



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.

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Conference Programme*

Wednesday 5 June

	Shuttle service from Barcelona airport to conference venue Shuttles will depart the airport at 16:30, 17:30, 18:30	
From 19:00	Registration and welcome reception The opportunity for delegates to renew established contacts across the industry as well as meeting delegates new to the PCMG family in this informal opening event	

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>	
09:30	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>John Hubbard</i>	
10:15	Networking break	
	Consistency - Collaboration	 Sponsored by
	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> <i>Antje Hindahl, Independent consultant</i>	

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12:00	<p>Successfully delivering on the Magic Triangle – How to ensure quality, speed, and value</p> <p>Why are good clinical outsourcing deals important for the Pharma Business? How can you ensure that the quality, speed and cost are delivered and effectively drive value? In this presentation, these subjects will be explored including examples of negotiation strategy, balanced performance incentives and how to structure a good outsourcing deal that delivers on the promise of bringing medicines to patients earlier.</p> <p><i>Richard Butterworth, Senior Director Alliance Management - Merck Group</i></p>
12:30	<p>Lunch and networking break</p> <p style="text-align: right;"><i>Sponsored by</i> PAREXEL YOUR JOURNEY. OUR MISSION.®</p>
13:45	<p>Introduction to the afternoon session</p>
	<p style="text-align: center;">Complexity - Collaboration</p>
	<p style="text-align: center;">Chairs: Dave Webber & Mark Bee</p>
13:50	<p>All aboard for Big Data – or are we?</p> <p>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.</p> <p><i>Francis Kendall, Senior Director Biostatistics and Programming , Cytel (Moderator)</i> <i>Nan Shao, VP, Global Head of Biostatistics and Statistical Programming, PAREXEL</i> <i>Sam Roosz, Head of Life Sciences, Datavant</i></p>
14:35	<p>Clinical trials with Medical Devices: what is the difference?</p> <p>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.</p> <p><i>Aly Talen, Genae</i> <i>Dorothee Walter, Bayer</i></p>
15:15	<p>Networking break</p>
	<p style="text-align: center;">All the Cs</p>
	<p style="text-align: center;">Facilitator: Samme Allen</p>
16:00	<p>Sailing ‘Closer to the Wind’ - Harnessing the Power of the PCMG Conference</p> <p>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 together on the Good Idea or Bad Idea outcomes. We may tear up meaningless CV formats or call time on performance metrics, you decide!</p>
17:15	<p>Presentation of the PCMG Life Time achievement award</p> <p>Who will be recognised for their outstanding contribution to the conduct and recognition of clinical outsourcing and procurement, and their unwavering support of PCMG’s principles for developing and maintaining best practice between fellow professionals.</p> <p>Awarded by Richard Scaife PCMG Chair and Gill Roberts PCMG Vice-Chair on behalf of the Committee.</p>
17.30	<p>Close of conference day 1</p>
From 19:30	<p>The PCMG Gala Dinner at La Finca Mas Solers Hi Ho Silver – 25 years of PCMG Coaches depart at 19:15</p> <p style="text-align: right;"><i>Sponsored by</i> COVANCE</p>

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Friday 7 June

09:00	Introduction to day 2 and the morning session
	Change - Complexity
	Chairs: Pia Sauer Larson & Graham Belgrave
09:15	<p>Keynote session: Practice not politics – Are you Brexit ready?</p> <p>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?</p> <p><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, QP, Geryon Pharma</i></p>
10.00	Networking break
	Complexity - Collaboration
	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
12:45	Introduction to the final session
	Complexity - Compatibility
	Chairs: Sandra Johnson & Jean Edwards
12:50	<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>

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Friday (cont'd)

13:50	Procurement – Outsourcing with lives at stake: ideas practices and lessons from the defence sector 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. <i>Professor Trevor Taylor, Royal United Services Institute</i>
14:35	Closing remarks
14:50	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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