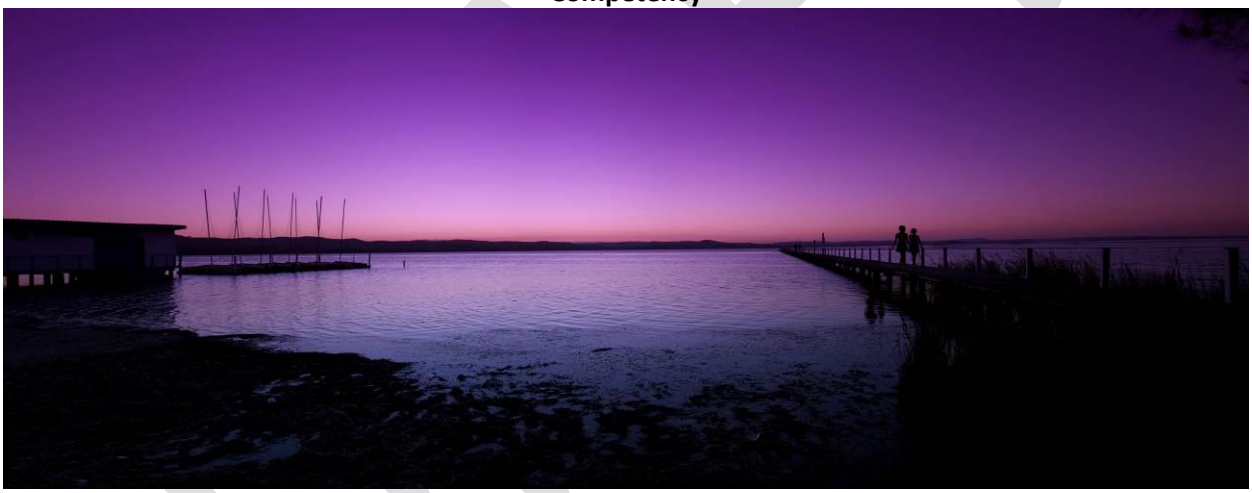
Pharmaceutical
Contract Management Group

Annual Conference 2019

5-7 June

The Melia Hotel, Sitges, Nr Barcelona, Spain

The 2019 PCMG Annual Conference sets sail to cross '7C's' of Clinical Outsourcing: Consistency, Continuity, Consolidation, Collaboration, Change, Complexity & Competency



We will identify and clarify issues to provide answers that could guide sponsors and providers journey across the high seas of clinical development. For those familiar with PCMG's unique approach to conference, enjoy. We're back. For those new to the concept; no exhibition booths to distract, no multiple streams to divide delegates, no 'paid' podiums – just two days of all-in interaction, information sharing, networking and improvement in working theory and practice.

Follow us on @PCMGorguk

LinkedIn® PCMG Group

tweet about the conference at #PCMGBCL19

* Programme is subject to change as structure, content and timing is refined to provide best possible experience.

Conference Programme*

Wednesday 5 June

From 15:00	**Shuttle service from Barcelona airport to conference venue** Running every 30 minutes to 18:30
From 19:00	**Registration and welcome reception** A chance to meet established and new contacts across industry sponsors and providers. We're all in the same boat ***Sponsored by*** Syneos Health

Thursday 6 June

08:00	**Registration**
08:30	**Welcome and introduction to the conference**
08:35	**Review of the PCMG year** – The ups and downs of industry change and PCMG's activities on behalf of it's members *Richard Scaife, PCMG Committee Chair* *Gill Roberts, PCMG Committee Vice-Chair*
08:55	**Introduction to morning session**
09.00	**There be Dragons...** A leading financial analyst assesses the past and future directions that will be taken by sponsors and providers, charting the continuing hazards and trade winds that will have direct and indirect impact on the way we work across the 7c'S of Outsourcing. *Speaker: TBC*
09:45	**Pharma and CRO consolidation, expansion and extension – what are the goals, options and implications for outsourcing practice?** Our industry continues to attract investment from private and public sources, from Biotechs taking products through to registration, 'mega' CRO creation, acquisition and consolidation of smaller CROs and funding acquisition of specialist services to bolt-on to large and small CROs. Is this funding creating new opportunities for improved productivity or reducing choice and flexibility? Our expert panel from stakeholders of Finance, Pharma and CRO provide the latest insight and guidance. *Bill Burns, Non-exec. Director, Shire Pharmaceuticals & Wellcome Trust Governor* *Ludo Reydners, CEO, Premier Research Inc.* *Labcorp-Covance speaker TBC* *Private Equity TBC*
10:30	**Networking break**
11:15	**Collaboration with Academia** Can expectations be managed through outsourcing clarity? Academic units are increasingly engaged by BioPharma but may not share the same expectations of contracting, timelines, systems and operational processes. What are the risks and mitigating outsourcing actions required to achieve high-quality, timely output through consistent and productive relationships with these important institutions? *PCMG Committee & academic representation*
12:00	**(Passion 4 Patients) + (Pay 4 Performance) = Quality, Speed and Value** **Balancing the equation in a dual CRO alliance** Incentivising efficiency and innovation; Enhancing dedicated resources; Increasing capabilities Competitive pricing; High performance delivery of new product portfolio; Aligning sponsor objectives to CRO alliance partner objectives. *Richard Butterworth, Senior Director Alliance Management - Merck Group*
12:30	**Lunch and networking break**

* Programme is subject to change as structure, content and timing is refined to provide best possible experience.

13:45	**Introduction to the afternoon session**
13:50	**All aboard for Big Data – or are we?** Oil tanker agility or speedboat capacity? What is the realizable capability of the Pharma and CRO drive to harness big data in practice now and tomorrow. A renaissance for clinical development practice or a polarization of have and have-nots for CRO selection and the range of dependent sponsors. *Francis Kendall, Senior Director – Biostatistics and Programming, Cytel*
14:35	**Clinical trials with Medical Devices: what is the difference?** Largely adrift from 'mainstream' ClinDev outsourcing, medical device technology is emerging as a key competitive edge for some treatments. We examine background, the application of device technology, approval pathway, Medical Device Regulations on clinical trials important to development outsourcing. *Aly Talen, Genae & speaker to be confirmed*
15:15	**Networking break**
16:00	**Achieving Consistency in the Face of Chaos**
17.00	**Close of conference day 1**
From 19:15	**The PCMG Gala Dinner at La Finca Mas Solers** **Coaches depart at 19:00** ***Sponsored by*** COVANCE

Friday 7 June

09:00	**Introduction to day 2 and the morning session**
09:15	**Keynote session: Practice not politics – Are you Brexit ready?** By the time of conference, we (hope) we will know some of the outcomes and implications of the anticipated departure of the UK from the EU. Our expert panel will examine the known and unknown results of changes and actions from moving data and materials, to access of sites and specialist that will drive outsourcing practice for future years. How bad can it be? *Panel Chaired by Steve Martindil PCMG Director & Exec. Director Clinical Operations, Gilead* *Bill Burns* *Regulatory TBC*
10.00	**Networking break**
10:45	**Far Horizons & Close Calls – Managing the Change of demand for outsourced clinical studies in Japan** Estimates forecast Japan's $84b (2017) prescription pharmaceuticals market generic drug value growing by an estimated 45% in three years to help manage costs for an increasing elderly population. The increased flow of new drug development and registration is meeting unique logistical and cultural hurdles in this most traditional of working environments. Our panel of local and global experts examine the realities of supply meeting demanding timelines for domestic and internationally led companies. Including: • 'Western' CROs expansion into Japan • Site challenges and capacity • Effective Clinical Supplies planning and implementation
12.00	**Lunch and networking**
13:00	**Introduction to the final session**
13:05	**Time, Cost, Quality and Patient Centricity – should this be the 4th consideration in clinical trial outsourcing?"**

* Programme is subject to change as structure, content and timing is refined to provide best possible experience.

	The concept of patient centricity has been discussed at length by drug developers, service providers, and patient groups. It is widely recognised that patient recruitment and retention in is critical to success and that conducting research with the perspective of the patient incorporated is of benefit to all stakeholders. How much are sponsors and drug developers thinking about patient centricity in clinical trials and what are the considerations for procurement and outsourcing? Is Pharma willing to pay the price and how should success be measured to justify return on investment? *Speakers to be confirmed*
14:05	Procurement - Speculative Development and Accepting Risk of Failure
14:50	Closing remarks
15:00	**Coach transfers to airport**

Acknowledgements
Our thanks to the PCMG Annual Conference Steering Committee and PCMG Committee for their time and dedication in creating an engaging conference for all

* Programme is subject to change as structure, content and timing is refined to provide best possible experience.