



Pharmaceutical
Contract Management Group

Annual Conference 2017 Programme

Think Global, Act Local

*Meeting strategic ideals with real-world outsourcing
practices*



7-9 June 2017

The Radisson Blu Scandinavia, Copenhagen, Denmark



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Conference Programme*

Wednesday 7 June

From 16:30	Airport shuttle service Airport shuttles will run every 30 minutes between 16:30 and 19:00 (last coach)	 the investigator space experts®
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 8 June

08:00	Registration	
08:30	Welcome and introduction to the conference	
08:35	Review of the PCMG year And what a year it's been. The 'pointy end' of the PCMG Committee reflect and analyse industry (non-alternative) facts and trends that set the scene for the conference and year ahead for members and our global industry overall. Richard Scaife - PCMG Chair Gill Roberts - PCMG Vice-Chair	
Section 1. Anticipation Chairs: Antje Hindahl & Mike Ryan		
08:55	Introduction to morning session	
09.00	Opening Keynote address Increasing technology adoption in global clinical development: Promises and risks Increasing adoption of technologies often means taking humans out of the equation. In the clinical development sector, automation is as valid as other industries. Are global development strategies disconnected from operational need creating innovative inertia and will CROs or technology vendors and systems integrators take the lead? Bryan Spielman - Strategic Projects, Verint Systems (Former Exec V-P Medidata)	
10:00	Networking break	 WORLDWIDE CLINICAL TRIALS
10:45	Stormy outlook: Surviving the CRA drought CRA resourcing has become a global priority for CROs and sponsors. Study data quality, site relationships, costs, timing (and more) are at risk. ICH GCP is likely to increase expectations of site management to improve subject safety and data integrity. How can Sponsors square this circle in practice? Sue Stansfield - Clinical Operations Expert Prof Joe Eustace - University College Cork, Ireland	
11:30	Tomorrow's PCMG World We may have the Technology...but are we willing to unleash it? A PCMG panel of industry experts looks into the future to challenge current practice. Personalized medicine, wearable technology, data collection and ownership, nanotechnology, patient communities.... We examine their potential, who will drive these advances and consider who will be prepared to pay for them. Back to 'Today's World, what efficiencies and effectiveness can and should we build into studies now? Hosted by: David Davies – PCMG Treasurer Dawn Anderson - Deloitte, Bryan Spielman – Verint Systems Wolfgang Renz - Physicians Interactive, Graham Hughes - Independent	

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12:30	Lunch and networking	
13:30	Introduction to the afternoon session	
Section 2. Change Chairs: Susan Tio-Gaillard & Graham Hughes		
13:35	It's in the POST Hard or soft, Brexit has unleashed a world of uncertainty regarding the conduct of development projects and registration in the UK. From global to local player? We get an insight into the who, what, how and why of the report being prepared and some early conclusions. Sam Bunce - Postgraduate Fellow, Parliamentary Office of Science and Technology (POST), Houses of Parliament	
14:15	It's all about data: The impact of new global data protection changes Studies run on data but are sponsors and providers planning sufficiently to stay data compliant? Identifying risks and solutions for stakeholders at all levels. Sponsor impact - Olena Goloborodko - Celgene Technical impact – Richard Young - Veeva Patient impact – Ray Collia - Greenphire	
15:00	Networking break	 Your cardio-respiratory partner
15:45	Change is good? A new outsourcing concept becomes reality The recent PRA/Takeda collaboration has divided opinion. Is it the demise of pharma operations or an innovation that will be the future of clinical outsourcing? Considerations of pros, cons and unknowns. Bryan Haas - PRA Health Sciences Dominika Kovacs - Takeda	
16:30	Universally Challenged Our best intercollegiate brains compete to close the day by showing who knows the most facts about outsourcing and general global knowledge. CRO University of Chanje & Öder vs Pharma University of Valluphermaneigh Don of the day: Steve Martindill - Gilead UC Pharma: Captain Dan Nicholson (Celgene), Morten Noregaard (LEO), Kristine Dalsgaard Cohen (Novo Nordisk), Dorothee Walter (Bayer) Team CRO: Captain Richard Young (Veeva), Graham Belgrave (Cmed), Javier Revuelta (Premier research), Andy Copestake (Julius Clinical)	
17:15	Close of conference day 1	
18:30	River transfers to the Gala dinner departing from Aristo Bar & Restaurant	
From 19:30	The PCMG Gala dinner All delegates and speakers join in the social & networking event of the year.	

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Friday 9 June

09:00	Introduction to day 2 and the morning session
Section 3. Implementation Chairs: Pia Sauer Larson & Ray Collia	
09:05	Keynote address: Great Expectations A perspective in regional and global trends and challenges in the rapidly changing regulatory landscape and practical implications for Phase I-III study management. Thomas Senderovitz - CEO, Danish Medicines Agency and Member of EMA Management Board
10:00	Networking break
	 WORLDWIDE CLINICAL TRIALS
10:45	A missing link in study plan implementation? Mastering the complexities of global site budget implementation from interdependent stakeholders' perspectives. What Sponsors and Providers need to know but often overlook until late in the setup process. Sponsor - Diana Sims-Silbermann - Janssen Pharmaceuticals Clinical Investigator - Philipp Badorrek - Fraunhofer ITEM Provider - Wendy Baird - Synexus
11:45	Lessons in implementation & change management of a global procurement directive: A play in 7 acts Cutting costs. What's the problem? This PCMG role play highlights the risks to operational delivery and quality that emerge from a (hypothetical) Pharma HQ's tactical instruction to achieve a global strategic objective. Stage production - Julianne Hull - Wenstar Enterprises Adapted 'from the novel' & narrated by - Carl Emerson - InsideOut Solutions Performed by - The PCMG Steering Committee Wandering Players
12:30	Lunch and networking
	 the investigator space experts®
Implementation (cont.) Chairs: Sandra Johnson & James Dickinson	
13:30	Operationalising the Global Functional Service Provider Model Case study of the Bayer experience, challenges, successes, lessons learnt and realities of implementation in practice Nick Lewis - Bayer plc
14:15	Emergency PCMG Committee interactive discussion: CRO global consolidation – cause for celebration or concern? It started with LabCorp & Covance, then Quintiles and IMS. 2017 is facing a huge shift in the CRO landscape. The PCMG Committee and CRO guest speaker convene an emergency panel to analyse, debate and forecast the implications for outsourcing practice from small, medium and large company perspectives for staffing, continuity, costs. A summary session to consider Anticipation, Change and Implementation. PCMG Committee members: Antje Hindahl - Celegene, Thierry Escudier - Pierre Fabre, Susan Tio-Gaillard – ProQr , Dave Webber - Gilead Alistair Macdonald - CEO, INC Research Interactive Discussion and Q&A
15:00	Going Global. Wrap up, close of conference and.... 2018's venue! Gill Roberts, Susan Tio-Gaillard and Dan Nicholson - PCMG Steering Committee Co-Chairs
15:15	Coach transfers to airport At 15:15, 16:00 and 17:00
	 the investigator space experts®

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Acknowledgements

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PCMG Committee

Tarminder Baines
Lan Bandara
David Davies
Thierry Escudier
Antje Hindahl
Sandra Johnson
Steve Martindill
Dan Nicholson
Gill Roberts
Pia Sauer Larsen
Richard Scaife
Susan Tio-Gaillard
Rikke Winther

PCMG Annual Conference Steering Committee

Richard Baptista
Phil Birch
Mark Campbell
Ray Collia
Karine Danielyan
Steven De Hertefelt
James Dickinson
Carl Emerson
Jacqui Gatehouse
Regine Hauck
Graham Hughes
Julianne Hull
Dan Nicholson
Baljit Panesar
Gill Roberts
Mike Ryan
Richard Scaife
Susan Tio-Gaillard