

CRO Oversight – Praxis bei Mitgliedern des vfa

PD Dr. Michael Hennig
Head of Biostatistics &
Epidemiology,
GSK Germany

- This work is presented on behalf of two working groups within the vfa
- These working groups planned, conducted and analyzed a survey among members of the vfa

Working group 1

Michael Hennig¹

Ferdinand Hundt²

Susanne Busta³

Stefan Mikus⁴

Per-Holger Sanden⁵

Andrea Sörgel⁶

Thorsten Ruppert⁷

1 GlaxoSmithKline GmbH & Co.
KG, Munich, Germany

2 Doc-Dog-Consulting, Berlin,
Germany

3 Bristol-Myers Squibb,
Munich, Germany

4 Pfizer Pharma GmbH, Berlin,
Germany

5 Merck KGaA, Darmstadt,
Germany

6 MSD Sharp & Dohme GmbH,
Munich, Germany

7 vfa, Berlin, Germany

Working group 2

Michael Hennig¹

Dietrich Knoerzer²

Armin Schüler³

Daniele Compagnone⁴

Ferdinand Hundt⁵

Thorsten Ruppert⁶

1 GlaxoSmithKline GmbH & Co.
KG, Munich, Germany

2 Roche Pharma AG, Grenzach-
Wyhlen, Germany

3 Merck KGaA, Darmstadt,
Germany

4 AbbVie Deutschland GmbH
& Co. KG, Ludwigshafen,
Germany

5 Doc-Dog-Consulting, Berlin,
Germany

6 vfa, Berlin, Germany

Framework

Survey

Main Results

Conclusions

The ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor.

The sponsor should ensure oversight of any trial-related duties and functions carried out on its behalf [...]

Phrase	Definition
CRO Oversight	<p>Any measure to control</p> <ul style="list-style-type: none">• the performance• the deliverables• the efficiency <p>of CROs performing outsourced tasks on behalf of a pharmaceutical company / or acting as the sponsor of a clinical study</p> <p>Other terms typically used: “CRO management” / “CRO supervision”</p>
Global / Local	<ul style="list-style-type: none">• refer to international companies with local subsidiaries in various countries• “global” refers to the CRO outsourcing at the international level within a company• “local” refers to the German subsidiary and studies at the local German level



Survey

Structure and content of questionnaire



Section	Content / Number of questions		
1. General	<ul style="list-style-type: none">Local/global perspectiveOutsourcing Model	<ul style="list-style-type: none">Outsourced ServicesDecisions: How / Who	16
2. Oversight	<ul style="list-style-type: none">SOPsChecking qualificationsAuditsOversight tools	<ul style="list-style-type: none">Escalation processLessons learnedSize of CROs	21
3. Biostatistics & Data Management	<ul style="list-style-type: none">Preferred CROsDecisions	<ul style="list-style-type: none">Requirements for: Coding, Data, OutputsChecking adherence to requirements	15
Total number of questions			52

Companies addressed and responding

Time frame of the survey: August – October 2015



Companies within vfa: **46**

Representing 2/3 of pharmaceutical market in Germany

Companies addressed: **25**

Major companies, participating in the vfa committees
“Clinical research and quality assurance” resp. “Biostatistics”

Companies responding: **18 (72%)**

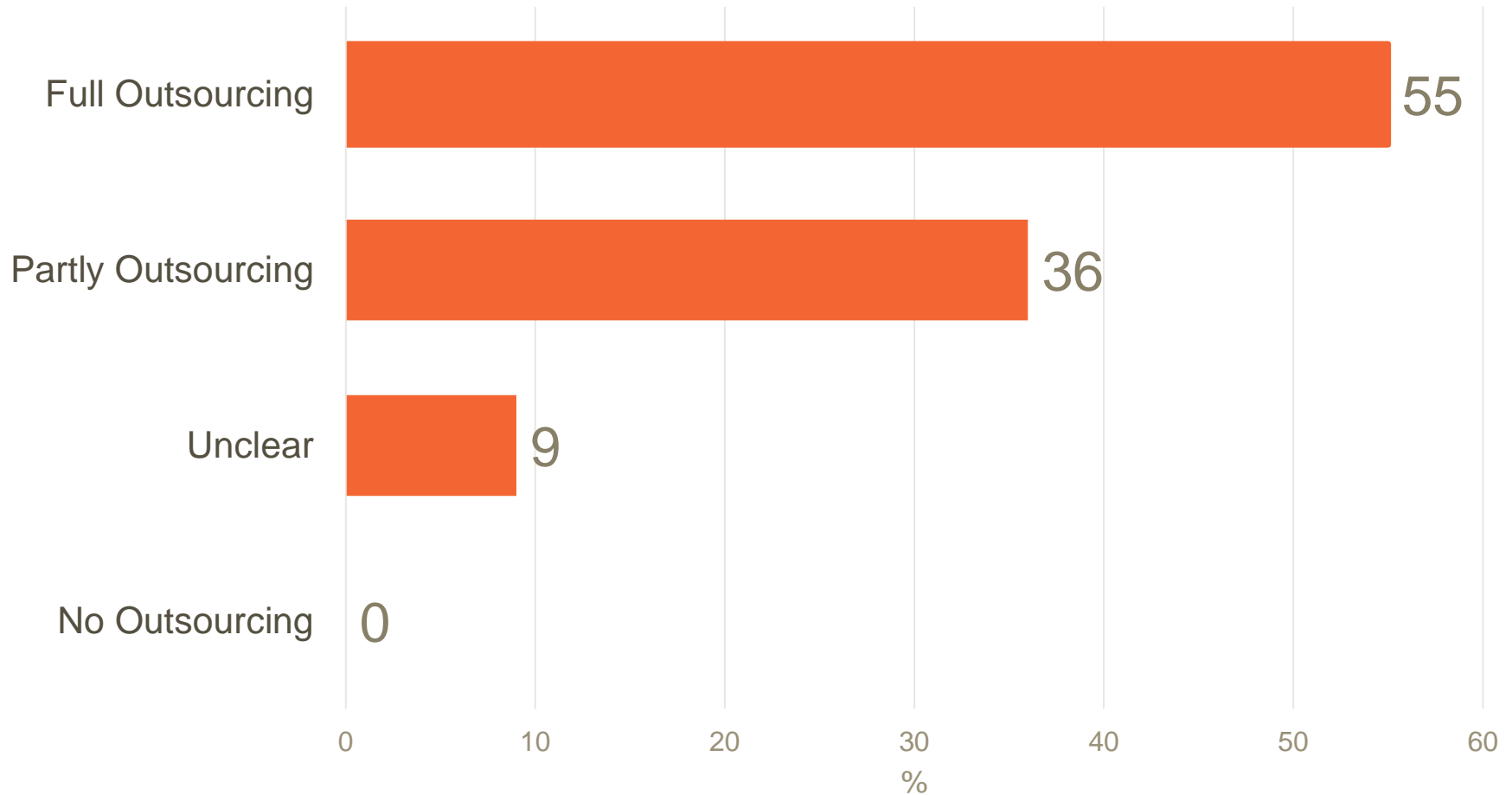
Available questionnaires: **22**

Multiple questionnaires from 3 companies, covering different aspects



Main Results

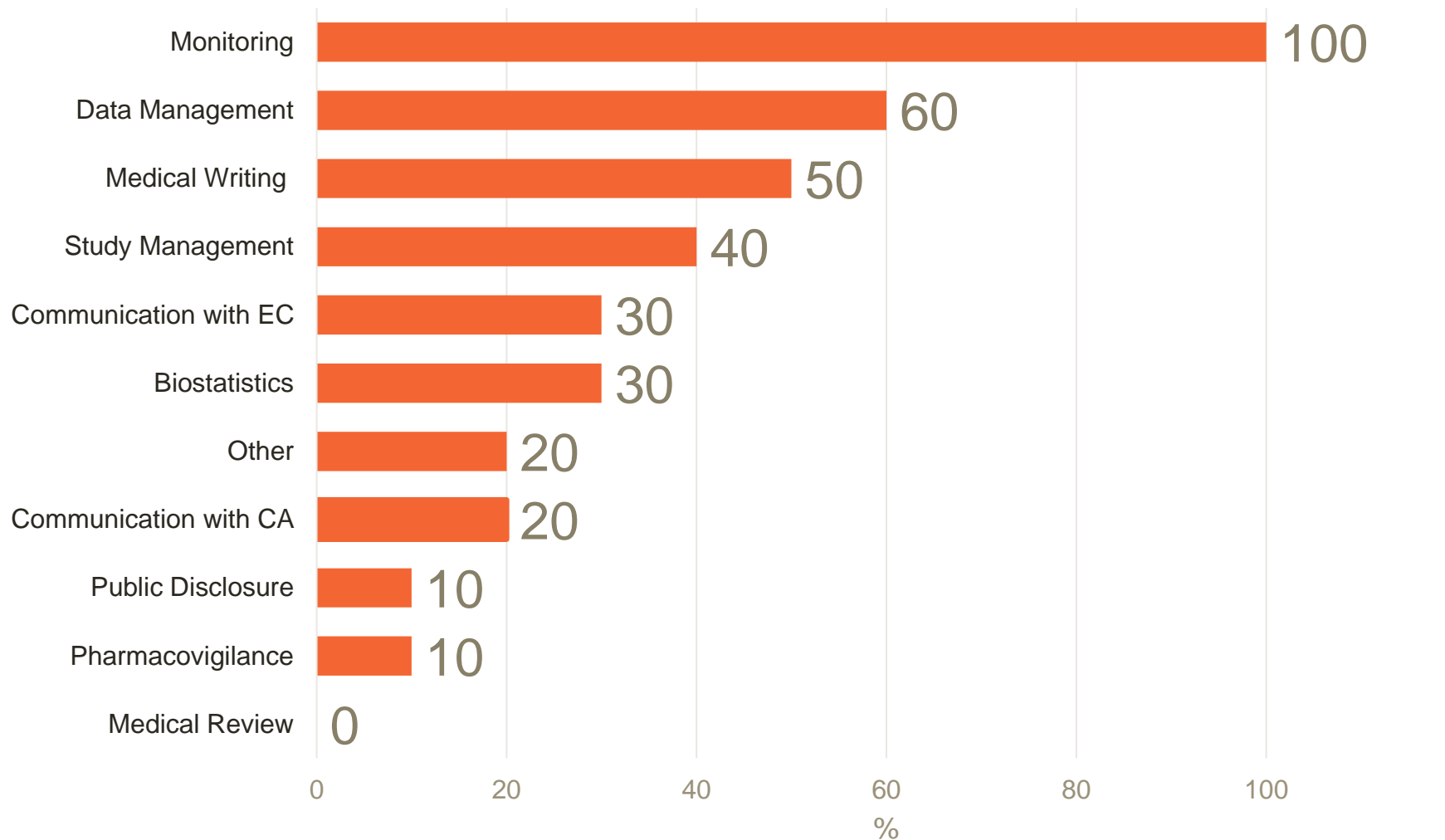
Outsourcing Models



Partly Outsourcing: Which services do you typically outsource?

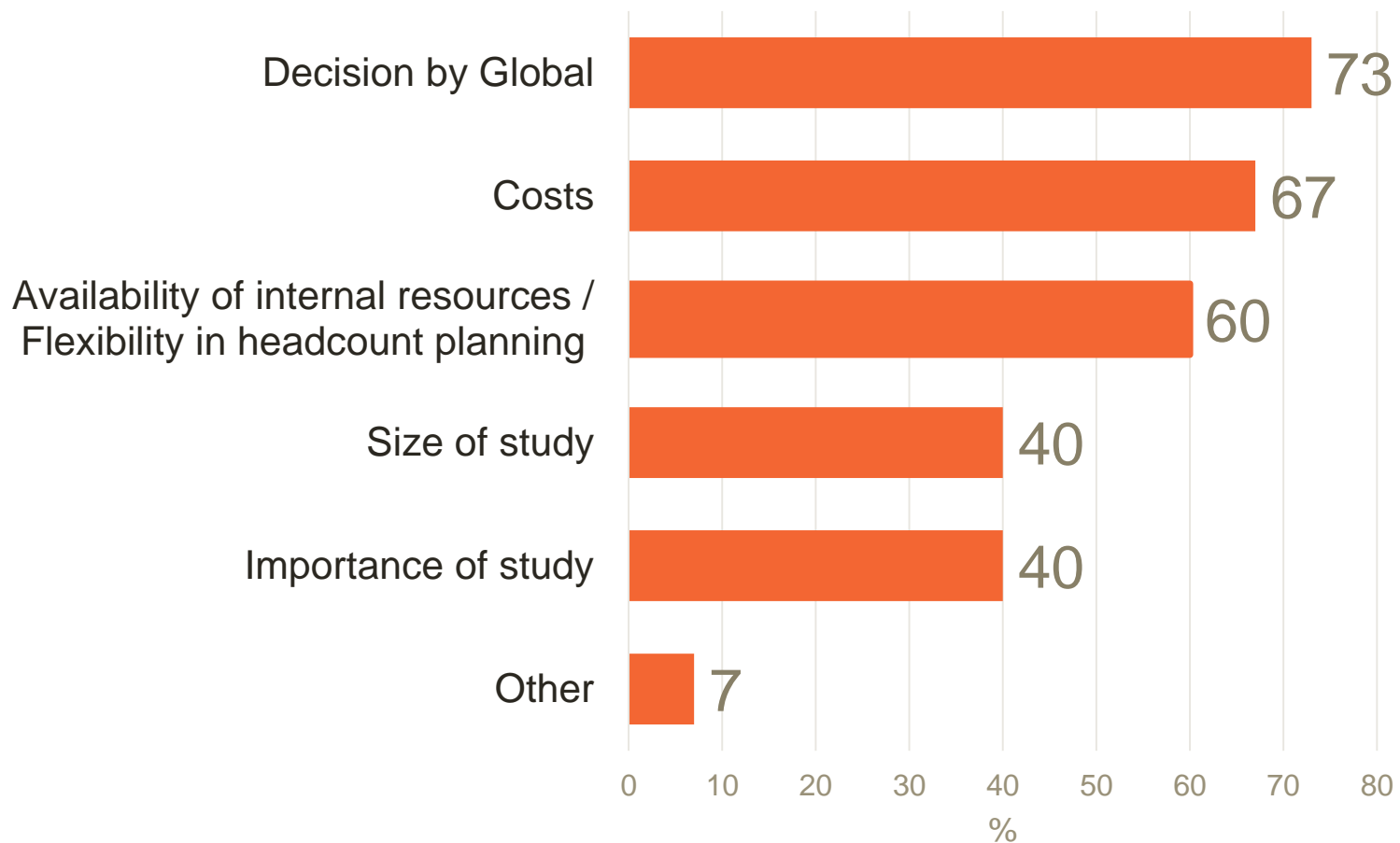


Multiple Answers



Criteria for Outsourcing

Multiple Answers

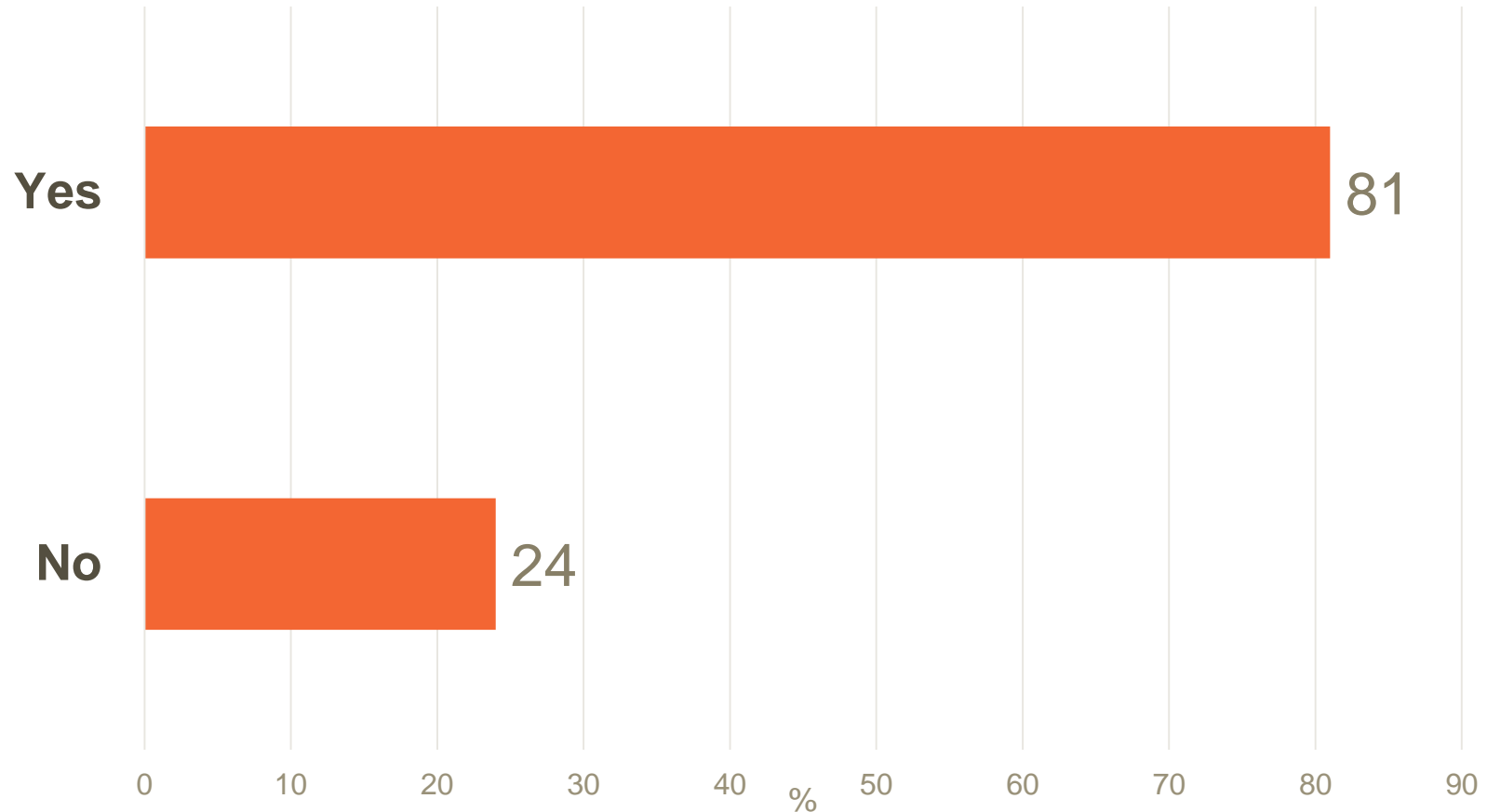


Full Outsourcing: Preferred Provider



Question (Number of questionnaires with data)	Answer	Response % ¹
Do you apply a preferred provider model? ² (N=15)	Yes	93
	Mix	20
	No	0
In case of application of a preferred provider model: With how many CROs do you cooperate? (N=14)	One CRO	36
	More than one CRO	64
In case of application of a preferred provider model and more than one CRO: With how many CROs do you cooperate? (N=14)	Mean Minimum, maximum	3.1 2-5
¹ Responses are ordered by decreasing frequency ² Multiple answers were possible or provided: percentages sum up to >100%		

Is there an SOP or any other guiding document addressing the topic „CRO oversight“ available in your company?

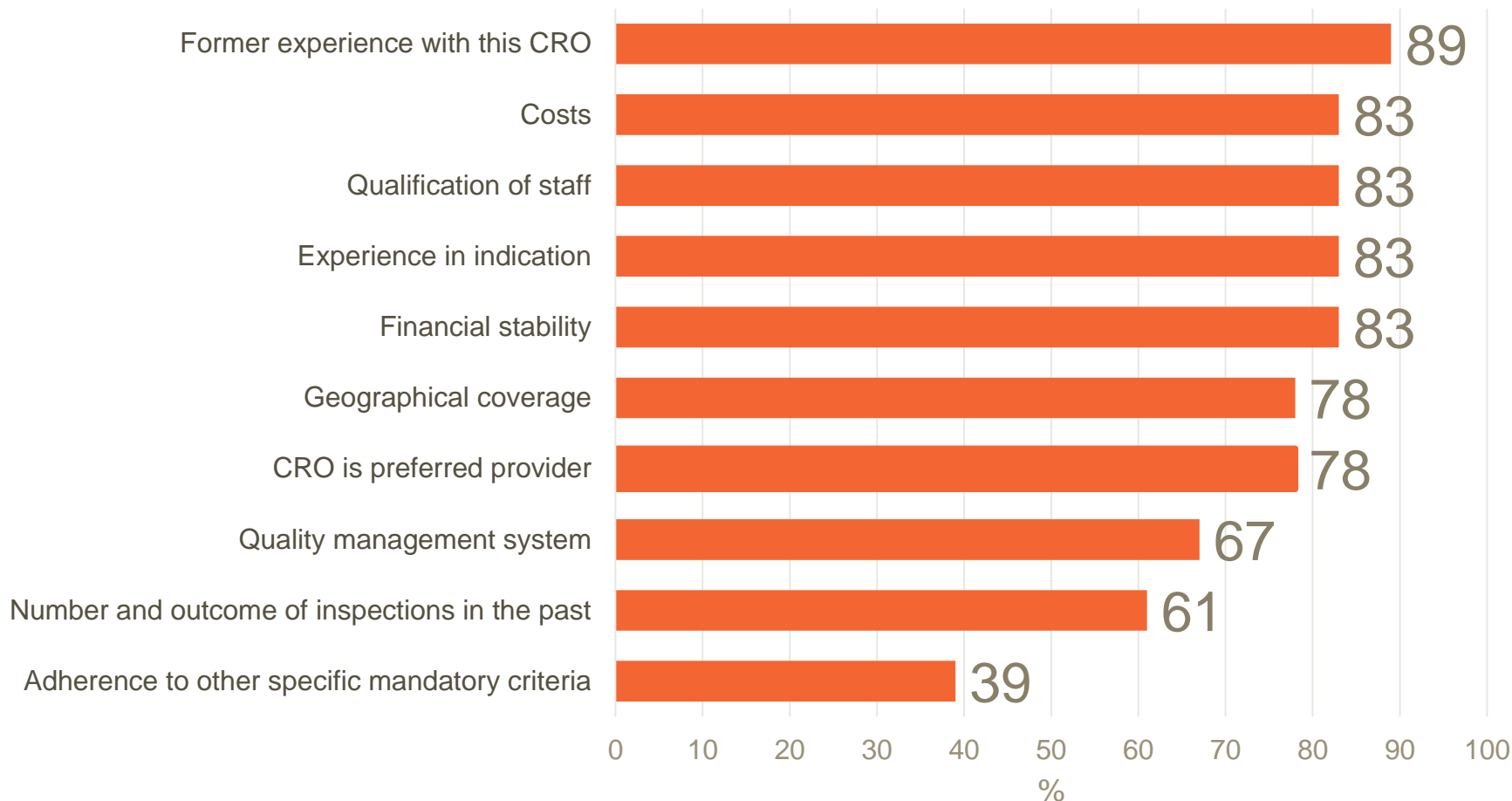


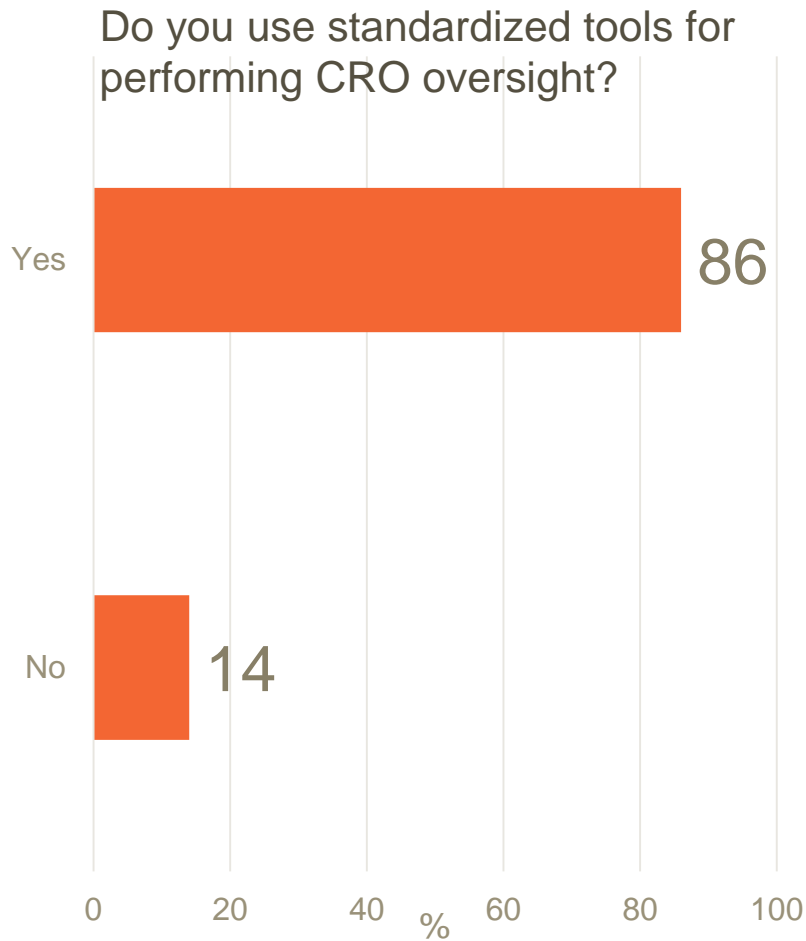
One multiple answer: yes (Clinical Operations) / no (Biostatistics)

Qualification checks before procurement



Which criteria do you check regularly during selection phase? (multiple answers)

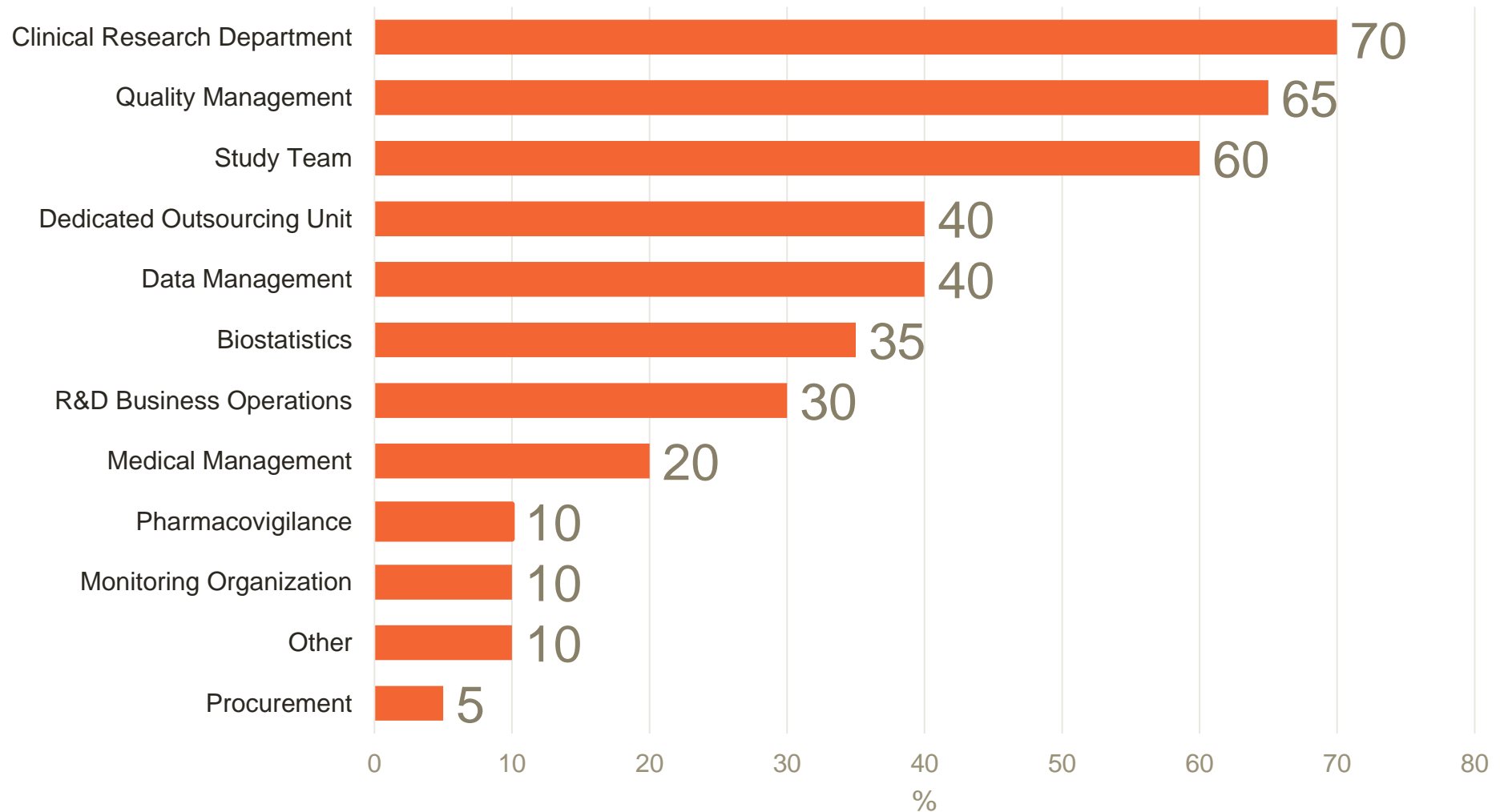




Oversight during study



Which department conducts CRO oversight? (multiple answers)



Question (Number of questionnaires with data)	Answer	Response %
If you have operational issues with the CRO, do you escalate according to an established escalation plan? (N=21)	Yes	90
	No	10
In case of QA findings during oversight assessments – are actions taken? (N=21)	Yes	100
	No	0

Conclusions

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- Transparent communication
 - Clearly established expectation for quality
 - Precise definition of accountability and responsibility
 - while avoiding silo mentality
 - Comprehensive documentation of oversight evidence

For globally acting sponsors:

- Alignment of oversight processes at global and local level

Conclusion

Survey results



Current implementation of oversight processes covers all relevant areas to ensure highest quality and integrity of data produced by the outsourced clinical trial

It remains the ultimate responsibility of any sponsor to apply the implemented measures adequately

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- Hennig M, Hundt F, Busta S, Mikus S, Sanden PH, Sörgel A, Ruppert T.:
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Thank You