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European Network of Centres for Pharmacoepidemiology

Investigating the role and impact of ENCePP – a qualitative study

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Introduction

Research question and approach

ENCePP Work Plan: version June 2024

Objective 3: Increase the impact of ENCePP in Europe and globally

3.1 Qualitative study to inform continued ENCePP strategy: insights into relevance, usefulness and positioning of ENCePP in the RWE and PE/PV environment

- Semi-structured interviews
- Qualitative survey

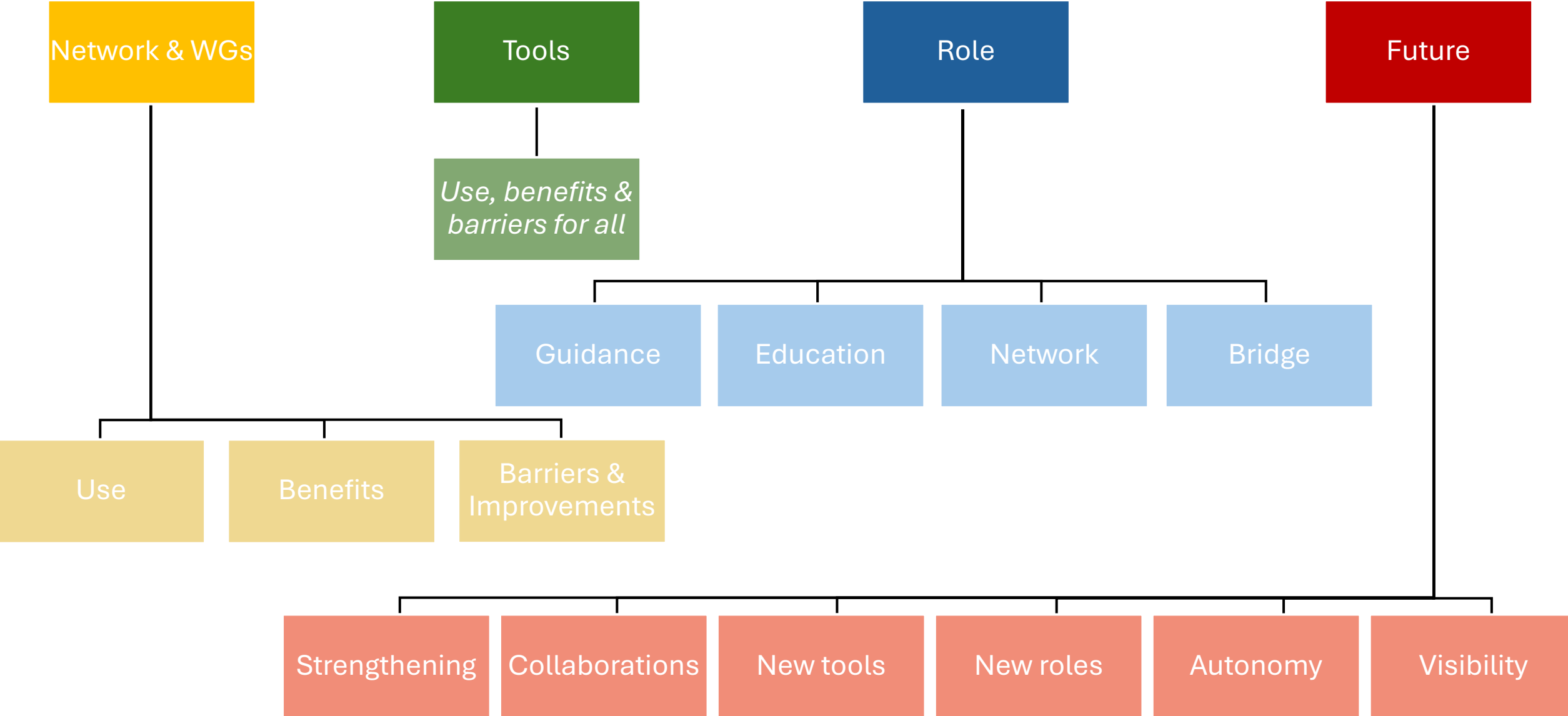
Methods

Methods

Interview and survey study design

	Interviews	Survey
Study population	SG / WG members, ENCePP Partners, regulators, others	ENCEPP Partners, regulators, others
Method of contact	Invitations sent by researcher	Invitations by ENCePP secretariat, LinkedIn post
Timeline	June- August 2024	September – October 2024
Scope	Knowledge/awareness of ENCePP Use of ENCePP tools Experience (benefits and barriers) Role of ENCePP today Future	Mandate and workplan Networks and WGs Code of Conduct ENCEPP Seal Checklist for Study Protocols Methodological Guide
Data analysis	Microsoft Teams, AmberScript, NVivo	Qualtrics, SPSS

Coding framework



Results

Interview Results

Participant characteristics

- 74 invitations sent, 32 responses, and 18 final interviews
- Average duration of interviews: 30 minutes
- Interviewees from 10 European and 1 non-European countries; most from NL (n = 3)

Institution type	Count	Percentage (%)
Regulatory body	5	27.8
Academic institution	4	22.2
CRO (for profit)	4	22.2
CRO (not-for-profit)	2	11.1
Pharmaceutical company	2	11.1
Other	1	0.6
Total	18	100

Survey Results

Participant characteristics

- 89 responders; 52 (58.4%) completed responses
- Respondents from 20 European and 2 non-European countries; most from NL (n = 8)
- 34 ENCePP Partners, 16 non-ENCePP Partners

<i>Countries</i>	<i>Count</i>
Belgium	1
Canada	1
Croatia	2
Denmark	5
Estonia	1
Finland	2
France	2
Germany	5
Greece	3
Iceland	1
Italy	4
Latvia	1
Lithuania	1
Montenegro	1
Netherlands	8
Norway	4
Portugal	1
Spain	7
Sweden	1
Switzerland	1
United States of America	1
United Kingdom	1
<i>Missing</i>	<i>1</i>
<i>Total</i>	<i>51</i>

Survey participant characteristics

Question	Options	Count	Percentage (%)
What type of institution do you currently work at?	Regulatory body	20	38.5
	Academic institution	14	26.9
	CRO (for profit)	5	9.6
	CRO (not-for-profit)	4	7.7
	Hospital / clinic	5	9.6
	Pharmaceutical company	2	3.8
	Other	2	3.8
How many years of experience with non-interventional studies do you have?	No experience	1	1.9
	Less than 1 year	1	1.9
	1 – 5 years	15	28.8
	6 – 15 years	21	40.4
	More than 15 years	14	26.9
For how many years have you been involved in ENCePP? (through the network of use of tools)	Not involved	5	9.6
	Less than 1 year	7	13.5
	1 – 5 years	19	36.5
	6 – 10 years	10	19.2
	10 – 15 years	11	21.2

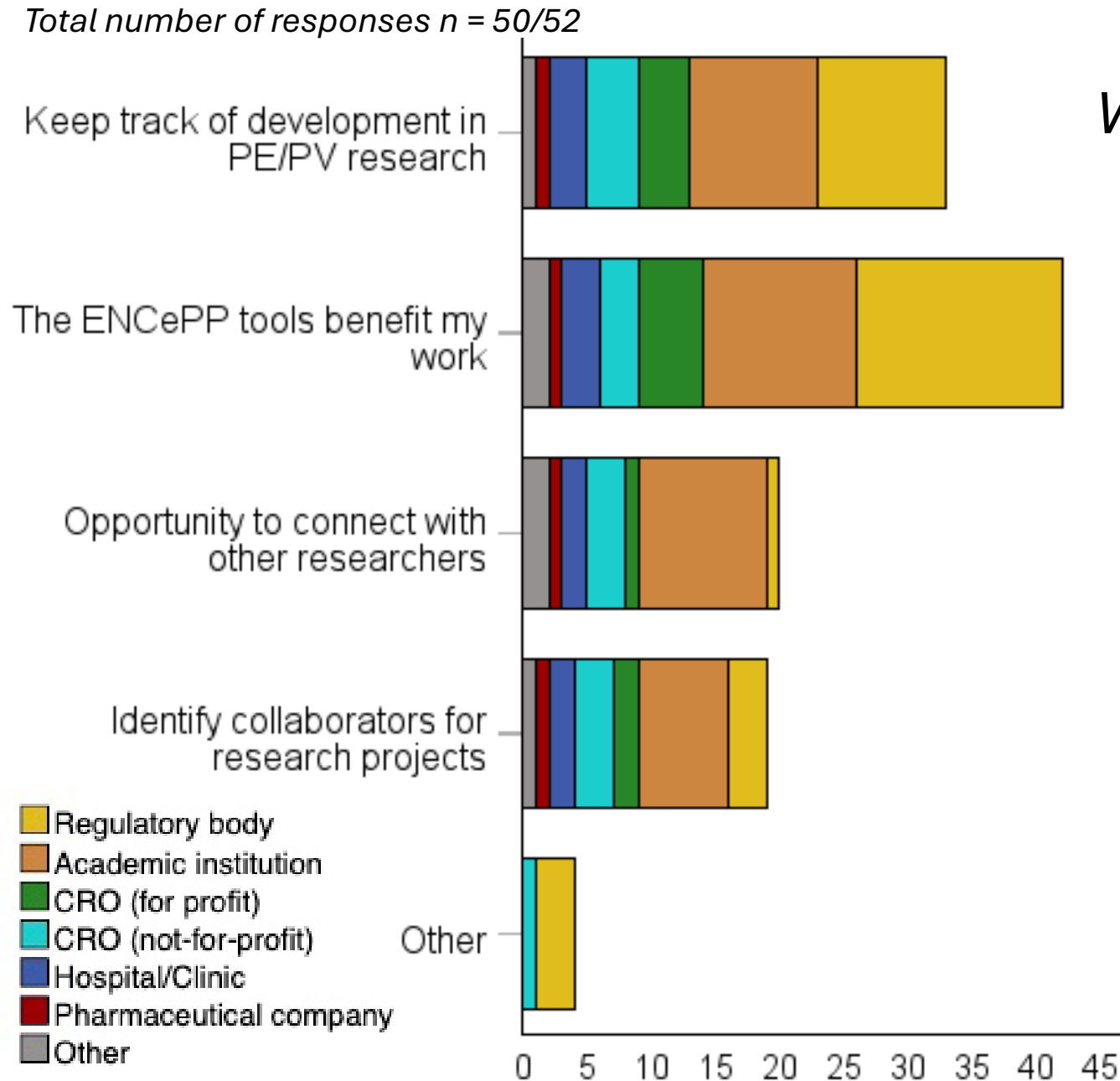
Networks & WGs

What benefit do you get from ENCePP?

“When you are a member of ENCePP, you are quite well informed on what’s going on - at least at the EU level - in the case of PE research.” [L109]

“I have the opportunity to know the most important researchers in Europe because most of them are involved in ENCePP.” [L101]

“Sometimes I feel like we are too siloed – people who are in pharma industry do their thing, and people who are in academia do their thing. So it’s a good forum for collaboration.” [L107]

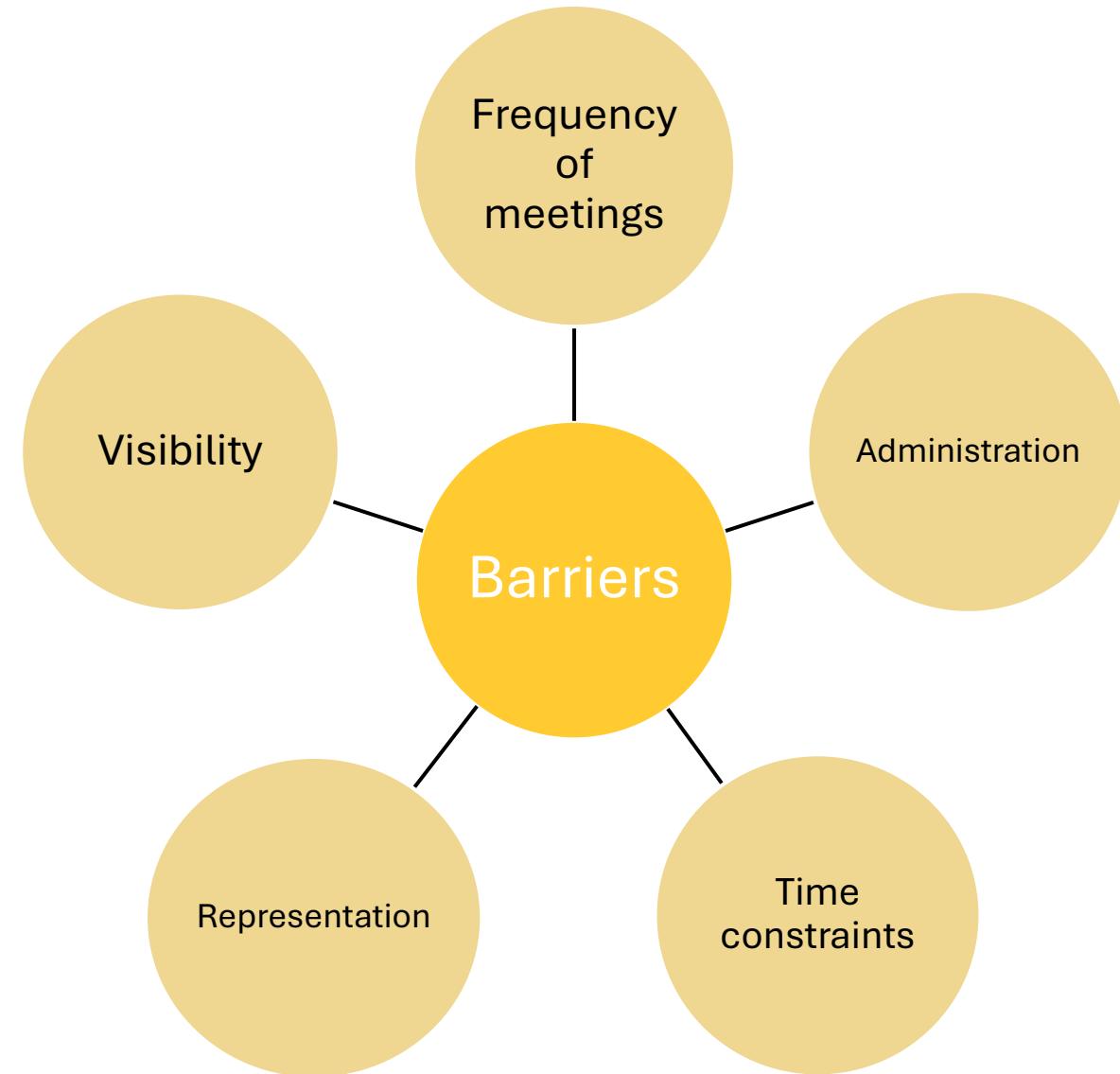


Networks & WGs

Barriers and Improvements

“One general assembly a year is not enough. We should probably have a bit more webinars, or kind of knowledge-sharing events.” [L110]

“All of us are very busy and do not have enough time to check the ENCePP Page. It would be nice to receive maybe more newsletters or some general information about activities.” [L203]

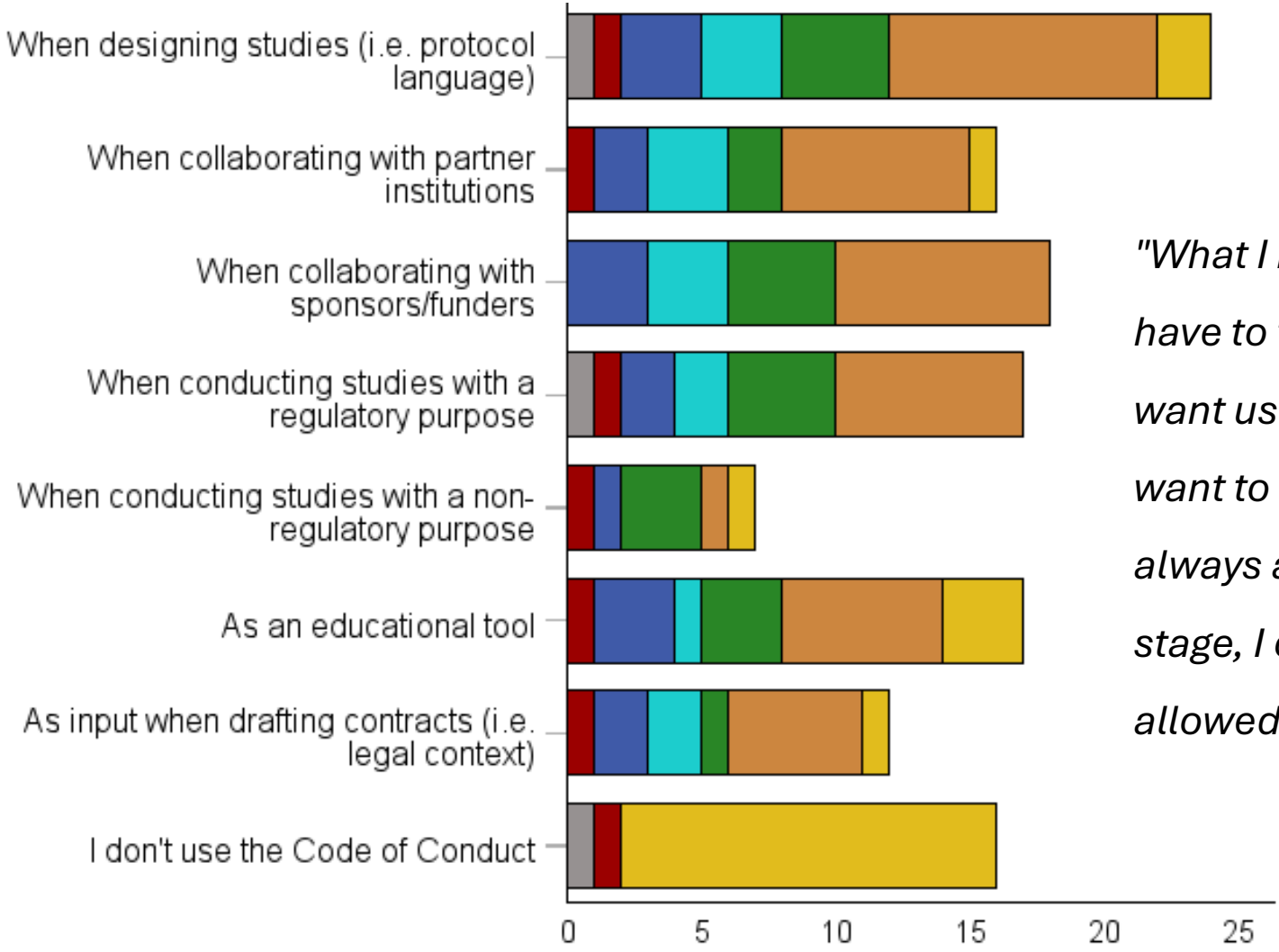


Code of Conduct

How do you use the Code of Conduct?

- Regulatory body
- Academic institution
- CRO (for profit)
- CRO (not-for-profit)
- Hospital/Clinic
- Pharmaceutical company
- Other

Total number of responses n = 50/52

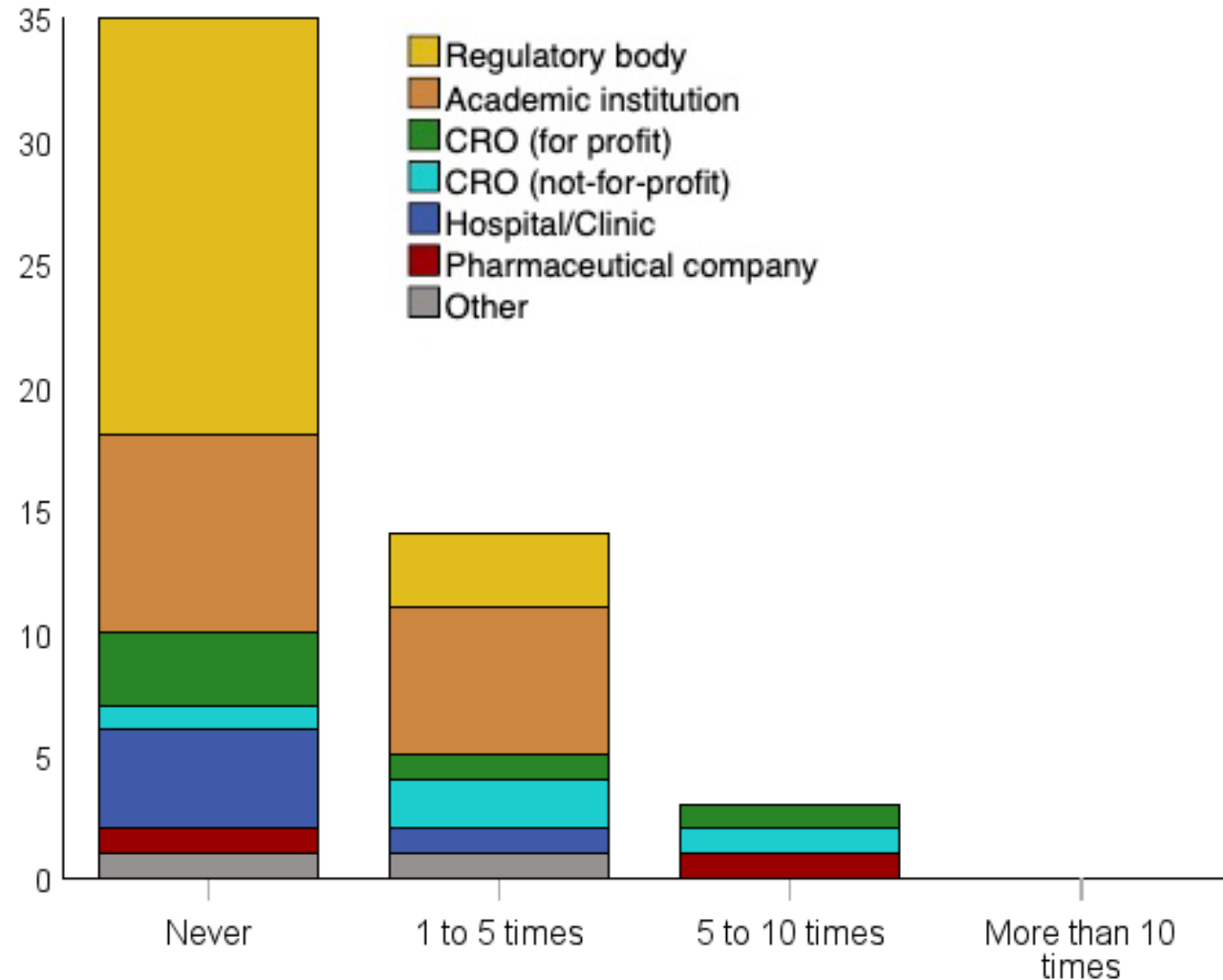


"What I really like with the Code of Conduct, it helps me when I have to talk with with the pharmaceutical industry. When they want us to do a study, and then I say, 'yes, we do it and we want to do it according to the ENCePP Code of Conduct'. They always agree, so then when they want to be involved on a later stage, I can say, 'well did you read it? It says you're no longer allowed to be involved'. So, it is really, really helpful." [L103].

ENCePP Seal

How many times have you applied for the ENCePP Seal?

Total number of responses $n = 52/52$



“The ENCePP Seal is kind of a nice idea, but it’s not really possible typically [given] the data permits that we have...there are [often] very restricted data permits / regulations that prevent the data to be shared anywhere.” [L107]

“Sponsors are reluctant to include in contract, because they do not see regulatory value/benefit of using [the Seal].” [L111]

“Going through all the requirements improved our thoroughness. Some questions weren’t entirely clear or applicable to us, but I guess this is normal. I would personally apply for [the Seal] in the next project again.”

Responses from Regulators (n = 20)

Do you perceive studies that have are conducted according to the Code of Conduct / have the ENCePP Seal to be of a higher quality than those that don't?*

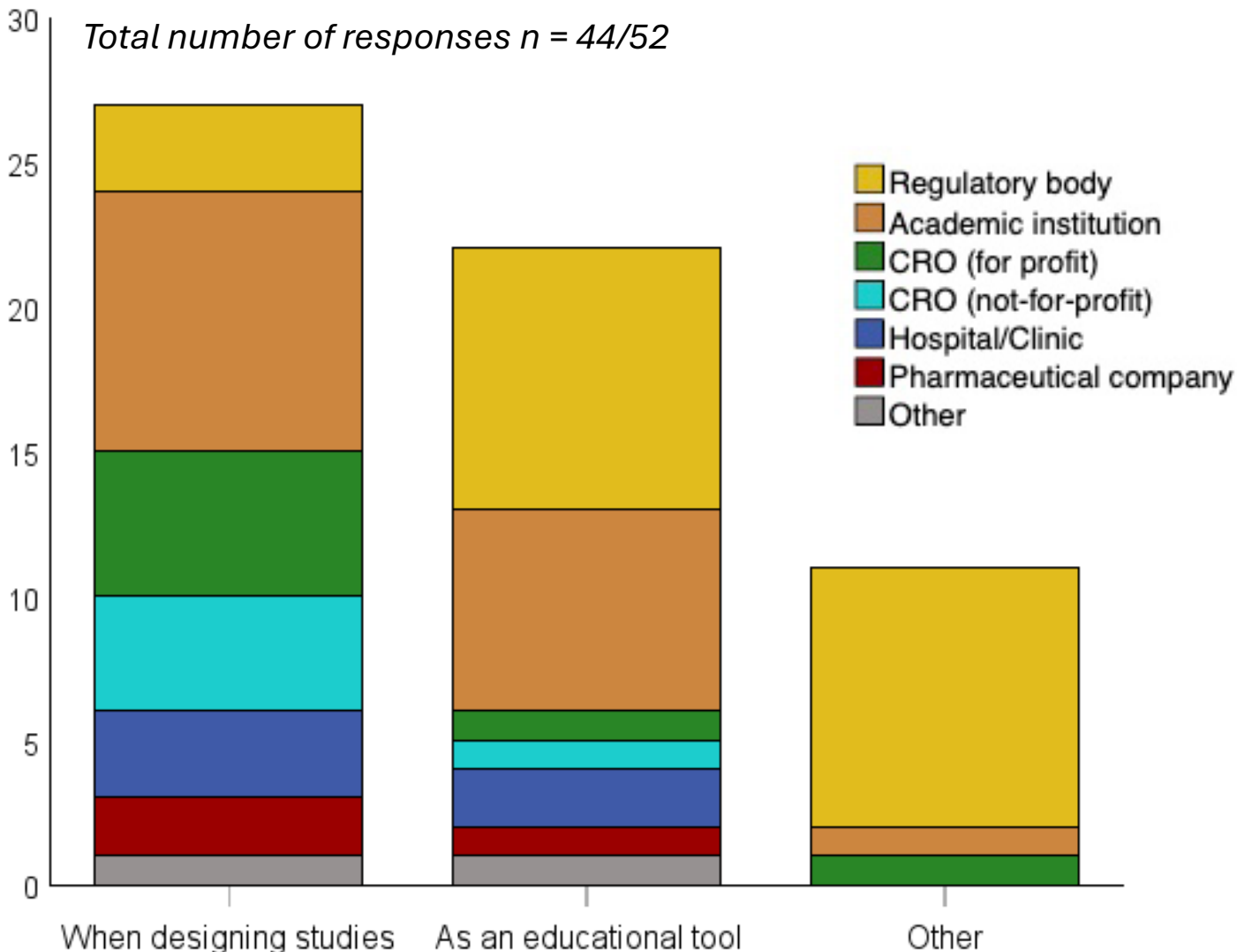
Responses	Code of Conduct		ENCEPP Seal*	
	Count	Percentage (%)	Count	Percentage %
Yes	11	55	12	60
No	3	15	4	20
Other (open text)	4	20	3	15
	<i>'Perhaps, depending on the type of study.'</i>		<i>'It may give greater trust, but not entirely.'</i>	
No answer	2	10	1	5

**Note: studies with the ENCePP Seal always follow the Code of Conduct*

Checklist for Study Protocols

How do you use the Checklist for Study Protocols?

Total number of responses $n = 44/52$

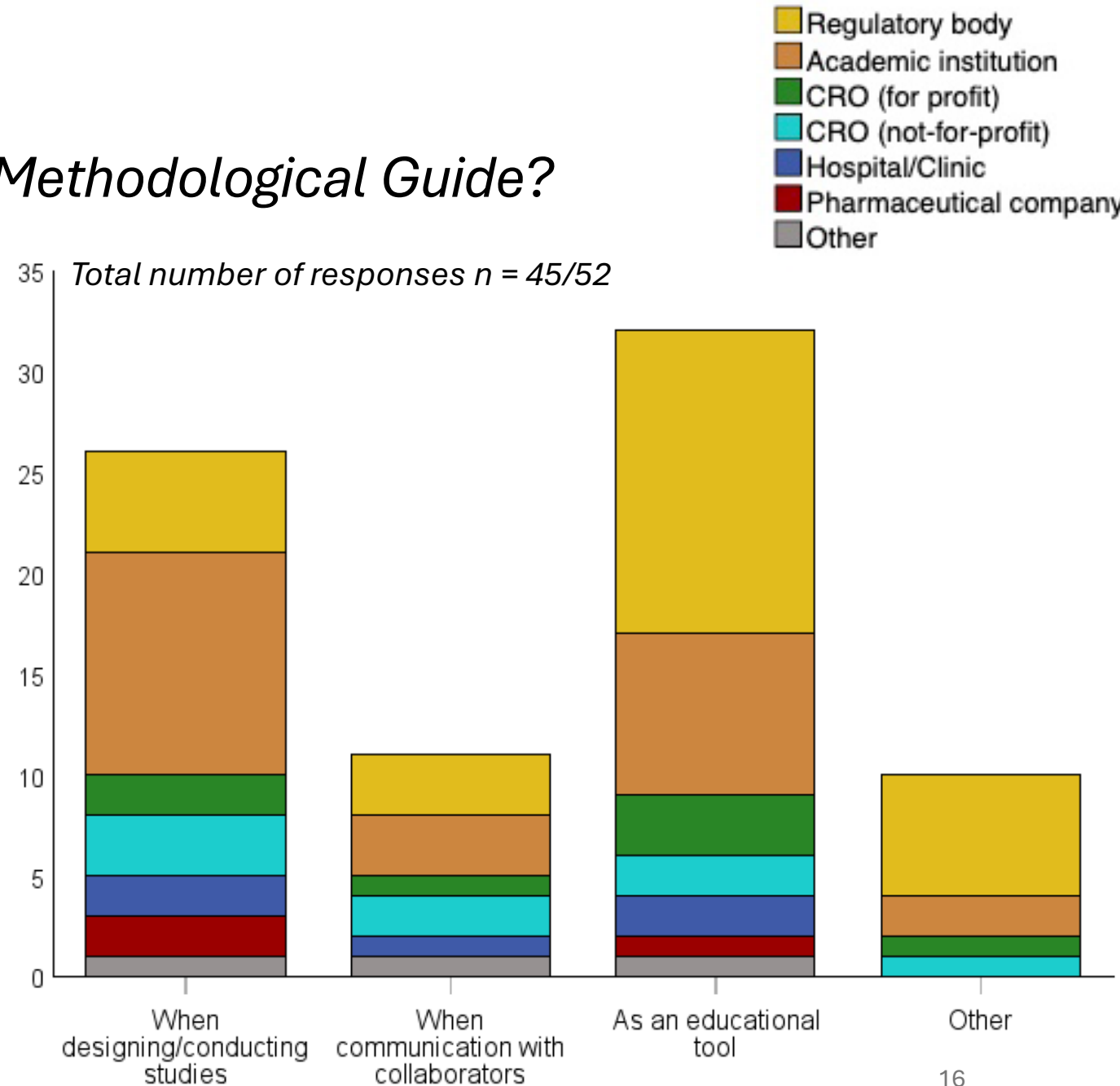


- 40% of respondents reported using the Checklist ‘occasionally’ to ‘very regularly’
- ‘Other’ use by regulators –
 - Evaluating PASS study protocols
 - Assessing studies for PRAC
- Similar use by interviewees
- Barriers; alignment with other checklists, extent of criteria

Methodological Guide

For what purpose(s) do you use the Methodological Guide?

- 27% of respondents reported using the Guide ‘regularly’ to ‘always.’
- ‘Other’ uses include –
 - Assessment of PASS
 - When authoring SAP and study reports
 - To address queries from sponsors



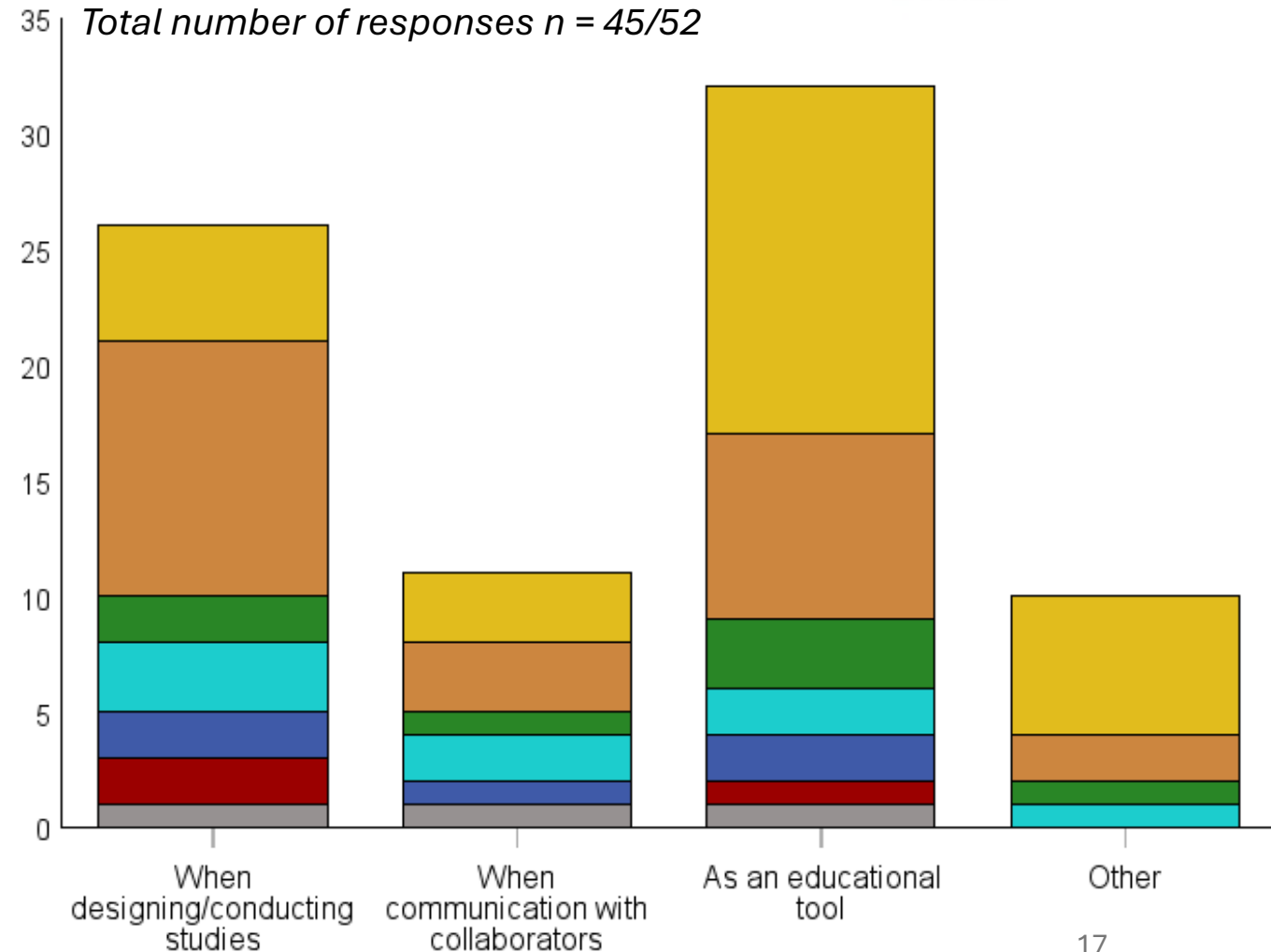
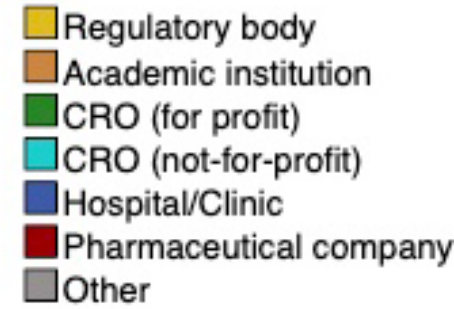
Methodological Guide

For what purpose(s) do you use the Methodological Guide?

- Mentioned by more than half of the interviewees;
similar uses

“The ENCePP Guide, I know is used a bit everywhere, because this is one of the only guide of this type that exists, and with so many references that are directly accessible by researchers. So I know it is used, for example, for training, [and] it is used by many universities around the world.” [L105]

“So before I knew ENCePP I would go to epidemiology textbooks, but now I can go to guidelines, and they are actually updated more than usual textbooks.” [L301]



(Current) Role

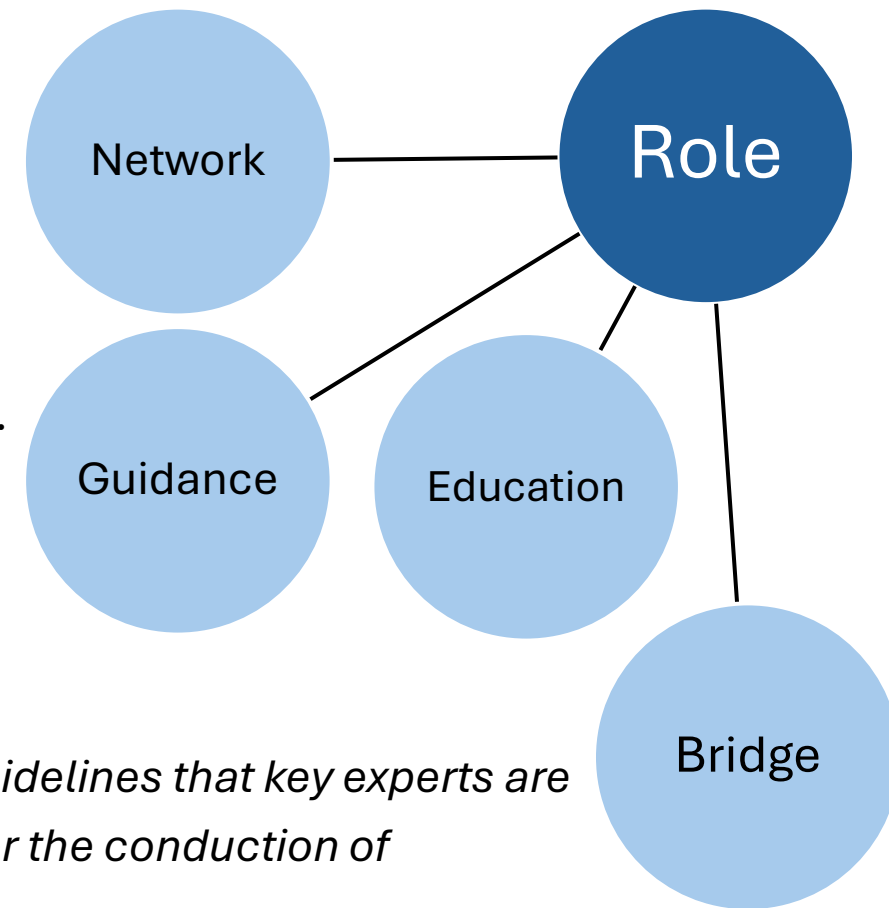
What do you see as the key role of ENCePP today?

“For me, ENCePP is like a library and cafeteria for pharmacoepidemiologists. A place where we know that there are colleagues with the same interests; where we can ask for methods, guidelines, templates - in which we can express our ideas and get comments from others.” [L106].

“It’s not only a regulatory perspective, but also a set of methodologies and guidelines that key experts are developing to help researchers conduct their studies... it’s really important for the conduction of observational studies, not only in Europe but also worldwide.” [L101]

“[The role of ENCePP is] to keep the balance of encouraging people using RWD, but also teaching them how to do it right.” [L103]

“[The role of ENCePP is] to bring together EMA, industry, researchers, and patients.” [L109]



Future

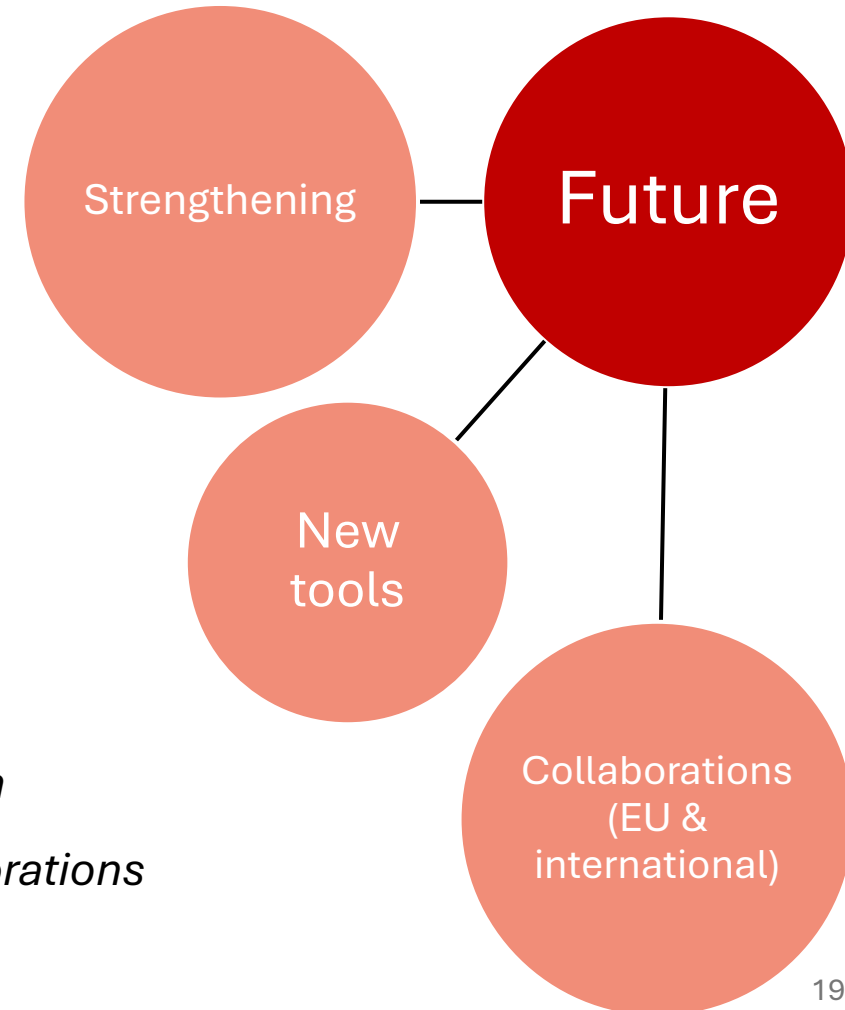
Where do you see ENCePP in 5 – 10 years from now? /

How do you see ENCePP contributing to the developments in the RWD landscape?

“I think ENCePP should just go on as they are doing and try to catch up with what was lost during the pandemic.” [L103]

- Suggestions for new tools:
 - Academic/educational material
 - New WGs / SIGs on i) patients and ii) AI
 - Tool for evaluating studies
 - Facilitate access to data
 - Improve or assess data quality measures

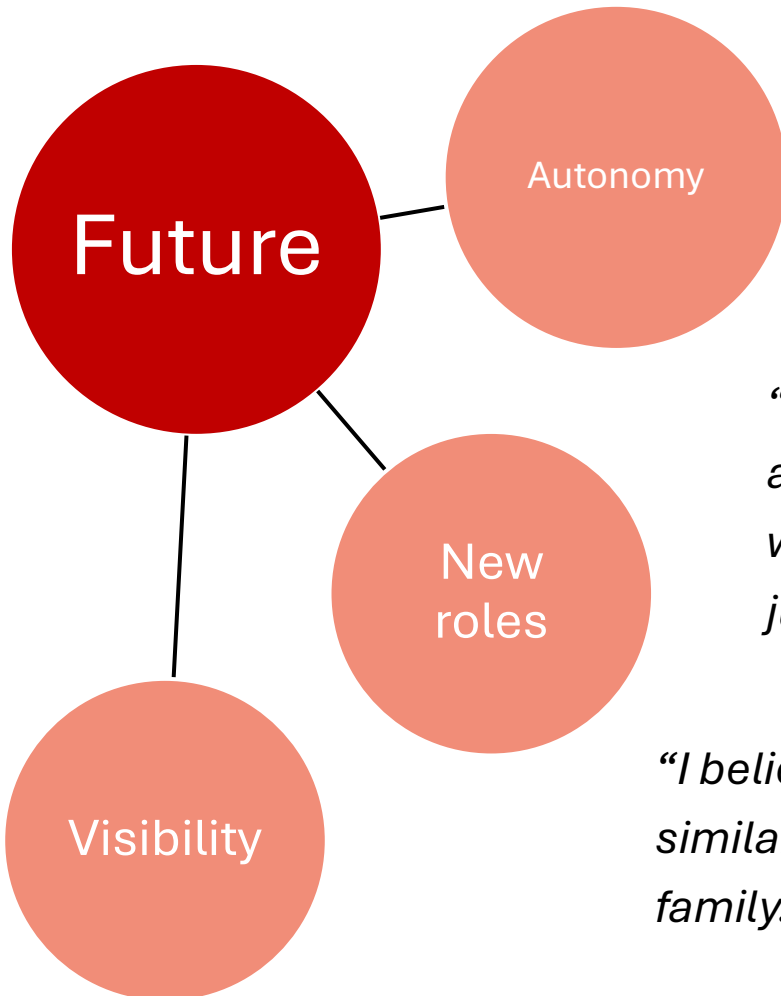
“The ‘European’ bit doesn’t have to be anything restricting. We just started as a European Medicines Agency, so Europe was the focus. But absolutely, collaborations with others outside Europe, definitely.” [L110]



Future

Where do you see ENCePP in 5 – 10 years from now? /

How do you see ENCePP contributing to the developments in the RWD landscape?



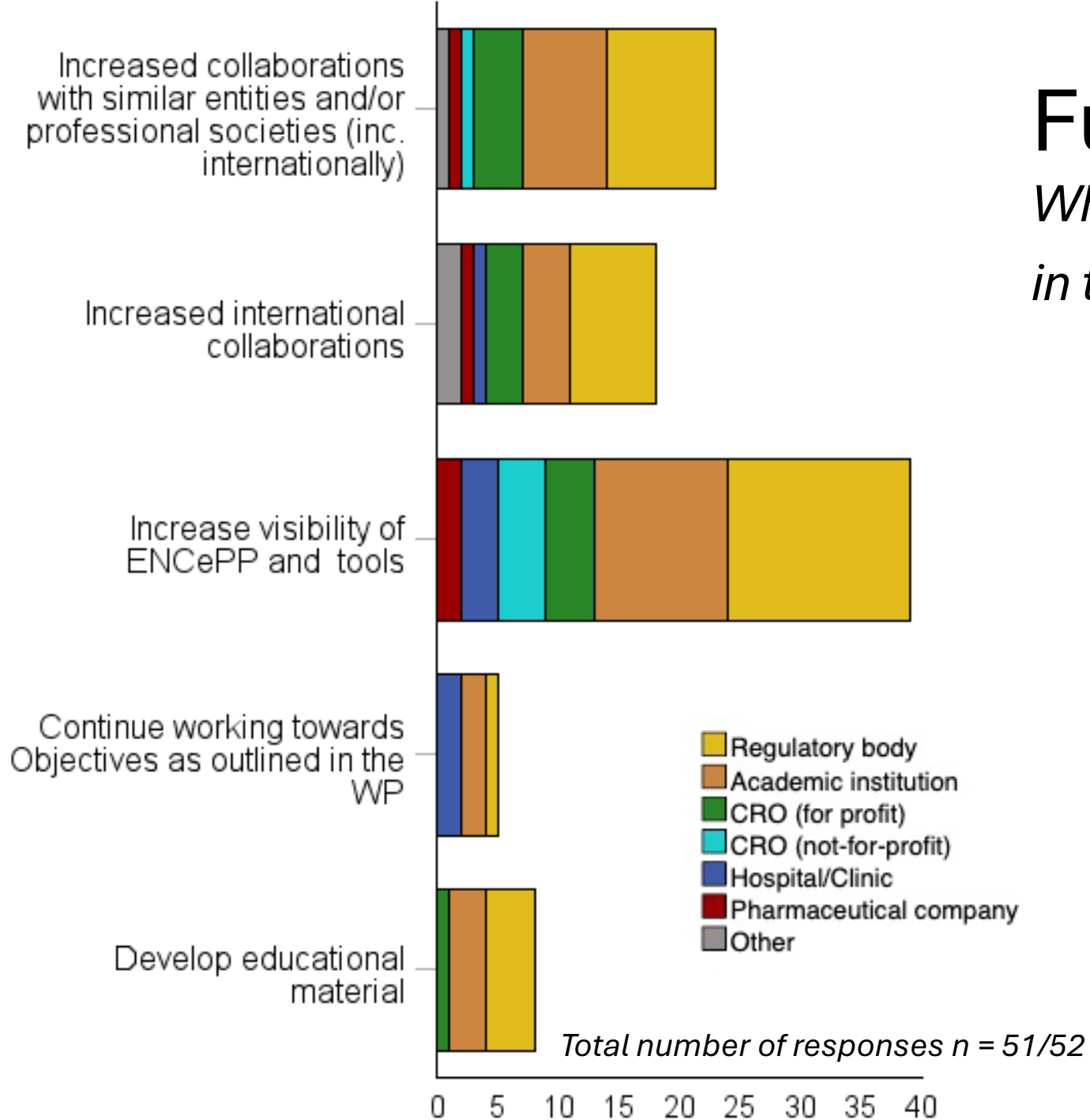
“ENCePP is long standing, it's been around a long time and it is very comprehensive, so I could see it take a leadership role in creating a common threshold for methodological rigor globally.” [L304]

“To write something which could then be cited in the sense of 'new data is emerging, a lot of people are doing it, and some of these studies are not good because they do well-known things wrong. But if you do them right, Real World Data can be used' - just to repeat saying this. “ [L103]

“I believe that there are many people outside ENCePP that might be involved in the similar studies, but they have never heard of ENCePP, and we need to gather them in our family.” [L109]

Future

What do you think ENCePP should focus on in the future?



- Increase visibility through:
 - Clarifying (primary) objective
 - Internal visibility
 - External visibility
 - Utilising different forms of communication

Discussion

Current and future position of ENCePP

- Hosts a network of expert researchers, fosters collaborations
- Inspires and guides researchers through an evolving RWD landscape
- Has a respected voice on the quality and validity of methodological practices

- Clarity on objective and positioning, widespread visibility
- Continue to adapt network and tools to reflect the current, post-pandemic, highly-digitalized time

Discussion

Strengths and limitations

- *Strengths*: design allows both an in-depth analysis and a high-level overview, input from a wide range of stakeholders
- *Limitations*: overrepresentation of active ENCePP members in interviews, most responders from Western Europe, incomplete survey responses

Conclusion

- Qualitative study investigating the role and impact of ENCePP
- Results confirm relevance and benefit of ENCePP in the PE/PV landscape
- Provides valuable additional insights into how ENCePP can move forward
- *Next steps*: continue with analysis of results, complete report, hand over to ENCePP SG

Acknowledgements

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