PCMG
Pharmaceutical
Contract Management Group

Pharma/CRO/3rd Party Contracting Models: Theory vs. Reality Understanding All Aspects

Thursday 27th April 2016
Forrestal Marriott, Princeton, NJ

To avoid breaching any competition legislation participants are reminded not to engage in any discussion which could be considered potentially anti-competitive. These include (but are not limited to) information regarding pricing, market shares, terms of sales, investment plans, individual terms of business or any other action which may restrict competition. Participants are also reminded to adhere to their company policies and should inform the organisers about any discussion which may breach their policies or the competition legislation.

PCMG

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The PCMG World

What is PCMG?

..& why is it '*The leading clinical outsourcing community*.'

Non profit organisation active for over 20 years managed by senior pharma members to:

- **Support** the role of the outsourcing function
- **Evolve** practice standards through collaboration
- **Develop** members' skillbase
- **Link** with associated bodies
- **Facilitate** knowledge sharing via conference, workshops and other communication forums

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Value for members:

Annual fee includes access to a range of forums and tools.

- OWL Q&A Forum
- Toolkit
- PLEDGE Legal sub-team
- Workshops
- Webinars
- Job posting
- Conference
- Training course

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PCMG Toolbox

Member area of PCMG website (standard templates)

- CRO Scope of Work and Budget Grid
- CRO Selection Scorecard
- Relationship Management Plan
- Lessons Learned Template
- CRO Performance Metrics
  - Biostats
  - Outsourcing
- Phase I SOW/Budget grid

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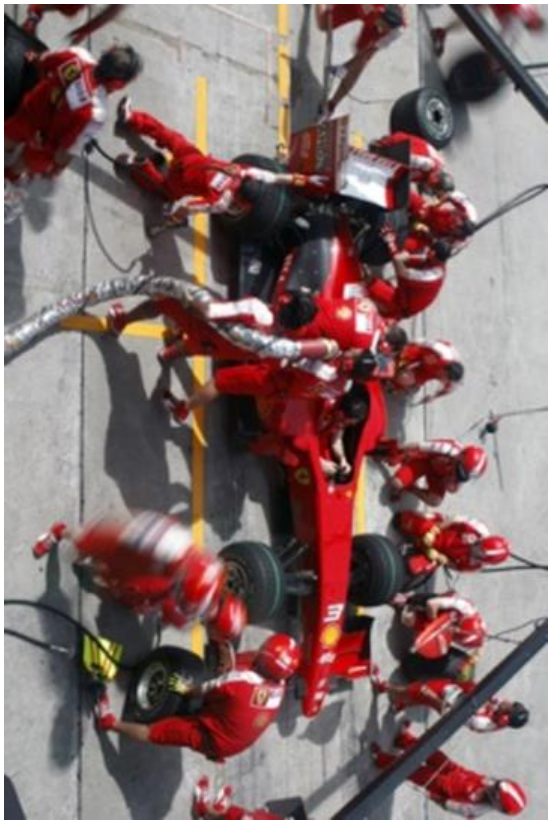
PCMG Workshops



- EU: Three per Year e.g.
  - Lessons Learnt mgt.
  - Financial mgt.
  - Operationalizing the contract
- US : Two per Year
  - April / October
- Historic workshop info. online for members

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PCMG Annual Conference *A Unique Industry Event*

- Managed by PCMG
  - Theme and content relevant to current issues
- Open discussion
  - Pharma/Provider 1:2 ratio
- No exhibition stands
  - Networking, not sales pitch
- **"Think Global Act Local"**
  - **7-9th June – Copenhagen, Demark**

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Annual Membership Options

- Full membership
  - Access to all events and website approx **$540**
- Corporate membership
  - Eight memberships for approx **$2,160**
- Associate Membership
  - Access to all same benefits <u>except</u> conference **$180**

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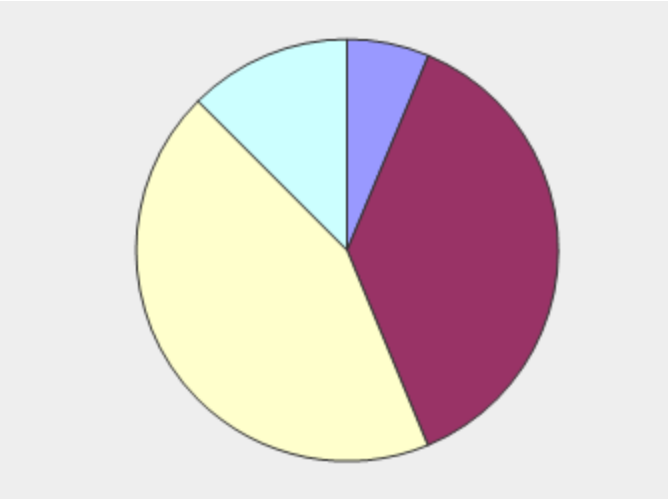
PCMG Survey - April

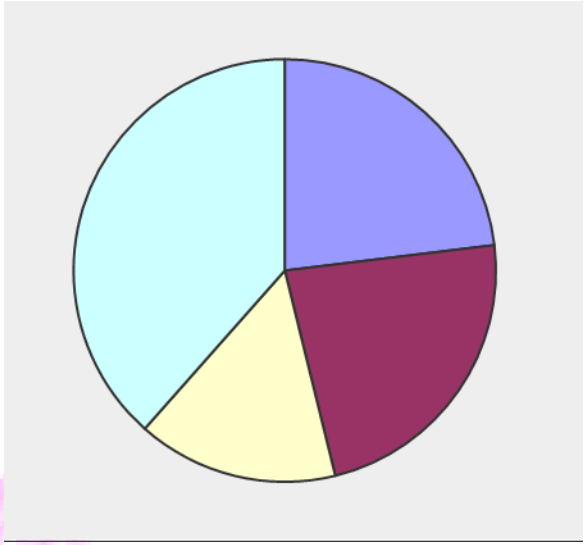
EU

Company < 500 total employees	18,8%
Company 500-10,000 total employees	56,3%
Company < 10,000 total employees	25,0%

US

Company with less than 500 total employees	15.4%
Company with 500-10,000 total employees	61.5%
Company with more than 10,000 total employees	23.1%





- Fee for service
- Unit based model
- Fixed Price model
- Other

PCMG Survey – Contract Models Advantages

- Unit Based
  - Allows for flexibility
  - Only pay for actual
  - Forecasting
- Fixed Price
  - Defined budget
  - Reduced COs
  - Transparency/ forecasting
  - CRO takes some risk
  - Both parties know what they sign up for

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PCMG Survey – Contract Models Key Challenges

- Unit Based
  - Endless small Scope changes
  - Variability of final budget – a challenge to manage internally
  - Different CRO units
- Fixed Price
  - Extremely exhaustive assumptions
  - To agree with the CRO what is fixed
  - Keep initial timelines
  - High costs
  - Conflict of budget vs activities to be performed

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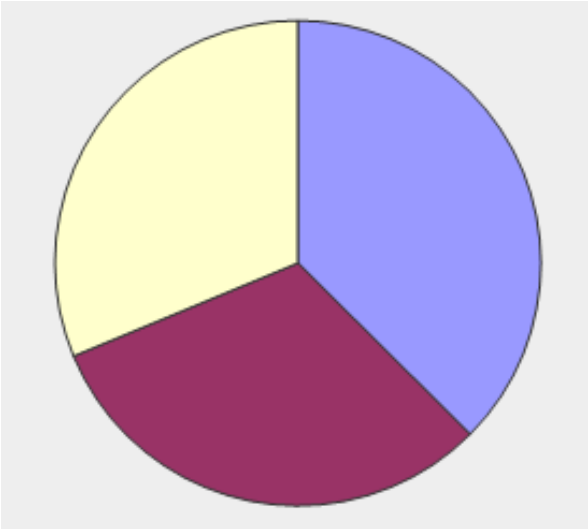
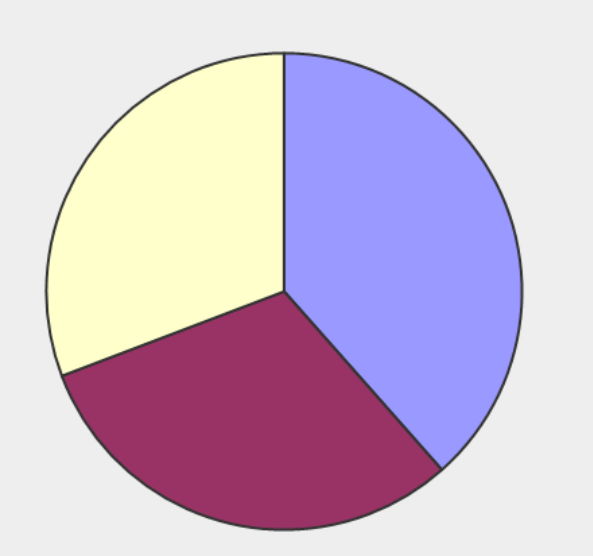
PCMG Survey Outsourced 3rd Party vendors

EU



US



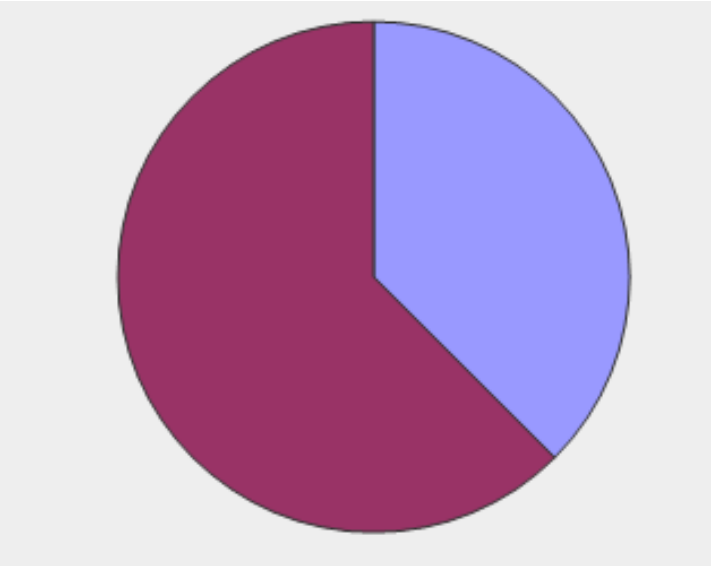
- Sponsor contracts and manages third parties
- Sponsor contracts and CRO manages third parties
- CRO contracts and manages third parties

Outsourced to CROs

- Central Lab
- Spirometry
- eDiary / eCOA
- Translation Services
- Investigator Meetings
- Distribution of Clinical Trial Supplies
- Cardiac Safety /ECG
- Archiving
- CDISC data formatting
- BA / Imaging
- EDC,IVRS

PCMG Survey – Do you include bonus/penalty clauses in the contracts for CROs or other suppliers?

EU



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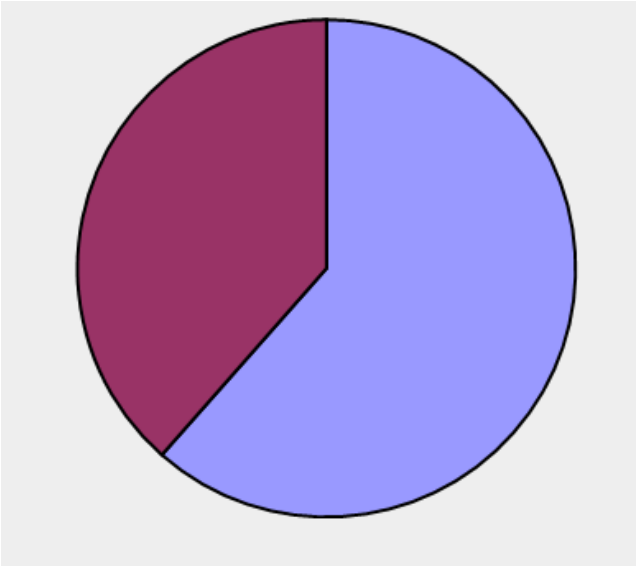

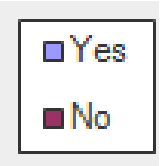

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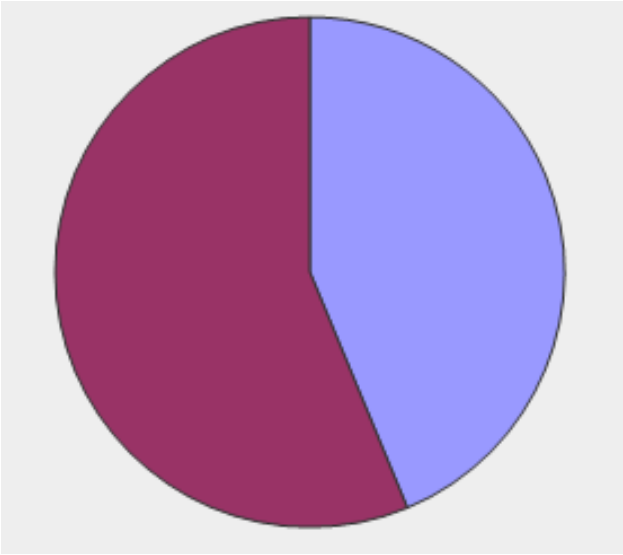
PCMG Survey – Do you include other performance clauses or KPIs in your contracts for CROs and third parties?

EU



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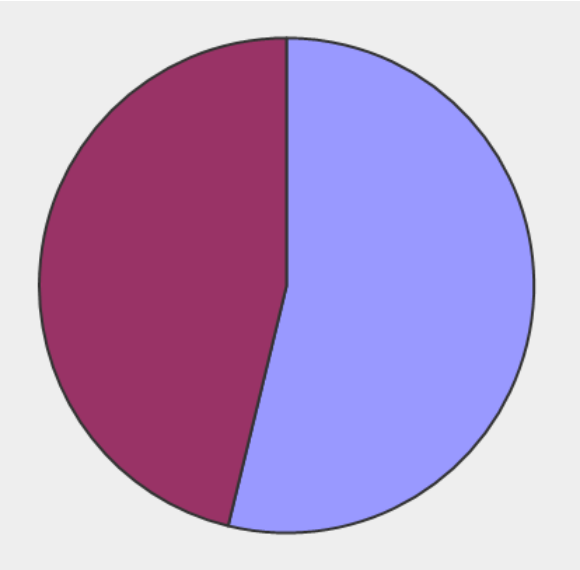

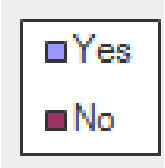

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Summary

- Good mix of small, medium and large Pharma
- Data for US and EU quite similar
- Experience with
  - Fixed and Unit based model
  - 3rd Party Suppliers
  - Bonus-penalty clauses

- Create a good background for todays workshop

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