PCMG

Pharmaceutical
Contract Management Group

Annual Conference 2015 Programme

Risk, Complexity & Compliance in Clinical Development Outsourcing to succeed or survive?

10 – 12 June 2015
Westin Hotel, Warsaw, Poland

Introduction to the 2015 Conference Programme

It's not getting any easier out there. Commercial realities of limited patent life, the generic cliff, payer restrictions, studies becoming more complex and increasing demands for transparency of data and business conduct. This places increasing pressure on the outsourcing function to support the search, selection and ongoing management of the external providers to help meet these challenges.

Welcome to the PCMG 2015 Annual Conference!

Clinical Study Outsourcing, originally a capacity management strategy, has evolved into an essential methodology for pharma survival. In this ever-changing business, and it is a business, pharma sponsors appear increasingly risk-averse, minimising financial exposure in the development pathway wherever possible. However, searching for more cost-effective solutions has to be balanced by confidence in their success while still meeting stringent regulatory and statutory requirements. We've been hearing ideas of **Risk-Based Monitoring** for years, but does it work in practice? Are CROs truly motivated to become more efficient in one of their main revenue sources? We aim to go beyond the concept and find out what happens in the real world for smaller, as well as large pharma clinical studies. We also consider the sharp end of the RBM formula – how do sites find the idea? Are there regulatory issues? Do increased visits cause more problems than they solve? What does the data say?

Linking the first to the second, **complexity** segment, we will consider how well outsourcing manages that most precious resource – people. As valuable as processes and systems are, without the right individuals, how can complex study challenges be overcome? However, what is complexity? Are we well equipped in pharma and CROs to manage it? Is it art or is it science? What should we look for internally and externally to manage the complexity puzzle?

The signs of increasing need for transparency in business practices started in the financial sector with the Enron scandal. There have been multiple incidents in recent years where pharma business conduct and integrity has been inadequately overseen. The resulting urgent measures to increase and implement **compliance** measures have come thick and fast. As outsourcing professionals, we have clear responsibilities to develop, implement and adhere to high clinical and business compliance standards. Interaction between pharma and providers is particularly sensitive, so we need to share understanding of best practice regionally and globally.

On a lighter note, this conference continues to work because it is not a standard 'sales conference'. It is a meeting of people and minds. People make standards, systems and processes work, not the other way round. Our unique forum allows open sharing of best practice, new ideas and good communication at personal and professional levels. New for 2015 is a chance to voice the issues that cause the most unnecessary pain, frustration and problems in conducting and managing clinical study outsourcing and conduct. **PCMG's Room 101** session will vote to send the worst elements of practice to Room 101 and identify solutions that need to replace them – as well as donating £2,000 to a charity of the winning nominee's choice.

And, of course, this year's traditional PCMG Oxford debate. This time, our panel of industry sages will be providing arguments for and against the rising tide of the **procurement** approach to clinical development outsourcing… let battle commence!

Finally, on behalf of the delegates, I would like to thank the PCMG Conference Steering Committee. Comprising of main committee pharma and CRO provider members, they have worked tirelessly (OK, sometimes very tired) to create the conference content, identify and recruit speakers and develop the programme since September 2014.

Enjoy the event!

Richard Scaife, PCMG Committee Chairman

Conference Programme

Wednesday 10 June

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. ***Sponsored by*** KCR

Thursday 11 June

08:00	**Registration**
08:30	**Welcome and introduction to the conference**
	1. Review of the PCMG year Ups, downs and consideration of trends in risk, complexity & compliance that are shaping our business and the theme of the conference. **Richard Scaife,** General Manager, Vendor Mgt., Mitsubishi Pharma Europe (PCMG Chairman) **Lan Bandara,** Global Head Clinical Outsourcing, Eisai (PCMG Vice-Chairman)
09:00	**PCMG's Room 101 – 'Episode 1: The first offenders'** ***Sponsored by*** World Courier AmerisourceBergen What outsourcing practices should be condemned to oblivion and what solutions should replace them? A series of (painfully) familiar cases to be shown through the conference, culminating in the audience voting for the best example, whose 'owner' wins the right to nominate the charity for the sponsor's donation. **Mike Ryan,** Vice President Sales, Medidata **Peter Davidson,** Executive Account Director, Theorem Clinical Research
09:15	**2. Risk Based Monitoring: How does it work in practice?** There has been a great deal of theoretical practice and benefits discussed. How has RBM been realised (or not) in: **Earlier phase low-scale studies?** **Stephen Nabarro,** Head of Clinical Operations and Data Management Drug Development Office Strategy and Research Funding, Cancer Research UK **Charlotte Allcock,** CRA, Cancer Research UK **Later phase, large-scale studies?** **Julianne Hull,** CEO, Wenstar Enterprises (Formerly Wyeth) **What does the data say?** An analysis of 16 TA's, 143 sponsors, 5,200 studies and 147,000 sites comparing data quality, entry and cycle times. **Richard Young,** Vice President, Global Consulting Partners, Medidata
10:15	**Networking break** ***Sponsored by*** Vitalograph Your cardio-respiratory partner
11:00	**3. Risk Based Monitoring: Contracting realities** What changes impact the RFP costing for RBM vs 'normal' monitoring scenarios? Are there any essential contractual changes that need to be negotiated early? What and where are the potential wins and losses for the CRO in RBM agreements. Is the financial risk to CROs slowing the potential rapid adoption and benefits for sponsors? **Clara Heering,** Vice President, Clinical Risk Management, ICON Clinical Research
11:45	**4. Risk Based Monitoring: Conclusions and next steps** Following reports of implementation, will RBM become the standard rather than the exception? Do CROs really support the concept or is it a risk to profits? Will the regulators, ethics committees and sites support or challenge RBM's expansion? Interactive panel discussion with previous speakers plus: **Kieran Doran,** Senior Healthcare Ethics Lecturer, University College Cork **Ann Meeker-O'Connell,** Head, Risk Management and External Engagement, BioResearch Quality & Compliance, Johnson & Johnson
12:30	**Lunch** ***Sponsored by*** inc Research

13:45	**Introduction to the afternoon session** **Session chair,** PCMG Committee Member
13:50	**PCMG's Room 101** **'Episode 2: How bad can it be?'** ***Sponsored by*** World Courier AmerisourceBergen
14:00	**5. People: the greatest asset or biggest risk?** CRO SOPs, systems, processes are a big element of selection at strategic and tactical levels, but what about the people? CRO 'A-Team' at Bid Defence and 'B-Team' allocated at win is well known, but how can the risk of losing key personnel be mitigated within outsourcing processes? We examine current practices and opportunities to improve at contractual and process levels. **Thierry Escudier,** Head of Clinical Operations, Pierre Fabre Medicament (F) **Michelle Noble,** Director Resourcing Europe, Novella Clinical Resourcing
14:30	**6. The Bank Job: Complexity management goes down the tube** The London Underground Bank Station is one of the most complex intersections on the network and is about to undergo a major renovation. This requires the latest thinking to ensure contractors are able to propose, plan and execute activities to minimise disruption but optimise productivity. Openness, innovation, expertise transfer…. how can that relate to clinical trial outsourcing? **Simon Addyman MSc (dist), MAPM (CPM)** – APM Project Professional of the Year Award 2013 - London Underground Bank Station Capacity Upgrade Project
15:30	**Networking break** ***Sponsored by*** QUINTILES
16:15	**7. Managing Complexity: PCMG contracting tools** The PCMG Legal interest group, legal and contracting experts across PCMG member companies, have produced a range of tools to help simplify site contracts negotiation process and share best study contracting practice. This update will highlight the value of these tools developed for PCMG members and the on-going work of this PCMG initiative. **Olena Goloborodko, LL.M.** Senior Manager, Global Contracts and Outsourcing Management, Astellas Pharma Europe B.V. **Glen Scarlett,** Associate Contract Manager, Celgene International Sarl
16:45	**8. The PCMG Oxford debate:** *"This house believes that the procurement process has damaged sponsor-CRO relations and the conduct of clinical trials"* The PCMG Conference favourite will see verbal battle commence once more. This time we debate the fiscal benefits of procurement processes vs impact on the relationships between sponsor and provider. Can the two co-exist or are they mutually exclusive? **Invigilator: Richard Scaife, PCMG Chairman** **Supporting the motion: Anna Matranga, Senior Director,** Global Scientific Affairs & Strategic Sourcing, Ipsen Innovation **Roger Joby,** R&NR Consulting Ltd **Against the motion: Jean Edwards,** Procurement Director, Europe, Australia & Japan, Eli Lilly **Vanessa Cooke,** Global Head, Strategic Sourcing R&D, Bayer Healthcare Procurement
17:30	**Close of conference day 1**
19:30	**Gala dinner** **Theme: 1980's – A risky decade for a risky business** (Coaches will depart from 19:15) ***Sponsored by*** medidata

Friday 12 June

09:00	**Introduction to day 2 and the morning session** **Session chair,** PCMG Committee Member
09:05	**9. Project Complexity: Structural, cultural or a combination?** What sort of managers are ideal for the increasing complexity in clinical development projects: All-rounder or analytical? People or detail orientated? Risk-averse or innovative? How can either side of the project team best adapt to their counterparts? We consider how this knowledge can be used to ensure 'best fit' when selecting providers. **Stephen Carver,** Lecturer, Consultant & Speaker in Project & Programme Management, Cranfield University School of Management (UK)
10:05	**PCMG's Room 101 – 'Episode 3: The next batch'** ***Sponsored by*** World Courier AmerisourceBergen
10:15	**Networking break** ***Sponsored by*** QUINTILES
11:00	**10. Compliance: What is it?** Ignorance is no defence. Our industry is under greater scrutiny than ever before following concerns of transparency and investigations and convictions across the global clinical trial environment. We determine what the definitions and essential rules are. **Rikke Winther,** Senior Director, Outsourcing Management R&D, Lundbeck (DK)
11:15	**11. Compliance: The Regulatory (EFPIA) landscape** Enactment of the EFPIA code. Recent compliance requirements in pharma affecting the cooperation with CROs **Marie-Claire Pickaert,** Deputy Director General, EFPIA
12:00	**12. Compliance: (How) does pharma & CRO implement EFPIA/Sunshine Act reporting requirements?** **Uffe K Rasmusen,** Senior Director, Corporate Compliance, Lundbeck (DK) **Corina O'Connell,** Associate Director, Transparency Reporting, ICON Clinical Research
12:45	**Lunch** ***Sponsored by*** COVANCE SOLUTIONS MADE REAL
13:45	**13. Compliance: Is R&D meeting all other related requirements - how are they integrated with good business practice?** **Q&A Session** **Paul Strickland,** Independent QA Consultant **Pauline Van Heinigen,** Senior Manager, Operations & Compliance, Reckitt Benckiser(UK)
14:45	**PCMG's Room 101 – 'Episode 4: Sentence is passed'** ***Sponsored by*** World Courier AmerisourceBergen
15:00	**Meeting close**
15:15	**Coach transfer to WAW Chopin airport** Departure times: 15:20 15:45 16:30 ***Sponsored by*** trifecta the investigator space experts

Speaker biographies (in order of appearance)

Richard Scaife
Mitsubishi Pharma Europe (PCMG Chairman)
Richard worked as an Intensive Care Nurse in the UK and Saudi Arabia, before managing a Medical Centre for British Aerospace at a Saudi Arabian airbase. On returning to the UK in 1990, he joined Ciba-Geigy in Pharma sales roles, followed by Sales Management and ultimately CNS portfolio Brand Management. He moved to the CRO sector in 1997 with Covance, then Fisher in Health Economics/ Reimbursement and Marketing roles respectively, then setting up a BD and Proposals unit at Quintiles before joining Daiichi-Sankyo in 2005. The subsequent ten years in clinical development outsourcing (moving to Mitsubishi Pharma's London office in 2009) have included global and EU outsourcing responsibilities ranging from creating a new outsourcing function to negotiating global CRO agreements and setting up global oversight structure and processes to build long-term, effective, working relationships, working closely with colleagues in Japan and US offices.

A member since 2006, Richard has been PCMG Committee Chairman since 2012. In the remaining time available, his other interests include motorcycles, scuba diving and learning to sail!

Lan Bandara, BSc PhD
Eisai Product Creation Systems (PCMG Vice Chairman)
Lan is the global head of outsourcing for Eisai and has over 15 years industry experience, including knowledge of preclinical and clinical outsourcing. Lan joined Eisai in 2005 to set up the European clinical outsourcing and contracting function where his group was responsible for outsourcing a wide range of clinical services. Now as a global team he is also responsible for global clinical vendor management including the implementation of strategic global outsourcing models. Prior to joining Eisai he was part of the clinical outsourcing group in AstraZeneca and also worked for a number of biotechnology companies. Lan has a PhD from the National Institute for Medical Research in London and is also the Vice Chair of the Pharmaceutical Contract Management Group (PCMG).

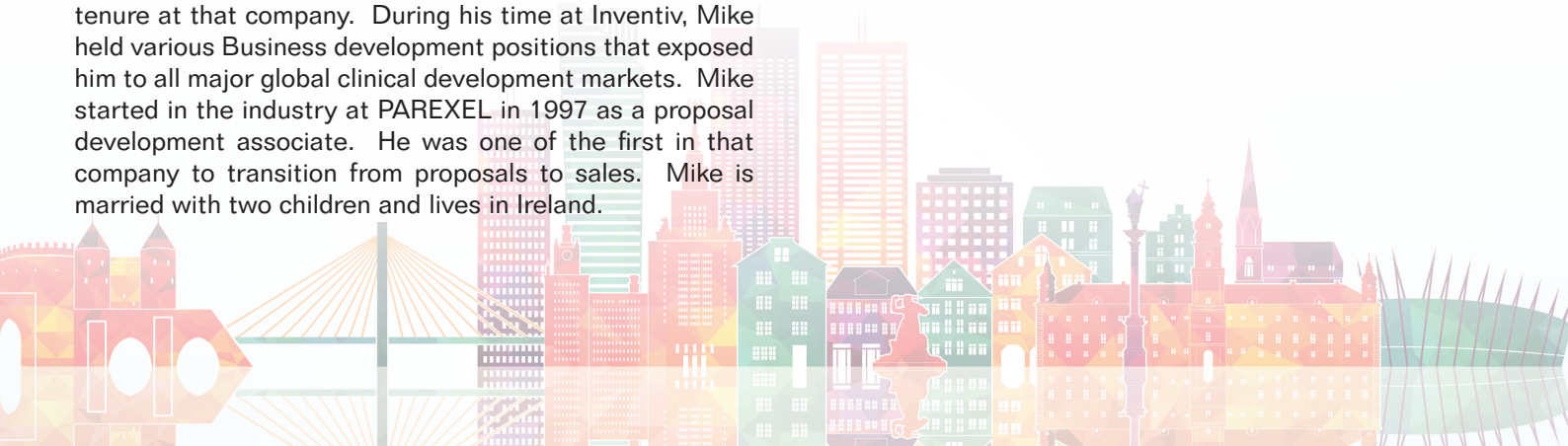
Mike Ryan
Medidata
Mike Ryan is Vice President of Strategic accounts at Medidata since April 2015. Prior to this he was global head of Inventiv's Phase II-IV Business Development team, a position he held for the final year of his 15-year tenure at that company. During his time at Inventiv, Mike held various Business development positions that exposed him to all major global clinical development markets. Mike started in the industry at PAREXEL in 1997 as a proposal development associate. He was one of the first in that company to transition from proposals to sales. Mike is married with two children and lives in Ireland.

Peter Davidson
Theorem Clinical
Peter Davidson joined Theorem Clinical Research in the role of Executive Account Director in March 2013. Peter has worked in the CRO industry in business development since 1996 where he has worked at ClinTrials Research, ICON and PAREXEL. He holds a degree in Biochemistry from University of Manchester.

Stephen Nabarro
Cancer Research UK
My scientific career to date has been underpinned by Cancer Research UK's vision 'to bring forward the day when all cancers are cured': from my first ever summer job doing pre-clinical in vitro experiments at the Institute of Cancer Research; my PhD in paediatric oncology at University College London; seven years and counting working at Cancer Research UK; culminating in my current role as Head of Clinical Operations and Data Management in the CRUK Centre for Drug Development.

Charlotte Allcock
Cancer Research UK
Charlotte Allcock is a Clinical Research Associate at the Centre for Drug Development (CDD) at Cancer Research UK, monitoring Phase I/II oncology clinical trials at multiple academic centres across the UK. Prior to this role, Charlotte was a Clinical Trial Assistant and Quality Management Assistant in the CDD. Before joining CRUK, Charlotte completed BSc Hons. Neuroscience at the University of Nottingham, UK.

Julianne Hull
WenStar Enterprises
For more than 25 years, Julianne has successfully held global leadership roles in outsourcing and operations for several pharmaceutical companies (Pfizer, Wyeth, Marion Merrell Dow, Biogen Idec and Ipsen). She is an accomplished manager and motivator of global staff. Julianne ran the key cross functional governance body driving successful delivery for inspection ready clinical trials for Wyeth. Responsible for strategic development and implementation of unique, quality and cost effective methods of outsourcing CDM led to the ground-breaking Wyeth Accenture strategic alliance for which Julianne had business and operational oversight. Julianne is CEO of WenStar Enterprises providing training and consultancy in the areas of outsourcing and clinical development.



Richard Young
Medidata
Richard has over 20 years of operational and business development experience within Pharma, Biotech, CRO and technology. Richard's extensive background in data management and clinical operations has seen him serve in multiple capacities across the globe, assuming full responsibility for client relations, trial design and execution, proposal and contract management, and process re-engineering.

Richard has spent time working in Europe and the United States for both sponsor and vendor organisations, and has focused on targeted monitoring, adaptive trial designs, CDISC standardisation and strategic technology reviews, across multiple therapeutic hours (especially oncology, HIV, respiratory, diabetes and GI).

Richard is a member of the several professional bodies, and actively participates in these communities. Having spent 5 years overseeing Medidata's Mid-Market team in EMEA, Richard has recently assumed a new role, managing the global consultancy organisations, and establishing new links to the industry leadership across the globe.

He graduated with honours from Coventry University in England with a B.S. in Biochemical Sciences.

Clara Heering, MSc, MSc,
ICON Plc
Clara holds degrees in Medical Biology and Risk Analysis. Clara has extensive experience in Clinical Research, starting her career as Research Fellow at Harvard Medical School, followed by 16 years in Pfizer where she started as a CRA and grew to the role of Director of the Business Innovation Unit, followed by 6 years of senior Clinical Operations roles at large CROs.

During her Clinical Research career, Clara has been involved in many initiatives and is a seasoned designer and implementer of innovation and change; including the design and implementation of Risk Based Monitoring at ICON.

Clara is an executive, past Chair of the Board of ACRP, member of the Board of EFGCP, past theme leader at DIA Europe and has been a volunteer in multiple taskforces and initiatives over the years.

Dr Kieran Doran
University College Cork
Dr Doran is currently the Chair of the Irish College of General Practitioners Research ethics Committee and also Legal Advisor to the Clinical Research Ethics Committee for the Cork Teaching Hospitals. He has also been on the Royal College of Physicians REC up until the end of last year.

Ann Meeker-O'Connell
Johnson & Johnson Quality and Compliance
Ann Meeker-O'Connell is the Head, Risk Management and External Engagement for J&J's Bioresearch Quality and Compliance organization. Previously, Ann served as the Senior Director for Clinical Strategy within Janssen's R&D Quality Assurance group. Prior to J&J, Ann was the Director of the Division of Good Clinical Practice Compliance within CDER's Office of Scientific Investigations at FDA. Ann is an Certified ISO 31000 Lead Trainer and a Certified Compliance and Ethics Professional.

Thierry Escudier
Institut de Recherche Pierre Fabre
Thierry has worked for more than 25 years in clinical operations in pharma (Rhône-Poulenc Rorer then Pierre Fabre), first as a monitor, then clinical trial manager and now as head of clinical operations.

Thierry has two main areas of responsibilities; firstly managing a team in charge of implementation and conduct of clinical trials (phase I to III) in various therapeutic areas worldwide; and secondly, selecting and supervising the best service providers (global CRO, local ones, central lab, central ECG, etc.). Thierry is a current member of the PCMG Committee.

Michelle Noble
Novella Clinical Resourcing
Michelle has been with Novella Clinical since 2010. As European Director of Novella Clinical Resourcing, the staffing division of Novella Clinical, Michelle has responsibility for the delivery of quality resourcing services both within Novella and to Pharmaceutical, Medical Device and Biotech clients with resourcing needs throughout Europe.

Michelle has extensive managerial experience in various commercial businesses as well as holding a senior role with the Institute of Clinical Research. She has built a successful team of experienced clinical recruiters for Novella that serves their client organisations and has recruited for more than 20 client programmes across multiple disciplines at all levels from new graduates to Directors and Executives.

Simon Addyman
Bank Station Capacity Upgrade Project
Simon Addyman started his career in property refurbishment before moving overseas to work on a major school building programme for the World Bank in The Gambia, West Africa. Simon then moved into humanitarian relief work with the engineering services division of United Nations Protection Force in the Former Yugoslavia. He then joined an international aid organisation as their construction programme manager, delivering a housing resettlement programme for refugees in Macedonia.

Before returning full time to the UK, Simon gained a distinction in his MSc in Construction Project Management from Heriot-Watt University. He joined London Underground in late 2000 and continues his professional development, becoming an APM Certificated Project Manager in 2008 and is currently undertaking a part-time PhD in Project Management at University College London.

Simon has spent his career in LU, from assistant project manager to programme manager, working on station infrastructure projects. He is currently the project manager for the Bank Station Capacity Upgrade project. The project has successfully implemented LU's novel Innovative Contractor Engagement procurement route for which Simon was awarded Project Professional of the Year at the APM Awards 2013.

Olena Goloborodko
Astellas Pharma Europe B.V
Ms Goloborodko's team is responsible for clinical outsourcing and contractual management of Astellas Global Development. Astellas Global Development division focuses on brining to the patients innovative therapeutics by thoroughly evaluating the potential of the Astellas portfolio and achieving regulatory approvals.

In her role Ms Goloborodko manages vendor selection, contractual solutions and vendor relationships, including defining of outsourcing strategy and vendor governance. She is also responsible for site and investigator's contracting within legal and compliance framework of Astellas.

Ms Goloborodko joined Astellas in 2007 and previously held various positions at the law firms and research industry. She holds Advanced Law degree from National Law Academy of Ukraine and Master in Corporate Law from Leiden University, The Netherlands.

Glen Scarlett
Celgene International Sarl
Glen Scarlett is an Associate Manager of Global Site Contracts at Celgene International Sarl, Switzerland, within the Portfolio Sourcing and Relationship Management group. The group is responsible for third party vendor Outsourcing, Contract and Alliance management.

He is responsible for oversight and management of the contract and budget negotiation process of clinical study sites for sponsored trials, actively supports the development and update of department processes and tools, as well as contributing to corporate initiatives.

Mr Scarlett is a qualified Solicitor and member of the Law Society in England and Wales, and has been a member of PCMG (Pledge) for a year and a half.

Roger Joby
R&NR Consulting Ltd
An international project management consultant and educator in project management, with over 40 year experience, principally in the pharmaceutical sector. Roger is also involved in academic research and has published papers and written articles on the application of Earned Value Management in clinical research with colleagues at Liverpool JM University. Roger specialises in customising project management tools like EVM, risk analysis, etc to suit his client specific needs in the highly uncertain world of drug development.

Anna M.C. Matranga, PhD, MBA
Ipsen Innovation
Anna has worked in pharma over the last 20+ years working for Eli Lilly (Erl Wood, UK), Allergan (Sophia Antipolis, France), Galderma (Sophia Antipolis, France) & is currently at Ipsen Innovation (Paris, France). She holds a PhD in microbiology (from Bristol University) and an MBA in general management/finance (from Henley Management College). She has strong experience in project management/leadership, training, benchmarking and relationship management. She has been in the R&D purchasing & outsourcing arena for the last 14 years. In her current position at Ipsen, she is responsible for the optimization of Ipsen R&D out & in-sourced activities and the relationship management of strategic sourcing partners.

Anna is a member of the Pharmaceutical Contract Management Group (having held chairperson & treasurer roles), is a regular industry speaker at pharma conferences and has also lectured in Organisational Behaviour (Skema Business School).

Jean Edwards
Eli Lilly and Co. Ltd
Jean is currently responsible for the procurement of multiple categories of spend including sales and marketing, travel, fleet and temporary labour across Europe, Japan and Canada at Lilly.

She moved to this role in 2012 following a spell back in clinical development within the Chorus organisation at Lilly as Chief Operating Officer. Before this she had spent eight years in the Procurement at Lilly having responsibility for the coordination of clinical outsourcing across Europe and ensuring that Lilly gets best value from their clinical suppliers. Prior to joining Lilly Jean spent most of her career with Bayer working in Clinical Research, Medical Writing, Quality Management and Contract Resource Management Groups.

Vanessa Cooke
Bayer HealthCare
A graduate in Pharmacology & Physiology. I joined the Pharmaceutical industry in 1986 as a CRA and worked for Bristol Myers and Wellcome. In 1990 I joined my first CRO as a Project Manager and spent 11 years working for 3 large CROs gaining global experience at a senior level in clinical operations, business development and executive management.

I joined Bayer in 2001 as Head of Global External Supplier Management, responsible for global outsourcing for phases II – IV within the Medical Department of Bayer Pharmaceuticals. In 2007 the remit of my team expanded from Pharma to HealthCare reporting into the Global Procurement function. I was appointed to my current position of Global Head of Strategic Sourcing R&D.

My team manage all external sourcing activities globally across the R&D functions of Bayer HealthCare. Including Research & Early Development, Pharma Development, Consumer Care, Diabetes Care, Animal Health and Laboratory Supplies. Our focus is on strategy, innovation, market intelligence, internal stakeholder alignment and collaboration and external supplier management.

Stephen Carver
Cranfield University – School of Management
Stephen is one of the top rated lecturers at Cranfield. Unusually for an academic he has spent most of his career working in the real world and his general attitude is "if you haven't done it you shouldn't teach it". Stephen lectures in Project & Programme Management and specialises in complex and VUCA change environments.

Rikke Winther
Lundbeck A/S
Rikke has worked in the CRO and Pharmaceutical industry for the past 22 years and has experience from Clinical R&D, Business Development and Contract/Outsourcing Management. During the last fourteen years she has built up, and is now globally responsible for Outsourcing Management R&D function at Lundbeck covering both contractual, operational and relationship related activities with all vendors as well as contribution to selected Lundbeck outsourcing strategies.

Prior to her employment at Lundbeck, Rikke worked for five years within bio-analytical research and clinical development in hospital settings. This was followed by four years of employment in a larger CRO – first as International Project Manager and then followed by setting up the first South East Asia office working as Business Development Manager and Line Manager.

Rikke is a Steering Committee member of the Pharmaceutical Contract Management Group (PCMG) in Europe. She is a contributing author of the book: "Outsourcing Clinical Development, Gower Publishing Limited".

Marie-Claire Pickaert
Deputy Director General, EFPIA
Ms Pickaert is the Deputy Director General of EFPIA, member of EFPIA's General Management. She also holds the position of Chief Finance Officer (CFO).

Ms Pickaert is Secretary to EFPIA's bodies. In this capacity, she is the guardian of the EFPIA Statutes.

She leads EFPIA's activities relating to **country support** and oversees **compliance activities**. She directs work on codes compliance and ethics, and coordinates transposition of EFPIA Codes into national codes. As part of her responsibilities in the day-to-day management of EFPIA, Ms Pickaert leads the Office Management Team, including human resource management.

Ms Pickaert joined EFPIA in 1989 to set up its Economic & Social Policy Committee. Building on her practical experience in pricing and reimbursement negotiations with national authorities earlier in her career, she advises membership and ad hoc groups in the area public policies on pricing and healthcare coverage.

Before joining EFPIA, Ms Pickaert was economic adviser, then Director of Economic and Social Affairs and Statistics & Information Processing at AGIM (Association générale de l'Industrie du Médicament en Belgique).

Uffe Rasmussen
Lundbeck A/S
Chief Compliance Officer at Lundbeck. Since 2009, responsible for developing the Lundbeck Group Compliance Structure, including the Lundbeck Code of Conduct and related global procedures and processes. Member of the Lundbeck Compliance Committee, which is headed by the acting CEO and chairman of the Board. Responsible for Lundbeck Corporate Social Responsibility Strategy and related projects, including Lundbeck's commitment to the UN Global Compact Principles. Working within the pharmaceutical industry for 15 years with Compliance, Corporate Social Responsibility (CSR), strategy development and implementation, project management, communication and auditing.

Corina O'Connell
ICON Clinical Research
Corina is Associate Director, Transparency Reporting for ICON Clinical Research. Corina leads the group responsible for the submission of reporting to Sponsors under current transparency legislation/codes and is directing the rollout of EFPIA reporting within ICON in anticipation of the first disclosure by its Sponsors in 2016. Corina has worked with ICON since 2003 and holds a BA in Accounting & Finance.

Paul Strickland
Strickland Quality Assurance Ltd
Paul Strickland has 23 years of experience in Clinical QA. He has audited across the world, given GCP training and refresher courses, and has facilitated many regulatory inspections.

Pauline van Heiningen
Reckitt Benckiser(UK)
Pauline van Heiningen joined RB's Healthcare Clinical Department as R&D Clinical Outsourcing Manager in February 2013 but moved into the role of Senior Manager Operations and Compliance in August of last year. She has over 25 years of experience both in the Pharmaceutical industry and in Contract Research Organizations (Astellas, Novartis, PRA's phase I unit (previously Pharma Bio-Research) and Chiltern) where she held a range of positions in project management, line management and clinical outsourcing.

Pauline is a trained pharmacist (D. Pharm) with a Ph.D. in cardiovascular pharmacology.

Notes

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ACKNOWLEDGEMENTS

PCMG Committee

Tarminder Baines
Lan Bandara
David Davies
Thierry Escudier
Antje Hindahl
Steve Martindill
Baljit Panesar
Gill Roberts
Richard Scaife
Susan Tio-Gaillard
Rikke Winther

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