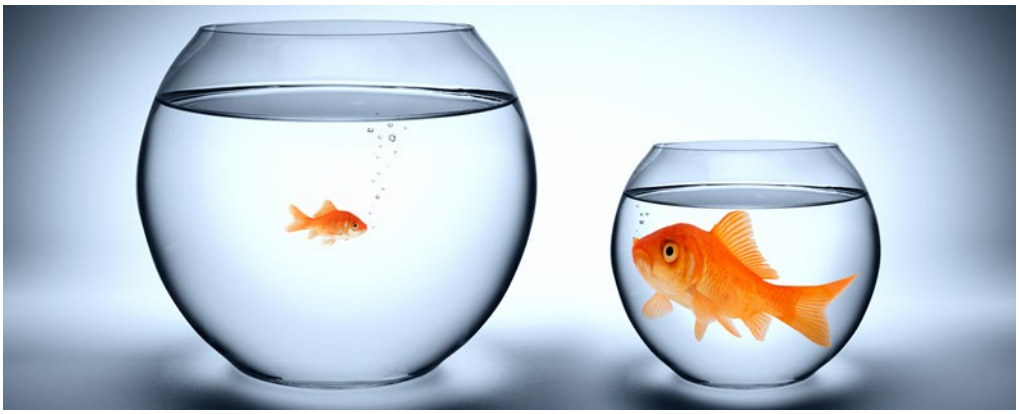
PCMG SPRING WORKSHOP
BIG LESSONS FROM SMALL COMPANIES.
Thursday 28th April 2022
Scandic CPH StrandPark Hotel
Amagerstrandvej 401
2770 Kastrup
Denmark

Pharmaceutical
Contract Management Group

What ALL sponsors can learn from biotech and small pharma and outsourcing experience.

The outsourcing reality in pre-revenue, smaller clinical trial sponsors is often very different from the established and formalised outsourcing functions in large pharma. A tiny infrastructure lacking support functions, a small number of assets in development with highly visible outsourcing outcomes, highly focussed core competencies and often with no commercial income.

It's the sort of environment that encourages rapid and effective decision-making with no hiding place for failure, including outsourcing management. PCMG has identified key points from this growing category of outsourcing that are relevant to large as well as smaller-scale trial portfolios.



AGENDA

09.00 Workshop Registration, tea & coffee

09:20 Workshop introduction
Co-Chairs: Richard Scaife (PCMG), Mark Bee (Worldwide Clinical Trials)

09:30 Session 1: Biotech Life after Acquisition
Susan Tio, PhD Clinical Sciences & Operations Site Head Early Development Operations Group Leader Sanofi
After seventeen years as a standalone biotech company, Ablynx was acquired by Sanofi in 2018. That was just the start of the journey into integration and product launch that will be shared and discussed to identify lessons that direct best outsourcing practices, including experience of:

- Managing operational and outsourcing continuity
- Integration challenges and opportunities
- Realising the 'best of both worlds'?

10:30 Refreshment break

11:00 Session 2: Rescue Me?
Rich Bennett, former Biopharmaceutical Clinical Program Leader and currently a Senior Director, Therapeutic Strategy Lead, Worldwide Clinical Trials
Ian Marriott, Director, Project Management, Worldwide Clinical Trials
The implications for a smaller company of having to change a CRO mid-way through a trial are profound and wide-reaching. Identifying the risk factors and measures to avoid the rescue scenario and understanding the implications of this ultimate outsourcing option that occurs all-to frequently for smaller sponsors. The session will include presentation and discussion including:

- Why do rescue situations arise, is it an issue with feasibility and/or resourcing?
- Tip of the iceberg – do you **really** understand the full implications of the rescue option?
- It's not you, it's me. How can governance and relationship management steer a course away from the iceberg
- If a rescue is required, what steps should be taken to fully plan for the inevitable challenges

12:00 Lunch break & networking time

13:30 Session 3: Perfect Hindsight:
Balancing timescale, trust, and due diligence at the CRO selection stage.
Richard Scaife, VP Outsourcing Strategy and Vendor Management, VectivBio AG
Hasse Kromann, Head of R&D, Leo Pharma

The investment trend for Small and Biotech companies has changed dramatically through recent months. This makes the ability to evidence systematic selection and control of CRO activities and spend a key investment factor. With limited availability of outsourcing expertise and even less time to assess and select CROs, the balance of trust and due diligence needs careful management and has lessons for the large and small sponsor. We will explore:

- **How due diligence can be integrated in CRO selection for small/biotech**
- **Balancing trust and due diligence in the categories of:**
  - **Outsourcing strategy**
  - **Financial management**
  - **Contractual management**
  - **Quality management**
  - **Performance management**
- **Expediting while maintaining integrity in the selection process**

14:30 Session 4: Sandpit Session: General interaction on hot topics for the biotech and small pharma sector led by the PCMG panel
Richard Scaife, Mark Bee, Susan Tio, Hasse Kronmann

Open discussion based on survey feedback that can include:

- Bigger is better? Are small companies wise to rely on larger CROs?
- Trial feasibility do's, don'ts and…..it depends.
- Medical Writing insourcing, outsourcing or functional outsourcing?
- Effective outsourcing of site agreement negotiation and contracting

15:45 Summary and conclusions

16:00 Workshop Close

This workshop is led by PCMG, a not-for-profit organisation with expert content support and sponsorship from:

WORLDWIDE CLINICAL TRIALS

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