

## Out on our own

We decided to ask freelance colleagues we work with to give us their angle on working with medical writers, and to ask them what is good about it and where we might improve things. In this edition, in line with its theme, Peter Wilkinson, a freelance statistician in the UK, tells us about how he became a freelancer and his experience of working together with medical writers. I am happy to say that we come off very well!

Even so, take note of what Peter has to say about ‘must-haves’ and ‘nice-to-haves’ with regard to what every medical writer ought to be able to understand about statistics (see box). The unfortunate thing is that salaried employees often enjoy good training opportunities on what Peter mentions, and freelance colleagues often have to pay dearly for this type of training, although obviously, a great deal can be learned during our daily work. We have a couple of very successful EMWA workshops on statistics, but I’m not sure they cover all the ‘must-haves’, so maybe our statistics workshop leaders can look out for this. Some day we’ll get our own back and ask a medical writer colleague to tell us what they think statisticians should know about medical writing!

Elaine O’Prey tells us about a typical week—but because she doesn’t have a typical week, she tells us about one of

the more exciting—if exhausting—weeks in her life as a freelance medical writer working on a daily newsletter at a conference. Sounds like the sort of thing that would make a great change from endless regulatory writing—how do you come by contracts like this Elaine?

After the Ljubljana meeting, we held our first Freelance User Group Meeting in June. The main topics were how to make savings at conferences, the setting up of a Freelance Support Centre on the website and a freelance discussion forum ‘outside’ the website. Some of the suggestions for savings at conferences have already been realised, and Helen Baldwin explains in this issue that things cannot be made cheaper in general, but that various cuts have been made and that sponsorship efforts have been intensified. Work has already started on the Freelance Support Centre on the website—thanks to Ingrid Edsman and Neil Fisher for volunteering for this. And work has also started on the Discussion Forum—thanks to Debbie Jordan.

We look forward to seeing you at the Freelance Business Forum in Frankfurt on Friday 13 November at 17:30.

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## Have you ever met a statistician and wondered how they got that way?

by Peter Wilkinson

### Introduction

All answers are intended to be factually accurate if not necessarily relevant. It is left to the reader (it would be good to meet you) to decide which answers are the serious ones.

### How did I become a statistician?

Probably a more relevant question is ‘Why’, rather than ‘How’. I suspect that medical writers may regard us statisticians as being something of a species apart, an anomalous accident of humanity. This view is summed up by Tom Lehrer, who asked “Have you ever met a mathematician and wondered how he got that way?” I usually choose to ignore such comments, based on the following reviews:

“Mr Lehrer’s muse is not fettered by such inhibiting factors as taste.”—New York Times

“More desperate than amusing”—New York Herald Tribune

“He seldom has any point to make except obvious ones”—Christian Science Monitor

When I attended my first PSI (Statisticians in the Pharmaceutical Industry) meeting there was an especially fascinating debate taking place about the abstract beauty of numbers, and my attention wandered round the room. I noted that out of perhaps sixty medical statisticians present there were only eight (including myself) without beards! Chivalry prevents me mentioning how many of the fairer sex were there! There is nothing wrong with beards, as long as they are intentional, but it was a little alarming to realise that I had become part of this rather strange group (medical statisticians, not the fairer sex).

My own history involved spending three years in that upper class holiday camp in the fen country, otherwise known as Cambridge University. Following this was Imperial College (London) to learn the more practical aspects of statistics. After a few years as a bean counter (statistician for HJ Heinz, rather than an accountant), I moved into medi-

## How statisticians get that way

➤ cal statistics, working for a couple of large pharmaceutical companies for a number of years.

### Why did I become a freelancer?

Some aspects of corporate life seemed uninspiring, for example the departmental meeting every Monday where most agenda items involved detailed justification of why no progress had been made since the previous Monday! My favourite corporate moment was when senior management realised that the company had become bogged down by bureaucracy—the solution (obvious really): create an anti-bureaucracy committee! Naturally this was populated by managers whose roles in vital projects might be described as ‘sub-prime’. The committee met monthly and generated (you’re possibly ahead of me) huge quantities of pointless questionnaires and bureaucracy. It was axed after 6 months.

Becoming a freelancer provided the opportunity to practice what I preached and be involved in much more varied, interesting and purposeful work. A few years later I expanded into data handling in addition to the statistical consultancy.

### Was it easy to become a freelancer?

The initial switch to freelance was a little daunting. The PC (computer, as well as political correctness) was much less widely used, and home working was not nearly so well established. Ditching a regular salary in favour of an irregular income which only appeared between one and four months after the completion of a project took a little nerve. However I was fortunate in that I managed to acquire work from former colleagues. Without this it would have been much more difficult to get started.

### Why are there so few freelance statisticians?

I was slightly mystified by this question. There are quite a few freelance statisticians around, but many of them are tied in to specific companies, and some specialise in pre-clinical work. Quite a few freelance statisticians are associated with academia, and some who advertise themselves as freelance statisticians are, I suspect, academics seeking to redistribute perceived pharmaceutical wealth in their direction. Many of the academic statisticians I have met are excellent from a theoretical and technical viewpoint, but the GCP and regulatory requirements of the majority of industry studies can range between boring and incomprehensible to those who have not worked in the industry.

### Have you been able to specialise as a freelancer, or have you had to widen your spectrum of activities as a freelancer?

As a freelancer there is a much wider variety of work, in different indications, and using different statistical techniques. Often freelance statisticians perform analyses which have been prespecified by another statistician, and are sometimes unfamiliar, but still have to be learnt. New techniques thus spread in a viral manner through the statistical community! Although I originally specialised in phase III and IV studies, I am now equally at home with all

study phases, and only occasionally have the excitement of a study in an indication which is totally new to me.

### Is it easier if you market yourself as a specialist in, say PK/ADME, than just an ‘allround’ statistician?

I have never really marketed myself at all. I have always been lucky enough to find work through personal recommendation. However my company (Wilkinson Associates), which now also carries out data handling, has a website, which I suppose counts as marketing.

### Do you always work in the pharmaceutical area?

Yes—that’s what I’m best at, although I have also worked on a number of appliance studies, also a few herbal and veterinary studies. I also get involved in more strategic areas such as the design of clinical research programs and representing companies at meetings with regulatory bodies.

### How much do you write, and what sort of documents usually?

“In the beginning was the (written) word”—it was a major part of the job as statistician to write a stand-alone statistical report, but in 1995, the ICH report was born and the stand-alone statistical report withered and is dying, but is not sadly missed, as far as I know. Most statisticians’ writing is now mainly limited to specifically statistical areas such as protocol statistical sections, SAPs, and statistical sections for clinical study reports. So the writing of large documents has largely gone out of the life of most statisticians. This is obviously to the benefit of the younger statistician, who was like, sort of, really really relieved, you know, like.

In a conversation with a medical director of Chinese descent who had recently returned from the USA, I asked if he knew why so many US medical statisticians were Chinese. His answer was that Chinese Americans with a poor grasp of English often selected statistics as a career because good English was not required in the job! Earlier in the year I had ‘enjoyed’ a transatlantic phone call on a bad line to a Chinese American statistician with ‘challenged’ English and a very strong deep south accent. I don’t think I would agree that good English is not required!

### Do you like writing?

I learnt scientific writing the hard way. Writing a report which satisfied a statistical director (with a PhD in nit-picking) and also an old-school medical director at the same time was about as easy as sewing buttons on a custard! To some extent this experience is now wasted for a statistician, and almost certainly a lost art as far as young statisticians are concerned. Yes, I do miss the writing, however aspects I don’t miss are:

- Inconsistent review comments
- Review comments that are simply wrong!
- Seemingly endless reviews
- Dealing with the clinical study report appendices

## How statisticians get that way

**What can statisticians learn from medical writers?**

I can answer this in two words: “How to write” (apologies for the outdated George Bush joke). In particular the ability to communicate clearly about specialist topics to a relatively non-specialist target reader.

Another thing which medical writers bring to the statistical party is an objective and more arm’s-length view of study results. This aspect can be difficult to achieve for a statistician closely involved in a study. The medical writer can often see the overall study results more clearly, and can better highlight the most important aspects.

**What are the best ways for freelance medical writers to get adequate training on statistics?**

I am often asked this. Sadly I can’t help much—many statisticians I meet aren’t especially good at explaining their subject to the uninitiated. A notable exception was the fantastic Ken McRae, Professor of Medical Statistics, who would bring the subject to life, with a style and humour reminiscent of Billy Connolly. I always referred people to Ken’s courses, which very sadly had to end when in 2002 I was asked to take over a series of lectures because Ken had just tragically died.

There are statistical courses that teach participants how to perform some significance tests. These are not going to be helpful to medical writers, who need to work with statistical output and the statistician, rather than perform the tests themselves. I’m sure that there are some good statistical courses—if anyone has been on one please let me know so I can pass on the information.

**Are the medical writers you work with well-informed enough about statistical issues?**

The experienced medical writers I have worked with are usually very well informed about statistics—I suppose that they have to be, in the same way that football commentators have to be well informed about football. A great skill for a medical writer seems to be to know which statistical areas require understanding in more detail, and which are best left to a statistician.

**Where are the main deficits?**

The worst examples of the misuse of statistics I see are in some medical journals, usually journals with no statistical review. Practices range from the simply annoying via the downright misleading to totally inappropriate statistical analyses. However, I am sure that the usual perpetrators of such practices are our medical brethren, rather than medical writers!

**What is your experience of interacting with medical writers?**

On the basis that this question relates to the work environment I can honestly say that the experience has been almost

uniformly excellent. My only unfortunate experience was with the Medical Writer from Hell who appeared to hold me personally responsible for every word completed on the CRF. If any CRF wording or even clinical outcome was inconvenient then the CRF had to be changed! With this one notable exception, I always feel empathy with medical writers. We are both working to a common goal along the same timelines with the clinical study report as the ultimate end product.

**Do companies expect to get ‘double-value’ from you by expecting you to write as well perform the evaluations?**

I have never had such a problem—but I try to make it clear up front exactly what I will provide. I do offer medical writing as an additional service to clients, but I would not normally carry this out myself—the work would be done by a specialist medical writer.

**In conclusion**

The above represents some distinctly personal views based on my own experiences. I would be very interested to receive any feedback, however abusive!

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**Basic statistical concepts that every medical writer should understand**

<b>‘Must-haves’:</b>	<b>‘Nice-to-haves’:</b>
Meaning of statistical significance	Basics of Kaplan-Meier estimations
Difference between statistical and clinical significance	Basics of survival analysis
95% confidence intervals	Basics of multiple comparisons
Why significance testing is inappropriate for baseline data	Basics of interim analyses
Why changes should be related to a pre-treatment baseline	The relationship between parametric and non-parametric tests
Why changes from a post-treatment baseline are statistically invalid	Medical review comments on statistical issues in manuscripts may not be backed up by any statistical understanding *
When correlation coefficients should be used (as little as possible!)*	
The relative merits of means and medians	
The scientific value of a publication is not proportional to the number of p-values it contains*	
All summary statistics such as means, standard deviations, standard errors and in particular error bars must be clearly labelled. It is pointless having an error bar which no one can interpret.	

\*These apply much more to our medical brethren than to medical writers