

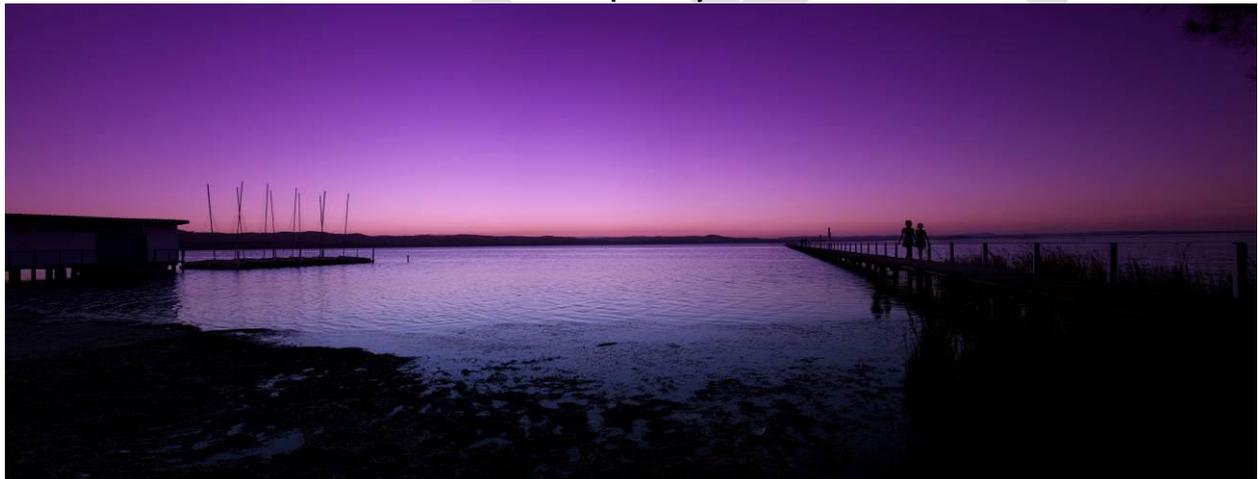


Annual Conference 2019

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.

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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 

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 <i>Richard Scaife, PCMG Committee Chair</i> <i>Gill Slater, PCMG Committee Vice-Chair</i>
08:55	Introduction to morning session
	Consolidation - Collaboration
	Chairs: Gill Slater & Dan Nicholson
09:00	There be Dragons... A leading industry expert 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. <i>John Hubbard, member of the board of Directors of CRF Bracket, a portfolio company of Genstar Capital</i>
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. <i>Bill Burns, Non-exec. Director, Shire Pharmaceuticals & Wellcome Trust Governor</i> <i>Ludo Reynders, CEO, Premier Research Inc.</i> <i>Labcorp representative</i>
10:00	Networking break
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	Consistency - Collaboration
	Chairs: Dorothee Walter & Natalie Fforde
11:15	Collaboration with Academia – hard truths 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? <i>Jean Edwards, formerly Eli Lilly Co Ltd</i>
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

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	CRO alliance partner objectives. <i>Richard Butterworth, Senior Director Alliance Management - Merck Group</i>
12:30	Lunch and networking break Sponsored by  PAREXEL YOUR JOURNEY. OUR MISSION.®
13:45	Introduction to the afternoon session
	Complexity - Collaboration
	Chairs: Dave Webber & Mark Bee
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. <i>Francis Kendall, Senior Director – Biostatistics and Programming, Cytel</i> <i>Sam Russe, Head of Life Sciences, Datavant</i> <i>Nan Chou, Parexel</i>
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. <i>Aly Talen, Genae</i> <i>Dorothee Walter, Bayer</i>
15:15	Networking break
	All the Cs
	Chairs: Richard Scaife & Roger Joby
16:00	Sailing ‘Closer to the Wind’ - Harnessing the Power of the PCMG Conference PCMG is different to any other outsourcing conference, including our use of novel interactive formats to close the first day’s presentations and discussions, from the PCMG Oxford Debate to ‘Universally Challenged’ and even ‘PCMG’s Room 101’. This year we will explore some of the 7C’s of Outsourcing, identifying key challenges in a competitive format for delegates to discuss, debate, define and then vote on the most practical solutions to be adopted and shared as PCMG standards of practice. Whether it be tearing up meaningless CV formats or how to give ‘Lessons Learnt’ practical meaning, we will identify competencies and actions that should (and should NOT) be included.
17.15	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
	Change - Complexity
	Chairs: Rikke Winther or Pia Sauer Larson & Graham Belgrave
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? <i>Panel Chaired by Steve Martindill PCMG Director & Exec. Director Clinical Operations, Gilead</i> <i>Bill Burns, Non-exec. Director, Shire Pharmaceuticals & Wellcome Trust Governor</i> <i>Christopher Clare, Covance Laboratories Ltd</i> <i>Representative from MHRA</i> <i>Pam Turner, Geryon Pharma</i>

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10.00	Networking break
	Change - Continuity
	Chairs: Antje Hindahl & Mike Ryan
10:45	<p>Far Horizons & Close Contact – Managing the Change of demand for outsourced clinical studies in Japan</p> <p>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:</p> <ul style="list-style-type: none"> • ‘Western’ CROs expansion into Japan • The realities of achieving effective communication and outcomes • Site challenges and capacity • Effective Clinical Supplies planning and implementation <p><i>Panel Chair: Rob Aitchison, Head of Outsourcing & Contracts, Ono Pharmaceutical UK</i> <i>Dan Feldman, VP, Asia Pacific, Medpace</i> <i>Eunhee Chung, PhD, Director, Global Clinical Development, SOUSEIKAI Global Clinical Research Center</i> <i>Brendan Ellis, Global Project Manager, Asahi Kasei</i></p>
12.00	Lunch and networking
13:00	Introduction to the final session
	Complexity - Compatibility
	Chairs: Sandra Johnson & Jean Edwards
13:05	<p>Time, Cost, Quality and Patient Centricity – should this be the 4th consideration in clinical trial outsourcing?”</p> <p>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?</p> <p><i>Thierry Escudier, Pierre Fabre Medicament</i> <i>Bruce Hellman, CEO - uMotif</i></p>
14:05	<p>Procurement – Outsourcing with lives at stake: ideas practices and lessons from the defence sector</p> <p>More than 60 per cent of the UK defence budget is now spent with the private sector for the supply of goods and services. This presentation will spell out the drivers for defence outsourcing, the forms it has taken, and the challenges of coping with this complexity and successes encountered, generating opportunities for lessons learned applicable to other sectors.</p> <p><i>Professor Trevor Taylor, Royal United Services Institute</i></p>
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

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