manually.

My table of contents formatting keeps vanishing

Word has powerful tools for creating table of contents (TOCs) that automatically update to reflect the changes in the document. A common complaint, however, is that the formatting you have applied to a TOC will vanish without warning and you will have to start all over again. Frustrating! The fact is, however, that you should not be manually formatting your TOC. You will see why, once you understand how Word TOCs work.

A TOC is generated automatically by Word based on the headings in your document. The appearance of the TOC is controlled by styles, just like the other text. These special styles are named TOC 1 (controls the appearance of the top-level TOC items), TOC 2 (second-level items), and so on. These styles do not show up in the style list because they are used only with the TOCs, but they work just like other paragraph styles to control font, alignment, indentation, justification, etc.

Here's what happens when you manually format a TOC in your document. Subsequently, you will almost surely update the TOC to make sure it accurately reflects the document. The update means that Word deletes the old TOC and generates a new one by using the assigned TOC styles – and of course your manual formatting vanishes to be replaced by the TOC style formatting.

The bottomline, then, is that you must modify the TOC styles in order to change the TOC formatting. We would not go into the details of working with styles, but a TOC style is really not different from a regular paragraph style and you work with it the same way. It is a bit tricky to find these styles, however! Here are the required steps:

1. Place the editing cursor anywhere in your active TOC.

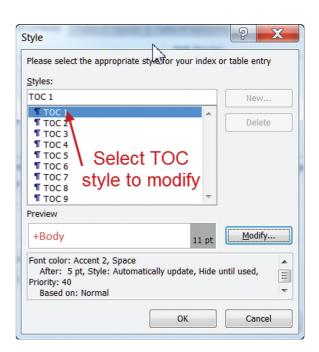


Figure 4: Selecting a TOC style to modify.

- 2. Click the **Table of Contents** command in the **Table of Contents** group on the **References** tab.
- 3. Near the bottom of the menu, click the **Insert Table of Contents** command.
- 4. In the next dialogue box, click the **Modify** button to display the **Style** dialogue box (Figure 4). You can see that the various TOC styles are listed here.
- 5. Click the TOC style that you want to change, then click the **Modify** button. This opens the **Modify Style** dialogue box where you can make the desired changes to the selected style.
- 6. Repeat step 5 as needed to change the other TOC styles.
- 7. Close all the dialogue boxes. When Word updates your TOC you will see the formatting changes applied.

Now that you know how TOC formatting works you would not waste any more time trying to do it manually.

A few dos and don'ts

We are going to wrap up this article with a short list of things you should not do in Word and the proper way to get the same result. Some of these are pretty basic but they can make a big difference in the ease of working with Word documents.

If you want some white space between paragraphs, don't press the 'Enter' key twice. This adds an extra, blank paragraph that can cause problems later. Do define the paragraph's style

to include some space before and/or after each paragraph.

Don't press 'Enter' repeatedly to move an item to the top of the next page. This may look fine initially, but things will shift as text is added to and deleted from the document. Do insert a hard page break by pressing the 'Ctrl' and 'Enter' keys simultaneously before the item or use the Keep with next option by accessing the dialogue box in the Paragraph group on the Home tab or the Insert tab.

Don't press the spacebar repeatedly to move a word to the next line. **Do** press 'Shift' and 'Enter' to start a new line without starting a new paragraph.

In summary

As medical writers, our job is to use our writing and scientific expertise to create high-quality documents. We should not be wasting our time fighting with the word processor! The information in this article should help you get a handle on Microsoft Word.

Author information

Peter Aitken, PhD served on the faculty at Duke University Medical Center, Departments of Cell Biology and Surgery for 18 years participating in clinical and preclinical research and teaching medical and graduate students. Since leaving academia 12 years ago he has specialised in writing regulatory and educational documents for the pharmaceutical industry.

Maxine Okazaki, PhD received her degree in pharmacology and was a research scientist and faculty member in the Department of Pharmacology and Cancer Biology at Duke University Medical Center from 1984 to 2001. Since leaving Duke she has worked for several pharmaceutical companies and contract research organisations and is currently an independent consultant.

Both the authors are principals at Piedmont Medical Writers LLC, a small firm providing writing and consulting services to the pharmaceutical industry. They also authored the book *Microsoft Word 2010 for Medical and Technical Writers* (see http://www.tech-word.com and a review of the book in this edition of MEW, page 67).

The secrets of Microsoft Word[®]. Part I – 'Find and Replace' and en-dashes

Alistair Reeves

Ascribe Medical Writing and Translation, Wiesbaden, Germany

Correspondence to:

Alistair Reeves Schäferweg 10, 65207 Wiesbaden, Germany a.reeves@ascribe.de

Abstract

Almost everyone uses Microsoft Word® – but do you use its standard functions to the full to make your job easier? It is worth spending a little time getting to know how you can exploit functions like 'Find and Replace' or change or understand some of the 'factory settings' that can sometimes be annoying.

Keywords: Microsoft Word, Word processing, Software

Many years ago, in the mid-1980s, when electronic word processing was first introduced, most people working for companies had courses which gave them a comprehensive grounding in the basics and a few special uses. This was followed by a half-day course or a couple of hours each time a new version of the respective software was issued. Nowadays, people are just expected to be able to use word processing (rather like being able to drive). The result is that word processors are used like a glorified typewriter by many, as is confirmed by not just a few of the articles I receive every year.

Many large companies send just a few administrative assistants to receive training on Microsoft Word[®]. These people are then expected to pass on the knowledge gained to the rest of their colleagues. This means that really useful things that you can do with Microsoft Word do not filter through to those who need them most – authors and editors.

The hidden secrets of 'Find and Replace'

I am often surprised at my courses that the delegates' attention has never been drawn to simple things you can do to help yourself such as using 'Find and Replace' for checking and not just doing simple searching and replacing. If you start digging deeper into what you can do with the 'Find and Replace' function, I am sure you will

make much greater use of it, as it eases some of the thankless tasks of writing and editing. The main thing to remember is to think hard before you press the 'Replace all' button. It is almost always better to replace items individually.

Many people are not aware that you can search spaces, punctuation, strings, and codes in the 'Find what:' field, and that there are entries you can make for 'any character', 'any digit', and 'any letter', for example. At the bottom of the 'Find and Replace' dialogue box is a button that says 'Special'. Open this up, and you will see some of the 'special' things you can search and replace (Figure 1). The list is longer for the 'Find what:' field than for the 'Replace with:' field.

'Any letter' is useful if you are dealing with text from different authors who have used one or two spaces after a full stop. If you want to check that you always have one space after a full stop, for example, and not a mixture of one and two, you type '\\$.[space][space]\\$' in the 'Find what:' field. \\$ is the entry for 'any letter' and is followed by the full stop and two spaces with the space bar (Figure 2). You then search with 'Find next' and can delete one space each time you have typed two (automatic replacement does not work with 'any letter'). Adjust the number of spaces you enter to the number you want to find.

'Any digit' is useful when checking for the comma used as a decimal point in texts from Continental European authors. Enter '\#,\#' into the 'Find what:' field and start searching. Again, you have to replace here manually, but at least you find all the instances.

The list under the 'Special' button also includes the paragraph mark. You may think you would never need to search for the paragraph mark, but I am sure that you deal with text (sometimes pages of it) copied into Word from PDF documents, emails, or other unformatted sources with paragraph signs at the end of each line and no space

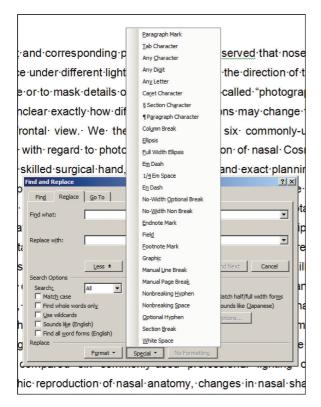


Figure 1: This list opens in 'Find and Replace' after you click on the 'Special' button with the cursor in the 'Find what:' field. To review the list for 'Replace with:', click on the 'Special' button with the cursor in the 'Replace with:' field. The list for 'Replace:' is much shorter because the elements that can be replaced are limited.

between the last letter and the paragraph sign. Enter ' \land p' into the 'Find what:' field and a space into the 'Replace with:' field. This will inevitably mean that you will have some instances of two spaces in your text, but nevertheless you can probably afford to click on 'Replace all' in this instance to get rid of all paragraph signs and insert spaces instead because you are likely to be heavily editing this sort of text anyway. And depending on the length of the text, you could search for two spaces and replace with one.

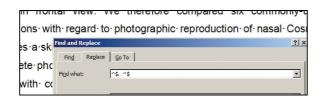


Figure 2: Finding full stops with two spaces after them: with the cursor in the 'Find what:' field, click on the 'Special' button and then on 'any letter'. ^\$ appears in the 'Find what:' field. Type a full stop after this and then two spaces, then click on the 'Special' button again and click on 'any letter' again. The full entry in the field is ^\$.^\$. You can, of course, also type in this string instead of using the 'Special' list. This function (like searching for the full stops with 'any letter') can be done with either the 'Find' or 'Replace' tab activated.

Explore what else you can do with the items under the 'Special' button as they really do allow you to cut some corners and save time.

Enter 'space comma' into the 'Find what:' field and a comma into the 'Replace with:' field to search for commas that still have spaces before them, because the text was so messy with track changes that you could not see the spaces before the commas. Do the same for opening and closing brackets, semi-colons, and full stops. The list of checks you can do is endless.

If you want to bind units to values so they are not separated over and automatic line break, enter a space followed by 'mg' (or the unit concerned) into the 'Find what:' field and a non-breaking space in the 'Replace with:' field (\inftys, or via the 'Special' list) followed by mg, and search. This catches all units starting with 'mg', such as mg/dl. Brave souls will do this with 'Replace All'; I still prefer to do this individually, or enter the non-breaking space while typing via <CTRL + shift + spacebar>.

However, this is not all you can do with Find and Replace. Lots of other strings can be entered in the 'Find what:' field to make your job easier. For example, James Visanji of Trilogy Writing showed me how to highlight all capital letter abbreviations in your text that have at least two letters by:

• In Word 2003, entering '[A–Z]{2}' into the 'Find what:' field under the 'Find' tab, selecting 'Use wildcards', selecting 'Highlight all items found in: Main Document', and clicking 'Find all' (Figure 3).

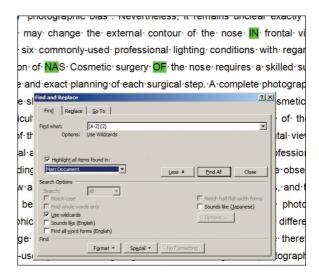


Figure 3: Finding and marking capital letter abbreviations with at least two letters using Word 2003. This can only be done with the 'Find' tab activated. Enter the string shown in the 'Find what:' field, activate the required settings, and click 'Find all'.

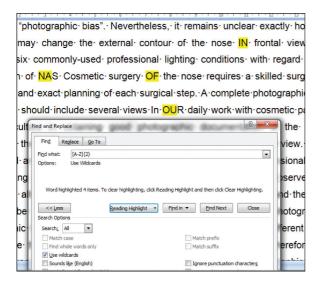


Figure 4: Finding and marking capital letter abbreviations with at least two letters using Word 2007. This can only be done with the 'Find' tab activated. Enter the string shown in the 'Find what:' field and activate the required settings. As soon as you choose 'Highlight All' (not displayed after you choose it!) from the Reading Highlight box, the abbreviations are highlighted.

• In Word 2007, entering '[A–Z]{2}' into the 'Find what:' field under the 'Find' tab, selecting 'Use wildcards', and selecting 'Highlight all' under 'Reading highlight' (Figure 4).

This can only be done with the 'Find' tab activated. All instances in the document are highlighted. In Word 2003, change the highlighting colour and print your document with all abbreviations marked. In Word 2007, you have to review them on the screen (I have not found a way of printing with highlighting, so it would be good to know

Author information

Alistair Reeves has worked in the pharmaceutical industry for almost 40 years as a translator, writer, editor, and trainer, and for the last 12 years as a freelance trainer and editor. He is a regular contributor on language issues to *Medical Writing*, an honorary member of EMWA, and EMWA Conference Director.

if this is possible.). This is nowhere near automatic preparation of your list of abbreviations, but is a great help in a document with more than a few tens of pages.

It is well worth printing out the online help for 'Find and Replace' as it offers a wide range of possibilities for finding and checking many other things. As you try things out, you will learn which functions have to have the 'Find' tab activated and which have to have the 'Replace' tab activated.

Those tricky en-dashes

An en-dash is the symbol that should be used for ranges, for example, 17-25 pg/ml. The 'factory setting' in Microsoft Word automatically changes hyphens into an en-dash. Unlike several other preset functions such as 'drag and drop' and 'smart cursoring', I have not switched this one off. Again, many people in my courses see this happen but do not realise what is happening. When Word thinks you are typing a range such as '... 17–25 pg/ml ...', you type '17-space-hyphen-space-25' and as soon as you type the space after the 25, it converts the hyphen you typed into an 'en-dash'. It does not remove the spaces, but in traditional typesetting the en-dash has no spaces. I think we will have to bow to Word and realise that very soon the en-dash will usually have spaces. I have already given up taking them out! The way to insert an en-dash manually is $\langle CTRL + - \rangle$ on the numeric keypad.

Word has many other 'factory settings', and I shall be telling you why I have rejected some of them in a future issue.

Organising the review process in Microsoft Word®

Alexander Nürnberg

CRS Clinical Research Services Mannheim GmbH, Grünstadt, Germany

Correspondence to:

Alexander Nürnberg CRS Clinical Research Services Mannheim GmbH, Richard-Wagner-Strasse 20, 67269 Grünstadt, Germany alexander.nuernberg@crs-group.de

Abstract

Regulatory documents are prepared in a highly collaborative process within tight timelines. The time and the resources required for collecting input, organising document review, and processing the reviewers' responses often dwarf those invested in the actual writing. In our company, I have developed Microsoft Word[®] macros to manage and document the review process. This solution, combined with the modifications of the review workflow, is efficient and, as it relies on the features already contained within Microsoft Word, does not require additional software.

Keywords: Macros, Document review, Microsoft Word

Review is the key process in document development, which ensures the quality and the credibility of the document. It is also one of the most time-consuming steps for medical writers, which has, if poorly organised, a high potential for introducing errors and inconsistencies into the document. Software tools can speed up and greatly assist in the organisation and the conduct of document review; yet, software solutions that meet the medical writers' expectations are remarkably scarce.

Usually, documents are distributed in Microsoft Word format and reviewed by using tools available in Microsoft Word. These review tools, e.g. tracked changes and comments, are not only widespread and broadly accepted; they are also easily customisable with macros. We, therefore, decided to adapt them to our needs, aiming at a solution that:

- Is intuitively clear and does not need initial (or worse, on-going) training;
- Promotes a strict separation between the review itself and its implementation, with the reviewers concentrating on the content and the medical writers caring for the implementation, proper wording, and consistency check;

- Guides the reviewers through the document, focusing them on relevant issues;
- Allows a parallel review and an unproblematic consolidation of the reviewers' responses;
- Provides a clear documentation of the review process, discussions, and resulting decisions;
- Facilitates review organisation and processing by the medical writers;
- Leaves the ultimate control over the document in the hands of the medical writers.

Our solution consists of changes in the review practice and the programming adaptations of the commenting functionality in Microsoft Word, involving rules for tagging comments and a set of macros.

Changes in review practice

We have abandoned the 'track changes' mode, which is an excellent tool for indicating changes in a single distributed copy, but is not practical if several reviewers are involved in the review. Instead, we distribute document copies that permit commenting only and ask the reviewers to provide their opinions as comments in the document. This way, the medical writer retains ownership of the document.

Upon review completion, comments from the returned copies are automatically transferred into the master document without producing conflicting insertions and deletions. The resulting master document containing all the comments represents a clear record of the review process. This document can then be conveniently processed by using dedicated macros.

Tagging a comment

A comment in Microsoft Word conveys three major pieces of information: the comment itself, the author, and the scope (i.e. the marked text to which the comment is attached). For an efficient processing, we additionally specify the addressee, the relevance, and the status of a comment by

introducing standard descriptive phrases (tags) into the comment's body.

Addressee

The addressee of a comment is given by a boldfaced upper case expression like '@SOMEBODY:' (Figure 1A and B). By using this tag, we provide guidance for the reviewers, denoting the comments that need special attention. As the tags are in bold uppercase, we reduce the risk of the comments or the questions being missed. Unified abbreviations implemented in the macro, e.g. @INVESTIGATOR, or @STAT, contribute additionally to the clarity. In the end, this approach saves the reviewers' time, especially when the documents contain numerous comments (a typical situation in the early stages of document development).

Relevance

The relevance (in our parlance 'rating') is shown in the first line of a comment as boldfaced 'Rating:' followed by one of the five categories (in descending order): critical, major, minor, note, or editing (Figure 1B and C). Assigning relevance to the comments and the questions allows us to prioritise their processing and to quantify document quality. In addition, we introduced escalation rules, e.g. the critical comments must be immediately clarified with the team, the major comments need to be confirmed and followed up, the minor comments require confirmation only if declined, and the notes can be implemented or rejected at the medical writer's discretion.

Status

14

We specify the processing state of a comment by assigning the 'status' using four categories: done,

pending, declined (rejected), and confirmed (Figure 1B and C). Similar to the rating, this tag can be smoothly added or changed by a macro.

Renlies

Although Microsoft Word provides functionality for replying to a comment, such replies appear as normal comments, with the only visible difference being an 'R' added to the author's initials (It has been changed in the newest version, Microsoft Word 2013, where the replies are displayed as a discussion tree. Comments can be also marked as 'done' in this version.). Often, however, people add replies as a new comment, sometimes at a rather arbitrary location. In either case, the original comment and several replies form a bewildering array, which becomes even more disorganised if several unrelated issues are discussed within one page.

Our strategy is therefore to discuss each issue within one comment, keeping the discussion thread together. For this, we place a new reply directly at the end of the initial comment and any previous replies therein. Each reply starts with a boldfaced expression 'REPLY(Initials):' (added automatically) and is followed by the actual reply (Figure 1B and C). Of note, our macro prevents addition of the eighth reply, notifying the user that a telephonic conference may be a better solution.

Managing comments

Although it is already a great improvement when a comment clearly states what has to be done and who has to do it, the full effect of these ideas is only seen on a document-wide macro solution. Such a macro analyses the comments within the document,

Comment [CRS/em13]: @BA/@STUDYNURSE: Please check blood volume. Is it sufficient for all analyses? Which anticoagulants will be used?

Comment [SPONSOR42]:

В

Rating: Critical Status: Declined
The total volume of PK-samples should
be reduced if possible.

@BA(CRS/em): Can we do it? If not,
we may need a statement for the EC,
because the total volume is quite high.
REPLY(CRS/ba): We need at least 0.6
mL. With less plasma, re-analysis will
be impossible. We can prepare a
statement if needed.

Comment [CRS/em73]:

Rating: Major Status: Pending @STAT: Please check criteria for the interim analysis (taken from the updated outline).

REPLY(CRS/mm): Changes from baseline are not applicable since concentrations are baseline-corrected. Descriptive statistics are not appropriate. Note: no formal interim analysis will be performed. REPLY(CRS/dm): The definitions should be more specific. We will discuss it in TC.

Figure 1: Examples of Microsoft Word comments in our format. (A) A comment addressed to a bioanalyst and a study nurse during an internal review. (B) A comment from a sponsor that we rated as 'critical' and redirected to the bioanalyst. The bioanalyst replied, declining the proposal. Hence, the status of the comment is 'declined'. (C) A comment to the statisticians during an internal review. There are two replies from the statisticians. Note that we set the user initials in Microsoft Word to 'company name/initials' to distinguish in a better manner between the internal and the external comments and to provide clarity for our customers.

extracting information on the addressees, the ratings, the status, and the replies. The extracted information can be used in several ways.

Comments can be selected on the basis of their tags (Figure 2). The macro allows a flexible combination of tags, e.g. selection of all the comments to the investigator that are pending and critical, and do not contain replies. The selected comments can then be exported into a Microsoft Word or Excel[®] file, with the tags and the replies displayed in separate columns (Figure 3). We use these lists for documentation of the review process, for overviews, for preparing telephonic conferences and meetings, and as supportive documents for the reviewers.

Alternatively, the comments can be selectively deleted from the document. We routinely remove unrelated comments from the distributed copies, leaving the complete set of comments in the master document only. This approach is especially useful for an interim clarification of a single issue: in this case, we can easily create an ad hoc copy of the document that contains only issue-specific comments.

Other applications of the macro include quality metrics, with the overall number and relevance of the comments being measures of document quality, estimation of the remaining work load using the status tag, and work allocation. The macro can also control the proper implementation of the reviewers' comments, e.g. requiring that all the declined comments are replied or that all the critical and major comments are processed. Finally, small and handy tools incorporated into the macro, e.g. predefined replies or copy/paste of the entire comment, provide good assistance and enhance productivity.

Summary

Certainly, the presented approach requires accustoming and some tuning of the review workflow, but its benefits clearly stand out: document development becomes more standardised and efficient. Although we mostly use these tools internally (external reviewers are invited but not required to mark comments in our way), this approach has been already accepted by several sponsors due to its obvious benefits. Other companies also use macro-assisted approaches in a similar manner with a noticeable increase in the productivity and the streamlining of the review process (Gwyn Hopkins, personal communication). One macro of particular interest in this context extends the compare/combine functionality of Microsoft Word to be able to combine the comments of several documents in one go, again demonstrating the power of macro programming and its opportunities.

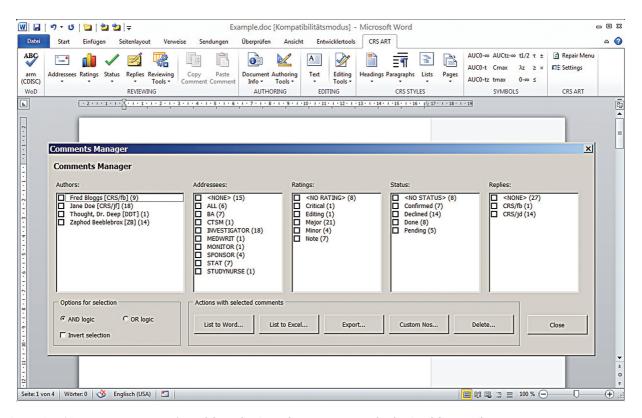


Figure 2: 'Comments manager' used for selection of comments on the basis of five attributes.

Rating	Status	Context	Addressees	Comment	Replies
Major	Declined	Page 73, 6.1.1. Blood Sampling and Handling	BA	Comment by: John Doe [SPONSOR]	Reply by: CRS/ba We need at least 0.6 mL. If we
		Blood samples will be collected in		Show in the original document	reduce further, re-analysis will
		EDTA sampling tubes. Samples will be		The total volume of PK-	be impossible.
		centrifuged at approximately 4°C at		samples should be reduced if	
		$2000 \times g$ for 10 minites. At least 1.2 mL		possible.	
		plasma will be then transferred into 2		@D A (CDS (cms)): (Case 45: 59	
		polypropylene tubes (1st aliquot and		(#BA(CKS/eIII): Call we do IL:	
		backup; 0.6 ml each) and stored at			
		approximately -20°C until shipment.			

An example of an exported comment. For clarity, the macro exports the whole paragraph surrounding the comment's scope. The scope (i.e. the marked text to which the comment is attached) is then automatically highlighted In conclusion, the author wants to encourage medical writers to use macros in their daily work and to invite them to discussions and exchange of ideas. Macros are useful for a variety of tasks performed by medical writers, saving time, resources, and improving document quality. They can also promote new ideas: forcing people to manually add predefined text expressions in a specific format most probably would have failed, whereas the same ideas provided as easy-to-use menu buttons were highly appreciated.

Acknowledgements

I thank Dr Gwyn Hopkins and Nadja Faißt for discussion and comments on the manuscript. I am also grateful to all my colleagues who supported these ideas. A special thanks goes to Anja Lerps, Hannelore Putz-Geißler, and Tanja Knerr for testing the macro and providing suggestions.

Conflicts of interest and disclaimers

The author is an employee of CRS Clinical Research Services Mannheim GmbH. This is an independent publication and is not affiliated with, nor has it been authorised, sponsored, or otherwise approved by Microsoft Corporation.

Permissions

The screenshot of Microsoft Word shown in Figure 2 is used with permission from Microsoft.

Supplementary material

Online supplementary material 1 of a demonstration file, containing the simplified macros described above, is available.

References

- 1. Van Der Geest T, Van Gemert L. Review as a method for improving professional texts. J Bus Tech Commun 1997;11(4):433–50.
- Bernhardt SA. Improving document review practices in pharmaceutical companies. J Bus Tech Commun 2003;17(4):439–73.
- 3. Cuppan GP, Bernhardt SA. Missed opportunities in the review and revision of clinical study reports. J Bus Tech Commun 2012;26(2):131–70.

Author information

Alexander Nürnberg is a medical writer at CRS Clinical Research Services Mannheim GmbH.

Document templates for medical writers

Raquel Billiones

Clinipace Worldwide, Volketswil (Zurich), Switzerland

Correspondence to:

Raquel Billiones Clinipace Worldwide Volketswil (Zurich) Switzerland rbilliones@clinipace.com

Abstract

A document template is defined as 'a file that serves as a starting point for a new document'. This article looks at the specialised templates used by medical writers in their trade with a focus on the commercially available products. Templates allow a medical writer to prepare standardised documents that comply with the regulatory format requirements, and they increase productivity and allow rapid troubleshooting and document repair. The advantages and the disadvantages of using templates and some criteria of what makes an effective template are discussed. Templates available commercially are briefly presented.

Keywords: Templates, Regulatory, Documents, Commercial

Introduction

The etymology (1670s) of the word 'template' is rooted in craftsmanship, with definitions ranging from a 'weaver's stretcher' to a 'plank or rafter' that provides support or serves as guide for a piece of work. Centuries later, templates in many different forms still play an important role in professional life. For medical writers, templates are a part and parcel of the job and the advent of eCTD reinforced their importance. This article looks at the templates used by medical writers in their trade, with a focus on the commercial templates used in regulatory medical writing.

Different types of document templates

In Microsoft Word[®], a document template is 'a file that serves as a starting point for a new document'.² This file contains pre-specified formats and styles and has the file extension '.dot'. When you create a new Word document, by default, it is formatted based on the normal.dot template. However, templates can actually mean many things and come in

many different forms. The most common examples are listed below.

Built-in word templates

Ready-made templates for Word are available from office.com. These range from templates for blog posts to project proposals to party invitations (Figure 1). These are especially handy for the average Word user. Unfortunately, they are not necessary suited to medical writing needs.

Self-made templates

For the more technically inclined who aims for individuality, one can create a template in Word by defining different styles. The template can be saved as a '.dot' file. These files can even be shared with the Word user community on office.com.

Old documents as templates

In the medical writing world, we are frequently asked to use old documents as 'templates' by deleting the existing text but retaining the headings and the subheadings that are usually standard for that specific document. Unfortunately, these old documents may come with a lot of baggage, including unruly headings and rogue styles and are therefore not the ideal foundation for a new document.

Guidance templates

Publishers and journals usually provide templates as part of their Instructions to authors. For example, MEW has one available for feature articles. Regulatory bodies provide templates for certain regulatory documents that can be downloaded for free. These templates contain standardised headings and subheadings as well as instructional texts but the styles may or may not be defined.

Commercial templates

These are ready-made templates designed by technical professionals and must be purchased. Although most of these are Word-based templates, they come

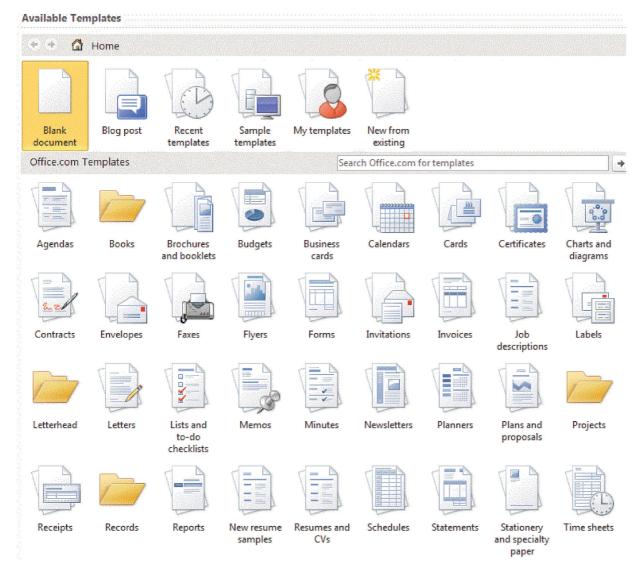


Figure 1: Office.com templates available in MS Word.

with extra plugins and macros that facilitate the writing and development of long and complex documents. These usually come as part of a set of content templates included in a document management package tool. Word classifies these as 'installed' templates.

Why use templates? Why not?

There are pros and cons associated with using templates, and they are discussed here with a focus on the commercial templates in regulatory writing.

Pro: Standardised documents

Companies, regardless of industry, require the use of templates in their documentation mainly to maintain a degree of consistency in the many documents that their employees write every day, from internal office email memos to full project proposals. Templates help maintain corporate identity by using standard headers and prespecified texts.

In medical regulatory writing, templates give different documents a uniform look. Whether they are used by multiple writers working on a single document or by a whole global team working on a set of documents for a dossier, templates (and the standard headings, and boiler plate and instructional texts therein) ensure that the documents are standardised in terms of formats and styles as required by the guidelines and company standard operating procedures.

Pro: Regulatory compliance

In the pharmaceutical industry, templates have a more specific and crucial function – guidance compliance. Regulatory templates are supposed to be designed to comply with the eCTD format requirements and to facilitate electronic submissions by providing correct section numbering and headings. For those who are not familiar with regulatory medical writing, the investigational medicinal

TABLE OF CONTENTS

2.2.1	INTRO	ODUCTION	4
2.2.1.S	DRUG	SUBSTANCE	5
2.2.1	.S.1	General Information	5
2	.2.1.S.1	.1 Nomenclature	5
2	.2.1.S.1	.2 Structure	6
2	.2.1.S.1	3 General Properties	6
2.2.1	.S.2	Manufacture	6
2	.2.1.S.2	2.1 Manufacturer(s)	6
2	.2.1.S.2	Description of Manufacturing Process and Process Controls	6
2	.2.1.S.2	2.3 Control of Materials	6
2	.2.1.S.2	2.4 Controls of Critical Steps and Intermediates	6
2	.2.1.S.2		
2	.2.1.S.2	2.6 Manufacturing Process Development	6

Figure 2: A part of the table of contents of an IMPD.

product dossier (IMPD) is a good example illustrating the complexity of regulatory documents. The headings and the subheadings in an IMPD (see Figure 2) can be challenging for a writer not familiar with Word numbering functions.

Another issue is the font type and size. The regulatory writers are aware that most regulatory agencies prefer Times New Roman, Arial, and Courier New with a minimum size of 9 point.³ The newest Word versions include Calibri as the default font for the body text in a new document. This can easily be mistaken for Arial, but it is not the same. In addition, Word offers many fonts that unfortunately have no place in a regulatory document.

Beyond the writing itself, the templates should also work seamlessly with electronic publishing, which compiles different documents into a single electronic dossier.

Pro: Increased productivity

By pre-defining headings, styles, and formats, the templates allow the writer to concentrate on generating content rather than (re)formatting. Template plugins and macros, which appear as icons in the Word ribbon, enable the writer to carry out complicated commands with a single mouse click. For example, inserting a landscape page in a document that is in standard portrait layout takes at least nine steps to accomplish in Word 2007. With the 'installed'

template I am currently using, it can be accomplished in two mouse clicks (Figure 3), without having to worry about header and footer alignments. Another useful feature is the pharmacokinetics symbols available in a pulldown menu (Figure 4).

Pro: Rapid troubleshooting and repair

Many medical writers have experienced how documents that have changed hands during the writing and review process can come back with bizarre formats and styles. Some of these changes may have been inadvertent, having been 'infected' by styles defined in other normal.dot files. Copying and pasting formatted text can also introduce rogue styles into documents. However, there are also users who just cannot resist changing or even creating new styles. A document may end up suffering from the so called 'snowflake syndrome', which is where almost no two paragraphs are formatted alike.⁴

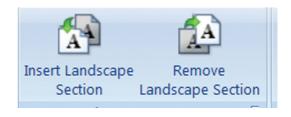


Figure 3: Icon in MS Word ribbon for inserting and removing a landscape section in a portrait document.

_		
AUC _{o-t}	Area under the curve from zero up to time t	
AUC _{o-inf}	Area under the curve from zero up to infinite time	
Aave	Average amount in the body at steady state	
DM	Maintenance dose	
DL	Loading dose	
Cp	Plasma concentration	
Cs	Serum concentration	
Cu	Unbound plasma concentration	
Cur	Drug concentration in urine	
Cav,ss	Average concentration at steady state	
C _{max}	Observed maximum concentration	
C _{max,ss}	Maximum observed concentration at steady state	
C _{min,ss}	Minimum observed concentration at steady state	
t _{max,ss}	Time to maximum concentration at steady state	
t _{1/2}	Terminal half-life	
tmax	Time to reach Cmax	
CLint	Intrinsic clearance	
CLCR	Creatinine clearance	
CLm	Metabolic clearance	
CLR	Renal clearance	
fe	Fraction of intravenous drug excreted unchanged in urine	
f _e /f	Fraction of orally administered drug excreted into urine	
frel	Fraction of the dose in comparison to a standard (not ${\mathbb N}$)	
ke	Elimination rate constant from the central compartment	
k _{ren}	Renal elimination	
Frel	Relative bioavailability in %	
Km	Michaelis-Menten constant	

Figure 4: PK symbols from a pull-down menu in MS Word ribbon.

Templates solve this problem by including formatting styles that are protected and not easily altered or renamed no matter how many times the document changed hands.

Word has other quirks and instabilities, like the nightmare of disappearing cross-links and out-of-control autonumbering. Commercial templates have (theoretically) been tested for stability, and they have builtin repair systems that help fix formatting issues. The snowflake syndrome, for example, can easily be repaired with a few mouse clicks. In addition, for dire cases, there is usually technical support that can be contacted.

Cons of using templates

The main disadvantage of the commercial templates is the financial aspect, which can range from a one time licence fee (plus extra for updates) or an annual subscription fee. Another objection to the templates is their rigidity, which may 'cramp' the style of some writers. Commercial templates also make the writer dependent on the macros and plugins, causing them to forget the standard Word functions in a template-free environment.

What makes a good template?

Not all that glitters is gold. Some templates and document management tools may not actually live up to their claims. In shopping for templates, here are a few suggested criteria to consider.

Ease of use

The template and its accompanying plugins should be easy to use, otherwise it will decrease rather than increase productivity. A user with a moderate level of Word skills should be able to use the template with minimal training.

Effect on word functionality

Macros and plugins should not interfere with the standard Word functionality or drastically slow down any standard software. In addition, the document should still be readable and write enabled by other users who do not have the template installed in their computer.

Stability

The template should be acceptably stable and not lead to too many 'crashes'. Ask the vendor for their stability testing procedure.

Technical support

A minimum degree of technical support should come with the template package. User's manuals and online resources are useful, but a hotline can be crucial when a template crashes while chasing a deadline.

Adaptability

The drug regulatory process is continuously evolving and so are the documents that go with it. The template should therefore be adaptable to changes in regulations or region specific requirements. The simplest example is changing a document from US Letter to A4 size. Does your template allow this without breaking your document apart?

Price

Finally, the price of the template is, of course, of prime importance. Normally, to justify the cost of buying a set of templates, a certain critical mass of writers and regulatory documents is needed. Over the years, my experience is that big pharma companies with an extensive product pipeline can afford (and should have) these templates, whereas startups cannot necessarily afford them. In a 2010 Europharm survey, only 44% of small- and medium-sized pharmaceutical enterprises in Europe had an eCTD management tool. The rest were, at the time, still checking out vendors or opting to outsource the eCTD publishing process.⁵

Commercial templates: What's available?

Many software companies offer regulatory templates. Unfortunately, almost no data are freely available comparing the functionality, the price, and the market share of these software packages. Two of the most popular template sets are ISIWriterTM and Liquent SmartDeskTM.

ISIWriter by CSC prides itself for having been created by 'expert medical writers', so it can cater in a better manner to a medical writer's needs. This template set covers the full documentation workflow from authoring to repairing and publishing, and promises a 'submission ready' end product. ISIWriter™ boasts of more than 200 content templates for regulatory submissions, including the different modules of CTD.⁶ This is the template I am most familiar with.

SmartDesk for Authoring™ by Liquent is another document template and authoring system for regulatory writing. It too covers the dossier preparation process, including writing, rendering, publishing, and preparing the eCTD. In addition, it offers a Regulatory and Clinical Services Authoring Style Manual that facilitates consistency in authoring.⁷ I have never used Smartdesk™, but I have heard positive feedback from colleagues who have.

Other template systems include the DART by Yeldell Scientific and TRS Writer by CSC.

Conclusions

We have come a long way from the weaver's stretcher or the builder's rafter as templates of craftsmanship. In the digital era, our templates reside in our computers.

Author information

Raquel Billiones is a life scientist (BSc, MSc, PhD in Biology) and medical writer with more than 20 years experience in scientific research, teaching, and writing. She switched from academia to medical writing in 2006 and never looked back. She is currently working as a senior medical writer for the digital CRO Clinipace Worldwide EU HQ in Zurich, Switzerland.

Templates are an important part of medical writing. However, take note that I never used the term 'quality documents' in this article, a buzz word that template vendors like to use. Templates enable medical writers to efficiently prepare standardised, regulatory format-compliant documents. However, at the end of the day, templates do not guarantee quality documents. Like the weaver and the builder, we, medical writers, are still fully responsible for the content.

Disclaimers

The views and the opinions written here are purely those of the author and do not necessarily reflect those of Clinipace Worldwide.

References

- 1. Online Etymology Dictionary. [accessed 2013 Nov 25]. Available from: http://www.etymonline.com/index.php?term=template.
- 2. The Tech Terms Computer Dictionary. [accessed 2013 Nov 25]. Available from: http://www.techterms.com/.
- 3. ICH M2 EWG Electronic Common Technical Document Specification V3.2.2 16 Jul 2008.
- Taming unruly formatting in your Word documents. [accessed 2013 Nov 25]. Available from: http://office. microsoft.com/en-us/word-help/taming-unruly-for matting-in-your-word-documents-HA001034921.aspx? CTT=1.
- Europharm smc. Europharm-smc position paper on eCTD implementation in Europe May 2010 [accessed 2013 Nov 25]. Available from: http://www.euro pharmsmc.org/default.asp?SHORTCUT=143.
- ISIWriter. Available from: http://www.imagesolutions. com/isiwriter/. [accessed 2013 Nov 25].
- SmartDesk for Authoring. Available from: http://www.liquent.com/technology/smartdesk-authoring. [accessed 2013 Nov 25].

Getting more out of PowerPoint®

Diarmuid De Faoite

AO Clinical Investigation and Documentation (AOCID), Dübendorf, Switzerland

Correspondence to:

Diarmuid De Faoite
AO Clinical Investigation and
Documentation, Stettbachstrasse 6
8600 Dübendorf, Switzerland
diarmuid.defaoite@aofoundation.org

Abstract

PowerPoint[®] is unavoidable in today's society. It is equally loved and hated. Although it is ubiquitous, many users of the program fail to understand why their presentations are not achieving the desired effects. The answer to this lies in part with the information summarising function that is central to PowerPoint. In addition, users are often unaware of keyboard shortcuts which would help them to improve the flow of their own presentations. There are free alternatives to PowerPoint as well as very professional templates available online which may also help to improve presentation styles.

Keywords: PowerPoint, Presentations, Tips, Online resources, Templates

'We have met the enemy, and he is PowerPoint'

This was the dramatic heading in a New York Times story in 2010 on US military strategy in Afghanistan.¹ 'When we understand that slide, we'll have won the war', General McChrystal is reported to have dryly remarked (see Figure 1). While medical writers might not be part of complex military planning, how many times have you seen a PowerPoint® presentation only to be similarly bewildered by what it was all about? Strange, isn't it? Especially, since PowerPoint is supposed to be a communication aid. (As an aside, how often have you seen that iconic PowerPoint image of a stickman scratching his head appear in meetings you have attended? A comment on the presentation itself perhaps?) (Figure 1).

A lot of the negative comments about PowerPoint also relate to the information organising function, which is intrinsic to any presentation created with the program. As one author noted, 'It helps you make a case, but it also makes its own case: about how to organise information, how much information to organise, how to look at the world'.² In fairness, PowerPoint has not helped to deflect such

criticism by including elements like 'auto-content'. Yes, if you need to create slides on – 'Managing Organisational Change' or 'Communicating Bad News' – PowerPoint already has the content for you! This feature used to be built in to every version of PowerPoint but is now a wizard, 'which automatically generates a presentation with generic content based on information that the user entered in the wizard'.³ Apparently the name 'auto-content' started as an internal joke, one that Microsoft took and ran with!²

'According to most studies, people's number one fear is public speaking. Number two is death. Death is number two. Does that sound right? That means to the average person, if you have to go to a funeral, you're better off in the casket than doing the eulogy.'

- Jerry Seinfeld⁴

The Seinfeld quote goes a long way to explaining the popularity of PowerPoint. It calls to mind Lang's famous (and overused and unsourced I admit!) quote about statistics, 'He uses statistics as a drunken man uses lamp-posts...for support rather than illumination'. It makes sense. If the presenter is in any way unsure about presenting, the attention is focused on the screen and not on themselves for the duration of the presentation. But does what suits the presenter suit the audience? The Swiss Anti-PowerPoint political party is unlikely to agree with this.⁵

The fact that some people are presenting when they would rather be dead is obvious to many in the audience (who feel like they *are* dying). Would be novelists are always being urged to show, not tell. How many times have you attended a PowerPoint presentation where you were not only shown but told the exact same? Usually, by a presenter who has to awkwardly rubberneck to the screen behind them ensuring that they sound like someone shouting in the wind.

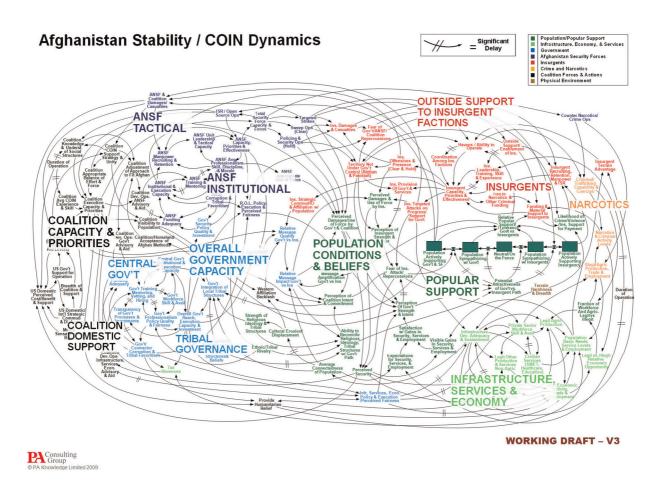


Figure 1: The PowerPoint slide that baffled the American military.

Alternatives to PowerPoint

Do not have the money for PowerPoint software? Then, download Apache OpenOffice, which is an open-source office productivity software suite (http://www.openoffice.org). This free software includes a presentation application which allows you to save presentations in the PowerPoint format.

Before your presentation

It should go without saying, but unfortunately it does need to be said:

- Make it easy on your audience.
- Do not overload your slides with information.
- Do not choose a font that is too small or unreadable.
- Do not overdo animation and if the thought ever crosses your mind that it would be a good idea to use different colours for different sentences, get up from your desk and go for a long walk.
- Consistently use the same font face and sizes on all slides. Like multi-coloured sentences, it irritates the audience when every slide feels like a style ambush.

Be realistic about the number of slides

Too many people overestimate how many slides they need. Assuming you know what you are talking about, the oft quoted phrase of one slide per minute is far too optimistic. Just think, each slide usually contains up to five lines or points. At one slide per minute you are allocating about 12 seconds to each item. This is the reason why many people end up having to skip over slides during their presentations or racing through them, clicking onto the next slide before the audience have even read half of the one they were on.

Use a good template

If you do not already have a predefined company template, use a good one. The following websites have a large selection of free PowerPoint templates on a variety of topics:

http://tinyurl.com/98o7678: This redirection link will bring you to the official Microsoft site which contains some very advanced templates – an animated spinning globe, for example. One to visit for when you need to impress!

http://www.slideshare.net: This site is actually also useful for content ideas. A go-to resource for when you have to put together a presentation in a very short time.

Get help

Stuck while putting your presentation together? The F1 button will open the help box in PowerPoint. If you cannot find the answer there, I find doing a simple Internet search for *How to do XYZ in PowerPoint* usually reveals what I need to know.

Rehearse

Obviously, before you actually give your presentation you have to rehearse it for timing reasons but also to make sure that you have correctly programmed any slide transitions or animations. This is something which is easy to forget, especially since most people just whizz through slides, but crucially do not play them, prior to giving the presentation.

During your presentation

Start on the right foot with F5

To start playing a presentation from the first slide, press F5.

Need a pointer?

Forgot to bring a pointer? Not a problem. Just press A or = to have one appear onscreen which you can manoeuvre with your mouse. Press the same button again to make it disappear.

Create a blank screen

Ever given a presentation which ignited debate in the audience? If you feel that the focus is temporarily on the discussion happening and not on your presentation, simply press W for a white screen or B for a black screen. This will stop the audience from being distracted. Once you are ready to continue press the same button again. If the need arises, you can also stop or restart an automatic presentation (i.e. one which is looping) by pressing S.

Jump to the right slide when you need it

How many times have you seen someone flicking back through 30 or so slides during the Q&A section at the end of their presentation to find and re-show a slide from near the start of the presentation? There is no need for this. Simply press and hold the right and left mouse buttons for 2 seconds to return to the first slide and advance the presentation from there. This trick does take a bit of practice though. Alternatively, if you know the slide number you want to go to, while the

presentation is running just type in the slide number +ENTER to go directly to it.

Further information on shortcuts

You can find more useful shortcuts at the official Microsoft site. Go to http://tinyurl.com/2837dz3 to be redirected there.

After your presentation

In the same way as business people ignore all of the research that says brainstorming is ineffective, PowerPoint is unlikely to go away anytime soon. So, do yourself a favour and try to improve your PowerPoint presentations. Dozens of people in darkened rooms over the course of your career will thank you for it! Who knows? Maybe like Al Gore you will make the leap and turn your PowerPoint presentation into a best-selling book and film!

A quote from the US military opened this article, so I will give them the dubious honour of closing it too. Good luck with your future presentations!

'PowerPoint makes us stupid.'

- Gen. James N. Mattis of the Marine Corps, the Joint Forces commander. ¹

Conflicts of interest and disclaimers

Please note that any tips relate to the PowerPoint software version 2010. Some features or the actual path to get to certain features may differ on your version of PowerPoint.

References

- 1. Bumiller E. We have met the enemy, and he is PowerPoint. *New York Times*, 2010 Apr 26 [accessed 2013 Oct 27]. Available from: http://www.nytimes.com/2010/04/27/world/27powerpoint.html/?_r=1&c.
- 2. Parker I. Annals of Business: Absolute Powerpoint. *The New Yorker*, 2001 May 28.
- 3. PowerPoint Wizards. Microsoft Development section [accessed 2013 Oct 27]. Available from: http://msdn.microsoft.com/en-us/library/office/aa141265(v=office. 10).aspx.
- Ricker S. Face your fear of public speaking. Chicago Tribune, 2013 Jun 14 [accessed 2013 Oct 27]. Available from: http://www.chicagotribune.com/clas sified/jobs/chi-face-your-fear-of-public-speaking-2013 0614,0,3573369.story.
- Official website of the Anti-PowerPoint political party [accessed 2013 Oct 27]. Available from: http://www. anti-powerpoint-party.com.

Author information

Diarmuid De Faoite is best known as the EMWA Website Manager and leader of the workshop An Introduction to

Marketing for Medical Writers. In his day job, he spends an inordinate amount of time preparing PowerPoint presentations.

Consolidated data analysis and presentation using an open-source add-in for the Microsoft Excel® spreadsheet software

Daniel Kraus

First Department of Medicine, Division of Nephrology, Würzburg University Hospital, Würzburg, Germany

Correspondence to:

Daniel Kraus First Department of Medicine Division of Nephrology Würzburg University Hospital Oberdürrbacher Strasse 6 97080 Würzburg, Germany daniel.kraus@uni-wuerzburg.de

Abstract

A free and open-source software tool is presented that facilitates the analysis and the visualisation of data in basic life science. Daniel's XL Toolbox is an add-in for the Microsoft Excel® spreadsheet software. It enables scientists to store their data in one place and obviates the need to use separate tools for the analysis and presentation of the data. The Toolbox offers analysis of variance with post hoc multiple comparison testing and linear correlation and regression analyses. It can apply error bars to the graphs automatically, and style the graphs in a way suitable for publication. The graphs can be exported in high resolution to TIFF, PNG, as well as to EMF file types. Finally, the Toolbox offers several work flow and productivity features such as automatic time-stamped backups, transposition assistant, worksheet management, and much more. The Toolbox is available at http://xltoolbox. sourceforge.net.

Keywords: Analysis, Visualization, Work flow, Software, Open source

For the storage and the exchange of small- to medium-sized datasets, Microsoft Excel® is the *de facto* standard software tool. However, while the data can be grouped and labelled and graphs can be created very easily by using Microsoft Excel, the software lacks the ability to perform certain statistical analyses that are commonly used in biomedical research, and it has only limited capabilities to create publication-ready figures. Therefore, scientists often resort to specialised separate software tools to accomplish these tasks. However, the duplication of data by using 'copy and paste' between applications may leave the data in a disparate state. This often makes it difficult to comprehend the entire analysis and work flow unless the scientist

takes extra time for meticulous documentation and labelling of every copy of the data. Experience tells that this is rarely the case.

To remedy the shortcomings of Microsoft Excel with regard to the needs of scientific data analysis, an add-in was developed by using Excel's built-in extensibility feature. This project was started in 2008 as a set of macros intended for personal use. Over time, more and more features were added, turning the add-in into a versatile tool for all Microsoft Excel versions from 2003 through 2013. The add-in was named 'Daniel's XL Toolbox' and made freely available via an open-source software platform under the GNU General Public License; it can be downloaded at http://xltoolbox.sourceforge .net. Users can investigate the source code either online or by summoning Microsoft Excel's built-in Visual Basic Editor by pressing the ALT and F11 keys while Excel is running. An overview of the features is given in Table 1 and Figure 1. A few of them are described in this article.

Planning an experiment

Stratification of study groups is a norm in large-scale clinical trials. It is, however, uncommon for basic research involving only a few dozen study subjects, e.g. mice. Yet, random differences between the individual characteristics may have a large effect on study groups with few subjects. To ensure equality between the group characteristics, the XL Toolbox offers two alternative algorithms to allocate the study subjects. The first is derived from an algorithm described by Endo *et al.*¹ It uses Kullback–Leibler divergences to assess differences between the study groups, and assigns the study subjects to a group so that the groups diverge as little as possible. The second algorithm performs analysis of variance (ANOVA) and allocates the

25

Table 1: Overview of the XL Toolbox features

Data analysis	Data visualisation	Work flow
 One-way ANOVA Two-way ANOVA Formula builder Frequency analysis (histogram) Group allocation (stratification) Linear correlation Linear regression Post hoc testing after one-way ANOVA Transpose wizard 	 Automatic error bars Graph annotation (asterisks, labels, colours) Simple, reusable graph design Graph watermarks Graph export to high-resolution files Copy graph properties to other graphs 	 Automatic, time-stamped backups Copy worksheet properties to othe worksheets Open file from file name in worksheet cell Selection assistant Simplified worksheet management (add, delete, move, rename) Special paste functions

study groups to the subjects so that the ANOVA's *P*-value is maximised. Both the methods allow for a certain degree of randomisation to make the allocation unpredictable. While the algorithms offered by the Toolbox are not nearly as sophisticated as those of dedicated software packages, they are well suited for small- to medium-sized experiments or clinical trials if only a few characteristics are to be stratified.

Arranging and describing the data

Many laboratory machines such as polymerase chain reaction cyclers and microplate readers produce output in Microsoft Excel files. A common task, then, is to re-arrange the layout of the data on a worksheet. Getting these data into an order that makes sense for the experiment at hand, is a cumbersome and error-prone process of repeatedly copying and pasting. The XL Toolbox's Transpose Wizard automates this process and includes functions to summarise the transposed data and calculate standard curves.

The Formula Builder command assists with the analysis of the unordered data of several experimental groups. Thus, the raw data can be written in the order in which it is obtained, e.g. from a cohort of study subjects, where the adjacent subjects may belong to different groups.

Performing statistical analyses

The Analysis ToolPak add-in that is shipped with Microsoft Excel, offers a one-way ANOVA that can be used to test for statistically significant differences between three or more groups of data. However, its usage is not straightforward. It forces the users to

arrange the data in a specific way, and it does not support *post hoc* multiple comparison testing. The improved ANOVA that is offered by XL Toolbox is able to perform analyses regardless of how the data are arranged, and it includes three different *post hoc* testing algorithms (Bonferroni–Holm, Holm–Šidák, and Tukey). The data may be laid out in horizontally- or vertically oriented tables or lists, as long as they are labelled consistently. The one-way ANOVA checks the assumption of homoscedasticity (homogeneity of variance) by using a modified version of Levine's test as described by Glantz and Slinker.² If the assumption is not met, non-parametric methods must be used, yet currently the XL Toolbox does not offer one.

If there are two independent variables rather than one, the Toolbox's two-way ANOVA can be used. This function is also very flexible with regard to the layout of the data. Even lists of data with combined group labels in the form 'genotype/treatment' or 'gender, age' and similar are accepted. The XL Toolbox can analyse the data from repeated intraindividual measurements. *Post hoc* testing is currently not offered for the two-way ANOVA.

Creating publication-ready graphs with error bars

Scientists and journal editors often prefer graphs with a clear, minimalistic design. By default, Microsoft Excel produces rather colourful graphs that are not suitable for publication in scientific journals without further modification. The most basic and arguably most efficient graph design uses only black and white, clearly distinguishable symbols, and readable labels. The XL Toolbox

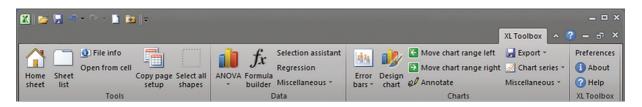


Figure 1: The XL Toolbox 'ribbon' user interface. The application shown is Microsoft Excel 2010.

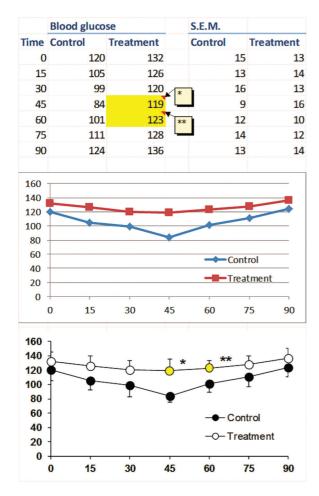


Figure 2: A representative graph of made-up data before (top) and after (bottom) using the 'Chart design', 'Annotate chart', and 'Error bars' commands of the XL Toolbox. After inserting the graph, the size was adjusted, the legend was moved over the chart area, and the X-axis scale and interval were adjusted. The subsequent modifications were performed with just a few mouse clicks by using the XL Toolbox.

enables scientists to define simple, professional designs that meet these criteria and apply them to their graphs with a few clicks.

Adding error bars to scientific graphs by using Microsoft Excel's built-in commands is very time-consuming. Therefore, a user-friendly and fast way to add custom error bars was implemented for the XL Toolbox (Figure 2). Users can either rely on fully automatic detection of the error data, or take advantage of an interactive mode. If requested, the error bars for a line graph can be automatically pointed in the positive or the negative direction so as to minimise the overlap.

Exporting to high-resolution graphic files

Many scientific journals require high-resolution graphic files in the TIFF format; some journals accept TIFF files exclusively. The XL Toolbox can

produce such files from one or many graphs or a combination of graphs and other drawing objects or even spreadsheets. The 'export for publication' command offers the following options:

- File formats: TIFF, PNG, and EMF
- Colour spaces: Black and white, greyscale, RGB, and CMYK
- Colour management: Available for chart export (however, Microsoft Excel itself does not support display colour management for graphs)
- Any resolution within reasonable limits

Spreadsheets can be used as layout tables to produce figures that contain several panels. If the ALT key is held while a graph is clicked and dragged with the mouse, the graph will snap to the grid of the spreadsheet. To add a panel letter to a graph, first select the graph, and then insert a text box. The text box will be linked to the graph and stay with it when the graph is moved. The 'select all shapes' command of the Toolbox followed by Microsoft Excel's 'group' command can be used to obtain a single multi-panel figure. Alternatively, choose 'all graphic objects on the current worksheet' when exporting for publication.

Technical limitations

Daniel's XL Toolbox requires Microsoft Excel running on the Windows[®] platform. Owing to major differences between the Windows and the Macintosh[®] editions of Microsoft Excel, the add-in does not run on the Macintosh. The Toolbox is not compatible with OpenOffice and LibreOffice, since these office suites employ an entirely different extensibility technology.

Perspective

Currently, a major rewrite of the XL Toolbox is under way that implements modern programming concepts and is based on the Microsoft[®] .NET framework. This will facilitate maintenance of the code as well as the addition of new features. For example, it is planned to add SVG and PDF export capability and expand the set of methods for statistical analyses.

Conclusion

Daniel's XL Toolbox offers many tools for the analysis, visualisation, and management of scientific data. Only a few of them could be described in this article. Interested medical writers are invited to explore the extensive online documentation at http://xltoolbox.sf. net. The author welcomes feedback and suggestions.

Acknowledgements

The author has drawn on the programming experience and statistical expertise of many people. An exhaustive list of acknowledgements can be found on the Toolbox's website at http://xltoolbox.sf.net/about. The author is especially grateful to all users who acknowledge the Toolbox in their articles.

Conflicts of interest and disclaimers

Although the XL Toolbox is available free of charge, the author accepts voluntary payments ('donations') for this software on the website. This software project is maintained in the author's own time; it is not officially endorsed by the author's employer. Daniel's XL Toolbox is an independent software

Author information

Daniel Kraus is a physician-scientist with a long-standing personal interest in computer programming. He works as a staff physician at Würzburg University's main hospital. In his laboratory, his team study basic mechanisms of energy metabolism in adipose tissue.

and is not affiliated with, nor has it been authorised, sponsored, or otherwise approved by Microsoft Corporation. Microsoft, Windows, and Excel are either registered trademarks or trademarks of Microsoft Corporation in the USA and/or other countries. Macintosh is a trademark of Apple Inc., registered in the USA and other countries.

References

- Endo A, Nagatani F, Hamada C, Yoshimura I. Minimization method for balancing continuous prognostic variables between treatment and control groups using Kullback-Leibler divergence. Contemp Clin Trials 2006;27(5):420-31.
- Glantz SA, Slinker BK. Primer of applied regression & analysis of variance. 2nd ed. New York: McGraw-Hill; 2000

Datavision[™] – What do medical writers need to know?

Russell Traynor¹, Thomas Gegeny²

¹Envision Pharma Group, Horsham, UK ²Envision Pharma Group, Southport, CT, USA Correspondence to:

Russell Traynor Envision Pharma Group, Envision House 5 North Street, Horsham West Sussex RH12 1XQ, UK russell.traynor@envisionpharmagroup.com

Abstract

Datavision™ is a publication planning software tool that is widely used across the healthcare industry to manage publication programmes. Medical writers are one of the key Datavision user groups, and need to know how to use the elements of the tool that are relevant to their tasks and responsibilities. Within Datavision, a medical writer's activities will be focused on the Workbench to manage their assigned projects; the Journals, and Congress database to identify potential targets for discussion with authors; and the Documents management area for managing project specific details, sending out drafts for review and approval, and collating comments and feedback received.

Keywords: Datavision, Publication planning, Software

What is Datavision™?

Datavision is a software tool for publication planning and management that is used by more than 50 pharmaceutical, biotechnology, and device companies worldwide. It provides global transparency and consistent management of their publication programmes and related projects, to help ensure compliant data disclosure. Given the widespread use of the system within the healthcare industry – there are currently 85 000 registered users – if you have not yet come across Datavision it is likely you will do so in the future.

Datavision is built around three workflows that encompass the overall publication planning process:

- 1. Planning (including needs assessment and budget approval)
- 2. Project Execution (GPP2 supported workflow templates)
- 3. Tracking and Reporting (global transparency and a metrics programme)

As with many software solutions, users will have different roles and responsibilities and will therefore

access and use distinct areas of the software. The work of medical writers is centred on two core areas: (1) translation of information and data, both written and verbal, into an effective communication piece; and (2) project management to ensure timelines are met such that delivery of the project meets the expectations of the authors and the stakeholders. This article focuses on the second workflow – Project Execution – as this is where functions and processes most relevant to the work of medical writers are.

Who uses Datavision?

Datavision is used by various parties involved in publication planning and development, both internally within a company and externally among its collaborators, including:

- Publication managers
- Internal auditors
- Medical writers
- Project managers
- Authors (internal and external)
- Reviewers and approvers (including statisticians, medics, legal and intellectual property officials, and regulatory team members)
- Senior decision makers, e.g. medical directors, compliance leads

Some of these individuals (publication managers and project managers) as well as system administrators will access Datavision through the desktop application, which effectively serves as a publication plan or programme management interface, while others (authors, reviewers, and approvers) will access it through the web-based review portal. Senior management within a pharmaceutical or healthcare company, in addition to potentially being reviewers on some publications, may view metrics through an 'Executive Window' to enable them to evaluate their publication programmes in terms of compliance, financials, effectiveness, and

29

efficiency. Medical writers can access Datavision through either the desktop application or through a specialised web-based portal known as the 'Writers Workbench', depending on their clients' preferences for user functions and access rights (Figure 1).

Core aspects of Datavision for a medical writer

The complete functions of Datavision cover the wide range of roles outlined above, and include reports and charts that are often used to monitor the publication plan, and to organise individual document records according to key criteria such as congresses or clinical trials relating to the publication. However, the core tasks of medical writers involve individual publication projects and therefore require them only to access 4 of the 10 functional tabs within Datavision: Workbench, Journals, Congress, and Documents.

Workbench – for managing my projects

The Workbench tab of Datavision allows writers (and indeed all users assigned tasks for publications) to see all their current, upcoming, and/or overdue tasks and publication plan items, and to link directly to the relevant document record from the Workbench tab itself (see Figure 2). This functionality enables writers to manage their time and tasks effectively and efficiently. In addition, the

Messages and Tasks sections of the Workbench will highlight any review or approval feedback on your assigned documents.

Because the Workbench feature extends to all individuals who are assigned document-related tasks, writers can use the Workbench to view the tasks assigned to others (including authors and reviewers), allowing teams to manage their overall workloads according to deadlines and priorities. Alongside the Workbench, the Datavision Chart View can allow a writer or team to visualise all the projects that comprise a publication plan and how these projects fit into the overall plan (Figure 3).

Finding journals and congresses

Datavision has a built-in Journals and Congress database that gives access to details of approximately 5000 journals and 3000 congresses. The details of these journals and congresses are maintained by a dedicated team that works with publishers and societies to ensure the information is as up-to-date and complete as possible. This database constitutes an invaluable resource to writers (see Figure 4).

In addition to searching the full database, users can add specific journals and congresses to the Datavision publication plan they are working on to give a succinct target list for the plan. Also, the journals and congresses can be linked directly to

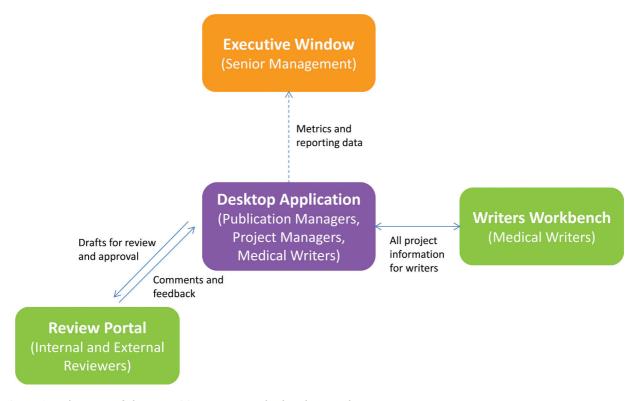


Figure 1: Elements of the Datavision system and related user roles.

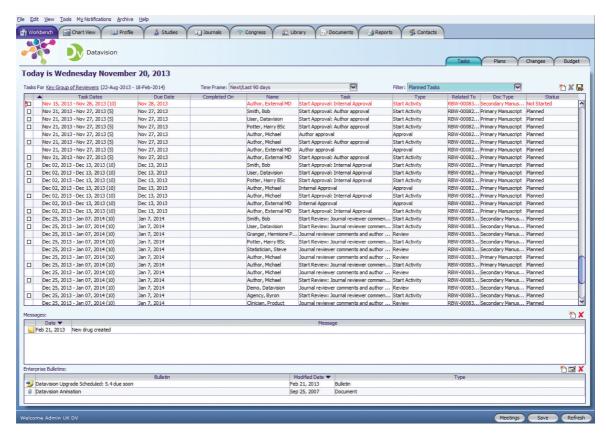


Figure 2: Managing projects with the Datavision desktop workbench. The Datavision desktop workbench enables an individual to manage all their projects in one place, creating clear focus for a writer.

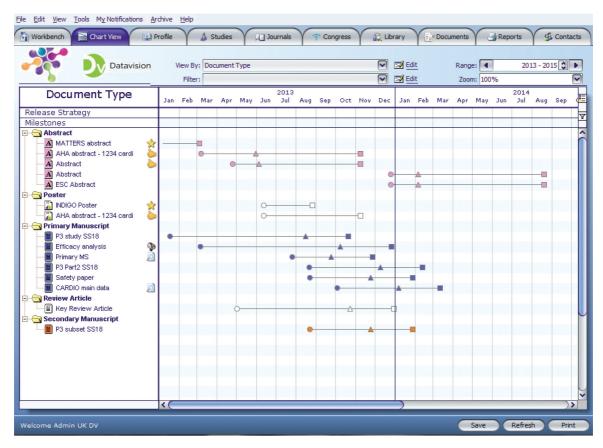


Figure 3: Visualising the publication plan via the Datavision Chart View. The Datavision Chart View allows a user to view the overall plan and how specific projects fit into this plan.

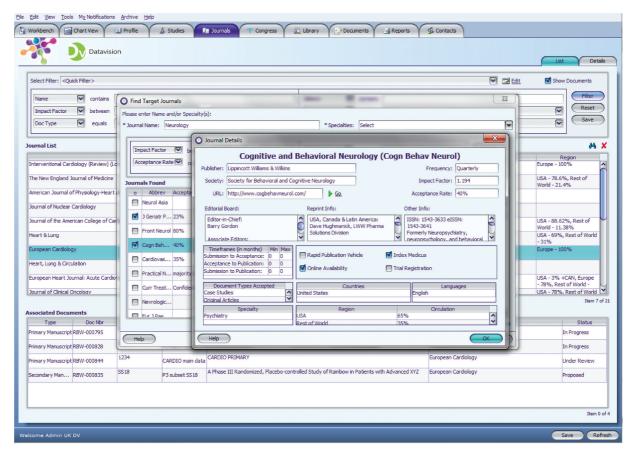


Figure 4: Searching the integrated Journals and Congress database.

project document records. This allows for specific planning around 'real' timelines; the linking of all abstracts for a particular congress to view all relevant activities; and tracking of the number of times a particular team submits to any one journal (for example). In addition, this helps the team to develop metrics around output and productivity, highlighting the good work being done by the team

If you cannot find a journal or congress within the current database, you can at the click of a mouse ask the Datavision team to search for it and add its details. This new record will be added within one working day and will be maintained along with the rest of the database. In the case of a congress, subsequent years' events will be added as details become available from the organisers.

Document reviews and approvals

The core feature of Datavision from the medical writer's perspective is the Documents tab. From this tab, and its sub-tabs, you can manage all of a particular document's details, the time plan for the project, versions and drafts of the document, and reviews and approvals, together with associated feedback as the document's development enters its final stages.

The Documents tab has a number of sub-tabs and functions (see Figure 5):

- The List sub-tab allows you to view details of all publications within a publication plan, or a particular subset. This document list is actually a flexible ad hoc report to use as needed; columns can be added, removed, rearranged based on any of the available fields. The resulting display table can be filtered by chosen criteria and exported to a selected file output such as Adobe PDF or Microsoft Excel. In addition, users may create 'watch list' tables focusing only on their specific projects, which can be manipulated and exported in the same manner. All these tables are 'active', which means that double-clicking on any project displays its details and corresponding Plan tab to facilitate direct management of that specific project. The default plan for a document uses incorporated timelines based on templates that are defined to match the company's standard operating procedure (SOP) and publication best practices, thereby facilitating straightforward project management.
- The Details sub-tab allows users to manage all the elements related to a specific project:

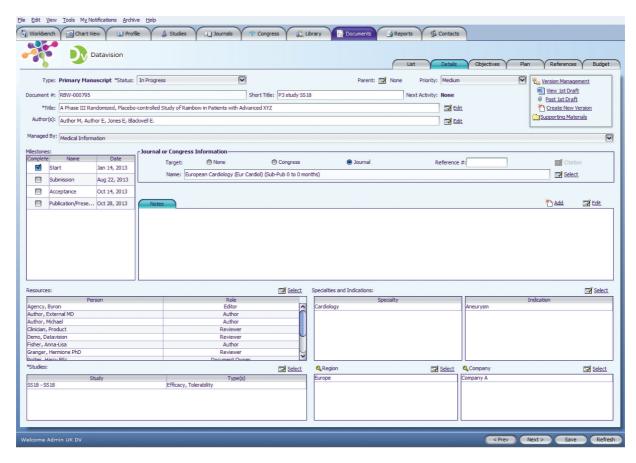


Figure 5: The Documents sub-tabs and Details page.

document versions and drafts, authors and other people involved in the project, links to related studies, specialities and indications, assigned target journal or congress, and notes relating to the progress of the project.

• The Plan sub-tab houses the project plan for the document, which was previously set up at document creation using templates appropriate to the company's SOP (as described above), and is where users can set up and send out reviews and approvals, and also view and download the feedback received from authors and other stakeholders who review or approve documents. The plan templates are built around the SOPs of the client sponsor, but additional review steps, for example, can be added as and when required (see Figure 6).

The web-based Writers Workbench

Some companies using Datavision have chosen to implement the optional web-based Writers Workbench. This web-only portal condenses all the features of the Documents tab into one interface, without any of the other Datavision functions, and so allows medical writers to focus only on the tasks and actions relevant to their job and to their

workload (see Figure 7), and helps them to ensure best practice and compliant documentation with respect to potential audits of the client company's publication department.

The Writers Workbench includes wizards for starting reviews and other actions for ease of use, and will show you only those projects you are currently working on. In all other aspects, this portal functions similarly to the desktop-based user application in terms of managing project details, the time plan, reviews and approvals, and document feedback.

Summary

For medical writers who assist with industry-supported publications and publication plans, Datavision is an interface and tool they will likely use to help facilitate and document their work. Datavision encompasses features that enable medical writers and the teams with whom they work to plan, execute, and track publications as they progress from their earliest stages to the final published or presented versions. As a central resource for both internal and external stakeholders, Datavision accounts for the collaborative nature of medical and scientific publications by ensuring all

reviews, inputs, decisions, and relevant correspondence are accounted for across each document's 'lifecycle'. Whether interfacing with Datavision

through the desktop application or the web-based Writers Workbench portal, medical writers can develop and manage publications in a detailed,

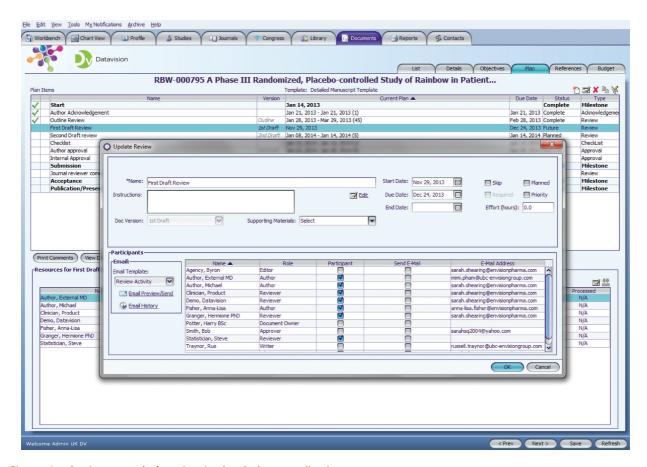


Figure 6: Setting up a draft review in the desktop application.

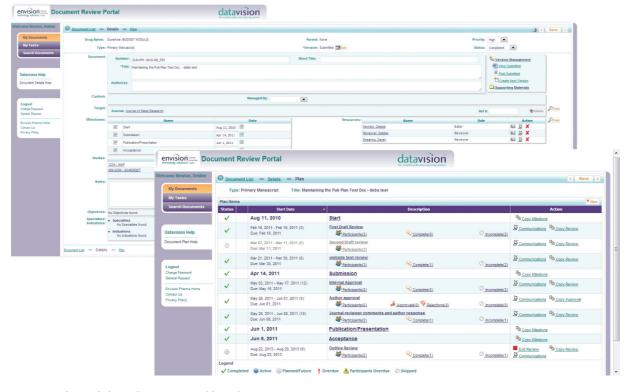


Figure 7: The web-based Writers Workbench.

consistent, and compliant manner to achieve the goals of their clients and authors as well as the expectations of both their profession and the medical publication industry.

Author information

Russell Traynor, BSc, MSc, is Business Lead at Envision Pharma Group. He is responsible for working with clients to identify and implement technology solutions to meet their needs. He has served on the Board of Trustees of the International Society for Medical Publication Professionals (ISMPP) for 5 years and is a former ISMPP Chairman. He is an ISMPP Certified Medical Publication ProfessionalTM.

Thomas Gegeny, MS, is a Senior Scientific Lead at Envision Pharma Group, which he joined in 2006. As an editor and writer, he has over 15 years of experience across diverse medical publication environments. Thomas is a fellow and past president of the American Medical Writers Association (AMWA). He is an ISMPP Certified Medical Publication ProfessionalTM.

Conflict of interest statements

RT and TG are employees of Envision Pharma Group, the developers of Datavision.

Software for translators

Laura Carolina Collada Ali¹, Laurence Auffret²

¹OnTranslation, Italy ²Cinetique Translations, UK **Correspondence to:**

Laura Carolina Collada Ali OnTranslation, laura.collada@ontranslation.it

Abstract

In recent years, a myriad of software has revolutionised the translation sector. This article presents a series of translation tools commonly used in the translation industry, depicting their main features and the way they have transformed the translation process from project assessment to delivering client-ready documentation. This article is written from a translator's perspective and aims at explaining how this software is included in the intricacy of a translation project.

Keywords: Translation software, Translation tools, Computer-assisted translation

In the past 15 years, the increasing use of Computer-assisted translation (CAT) tools has radically changed the translation process. With an ever increasing volume of software on the market, sometimes claiming to be 'the solution' to all translation requirements, it can be challenging to understand the way CAT tools are integrated in the translation workflow and what their use means for translators, agencies, and clients alike.

This article presents the main features of CAT tools frequently used by translators, their role in the translation process, and their major advantages.

Counting content

Freelance translators, as well as translation managers and agencies, often issue quotations and invoices based on document text analysis, of which length – measured in terms of characters, words, lines, pages, and sometimes including repetitions – is one of the most important characteristics. It may seem simple to measure the number of words and pages in a Word document, but in real life, translators work with a myriad of different formats. Thus, software that is able to measure content no matter what the format is essential. Let us see two examples of the available tools in the following sections.

CATCount

Translation agencies often provide translators with a rate scheme using the volume of recurrent content in the source text(s); CAT tools are able to memorise this in the translation memory, as we will see later.¹ Professional translators are not always happy with this approach, because repetitions in a given target text may still need to be translated differently according to the context and, thus, they can take as much time to translate as the non-recurrent content. However, a tool such as CATCount may help in calculating the final rate, as it converts complex CAT schemes into one easy number.² In addition, it provides great features for the printing and export of used CAT schemes together with the original word counts, and the resulting CATCount.

The concept of using a single number of words in a given text is not new, and has been used extensively by many translation agencies worldwide under various names: leveraged word count, weighted word count, equivalent word count, etc.

CATCount is a freeware product.

FineCount

FineCount analyses documents in a vast array of formats and provides advanced text statistics. There is a free version, which is available only for single-computer and non-commercial use, and a professional version, which is also able to count the content in websites, export text, and prepare invoices and reports.

Computer-assisted translation

Translators use CAT tools to support, improve, and facilitate the translation process. 'CAT tool' is a broad and imprecise term covering a range of software, from the fairly simple to the more complicated. These tools are not to be confused with machine automatic translation, which is a sub-field of computational linguistics that uses software to translate text from one language to another. A very popular software in this field, although its results are far from satisfying, is GoogleTranslate.⁴

These tools can include:

 Project management software that allows linguists to structure complex translation projects, assign the various tasks to different linguists, and track the progress of each of these tasks.

- Grammar checkers, either built into word processing software or as add-on programs.
- Electronic dictionaries, monolingual or bilingual.
- Terminology databases, either on the host computer or accessible through the Internet, such as TERMIUM Plus⁵ or Grand dictionnaire terminologique from the *Office québécois de la langue française*.⁶
- Terminology managers, which allow the translator to manage their own terminology database in an electronic form. This can range from a simple spreadsheet, to a database created in a program such as FileMaker Pro⁷ or, for more robust (and more expensive) solutions, specialised software such as SDL MultiTerm, ⁸ LogiTerm, ⁹ Termex, ¹⁰ etc.
- Translation memory (TM) tools, consisting of a database of text segments in a source language and their translations in one or more target languages.
- Full-text search tools (or indexers), which allow the user to query already translated texts or reference documents of various kinds. Examples of indexers are ISYS Search Software¹¹ and dtSearch Desktop,¹² among others.
- Concordancers, which are programs that retrieve instances of a word or an expression and their respective context in a monolingual, bilingual, or multilingual corpus, such as a bitext or a TM.
- Bitext aligners, which are tools that establish an in-depth comparison and match from a source text and its translation; the resulting database can then be analysed by using a full-text search tool or a concordance.

Workflow	Activity	CAT tools
File submission	Project analysis Workload estimation pricing	Wordcount Analysis of recurrent segments
Project start	Organisation of reference materials Linguistic guidelines	Alignment Glossaries Concordancers
Translation	Translation	TM
Editing Proofing	Editing Proofing	Spellcheckers
Quality	QA	TM
assurance (QA)		Linguistic guidelines
Project close	Archive new translation in the TM	TM*

*This updated TM can then be re-used to analyse, translate, and proof future projects.

We find the following among the most frequently used features of this kind of software.

Translation memory

TMs are databases that store source sentences and their translations into manageable units known as 'segment pairs'. The TM 'remembers' each source-target segment that is translated, and as you work through a document, if the program finds an identical or a similar matching source segment in its database it provides a previous translation for re-use, and thus, it does not need to be translated from scratch. If the program does not find an identical or a similar matching source segment, it allows you to enter a translation for the new segment. After the translation is completed, the program stores the new translation and moves on to the next segment. This technology offers three main advantages:

- Faster turnaround times and cost-savings than when the TMs are not in use, as repetitive content can be translated quickly.
- Better consistency and readability, as you can make sure that the program does not translate the repeated occurrences of the same sentence differently, which can confuse the readers.
- A CAT system can automatically scan the documents and identify places where numbers have been mistranslated, simple typos, or incorrect punctuation.

Alignment

When you start using a TM tool, you will have to fill it with your own translations, as the database is empty at the beginning of the project. Alignment programs take completed translations, divide both the source and the target texts into segments, and attempt to determine which source and target segments can be matched in order to build a TM database with the given content. These segment pairs can then be imported into your TM database. This technology is invaluable to easily re-use your previous translations.

Terminology databases

Terminology databases are similar to electronic dictionaries. Rather than storing whole source-target segments as translation memories do, they contain single words or expressions. Creating and maintaining terminology databases is useful for storing organisation-specific, customer-specific, or product-specific terms, which cannot be found in standard dictionaries.

When translating a document, the source sentences are automatically searched for relevant terminology in the background. The corresponding target terms can then easily be inserted into the translation.

This saves you the trouble of having to open a separate application in order to do time-consuming research work. Some of the more advanced systems enable the translators to check – interactively or in batch mode – if the correct source-target term combination has been used within the TM segments in a given project. Terminology databases offer the following main advantages:

- Cost and time savings, as you avoid extra work such as researching and typing long-winded expressions.
- Readability improves, as the same expressions are used consistently throughout a document.
 The terminology databases help you to effectively avoid unnecessary variations, which can confuse the readers.
- You can create and manage terminology that is customer- or product-specific and that cannot be found in any standard dictionary.

Some notable CAT tools

The list below includes some of the most frequently used tools available on the market, although several relevant tools are missing. ¹³

Tool	Supported file formats	Operating system	Licence
MetaTexis	Microsoft Word, Excel, and PowerPoint, and all kinds of text formats	Microsoft Office Word add-in	Proprietary
MemoQ	Microsoft Office files, HTML, Adobe FrameMaker, Adobe InDesign, XLIFF, XML, Scalable Vector Graphics (SVG), Typo3, and many others	Windows	Proprietary
OmegaT	Microsoft Word, Excel, PowerPoint, XHTML, and HTML, Open Document Format, MediaWiki, Plain text, and many others	Cross-platform (Java)	GNU GPL
SDL Trados	Microsoft Word, Excel, PowerPoint, Open Office, InDesign, QuarkXPress, PageMaker, Interleaf, FrameMaker, HTML, SGML, XML, SVG	Windows	Proprietary
Wordfast	Microsoft Word, Excel, PowerPoint, PDF, SGML, HTML, XML, InDesign, FrameMaker, tagged documents, XLIFF	Cross-platform (Java)	Proprietary

According to a 2013 survey undertaken by Jared Tabor of over 3000 translation professionals from different countries, primary tool usage was reported as follows: SDL Trados (43.2%), Wordfast (11.5%), MemoQ (8%), and other softwares (37.3%).¹⁴

Voice recognition

Typing is considered to be an 'old activity' and some still seem to be reticent about abandoning it, yet it strains the fingers, the eyes, the wrists, and the back. Translators may type from 2000 words a day – if the source texts are rather technical or research in the field is needed, to 3000 words a day – if the subject matter corresponds to their specialisation domain. Typing may be slow and exhausting.

Human speech is 5 to 7 times faster than typing; cognitive processing about 10 to 15 times faster, states Hendzel. Nevertheless, our translating brains actually work closer to these speeds – think, for example, about simultaneous interpreting!

In this context, voice recognition may seem a miracle, yet modern voice-recognition software has matured in accuracy to a point that it is difficult to talk faster than the computer processing speed. What are the highlights? This methodology is fast, always available, accurate, and never gets tired. Thus, it enables professional-quality translation at lightning speed.

Professional-quality voice-recognition software must be available in your target language. Dragon Naturally Speaking v. 12 is available in US English, UK English, French, German, Italian, Spanish, Dutch, and Japanese.

However, dictated translations are still drafts that require review and editing, although as you develop and refine your dictation skills you will reduce the volume of editing required, although as in any quality translation process, translations always need to be reviewed.¹⁵ You may also need some interpreter DNA to verbalise translations.

Proofreading

Tracking changes in the translation process is essential for QA. In some regulated industries like clinical trials, all the changes have to be well documented and approved; this means that tracking changes is an everyday task for many translators, reviewers, and project managers.

ApSIC Comparator

ApSIC Comparator is a freeware tool that allows you to create side-by-side reports with all the changes made to a translation by a reviewer in different document formats. These comparison reports can be used both to evaluate the quality of the translation and to provide feedback to the translator.¹⁶

ChangeTracker

ChangeTracker is a freeware tool for tracking changes in bilingual documents and comparing

translations. This tool generates a report flagging all the changes implemented by a reviewer, in a similar way to Microsoft Word's 'Track Changes' feature. This report can then be edited with the addition of comments and error classification codes. ChangeTracker also allows reports to be exported to Microsoft Excel.¹⁷

Translation quality assurance

Translation quality assurance (TQA) software compares the source and the target segments of bilingual texts in order to detect translation errors, such as:

- Inconsistencies
- Terms that have not been translated using a project glossary
- Omissions
- Target segments, which are identical to the source segments
- Punctuation, capitalisation, number value, and formatting errors
- Incorrect untranslatables and tags

TQA tools cannot detect mistakes arising from an incorrect understanding of the source text, poor stylistics, or an inappropriate choice of language register. Furthermore, often TQA tools expect the source text to be correct, which is not always the case. Thus, these tools may be very helpful, but they need to be used with care.¹⁸

One of the most popular ones is ApSIC Xbench, which provides powerful QA features in one single view and supports many different CAT tool formats. Its spellchecker is available in 33 languages. It comes with some predefined quality checks for completeness, consistency, numbers, tags, key terms, and so on, but you can also create your own personal checklists. It is even possible to upload hundreds of files at a time and edit only those that have spelling issues.

In terms of practicality, CAT tools have very clear advantages as they offer translators convenient features such as the possibility of working between several documents without having to look back and forth between them and they allow focusing on the very expression being translated. As the translators save time looking up terminology in hard copies of reference materials, they can dedicate more time to writing and are more productive. CAT tools also eliminate the need for typing several occurrences of the same expression. Above all, they ensure consistent use of terminology and style across all documentation and this has a significant impact when working on large projects.

However, stemming from these advantages, using CAT tools without a clear knowledge of translation issues or adequate training, can also bring a number of problems. First and foremost, focusing on one segment or sentence at a time is detrimental to producing a good overall style for a document. It is essential, therefore, to operate a final proofing stage on the fully translated document, aside from the source. Furthermore, the automatic generation of translation 'segments' carries the risk of disseminating an error. So, it is important to clean up the terminology database prior to starting a new project. Regrettably, this is often overlooked because of the time constraints.

As professional translators, we could not work without these tools and would like to encourage any aspiring or established translators or proofreaders to invest in these resources and undertake proper training before starting to use them. Being up-to-date in our own field of experience also means being able to implement up-to-date technologies to ensure a better quality for our outputs.

References

- Translation memory. Wikipedia [cited 2013 Oct 09]. Available from: http://en.wikipedia.org/wiki/Translation_memory.
- CatCount [cited 2013 Sep 20]. Available from: http:// www.catcount.com/.
- Tilti Systems. FineCount [cited 2013 Sep 20]. Available from: http://www.tilti.com/software-for-translators/finecount/.
- 4. Google Translate [cited 2013 Oct 09]. Available from: http://translate.google.it/.
- 5. Public Works and Government Services Canada. Termium [cited 2013 Sep 20]. Available from: http://www.btb.termiumplus.gc.ca/.
- 6. Office québécois de la langue française. Le grand dictionnaire terminologique (GDT) [cited 2013 Sep 20]. Available from: http://gdt.oqlf.gouv.qc.ca/.
- 7. File Maker [cited 2013 Sep 20]. Available from: http://www.filemaker.co.uk/.
- SDL MultiTerm Desktop 2011 [cited 2013 Sep 20]. Available from: http://www.sdl.com/products/sdl-multiterm/desktop.html.
- Terminotix [cited 2013 Sep 20]. Available from: http:// www.terminotix.com/index.asp?content=brand&brand= 2&lang=en.
- 10. Take[lab]; TermX v1.0 [cited 2013 Sep 20]. Available from: http://takelab.fer.hr/termex/.
- 11. Perceptive software [cited 2013 Sep 20]. Available from: http://www.perceptivesoftware.com/products/perceptive-search.
- 12. dtSearch [cited 2013 Sep 20]. Available from: http://dtsearch.com/.
- Computer-assisted translation [cited 2013 Sep 20]. Available from: http://en.wikipedia.org/wiki/Computer-assisted_translation.
- 14. Tabor J. CAT tool use by translators: what are they using? [cited 2013 Sep 20]. Available from: http://prozcomblog.com/2013/03/28/cat-tool-use-by-trans lators-what-are-they-using/.

- 15. Hendzel K. Professional-quality translation at light speed: why voice recognition may well be the most disruptive translation technology you've never heard of [cited 2013 Sep 20]. Available from: http://www.kevinhendzel.com/professional-quality-translation-at-light-speed-why-voice-recognition-may-well-bethe-most-disruptive-translation-technology-youve-never-heard-of/.
- Author information

Laura Carolina Collada Ali, freelance translator and writer – OnTranslation She started her career as a medical translator and writer at the European Organisation for Research and Treatment of Cancer (EORTC) in Belgium. She then moved to Italy, where she worked for a not-for-profit research organisation specialising in haematology (GIMEMA). In 2011, she became a freelancer and she now offers translation and editing services.

Laurence Auffret MSc Bioeng, MA Ling - CINETIQUE Translations Laurence founded CINETIQUE Translations (ISO 9001:2008) in 2003 after working as a scientist in France and a language lecturer in UK universities (Translation, Computer-assisted learning, Erasmus). CINETIQUE Translations specialises in language services for the life science industry with a strong focus on clinical trial and biotech documentation. Laurence currently manages large translation projects for European- and US-based clients as well as developing her company's activities. In May 2009, Laurence also became part of EMWA's EC and is a past President of the EMWA.

- 16. ApSIC Comparator [cited 2013 Sept 20]. Available from: http://www.apsic.com/en/products_compara tor.html
- 17. Technolex software. ChangeTracker [cited 2013 Sep 20]. Available from: http://www.change-tracker.com/.
- Gerasimov A. Review of translation quality assurance software [cited 2013 Sep 20]. Available from: http:// www.translationdirectory.com/articles/article1253.htm.

Graphing software for medical writers

Jesslynn Ooi^{1,2}, Daniela Traini^{1,2}, Paul M Young^{1,2}

Correspondence to:

Paul M Young Woolcock Institute of Medical Research, 431 Glebe Point Road, Sydney NSW 2037, Australia paul.young@sydney.edu.au

Abstract

The production of high-quality graphical figures of scientific data is an important aspect of medical writing, since the significance of the research findings can be lost to the audience if the data are presented poorly or inaccurately. This review highlights the various requirements that a writer may encounter when preparing data in a graphical format for presentation and gives an overview of 15 graphing software packages that are available on a number of platforms.

Keywords: Graphing software, Windows, Apple OS X, Linux, Figure preparation, Data analysis

Introduction

High-quality graphical figures of data should always be a priority when preparing a manuscript or presentation. The significance of a study or clinical trial can be lost to an audience if the data are presented poorly or inaccurately. It is important to choose a suitable graph format and represent your data in the clearest way possible. There are countless ways of representing datasets; the nature of your graph and the choice of graphing software will be dependent upon the type of data and the field of research. Depending on your data, you may wish to produce a scatter plot, a bar graph, a pie chart, or a multivariable three-dimensional (3D) plot. The type of graphical software that you settle on will be dependent on the output that you wish to generate.

When choosing a package it is important to consider the usability, the output formats, the programmability, and the availability of advanced features. Fifteen graphical programs across the Windows[®], Mac OS X[®], and Linux[®] platforms are briefly described and discussed in this review along with the basic requirements that a medical writer may have.

Identifying specific graphing requirements

The first step to choosing a suitable graphing software package is the successful identification of the user and the final output requirements. Medical writers may use multiple packages since not all the packages offer the same functionality, output options, and user interface. For example, a medical writer may require a graphical software package that has advanced statistical and regression features for one application, and an interactive 3D graph that can be outputted as a movie for another.

Generally, the best place to start when choosing a graphing package is to consider the following three questions:

- 1. How do you want to process and handle data?
- 2. What output format do you require?
- 3. What user interface are you comfortable with and what operating system are you using?

When answering these three questions, specific requirements should be considered. These requirements include: command line interface or graphical user interface, programmable functions, advanced regression features, output in multiple pixel and vector image formats, the ability to update graphs in real time, video output, and the inclusion of statistical functions and integrated graphing.

By asking these three specific questions, a medical writer will be in a position to narrow his/her choices to a few packages and then settle on the one that is most suitable.

Fifteen current scientific graphing packages

There are numerous graphing packages available to the medical writer. Here, we discuss 15 such packages across the Windows, Mac OS X, and

¹Respiratory Technology, Woolcock Institute of Medical Research, Sydney, Australia

²Discipline of Pharmacology, School of Medicine, University of Sydney, Sydney, Australia

Linux platforms and highlight some of the key features that these packages offer.

DataGraph (Visual Data Tools)

DataGraph is a native Mac OS X software which is primarily used for clean 2D figure production. The list of graph types is restricted to basic scatter and line plots, histograms, basic function fitting (linear, polynomial, power, exponential, and arbitrary functions), bar charts, and scatter and line plots. This program deals with the data in columns and rows instead of individual spreadsheet cells, which indirectly increases the maximum handling capacity (it can deal with 'millions' of rows and 'thousands' of columns). The user interface for DataGraph is a series of panels that control each aspect of the output graph, allowing for very precise and easy adjustment of all the presentation aspects. This program's strength lies in its ease of use and quality figure production.

DataTank (Visual Data Tools)

DataTank is the big brother of DataGraph. It is capable of plotting 2D and 3D graphs from the templates of more than 80 graphs. Mathematically, it can handle 2000 computational actions and can compile 3D videos in QuickTime Virtual Reality format. DataTank is a native MAC OS X program and uses the Quartz and the Open Graphics Library (Open GL) programming languages to draw 3D graphics.

DeltaGraph (Red Rock Software)

Available on both the Microsoft and the Mac OS X platforms, DeltaGraph has an easy to use interface with Pantone[®] colour matching (Pantone being a proprietary 'colour space' used in the printing industry for standardised colour matching) and various raster and vector output options. The users can select from 25 built-in mathematical functions, 50 statistical functions, and 80 graphing templates (which include both 2D and basic 3D graph outputs).

Excel[®] (Microsoft)

Excel is a part of Microsoft's mainstay Office suite and many people use it for graphing purposes. While it is excellent for handling simple datasets, conducting routine calculations, and plotting data, it has a lack of graph types, and formatting and output options. Generally, medical writers will use Excel for handling and organising data before copying/exporting data into a scientific graphing program for figure production.

Grapher (Golden Software)

Grapher contains more than 60 types of 2D and 3D graphs covering features such as parametric function plots, basic function plots (x, y; and x and y as a function of z), polar graphs, ternary graphs, 2D and 3D vector plots, contouring, and basic fitting with 16 pre-determined fitting functions. The plots can be exported in a variety of vector- and raster-based formats. Grapher can also be automated by using the programming languages Visual Basic, C++, and Perl. This program is available only on the Windows platform.

GraphPad Prism (GraphPad Software)

While it was first designed for experimental biologists, this program is excellent at handling nonlinear regression, curve fitting, and basic statistical tests (*t*-tests, non-parametric comparisons, one-and two-way analysis of variance (ANOVA), analysis of contingency tables, and survival analysis). It is very popular and allows for quick no-fuss statistical calculations, which integrate directly into the outputted graphical figures. GraphPad Prism is available on both the Microsoft and the Mac OS X platforms.

IGOR Pro (WaveMetrics)

The target market for IGOR Pro, which is capable of producing quality 2D and 3D plots, is the science and engineering disciplines. Curve analysis is the mainstay of this program and it can handle curve fitting, peak analysis, signal processing, and basic statistics with ease. Of particular interest to medical writers is the 3D plotting program, which is useful for the analysis and the presentation of 3D volumetric data, e.g. from medical magnetic resonance imaging (MRI) or X-ray computed tomography (CT) scans. It is possible to create short 3D animations through manual manipulation or through programming. Moreover, the users may install third-party plugins (or write their own in C or C++) to acquire data in real time. IGOR Pro is available on both the Microsoft and the Mac OS X platforms.

KaleidaGraph (Synergy Software)

KaleidaGraph is a 2D scientific graphing software package intended for statistical analysis and graphics production. It has a range of 2D graphs, including line and scatter plots, probability graphs, histograms, and stacked, column, polar, pie, and function charts. This program allows for fine control over presentation, and boasts of extensive curve fitting functions and features such as the ability to plot up to 99 dependent variables on a

single set of axes. The formulae are available in the datasheet and standard templates can be constructed. The program can run on both the Windows and the Mac OS X platforms.

MagicPlot (Magicplot Systems)

MagicPlot is a cross-platform graphing software based on Java for plotting 2D *X*–*Y* graphs in the Windows, Mac OS X, and Linux systems. Most functions are basic but the program does include nonlinear curve fitting and 2D waterfall graphing functions.

Maple (Maplesoft)

Maple's targeted application areas are financial modelling, statistics and process control, physics, and control design. The statistics package can analyse distribution parameters, compute crosscorrelation and autocorrelation, smooth data to various degrees, and perform 11 types of hypothesis testing. Aside from the statistics, Maple is able to generate 170 plot types, including 3D, vector field, contour, polar, conformal, and density plots. In addition, Maple can conduct ordinary and partial differential equations and produce statistical plots. The program allows the user to fine-tune the graphical output (e.g. surface style, lighting, and glossiness) of 3D plots. Maple also features a code generation option, which allows users interested in programming to develop a prototype or solution in the Maple language and to generate Visual Basic, MatLab, Java, C, C#, or Fortran code. Maple is available across the Windows, Mac OS X, and Linux platforms.

Mathematica (Wolfram Research)

Mathematica is a high level and extremely diverse program suitable for multiple applications, including pure statistical and data analysis, social network analysis, 3D volumetric and imaging data, control systems, signal processing, engineering, parallel computing, wavelet analysis, financial engineering, geographical analysis, and computational biology. It claims to have the 'largest collection of algorithms in a single system', which is relevant for users who wish to perform enhanced statistical analysis. The program is also capable of creating and analysing volumetric and 3D imaging data, which is useful for individuals who wish to create 3D slices or pattern recognition algorithms from MRI or X-ray CT scans. Mathematica also has a suite of highly customisable bioinformatics functions, including computable genome and protein data analysis, sequence alignment, and protein structure rendering. While these features are not specifically graph related, they may be of use to medical writers who need to present genome- or protein-related data in a publishable form. Mathematica is available across the Windows, Mac OS X, and Linux operating systems.

MATLAB® (MathWorks)

MATLAB is a high-level language intended for numerical computation, programming, graphing, and application development. It has a wide range of science and engineering applications, including signal processing and communications, image and video processing, and computational biology. The program is capable of applying numerical computation methods to analyse data and develop algorithms, and can be used to output both 2D and 3D models. It can easily deal with linear algebra, statistics, Fourier analysis, filtering, optimisation, intedifferential gration, and equations. acquisition in real time is possible with add-on products. MATLAB is touted on its website to be 'faster than traditional software' when it comes to data acquisition, visualisation, and analysis. New users should allow some time to familiarise themselves with the MATLAB language. The program is available for the Windows, Mac OS X, and Linux systems.

Numbers (Apple Inc.)

While visually appealing and functionally easy to use, this program is not targeted towards the scientific community. However, for the medical writer who wishes to produce sharp presentation graphics for media purposes, Numbers has a range of 3D graphics options with realistic finishes (i.e. bar graphs or pie charts with polished metal, cloth, or wood grain textures). In addition, basic curve fitting and error bars can be incorporated into some 2D graphs. Recently, Numbers has been updated to integrate between Apple's desktop OSX and mobile iOS platforms via iCloud. This makes Numbers a feasible choice for medical writers who are 'on the go' and require a tablet option that synchs seamlessly with their desktop version at home.

OriginPro (OriginLab)

OriginPro is predominantly a data analysis software package capable of polynomial, linear, and non-linear curve fitting, peak analysis (subtraction, detection, integration, fitting, batch analysis), statistics (descriptive statistics, hypothesis testing, ANOVA, non-parametric analysis, multivariate analysis, survival tests, power and sample size tests, receiver operating characteristic curves), and

mathematical function analysis (interpolation, extraction, differentiation, integration, area and volume calculation). Newer versions of OriginPro have introduced 3D graphing functions (3D parametric plots, waterfall functions) and 3D animations. OriginPro is a Microsoft-based program.

SciDAVis (Open source)

A free interactive application with similar functions to OriginPro and SigmaPlot (see below), SciDAVis aims to deliver publication-quality 2D and 3D plots. Cells in tables can be computed to standard level and special functions if coupled with the Python programing language. Analysis of data and curves includes multiple curve fitting, filtering, interpolation, non-linear curve fitting, fast Fourier transform analysis, correlation, and the deconvolution of data. Plots can be exported in a variety of vector- and raster-based formats. This software is available across the Windows, Mac OS X, and Linux operating systems.

SigmaPlot (Systat Software)

SigmaPlot, a Windows-based software package, has a number of functions relevant to scientific research and is operated through its easy to use graphical user interface. SigmaPlot 12.5 (the latest version at the time of writing) boasts of more than 100 2D and 3D graph templates, including 2D vector plots, 3D mesh plots, contour projections, radar plots, and dot density graphs. One of the features of this program is the ability to embed graphs in Microsoft Word® or Excel through the Visual Basic script; medical writers who prefer to operate on PC platforms may find this useful. In addition, tasks can be automated within SigmaPlot in macro language. Descriptive statistical analysis can be

performed easily alongside more advanced tests such as Deming regression analysis, three-way ANOVA, and non-parametric one-sample *t*-tests. SigmaPlot is also capable of data transformation. An interesting aspect of the SigmaPlot program is the inclusion of an Enzyme Kinetics Module, which comes with additional analysis features and graph types (e.g. Lineweaver–Burk, Eadie–Hofstee, and Scatchard graph types).

Summary

There are many graphing packages available to the medical writing community and the choice of package will be specific to the dataset and the output requirements of a particular project. Many of the packages have simple to use graphical interfaces, while others have command line interface options and integration of a number of programming languages. The output formats also vary between packages, although the majority now offer common graphical formats required by most journals. Ultimately, the best way to identify the most suitable package is via hands-on experience. Luckily, most packages offer users the opportunity to 'try before you buy' and thus, after identifying a few potential candidates, the user can process their data by using a few options before settling on their final choice.

Acknowledgements

PMY is the recipient of an Australian Research Council Future Fellowship (project number FT110100996). DT is the recipient of an Australian Research Council Future Fellowship (project number FT12010063). JO is the recipient of an Endeavor Scholarship.

Author information

Jesslynn Ooi is a PhD student at the University of Sydney and the recipient of multiple early career awards, including a European Framework 7 scholarship in nanotechnology and an Endeavour Research Fellowship.

Daniela Traini is an Australian Council Future Fellow and Associate Professor at Sydney Medical School.

Paul M Young is Head of Respiratory Technology at the Woolcock Institute of Medical Research and Associate Professor at the Sydney Medical School, University of Sydney.

The authors are strong supporters of early career researchers and founding members of http://www.ecr2star.org.

A medical writer's must-have software

Shirin Ghodke

Montpellier, France

Correspondence to:

Shirin Ghodke 38 rue Pierre Cochereau 34 Residence les Jardins du Chateau, 34000 Montpellier, France shirin.ghodke@gmail.com

Abstract

This article provides a list of software useful to medical writers according to the booklet 'The WRITE tool for the job' compiled by Emma Hitt. Software categories include: word processors; reference managers; PDF readers; project planning and mind mapping; backup; file transfer; time tracking and invoicing; speech recognition and transcription; medical dictionaries, grammar and spell-checker; rest break; imaging; and anti-virus and internet security.

Keywords: Software, Operating system, Compatibility

Medical writing strays far away from the other artistic genres of writing, and a simple pen and paper may not suffice. A variety of software is available to help. In the booklet 'The WRITE tool for the job', Emma Hitt¹ compiled the 'collective wisdom of writers'. The full booklet contains detailed comments from medial writers about software they find useful. Below is a summary of the categories, software packages, and their compatibility with different operating systems (Table 1).

Conflicts of interest and disclaimers

All of the proprietary software mentioned in this article has not been authorised, sponsored, or otherwise approved by the respective product companies.

Reference

1. Hitt E. The WRITE tool for the job. 2013. Available from: http://www.hittmedicalwriting.com/hmw/.

Table 1: A list of the preferred software used by medical writers

Software category	Software	Compatibility
Word processor	Microsoft Office®	W, M
	Open Office	W, M, L
	Scrivener [®]	W, M, L
Reference managers	Endnote [®]	W, M and
		Web
	Reference Manager®	W
	Mendeley® (free)	W, M, L
	Zotero (free)	W, M, L
PDF readers	Adobe Acrobat®	W, M
	Foxit Reader® (free)	W
	Bluebeam® Revu®	W, M
	Skim (free)	M
Project planning and	MindManager	W, M
mind mapping	Docear (free)	W, M, L
B . I	Evernote [®]	W, M
Backup	Carbonite™	W, M
	Crashplan	W, M, L
F1	Dropbox (free) Filezilla® (free)	Online
File transfer	Filezilla (free)	W, M, L
T: 1 1: 1	Dropbox [®]	Online
Time tracking and	TraxTime	W
invoicing	QuickBooks [®]	W, M
	WorkingPoint	Online
Consol responsition and	Freshbooks	Online
Speech recognition and	ExpressScribe (free)	W, M, L
transcription	Dragon Naturally	W, M
Madical distinguiss	speaking Stedman's Plus	VA/ N.4
Medical dictionaries,		W, M
grammar and	medical spellchecker Taber's Medical	Online
spellchecker		Offilitie
	Dictionary WhiteSmoke Writer™	\A/ \A/
Rest break	Workrave (free)	W, M W, L
rest bleak	Workpace [®]	W, L
Imaging	Adobe Photoshop®	W, M
magnig	Adobe Illustrator®	W, M
	GIMP (free)	W, M, L
Anti-virus and internet	Norton [™] Antivirus	W, M
security	Sophos [®] Antivirus	W, M, L
security	Avast! Antivirus (free)	W, M
	AVG Antivirus (free)	W, M
	ANG AIRIVII (II CC)	v v , I V I

Abbreviations: W, Windows®; M, Mac OS®; L, Linux®.

Author information

Shirin Ghodke is a research scientist with a strong interest in a medical writing career. She currently volunteers for

the European Medical Writers Association's journal 'Medical Writing' as an Associate Editor.

45

Zotero: A free and open-source reference manager

Julie Courraud

Clinical Research Department, Institut régional du Cancer de Montpellier (ICM), Val d'Aurelle, Montpellier, France

Correspondence to:

Julie Courraud, Institut régional du Cancer de Montpellier (ICM) Val d'Aurelle, 208 rue des Apothicaires, 34298 Montpellier Cedex 5, France julie.courraud@icm.unicancer.fr

Abstract

Zotero is a free, open-source reference management program compatible with Linux[®], Mac[®], and Windows[®] operating systems. Libraries are backed up online allowing sharing between computers and even multiple users. Zotero makes it easy to keep your reference library organised and 'clean'. Reference libraries are compatible with other reference management programs, and difficulties can be quickly addressed via online forums. For these reasons, Zotero can be a valuable resource to medical writers.

Keywords: Reference manager, Bibliography, Medical writing, Open source, Freeware

You may remember the time when inserting references in a text was one of the most time-consuming and arbitrary tasks. With time and projects flying by, your bibliography may have become a jungle where finding a specific article began to resemble cave exploration. Fortunately, reference management programs have been developed to make writers' lives easier. 1 Several programs are available, including Mendeley® (acquired in 2013 by Elsevier), EndNote® (Thomson Reuters), and Biblioscape (CG Information). In contrast to previous articles comparing several reference managers, 2,3 this article focuses Zotero, a free and open-source program originally developed by the Center for History and New Media at George Mason University and the Corporation for Digital Scholarship in the USA.

What you can do with Zotero

Collecting and organising references

Zotero is useful at all stages of citing sources, from conducting bibliographic searches to writing documents. When you read citations on a computer, tablet, or mobile device, ⁴ Zotero automatically collects 'metadata' (details such as authors, title, and date) that are stored in your electronic library. Metadata can also be recovered from the PDFs of

the published articles (at least dating from around 2000) or by using article identification numbers. Libraries can be organised in collections as you would organise file folders on your computer (Figure 1), and files, notes, or links, even full texts, can be associated with each reference. PDF files are automatically downloaded when available (open access articles, for instance) and Zotero can rename them according to first author, year, and title. Zotero includes a search bar that helps find references within your library. This search function even includes the text within PDF files. Zotero also has a 'locate' button that helps finding items online. Libraries from other reference managers may be imported in Zotero.⁵

Inserting citations into a document

Zotero is compatible with Microsoft Word[®], LibreOffice, OpenOffice, and NeoOffice. When writing a document, you may easily insert citations by clicking on Zotero buttons. Your reference list is also automatically created and you can switch citation format as often as needed. A style repository containing more than 6700 styles is available online;6 if the style you need is not on the list, you may find a similar style using the 'search by example' tool. In-line citations and bibliographies may be personalised (e.g. remove author or add page numbers), and journal titles may be automatically abbreviated when needed. Some styles also include a translator that adapts terms in cited references (e.g. 'available at', 'accessed', etc.) to a specific language.8

Saving, synchronising, and sharing libraries

Zotero works much like Google Docs[®] or Dropbox[®]. When you create a personal account on Zotero, you receive 300 MB of free online storage, although this can be increased for a small fee.⁹ Zotero synchronises your computer with your online account so that all of your references are backed up on Zotero servers. You can even synchronise several

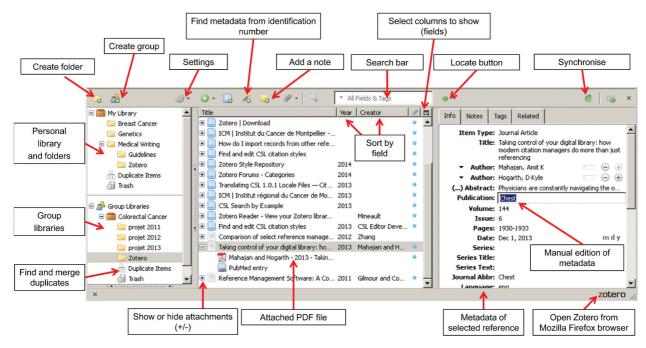


Figure 1: Screenshot of Zotero window. Identification numbers include Digital Object Identifier (DOI, unique for each article), International Standard Book Numbers (ISBN, unique for each book), or PubMed ID numbers.

computers to a single account so that you are always working with the latest version of your bibliography, regardless of which computer you are using. Furthermore, by logging into zotero.org, you can access your library from anywhere.

References may be shared between different users through group libraries. The owner of the group can invite anybody to join (a Zotero account is necessary) and configure reading and editing rights for each member. Groups are particularly useful when several authors contribute to writing a common document. Indeed, each author can edit citations using Zotero, provided that the references cited in this document come from a group library. Groups may be public or private. Creating a public library is a free and easy way to list collective or individual publications and make them more widely known. Moreover, because Zotero is open-source, a developer can easily post online and keep up to date your list of publications (e.g. see the website for the Institut du Cancer de Montpellier¹⁰).

How to install Zotero

Zotero is compatible with Linux, Mac, and Windows operating systems. ¹¹ It was initially developed as an add-on to the Mozilla Firefox [®] web browser. People preferring other browsers can download the Zotero Standalone version completed by a browser extension (for Safari [®] or Google Chrome [®]) or a bookmarklet ¹² (for all other web browsers). Both versions offer exactly the same services, although the Firefox add-on opens as a window

within the browser while Zotero Standalone runs as an independent application. However, in contrast to Zotero Standalone, the Firefox installation (including Zotero add-on) does not require administrator rights on the computer. A plugin for word processing programs must also be installed to allow the insertion of citations in the text.¹¹

Strengths and limitations of Zotero

Strengths

- Zotero is free and open-source. Worldwide developers continuously contribute to its improvement.
- Zotero can be installed without administrator rights.
- A wide variety of styles is already available, and finding the appropriate style is easy.
- Libraries can be shared, allowing collective use and pooling of bibliography searches.
- The metadata retrieval tool allows you to 'tidy up' PDF files stored on your computer, which comes in handy when the file names are unclear.
- A quick-start guide and numerous tutorials are available in multiple languages.¹³
- Difficulties and style requests can be quickly addressed via online forums.¹⁴
- Libraries are compatible with other reference management programs.⁵
- Many 'tips and tricks', including applications for tablets or mobiles, are available to simplify reading and collecting citations in your bibliography. 4,15

Limitations

- Editing and creating styles can be difficult. I recommend using the visual editor at http://editor.citationstyles.org/visualEditor/.
- So far, the quick search bar can look for references within a single group library but not within all group libraries simultaneously.
- Computers may be slowed while citations are inserted or the library is synchronised.

Conclusion

Collecting, organising, citing, and sharing references used to take an enormous amount of time. The task is now much simpler thanks to reference management software. Zotero is a free and open-source reference manager program that has many advantages and should be considered by medical writers. For more information about Zotero, take a look at zotero.org.

Acknowledgements

I thank Dr Sylvain Rouanet who introduced me to Zotero and the Zotero press team who checked the technical accuracy of this article.

Conflicts of interest and disclaimers

J. declares that she received honoraria in 2013 from the University of Montpellier and from Fresenius Kabi Laboratories for holding conferences on Zotero.

References

 Mahajan AK, Hogarth DK. Taking control of your digital library: how modern citation managers do more than just referencing. Chest 2013;144(6):1930-3.

Author information

Dr Julie Courraud, PharmD, PhD, works as a medical writer in the Clinical Research Department of the Montpellier Cancer Institute, Montpellier, France. She assists researchers in writing documents such as publications and study protocols. She teaches PhD students, pharmacists, physicians, and researchers about bibliography management.

- 2. Zhang Y. Comparison of select reference management tools. Med Ref Serv Q 2012;31(1):45–60.
- 3. Gilmour R, Cobus-Kuo L. Reference management software: a comparative analysis of four products. Issues Sci Technol Librariansh 2011;66:63–75.
- Zotero for Mobile. [updated 2013 Sep 8; cited 2014 Jan 9]. Available from: http://www.zotero.org/support/mobile.
- 5. How do I import records from other reference managers systems? [updated 2013 Oct 25; cited 2014 Jan 9]. Available from: http://www.zotero.org/support/kb/importing_records_from_endnote.
- 6. Zotero Style Repository. [updated 2014 Jan 10; cited 2014 Jan 10]. Available from: http://www.zotero.org/styles.
- 7. CSL Search by Example. [updated 2013 Sep 13; cited 2014 Jan 10]. Available from: http://editor.citation styles.org/searchByExample/.
- Translating CSL 1.0.1 Locale Files Citation Style Language 1.0 documentation. [updated 2013 Sep 19; cited 2014 Jan 9]. Available from: http://citationstyle-language.readthedocs.org/en/latest/translatinglocale-files.html.
- Zotero Storage. [updated 2013 Jul 25; cited 2014 Jan 9]. Available from: http://www.zotero.org/support/ storage.
- 10. ICM | Institut régional du Cancer de Montpellier Publications. [updated 2013 Dec 19; cited 2014 Jan 9]. Available from: http://www.icm.unicancer.fr/fr/publications.
- 11. Zotero Download. [updated 2013; cited 2014 Jan 9]. Available from: https://www.zotero.org/download/.
- 12. Zotero Bookmarklet. [updated 2013; cited 2014 Jan 9]. Available from: http://www.zotero.org/download bookmarklet.
- 13. Zotero Support. [updated 2013 Dec 13; cited 2014 Jan 9]. Available from: https://www.zotero.org/support/.
- 14. Zotero Forums Categories. [updated 2014 Jan 10; cited 2014 Jan 10]. Available from: https://forums.zotero.org/categories/.
- 15. Zotero tips and tricks. [updated 2013 Apr 22; cited 2014 Jan 9]. Available from: https://www.zotero.org/support/tips_and_tricks.

Origin and development of English for Medical Purposes. Part I: Research on written medical discourse

Françoise Salager-Meyer

Graduate School of Medicine, English for Medical Purposes Unit, University of the Andes, Mérida, Venezuela **Correspondence to:**

Françoise Salager-Meyer Mérida, Venezuela francoise.sm@gmail.com

Abstract

In this two-part review, I present the birth and growth of 'English for Medical Purposes', a branch of applied linguistics. This first part summarises the research conducted on English-medium written medical discourse, from early register analysis in the mid-1980s that had a clear pedagogical aim (i.e. teaching reading English-language medical discourse to non-Anglophone medical students and health professionals) to more sophisticated genre and rhetorical studies later on.

Keywords: Medicine, English, Written discourse, Genre

Introduction

The birth and rise of the English for Medical Purposes (EMP) field is related to the mid-twentieth century emergence of English as the *lingua franca* of scientific communication in general, and of medicine in particular. The evolution is now well documented in a number of publications.¹

A few telling figures: by the end of the 1980s, some two million medical papers were published by about 25 000 medical journals, 15 000 of which – all Anglo-American – were considered 'serious' journals. By the year 2000, over five million medical papers were published annually.²

If we add to this figure the 500 or so journals in nursing and dentistry, the final figure is 10 million health-related peer-reviewed papers published every year, over 80% of them being written in English. It should be kept in mind that many medical journals that used to be published in national languages have recently switched to English as their language of publication. This is the case of the *Croatian Medical Journal*, the *Mexican Medical Journal*, the *Saratov Journal of Medical*

Scientific Research (Russia), and many other medical journals in Latin America, Eastern and Western Europe, Asia, and the Middle East. Incidentally, this linguistic shift is quite frequent also in other disciplines, both the 'hard' and 'soft' sciences. It should also be stressed that not only English-medium 'conventional' medical journals but also journals on alternative and complementary medicine are steadily on the increase.³

This undeniable growth in the volume of Englishlanguage medical literature has been accompanied by an important body of linguistic and sociolinguistic research on English written and oral medical discourse, a field that is commonly referred to as 'English for Medical Purposes'. It is the purpose of this paper to outline briefly its origin and development.

Research on written medical discourse

Early EMP research on written medical discourse: The EMP Newsletter and register analysis

In 1983, a group of English for Specific Purposes practitioners met at a conference for the Arab world. A subgroup discovered by chance a mutual involvement in English for the Health Sciences, and two British linguists, Nigel Bruce and Liz Nakhoul (who then worked at the University of Kuwait) volunteered to initiate an information network. This is how the first EMP journal, the EMP Newsletter, was launched. The Newsletter was welcomed by applied linguists and English language practitioners involved in EMP. The journal was published twice a year and was distributed free of charge across 60 countries to about 450 subscribers. Very sadly, though, Operation Desert Storm in 1990 wiped out Nigel and Liz's work in the Arab world, and the EMP Newsletter ceased

49

publication. As a consequence, those interested in conducting research on medical discourse had to look for new outlets for their publications (Nigel Bruce, personal emailed communication, July 12th 2013)

The research published in the EMP Newsletter and elsewhere in the early 80s was mainly oriented towards solving problems of a pedagogical nature, because the need for assessment was fundamental to EMP curriculum design. That research - based on rather small linguistic corpora - tended to be descriptive, involving statistical (quantitative) analyses of grammar, sentence patterns, and lexis of medical discourse, i.e. a kind of research that is referred to as 'register analysis'. Salager-Meyer, 4,5 for example, analysed a corpus of 100 000 words drawn from 12 medical specialties that enabled her to determine the core lexis of medical articles written in English, i.e. the lexical items that are homogeneously distributed across the medical spectrum, irrespective of the medical specialty. EMP course design studies then became very popular, and a variety of short or intensive EMP courses and tailor-made in-house textbooks saw the light around the world, especially in the Middle East and Latin America. But course-design papers based on these early register studies became scarcer, and EMP research started being more empirical.

Later EMP research on written discourse

I shall start this sub-section by referring to medical word lists. Medicine, as is well known, has a large corpus of technical and specialised terms, mainly borrowed from Greek and Latin. Chung and Nation, for example, report that technical/specialised words – i.e. words with a narrow range of occurrence and unknown in general use – account for as much as 37.6% of all word types in an anatomy text, compared to 16.3% in an applied linguistics article. As Ferguson rightly argues, specialised vocabulary is better learnt while studying medicine, and the difficulty in understanding it depends, to a great extent, on the learners' mother tongue and on their level of medical knowledge.

By contrast, there is a general consensus that the semitechnical vocabulary presents the greatest obstacle for intermediate non-native English EMP students; it is thus that part of the medical English lexis that should be emphasised in EMP reading courses. That is why Chen and Ge⁸ and Wang *et al.*⁹ devoted their attention to this semitechnical vocabulary, so as to create an academic medical word list. Wang *et al.*⁹ analysed over one million running words from research articles from a wide range of medical specialties and drew a list of 623

word families that account for 12.24% of the tokens making up their linguistic corpus. To our knowledge, the latest lexicographic study that has been conducted on medical discourse is Mungra and Canziani's academic word list for *clinical case histories*. ¹⁰

Regarding generic studies on medical discourse, the most frequently researched genres (or text-types) are the research article abstracts, 11-13 research articles per se either from a diachronic perspective or from a structural standpoint, 15-16 and case reports. 17-19 Other medical genres, such as book reviews, 20 editorials, 21 letters to the editor, 22 narrative and systematic review articles, 3 and the acknowledgment paratext 24 received the attention of applied linguists as well, but not to the same extent as the research article and the case report.

Most of these EMP genre studies combined the investigation of a given genre communicative function with the study of certain lexico-grammatical features, but some exclusively focused on a specific feature, such as hedges, 25 'if conditionals' across medical genres or the expression of criticism 27,28 examined from a cross-linguistic, cross-generic, and diachronic perspective.

Summary

Although very brief, this review of the research that has been carried out over the past 30 years on written medical discourse shows how the field has evolved from quantitative analyses of syntax and lexis to more socially-oriented studies. The second part of this review will deal with research conducted on oral medical discourse.

Acknowledgements

This paper was written thanks to grant no. 1039-13-06-B from the Scientific, Technological, Humanistic and Artistic Research Center of the University of the Andes, Mérida (Venezuela).

References

- 1. Gunnarsson BL. Professional discourse, London: Continuum; 2009.
- 2. Cooter M. News notes. Eur Sci Editing 2000;26(2):67.
- Salager-Meyer F, Alcaraz Ariza MA, Pabón M, Zambrano N. Paying one's intellectual debt: acknowledgments in scientific/conventional and complementary/alternative medical research. In: Gotti M, Salager-Meyer F. editors Advances in medical discourse analysis: oral and written contexts. Bern: Peter Lang; 2006. p. 407–31.
- Salager-Meyer F. The core language of English medical literature: classificatory frame-work and rhetorical function. Reading Foreign Language 1983;1(1): 54–64.
- Salager-Meyer F. Specialist medical English lexis: classificatory framework and rhetorical function: a

- statistical approach. English Medical Purposes Newslett 1985;2(2):5–18.
- Chung TM, Nation P. Technical vocabulary in specialized texts. Reading Foreign Language 2003;15:103–16.
- Ferguson G. English for Medical Purposes. In: Paltridge B, Starfield S, editors The handbook of English for specific purposes. New York: John Wiley and Sons; 2013. p. 243–61.
- 8. Chen Q, Ge GC. A corpus-based lexical study on frequency and distribution of Coxhead's Academic Word List word families in medical research articles. English Specific Purposes 2007;26:502–14.
- 9. Wang J, Liang SI, Ge GC. Establishment of a medical academic word list. English Specific Purposes 2008;27: 442–58.
- 10. Mungra P, Canziani T. Lexicographic studies in medicine: academic word lists for clinical case histories. Ibérica 2013;25:39–63.
- 11. Salager-Meyer F. A text-type and move analysis study of verb tense and modality distribution in medical English abstracts. English Specific Purposes 1992; 11(2):93–115.
- 12. Salager-Meyer F. Discoursal flaws in Medical English abstracts: a genre analysis per research- and text-type. TEXT 1990;10(4):365–84.
- 13. Salager-Meyer F, Alcaraz Ariza MA, Lewin B. Abstract quality in complementary and alternative medicine papers: a structural and cross-generic analysis. In: Bondi M, Lórez L. editors. The language and structure of abstracts: variation and change. Bern: Peter Lang; 2014, in press.
- 14. Atkinson D. The evolution of medical research writing from 1735 to 1985: the case of the Edinburgh Medical Journal. Appl Linguistics 1992;13:337–44.
- 15. Nwogu K. The medical research paper: structure and functions. English Specific Purposes 1997;29:43–53.
- Li L, Ge GC. Genre analysis: structural and linguistics evolution of the English-medium medical research article (1985–2004). English Specific Purposes 2009; 28:93–104.
- 17. Taavitsainen I, Pahta D. Conventions of professional writing: the medical case report in a historical perspective. JEnglish Linguistics 2000;28:60–76.
- Taavitsainen I. Medical case reports and scientific thought-styles. Rev Lenguas Fines Específicos 2011; 17:75–98.

Author information

Françoise Salager-Meyer completed her MA in Russian language and literature at the University of Lyons (France) and her PhD (Linguistics) at the University of Texas at Austin (USA). In 1994 and 2004, she was awarded the Horowitz Prize for her works on the pragmatics of written medical discourse. She was the section editor of the Language and Medicine section of the second edition of the *Encyclopedia of Language and Linguistics* (Elsevier, 2006) and is currently coordinating the Multilingual and Multidisciplinary Research Group on Scientific Discourse Analysis, Graduate at the University of the Andes, Mérida (Venezuela).

- Salager-Meyer F, Alcaraz Ariza MA, Luzardo Briceño M. The medical narrative from a diachronic perspective (1840–2009): titling practices and authorship. In: Gotti M, Sancho Guinda C. edtors Narratives in academic and professional genres. Bern: Peter Lang; 2012. p. 293–319.
- Salager-Meyer F, Alcaraz Ariza MA, Berbesí M. Collegiality, critique and the construction of scientific argumentation in medical book reviews: a diachronic approach. Journal of Pragmatics 2007;39:1758–74.
- 21. Giannoni DS. 'Don't be stupid about intelligent design': confrontational impoliteness in medical journal editorials. In: Salager-Meyer F, Lewin BA. editors Crossed words: criticism in scholarly writing. Bern: Peter Lang; 2011. p. 79–98.
- 22. Magnet A, Carnet D. Letters to the editor: still vigorous after all these years. A presentation of the discursive and linguistic features of the genre. English Specific Purposes 2006;25:173–99.
- 23. Mungra P. Macrostructure and rhetorical moves in secondary research articles: the meta-analysis and the systematic analysis. In: Gotti M, Salager-Meyer F. editors Advances in medical discourse analysis: oral and written contexts. Bern: Peter Lang; 2006. p. 331–57.
- 24. Salager-Meyer F, Alcaraz Ariza MA, Pabón Berbesí M. Backstage solidarity in Spanish- and English-written medical research papers: publication context and the acknowledgment paratext. J Am Soc Inform Sci Technol 2009;60(2):307–317.
- 25. Salager-Meyer F. Hedges and textual communicative function in medical English written discourse. English Specific Purposes 1994;13:149–170.
- 26. Ferguson G. If you pop over there. A corpus-based study of conditionals in medical discourse. English Specific Purposes 2001;20:61–82.
- Salager-Meyer F, Alcaraz Ariza MA, Zambrano N. The scimitar, the dagger and the glove: intercultural differences in the rhetoric of criticism in Spanish, French and English medical discourse (1930–1995). English Specific Purposes 2003;22:223–47.
- 28. Salager-Meyer F, Alcaraz Ariza MA, Pabón Berbesí M. Expert knowledge holders vs. factual reporters: critical voices in written medical genres. In: Salager-Meyer F, Lewin B. editors Crossed words: criticism in scholarly writing. Bern: Peter Lang; 2011. p. 173–202.

Profile

An interview with Karina Ruth Tabacinic on some fundamental concerns of medical translation

Correspondence to:

Laura Carolina Collada Ali Freelance translator and writer at OnTranslation, Italy laura.collada@ontranslation.it @ColladaAli

Medical translation has had a fundamental role in the history of scientific knowledge – ancient, past, and modern. It involves a larger array of working parts than is commonly brought to bear upon the study of other semantic activities. It calls directly on such concepts as authorship, cultural displacement, originality, textual transmission, literacy and orality, and so on.¹

Karina Ruth Tabacinic has a deep understanding of medical translation concerns. She studied technical, scientific, and literary translation at the Institute of Higher Education in Modern Languages 'J. R. Fernández' in Buenos Aires, Argentina, where she is a scientific and technical translation instructor and tutor of the biomedical translation internship. She is currently working as a freelance biomedical translator (English <> Spanish). She is a certified sworn translator (by the University of Belgrano, Buenos Aires, Argentina), an American Translators' Association (ATA)-certified translator from English into Spanish, a member of the Association Argentine of Translators Interpreters (AATI) (Treasurer since 2010), and a member of the International Association of Translators and Editors in Medicine and Allied Sciences (Tremédica). She is also registered with the Sworn Translators' Association of the city of Buenos Aires (CTPCBA). We turned to her to address some of the most interesting issues in this field.

Medical Writing (MEW): We tend to think of English as a lingua scientia able to bridge all differences. Nevertheless, the growth of scientific disciplines in many countries has been indivisible from translation. Many do tend to think science, as well as many other disciplines, gets lost in translation as no discourse has sufficient power to defeat all the localising effects that a certain language imposes on its speakers. What's your opinion on this?

Karina Ruth Tabacinic (KRT): It is an interesting topic that goes hand-in-hand with the concept of untranslatability. However, to my mind, untranslatability should not be an issue within scientific and technical

translation. Of course, some nuances may be lost in translation, but these are usually not relevant within the broader picture, or at least they should not be. Good translators know how to convey all the semantic content of the source text to provide the final readers with a target text that operates as a functional equivalent of the source text, albeit with some linguistic changes. In this regard, I believe some of the most recent theories in translation studies (especially the functionalist approach by Reiss, Vermeer, and Nord²) have successfully explained and can be applied to manage this problem.

MEW: It is popular to speak of the translated word as 'fixed' or 'stable'. Once offered to readers beyond the translator's reach, words are thought to be perdurable and able to persist in form. However, often science books get updated and need to be translated again, implying that some extracts may still be identical to previous version and, yet, retranslated. In your experience, is translation 'stable'? Does it change with time?

KRT: It certainly changes, as language and life itself change. So far, I have had to retranslate the new editions of two books I had previously translated, and it has been a very insightful and rewarding task, even though it certainly evoked mixed feelings: you have to reread a translation done several years before (and hopefully find many passages you would have translated some other way) and perhaps do a significant amount of retranslation and sometimes include new or revised information. Furthermore, terminology and language rules (e.g. spelling and punctuation), as well as company decisions or science itself, may have changed. No, I would not say translation is stable at all.

MEW: Your research on headache-causing prepositions and the recently published article 'Prepositions as connectors in the biomedical discourse' has been very much acclaimed among field professionals. Indeed, successfully translating prepositions may not be as easy as it seems at first sight. What are the main concerns in this field?

KRT: Basically, the literal translation – i.e. syntactic calque - of some of these prepositions can often result in an unnatural or ungrammatical Spanish text, which can even communicate a different meaning or, at least, introduce ambiguity where there is none - something not desirable at all in scientific discourse. By way of example, the literal translation of the prepositions in 'The major cause of morbidity with low-grade astrocytomas is dedifferentiation to a more malignant grade' into Spanish would result in an ambiguity or a change in meaning ('with' expresses cause here, not properly rendered with the Spanish preposition 'con') and in an unnatural and excessively concise rendering ('to' connects a process with its result, a meaning that cannot be conveyed with the prepositions 'para' or 'a'; in this case, both prepositions should be expanded). A full discussion of this point goes beyond the scope of this interview, but this example shows that prepositions cannot be overlooked assuming they are devoid of any 'extra' semantic content because, in fact, they operate as logical connectors. Sentences like the one above prompted my analysis to explain why prepositions used as connectors should not be translated literally and to provide alternative strategies to understand and transfer their meaning correctly. I have to acknowledge the help of many colleagues, but I am especially grateful to Fernando Navarro for suggesting that I should pursue this research.

MEW: You have worked for a myriad of different clients, among which are the Pan-American Health Organization, pharmaceutical companies such as Schering-Plough S. A. or publishing houses such as Ediciones Journal S. A. These may entail different specialisation domains within medical translation. Would you advise novel professionals to specialise as much as possible or a general base knowledge of a broad field (medicine) may be a safer source of work?

KRT: Although I have always been drawn to medical topics, the fact is that medical translation just 'happened' to me. It was not a specialisation I pursued and training opportunities were lacking after I graduated. Indeed, I got a hands-on, practical specialisation from my work for the publishing company in particular, since I not only translate but also review every book after its scientific revision – a kind of continuous conversation with doctors in every field of the books I translate (I even had personalised lectures on neurosurgical

techniques from a renowned neurosurgeon!). Nowadays, training opportunities abound: biomedical translation and medical content workshops, graduate courses, conferences, and lectures are delivered throughout the world in many different languages, and many can be attended through the Web or mobile devices. I would recommend any new professional to get translation training and content knowledge on the specific area they want to specialise in, but not to limit their job possibilities by, say, focusing solely on clinical trials, cardiology, or radiology. For biomedical translators, as for any translator, curiosity is a must. As I always tell my students, translators have to know as much as they can of the topics and text types that are usually translated within their area of interest or expertise, particularly considering the tight turnaround time that is required today and the fact that you never know beforehand what your next translation assignment will be. I would say that a general base knowledge of medicine (or of any area) is a good starting point. However, I believe translators should have a sound command of the source and target languages, and in scientific translation especially, a thorough knowledge of documentation and research resources and methods. In other words, rather than having the knowledge, the path to success lies in knowing which tools will lead you to the required knowledge.

Indeed, knowing which information-generating tools can help you in giving your utmost to a certain project is a must, not only for medical translators but for writers themselves. Knowledge is the basis of research, and thus, of science. Karina Ruth Tabacinic has given us a broad view of what medical translation entails and of some of the 'big concepts' in translation – such as untranslatability or training for medical communication professionals – but she has also introduced less explored issues such as the translation of English prepositions into Spanish as used in medical discourse, and we thank her for this contribution!

Karina Ruth Tabacinic can be contacted at karina@taba cinic.com.ar; @KariTaba; http://www.tabacinic.com.ar

References

- Montgomery SL. Science in translation. Movements of knowledge through cultures and time. Chicago: The University of Chicago Press; 2000. p. 271–94.
- Nord C. Translating as a purposeful activity. Manchester: St. Jerome Publishing; 1997.
- Tabacinic KR. Preposiciones como conectores en el discurso biomédico. Published in Panace@ 2013;14(37): 66-79.

A first-timer's perspective on the 2013 EMWA conference in Barcelona

Derek K Ho

Haartman Institute, Immunobiology Program, University of Helsinki, Helsinki, Finland **Correspondence to:**

Derek K Ho Haartman Institute Immunobiology Program University of Helsinki Helsinki, Finland derek.ho@helsinki.fi

This story may sound familiar. Having spent my entire career on the academic bench, I decided it was time for a change. I still want to use my brain, I still want to be a part of the biomedical sciences, but I am ready to put the pipette down for good. After some self-reflection, I realised that writing grants and manuscripts is the most enjoyable part of my job. This is in contrast to some of my colleagues, who view writing as a chore which takes time away from research. Fortunately for me, I discovered that medical writing is a viable career option for people who are both passionate about science and about communicating the message it contains.

Anyone contemplating a career change will probably hear two pieces of advice: learn as much as possible about the new career, and meet the people who actually do it. Once I decided to pursue medical writing as my next career step, I engaged in self-study. I learned about what medical writers do on a daily basis, where they come from, what kinds of backgrounds they have, and who employs them. I read numerous FDA and ICH documents. I studied textbooks on drug development and clinical trials. During this time, the internet was a valuable resource, in particular, the EMWA and the AMWA websites.

As my enthusiasm for medical writing grew, the next logical step was to not only meet the people who are medical writers, but to learn from them. The EMWA conferences are ideal in this regard. In

addition to providing extensive networking opportunities, it is also possible to participate in professional workshops taught by experienced medical writers. I was eager to take this next step in my career development, so it was not difficult to convince myself to go to Barcelona and leave behind the cold and dark Finnish autumn for a few days!

I knew almost immediately after collecting my name tag that this conference would fulfil my goals of both learning and networking. The lunch and coffee breaks, talking to workshop leaders, and just chatting with classmates provided me with numerous new contacts. I had read before attending the conference that medical writers are nice people, now I know first-hand that this is true!

I was truly amazed at the level of instruction at the workshops, regardless of the subject matter. In particular, my statistics instructor was able to so clearly convey the material that I left the course feeling ready to apply the concepts discussed right away. The workshops which covered documents such as investigator's brochures and clinical study protocols provided me with a solid foundation to build upon, should I encounter these documents in the future.

While my transition from the laboratory into medical writing is a story which is still unfolding, I now feel confident in moving forward with the knowledge, ideas, and contacts I gained from attending the EMWA conference in Barcelona.

I look forward to seeing you all next time.

English Grammar and Style

Good Writing Practice

Section Editors:

Wendy Kingdom info@wendykingdom.com

Alistair Reeves a.reeves@ascribe.de



The trouble with apostrophes (1)

The purpose of the articles in the Good Writing Practice section is to focus on style, not on punctuation or grammar. However, apostrophes are a stumbling block for many writers and so

require some discussion. Some people have simply not learned how to use them correctly. If you fall into this category, or if you would like a refresher, Lynne Truss has succeeded in making a book on punctuation funny as well as informative, and we recommend it.¹

In terms of writing style, the best approach to apostrophes is to avoid them whenever possible. Apostrophes fulfil two main functions: to show that one or more letters have been missed out and to show possession.²

If an apostrophe is used to show that something is missing, the resulting language is consistent with spoken English but is sloppy writing, e.g. won't for will not, wouldn't for would not, they're for they are (not to be confused with their and there). Words such as can't, would've, it's, etc. do not have a place in professional writing. It is better to write the words in full.

Apostrophes that are used to show possession are the ones that cause the most problems for writers, particularly when the precise meaning of a word or phrase is open to interpretation. Why does EMWA stand for European Medical Writers Association and not for European Medical Writers' Association? The explanation is that EMWA is an association of medical writers, or equally, that EMWA is an association for medical writers. EMWA is not an association that belongs to medical writers and so we do not need to use an apostrophe. Now, one can argue that legally, EMWA does belong to its members and, therefore, that Writers should have an apostrophe. This is how disputes arise; the argument in favour of using an apostrophe is reasonable and some people will feel strongly that Writers should have an apostrophe. In the absence of a referee, since all of the arguments carry equal weight, we recommend applying the reasoning that results in the most straightforward text, i.e. without the apostrophe.

Having established that we do not need an apostrophe for European Medical Writers Association, the same reasoning can then be applied to an Investigators Brochure rather than an Investigators' Brochure or even an Investigator's Brochure. The brochure does not belong to one or more investigators; the brochure is for the investigators to use. Again, one could argue that the brochure belongs to the investigators after it has been given to them, but this reasoning seems to be an attempt to justify using an apostrophe. There are no prizes for using apostrophes, just as there are no prizes for using abbreviations. We recommend avoiding apostrophes whenever possible.

Sometimes apostrophes creep into text because of the way the sentence is structured. In such cases, it is better to restructure the sentence to remove the apostrophe. Taking an example from a report of a study in patients with cancer:

To investigate survival, the patient's status was followed-up monthly.

This raises the question of whether we mean that only one patient was followed up or whether we mean that each patient was followed up. We could have written:

To investigate survival, the patients' status was followed up monthly.

This makes it clear that we mean more than one patient, but the reader is likely to backtrack to check that the apostrophe is in the right place. We could remove the apostrophe by replacing it with the missing words and restructuring the sentence slightly:

To investigate survival, the status of the patients was followed up monthly.

This is clear but at the price of lengthening the sentence. If we give the meaning of the text a little thought, we do not need the word 'status'.

'Survival' implies that patients are being followed up to determine their status so we could write:

To investigate survival, patients were followed up monthly.

No apostrophe, no confusion, or backtracking.

As an aside, we would also suggest removing the need for the comma at the same time as prioritising the action that was done:

Patients were followed up monthly to investigate survival.

References

- Truss L. Eats, shoots and leaves. UK: Fourth Estate. 2009. ISBN-10: 0007329067, ISBN-13: 978-0007329069.
- Seely J. Oxford A–Z of grammar and punctuation. Oxford, UK: Oxford University Press. 2013. ISBN-10: 019966918X, ISBN-13: 978-0199669189.

Wendy Kingdom Wendy Kingdom Ltd info@wendykingdom.com

'Ups' and 'downs' in (medical) writing (1)

This topic is also inextricably bound up with one punctuation mark – the hyphen – but is also a matter of style, personal preference, and frequency of usage, so we think it is worth saying a few words about it.

Do you write *set-up* or *setup*, or *work-up* or *workup*? Are drastic measures a crack-down or crackdown? Is a disappointment a let down, a let-down, or a letdown? All of these terms are derived from a very frequent language construction in English: verb + preposition, resulting in a meaning sometimes completely different from that of the core meaning of the verb. For simplicity, I am using verbs together with only up and down, but many other prepositions are used in this way. This is an unregulated area as far as grammar is concerned, but one thing is certain: when the verb is used together with the preposition, they are never hyphenated, regardless of the tense. Follow and up, set, and back and up are not hyphenated in the following sentences because these are being used as verbs with prepositions:

We decided to follow up patients with levels higher than

The study was set up to include patients with a KPS of

The system is backed up every 24 hours.

The question of hyphenation or writing the words together only occurs when adjectives and nouns are formed from the verb + preposition:

Follow-up (adj.) investigations every 4 weeks were planned.

There was no follow-up (noun) in this study.

A build-up (noun) of gas in the intestine caused

And this is where personal preference and style come in, as no rules govern this. Most of us would agree that *followup* and *buildup* look strange (without being able to say why) and that it is highly unlikely that the hyphen will ever be dropped, as has happened with *setup*, *workup*, and *backup*:

System backup is performed every 24 hours. Laboratory workup included Study setup did not permit

Some writers still prefer to use back-up, work-up, set-up, etc., and this is quite legitimate. It really depends on how you feel about hyphens. If you try to avoid them as far as possible (as I do), then you will no doubt opt for the unhyphenated version. It is impossible to say when a term firmly crosses the non-hyphenation threshold and is usually only ever written together, but this obviously happens: layout and breakdown are examples. The most likely reason for this is the frequency of usage. If followup and buildup were used frequently enough, it may well be that one day they would make this transition. But somehow I do not think they will.

An issue when using term of this sort is how consistent you need to be, and this is one area where you have to be pragmatic. You will never achieve consistency across terms, i.e. hyphenating them all or writing them all together, and that would be a complete waste of time. Also, achieving consistency across different texts is illusory. The best thing to strive for here is consistency by term in one text, which means that you should always use workup and not a mixture of work-up and workup in one text. I think that the readers do not expect

consistency here – by that I mean that readers will not be irritated if *workup* and *set-up* are used in the same text. They have probably been in the same quandary themselves.

An important stylistic issue for authors of medical and scientific texts is that a wide range of these 'verb + preposition' terms are used in speech or in informal or journalistic writing, but not in formal writing. The following examples illustrate the informal nature of these terms:

The conference got a very good write-up. His comments on her skill as a surgeon were something of a put-down.

They backed down when they realised how unreasonable they had been.

Government cracks down on hospital waiting lists. Last year's models were sold at knockdown prices. That really messed up my plans.

Obviously workup, backup, setup, breakdown, and many others are in normal use in any type of scientific or medical text, but care should be taken if they sound unusual that they are not too informal or inappropriate to the style of your text.

Alistair Reeves
Ascribe Medical Writing and Translation
a.reeves@ascribe.de

Regulatory Writing

Document authoring and review cycles: Harnessing technological advances

Section Editor:

Greg Morley greg.morley@docuservicio.com



Regulatory documents are complex beasts, often requiring input from many different authors. Sometimes, different departments will be responsible for authoring certain sections and the role of the medical writer could perhaps be more accurately described as a coordinating

editor, who manages timelines and ensures that the contributors are aware of what is expected of them. Regardless of the amount of writing a medical writer actually does on a document, he or she will need to usher the document through at least one review cycle with multiple reviewers before sign-off can happen.

In the traditional approach, the review cycle involves the medical writer (or someone else) sending the document out to the reviewers who then review the document and provide their comments and make changes, usually in track-changes mode. The reviews and comments then find their way back to the medical writer, who then collates and resolves comments. The medical writer might need to arrange an adjudication meeting for particularly contentious comments or in instances where there are contradictory comments made on the same part of the text.

Often, a reviewer copies the other reviewers when providing his or her comments so that additional comments can be made on top of what is already there, thereby saving work in collating changes and comments. In addition, some comments from early in the review round can already be addressed by subsequent reviewers, with a subsequent reduction in the number of issues for adjudication. Although these serial reviews can lead to messylooking, difficult-to-read documents, track-changes mode in Word® allows the reader to isolate comments and edits by a particular reviewer. Word also has the useful option of only displaying certain type of changes and hiding others (such as formatting changes). Track-changes mode has not always been user-friendly; the feature on early versions was rather clunky and often made documents unstable (especially when lots of hyperlinks were present).

Despite the practice of copying other reviewers into returned comments, the medical writer will find him or herself receiving comments in many different versions. And so the work of sifting through the comments and changes and unifying them in a single document (or transferring to a master copy) can be time-consuming. The upside though is that the medical writer retains considerable control over the document (or ownership as some like to call it).

E-mail-based review rounds are of course still commonplace, but technology does not stand still and applications are now available that not only allow a document to be stored centrally for serial editing but also enable editing and reviewing at the same time (parallel editing). Web-based collaborative review applications now enable a document to be stored in a central location (safely behind the company firewall if appropriate) and accessed by the reviewers (after the necessary permissions have been granted).

For review cycles based on editing documents using these applications, the medical writer sends out a link to the document and instructs the reviewers to make any comments and changes directly on the central document. Now, with this more dynamic process, reviewers can see the comments and changes made by other reviewers. And of course the edits are all in one place, saving time for the medical writer who can now, in theory, spend more time resolving the issues.

There are, however, potential downsides to the use of such technology for document authoring and review cycles. With e-mail-based review rounds, the medical writer can filter out extraneous noise and keep discussion focused. The medical writer has less control over the discussion in a document-sharing approach, and so there is a potential for needless bickering. Another issue that has to be dealt with is version control. With e-mail-based reviews, in the event of problems further down the line, the writer (provided he or she diligently archives the reviewed documents) will have a ready record of who did what and so should be able to identify where a mistake or inappropriate edit occurred. With document-sharing approaches, this becomes more difficult. Reviewers can accept changes (often just to make a document more readable if it has been edited by multiple reviewers), but in so doing, may erase a change forever. Regular backups may go some way towards providing a detailed record of changes but all of these might not be captured. If these backups are available and visible to all reviewers (for the sake of transparency for example) but not appropriately labelled, there is a new danger that reviewers may edit the wrong document.

In conclusion, like any new technology, systems to enable collaborative editing have the potential to make our lives easier but it is important to think carefully about the processes involved. The medical writer would be well advised to make an effort to retain ownership of the document to help keep everyone focused.

Document management and publishing systems

Pharmaceutical documentation is often complex. For example, a clinical study report is made up of numerous components (in addition to the synopsis and report body, statistical outputs, a protocol (and amendments), and other study information such as audit certificates and investigator CVs may also be included). Moreover, in recent years, the conduct of the pharmaceutical industry has come under closer scrutiny and there is increasing pressure for greater transparency; therefore, any changes to documents and versions should be duly reflected in an audit trail (to show that there has been no retrospective fiddling with the documents). At the same time, pharmaceutical companies often hold commercially sensitive information that needs to be protected but loss of productivity may result if there are barriers to access for appropriately authorised individuals. To add to the mix, large pharmaceutical companies are also global operations, where the members of a project team who have to work on a given document (or approve it) may be spread over different continents.

The way that pharmaceutical companies produce and publish documents, whether for internal or external readership, is therefore a challenge. To cope with so many requirements, large pharmaceutical companies will likely have a document management and publishing system (often built to specification). In addition to providing passwordprotected access and a record of any changes to documents, the final published documents may be transferred to document repositories for ready search and access by other individuals (e.g. if you are writing an investigator's brochure update, you may need to have access to certain clinical study reports). Once final, some types of document may need to be distributed outside the company and this should be carefully controlled. For example, an investigator's brochure will need to be distributed to the appropriate investigators; it is therefore important that the persons responsible for distribution are duly notified and receive the correct version of the document itself. The assembly and publishing of documents (usually as a hyperlinked pdf) will often be outsourced or at least performed by someone other than the medical writer (who will nevertheless need to check the final document) as this can be painstaking work.

Of course, a document management system is not in itself going to ensure that all documentation requirements are met. For large pharmaceutical companies, with increasing complex documentation requirements and regulatory burden, such systems can however be considered as a minimum essential requirement.

The Webscout

Section Editor:

Karin Eichele karin.eichele@novartis.com



Software – What will help me?

The right software can save you a lot of time and make your life much easier. You can choose from a huge range of packages for different medical writing or related activities.

It is worth taking a look at what other medical writers recommend to use. Here is a compilation of suggestions and recommendations from medical writers for medical writers:

http://www.hittmedicalwriting.com/hmw/wp-content/uploads/2011/03/Week2_EquipmentandSoftwarefor MedicalWriting_10042011.pdf.

The web offers many presentations and tutorials to help you decide which software to use and to help you get familiar with it. On the basis of the above compilation I have surfed the web for more information on some of the suggestions.

Word processing software is by virtue of our profession obviously one of the most important tools. It is needless to talk about Microsoft Word[®], but there are alternatives out there, such as the now also widely used Open Office with its word processor 'Writer' and the Open Office spin-off LibreOffice:

http://www.youtube.com/watch?v=sloEMUt7n5Q.

Open Office Writer is not very different from Microsoft Word. Convince yourself by having a look at this tutorial:

http://www.youtube.com/watch?v=EtPlL-L6OuY.

Another word processing software tool mentioned in the compilation is Scrivener:

http://euanlawson.com/scrivener-medical-writing/.

It is familiar among fiction writers, but could be an interesting resource for medical writers as well.

Spelling and consistency checks are standard activities when it comes to quality control. Again, software can help you. Unfortunately, spell-checking utilities that come with word processing software do not know too many pharmaceutical or medical terms. To overcome this, you can install

Stedman's spellchecker, which then replaces the original spellchecker of your word processing software:

http://lww.custhelp.com/app/answers/detail/a_id/5100.

By the way, Stedman's Medical Dictionary is one of the most trusted databases for medical terms and definitions. Look what it offers:

http://www.youtube.com/watch?v=GnQv2xc9lX4.

For consistency checks, you can use software like PerfectIt. It helps you to check for consistent hyphenation and capitalisation, for example:

http://www.copyediting.com/perfect-your-documents-consistency-tests.

The right referencing software might be a matter of taste, but choosing unsuitable software can cause you a lot of distress. EndNote[®] is well known, but in Mendeley[®] and Zotero you have alternatives with more or less the same basic package. Some differences exist and are worth considering:

http://www.libraries.psu.edu/psul/lls/choose_citation_mgr.html.

When you have finished your work you might wish to create a pdf to share, or you might need to edit your pdfs at some point. If you use Open Office, you can use its pdf-creating and -editing utility, which you need to install separately:

http://www.youtube.com/watch?v=wTkf2ciZzuM.

Foxit Reader[®] is a pdf reader with some typewriting and commenting functions:

http://www.youtube.com/watch?v=Tm5gi7dBB4I.

For further editing or optical character recognition, Foxit Phantom might be your choice:

http://www.youtube.com/watch?v=-HJKcTTIiRg.

Anyway, there are many alternatives to Adobe software.

Do you sometimes struggle to keep track of your projects? Maybe you could see whether planning software would help you. MindManager can be used for mind mapping:

http://www.youtube.com/watch?v=N8JhAMufFcY.

It can also be used for project planning:

http://www.youtube.com/watch?v=CkU7UbVccdQ.

Time-tracking software can help you organise yourself and manage your clients. TraxTime is worth a try:

http://www.spudcity.com/traxtime/.

As we near the end of this Webscout section, we are going to experience every medical writer's nightmare:

http://inkthinkerblog.com/2009/06/02/massive-computer-crash-simultaneous-backup-failure-writers-worst-nightmare/.

Backing up your work saves lives. Well, no it does not, but it saves your files and nerves! A well-recognised online back-up system is Carbonite:

http://www.youtube.com/watch?v=LH8sBDgnWyE.

See whether it could be the right choice for you. Another suitable solution is CrashPlan. Just watch this video to learn about it:

http://www.youtube.com/watch?v=OjtWYOhPATA.

Did this Webscout section help you or do you have any questions or suggestions? Please feel free to get in touch and share your thoughts.

Medical Communications

Section Editor:

Lisa Chamberlain James lisa@trilogywriting.com

Dear all,



I must admit to feeling very strongly about information that is written for patients – both about the quality and the appropriateness of the information itself, and about how it is communicated. Thankfully, this topic is now enjoying some

long overdue attention from the Regulatory Authorities and the Pharmaceutical Industry.

This has led to a plethora of research articles on communication strategies in healthcare, and one would imagine that the vocabulary used would be fairly crucial, and therefore the subject of intense discussion and research. However, as our contributor to this issue, Catherine Richards Golini, points out – very little is known about the influence of vocabulary in this area.

Catherine has taught English for 23 years, in the UK, France, Italy, and Switzerland. She specializes in English for Specific Purposes (ESP) and is currently at the *Scuola superiore medico tecnica* in

Locarno, Switzerland, where she teaches trainee medical radiographers and medical assistants. She is mid-way through an Applied Linguistics PhD at the University of Swansea, where she is investigating the nature of healthcare vocabulary and is also the co-founder of EALTHY, the European Association of Language Teachers for Healthcare. In her spare time (!), she is also a free-lance writer.

Catherine's article makes for fascinating reading, although its implications are slightly depressing. I can only hope that the research being lavished on the ROI of using higher quality communication is extended to some of the more basic concepts such as the vocabulary and its use.

In the meantime, enjoy the spring, and do feel free to send in your thoughts or comments – I am always happy to hear from you, and you may well end up in print!

Bestest, Lisa

How important is vocabulary in healthcare communication?

Healthcare communication is an increasingly important field of study – though it was certainly not always so. Much has changed from the days when medical schools failed to take communication seriously, let alone include the topic on the curriculum. Today, associations, organisations, journals, and specialist books proliferate; universities frequently have departments dedicated to the topic, and in 2010, there were more than 50 graduate schools in the USA alone offering a healthcare communication post-graduate degree.

In the light of this burgeoning interest in healthcare communication, then, it seems very odd that we know so very little about the nature of healthcare vocabulary.

A closer analysis reveals a couple of likely explanations for this peculiar absence: while research into communication has indeed mushroomed, the majority of the academic interest has come from the field of sociolinguistics, anthropology, or related fields – with much of the research concerned

with aspects of cross-cultural or intercultural communicative competence. Vocabulary seems to be of little interest in most of these studies.

Studies suggest that nurses and doctors use different communication styles and tend to use different proportions of vocabulary 'type'.^{1–5} Nurses, often described as 'communication brokers', are able to switch between more technical vocabulary and the general vocabulary of their patients. Doctors, on the other hand, seem to be less successful at switching, and they are also less aware of their communicative limitations. Put another way, doctors can have a distorted view of their communication skills.

We also know something about the difficulties that an ever-growing number of non-native-speaking (NNS) professionals have with English. Many NNSs struggle with the vocabulary: having enough and knowing what to use and when to use it being particular problems. In fact, vocabulary is consistently cited as the primary barrier to successful communication for NNS healthcare professionals. What is particularly interesting is that it is frequently the vocabulary needed to interact

socially that is lacking, and not necessarily the 'technical' vocabulary of the job.

Nor are vocabulary problems the preserve of the NNS. Studies from both sides of the Atlantic have shown that, unbeknown to the professionals treating them, native-speaking patients often fail to fully understand common terms. 1,6,7,8,9 Words that frequently cause problems include *fracture* and *break; sprain* and *sprained; tendon* and *ligament*. While it is the case that problems defining or explaining terms were magnified in those patients who had English as a second or other language, it cannot be assumed that native speakers fully understand the gravity or otherwise of their medical condition, even when apparently 'simple' terms are used.

There is a further imbalance in the literature when it comes to the type of medical profession that falls under the spotlight. As it currently stands, we know little about the communication styles or the vocabulary used by healthcare professionals other than doctors and nurses – and for many years even nurses failed to feature, a situation that was almost certainly a reflection of the traditional hierarchy in medicine.

For professionals involved in second language education for healthcare - course writers, course developers, and teachers - the lack of knowledge is compounded by (and results in) a lack of teaching for professionals. The commercial materials that do exist are generally aimed at medicine or nursing, pre- or post-training, and often show a disparate range of approaches and methodology. None seem to be focused on English as a lingua franca. This seems to be a curious omission, given the number of NNS professionals globally who use English to communicate with other NNSs. The vocabulary needs of a Filipino nurse in a British hospital are not always going to be the same as her Swiss counterpart in Geneva using English to communicate with a Turkish patient, or the Austrian doctor communicating with a Japanese tourist.

The ESP teacher is very often required to write a course from scratch or to adapt an existing course to suit the needs of her students. The vocabulary content of that course is vitally important.

Studies have consistently shown that vocabulary is the strongest predictor of success for language students. ¹⁰⁻¹⁴ The more words you know, the easier it becomes to acquire more, particularly through reading. The opposite is, sadly, also true. Coverage, i.e. the percentage of words a student needs to know in order to comfortably read a text, is estimated at between 95 and 98%. Put another

way, in a text of 1000 words the student needs to know between 950 and 980 words in order to understand the text without too many hours spent in the dictionary and to stand any chance of guessing the meanings of new words from the context. Too many unknown words can mean little or nothing is understood.

Luckily for the student, the first 2000 words in English should provide more than 85% coverage of most texts, including medical and other specialist texts. What this also means is that the students need to know the first 2000 words before they start to tackle the more complex technical and semi-technical items found in specialist English. In the past, it was assumed that students studying specialist English of any discipline were tertiary level students who had already achieved a reasonable level in the language. These days, for a variety of reasons (including the growth of medical tourism and consequent demand for English speakers and the seemingly unstoppable influence of English on the education systems), students can begin their ESP studies at secondary level with little more than basic competency in English. If students are lacking core vocabulary - the first 2000 words - it is essential that teachers tackle this deficit immediately before the so-called 'technical' vocabulary is introduced.

Medical and healthcare vocabulary has much in common with many other types of 'technical' English: it seems that there are different degrees of 'technical'. It is becoming increasingly apparent that two or even three categories of 'technical' exist, a fact which has significant implications for materials writers, teachers, and students.

Although the vast majority of studies to date have used research articles and academic and medical course-books as the source data – it seems reasonable to assume that the spoken data might reveal a different lexical picture – the information is nonetheless highly useful.

Thanks to the development of corpus linguistics it has become increasingly easy to analyse vast amounts of text, including websites, at the click of a mouse. Running a key word analysis, i.e. comparing the vocabulary in one text type with that of a different genre, can be of great help with teaching and materials development. Investigating word behaviour such as collocation and categorising words according to their degree of technicality is precisely the kind of research from the field of Applied Linguistics that helps us to understand more about the nature of specialist language.

The few studies that exist agree that medical and healthcare vocabulary can be categorised into various types: from the general and the non-specific, to the lay or the semi-technical, through to the fully technical. Lay or semi-technical vocabulary refers to the words that are related to the field of medicine but are likely to be known by the non-professional. Examples include *influenza*; *fracture*; *period*; *migraine*. As we have seen, however, the non-professional may not always fully understand the word. General and non-subject specific vocabulary is likely to be from the first 2000 words, while fully technical vocabulary contains those items that would be impenetrable for the non-professional – this is the category, incidentally, that is usually meant by the reference to 'medical English'.

Some researchers have added another category: hidden technical. These items are particularly interesting in that the students initially believe that they know the word but, in fact, the item in question possesses more than one technical meaning. An example of this is *protocol* which means one thing in IT, another in pharmacology, and yet another in business English.

Simon Fraser's work on technical vocabulary 17,18,19 suggests that not only is pharmacology particularly rich in hidden technical words, but also that the proportion of words that fall into the lexical categories referred to above are not consistent across disciplines. Fraser 17 found that anatomy text books had a greater proportion of fully technical words than did pharmacology textbooks, which in turn had more lay technical and more hidden technical items.

Polysemy is well-known to be a source of great difficulty for the language student and certainly knowledge of a word's multiple meanings is part of what it means to 'know' a word. The form/ meaning mapping, that is, the encoding and the subsequent assignment of meaning to a word, is just the tip of the iceberg - and sadly all too many teachers and students forget this. Collocation word partnership - is one aspect, as is connotation. Not all similar sounding or similar looking words are equivalent in either meaning or connotation across languages. Compassionate, for example, does not have a positive connotation for the Italian medical professional, suggesting an inability to keep emotions in check. The same is quite probably true of the word in other Romance languages.

A student also needs to be made aware of a word's morphology; its appearance in formulaic language, i.e. expressions and idioms; restrictions on its use – restrictions which may be a question of register and appropriacy or culture – and of course its pronunciation.

And just because a word exists does not mean it must be taught. A healthcare professional with a

Romance language as their mother tongue is already very familiar with a sizeable number of the fully technical terms he or she will meet during their English course. It seems to be a far better use of time to focus on the hidden technical terms and the semi- or lay technical terms, for these are the ones their patients are more likely to understand.

The dearth of research into ESP vocabulary and the current paucity of specialist healthcare English teaching material seems all the more surprising given what we know about the effect of poor vocabulary on healthcare communication, its role in the acquisition of a second language, and the difficulty involved in learning vocabulary for the student. Over 30 years ago, the Applied Linguist Paul Meara said that vocabulary was a neglected aspect of second language acquisition research;²⁰ I cannot help thinking that today, vocabulary has a new role as the neglected aspect of healthcare communication studies.

Catherine Richards Golini crichards.golini@gmail.com

References

- 1. Bourhis RY, Roth S, MacQueen G. Communication in the hospital setting: a survey of medical and everyday language use amongst patients, nurses and doctors. Soc Sci Med 1989;28(4):339–46.
- 2. Hydén L, Mishler EG. Language and medicine. Annu Rev Appl Linguist 2003;19:174–92.
- 3. Holmes J. How do nurses describe health care procedures? Analysing nurse patient interaction in a hospital. Aust J Adv Nurs 2008;25(4):58–70.
- 4. Holmes J, Major G. Janet Holmes and George Major. Communication on the wards: a pilot study. Language in the Workplace Occasional Papers No. 7 (March 2002), 2002;7(7).
- 5. Slade D, Scheeres H, Manidis M, Iedema R, Dunston R, Stein-Parbury J, *et al.* Emergency communication: the discursive challenges facing emergency clinicians and patients in hospital emergency departments. Discourse Commun 2008;2(3):271–98.
- 6. Azam N, Harrison M. Patients' perspectives on injuries. Emerg Med J 2011;28(7):601–3.
- 7. Bagley CHM, Hunter AR, Bacarese-Hamilton IA. Patients' misunderstanding of common orthopaedic terminology: the need for clarity. Ann R Coll Surg Engl 2011;93(5):401–4.
- 8. Dahm MR. Exploring perception and use of everyday language and medical terminology among international medical graduates in a medical ESP course in Australia. ESP 2011;30(3):186–97.
- 9. Lerner EB, Jehle DV, Janicke DM, Moscati RM. Medical communication: do our patients understand? Am J Emerg Med 2000;8(7):64–6.
- 10. Feldman K, Kinsella K. Narrowing the language gap in effective practice for adolescents with reading and literacy challenges. In Denti L, Gerin G editors. Effective pratices for adolescents with reading and literacy challenges. New York: Routledge; 2008, 3–24.

- 11. Folse KS. Vocabulary myths. Ann Arbor, MI: The University of Michigan Press; 2004.
- Hu M, Nation P. Unknown vocabulary density and reading comprehension. Reading Foreign Lang 2000; 13(1):403–430.
- 13. Kojic-Sabo I, Lightbown PM. Students' approaches to vocabulary learning and their relationship to success. Mod Lang J 1999;83:177–91.
- 14. Nation ISP. Learning vocabulary in another language. Cambridge: Cambridge University Press; 2001.
- 15. Wang J, Liang S, Ge G. Establishment of a medical academic word list. ESP 2008;27(4):442–58.
- 16. Chung TM, Nation P. Identifying Technical Vocabulary, *System* 32 2004;251–263.

- Fraser S. The lexical characteristics of specialized texts. In Bradford-Watts K, Ikeguchi C, Swanson M editors. JALT 2004 Conference Proceedings. Tokyo: JALT; 2005.
- 18. Fraser S. The nature and role of specialized vocabulary: what do ESP teachers and learners need to know? Hiroshima Stud Lang Educ 2006;9:63.
- 19. Fraser S. Breaking down the divisions between general, academic, and technical vocabulary: the establishment of a single, discipline-based word list for ESP learners. Hiroshima Stud Lang Lang Educ 2009;12:0151.
- 20. Meara P. Vocabulary Acquisition: a neglected acquisition. Lang Teach Linguist Abstr 1980;134:221-46.

In the Bookstores

Section Editors:

Alison McIntosh aagmedicalwriting@btinternet.com

Stephen Gilliver stephengilliver@gmail.com



Statistics: A Very Short Introduction by David J. Hand; Oxford University Press, 2008. ISBN: 978-0-19-923356-4. 7.99 GBP. 124 pages.



Epidemiology: A Very Short Introduction by Rodolfo Saracci; Oxford University Press, 2010. ISBN: 978-0-19-954333-5. 7.99 GBP. 145 pages.

Very short introductions to very big topics

To satisfy the inquisitive mind, Oxford University Press has since the year 2000 published books offering 'A Very Short Introduction' to a whole range of subjects. For example, 2013 saw the publication of introductory guides to, among other topics, happiness, food, fractals, Mao, medical law, the Napoleonic wars, and thought. Books in the series that may be of interest to medical writers include one on statistics and another on epidemiology.

Largely written in a readable, engaging style, *Statistics: A Very Short Introduction* introduces a subject the author considers to be 'at the heart of [...] most [...] aspects of human endeavour'. Rather than information of practical use, the focus is the philosophy of statistics; central tenets, concepts, and theories; and the evolving role of the statistician in what the author describes as 'a golden age' of statistics (the computing age). The book also provides a defence of statisticians, rejecting the suggestion that any lack of trust in statistics is their fault.

After an introductory first chapter that describes some of the applications of statistics in everyday life and that neatly illustrates the possible consequences of data collection errors using real examples, author David Hand next defines and explains some key terms (e.g. variable, median, standard deviation, and range). A laboured description of the mean and its calculation seems to assume that the reader lacks even basic knowledge of maths.

Subsequent chapters cover problems with data (incompleteness, errors), and how to minimise and

deal with them; and probability, including different forms of probability and probability distributions. Shortcomings include the term 'probability density' being used but not defined and a particularly opaque description of the Bernoulli distribution. Any reader who needed 'mean' defining for them may well struggle with the probability chapter (as the author himself pretty much acknowledges).

The fifth chapter ('Estimation and inference'), which covers point estimation, hypothesis testing, and decision theory, is also a bit of a slog. Relief comes in the next chapter in the form of introductions to different types of statistical models and their uses, including a clear explanation of the problem of overfitting.

Next to be introduced are some of the main statistical methods (regression, analysis of variance). Hand bombards his readers with new terms in a quick-fire manner, before rounding things off by briefly describing how computers have revolutionised statistics.

The second book, *Epidemiology: A Very Short Introduction*, is slightly longer and less well written. It covers all the areas you might expect it to, outlining the history and development of epidemiology before explaining prevalence, risk, incidence, and odds ratios, and describing how to calculate them. Again, the author (Rodolfo Saracci) assumes ignorance on the part of the reader, writing 'sugar' and 'of the lung' instead of glucose and pulmonary. One wonders how many of his potential readers do not know what glucose is.

As well as introducing core epidemiological study designs (e.g. cohort and case-control studies) and systematic reviews/meta-analysis, Saracci devotes a good few pages to the vexing problem of determining causality. While affording little in the way of detail, he also briefly introduces terms such as 'logistic regression' and 'Cox's regression', thereby providing a platform for further reading/research by the reader.

Unfortunately, his book has a number of flaws. Some of the example calculations are less than easy to follow and some figures are downright tricky to interpret. Several statements are tough to decode, and descriptions of polymorphism studies and genetic variation are unconvincing.

And, yet, there is no denying that the book offers some fascinating insights. I was most interested to

learn that monitoring patterns of Google searches for 'influenza' can detect outbreaks more quickly than traditional methods. Elsewhere, hot topics such as climate change get a mention, and a set of bullet points gives excellent guidance on when to trust health information on the Internet and in the media. Ethical issues such as data protection and genetic analysis of samples held in biobanks are highlighted. So too is the importance of epidemiology to clinical medicine and public health, and of socioeconomic status to health at the subpopulation level, with the author displaying commendable compassion and concern for disadvantaged populations. A generous 'Further reading' section finally directs anyone enthused by all this to textbooks, books of practical exercises, web resources, and intensive courses.

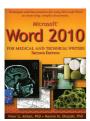
Both of these books seem to be aimed at people with high levels of intelligence or education, but

little or no knowledge of the subject of interest (or related subjects). Are they successful? Not entirely. While *Epidemiology...* arguably provides the more useful introduction, it also has the more obvious weaknesses. One weakness it shares with *Statistics...* is the lack of a glossary. This is a shame as glossaries can be an invaluable resource for newcomers to a particular subject. Happily, an excellent glossary of statistical terms may be found online.¹

Reviewed by Stephen Gilliver stephen.gilliver@med.lu.se

Reference

1. Department of Biostatistics, Vanderbilt University. Glossary of Statistical Terms [2012 Sep 16; cited 2013 Dec 13]. Available from: http://biostat.mc.vanderbilt.edu/wiki/pub/Main/ClinStat/glossary.pdf.



Microsoft Word 2010 for Medical and Technical Writers, Second Edition by Peter G Aitken and Maxine M Okazaki;

Piedmont Medical Writers, 2013. ISBN: 978-1-890586-24-9 (soft cover, spiral bound).

44.95 US\$. 200 pages.

Once upon a time vendors of computer software were more provident. My first version of Word® for Mac (MS Word 5) came with ample printed documentation, including a multi-page quick start guide and a separate, more detailed and, at that time for me, nearly forbidding volume of instructions. Although that manual skirted the issue of glitches inherent to the software and, perhaps only unintentionally, also many of its potentially befuddling intricacies and peculiarities, the instructions were adequate for my work. Nowadays, software at best comes on a CD, a tangibility that bolsters the sense of ownership, or it is sold on line for downloading, in either case leaving users little choice. Either one relies on the software's installed *Help* feature, which tends to be hard to navigate, feebly selfrevealing, and presumptuously incomplete, or one buys a third-party technical manual. Publishers of software have saved themselves the cost of printing and shipping, and they have shifted the responsibility of providing a decent user's manual to a specialised after-market niche of writers - wherefrom iPad 2 for Dummies, one example of technical titles that populate wide shelves in bookstores.

Like all serious professionals, we expect our tools to be well honed, smooth in operation, and unobtruding. Any tool that keeps reminding its users of its presence as an intermediary is a weak tool. We cannot avoid the learning curves needed for acquiring proficiency with the software we use. Yet, discovering bugs and omissions and inherent disabilities in various successive versions of Microsoft Word, most of us have been frustrated, lost faith, and finally have resigned ourselves to relying on systems that are imperfect or are not intuitively user-friendly. But our medical writing colleagues Peter Aitken and Maxine Okazaki were challenged to find ways to manipulate and outfox or neutralise those inbuilt shortcomings. They have girded themselves and put together and published Microsoft Word 2010 for Medical and Technical Writers (MSW'10MTW). The 'Second Edition' in its title refers to the fact that the volume succeeds the authors' similarly purposed book on MS Word 2003.

The authors provide the best capsule description of the book right on its cover: this is a book of 'Techniques and best practices for using Microsoft Word to create long, complex documents'. More than a tutorial, 'It summarizes the authors' extensive experience [over 50 years combined] with Word, presenting best practices, bug work-arounds, and proven techniques for using the program [...]'.

Even when applied to small documents, text-processing software can present writers and editors with challenges. The hurdles are multiplied and can become daunting when the length and complexity of the text to be treated increase (as in regulatory documents or books), or the same text is processed on different platforms. The primary utility of MSW'10MTW is as a travel guide to navigate the intricacies of a labyrinthine software – saving users of MS Word from time-consuming trial-and-error discoveries or, worse, from remaining oblivious to its labour saving features. Toolbar ('ribbon') preferences and options, styles, formatting, pagination, breaks, headers, footers and footnotes, fields, tables of contents, tables, templates, tracking: these are but some of the utilities and tricks of MS Word 2010 that are covered in adequate, albeit variable, depth in the book.

If not its dimensions $(21.5 \times 28 \text{ cm}^2, \text{ print version})$, then its spiral binding and soft cover make it easy to use. The font size and amount of white space generously host the reader and allow concepts to stand out. My own preference would have been for a serif typeface and justification of only the left margin - widely considered features that enhance readability, at least in print. Most ingratiating is the intimate and collegial tone of the authors' prose. Their advice is not something that is read in the book, but 'heard', as if a trusted sage friend or a relative is visiting and orally recounting experiences of one's life and sharing lessons learned from them. The book thus offers a most satisfying consultancy. What is further admirable, even enviable, is the dedication and stick-to-it-ness of the authors to ferret out and define potential problem areas, devise and test and re-test solutions, and gather all in a highly useful, though admittedly not comprehensive, guidebook. Revelations and advice abound. The more arcane material is presented in ample boxouts between expository and instructional main passages. For example: Eliminating a paragraph mark between two consecutive paragraphs will merge them as to style and format. Option settings are variably 'sticky', i.e. they may stamp all documents or just the one being worked on when the option is set. Though they are most useful, 'When used improperly [...] styles can make your life miserable'. To be able to see headers in Page Layout, the 'Show White Spaces Between Pages' option must be turned on. The list of insights that elicit an admiration-full 'Ah-ha' goes on and on. How to please clients who do not wish to have fields in the documents prepared for them... 'Keeping Table Rows from Breaking Across Pages'... 'Tables Within Tables' (!)... And one cautionary and admirably ingenuous boxout (slightly paraphrased): The authors advise against creating a template from a document created in any earlier version of Word, which seems to increase chances of future document problems, while confessing that they 'do not know of any way to tell which version of Word was used to create a document'.

I am not a geek, but I depend (perhaps more heavily than desirable) on digital devices and, therefore, the techies who keep them operational. A further limitation of this review requiring disclosure is that I use Macs only, and there are differences between MS Word for PCs (the focus of the book) and MS Word for Mac - though those may be slight. Wherefrom a disclaimer: I have not spent time specifically to check the accuracy of the directions the authors provide. Most of those I used worked for me on my Macs with minimal adjustments, many with none at all. There are differences (beyond the scope of this review to treat in detail) between basic, introductory level instruction manuals and advanced technical ones. MSW'10MTW occasionally seems to straddle the line between the two, but so too do most technical documents intended for 'advanced' users. A concept that is elementary to one reader may be considered complex and arcane by another less experienced. There is no question, however, that anyone who uses MS Word for work will have no trouble quickly recouping the purchase price of even the printed version of MSW'10MTW. It is sure to steepen the learning curve of using MS Word. Furthermore, engaging an IT technician for a one-onone consultation and resolution of a problem no doubt will cost more.

Living in times that complicate our lives and fragment our attentions by imposing on us a myriad of engagements and obligations, we crave instant gratification through instant mastery also of our tools. Yet, even if the ultimate, perfectly user-friendly version of Microsoft Word were possible, it would not be published in the near future. Change energises markets by stimulating consumption. Craftily timed, incremental releases of successive 'new and improved' versions of products boost profit margins. We can be certain that no *n*th version of Microsoft Word is going to be free of bugs or complexity. Harried users are going to continue needing help in the use of those future versions. One hopes that Peter Aitken and Maxine Okazaki will be there again to provide that guidance. They certainly are up to the task.

Reviewed by Jack Aslanian jaclanian@earthlink.net

You can explore the topic further by reading the article "Taming Microsoft Word" by PG Aitken and MM Okazaki on page 6 of this issue.

Manuscript Writing

Section Editor:

Phillip Leventhal pleventhal@4clinics.com

Manuscript Writing

A guideline for manuscript flow. Part 3 – The results

New medical writers and medical writing students are often unsure how to start writing a manuscript and need help in organizing their

thoughts. This is the third in a series of articles that explain how to link the sections and the information within them together, what I call 'manuscript flow'. The first two articles in this series covered the Introduction¹ and the Methods.²

Guidance from the ICMJE recommendations and the CONSORT statement

Manuscript content guidelines (e.g. CONSORT) and the ICMJE recommendations provide some guidance about the content of the Results section³ but little or no advice on how to organise the content. The journal's instructions for authors may also have some information on what to include, but they do not explain how to organise the flow of information.

The ICMJE guidelines state:⁴

Present your results in logical sequence in the text, tables, and figures, giving the main or most important findings first.

This is a bit vague, but putting the main or most important findings first is good advice. The ICMJE recommendations also state:

Do not repeat all the data in the tables or figures in the text; emphasize or summarize only the most important observations. Provide data on all primary and secondary outcomes identified in the Methods Section. Extra or supplementary materials and technical details can be placed in an appendix where they will be accessible but will not interrupt the flow of the text, or they can be published solely in the electronic version of the journal.

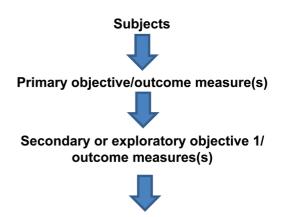
In addition, the CONSORT statement can be used to help guide the reporting of randomized clinical trials, although they can be adapted to other study designs. They require inclusion of the following information in the Results section:⁵

- Participant flow.
- Dates defining recruitment and follow-up.
- The demographic and clinical characteristics of each group.
- For each group, the number of participants included in each analysis and whether the analysis was by the originally assigned groups.
- For each primary and secondary outcome, the results for each group, and the estimated effect size and its precision, and for the binary outcomes, presentation of both the absolute and relative effect sizes is recommended.
- The results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing the pre-specified from the exploratory.
- Adverse events.

Although this does not give specific guidance on the logical flow, following the order of this list can help.

A general structure for the results

Described below and summarized in Figure 1 is a general structure that fulfils the requirements of complete reporting of the Results section for a



Further secondary or exploratory objectives/ outcome measures(s)

Figure 1: Summary of flow of the results.

69

clinical study, although this structure can be adapted to any type of study.

Start with a section describing the subjects

This section gives the reader an overview of the number and the characteristics of the subjects. Give the section a logical title, like 'Subjects' or 'Patients'. Begin the text of this section with a sentence describing how many subjects were included, when they were included, and how they were split up or randomized. Next, explain what happened to them and follow with a description of their baseline characteristics. If the study is complex, include a CONSORT flow diagram⁵ showing the flow of the subjects in the study, but if it is a simple study, the flow of the subjects can be summarised in the text. Below is an example:

A total of 2001 subjects were enrolled in the study (1001 in the XMD group and 1000 in the YMD group) between October 1, 2008 and March 26, 2009, and the study was completed on April 24, 2009. Ten subjects (6 in the XMD group and 4 in the YMD group) withdrew consent before receiving treatment. An additional 50 subjects (26 in the XMD group and 24 in the YMD group) did not complete the study, mostly due to loss to follow-up (Figure 1). Thus, 1941 subjects completed the study. In both groups, approximately 60% of the subjects were female, average age was approximately 41 years, most were White/Caucasian, and approximately 10% had previously been treated with corticosteroids (Table 1).

Follow with sections describing the primary outcome(s) and addressing the primary objective

The goal of the study and the main focus of the Results section should be to address the primary objective and therefore to present the primary outcome measure or measures. Present this information first. For example, if this is a study assessing the superiority of a vaccine compared with the current standard vaccine, start with the section on immunogenicity. Such a section might simply be entitled 'Immunogenicity'. Within the section, present the main analysis – in this case superiority analysis – first. Follow with additional related analysis, for example, presentation of antibody titres, cellular immune responses, and analysis of the factors

predicting immune responsiveness or lack of response.

Finish with the secondary or exploratory outcomes

The next section or sections should cover the secondary or exploratory objectives and outcome measures. Organise these sections into logical chunks, each with their own title. Within these secondary sections, as in that describing the primary outcomes, organise with the most important assessments first and follow with secondary information or more detailed or exploratory analyses.

For the example of a vaccine study, the next logical step might be to present safety information. This section could simply be called 'Safety' or 'Adverse events'. In such a section, the most important information might be expected or solicited reactions, such as injection-site swelling and itching. This might be followed by unsolicited adverse events and, finally, analyses of the risk factors for adverse events or solicited reactions.

A final note

Keep in mind that each method described in the Methods section should have results. It may help to organise the results in the same order as in the methods, namely, in the order of most to least important.

Phillip Leventhal pleventhal@4clinics.com

References

- 1. Leventhal PS. A guideline for manuscript flow. Part 1 the introduction. Med Writing 2013;22(1):59–60.
- 2. Leventhal PS. A guideline for manuscript flow. Part 1 the methods. Med Writing 2013;22(4):306–8.
- 3. Leventhal PS. Guidelines for manuscript writing: here to help. Med Writing 2012;21(2):164–8.
- 4. International Committee of Medical Journal Editors. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals: Publishing and Editorial Issues Related to Publication in Medical Journals: Preparing a Manuscript for Submission to a Medical Journal. [Accessed 2013 Dec 6]. Available from: http://www.icmje.org/manuscript_a.html.
- Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c869.

Out On Our Own

Section Editors:

Sam Hamilton sam@samhamiltonmwservices.co.uk

Kathryn White Kathryn@cathean.co.uk



Editorial

Welcome to the first edition of Out On Our Own (OOOO) for 2014. OOOO is packed with something for everyone! For the tech-savvy, Jane Tricker ends her excellent series on social media for freelancers, with a look at its potential role

in training and ongoing educational and professional development. With social media and other online networks providing platforms for sourcing and recruitment of contractors, Martina Reiter explores the concept of freelancing networks in selected northern European countries. Meanwhile, Alistair Reeves and Susanne Geercken begin a new series that will explore language resources, starting with the basic language resources for medical writers that they consider their personal 'best friends'!

We are always interested to hear what our freelance colleagues get up to in their spare time. Gina Dungworth, a qualified veterinarian, provides an insight into the diverse range of blogs and articles she produces when not authoring healthcare documents.

Freelancing can be a solitary occupation, so it is heartening to hear of initiatives and organisations that make us feel part of a group – to know that we are not alone in the challenges we face. This issue we welcome John Brazier, who many of you will have heard speak at the Freelance Business Forum (FBF) in Manchester in May 2013. John is actively involved in promoting the 'voice of the freelancer' through his involvement in organisations across Europe such as PCG and EFIP in the UK. In this, his first article of a new series, he describes the 'power of the collective voice'.

May is nearly upon us, and we look forward to seeing you at the FBF in Budapest on Thursday 15 May 2014 from 17.15 to 18.45. This is a fantastic opportunity for you to meet up with friends and colleagues, to share ideas and ask questions within a supportive environment.

Kathryn White Kathryn@cathean.co.uk Sam Hamilton

sam@samhamiltonmwservices.co.uk

A writer's 'best friends' – Recommended language resources for (medical) writers – The basics

Medical writers, like everybody else, carefully choose their 'best friends'. Best friends are tried and tested, reliable and trustworthy companions who are there to help when we need them most.

In this article, Susanne Geercken and Alistair Reeves will introduce you to their 'best friends' – their favourite writing resources. The recommendations in this article provide resources that help with the basics of writing texts in English. Forthcoming contributions will include other aspects and other types of resource. Ideally, this series will develop into a platform for exchanging culture and language-related resources. You are encouraged to send in contributions, sharing your 'writer's best friends' with the audience.

So here is Susanne's personal 'writer's best friend' toolkit:

1. A Grammar of Present-Day English¹

For some of you, grammar books spark unpleasant memories of boring grammar lessons back at school. So for you, they may feel like enemies rather than friends. But where do you turn for help if you are unsure about how to put 'I used to' into the negative (is there a negative form at all and if so, is it 'I did not use to' or 'I did not used to'), how to shift the emphasis in your sentence, where to put the adverb, or whether to choose the simple or progressive past?

'A Grammar of Present-Day English' will help you in these situations. While there are other, more sophisticated and comprehensive grammar books on my bookshelf, for my day-to-day writing problems, I prefer to consult this unassuming book written for advanced students of English. Readers who struggle with grammatical terms will particularly appreciate

this book thanks to its clear structure and many examples. It is probably best suited to non-native speakers of English, and I should mention that some examples are given in English and German, since the book was originally written for a German audience. While Germans may benefit most, to my mind, it is also very well suited to non-Germans.

2. The BBI Dictionary of English Word Combinations²

This book is an invaluable resource providing information on the correct use of collocations in everyday English. The dictionary not only covers typical combinations of noun + verb, noun + adjective, adjective + adverb, and verb + adverb but also gives phrasal verbs and lists verbs with their corresponding prepositions, with examples given for everything. In addition, it contains a number of idioms.

(Alistair: This is also one of my 'best friends'!)

3. Practical English Usage³

This book is a compilation of typical problem areas for non-native speakers who need to write (and speak) in English. The book is organised as a reference book, listing entries in alphabetical order across a wide range of subject areas. Hence, you will find rather brief entries on single words like 'control' (with the text pointing to the risk of misusing the word as a 'false friend') or 'presently' (explaining the different meaning of the word in British vs. American English) alongside longer entries dedicated to a more detailed analysis of subjects like 'articles', 'adverbs', or 'countable and uncountable nouns'. While the structure takes some getting used to, I recommend this book because it offers valuable, easy to find answers to typical problems for authors writing in English.

The next two suggestions are in a way 'collectibles' because they have, very regrettably, gone out of print. Like any valuable vintage item, they are, however, available second hand and are included here for your benefit:

4. Collins Cobuild English Language Dictionary⁴

While reference books like Merriam-Webster's are nowadays easily accessible on the Internet (http://www.merriam-webster.com), non-native speakers of English, in particular, may appreciate an English dictionary that offers enhanced information on usage. 'Collins Cobuild English Language Dictionary' is a (monolingual) dictionary deliberately focusing on real usage of ordinary everyday English. The book is the result of a language research project conducted at the

University of Birmingham. Every entry features an array of well-chosen examples, catering to the particular needs for context information of non-native speakers of English. Special feature boxes give structured, more indepth information: Have you ever wondered whether it is correct to write '12 a.m.' for 'noon' in English even though a.m. = ante meridiem' means 'before noon'? Collins Cobuild has the answer. Under the TIME special entry, you will find all the varieties of expressing time in English, including '12 a.m.' The dictionary also explains basic grammatical concepts in simple language so that it can be used as a basic all-in-one dictionary-cum-grammar book. To fully appreciate the wealth of linguistic information covered in this book, users are advised to carefully read the introduction which gives background information on the history, intent, and set-up of the dictionary.

5. The Synonym Finder⁵

I recommend this thesaurus for the sheer abundance of synonyms it offers – it claims to offer one million synonyms! I love this thesaurus as a rich source of inspiration for more varied and creative writing. The book is best suited to users who have a good command of English vocabulary and style, and native speakers, because the synonyms listed for the most part do not come with comments or explanations.

And now some of Alistair's best friends:

6. Oxford A-Z of Grammar and Punctuation⁶

This little book is €7.50 (or so) well spent. It is not a tome and will easily fit into a jacket pocket or handbag. It has a short, simple, but comprehensive introduction to English grammar and the structure of the language. The rest of the book is alphabetically arranged according to keywords with descriptions and lots of examples, including incorrect examples where appropriate. It has explanatory figures where helpful - for example, to illustrate different levels of grammar (sentence, clause, phrase, and word) or types, forms, and sentence position of adjectives. The entries are copiously cross-referenced so there is no repetition. In fact, the amount of information packed into these 192 pages is astonishing. My copy is well thumbed, as I often check definitions, concepts, and finer points, and it accompanies me on my travels. This is the ideal pocket grammar book for the non-linguist who needs clear advice unclouded by grammar gobbledygook.

7. Oxford Guide to Plain English (formerly the Plain English Guide)⁷

Another €7.50 or so well spent, 'The Plain English Guide' has been giving excellent advice for decades

and should be on every writer's bookshelf. It has an excellent section on 'Writing tight' with lots of examples of striking out useless words (one of the most rewarding activities when editing texts). It explodes some myths about English, including 'Never end a sentence with a preposition'. It includes a reference list of 'Plain English words' in its section on 'Use words your readers are likely to understand'. Unlike many books on good writing and style guides, the author, Martin Cutts, even has the courage to defend the use of the passive voice! Mr Cutts has also fortunately ditched the general recommendation in earlier editions that bullet points should end with a semi-colon (a messy business as far as I am concerned) and now provides much broader advice on putting together cogent bulleted lists (semicolons are now restricted to bulleted lists in legal documents). The latest edition also includes a short section on 'Clarity for the Web'.

The Plain English Campaign offers great resources on its website, but more of that in future editions.

8. Troublesome Words⁸

Bill Bryson's 'Troublesome Words' is every bit as good a read as his other books. And even though it is put together as an alphabetised reference work, it is perfectly possible to read it through like a novel and learn while you do so. He manages to point out a huge number of common errors in modern English, ranging from spelling to usage, without descending into nit-picking, and spends considerable time discussing difficult areas, such as the use of who and whom, subject and number of verb agreement ('The police is ..., The police are ...') and puts us straight on useless devices (e.g. fragmentary quotes), rampant wordiness, and words that are often confused. This book is more of a complement to more basic works, but is certainly worth getting to know.

9. The Careful Writer⁹

Issued more than 50 years ago and on my shelf for more than 30 years, this 'best friend' has given me sound advice on language in many situations and has often given me the confidence to defend my own opinion when it didn't seem to comply with a 'rule'. It is a scholarly work, but a 'fun read'. Would you like to read a balanced argument for and against 'different than'? Or how about how to decide whether words ending in 'ics' are singular or plural? And what about the placement of 'only' and 'not' in sentences? And much, much more. Google Books says it all: (http://books.google.de/books/about/The_Careful_Writer.html?id=qYd35

MUlSm4C&redir_esc=y): 'The Careful Writer is a concise yet thorough handbook, covering in more than 2,000 alphabetized entries the problems that give (or should give) writers pause before they set words to paper. It is perhaps the liveliest and most entertaining reference work for writers of our time – delighting while it instructs and amusing even as it scolds and cajoles the reader into skilful, persuasive, and vivid writing. The Careful Writer, Mr. Bernstein's major work on usage, is an indispensible desk reference, and a perennial source of continuing reading pleasure.'

10. Collins 'Cobuild English Guides' 10

Any of the Collins 'Cobuild English Guides' by this assiduous language publisher. Look them up on the Internet. Just enter 'Collins Cobuild English Guides' into your search engine; one is displayed in Amazon, and the others are listed below under other books people bought. Unfortunately, a couple of them are out of print (notably 'Linking words', a very useful one, but a few second hand versions are out there), and some are not cheap. They offer comprehensive, pragmatic advice on all aspects of using English for all writers, whether native speakers of English or not.

Finally, a word of warning about one 'false friend' for medical writers

You may hear medical writers praise 'The Elements of Style' (often referred to as 'Strunk and White¹⁰), a style guide with 'grammar' advice published in the USA more than 50 years ago that is widely regarded as a standard work in the USA. Geoffrey Pullum, Professor of General Linguistics at the University of Edinburgh and one of the world's leading grammarians, heavily criticised this work when its 50th Anniversary Edition was published a few years ago. 11 This prompted Alistair to support his opinion in an article in 'The Write Stuff'. 12 Let it suffice to say at this point that, as well as poor advice and a couple of glaring errors, it contains much basic advice that is not appropriate to scientific, technical, and medical writers, but rather to those involved in creative writing.

Some of the printed works given above are included in a boxed list of language and style resources for writers (without comments) that appeared in 'The Write Stuff'. This is also worth consulting.

References

- Ungerer F, Meier GE, Schäfer K, Lechler SB. A grammar of present-day English. Stuttgart: Klett; 2009.
- 2. Sinclair J. Cobuild English language dictionary. Stuttgart: Klett; 2002.

- 3. Rodale JI, Urdang L, LaRoche N. The synonym finder. New York: Grand Central Publishing; 2001.
- Benson M, Benson E, Ilson R. The BBI dictionary of English word combinations. Amsterdam/ Philadelphia: John Benjamins Publishing Company; 1997
- 5. Swan M. Practical English usage. Oxford: Oxford University Press; 2005.
- 6. Seely J. Oxford A-Z of grammar and punctuation. Oxford: Oxford University Press; 2013.
- 7. Cutts M. Oxford guide to plain English. Oxford: Oxford University Press; 2013.
- 8. Bryson B. Troublesome words. London: Penguin;
- Bernstein T. The careful writer. New York: Simon and Shuster (Free Press); 1995.

- 10. Strunk W. The elements of style. Massachusetts: Allyn & Bacon; 2000.
- Pullum, GK. 50 Years of Stupid Grammar Advice. 2009 April 17 [Accessed 2013 Nov 11]. The Chronicle of Higher Education [Internet]. Available from: http:// chronicle.com/article/50-Years-of-Stupid-Grammar/ 25497.
- 12. Reeves A. Braving the elements. TWS 2009;18(2): 89-92
- 13. Anon. TWS 2009;18(2);89.

Susanne Geercken susanne.geercken@pfizer.com Alistair Reeves a.reeves@ascribe.de

Online freelance networks in the DACH region – Real job opportunities or just waste of time?

Online freelance networks in the DACH region

Nowadays, membership of an online social or business network (e.g. Facebook, LinkedIn) is part of daily business life. These networks can help to find new business relationships and generate business opportunities. Online networks are also a good platform to promote services and skills and keep in touch with existing contacts. Members can join groups with different topics to share information or find contacts and job offers.¹

In addition, specific online freelance networks exist (e.g. freelance.de, freelancermap.de) which are similar to job boards but with a clear focus on freelance job positions. Companies post their job offers and freelancers register their profile and skills.^{2–7} Online freelance networks exist for international and regional projects, focusing on popular freelance business areas such as IT, web management, consulting, sales, media, and communication.

First impressions may suggest that these networks don't contain serious job offers. Ghostwriting and low-budget content writing requests are abundant, while there is serious competition from medical writers based in India, Asia or Arabic countries who can work for a lower hourly rate compared with European counterparts, especially in international networks. Regional and country-specific networks may provide better offers with the possibility to contact the client directly. So, this raises the question of whether these networks offer real job opportunities or are they just waste of time when searching for serious business prospects?

In this article I present information about existing, regional online freelancer networks in Germany,

Austria, and Switzerland (DACH), with the aim of giving an overview about the structure, membership options, job opportunities and related costs of online freelancer networks (Table 1).

Conclusion

The majority of freelancer networks within the DACH region exist in Germany and are mainly focussed on IT and web-related projects. Competition for medical writing positions is limited, but only because there a low number of medical writers found in the databases. Job offers are often for web content writing within all kind of categories, e.g. IT, automotive, finance, and many more. However, occasionally, interesting offers for medical writers can be found although few are for permanent positions or with good payments.

References

- 1. Benson V, Filippaios F, Morgan S. Online social networks: changing the face of business education and career planning. Int J e-Business Manage 2010;4(1):20–33.
- Freelancermap IT-Projekte für Freelancer, Selbständige und Freiberufler. Available from: https://www.freelan cermap.de/
- Freelancer, Freiberufler und Projekte Aufträge für Freiberufler bei Freelance.de. Available from: https:// www.freelance.de/
- 4. Projektwerk medical Healthcare Projekte Honorararzt Profile Jobbörse Gesundheitswesen. 2013 projektwerk GmbH. Available from: https://medical.projektwerk.com/de/
- 5. Textbroker. 2012 Sario Marketing GmbH. Available from: http://www.textbroker.de/
- Freelancer-Österreich.at Kostenlos Freelancer/ Freiberufler finden. Available from: http://www.free lancer-oesterreich.at/impressum
- 7. Servish.com Die Crowdsourcing Platform. 2010. Available from: http://www.servish.ch/

Table 1: Overview of existing online freelance networks in the DACH region

Network (users)	Location	Category focus	Categories for MW	Memberships	Costs €	How it works
Freelancer map (50 000)	Nuernberg, Germany ²	12 categories: focus on software development, web, telecommunication, IT consulting, SAP	'Graphic, content and media'	Basic, premium	14.99 (monthly)–6.49 (2 years)	Within the basic membership, freelancers register their profile and can view available projects free-of-charge. Only the premium package enables members to apply for jobs or read messages from clients, and is available for a monthly fee with various discounts on offer, for example, for incursors or continues.
Freelance (65 400)	Munich, Germany ³	11 categories: focus on IT, engineers, management, marketing, sales	'Languages, education, training, social', 'medicine, health care, health', 'research, development, science'	Basic, expert	9.90 (monthly)	for insurance or software. A basic membership enables freelancers to register, generate a profile and make 10 job submissions per day. In addition, an automatic search can be generated which sends one report per day, containing jobs fitting their profile. Expert membership gives unlimited access to projects and information about any visitors to a freelancer's profile.
Projektwerk	Hamburg, Germany⁴	6 categories: medical, consulting, creative, engineering, fashion, IT	Medical	Basic, starter, premium	monthly)	As a basic and starter member, you can register your profile for free but you are limited to a single profile, although projects of potential interest are accessible. Companies can only contact you if you are a starter or a premium member, for which a monthly fee is charged. Offered positions are mainly permanent.
Textbroker	Mainz, Germany ⁵	Ca. 80 different categories	Product descriptions, translation, science	Basic	0.7 to 4 cent/ word	Clients can post their requests for texts, while freelance 'authors' register and apply for the posted jobs. A ranking system based on a scale of 2 to 5 stars exists for authors. New members can only apply for jobs in the 3-star category. When an author has finalised a text for the client, the client and textbroker team give their feedback, which may enable the author to gain more stars and therefore apply for more jobs. The majority of job offers are from IT companies looking for authors to write short online pieces (200 to 400 words) which is why payment is low (2 to 4€ per article). Direct client requests generate higher income.
Freiberufler- oesterreich		21 categories	Language, text, trainer	Basic	2 hours of author's fee	Registration and project searches are free of charge but there is no possibility to see job offers. For a fee, the network will contact freelancers when profiles match a project.
Servish	Altdorf, Switzerland ⁷	5 categories: focus on science and technology	Science and technology, communication and media	Basic	5% of 'author's' salary	

Martina Reiter

Medwriting, Munich, Germany martina.reiter@medwriting.de

The power of the collective voice

A poignant reminder of the challenges of freelancing – Claudia Frumento's winning idea for EMWA's Out On Our Own logo is a figure juggling four Os.

'I think that is the way I feel quite often as a freelance medical writer,' she said. 'Having to do everything simultaneously: writing, accounting, acquiring new clients, IT support, travel, etc. But honestly, I would never want to go back to work for a company... I enjoy being my own boss and the more I practise the better I juggle'.

She's not alone – freelancers are the fastest growing group in the EU labour market. In fact, a quarter of the European workforce engaged in professional, scientific, and technical fields is made up of freelancers, also known as independent professionals, or iPros.

The figures come from an in-depth study concluded in 2013 by Professor Patricia Leighton under the directive of the European Forum of Independent Professionals (EFIP).¹ The study reveals that the 'growth in iPros in the EU since 2004 has been remarkable. Numbers have increased by 45% from just under 6.2 million to 8.9 million in 2013, making them the fastest growing group in the EU labour market'.

Recognised by clients, but not by government

The importance of iPro working is increasingly being recognised across Europe as more and more businesses understand that freelancers help them to remain flexible, agile, and innovative in a competitive market.

However, Professor Leighton also noted a common thread running through the interviews she conducted with 40 freelancers across nine EU states: 'the iPros interviewed did express a sense of being treated with suspicion or being marginalised, especially by fiscal and other authorities'.

The report concludes: 'Despite their growing economic significance, not much is known about iPros, the way they work and the barriers they face. They are virtually invisible in academic literature as they are generally subsumed in employer, entrepreneurship or SME (small and medium-sized enterprise) data'.

The research found that 'iPros want autonomy and freedom, and yet to be effective they need more support from governmental and regulatory bodies'. Often what they get is exactly the opposite: unnecessary bureaucracy and policies that actually

thwart the dynamism of the sector. One example is the tax legislation, IR35,² in the UK, which has seen an unacceptable number of freelancers hauled up before a judge to prove they were genuinely self-employed.

Stepping out of the shadows

A powerful way for freelancers to solve the 'invisibility' problem is to act in unison.

When IR35 was introduced by Tony Blair's Government in 1999, a group of UK-based freelancers joined forces to form their own trade association, the Professional Contractors Group. The purpose was to provide the missing link between the freelance community and policy makers, so that harmful policies could be prevented from becoming law in future. The idea captured people's imagination and spread rapidly – several thousand freelancers joined in the first few months.

Today the association is known as PCG, the voice of freelancing. With around 21 000 members from diverse freelance disciplines, PCG has become an active and influential voice in government and industry, creating the stimulus needed for freelancers, and their clients, to thrive and prosper.

PCG is also co-founder of EFIP (European Forum of Independent Professionals), a pan-European group working closely with the European Parliament to ensure that independent working is respected as a legitimate alternative to employment. Since its inception, EFIP has called for recognition of independent professionals as a vital force for the EU economy and for independents to be specifically considered by policy makers.

EFIP's membership is composed of a number of national associations representing the needs of free-lancers, including FediPro in Belgium, Aprotrad and FedAe in France, VGSD in Germany, ACTA and ANITI in Italy, PZO in the Netherlands, and PCG in the UK.

By joining any one of these associations, freelancers help to define their sector, highlight their economic value, and pave the way for more sophisticated regulation and government support.

A more systematic approach to freelancing

Another key role that professional associations play is in pooling the collective intelligence of the community to help members develop their businesses in a more active and coherent way. Professor Leighton's research found that many iPros do not have a systematic approach to many work related issues. For example, they typically gain work in informal ways and few have marketing plans or a strategy for accessing work.

A freelance business has to be managed just like any other business. An effective freelance medical writer needs to be fluent not just in science, but also in marketing, tax, finance, project management, and business administration.

The associations acting under the EFIP umbrella offer a wide range of support services to help their members develop better systems. For example PCG provides members with free tax and legal advice, tax investigation support, compensation for loss of earnings, contract paperwork, and guidance on growing the business.

They also provide opportunities for collaborative networking, which emerged as a key recommendation from the Leighton report. Freelancers stand to gain a great deal from interacting with others, rather than working in complete isolation – hence the importance of EMWA's Freelance Business Forum and the regional events organised by the EFIP associations. Sharing best practice, whether with colleagues from the medical sector or with freelancers from completely different fields, is a valuable way to take your business to the next level.

In future articles we will be exploring best practice in areas such as accounting, drawing up contracts with clients, key tax policies, and legal issues to be aware of.

John Brazier is President of EFIP and Director of European and International Affairs at PCG, the voice of freelancing. You can email him at john.brazier@pcg.org.uk

Association	Country	Website
FediPro: representing iPros from every discipline	Belgium	http://www.ipros.be
Aprotrad: representing translators and interpreters	France	http://www.aprotrad.org
FedAe: representing auto-entrepreneurs from every discipline	France	http://www.federation- auto-entrepreneur.fr
VGSD: representing self-employed persons, freelancers and small businesses with typically less than ten employees	Germany	http://www.vgsd.de
ACTA: representing autonomous workers from every discipline	Italy	http://www.actainrete.it
ANITI: representing translators and interpreters	Italy	http://www.aniti.it
PZO: a representative body for freelancers, organised as a collective of networks focusing on specific professions	Netherlands	http://www.pzo-zzp.nl
PCG: representing independent professionals from every discipline	UK	http://www.pcg.org.uk

References

- 1. Leighton P. Future working: the rise of Europe's independent professionals. 2013. Available from: http://www.pcg.org.uk/freelance-sector-research
- 2. For more information on IR35, please see http://www.pcg.org.uk/ir35

John Brazier

PCG, London, UK john.brazier@pcg.org.uk

The social web is your oyster

Networking and business development – the subjects of my first two articles for *Out On Our Own* – are perhaps obvious uses of social media for freelancers. In this article I want to focus on what was initially an added bonus for me, but which has since become an essential part of my business – namely the opportunities afforded for training and education.

The risk of losing touch with developments in our industry – and the industries that it serves – is a very real one for freelancers.

Just in terms of regulation, in the last 6 months of 2013 we saw the enactment of the Sunshine Act in the USA,¹ an update to the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals,² and

revisions to the Declaration of Helsinki³ and the International Committee of Medical Journal Editors' (ICMJE's) *Uniform Requirements for Manuscripts* (now rather less snappily called *Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals*).⁴

The increasing trend to digital communications with healthcare professionals and patients (either alongside or instead of print), and the ability to use different media and channels for delivering them, should challenge our perceptions about writing and presenting information for these groups. This is not restricted to marketing communications – online journals are commonplace; sales of ebooks are outstripping hard copy; and online crowdsourcing strategies are being trialled

for clinical study recruitment and for solutions to tricky clinical research questions.

More broadly, the ability of wearable devices to collect data on an individual's activity and vital signs and to transmit these data to a collection point (part of a phenomenon called the Internet of Things [IoT]) has the potential to transform how doctors interact with their patients.

How did I acquire the information in the paragraphs above? Mostly through Twitter $^{\text{\tiny B}}$, LinkedIn $^{\text{\tiny B}}$, and Google+ $^{\text{\tiny B}}$.

I follow organisations that are instrumental in drawing up regulatory guidelines; organisations whose members are directly affected by them (such as EMWA, the International Society for Medical Publication Professionals [ISMPP], Network Pharma and individual medical communications and PR agencies, and the UK National Health Service); news organisations (both general and pharma, and science- and technology-specific), leading journals (Nature, the British Medical Journal [BMJ], the Lancet, New England Journal of Medicine [NEJM], Biomed Central, and the Public Library of Science [PLoS]); and individuals whose knowledge and opinions I have come to appreciate and trust.

Of course, organisations publish relevant information on their websites for you to find, and individuals may have websites and/or blogs. Although some of these sites have rss (rich site summary) feeds that deliver information in regular emails, for me using social media simplifies this process by bringing all of the information to me and much, much faster. Moreover, in Twitter, information on specific topics or events can be aggregated through the use of hashtags, or I can create lists of people that I know comment on particular topics, which essentially allows me to file information on that topic in one place.

In addition to keeping up to date with events and changes in the medical writing world (and beyond) social media outlets have also helped me to use this information in my day-to-day work.

Discussions in some of the LinkedIn groups to which I belong have been invaluable in helping me to see all sides of the debate on transparency between the pharmaceutical industry, medical writing professionals, and healthcare professionals and have played a key role in my decision to take the CMPPTM qualification.

The PM Society (of which I became aware through Twitter) and the International Society for Medical Publications Professionals (ISMPP) run regular interactive webinars on topics of interest and importance to medical writers. It is possible to return to

the webinar later if the timing of the event is inconvenient (although you lose the opportunity to participate, of course).

My understanding of writing for digital publications and interacting with healthcare professionals and the general public through social media have been enhanced by attending physical workshops and lectures organised by the leaders of other LinkedIn groups that I belong to and in #hcsm-led 'Tweet-ups'. (A 'Tweet-up' is a meeting held on Twitter. The subject, time, duration, and hashtag for the meeting are agreed beforehand. Participants Tweet their viewpoints and pose/answer questions to/from other participants. By including the hashtag in the Tweet, participants ensure that everyone can see the entire conversation.).

Up to now I have concentrated on how others posting on social media benefits me. By definition, though, social media channels are interactive: I can respond to what I am reading by sharing it (rapidly) with my contacts/followers or by commenting on it and sharing my comments – to share my knowledge and to demonstrate to potential clients that I am making an effort to keep up to date with changes and issues affecting our industry.

Afterword

In my series of articles about how I use social media in my business I hope to have encouraged a few more of you to try it for yourselves. I do sincerely believe that freelancers have much to gain from fully engaging with social media and much to lose by ignoring it. You can find links to my social media accounts on my website – come join me!

References

- Centers for Medicare and Medicaid Services. Medicare, Medicaid, Children's Health Insurance Programs; transparency reports and reporting of physician ownership or investment interests. Fed Reg 2013;78(27): 9458–527.
- 2. Available at: http://www.farmindustria.it/pubblico/efpia-hcp-code.pdf [accessed 16 Nov 2013].
- World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. J Am Med Assoc 2013; doi:10.1001/jama.2013.281053.
- ICMJE. Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals [accessed 16 Nov 2013]. Available from: http:// www.icmje.org/icmje-recommendations.pdf.

Jane Tricker

Elmcroft Editorial Services Ltd, Maidstone, Kent, UK jane@freelancemedicalwriting.co.uk

Tool Box

What was 'app' in Barcelona?

At the 1995 World Conference on Educational Multimedia and Hypermedia in Graz, Austria, the following paper abstract was submitted by a fresh graduate computer scientist who later became my spouse:

'This paper presents the idea of a [system] which supports scientific conferences in novel ways. In accordance with the usual course of organizing a conference, we show how a modern distributed wide-scale system ... can improve, accelerate and advance conference issues like ... invitation, submission of contributions and registration ..., and the undertaking of the actual event, as well as post-event matters. Critical problems are discussed, technical solutions are proposed and an outlook over further developments is given.'

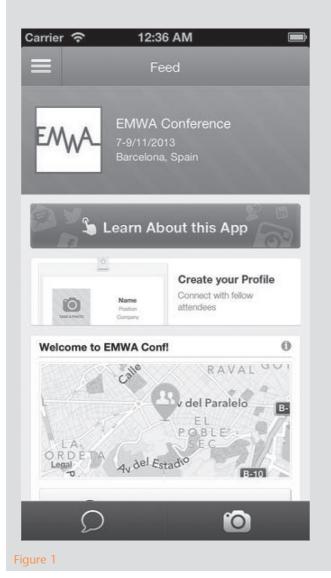
The idea of organising a conference over the world-wide web was so novel at the time that the orally presented paper based on this abstract won the Best Paper Award at the said conference.

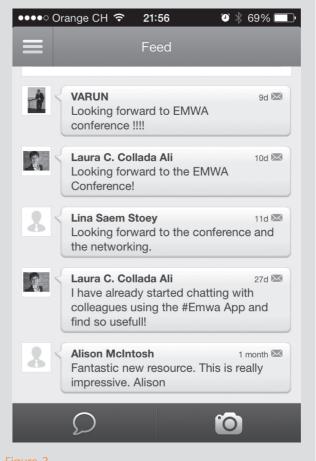
Let's fast forward to 2013 in Barcelona, Spain. The idea presented in that paper has long become a taken-for-granted reality. I am pretty sure everyone registered for the 37th EMWA conference online.

But we had something new in Barcelona - the EMWA conference app (see Figure 1)! As part of the 'know before you go' initiative, the app was announced 27 days before the start of the conference. A total of 120 people downloaded the app and it was accessed 1688 times from launch time till the end of the conference.

In addition to providing all necessary conference information (schedule, workshop leaders, exhibitors, etc.), the app's cool features included a virtual badge, news feeds, and chatting (see Figure 2).

I checked with a few delegates and the feedback I got ranged from 'wow' to 'it's about time', indicating the users were generally 'appy' with this resource.





rigure 2

The initiative was fully supported by the EMWA Executive Committee and the app development was implemented at a reasonable price at www.attendify.com.

A big thanks to EMWA PR Officer and social media expert Laura Collada Ali, who, between translation assignments and tweets, kept the social component of the app going with photos and news feeds.

But even though the Barcelona meeting is over, the EMWA app is here to stay. The app contents will be updated well in time for the next conference(s) but you can use it anytime. I am still using it and so can you. Try sending me a message right now by clicking on the speech bubble.

Don't have it yet? You can access the application in the App StoreTM and Google PlayTM using the keyword EMWA or by clicking on these links:

iPhone: https://itunes.apple.com/us/app/emwaconference/id722893143?l=ru&ls=1&mt=8

Android: https://play.google.com/store/apps/details?id=com.kitapps.android.builder.emwaconference

From any internet browser: http://conference.emwa.org

Back to the 1995 paper, it moved on to propose activities even outside the conference itself, including 'scientific exchange and communication' (networking!) and 'social and non-scientific matters' (social programme!), and concluded that the system was intended to facilitate only and not replace face-to-face meeting. 'We still consider conferences in their current form as essential and do not try to replace the personal contact as well as the verbal, direct communication between researchers.'

We completely agree. The EMWA app is a great resource to use before, during, and after the EMWA conferences. But nothing beats being at the conference itself! See you/app you in Budapest!

Reference

1. Maurer H, Schneider A. 1995. Conferencing: doing it the hypermedia way. Educational Multimedia and Hypermedia -Annual-; 436-441 Ed Media '95. Avaialble from: https://getinfo.de/app/Conferencing-Doing-it-the-hypermedia-way/id/BLCP%3ACN013519738.

Raquel Billiones

Clinipace Worldwide, (Volketswil) Zurich, Switzerland rbilliones@clinipace.com

Freelance foraging

Maybe we should all adopt the Aussie approach to non-imminent deadlines! This flight departures information board in Cairns International Airport photographed in August 2013 shows us the way.

