

PCMG Calendar

**Outsourcing
Essentials**

Risk Management
Finance & Legal
Negotiation
Communication
Relationship Management



**A New PCMG
Training Course
for:**

- Outsourcing managers
- Project managers
- Contracts negotiators
- Contracts managers
- CRO BD
- Proposal writers

**6+7 OCTOBER 2015
London.**

PCMG Members £600+VAT
Non-Members £700+VAT

**8th October 2015
London Workshop:**

**Outsourcing
Models:**

Decision drivers,
development trends
and consequences for
implementation.

**February 2nd 2016
London Workshop
(& AGM):**

**Contracts:
Standards, Conflicts &
Solutions.**

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**PCMG Warsaw 2015: “...great to bring industry together” -
“..useful real-life examples..” - “..educational”- “..no ‘us and
them’..” - “Well structured, with great opportunity to network”**



This Delegate feedback captures the spirit of PCMG Annual Conferences justifies the hours volunteered to support this unique event format. 2015’s Risk, Complexity and Compliance theme started by looking more closely at Risk Based Monitoring. Familiar territory? It “...**opened many perspectives on what my company could do to implement RBM**” was one of the audience responses. Steve Nabarro and Charlotte Allcock from Cancer Research UK reported practical experience of a **55% increase in CRA productivity**. Richard Young (Medidata) and Julianne Hull analysed data from 4,504 studies indicating that Queries are increasing but RBM is maintaining quality and starting to reduce on-site monitoring and study enrolment times. However, RBM should not be primarily considered a cost reduction tool – a point included in the panel discussion that included Dr. Kieran Doran, Senior HC Ethics Lecturer from University College Cork.



Is this the gap between pharma and outsourcing best practice?

- Sponsors insisting on only ‘experienced’ team members
- ‘Tame’ Conference panel discussions
- Badly designed paper diaries
- Over-engineered Bid Defence meetings

How many more items of frustration could be considered for obliteration by the audience in 2016?

Complexity doesn’t come much tougher than rebuilding the deepest London Underground station with four different lines...without shutting it down! Simon Addyman showed just how far behind other industries Pharma project management and outsourcing is, scoring an overall **85% ‘excellent’ or ‘good’ rating** by the audience. The other non-industry, but frequent flier of PCMG conference presentations, Steven Carver, had everyone fastening their safety belts as he graphically illustrated the manageable complexity of air traffic management, bringing us in for a safe landing on more familiar ground of clinical outsourcing challenges.

CONDEMNED to PCMG’s room 101 shortlist were a range of items for deletion from existence including....



Late notice of ‘pass-through’ costs for 101?

PCMG Oxford Debate: ‘This house believes that:

The procurement process has damaged sponsor-CRO relations and Clinical Trial Conduct’

After a heated debate feedback showed pharma delegate opinion hardened against the motion:

- Before Debate: 42% pharma /56% CRO supported the motion
- After Debate: 32% Pharma/57% CRO supported the motion

Are you Compliant?

In Day 2's Sessions on compliance, EFPIA Deputy Director General, **Marie-Claire Pikaert**, provided



guidance on the EFPIA Compliance Directive, focusing on our industry's interactions with Health Care Professionals in clinical trial situations.... using one of the conference sponsorship items as an example!

Moving from the regulator to the regulated, Uffe K. Rasmussen Senior Director,

Corporate Compliance, Lundbeck and Corina O'Connell, Associate Director, Transparency Reporting, ICON showed the importance of and methodologies of pharma and CRO working together. Much of the reality of HCP compliance and reporting still remains unknown, but key points were made, including the need for:

- Commitment from Corporate to operational level
- Joint scoping and planning to develop good tools
- Ongoing assessment and QC
- The ability to adapt to (inevitable) change

Lastly, Pauline van Heiningen and Paul Strickland took the audience from principles to the reality of integrating good business practices and quality management into clinical development oversight. Achieving an acceptable quality level to return 'the same conclusions as perfect quality' requires major financial investment. As some

companies have painfully discovered, the cost of compliance may be far less than the alternatives. Rikke Winther (Lundbeck) closed out the session using the interactive voting system – noting that some delegates were better prepared for compliance than others.....



"OK, who voted that it's not bribery if your fingers are crossed behind your back?"

So... you think we can improve on 2015?

Help form the Conference Steering Committee by contacting admin@pcmg.org.uk if you have ideas that can make 2016 a roaring success.

Other PCMG HIGHLIGHTS.....



First PCMG Workshop in Asia Completed

Over 30 pharma delegates attended this new venture by PCMG in Shanghai in April. The "Managing Supplier Relationships and Performance" included:

- Metrics and performance measurement
- Cultural awareness and relationship mgt.

This event proved the opportunity for PCMG to help share best outsourcing practice beyond the EU membership. The PCMG committee is now working to expand this interaction with the potential global membership



PCMG LEGAL TEMPLATES AVAILABLE

Olena Goloborodko and Glen Scarlett presented PCMG's Legal Development Group (PLEDGe) industry standard templates for PCMG Members contract management, currently including:

- Confidentiality Agreement
- CTA Country Database
- CTA Definitions

Go to: www.pcmg.org.uk

OTHER PCMG TEMPLATES

- CRO SOW and Bid Grid
- Relationship Management Plan
- Selection Scorecard
- Lessons Learned

2015 Conference Gala Dinner – 'Best of the 80's'



2016 Venue? (To be announced next month)