



## My second year in business: Update on freelance medical writing activities, October 2007 - September 2008

by Sam Hamilton

It feels as if I have barely started out and simultaneously that I have been doing it for ever—I feel born to it! I am of course talking about freelancing. In previous issues of *The Write Stuff* (TWS), you heard about my journey to freelance medical writing and my first year in business. As I embark on my third year, I take stock of and share with you an account of my second year in business. Exciting projects, returning and new clients and the holiday time I wanted (more or less) have melded into an addictive mix I absolutely love!

### Months 13 -15

#### October- December 2007

By October, it was becoming apparent that the large protocol writing project managed by my friend Helen in the US, was at the very least likely to slide significantly. Helen in particular had spent a great deal of time bidding, securing the contract and assembling her transatlantic team to execute the 47-strong protocol library project for a major American pharmaceutical client. Processes were in place and we wrote, quality controlled and submitted a grand total of ...one protocol in Q3 2007. We received great feedback, but Helen then began to hear whispers of changed priorities, possible mid-term project deferral and later, company redundancies. After maintaining dialogue with the client for several months, it slowly became clear that this huge project had simply 'gone away'. My strategy to continue to source other work throughout had left me unaffected, but Helen learned a salutary lesson. It took her several months to bring new avenues of work to fruition, but I am delighted to report that she is working at full capacity once again.

Another friend of mine took early retirement from her very successful regulatory affairs consultancy, and she was kind enough to recommend my services to some of her clients. As a result, new work came in the form of a virology protocol re-write for a niche German regulatory affairs consultancy. This was followed by an Investigator Brochure review and update of the clinical sections for the same client.

Having been accepted in quarter 3 2007 by EMWA's Education and Professional Development Committee (EPDC) as a workshop leader for an advanced EMWA course entitled 'Scheduling and Proposal Writing: The

Clinical Study Protocol and Report', I honed the materials to pretty much the final package by Christmas 2007. I just had to hope that there would be room for my workshop in the May 2008 Barcelona programme. I expected a final decision after the Christmas holidays.

It was my great pleasure to work on a project which Alistair put me forward for with one of his French clients who required clinical-regulatory writing expertise on a virological project. This project was to run and run over a period of 6 months, as it evolved and was extended. The developing document was of strategic and commercial value to the company globally, and for me this represented an interesting twist on the usual angle of writing pure regulatory documents. The material really was cutting edge and the writing was highly rewarding given my background as a post-doctoral virologist. The client was a delight to work with which always helps as new challenges arise and as scope evolves.

We spent the children's October half-term break on a week's family adventure holiday in Jordan. We swam in the Dead Sea; visited Petra and rode on donkeys up the precipitous steps to the monastery; camped in the spectacular rock and sand desert of Wadi Rum out under the stars; took a desert jeep safari; rode camels; visited the biblical city of Jerash and finished at the Red Sea where we snorkelled—Aanya (6 years) and Cameron (9 years) for the first time!

More specialist virology work appeared after our holiday from a different quarter as I began to develop a relationship with a London-based specialist Contract Research Organisation (CRO) which had sprung out of a renowned university academic group responsible originally conducting Investigator-led clinical trials. My initial brief was to assist the developing group with documentary and template requirements for specific virological protocols. After developing the first template, I went on to write an actual protocol they were contracted to design and conduct for their client. What a luxury to populate my own template! The deliverable was happily free from those annoying template-associated glitches one frequently encounters but cannot explain or solve!

Christmas holidays were looming as I tried to balance work and put in an appearance at all the delightful seasonal school events which, for Paul and I, help make parenting of primary school age kids so much fun. In the week before the holidays, I was somewhat run ragged through attending events, nights out and long hours at work to complete as much as I could before year end. However, hard work paid off and I enjoyed the full two-week holiday with my family.

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## &gt;&gt;&gt; My second year in business...

**Months 16-18***January – March 2008*

The New Year brought the good news that my workshop would have its first airing at the Barcelona meeting.

A second virology protocol from the London-based CRO followed hot on the heels of the first. Almost before I had completed this, the group approached me about writing a whole raft of manuscripts on legacy projects for submission to peer-review journals. There were a few interesting virological topic areas and together with their Head of Intellectual Property, Research and Development, and I began to work out a strategy and timelines for manuscript writing going forward. I prepared the first draft manuscript and advised on publication strategy for another. Preparing all the manuscripts would likely be an evolving medium-term undertaking.

I was approached by a friend and fellow freelancer, Iain Colquhoun, to help out with updating the Summary of Product Characteristics (SmPCs) for a range of well-known established-use medicines, in line with the January 2007 paediatric regulation. I worked on two of these Expert Statements and found the work made a refreshing change and was very enjoyable, not least because of working alongside my friend.

My first quarter seemed incredibly short given that we had another holiday planned towards Easter which was earlier than usual this year. We had decided to visit Paul's sister and her Australian husband in Sydney and planned to incorporate a 4-day stopover in Bangkok. After much self-wrangling, we decided to take the children out of school for a week to enable us to have almost a month away. It turned out to be a great decision as the kids learned so much on their travels that missing a week of school ultimately seemed neither here nor there. Family time was peppered with some real adventures, the best of which was hang-gliding over the spectacular coastline south of Sydney. The hero of the moment was our son, Cameron, who had the best ride of the day, soaring like a bird and whooping for joy as he and pilot Curt landed effortlessly (and upright) on the golden sand below Bald Hill.

**Months 19-21***April – June 2008*

I returned to see that the project with my French client had developed and I was contracted to write further sections of their strategic global dossier. I felt that I was really getting to grips with their economic and business perspective. My final material was submitted in June just ahead of product launch. What had felt like a huge challenge initially had turned out to be a marvellous personal development and learning opportunity.

I was really looking forward to the May 2008 EMWA meeting in Barcelona as I had decided to become a little more involved than in previous years. As well as delivering my own (under assessment) workshop, which, incidentally, was made substantive by the EPDC, I observed another

'under assessment' workshop and fed back comments. Alistair and I hosted freelance lunch tables (which was probably a bridge too far given my pre- and post-lunch activities that day) and the Freelance Forum as usual. I also volunteered to guest edit a forthcoming issue of *TWS* which would come out just ahead of the regulatory themed Ljubljana May 2009 conference. It seemed sensible to make the theme for that issue 'lesser known regulatory issues' or similar. I knew this was a major undertaking but, encouraged by Elise, I felt ready for the challenge. The social side was great fun as always, with time to catch up with friends and make new ones. I met up with an old friend whom I had not seen for many years since we were both in project management together. A medic by profession, she had since soared to Head of Pharmacovigilance for a major Spanish Pharma company, but we found we still had plenty in common and were able to pick up where we left off ten years previously. I rounded off the conference by promising Julia that I would think about her kind invitation to join the President's Sub-Committee and the Ljubljana Content Organising Sub-Committee.

On returning home, more work arrived at (very) short notice from my London-based client who required help with protocol synopsis development and subsequent protocol writing. I project-managed my client and their client teams and over a few short and very packed weeks, and delivered the goods in time for a very tightly scheduled Independent Ethics Committee (IEC) meeting.

***The work seemed, at last, to be finding me, despite my not actually noticing this transition!***

Recalling the lessons from Helen's experience, I was aware that I had written quite a lot of material for this single client during the past couple of quarters, and reminded myself to spread my net wide enough so that overall business would not suffer should any one or two particular clients go quiet for a period. As I was now building up my clientele, I felt I was at least heading in the right direction and a reminder from my husband Paul that I had not actually undertaken any formal business development activities since last November 2007 settled me again. The work seemed, at last, to be finding me, despite my not actually noticing this transition!

I took up Julia's offer and we had the first teleconferences for both committees.

I sounded out a friend and previous client team member, Tracy Farrow, Medical Writing Manager for ClinTec International, to assess her interest in co-developing an EMWA workshop with me. Both Steven de Looze and I felt there was scope for a workshop on Standard Operating Procedures (SOPs) in the programme, and I knew of Tracy's expertise in this area. Happily, Tracy agreed and we worked hard to compile and submit all our draft materials before our planned summer holidays. We then worked with our mentor and finalised all documentation by mid July. The new foundation workshop entitled 'SOPs:

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Processes and authoring' together with my scheduling and proposal writing workshop were both scheduled in to the November 2008 London conference programme.

I paid my first corporation tax at the end of June. In the UK, start-up businesses are given an 18-month tax holiday. That is to say that one does not pay any tax until 18 months have elapsed from the first day of trading. I had been steadily collecting the tax in a high interest internet account throughout the year, so I was able to make the payment painlessly.

I had been contracted to write a clinical study report (CSR) for one of my northern England-based clients and planned to write the shell report after my holiday. However, it seemed that my client's client wanted to see a shell sooner than I had time to write it, in order to comply with their board members' wishes. I advised my client to seek alternative resource if she needed to whilst I was away, but I decided to take the laptop on holiday with me, in any case, to keep abreast of developments.

### Months 22-24

#### July – end September 2008

I am slightly embarrassed to say that as the children broke up from school for the summer, we once again set off on our travels, this time to Biarritz in southern France, via Amsterdam and Paris. We took the car ferry enabling us to take our 'gear' with us. 'Gear' is Paul's loose term for bikes, canoes, life jackets, boogie boards and wet suits! We did actually have great fun using it all, and on returning home, I finally gave in to his request for a new garage to house it all in. Building work started and stalled annoyingly throughout the rest of the summer and was completed towards October.

Incidentally, my idea of monitoring progress by checking emails whilst on holiday was not one I will be repeating! Suffice to say that I was pleased my mobile broadband provider had the good sense to email me when £50 of credit was expended—and that was the cost of one email session!

I had a rather more intense return to work than I had planned for after our return from France as the shell deliverable was required within a week of my return, and my client had not been able to find anyone else willing to write it over the summer. I remembered how little I enjoy weekend working as my children became urchins for a few days. I met the shell deliverable deadline and took a look at the draft patient data listings as soon as they became available. Within a short time, it became clear that the database was not entirely clean, or even approaching it. The statistician and I broke the news to the client that further work would be required to bring it up to the required standard. As a result, the reporting timeline began to stretch out.

That actually helped as another protocol synopsis management and protocol development project landed from the London-based group. That too stalled after the first review of the synopsis. This break enabled me to prepare the shell of another CSR for my northern England client whose project above had stalled. For once I felt ahead of myself, but only momentarily.

***I remembered how little I enjoy weekend working as my children became urchins for a few days.***

I now had time to chase up potential contributors for the issue of *TWS* which I was guest-editing for March 2009. I would need sufficient time to review and edit articles and write the editorial coming up to Christmas 2008

in order to meet the publisher's deadline. As some article topics naturally fitted in with the theme of the Ljubljana conference, a couple of contributors were approached by me and my fellow members of the Ljubljana Content Organising Sub-Committee to speak. The sub-committee was by now meeting monthly by teleconference and conference content was developing nicely.

I was invited to partner with a resource management group who were expanding from specialist placement into clinical project services. I had a productive meeting with the Group Operations Director and we agreed to move forward together. My first brief was to help with proposal writing for a large phase IV project they were bidding for and also to help craft their website text. Should the bid be successful, the reporting responsibility would be mine. Medium term goals such as my project managing their SOP writing and joining them as needed at bid defence meetings, were also discussed. I felt this was a potentially exciting partnership with an amiable group of people who seemed to share many of my own ideals.

Unbelievably, it was time to gather together documentation for my second year accounts.

#### Closing thoughts...

I feel privileged to have had such a happy and successful year. Freelancing is everything I hoped it could be and more. I love my work, work hard and sleep like a baby at night, probably because I feel a greater degree of control than when I was employed. I have so far managed to take as much time off as family commitments require—and for my lot, that isn't inconsiderable! I look forward to the year ahead and writing with new-found clarity in my uncluttered space, which is now mercifully free from 'gear'!

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