Another PCMG Year Wiser?

Highlights of PCMG's activities and the changing world of Pharma & Clinical Outsourcing

Richard Scaife

Lan Bandara

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PCMG
A year of Added
Value for Members & Supporters

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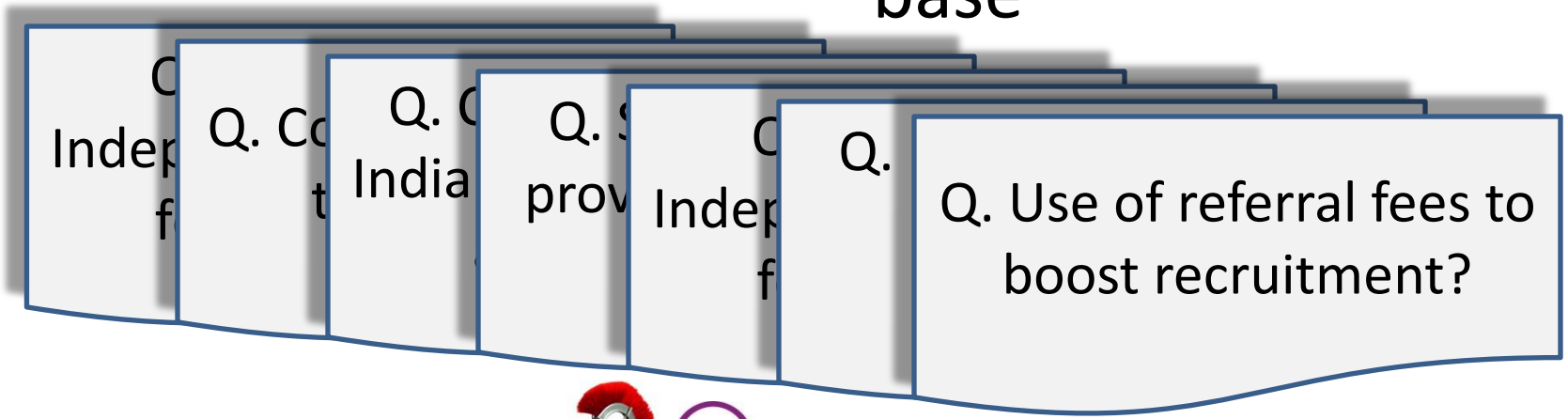
PCMG know-h**OWL**

(*Outsourcing Wisdom & Learning*)

Unique Q&A access to membership knowledge base



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PCMG Toolbox

All in 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

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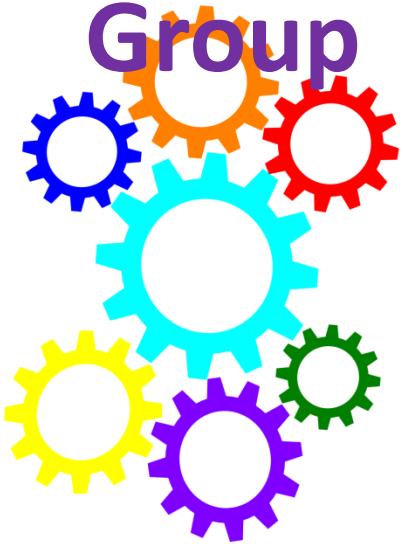
PCMG Toolbox (2)

- Biostats Metrics – Collaboration with EUCROF and PSI
  - 7 Quality metric, 4 timeline metrics and 1 cost metric
- Outsourcing / Procurement Department Performance Metrics
  - 6 KPIs for time, cost and quality
- CRO/Pharma Balanced Scorecard
  - 3 high categories
  - 5 high level KPIs
  - 27 specific items to measure
- Phase I SOW and budget grid in development

PCMG Workshops EUROPE

- Oct: Outsourcing Models
- Feb: Operationalizing the Contract
- Apr: Lessons Learned
- *Oct 2016: Managing budgets*
- *Feb 2017: 'Insourcing outsourcing'*

New PCMG Working Group



Management of Post-Authorisation Activities

- Company-sponsored non-interventional/observational studies
- Investigator-sponsored studies
- Managed Access Programmes

Interested? (PCMG members) contact Andrew Goodvin, Dir. Clinical Ops, Late Phase Gilead
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PCMG Workshops US

- Re-launching PCMG's US presence
- Led by PCMG EU
- Workshop 25th-27th October 2016
- Topic TBC
- US Outsourcing survey end May
- Sponsored by PRA
- Planning underway

PCMG Outsourcing Essentials Course

- Updated and improved to reflect current best practices
- First training session in London in October 2015 + Workshop.
- Good feedback and material
- Next session planned for **October 2016** before workshop likely to be held in Basel

PLEDGE (PCMG Legal Development Group)

- Second face to face meeting in London October 2015
  - Updated CTA definitions document and CTA database
  - Discussed impact of new EU Clinical Trial Regulations
  - Two new company representatives have joined group
  - Third meeting planned later 2016

A year of change for Pharma?

Merger Mania

Pfizer continued to look for a partner.. *Allergan?* ***$160b…whoops***

- Allergan due to complete $41b generics sale to Teva
  - Looking for it's own acquisitions and deals? ($3.3b Heptares deal)
- Pfizer buy Hospira (Biosimilars) for $17b + Anacor for $5.2b
- Biogen sell $6b Haemophilia arm to prep war chest
- Mylan $1b bid for Investment Co. Dermatology business
- Abbvie $21b Pharmacyclics oncology deal (May 2015)

Jilted?

Shire &

Balxalta

$32b

deal

Pricing

Pharma's dark side comes out of the shadows: Turing & Valeant

- Turing CEO Martin Shkreli finally falls foul of SEC after 5,000% increase of daraprim highlights 'gouging'
- Valeant CEO (keel)hauled in front of senate ctte. after 525% and 212% CV drug increase
- US election year 'punchbag'
- Oncology treatment success comes at a price…

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Pharma's tough times continue

- **Novartis** Entresto's whimpers, not bangs in US sales vs. EU's long-term viewpoint
- **AZ** waves goodbye to Crestor with $1.1b annual savings plan by 2018 but extends **WuXi** deal for biologics in China and $50m expansion of existing manuf. site
- **Sanofi** EUR 1.5b annual cuts and layoffs - swap of animal for consumer meds with BI
- **Lundbeck** turns corner in 2016 Q1 with $73m OpProfit vs 2015 loss
- **Novartis/GSK** swap starts to materialise with NICE melanoma OK, but payers demand pricing deals for market access

Pharma's tough times continue

- **Roche** Biosimilar threat to oncology pillar by Pfizer (Hospira) & Sandoz
- **DalcCor** Pharma $150m Phase III Personalised Medicine approach for Roche CETP 'failure'
- Patent fighting escalates – **Merck vs. Gilead** $17b/yr Hep B sales, **Amgen vs. Sanofi & Regeneron**
- **Novartis** Eye-watering Alcon $1b restructure
- **Daiichi-Sankyo** U3 acquisition closed and 1,200 + job cuts
- **Celgene** 5-year 23% growth and continuing expansion

Smarter, not harder?

Biotechs: Is Big Pharma shepherding or factory farming?

- Record PE investment in 2015
  - Fattening the calf before selling off to Pharma?
- Equity investment deals
- 'Incubator' parks to share resource and nurture possible acquisitions?
- Has the Big Pharma discovery model failed completely?
- Implications for CROs
  - Targeting biotechs but with Pharma partnership view

Consolidation of CROs stalls vs. Pharma?

- PPD joins the Pfizer 'pack'
- InVentiv IPO plan by PE owners
- **Quintiles & IMS merger to mirror LabCorp/Covance in quest for 'big data'**
  - **Gearing up for US 'pay for performance?'**
- Diverse smaller deals
  - Bolt-on IT/specialist services
  - Investigator site acquisitions (ICON, PRA,PPD…)
- Phase I vulnerability (BioTrial incident)

Implications for CROs & Outsourcing

- Extreme CRO polarisation?
- Linking biotech to big pharma?
- Further acquisition of ‘bolt-ons’
- Procurement absorbs outsourcing?
- Patient cohorts in PhI FIH?
- Consolidation of specialist labs
- Biotech small fry now big catches
- Technology steps not leaps

The Year to Come?

(US has 4.6% of global population but 30% of global spend*)

Pharma….. futures?

*FT Health Special report Apr 2016

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The Year to Come?

- Transatlantic Trade & Investment Partnership potential to for EMA to recognise FDA approvals?
- US to follow EU-style pay for performance?
- Biosimilars to hit US sales hardest? (IMS: '$110b potential')
- Compliance 'ghosts' to haunt Pharma
  - GSK 2004 Seroxat generic payoff $54m UK fine)
  - Novartis $3.4b US pharmacy deals lawsuit
- Pharma follows CROs into off-shoring? J. Jiminez: Managers to accept moves *"..through enlightened self-interest.."*

PCMG 2016 Theme: INTERACTION

Improving performance through engagement and collaboration

1. Conflict Management
2. Transparency
3. Performance and Motivation
4. Trust

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IT’S TIME TO INTERACT!

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Interaction

Which is your top priority?

1. **Change orders:** Clear and early
2. **CRO team CVs:** Achievements, not just responsibilities
3. **Termination and postponement terms:** Implementable and fair
4. **Sponsor recognition:** highlight success

Interaction: Which is your top priority? (Audience responses)

1. **Change orders:** Clear and early
2. **CRO team CVs:** Achievements, not just responsibilities
3. **Termination and postponement terms:** Implementable and fair
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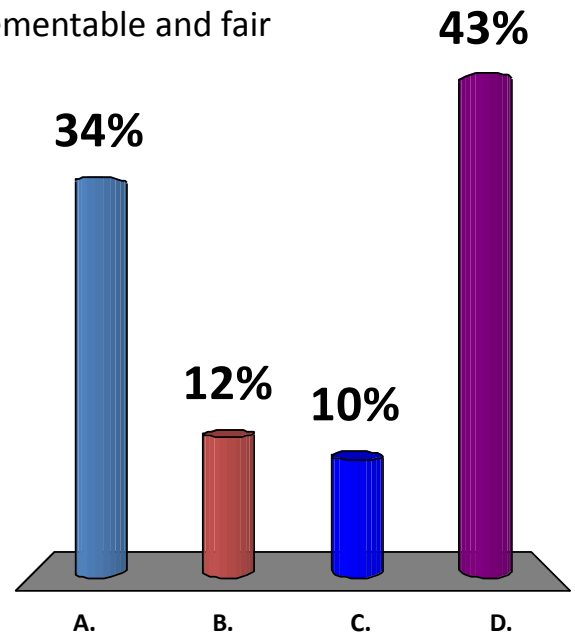

CAN WE IMPROVE ON 2015's ENGAGEMENT AND COLLABORATION?

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