Review of the 2019 Annual Conference

"Addressing the challenges of the 7 C's of clinical outsourcing"

Date: 5-7 June 2019
Location: The Melia Hotel, Sitges, Barcelona, Spain

DAY 1

08.30 - 08.55
Welcome
Richard Scaife (PCMG Chair) and Gill Slater (PCMG Vice-Chair)

Chaired by Gill Slater & Dan Nicholson

09.00 - 09.30
There be Dragons…
John Hubbard (Board member, CRF Bracket - a portfolio company of Genstar Capital)

09.30 - 10.15
Pharma and CRO consolidation, expansion and extension - what are the goals, options and implications for outsourcing practice?
Bill Burns (Non-Exec. Director, Shire Pharmaceuticals; Governor, Wellcome Trust), Ludo Reydners (CEO, Premier Research Inc.), John Hubbard (CRF Bracket)

Chaired by Dorothee Walter & Natalie Fforde

11.15 - 12.00
Collaboration with Academia - hard truths
Jean Edwards (formerly Eli Lilly & Company; PCMG Fellowship Member 2018), Antje Hindahl (Independent Consultant)

12.00 - 12.30
Successfully delivering on the Magic Triangle - How to ensure quality, speed and value
Richard Butterworth (Senior Director in Alliance Management, Merck Group)

Chaired by Dave Webber & Mark Bee

13.50 - 14.35
All aboard for Big Data - or are we?
Moderator: Francis Kendall (Senior Director in Biostatics and Programming, Cytel)
Panel: Nan Shao (VP and Global Head of Biostatics and Statistical Programming, PAREXEL), Sam Roosz (Head of Life Sciences, Datavant)

14.35 - 15.15
Clinical trials with Medical Devices: what is the difference?
Dorothee Walter (Strategic Sourcing Manager, Bayer AG), Aly Talen (Co-Founder and SVP of Business Development, genae)

Facilitated by Samme Allen

16.00 - 17.15
Sailing 'Closer to the Wind' - Harnessing the Power of the PCMG Conference

17.15 - 17.30
Presentation of the PCMG Lifetime achievement award
Awarded by Richard Scaife and Gill Slater on behalf of the Committee

Welcome, introduction and review of the PCMG

Richard Scaife and Gill Roberts (PCMG Chairman and Vice-Chair) opened the conference with a consideration of changes and innovations in this dynamic, evolving industry. The new PCMG website was highlighted and the value of PCMG membership emphasised, in particular a new Advanced Outsourcing training course, which builds on the success of the Essentials course and which places PCMG at the heart of best practice in clinical outsourcing and procurement.

There be Dragons…

John Hubbard described industry drivers and disrupters in a fascinating, evidence-based review of political changes and healthcare reform, the pharma services landscape and investment trends and predictions. He cited advances in diagnostics, robotics and AI, clinical innovation, policy and regulatory reform, value chain integration, new technology entrants, genomics, big data and analytics and asked how these developments would provide improved healthcare outcomes. Patients want new treatment options for ever-more complex indications, but they also want reasonable pricing.

FDA approved 59 new products in 2018 and there is increasing investment particularly in the innovative SME sector. Oncology is a key focus with more targets being identified and a greater understanding of cancer biology. CROs continue to grow, fuelled by increasing pharma spend and vertical integration of services through innovation and acquisition. There continue to be investor opportunities in the areas of CRO consolidation and innovation.

Focussing on outsourcing, John concluded there were no differences between full service and functional service provider (FSP) outsourcing models with regard to total cost and costs by function. There was a general perception of greater control with FSP model, but higher internal fixed costs to oversee and manage vendors. Most sponsor-vendor relationships are evolving into a partnering approach, regardless of outsourcing model, and that there was increased customer satisfaction with partnerships compared to 2017. However, he concluded the most important factors are organisational culture and vendor working models.

Consolidation, expansion and extension - what does it mean for outsourcing?

This was a fascinating and inspiring panel session with three industry luminaries giving their opinions on exciting developments and the implications for outsourcing. Ludo Reynders described a trend away from blockbuster approvals and towards orphan drugs, with accelerated development pipelines and regulatory value of real world evidence (RWE) data post-approval. He offered an enticing vision of future regulatory approvals routinely obtained on the basis of phase II clinical trial data and with pre-planned programs of large-

scale, patient-use data collected and submitted as a condition of the approval. The evolution of big data and evidence-based capabilities will drive greater speed and efficiencies in drug development and approval. There are big opportunities in the use of genomic sequence data and digitising source data to allow real time evaluation and the use of AI to refine analysis, improve accuracy and feed complex predictive modelling.

Bill Burns commented on the nimble, effective and efficient small pharma virtual model compared to big pharma. He discussed the accessibility of personal healthcare data versus the need for confidentiality. He highlighted exciting developments in Estonia, which could facilitate big data analytics for the population of whole countries to

John Hubbard routes out the dragons in the outsourcing industry

provide powerful predictive tools based on retrospective RWE and identify the best treatment pathways and patient outcomes.

John Hubbard considered the link between cost of development versus value of the asset. Some CROs are better than others at maximising the asset value during the early phases of clinical research. He also championed the emergence of drug development consortia; a collection of entities working with a CRO to resolve a common problem. He commented on the emergence of not-for-profit organisations progressing orphan drugs and cooperating with patient advocacy groups, philanthropic investors and charities to drive the development programs. He felt this will give rise to novel models in partnering with the CRO community, as key stakeholders, in future.

Collaboration with Academia - hard truths

Academic Research Organisations (AROs) have grown into broad research organisations offering CRO-like services and with independence as a key feature that is valued by regulators and patient advocacy groups alike. However, this has come with challenges, primarily because AROs have different motivations, expertise and core competencies. PCMG members reported increasing numbers of ARO contracts, but with greater complexity and a lack of templates, leading to delays in agreeing terms compared with CROs. Operational staff tended to conduct relationship management and oversight with little involvement from outsourcing. For example, outsourcing teams are involved in only 14% of ARO contracting and only 10% of award decisions. And in only a third of cases does the sponsor audit the ARO provider and in a quarter of cases there is zero or very limited due diligence. These factors might help to explain the quality issues.

Jean and Antje concluded an excellent and insightful presentation with some recommendations for Sponsors and CROs when working with AROs. PCMG is developing a guidance document to identify and share best practice to establish common, high standards of governance and oversight with AROs.

Successfully delivering on the Magic Triangle - How to ensure quality, speed and value

This was a fascinating and compelling account of one of the world's largest pharma companies aiming to achieve 20% cost savings across their entire global clinical trials program, whilst maintaining high quality standards and delivery on time. Richard commented that Merck has 450 global and local clinical trials currently underway with activities in over 70 countries involving over 4,000 investigator sites and more than 170,000 trial subjects. Their new outsourcing strategy is summarised in the acronym "P4P" ("pay for performance") and with a focus on delivery on time, to quality standards and at lower cost to generate greater value.

The change process was complicated and deep, but distilled down to some key principles, including clarity on the outcomes, building team knowledge for better outsourcing in the future, understanding the internal stakeholder

Richard Scaife and Gill Slater frame the expert panel (L-R) Ludo Reydners, John Hubbard, Bill Burns

needs and enshrining the agreed terms and conditions into new Master Service Agreements (MSAs) that would capture the principles of paying for performance, delivering on promises, generating value whilst being competitively priced. Key features included withholding payments until performance was delivered, skewed payment milestones dependent on delivery, minimal up-front investment and with "penalties" in the form of retained bonuses. The goal was for the CROs to propose the innovation, monetise the value creation, then commit to delivery as part of the contract. One year later, Merck have increased their CRO pool from one to two, with aligned goals and with a constructive, supportive alliance which is beginning to deliver tangible cost savings through cost avoidance.

All aboard for Big Data - or are we?

The session focussed on the use of technology to create "real world information pools" that link data from multiple platforms to create a holistic and longitudinal view of patient care. This provides a seamless, relevant "data lake" for analytics and can be used to support tasks such as protocol design, market sizing, patient eligibility criteria and selection.

The key challenges are to define the desired outcomes and to work backwards to define inputs and how the data will be integrated. Then to build a dedicated data network, populated by an open, "real-world data ecosystem" in place 24/7, receiving, integrating and analysing data on an ongoing basis. These are key steps to delivering real value from the promise of big data.

Clinical trials with Medical Devices: what is the difference?

Dorothee and Aly provided a detailed explanation of medical device classification, regulatory processes and risk-based quality management system (QMS). Medical device development has to comply with ISO13485 (not ICH GCP), which has a strong focus on risk identification and mitigation.

Medical device outsourcing has seen continuous growth and high value over recent years, with CROs now acquiring specialist medical device CROs to integrate this service into their portfolio. The CRO selection process is similar to pharma outsourcing. However, a key success factor is to work with a CRO experienced in developing devices and familiar with the medical device regulations.

Sailing 'Closer to the Wind' - Harnessing the Power of the PCMG Conference

Samme Allen chaired an informative and enjoyable session of team debates, with groups arguing for — or against — the following pertinent industry issues, such as: fixed price, outcomes-based contracts with bonus/ penalty clauses; CRO responsibility for third party vendors; full-service mega-CROs; Functional outsourcing; RFIs/mock proposals and strategic partnerships/ preferred providers. There were some outstanding performances and excellent arguments presented. On this evidence, debate is a core competence for outsourcing professionals!

Presentation of the PCMG Lifetime achievement award

Roger Joby was the proud and popular winner of the 2019 PCMG Lifetime Achievement in Outsourcing. Roger has worked for pharma and CRO companies in a long and distinguished career. He is an innovative thinker who questions the status quo in an endeavour to improve systems, processes, people and outcomes in the outsourcing interface. A long term PCMG supporter, Roger was presented with his award by PCMG Chairman, Richard Scaife.

Roger Joby receives Lifetime achievement award from Chairman Richard Scaife

DAY 2

Chaired by Pia Sauer Larsen & Graham Belgrave

09.15 - 10.00
Keynote Session: Practice not politics - Are you Brexit ready yet?
Chair: Steve Martindill (PCMG Director; Exec. Director Clinical Operations, Gilead)
Panel: Bill Burns (Shire Pharmaceuticals; Wellcome Trust), Christopher Clare (Covance Laboratories), Pam Turner (QP, Geryon Pharma)

Chaired by Antje Hindahl & Mike Ryan

10.45 - 12.00
Far Horizons & Close Contact - Managing the Change of demand for outsourced clinical studies in Japan
Chair: Rob Aitchison (Head of Outsourcing & Contracts, Ono Pharmaceutical UK)
Panel: Dan Feldman (VP Asia Pacific, Medpace), Eunhee Chung PhD (Director of Global Clinical Development, SOUSEIKAI Global Clinical Research Center), Brendan Ellis (Global Project Manager, Asahi Kasei)

Chaired by Sandra Johnson & Jean Edwards

12.50 -13.50
"Time, Cost, Quality and Patient Centricity - should this be the 4th consideration in clinical trial outsourcing?"
Thierry Escudier (Head of Clinical Development, Pierre Fabre Medicament), Bruce Hellman (CEO, uMotif)

13.50 - 14.35
Procurement - Outsourcing with lives at stake: ideas, practice and lessons from the defence sector
Professor Trevor Taylor (Royal United Services Institute)

Keynote Session: Practice not politics - Are you Brexit ready yet?

This session comprised two parts – a survey of the conference delegates and a panel discussion with concerned and motivated speakers providing their perspectives.

The two main issues of concern for the delegates were supply chain/ distribution (49%) and regulatory issues (trial and marketing authorisations; 34%). Many delegates were unsure of their employers contingency planning for a "no deal" Brexit and some were not aware of their vendor preparations for Brexit. The panel discussion reflected this confusion, with observations which were generally negative. Bill Burns voiced concerns about the rights of research academics from overseas to continue to support our innovation base. There are opportunities for Britain – for example translational medicine might be a strategic direction for UK future competitiveness in the world – and generate lots of value. So we need to protect it and retain EU workers in the UK, despite Brexit. Christopher stated there had been only one staff member lost from Covance in Harrogate, but there was no room for complacency. Pam reported on major regulatory consequences already manifest as a result of Brexit, including the relocation of the EMA office, the likely exclusion of Britain from the centralised procedure and the loss of rapporteur status. Chris expressed concern about QP release of product arriving from the EU after Brexit and the need for QP release after relabel. Covance had also amended 120 licences for the importation of chemicals.

The panel concluded that even now it was not clear what the consequences of Brexit would be on the UK and the rest of the member states. We need a sensible, long term approach to remain competitive.

Richard Butterworth explains how to get best value from your CRO

Far Horizons & Close Contact - Managing the Change of demand for outsourced clinical studies in Japan

This interesting session with well-informed panellists considered the opportunities presented by the Japanese pharmaceutical market; the second largest pharma market in the world. Eunhee reported that Japan was now "opening up" as the regulators

relax their restrictions towards foreign companies conducting clinical research in Japan.

Outsourcing by Japanese pharma is a relatively recent phenomenon and represents a huge opportunity for the Western CRO industry. Japanese CRO prices are approximately 1.8 times higher than those in the US and they are rising as the market is poorly served. Drug prices are x2-x3 the US prices, which again emphasises the value of the market. Dan stated that staffing was a big problem due to lack of appropriately qualified and skilled workers. There were not enough people, for example, for Gilead to recruit from the Japanese population alone. And Dan explained that Medpace have 40 CRAs in Japan, but Brendan commented that each CRA only monitors 3 sites because of the culture of forging deeper relationships with a smaller number of investigator sites.

The panel concluded that Japan was a huge potential market for Western CROs as the industry becomes de-regulated and restrictions are relaxed. The fundamental dynamics of the industry are attractive for the conduct of clinical research with excellent standards of GCP and excellent potential returns.

Brendan Ellis, Eunhee Chung and Dan Feldman discuss the potential of Japan (L-R)

"Time, Cost, Quality and Patient Centricity - should this be the 4th consideration in clinical trial outsourcing?"

Patients have increasingly become key stakeholders within drug development, evolving from clinical trial participants to being much more actively engaged with the research. However only 25% of delegates considered patient centricity to be a differentiating factor when choosing a CRO. Thierry

The team leaders for the "Sailing close to the wind" debates

championed an embedded culture of acceptance for the principle of the patient as a key stakeholder and customer, whose needs should be at the very forefront of the desired performance criteria for the product. Thierry felt there had been a welcomed strategic shift with enlightened sponsors and CROs moving from transactional relationships to partnerships with patient advocacy groups and patients themselves. Further, Thierry urged CROs to consider a patient-centric approach in their proposals as a differentiator of their services.

Bruce Hellman gave an engaging and impactful presentation to highlight the value of modern, simple, user-friendly data capture platforms. Bruce urged the audience to think about what would inspire patients and to appeal to these aspects. Information is a key tool. He cited the value of newsletters to inform subjects how a clinical trial is progressing and how their involvement is contributing to the bigger picture. Finally, Bruce urged the audience to start with the patient when designing trials, not with the product.

Procurement – outsourcing with lives at stake: Ideas, practices and lessons from the defence sector

Professor Taylor is an expert in the procurement of military hardware and services and provided an enlightened perspective. He cited a number of similarities between pharma R&D and defence procurement; they are both concerned with human wellbeing, they strive for world class performance and quality is a pivotal performance requirement. The defence industry is subject to political intervention and the vagaries of public perception, but outsourcing is currently considered an effective use of funds and 60-65% of the UK defence budget is spent on outsourced activities.

In a series of key recommendations, Professor Taylor encouraged the audience to be an intelligent customer, to constantly consider insourcing, to work on relationships as well as contracts, to look for agile, responsive and innovative suppliers, to actively manage the supply chain, to beware of low-priced offers, to allow time for innovation and to consider risk throughout the process.

Wrap up and close

Sandra Johnson (MMV & Steering Comm. Chair) closed the conference by thanking speakers, sponsors, the steering committee, the session chairs and finally the audience for their attention and inspired company.

The final announcement was that the 2020 PCMG Annual Conference will be held in Krakow, Poland and will take place during 3-5 June 2020. The theme, 2020 VISION, will focus on the near future of clinical study outsourcing and related compliance issues that are essential knowledge for all outsourcing professionals.

Put it in your diaries now!