



PIPA Training Programme: Analysis And Evaluation Of Clinical Information

Wednesday 23 To Thursday 24 May 2007

Summary

The first day of this course comprised of two sessions, Statistics in Clinical Trials and Clinical Trial Design and Reporting. Both were presented by Adrian Parrott, Joint Managing Director of PharmaSchool. Adrian is an expert in this area and was able to present ideas and concepts in a number of different ways, ensuring that the sessions were informative, easy to understand and dare I say it, fun!

The second day of the course given by Andrew Robson and Paul B Woods was split into two sections; evidence based medicine and promotional data evaluation.

Day 1 - Statistics in Clinical Trials & Clinical Trial Design and Reporting

By: Ben Poole, Scientific & Medical Information Advisor, Servier Laboratories Ltd

Statistics In Clinical Trials - Dull Hypothesis Rejected

Adrian Parrott, Joint Managing Director, PharmaSchool, presented. He is a well respected trainer and consultant in the area of clinical trial project management.

The word statistics never fails to send a shiver down my spine and I was somewhat apprehensive about spending half-a-day focusing on the statistics used in clinical trials. This is because I have always found that the topic of statistics can be a real minefield of concepts, which are very difficult to grasp.

Therefore I was pleasantly surprised and somewhat relieved by the good-humoured and light-hearted approach taken during this session. We even managed to take

advantage of the good weather. Once outside the group were sorted in order of their car engine size and then further divided according to petrol or diesel engine. This, the first of several interactive exercises was really effective in allowing the group to visualise basic statistical concepts such as mean, mode, median and confidence intervals.

Half-a-day is nowhere near long enough to cover such a huge topic. So it was decided to focus on some of the key issues and questions raised by the group, rather than wading through the fairly comprehensive slide set. This avoided getting bogged down in the many complexities of the methods of statistical analysis.

I am now much more confident when it comes to critically appraising clinical



Ben Poole



Beatrice Omisakin

trial data, as I now have a much better understanding some of the jargon and also the tricks of the trade used in clinical trial data analysis.

This session gave a really practical overview of the statistics used in clinical trials, demonstrating that statistics are the foundation of clinical trial design.

One valuable lesson to remember; just because something is statistically significant it doesn't necessarily mean it is clinically significant!

Clinical Trial Design And Reporting – No Longer A Headache

The second session of the day was spent discussing the components of clinical trial design and was very much a natural progression of the morning session.

A comprehensive overview of the essentials of clinical trial design was presented and discussed. These included:

- the starting point, purpose or reason for doing the trial
- clearly defined objectives, and are they met?
- types of trial design
- endpoints, primary versus secondary
- types of comparison
- patient Selection
- sources of bias in clinical trials
- results, how they are presented and what they mean.

Once the relevant terminology and concepts of trial design had been explained it was back to the sunshine, where we were split into small groups and were given the task of designing a clinical trial for a new product for the treatment of migraine. Fortunately, this didn't prove to be too much of a headache.

Working in groups allowed us not only to share our knowledge and experience but also to consolidate what we had learnt throughout the day. An element of friendly competition was introduced, as each team had to report back on their proposed MIGNOMORE clinical trial program to be judged by Adrian. As part of the winning team, I am sad to say there were no prizes

...it was really interesting to see how each team had interpreted the challenge differently...

involved. However, it was really interesting to see how each team had interpreted the challenge differently to arrive at several diverse solutions to the same problem.

The final topic of discussion was that of publications and journals, quickly followed by a wrap up session summarising the day's proceedings.

All in all the day went very quickly and whilst I can't profess to now know everything about clinical trial statistics and design, I do have a much better understanding of the key points to consider when reviewing clinical papers. Therefore I would not hesitate in recommending this course as a good starting point for anyone

interested in learning the basics concerning the use of statistics in clinical trials and clinical trial design.

Day 2:

By: Beatrice Omisakin, Senior Medical Information Pharmacist, Bristol-Myers Squibb Pharmaceuticals

When you consider the fact that hot summers in the UK are now becoming a rare and endangered occurrence, I and the other assorted delegates were lucky enough to be greeted with heat and sunshine on day 2 of the PIPA training course. After a recap of the previous day by Greg Barnes and Bukky Ayoade (the PIPA course co-ordinators) and an injection of strong coffee, day 2 was underway.

The second day of the course was split into two sections; evidence based medicine and promotional data evaluation.

Evidence-based Medicine: Andrew Robson

Andrew Robson is an independent consultant in information management with in-depth experience in the pharmaceutical industry and knowledge of the ABPI Code of Practice. He delivered the first half of the course by way of a presentation and workshop.

Evidence-based medicine (EBM) has become one of the major driving forces in the NHS, with an impact on education, policy making and research. It was therefore of direct interest and relevance to all of us.

Andrew explained the aims, the importance and the necessity of EBM. He placed

Andrew delivered a very pertinent and enthused presentation on EBM

particular emphasis on the National Institute of Health and Clinical Excellence, (NICE), as an example of EBM in use today at the highest level of healthcare. After a run through of the steps in EBM and an explanation on the hierarchy of evidence, critical appraisal of clinical trials was then covered.

The interactive session gave us a chance to use our brains. Sitting outside in the



sun did not distract us (well not too much) from developing a checklist for appraising clinical papers.

This was a useful exercise that helped us put a practical application to much of what we had just learnt. We then used that checklist to evaluate a clinical paper and present our findings to the team. My learning's from this part of the course were how to fully assess the quality of a clinical paper and to look a little deeper when considering whether or not a publication has fulfilled its brief.

Getting the measure of a clinical paper is a matter of asking the right questions. A brief overview of points to consider is given below:

- who wrote the paper? Are they affiliated to any company or group?
- was the objective clear?
- was the question clearly defined and answered?
- what method was used to evaluate the results and was it appropriate
- are the conclusions balanced, accurate and fair?

Take each section (study design, methods, results etc.) of a paper and consider whether it will stand up to the questions you ask.



Andrew delivered a very pertinent and enthused presentation on EBM. There are several publications and websites that aid with EBM, and critical analysis of clinical papers. It is worth looking into them for further guidance on something we routinely do in our jobs as information specialists.

Promotional Data Evaluation: Paul B Woods

Paul Woods is Global Compliance Policy and Assurance Director for AstraZeneca, so he was aptly well placed to deliver the last part of the course. He covered the do's and don'ts of promotional advertising with some highly colourful examples of adverts. We were shown some of the earliest unrestricted adverts for products such as "snake oil (will cure every disease known to man... and even some that aren't)" to the most recent adverts that have elicited complaints, to highlight the need for regulation and self regulation.

The copy review process was also covered to show that effective communication and advanced planning will build alignment between teams and produce successful promotional campaigns.

Some phrases you do not want hear on the copy review process, from the aspect of a reviewer and a producer of promotional material (courtesy of Paul Woods):



There was some emphasis on the importance of inter-company dialogue in the updated procedure.

Reviewers

"If we get caught we can always withdraw it..."

"It's not my fault – it's the agency..."

"I didn't think it needed to be approved..."

"I'm not sure when I can review this document..."

Producers

"I just don't like it, so I haven't approved it"



"I didn't spot the problem at draft stage (sorry!)"

"I won't be able to look at it for about a week"

The key to a good and timely review is preparation, keeping communication lines open, and managing expectations around the data.

Advertising controls globally, regionally and locally were reviewed, but focus was on the MHRA blue guide and the all too familiar ABPI code of practice. The complaints procedure was also discussed and highlighted by real cases that were presented to the Prescription Medicines Code of Practice Authority (PMCPA). There was some emphasis on the importance of inter-company dialogue in the updated procedure.

The interactive half of this section saw the team split into four groups, each representing a pharmaceutical company, making or defending a complaint regarding a piece of controversial promotional material. The cases were actual complaints that were presented to the PMCPA.

This was a situation that was familiar to most delegates, myself included, who often have input into building a case for complaint or defending a complaint.

The arguments made by each team were extremely detailed and precise, with good



reasoning for or against the claims based on the materials given. The presentations were delivered with some element of hilarity (intentional or unintentional); however the finale was a 'democratic' vote on whether the claims were in breach of the code based on the presentations. We were then given the verdict from the PMCPA and more often than not the group decision mimicked the outcome, although there were some surprises!

Paul delivered a very instructive presentation and stimulating workshop. The key learning from this session was to know the limitations and potential of any reference source used to formulate a claim, also to make sure the claim itself does not go beyond the scope of the reference source or what is realistically achievable by the product.

On the whole, day 2 was highly informative and well planned. The course co-ordinators and presenters injected the right level of enthusiasm, motivation and more importantly fun! I have recommended this course to my colleagues as a must for further development as information scientists.

Let's hope that the weather will also be as good next year! (But I wouldn't bet on it.)

Reference:

The Blue Guide can be found at:
www.mhra.gov.uk

For more information Ben can be contacted at:
ben.poole@uk.netgrs.com

Bea can be contacted at:
beatrice.omisakin@bms.com