



Collaboration with Academia hard truths

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Introduction

- Academia has been involved in the drug development process from the early days
- Originally as investigators, key opinion leaders, authors, site networks
- Over the last few decades: growth of academic centres as broader research organisations offering CRO-like services

Academic Research Organisation

**An academic or non/profit institution
that performs one or more functions in
the conduct of clinical trials**

Introduction (cont.)

- The range of services offered and contracted varies
- History from expertise in mega-trials
- Some institutions were trail blazers e.g. TIMI, EORTC

BUT..

Working with AROs has brought challenges



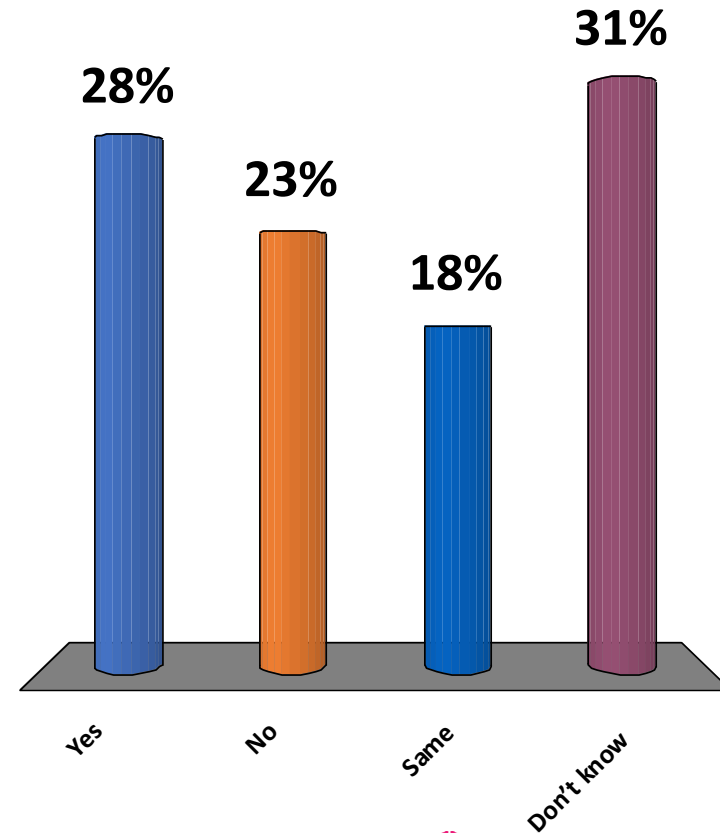
Introduction (cont.)

- They are different from other suppliers
 - Motivation
 - Level of expertise
 - Why they are chosen
 - Independence
- PCMG considering creating a best practice guideline
- Survey to validate the idea
- Questions for the audience first!



VOTING QUESTION 1: Are you seeing an increase in ARO contracts in your organisation?

- A. Yes
- B. No
- C. Same
- D. Don't know

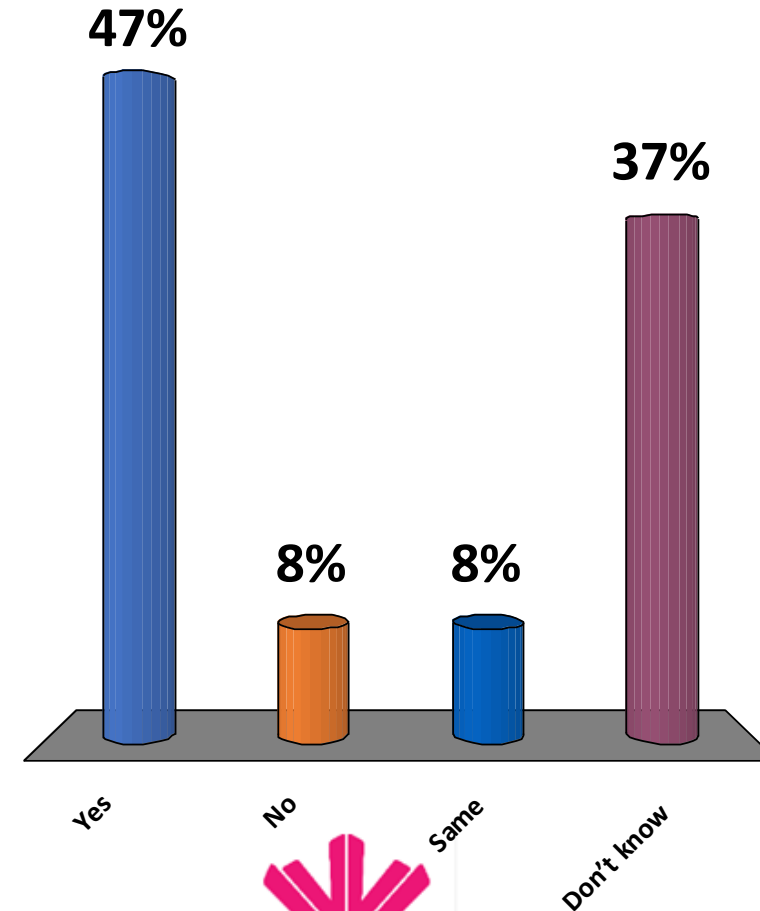


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VOTING QUESTION 2: Do you see more delays with ARO contracts than with other companies?

- A. Yes
- B. No
- C. Same
- D. Don't know



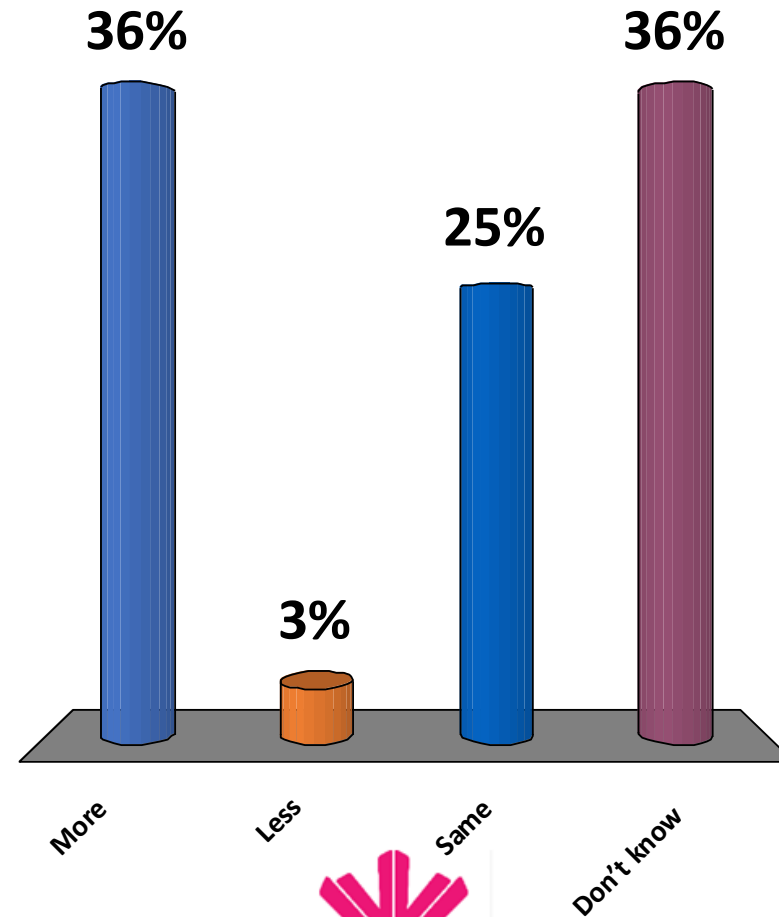
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PRAHEALTHSCIENCES

VOTING QUESTION 3: Do you see more or less performance issues with AROs than other partners?

- A. More
- B. Less
- C. Same
- D. Don't know



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SURVEY RESULTS

DEMOGRAPHICS

POPULATION



Demographics summary

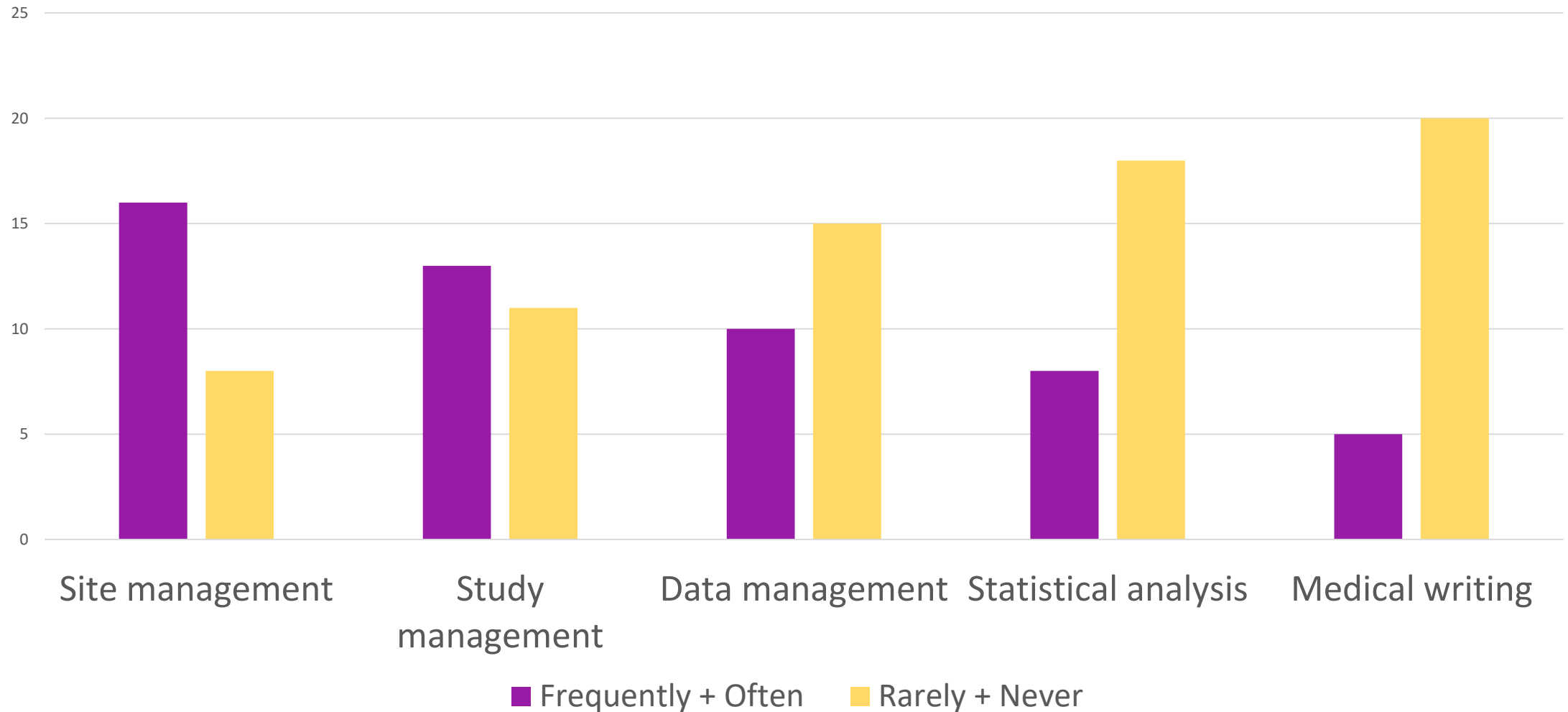
- 26 respondents from a mix of organisations (54% pharma, 42% CRO)
- Average experience of working in clinical development = 14.3 years
- Average experience of working with AROs = 5.1 years
- Good mix of functions
 - Business development
 - Operations
 - Outsourcing
 - Procurement
 - Commercial
 - Medical



EXPERIENCE

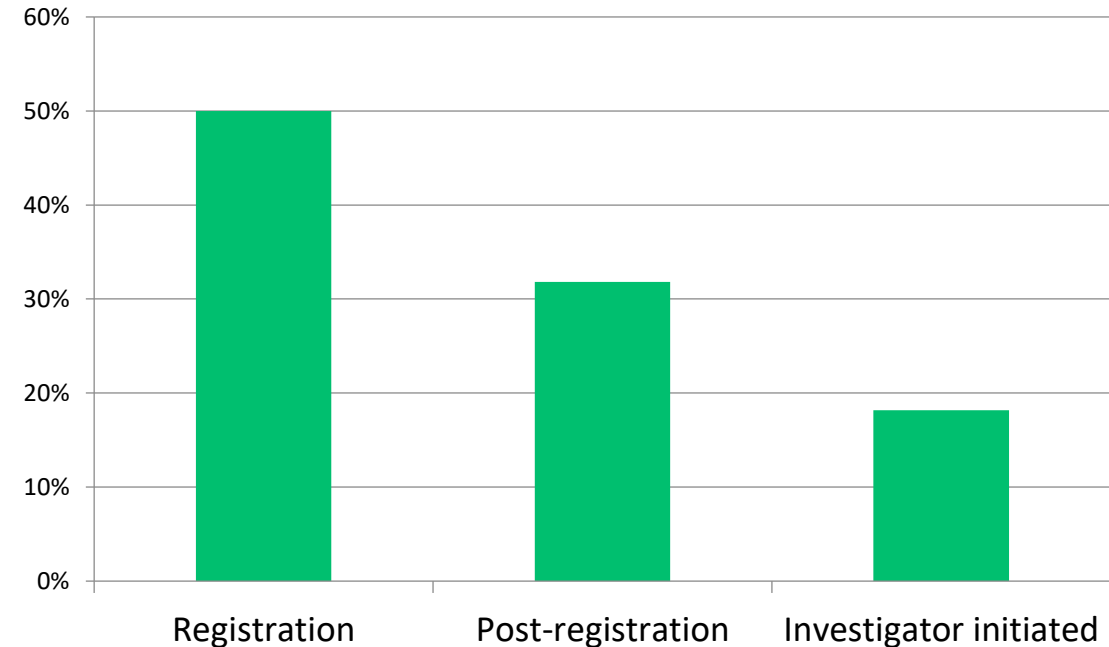


Type of services outsourced to AROs



Experience summary

- Over 80% seeing **similar or broader** services being outsourced to AROs
- Over 15% of AROs are managing vendors for sponsors
- Type of trials



CONTRACTS



Contracts Summary

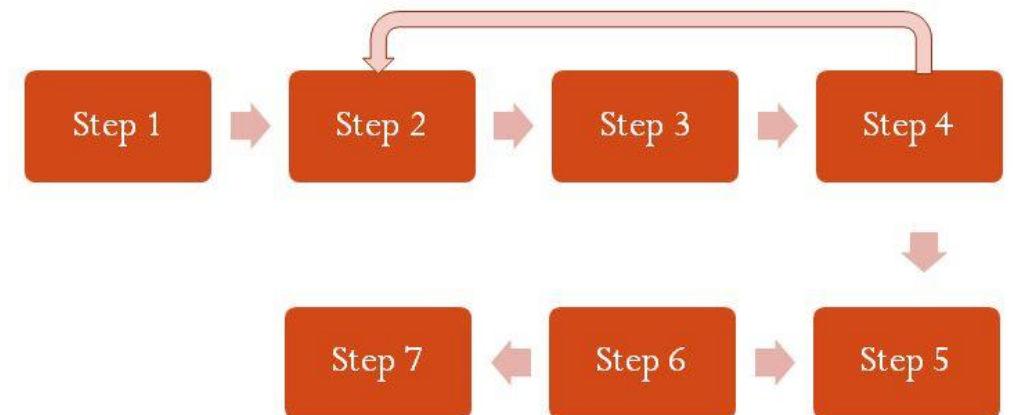
- 45% of respondents seeing **more** ARO contracts. Only 8% seeing less
- Nearly 80% are one-off service provision contracts
- Mix of contract models – often tripartite (with CRO)
- Only 30% of respondents have specific ARO templates
- It often takes longer to complete ARO contracts than CROs and labs



Contract terms

- Challenging areas
 - Ownership of data
 - Publication
 - Discovery rights
 - Payment and termination
 - Responsibilities of CRO vs ARO
 - Many!
- Some – no significant problems (compromises can be found)

PROCESS



Process – involved in selection

- 52% – cross-functional team
 - Procurement included - 14%
 - Outsourcing included - 14%
- 48% – other:
 - Therapeutic area
 - Medical Science
 - Study management
 - CRO
 - Clinical project managers
 - Head of development
 - Executive team
 - Feasibility Manager

Different from other vendor selection!



Process - Who makes the final decision?

- 29% Senior Management
- 19% team
- 19% Operations
- 9.5% Procurement or outsourcing involved
- Other
 - Medical
 - Clinical project Leaders
 - CRO
 - Feasibility Manager
 - Therapeutic area

Again – different from other vendor selection



Process - due diligence

- 37% complete an audit
- 37% carry out full due diligence
- 26% limited/none



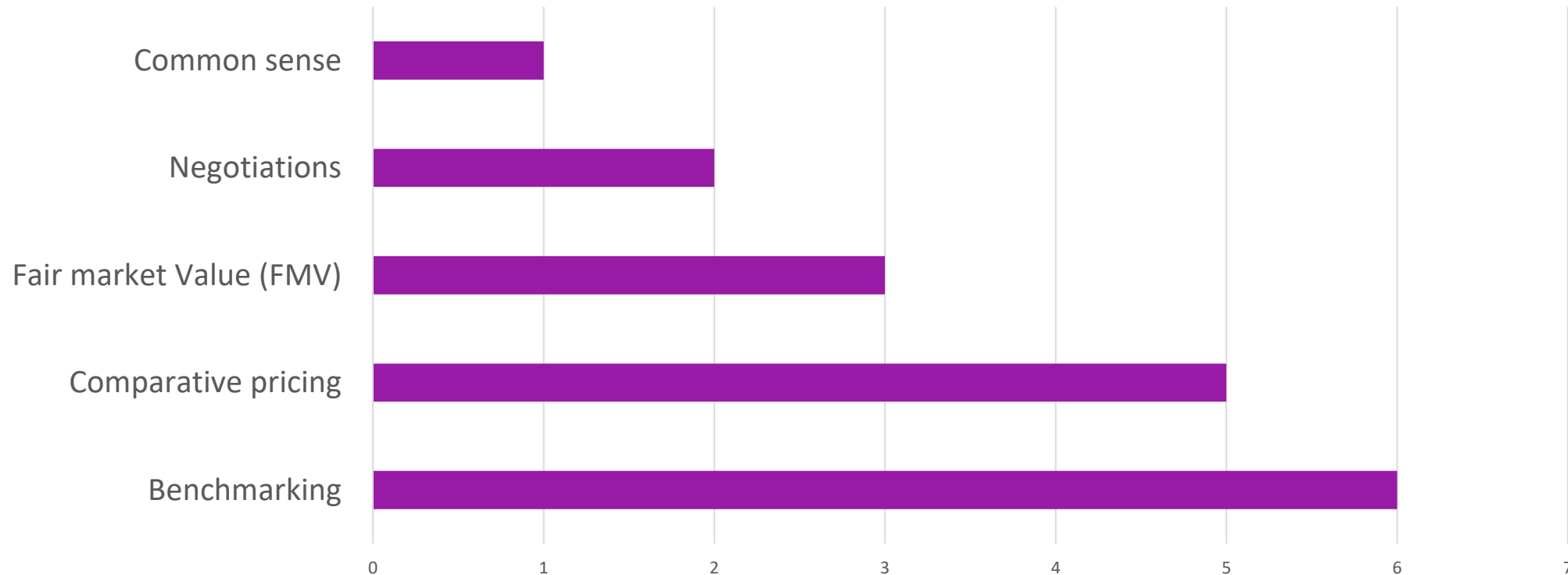
Process – selection same as other vendors?

- Yes: 52.2
- No: 47.8
- Reasons why process is different
 - More scientific decision
 - Based on their network and scientific capabilities
 - Skills & expertise of individual
 - They have data source
 - Difficult to have competition – less options

COMPLIANCE



How does your company ensure that the ARO is charging a fair price for services?



“This is difficult to analyse if you are not performing competitive bidding. Often their price looks cheaper at the start however in the long run, with delays, costs for capacity building and additional internal costs for QC/oversight, the total cost is not necessarily cheaper. However with time you hope that you have negotiated a fair price”.

Compliance

- Does your company have checks in place to ensure there is minimal risk that payment could be misinterpreted as an incentive for the ARO to support the company?

56% Yes

- Is the audit plan for an ARO similar to other partners?

78% Yes

Do you have similar payment terms with AROs as with other partners?

- 33.3% have different payment terms
 - More milestone payments
 - Salary payments
 - Mixture of milestones and salary

Invoice Details

Supplier	Sam's Electrical *
Customer	Joe's Fish Shop *
Date (dd/MM/yy)	10/01/09 *
Invoice Number	112 *
Reference	PO#112
Customer Reference	
Days Before Payment Due	15 NET *

Add Payment Terms

Add Postage

Payment Method	<input type="checkbox"/> Cash <input type="checkbox"/> Cheque <input type="checkbox"/> Credit Card <input checked="" type="checkbox"/> Direct Bank Transfer <input checked="" type="checkbox"/> Paymate <input checked="" type="checkbox"/> Paypal *
Currency	AUD - Dollars (Australia) *
Description	Fix to shop safety switch

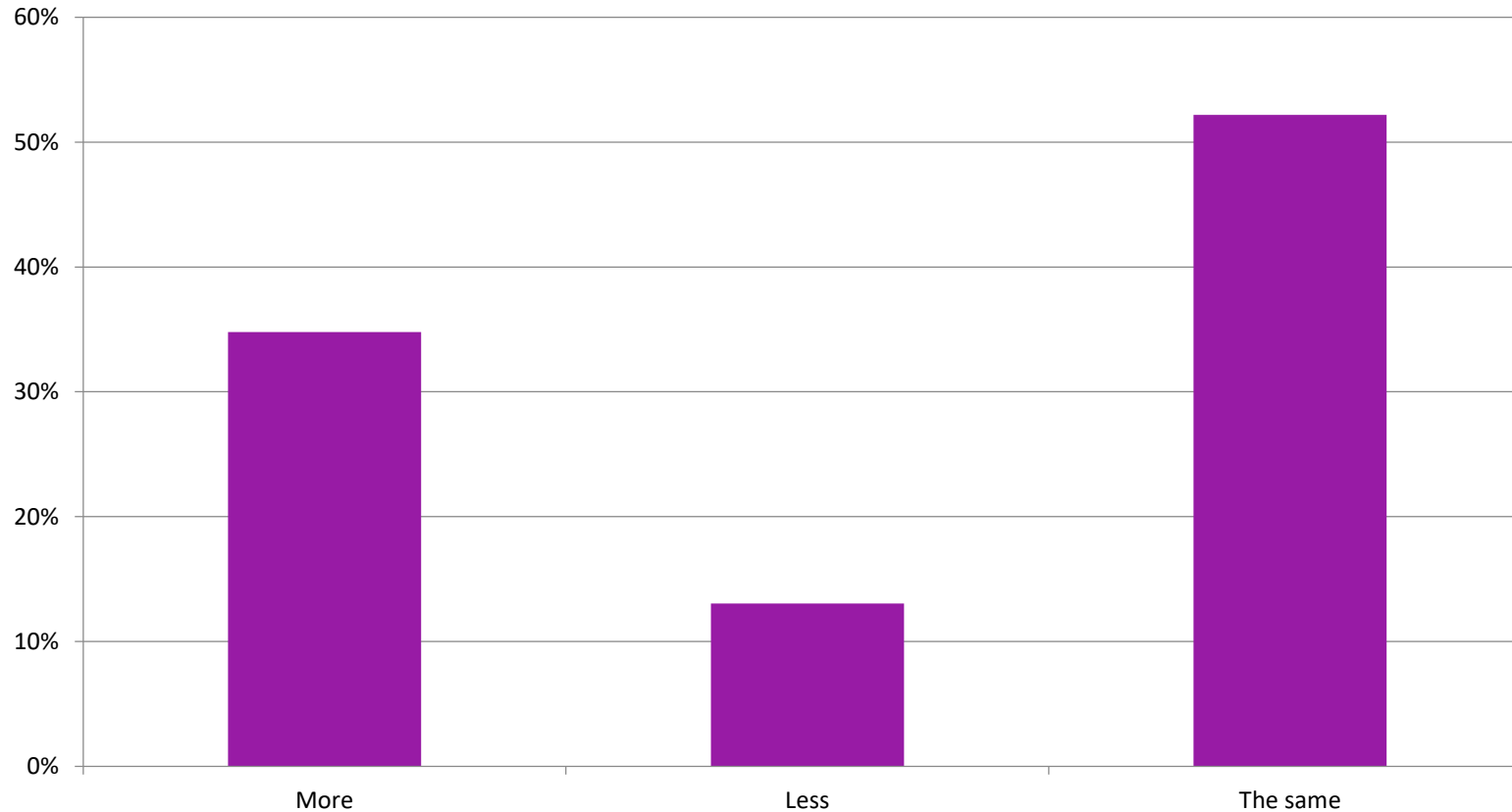
PERFORMANCE & SRM

PERFORMANCE



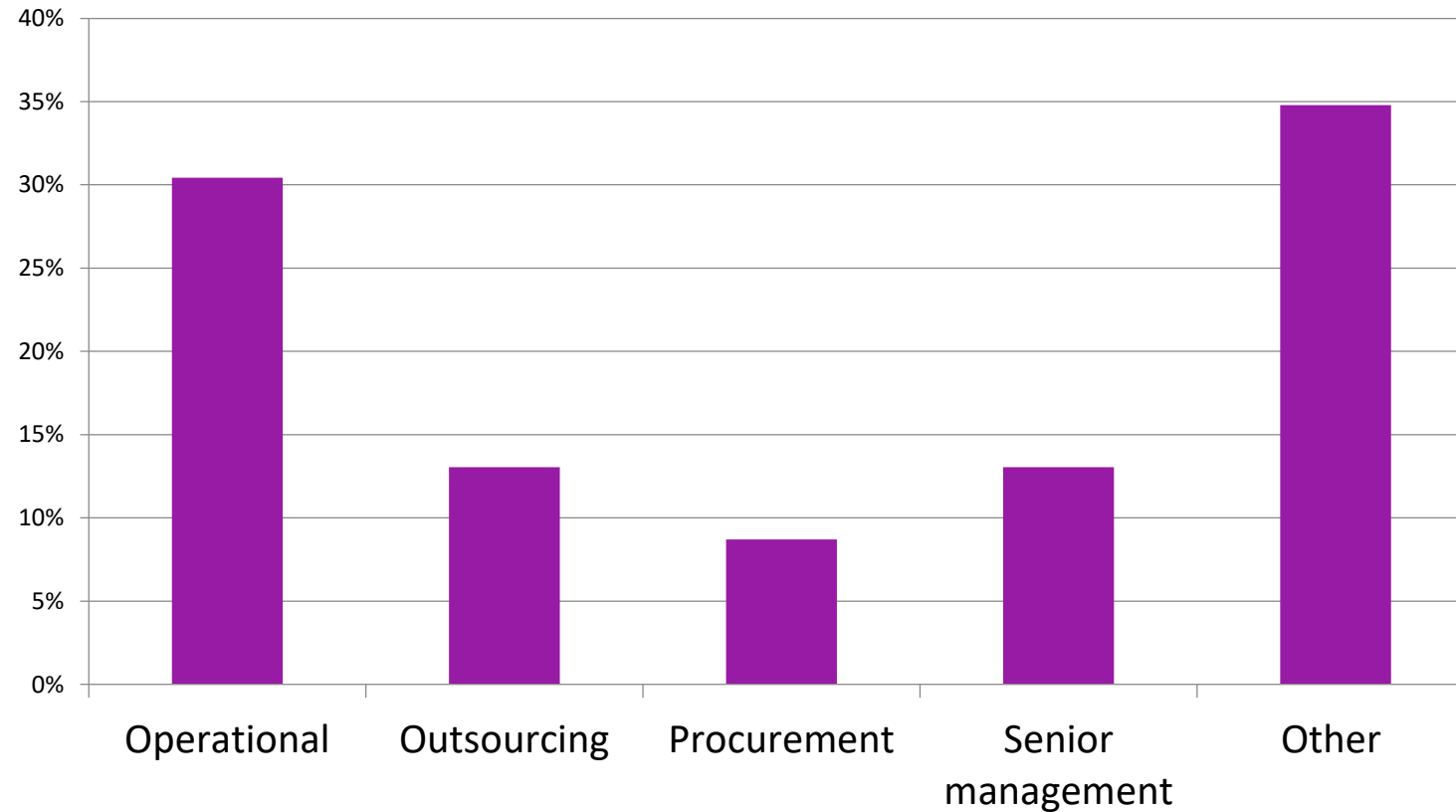
- ☒ **EXCELLENT**
- ☐ **GOOD**
- ☐ **AVERAGE**
- ☐ **POOR**

Do you generally see more or less performance issues with AROs than other partners?



Process for resolving issues the same as other partners in over 80% of respondents – although comments on can be more delicate to resolve with KOLs

Which parties are involved in relationship management and oversight?



NB: Procurement/Outsourcing involved here if not in selection process!

PROCESS IMPROVEMENT

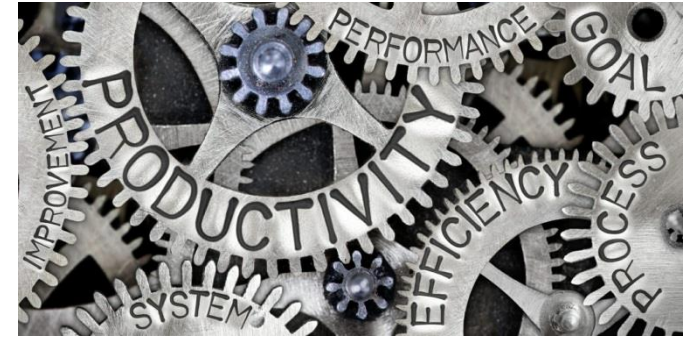


What solutions/processes have you implemented to improve working with AROs

1

Contracts

- Clearer contracts defining responsibilities
- specific templates,
- defined matrix for tripartite agreements
- fall back language when AROs do not accept Sponsor terms and conditions in a contract.



What solutions/processes have you implemented to improve working with AROs

2

Process

- More discussions up front during the RFP process:
 - Internally on expectations,
 - Clin CRO - on how they will manage the ARO, sponsor expectations, CRO experiences working with ARO.
- Tight collaboration before study start. ARO involvement in setting up timelines & studies milestones
- Always a tailored process working with the site staff directly.
- Processes to ensure all aspects of compliance are met

What solutions/processes have you implemented to improve working with AROs

3

- Governance
- Oversight committee
- Quality questionnaires
- Recruiting consultants to provide essential inputs and/or training to the ARO.
- Early notice and involvement with Medical Science to reduce 'urgent contract need' situation



- Every country's ARO has **different expectations** and 'statutory' requirements.

Responsibilities

- **Clarification of roles and responsibilities** are key, we see more change orders/cost increases with ARO's
- There needs to be much **clearer responsibility split**, it should be considered to invite the ARO into more operational meetings to discuss challenges and actions.



Quality

- To have a **robust risk mitigation plan** in place which includes the ARO study personnel and processes. To be very clear what you want to get out at the end and what quality standards you expect them to apply.
- Quality results are very variable!
- AROs generally need **capacity building** to support with systems validation, appropriate QMS and their personnel mostly do not have the right type of clinical research experience. In addition they do not have a service mindset and so it takes so much more time and patience to go from A to B with them compared to CROs.



LESSONS
LEARNED

Contracts

- **clearer contracts** and better review of ARO processes in advance
- Being patient and **open to AROs terms and conditions** is key.
- Ensure the contracts are detailed and that all understandings agreed during negotiations are documented and not left to the memory of the negotiators

Final Thoughts:

- To anticipate the worst and not make any assumptions.
- Many! ARO's are difficult organisations to contract and partner with but provide some scientific services that cannot be accessed at CRO's
- Play to their strengths

Conclusions

- AROs do not fit well with our standard outsourcing/procurement processes
- But use of AROs is growing for many organisations
 - 80% seeing similar or broader services outsourced
 - 50% are registration studies
- AROs are not easy organisations to work with
 - Contracting can be complicated and lengthy
 - Selection and decision making process is different (and probably should be!)

Conclusions (cont.)

- Compliance concerns for many organisations
- Often see more performance issues

Results confirmed by you or are there differences?

Next Steps

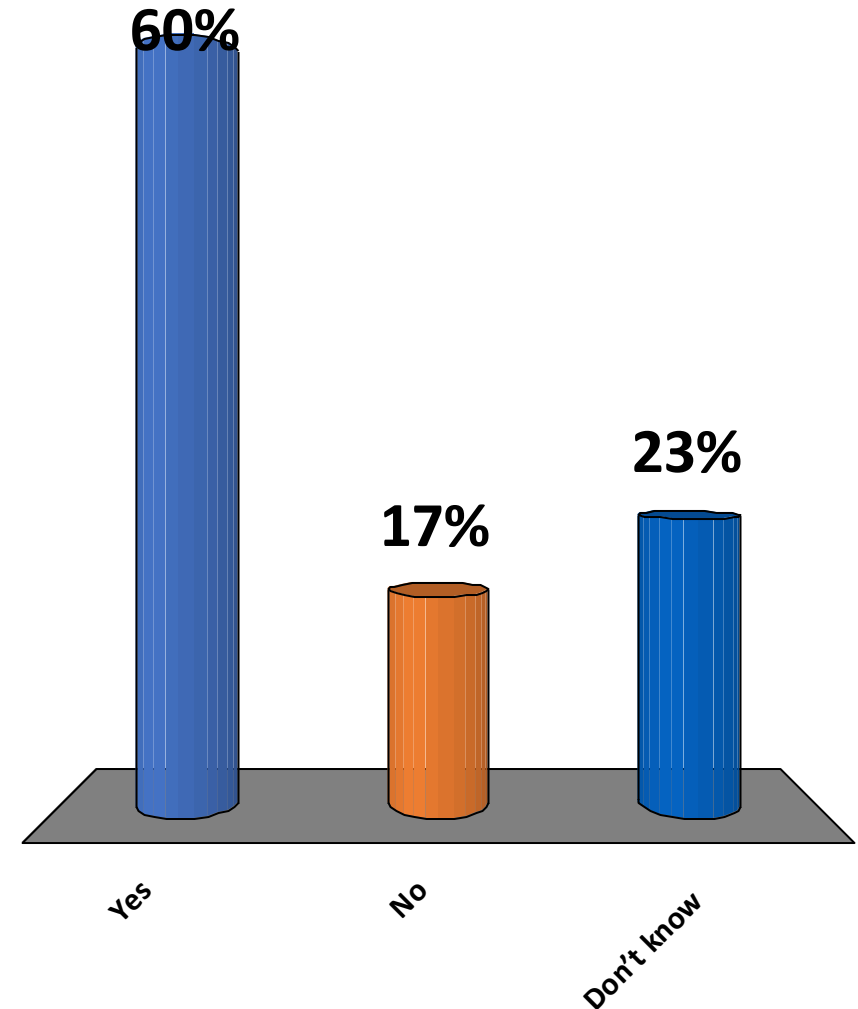
- Great feedback on solutions and lessons learned from the survey
- Practical advice, top tips and watch-outs!

What now?

PCMG considering if further guidance would be useful for members and CRO partners

Voting question 4: Is there a need for further guidance from the PCMG on working with AROs?

- A. Yes
- B. No
- C. Don't know





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