Review of the 2017 Annual Conference

Think Global, Act Local: Meeting strategic ideals with real-world outsourcing practices

Date: 7-9 June 2017
Location: The Radisson Blu Scandinavia, Copenhagen, Denmark

DAY 1

08.30 – 08.55
Welcome
Richard Scaife (PCMG Chair) and Gill Roberts (PCMG Vice Chair)

09.00 – 10.00
Keynote address: Increasing technology adoption in global clinical development: Promises and risks
Bryan Spielman (Verint Systems)

10.45 – 11.30
Stormy outlook: Surviving the CRA drought
Sue Stansfield (Clinical Operations Expert)
Prof Joe Eustace (University College Cork, Ireland)

11.30 – 12.30
Tomorrow's PCMG World
Group

13.35 – 14.15
It's in the POST
Sam Bunce (Parliamentary Office of Science and Technology)

14.15 – 15.00
It's all about data: The impact of new global data protection changes
Olena Goloborodko (Celgene)
Richard Young (Veeva)
Ray Collia (Greenphire)

15.45 – 16:30
Change is good? A new outsourcing concept becomes reality
Bryan Haas (PRA Health Sciences)
Dominika Kovacs (Takeda)

16.30 - 17.15
Universally Challenged
Group

Welcome, introduction and review of the PCMG year

Richard Scaife (PCMG Chair) and Gill Roberts (PCMG Vice-Chair) opened the meeting by discussing the past year and plans for the future.

Keynote address: Increasing technology adoption in global clinical development: Promises and risks

The world's population is aging and burden of healthcare resources is expected to double over the next decade. The cost of drugs has become an easy target for saving. Talk has focused aligning reimbursement with patient outcomes.

It is becoming incumbent on those likely to benefit from new treatments to pay for their development. Will medicines unlikely to provide a return on investment end up being developed? Clearly, real world data is essential when assessing the potential of new targets. Mergers such as that between Quintiles and IMS appear to reflect the concept of developing end-to-end solutions.

Data sits firmly at the centre of the future pharmaceutical industry. We will all be heavily monitored and whole populations might serve as trial participants. How much of the monitoring will be mandated and who owns the data? We are likely to see technology companies come to the fore as pharma's trillion dollar spend attracts conglomerates like Google and Microsoft. Pharma companies will need to look beyond the pill – possibly to devices that administer medicines intelligently, contextualising data, even dictating behavioural changes.

Stormy outlook: Surviving the CRA drought

Change to the clinical study over the last 10 years have been reflected in the role of the Clinical Research Associate (CRA). Increased per patient data and 'cleaning' requirements have seen the role evolve, with devolution of responsibilities such as site negotiations, fault-finding and submissions to specialist functions. Many feel the role has become devalued. There is a marked reduction in the number of available CRAs and an increase in turnover making resourcing a global priority for CROs and Sponsors. Study data quality, site relationships, costs, timing (and more) are at risk.
We need a better understanding of the current employment space. For example, why do CRAs change jobs so frequently? Perhaps it is time to provide more formal and competency-base approach to training so the arbitrary 2-years experience required can be modified.

Tomorrow's PCMG World

We may have the Technology... but are we willing to unleash it? In the format of the 1980's and 90's BBC television programme, Tomorrow's World, a panel of PCMG industry experts looked into aspects of current practice that they considered likely to be challenged in the future. We need to adapt to increasing costs of drug development and the changing face of ageing patient populations with multiple comorbidities. Many pharmaceutical companies are changing focus to more personalised treatments. In the rare and ultra-rare disease space the challenge is getting access

to patients, designing relevant protocols and enlisting suitably knowledgeable investigators. Clearly, access to electronic patient records will facilitate recruitment.

Is the classic pharma business model for the clinical trial dying away? Focus is being placed on the value of data gained in less formal settings. How will it impact on the role of the data manager and study monitor? Hope lies in the ability of intelligent automation and artificial intelligence to interpret the data. Will the machines be able to 'teach' people how to interpret what they find? What impact will this have on jobs?

The future will be about data exploitation. Emphasis is shifting to technology companies, like Samsung, and development of smart textiles, implantable chips and other means of collecting health data. Do we know what we are looking for? Pharmaceutical companies and CROs are currently on the lookout for the next industry-changing developments to exploit. The example provided was that of 23andMe, who collected information on over 800,000 people and have recently sold data on Alzheimer's disease to Genetech for $60 million.

All serious players have active innovation departments looking to 'bring in' or adopt new and effective practices. There remains the issue of how these changes will influence the workplace and when. The industry has always placed emphasis on recruiting highly educated candidates, however the current generation are looking to boot their own companies rather than enter a 25-year career. There is currently a shortage of CRAs but that will be nothing compared with the future need for analysts who can interface with the ocean of data before us.

It's in the POST

Hard or soft, Brexit has unleashed a world of uncertainty. Will the UK change from a global to local player? The Parliamentary Office of Science and Technology, who conduct research to provide evidence-informed scrutiny of government, is assessing the possible impact of Brexit on the life-sciences industry. The research posed five key questions focused on the status of the UK regulatory landscape, the impact of the CTD, the new EU CTR and portal and Brexit.

Generally, stakeholders agreed that the UK regulators provided a (relatively) streamlined process for approving clinical trials and took a lead in driving innovative practice within the UK. The new EU CTR is expected to introduce harmonisation across EU member states and provide a new EU-wide portal and trial database. There have been delays in the introduction of the new legislation and current timelines predict that this will not be before the end on 2018 and will most likely be after the Great Repeal Bill.

The EMA is expected to leave the UK and the UK to leave the European regulatory framework. The MHRA will need to expand its role in taking on new drug applications. It will take time to implement and is expected to result in a delay in the UK's access new medicines. Although Brexit may bring opportunities it will require a cooperative regulatory body, reduced bureaucracy and commitment to adjusting to paradigm changes within the industry.

It's all about data: The impact of new global data protection changes

Are we planning to be sufficiently compliant with new data protection requirements? The introduction of the EU General Data Protection Regulation (GDPR), requires data systems be designed from the bottom up for security. Olena Goloborodko shared Celgene's experience when they reviewed their data security protocols. A thorough assessment indicated that change was necessary and they are planning to transfer their systems to a cloud-based environment.

Richard Young from Veeva looked at the technical impact changes are likely to have on healthcare, life sciences and commercial environments. The challenge will be how to engineer processes that permits the ready (and secure) communication between the three otherwise unconnected systems. As ever more data is being collected the question arises as to how it will be utilised in ways that will ensure no third party will be able to 'triangulate' on specific patients.

An early win will be to transfer data in electronic medical records to commercial systems. How will these systems adapt to changes in patient requirements? As patients age their needs for medical intervention increases and they may change the way they feel about the data they share. Ray Collia from Greenphire gave a vision from the patient perspective. What are the approaches to pseudoanonymised patient data, can it be used beyond the collection criteria and are they patient-centric? Does changing the format of the data and rights also affect the patient's right to be forgotten?

Change is good? A new outsourcing concept becomes reality

The pharmaceutical industry has long investigated strategic partnerships. The recent collaboration entered into by PRA and Takeda has been heralded as a innovative agreement between two companies that share a common focus. Are we seeing the demise of pharma operations or the future of clinical outsourcing? Takeda underwent a series of changes in response to market challenges up to 2015. Takeda wanted to develop systems that would allow them to respond quickly to opportunities. It addressed this by building a closer relationship with PRA. Both organisations set themselves the target of doing things differently, aligning their goals and adopting a similar culture (both able to enter into arrangements with other organisations). The changes provided opportunities to rebuild the way things were done. Oversight formed part of the challenge with focus on reducing duplication, fire-walling and silo-ing of teams/data to prevent conflicts of interest and working towards a delivery-based 'return-on-investment' management model. Parallel and over-lapping work streams still exist but this will be corrected moving forward.

Universally Challenged

As light relief, the end to Day 1 was marked by a quiz between representatives from the pharmaceutical industry and from the world of CROs. At first competition between the two teams was fierce but Team CRO soon took a commanding lead, finally winning 34 points to 17.

DAY 2

09.05 – 10.10
Keynote address: Great Expectations
Thomas Senderovitz
(Danish Medicines Agency)

10.45 – 11.45
A missing link in study plan implementation?
Diana Sims-Silbermann
(Janssen Pharmaceuticals)
Philipp Badorrek (Fraunhofer ITEM)
Wendy Baird (Synexus)

11.45 – 12.30
Lessons in implementation and change management of a global procurement directive: A play in 7 acts
Ensemble

13.30 – 14.15
Operationalising the Global Functional Service Provider Model
Nick Lewis (Bayer)

14.15 – 15.00
Emergency PCMG Committee interactive discussion: CRO global consolidation – cause for celebration or concern?
Group

15.00 – 15.15
Close
Gill Roberts
Susan Tio-Gaillard
Dan Nicholson

Keynote address: Great Expectations

An increasing number of complex molecules are being studied in clinical trials that are adopting ever more intricate designs in a changing regulatory landscape. The industry is attempting to deliver on these challenges in an environment where there is a shortage of people with the necessary skill-sets and where trust in authorities is falling.

The discovery of ever more specific and informative biomarkers is empowering early intervention perhaps avoiding the secondary consequences of disease. This raises difficult risk:benefit questions relating to exposure of healthy people to potentially toxic medicines. Similar challenges are occurring with medical devices. What will happen with patient specific, 3-D devices printed on site? How will we evaluate the health benefits of augmented reality, tricorders, wearables, nanosensors and tattoo devices? New digitised approaches to healthcare and mobile health will see the current trend in health data collection keep growing. Numerous healthcare 'aps' are available but there is no requirement for testing or validation. We are facing a data avalanche, 90% of all data ever recorded was created in the last 2 years and more than 80% of it is unstructured. The challenge will be in contextualising and understanding the data.

The Danes leave their mark: Dr Thomas Senderovitz , CEO of the Danish Medicines Agency, predicting the future

The conclusion drawn was that we are currently in the middle of a revolution driven, in part, by a deluge of data. Appropriate discussions are needed to determine accessibility, ownership integrity and protection of this data. With an increasing trend towards outsourcing development plans, it seems prudent to review how safety signals are detected and communicated to relevant authorities and how to filter valuable data from white noise. This accommodation will be necessary to convince regulatory authorities that appropriate oversight is being provided because, when something goes wrong, they will be likely to lock down and reverse recent progress.

A missing link in study plan implementation?

The session looked at mastering the complexities of global site budget implementation from the perspective of the various stakeholders. From the perspective of an investigator at a non-commercial site, budgeting represents a significant challenge. Investigator contracts often involve fixed budgets based on sponsor-dictated fair market values, whereas CRO contracts are negotiated. Non-commercial sites do not have ready understanding of their actual overheads and how to modify budget assessments relating to the type and size of study.

Often, the Sponsor negotiates a budget with a CRO who passes the agreed budget to the site management organization (SMO) who is responsible for identifying sites. As we move down the supply chain the margins for each are pressured.

Not every situation fits into a set budget model. Effectively, the CRO and SMO want to be able to avoid repeatedly going back to the Sponsor for additional funds. All parties need to be able to trust proposed costs. Requests for 'economies of scale' made during negotiations demonstrate a failure to understand the delivery model.

The problem with the current drive to lower cost and requests for discounts, economies of scale and applied penalties, is that they fail to consider the complexity of the relationships required to deliver larger clinical studies. Sites are frequently pressured to accept lower costs.

Lengthening payment terms dictated by Sponsors only serve to apply further pressure which filters down to the sites, who are still expected to deliver the clinical trial in a face of budget restrictions. The potential is for sites to become disengaged and/or demotivated.

Lessons in implementation and change management of a global procurement directive: A play in 7 acts

In a change to the standard format to presentations, the organising committee arranged for a session to be presented on the motivations and consequences behind cost cutting initiatives in the pharmaceutical industry in the form of a play inspired by Carl Emerson (InsideOut Solutions). It focused on the problems that arise

when attempts are made to cut costs, highlighting the risks to operational delivery, employee motivation and quality.

Julianne Hull (Wenstar Enterprises) provided the stage production and members of the PCMG Steering Committee delivered performances as employees in a (hypothetical) pharma company struggling to implement a global strategic objective.

Polling the audience after the performance indicated few surprises, demonstrating their resonance the the underlying story-line and motivations of the characters. It was clear the industry continues to suffer from poorly considered strategies and initiatives that impact on job satisfaction.

Operationalising the Global Functional Service Provider Model

A case study described Bayer's experience of operationalising a global service provider model. At the start of the journey, Bayer had 380 clinical TAs in 44 countries with 103 different contracts in place with 79 suppliers. Bayer first needed to find what was happening in each country. Four different local influencing factors emerged from a period of consultation: legal, HR, Procurement and clinical operations. They also mapped stakeholder involvement and what influenced resource requisition.

Community forums allowed for information exchange identifying the different pathways being used. In the end, 320 of a target 350 operatives

We have been seeing considerable changes in the CRO landscape. It started with LabCorp & Covance, then Quintiles and IMS – further shifts are Annual Conference and attendance of

Emergency PCMG Committee interactive discussion: CRO global consolidation – cause for celebration or concern?

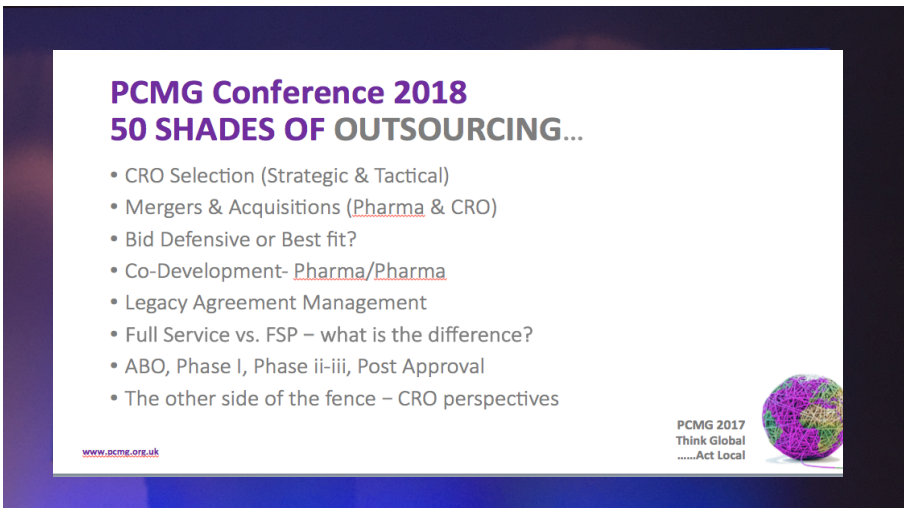
INC Research's CEO, Alistair Macdonald, to conduct a panel discussion session looking at the process of consolidation. Panel members representing the PCMG Committee included Antje Hindahl (Celegene), Thierry Escudier (Pierre Fabre), Susan Tio-Gaillard (ProQr) and Dave Webber (Gilead). The purpose was to analyse, debate and forecast the implications for outsourcing practice from the perspective of small, medium and large company and in relation to staffing, continuity of service and costs.

Discussions raised by the group covered a broad range of topics. It was agreed that changes in technology within the industry are likely to be driven by CROs and partner organisations as they try to differentiate themselves for competitors. Alistair Macdonald noted how INC Research partnered with a technology company rather than developing its own solutions in-house. The company decided it would be better served focusing on its core competency and selecting an off-the-shelf solution in Medidata. Changes in collaboration between the pharmaceutical industry partners and CROs have been interesting. We have seen new types of relationships develop around the optimal utilization of emerging technologies. The question was asked as to where the CRO will eventually sit as reliance on each other services has become business critical and have started to co-create solutions to common challenges.

One of the biggest changes to the industry is the amount of data being collected and what is being done with it. Clearly valuable information and understandings reside within the data. These may change the way the industry operates but we need to know what we have and work out how we can use it. The group discussed an example of placebo-controlled trials – the mainstay of any drug development programme. The question arose that, considering the number of healthy subjects that have received placebo in clinical trails (and the data that has been recorded), whether it is necessary to include placebo arms in future early phase studies.

Clearly, valuable information and understandings reside within the data. These may change the way the industry operates but we need to know what we have and work out how we can use it. Concerns have been raised over the integrity of the data and how to restrict access to confidential data?

CROs are competing in a capability war targeted currently at talent, scale and access. There are few opportunities for growth. With consolidation in the CRO space it will become ever harder for smaller CRO's to fulfil the requirements for 'big system' solutions that demonstrate compliance.



Announcement of the focus for the 2018 PCMG conference

Meeting close

In closing the meeting the PCMG Steering Committee summarised many of the key points and thanked all the participants for their enthusiastic involvement and contributions on behalf of the committee.

The final announcement was that the theme for the 2018 PMG Conference will be "50 Shades of Outsourcing" and that it will be held on 6-8 June a the Excelsior Hotel, Valetta in Malta.