

Investigating the role and impact of ENCePP – a qualitative study

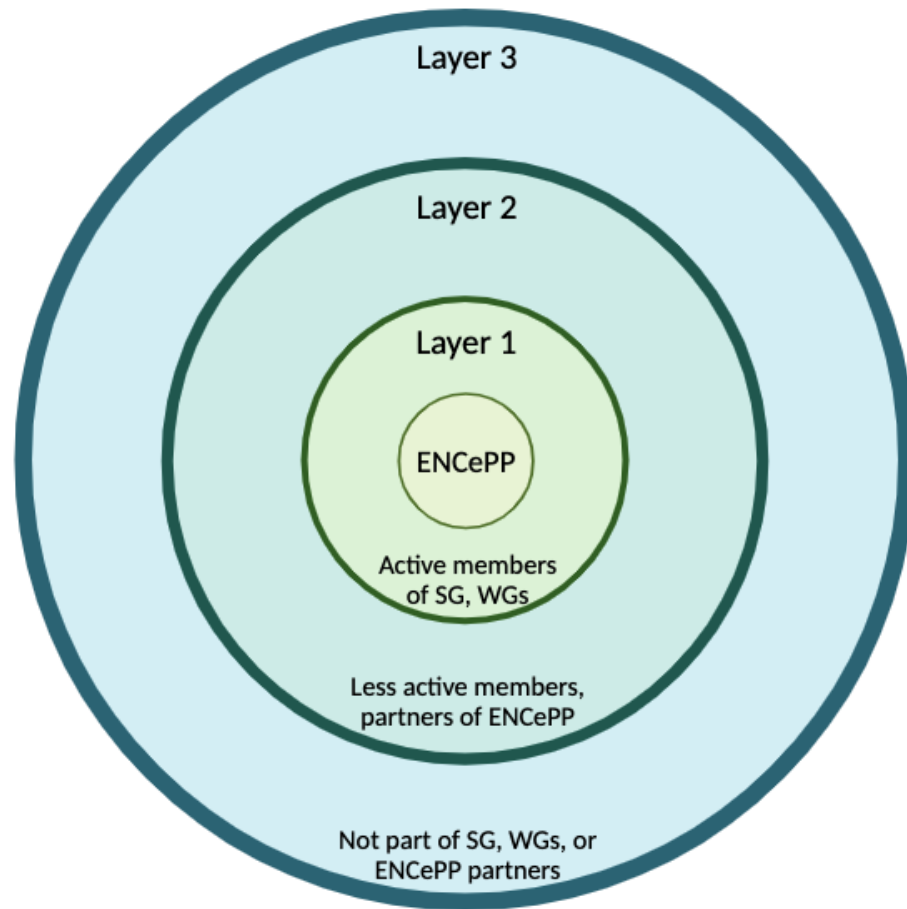
~ Interim results ~

27.09.2024

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Participant profile



Layer 1: Active members of ENCePP (SG / WG members)

Layer 2: ENCePP Partners, not part of SG / WG

Layer 3: Regulators

Participant info

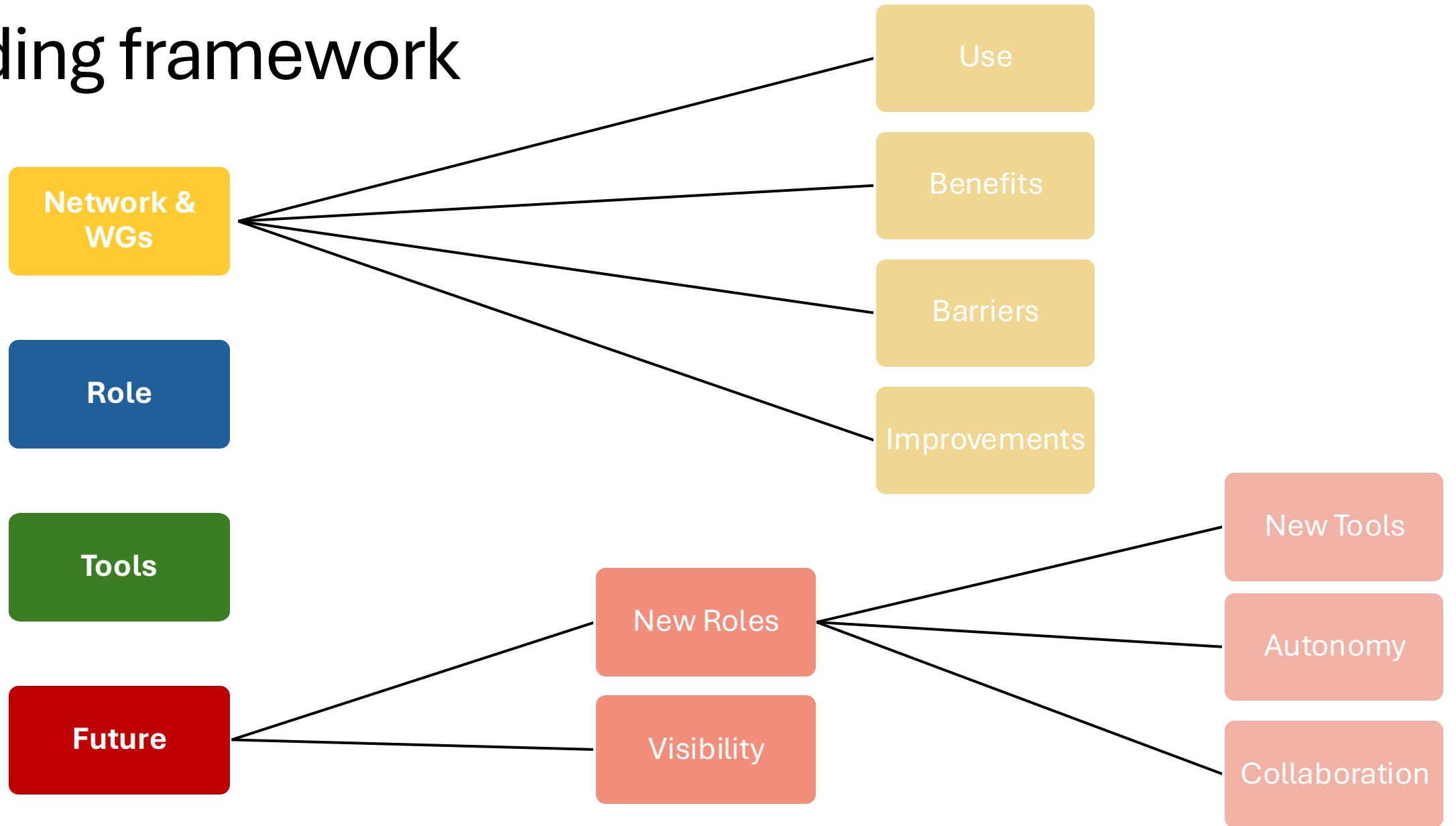
	Layer 1	Layer 2	Layer 3
Contacted	20	53 / 45*	15
Responded	15	9**	8
Interviewed	11	3	4

* Some emails did not work / the contact was no longer valid.

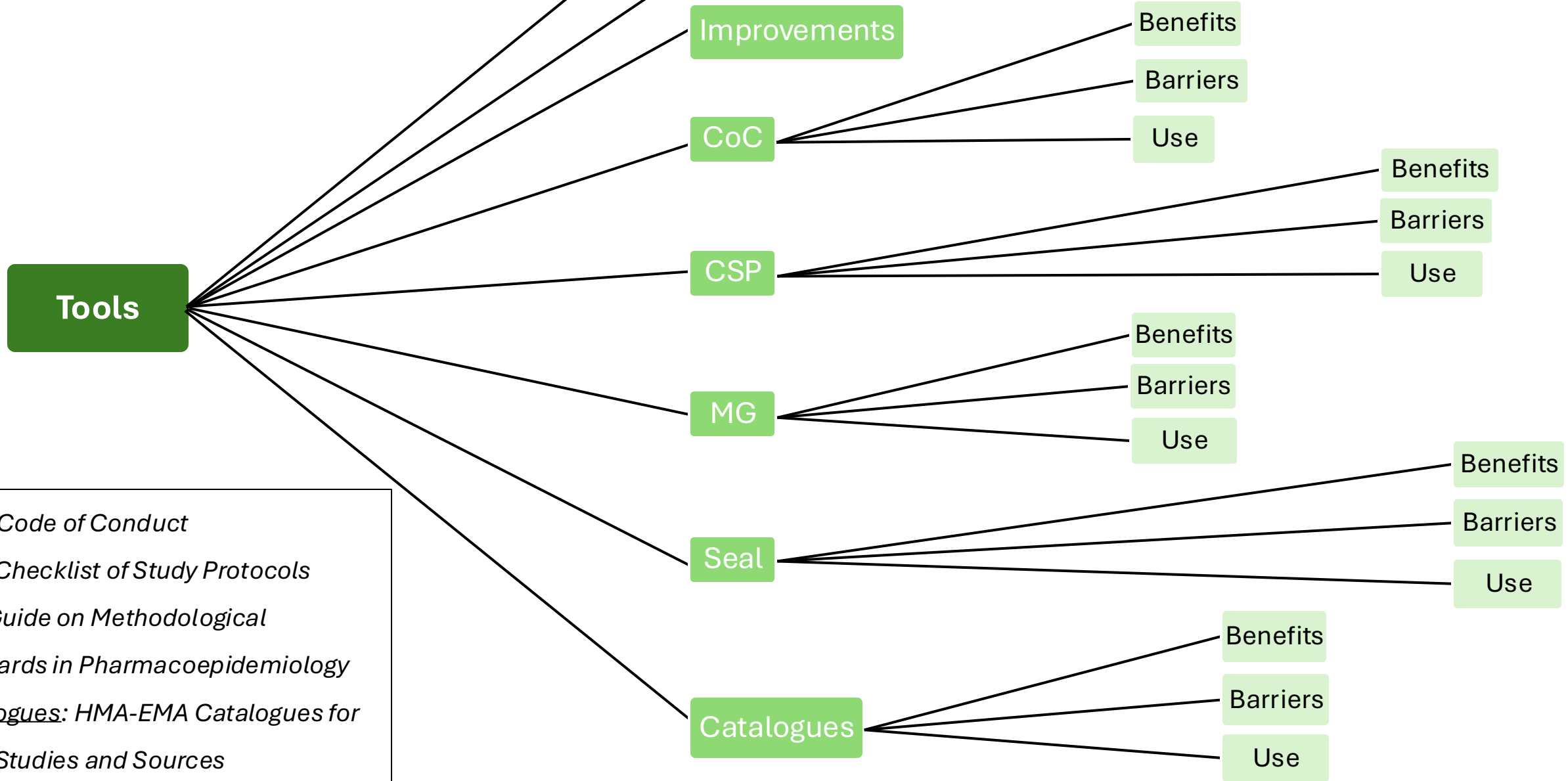
** Excluding auto-response emails.

- Invitations sent May - July '24
- Interviews held June – August '24
- Average duration of interviews: 30min

Coding framework



Coding framework



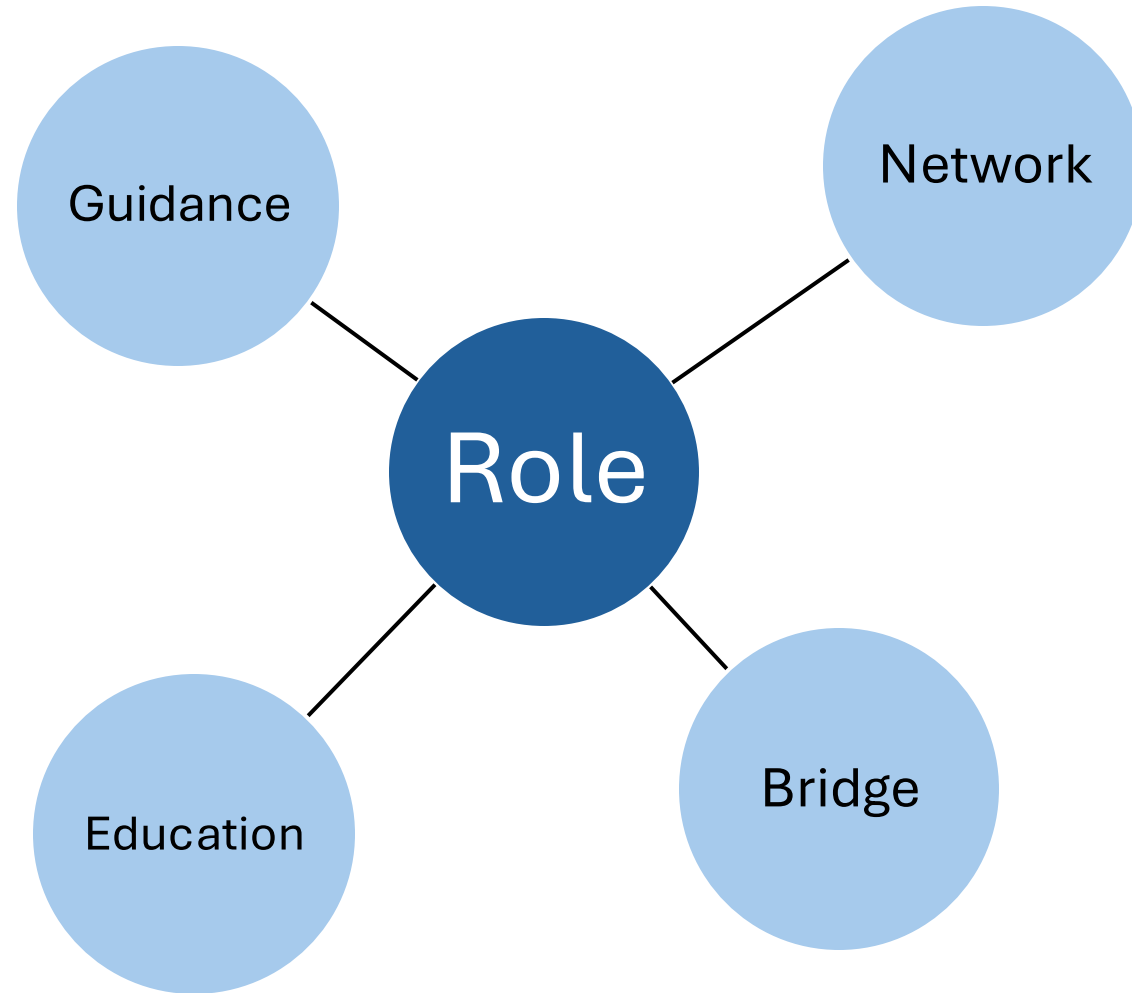
CoC: Code of Conduct
CSP: Checklist of Study Protocols
MG: Guide on Methodological Standards in Pharmacoepidemiology
Catalogues: HMA-EMA Catalogues for RWD Studies and Sources

Results – *Role*

“To bring together EMA, industry, researchers, and patients.”

“To keep the balance of encouraging people using RWD, but also teaching them how to do it right.”

“Being a central hub for everything there is to know about RWE.”

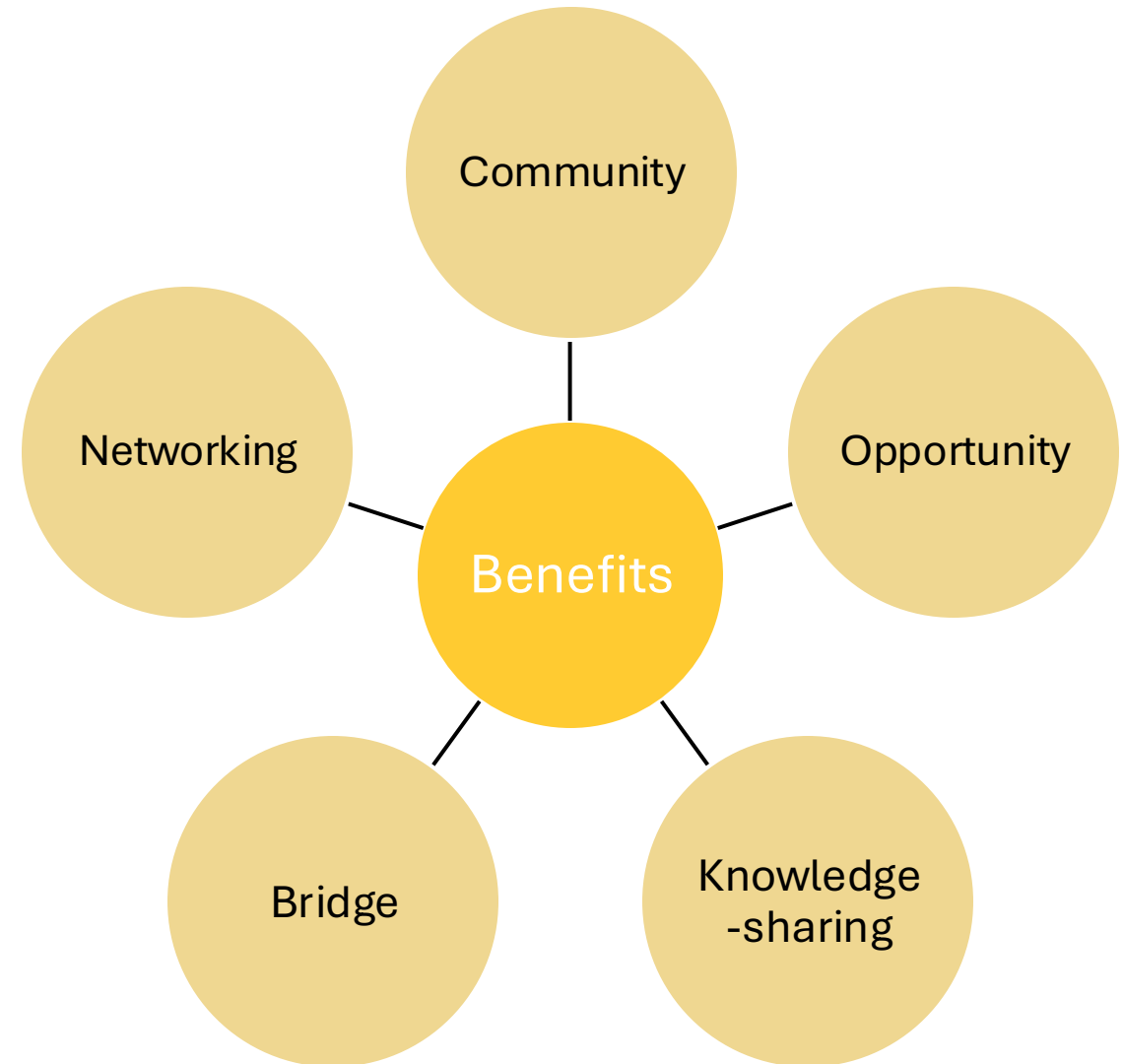


Results – Network & WGs

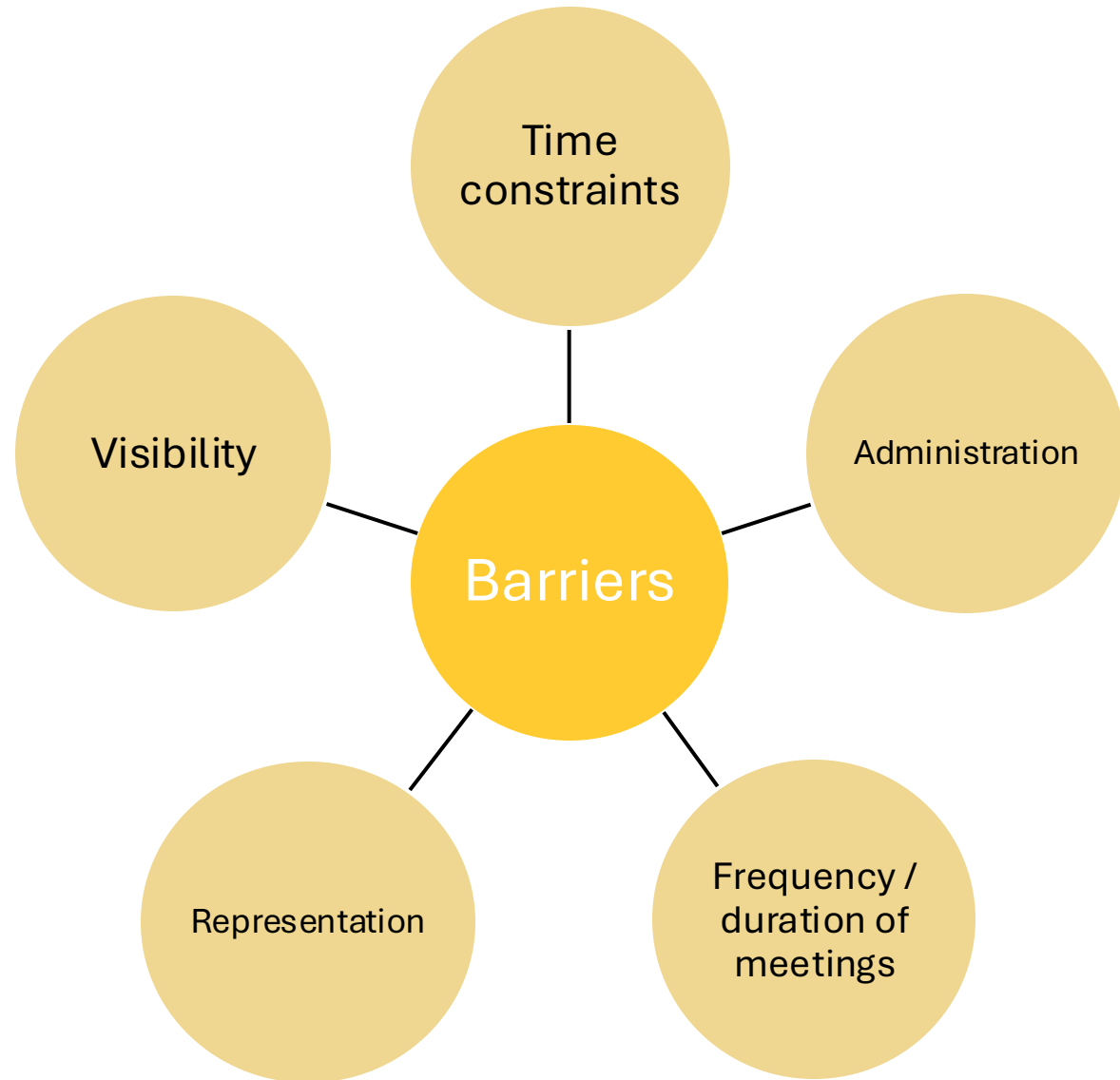
“Sometimes I feel like we are too siloed – people who are in pharma industry do their thing, and people who are in academia do their thing. So it’s a good forum for collaboration.”

“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.”

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



Results – Network & WGs



“I have had very limited time to review and provide input for those, so, I think that I could do a lot more if I had more time, but currently I'm more of a silent participant.”

“What is missing, I think, is that there isn't strong enough collaboration between members. We meet each other only for half a day, every six months.”

“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.”

“I'm not entirely sure in the end of what ENCePP as an organization actually is.”

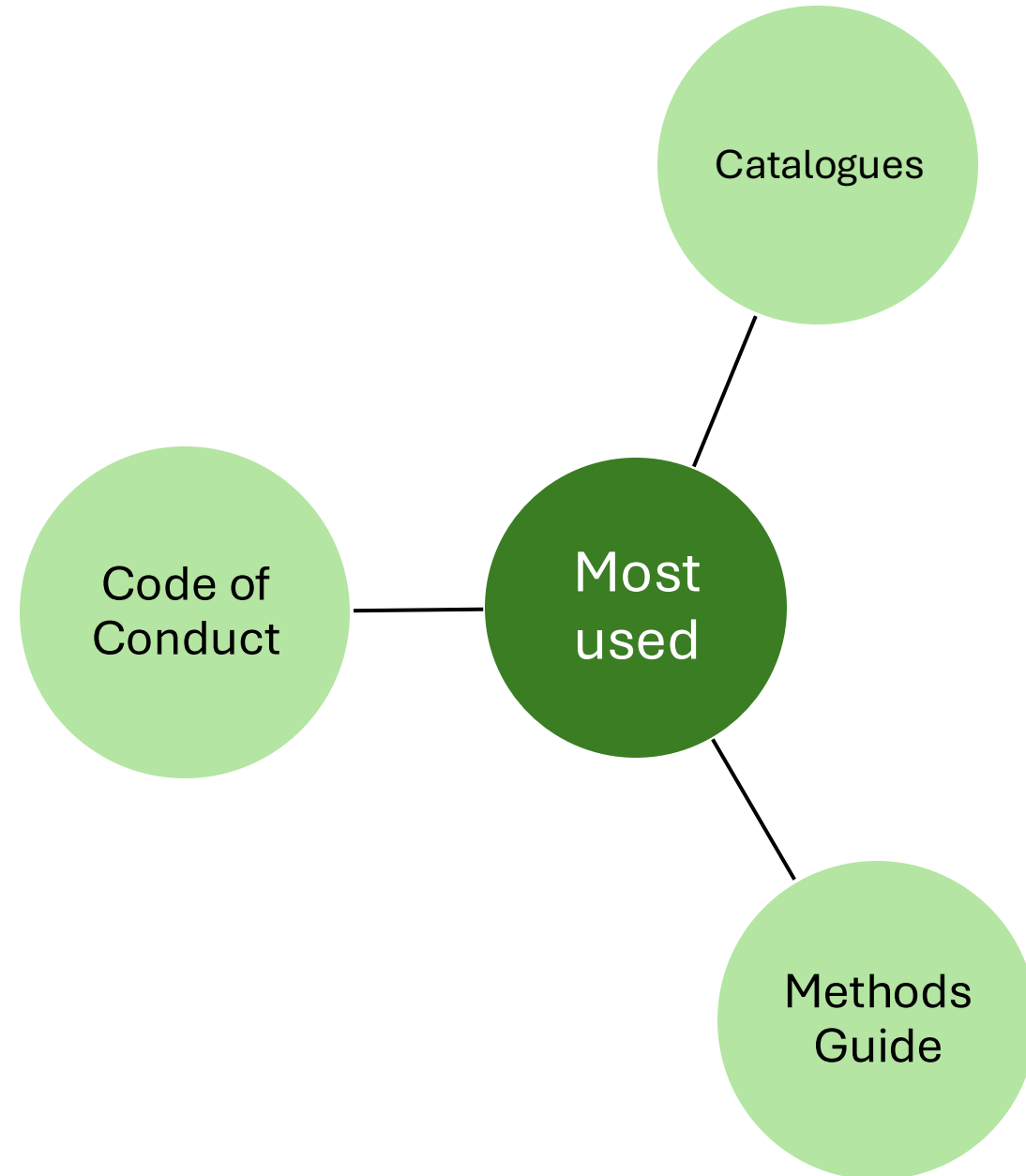
Results – *Tools*

- 15 / 18 interviewees mentioned the Code of Conduct.
- 13 / 18 mentioned the Catalogues
- 10 / 18 mentioned the Methods Guide.

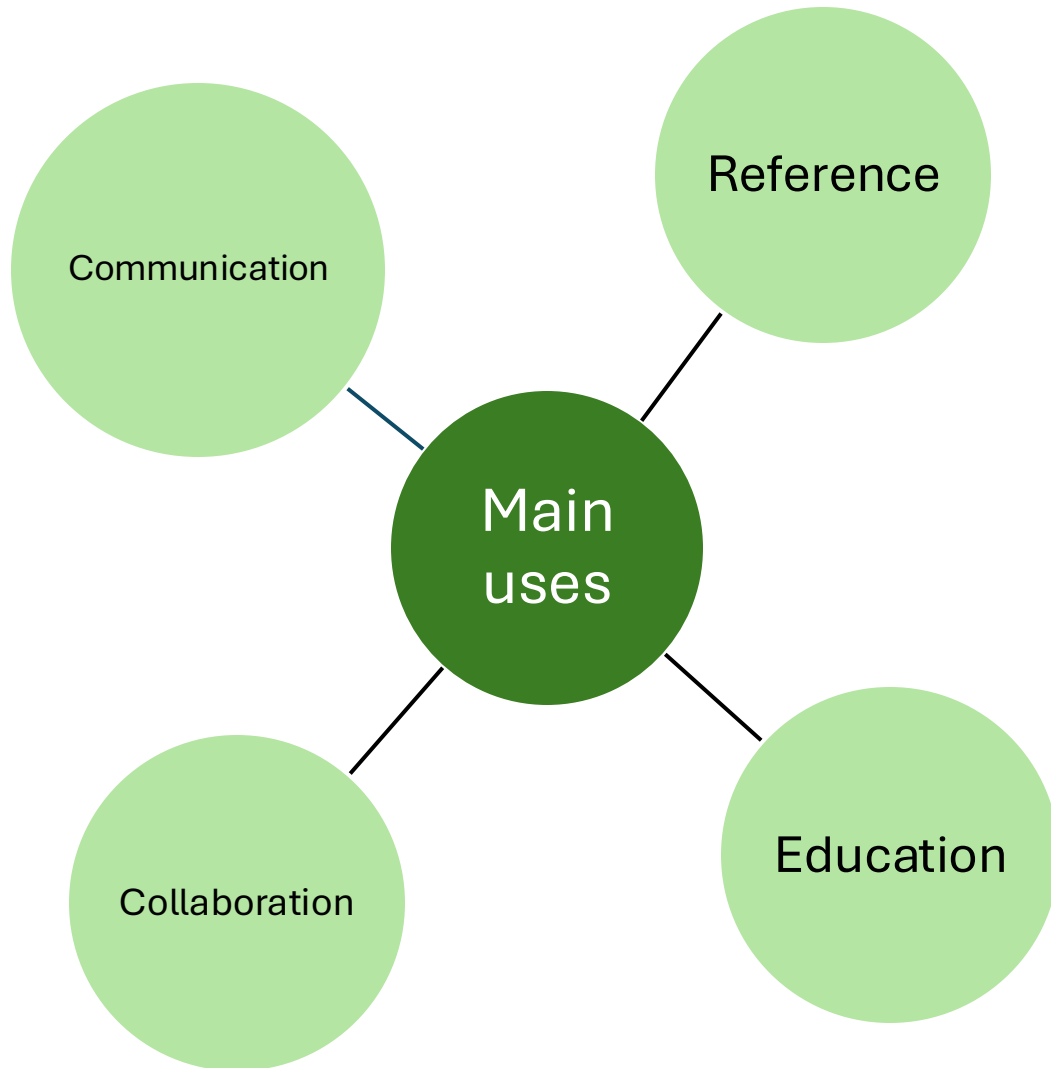
“I think if you do research, it’s important that you stick to the rules of the Code of Conduct, so that’s how I use it.”

“The two catalogues of studies are very useful for when we want to plan a study, because we can see what has been done already, and especially how it has been done, how certain challenges have been overcome and been handled, and also which data sources have been used.”

“The Methodological Guide is an everyday, go-to resource. I think for everybody in the world, frankly, not for me only.”



Results – *Tools*



“It really makes it easier to communicate with pharmaceutical companies about involvement, transparency, but also independence.”

“As we look towards more harmonization and convergence, it gets that conversation going. So we can land somewhere in the middle or one side or the other, but at least we're all in agreement as to what we're talking about in the approaches.”

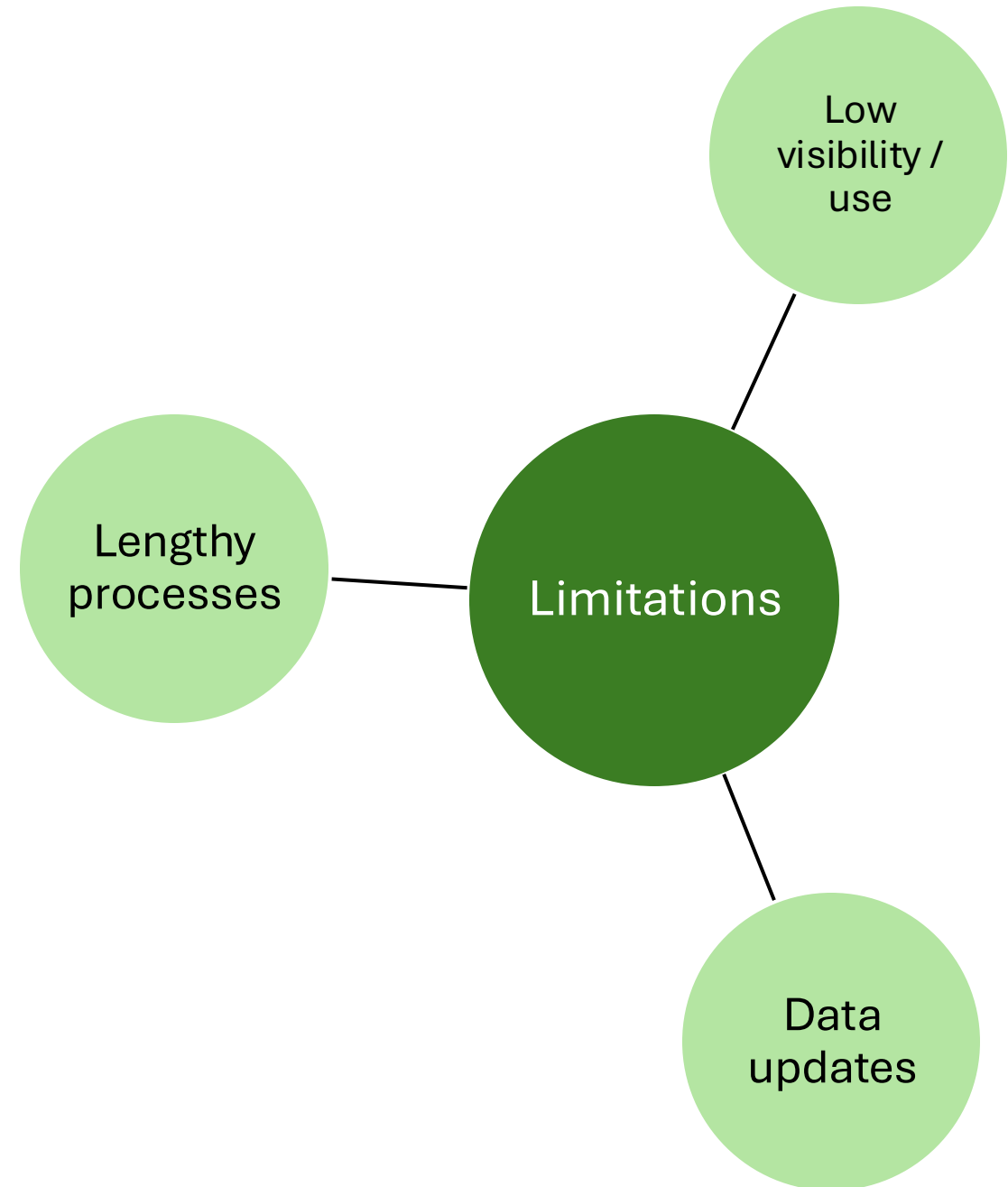
“I always encourage my students to check these documents before starting a study. I think it's a really important road map, let's say, to organize pharmacoepi studies.”

Results – *Tools*

“There is some resistance, I would say, particularly from sponsors, because they may see this Seal application first as an additional burden in terms of all the paperwork.”

“ENCePP will do a great job with all these documents, but I'm afraid that very few people follow these documents - even from ENCePP, and even less outside ENCePP.”

“Not a great success in the sense that, of course, you can find the companies, but with the data description, in the end, the real means of getting data access is often hard.”



Results – *Future*

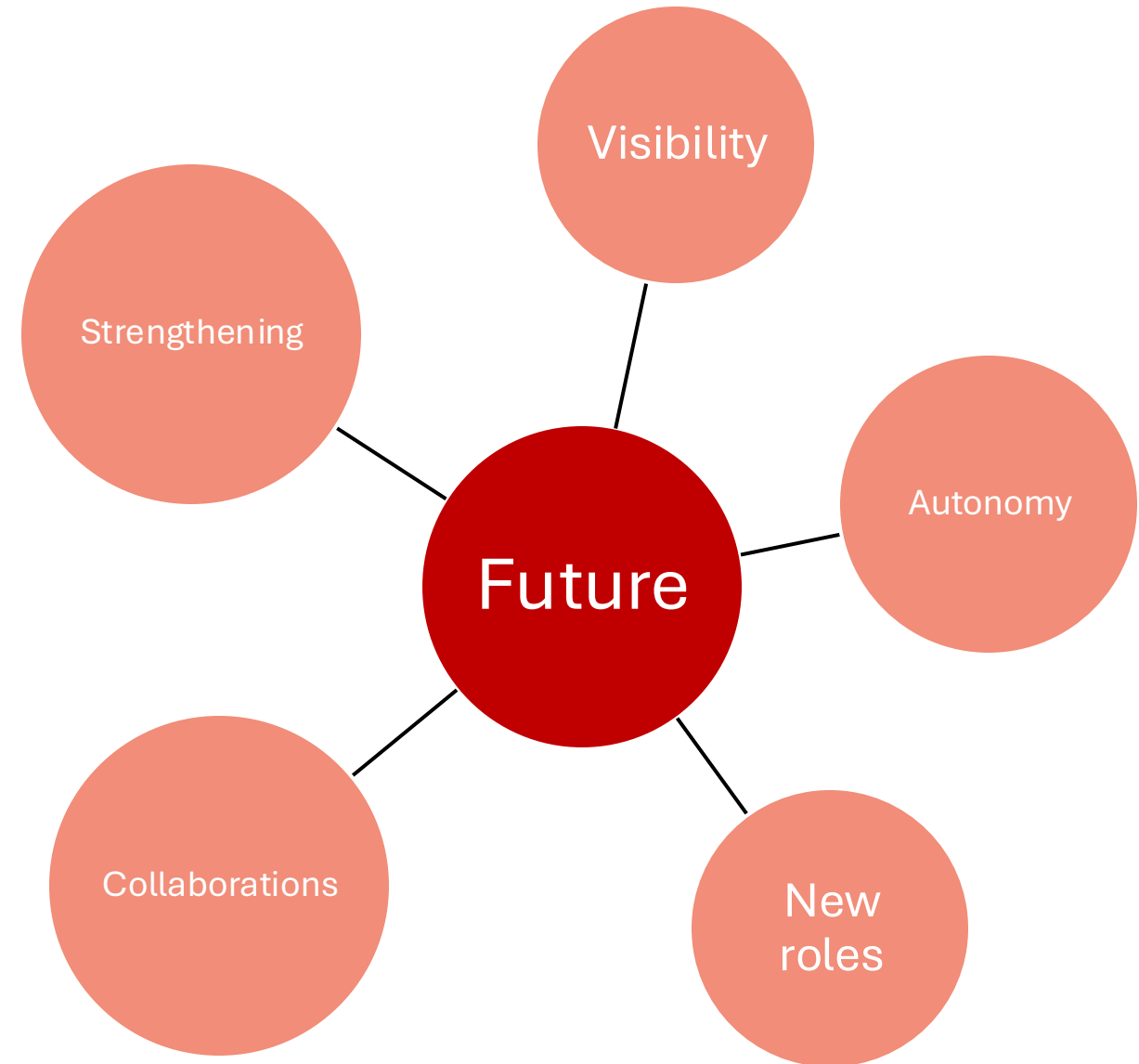
“I think ENCePP should just go on as they are doing and try to catch up with what was lost during during the pandemic.”

“What would be helpful is like to have something like white papers or recommendations.”

“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.”

“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.”

“So, what is Eu2P now being moved to ENCePP and having all academic centers attend collaborating in a sort of online masters or pharmacoepi courses. I think that ENCePP as a network has the capacity to merge all those skills and produce a very good learning tool.”



What's next?

- Continue analyzing results from interviews
- Survey on ENCePP tools
- Present at ENCePP Plenary in November
- Final report early December