

PCMG Calendar

2014/15 Events:

- September Compliance Webinar
 - Early Phase Workshop (Phase I /IIa)
8th October 2014, London
- REGISTRATION NOW OPEN!**
- November Outsourcing Phase IV studies Webinar
 - 28th January Late Phase Development Workshop + PCMG AGM *London*
 - April 15 Special Population Studies Workshop Venue TBC

Interested participants or potential sponsors for future events please see more details at www.pcmg.org.uk.

PCMG CIPS Academy Sept 2014

- Open to PCMG members only
- Two levels:
- Standard (£4,500) or
- Advanced (£5,700)
- Limited cohort size 12-16
- Duration appx. 14 months
- Each course supported by CIPS project team

Effective Negotiation 3-day PCMG CIPS Workshop Offer, 29th Sept. £499

(Refundable if you proceed with full course)

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PCMG Lisbon 2014. Thank You Everyone!

The dawn of another 20 Years starts in style

214 attendees. 48hours. 14 topics. Your feedback reflected that we achieved our goal of outshining the many 'free' commercial conferences that exist in our sector. All this was possible thanks to everyone's efforts since planning started last September. Main Committee, Steering Committee, Speakers, Meeting Organisers, Session Chairpersons, Sponsors and delegates – together they are all made it happen. In this newsletter, we'll highlight some of the brightest memories of this Anniversary event and look what's on PCMG's horizon.

Inspect a gadget

Technology's role is widespread and increasing way beyond EDC. Labs, Investigator Payments, data warehousing, CTMS, PV.....Karen Roy's lively presentation was a timely reminder

that it is not just novel ideas that are needed in our industry but ones that have longevity and tangible value. Our biggest challenge may not be to make individual systems work but how to join them all up within and across organisations!

Taking Debate....

Steve Martindill chaired the PCMG Oxford Debate which culminated in the audience siding with Dave Webber and Graham Belgrave's argument against strategic partnerships vs. Carol Collins and Leo James' staunch defence of the need for long term business relationships! Clearly a need to convince the audience – is this a challenge for Pharma or CROs?

"I wish I'd listened to Chie's PCMG session"

A world of potential misunderstanding

In the last 20 years, clinical development has truly gone global. Chie Misumi helped the PCMG audience grasp how effective communication goes beyond visible cues.

Societies' cultures have developed independently over centuries. Mastering these subtle differences requires understanding of non-verbal communication and the patterns of interaction to successful – and avoid painful embarrassment....M. President.

A Call for Action

Main Committee

At the end of 2014 Cliff Leat (Celgene) will be stepping down as Committee Member and Treasurer along with Alison Moor (Eisai). Thanks go from all the members and the Committee for all their hard work and numerous contributions over recent years.

Do you want to help steer PCMG into its next 20 years? We're looking for people who want to develop concepts into practice for our members and work with committee colleagues to make a difference for our members and industry. Contact Richard, Lan or any of the Committee via PCMG for more information.

Conference Steering Committee 2015

Have a topic that you want to see at the 2015 Conference? The SC is looking for Pharma as well as CRO members – let us know now if you're interested!

PCMG is on Twitter!

Keep up to date on the latest developments within PCMG and our views on the latest industry news by following PCMG tweets at @PCMGorguk.



**Coming up:
PCMG speaks on
Oversight/Due Diligence
at BOS Discovery/Early
Development
Conference 23rd Sept,
London
Free Attendance for PCMG
members (or deputies)
<http://www.bio2bevents.com/pcmgbos2014>**

**Special PCMG members
discount for PCT 2014
Barcelona available until
19th Sept! – Contact
PCMG for details**

Inflate your placebo using the mouthpiece....

It is a PCMG conference tradition to recruit expertise from a different field to stimulate the audience. All 'passengers' were strapped in securely and phones turned off to pay attention to Captain Manfred Mueller, GM Flight Safety Research at Lufthansa and Lecturer on Risk Management, University of Bremen. We like to think of clinical development as minimising risk. Lufthansa's objective is a failure rate goal of 1 in 100 million flights! As well as comparing risk management in the air we also encountered the potential for communication failure discovered from extensive research conducted into human error and crew interaction. Oh, and if you missed it – aircrew lifejacket demonstrations will never be quite the same.

Risk mitigation: A million uses for Duct Tape?

Not so small print

In his summary of PCMG activities in the past year, Lan Bandara reported how PCMG Legal Development Group (PLEDGe) has developed since 2013's conference review that instigated this initiative. Besides the CDA template, Site Agreement Legal Definitions and Country-specific database, watch out for the upcoming survey. This is your chance to identify key issues and priorities for the group to work on. Better still, we have 12 members, either you or a contracts/legal colleague can join the forum! You know the email to contact.....

Private Equity in the spotlight?

Lisbon's expert panel discussion on the role of PE in clinical outsourcing showed the urgent need for greater understanding of mechanisms, opportunities and risks of PE ownership of clinical development providers. PCMG will circulate a full review up of this topic to members in early August.

China Syndrome?

James Pusey and Zoe Doran shared a snapshot of the wealth of experience gained in managing Clinical Trials in China. This is no longer a 'nice to have' element in the Pharma industry. It is described as the largest single potential market for healthcare. Companies that understand the essential differences and requirements have a chance to adapt effectively to this dynamic environment.

Key facts for consideration included:

- Differences in standard treatments
- Contract with Institutions not sites
- 17 cities have the best HC centres
- High clinician workload
- No dedicated trial staff

Yesterday, today, ...and Tomorrow's PCMG?

Expanding Membership and adding value

It's an increasingly competitive environment for outsourcing conferences. The committee always has membership as a top priority. We will be increasing our publicity to ensure potential new members are aware of PCMG and the existing and new initiatives underway in the coming months, including:

- Redesigning and launching the outsourcing **Foundation Course**
- Creation of PCMG standard templates
- Running **workshops in China and the US**
- Broadening membership. Collaborating with EUCROF to arrange an outsourcing event in Paris (2nd Feb 2015) and co-sponsorship projects of mutual interest and avoid duplication of effort.

Roaring 20's Gala Dinner – A long way from Manchester 2004

Make the most of your membership!
Every company that has four members can add two more members free of charge!
This can apply to any colleague in the same company – even internationally.

Lisbon Feedback!

Thank you to the 114 delegates who took the time to complete the post-conference survey. Here are some highlights:

Top 3 rated presentations:

1. Airline Risk Management
2. Cultural awareness
3. Oxford Debate

When asked 'was the conference beneficial?'
81% of pharma delegates rated the conference as 4 or 5 on a 1 to 5 scale

71% Rated location suitability as excellent

Suggestions for 2015 topics include:

- More on PE & CRO ownership
- Compliance
- Health electronic records
- Risk sharing
- Governance for medium sized pharma
- Procurement tools

Lessons learnt for 2015:

- Earlier registration opening
- More interaction
- Increased oversight of presentation content
- Consolidate presentations under fewer topics
- Try to increase accessibility of venue

And finally.....

We will listen and act, but also not lose the key elements that keeps the PCMG Annual Conference unique:

- Content driven by need, not speaker sponsorship
- Fixed Pharma/Provider ratio
- No exhibition hall
- Venue picked for suitability not profit

Despite the last minute change of venue and the Lisbon inner city traffic, the Gala Dinner provided a welcome opportunity to dress up, wind down and celebrate 20 years of PCMG and 10 years of Annual Conferences.

Someone to Watch Over You...

PCMG's trial of interactive keypads in Lisbon proved very successful. Jennifer Martin, Senior GCP Inspector at the MHRA used the audience feedback to great effect when gauging the diligence exercised in assessing, selecting, contracting, delegating, managing documentation and general oversight of providers. This applied equally to providers sub-contracting as much as Pharma sponsors!

Is Risk Based Monitoring – risky?

Site Monitoring is an inescapable and costly element of Phase II/III studies. Mireille Zerola (Boehringer Ingelheim) & Christian Tucac (INC) looked at the key elements to consider when implementing a Risk Based Monitoring (RBM) approach to smarter use of precious resource:

- Impact is cross-functional, not just the clinical team
- Enhancement, not replacement of existing processes
- Site relationship improvement from fewer errors & repeat queries
- RBM is not a universal tool for all studies

Overall, RBM success relies on full alignment of expectations between Pharma and CRO and it takes time to realise material benefits.

Virtually Feasible?

Has feasibility evolved or is it just a CRO sales tool? PCMG surveyed Pharma and CROs before the conference considered whether feasibility has improved in the past 10 years. A key finding was that *68% Pharma & 67% CRO responders were not comfortable with reliability of feasibility data from sites*

Dr. Kasia Moscicka's presentation proposed that effective feasibility assessment relies on sufficient time planned into the project but also the growing complexity of the clinical trial environment (regulatory/standards of care/ comparators etc). A fixed price contract relied on the CRO having control of selection and number of sites *and protocol design*.

Times have changed since PCMG of 2002.
*Before functional outsourcing and EDC.
Youthful, carefree. and....David Davies is Harry Potter?*