EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Survey of ENCePP Centres

Results of survey on registering studies and the ENCePP Study Seal

ENCePP Plenary meeting, 25 November 2014

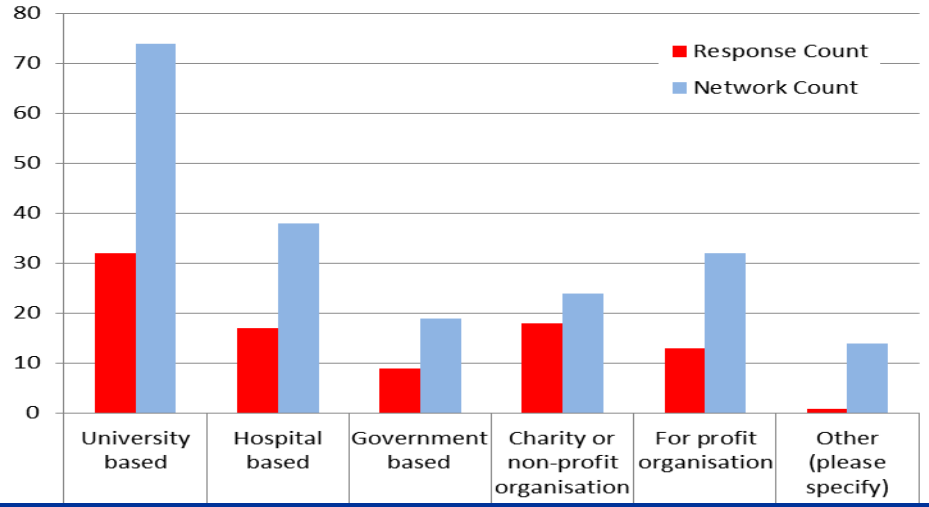
Presented by: Laura Yates
Chair of ENCePP Working Group Independence and Transparency

Survey details

- Title: *'Survey of ENCePP Centres on registration of studies in the ENCePP E-Register and uptake of the ENCePP Seal'*
- Purpose: to better understand how the E-Register (EU PAS Register) and the concept of the ENCePP Study Seal could be promoted in the future
- Survey dates: 29 April to 6 June 2014
- Sent to over 280 individuals registered in the ENCePP database of research resources (159 partner centres and networks)
- Response rate
  - At individual level: 71/280 (25%) (but some only partial responses)
  - At centre/network level: 62/159 (39%)

Category of ENCePP Centres which responded

Which of the following categories is your centre (multiple answers possible)?				
Answer Options	**Response Percent**	**Response Count**	**Network Percent**	**Network Count**
University based	47.1%	32	37%	74
Hospital based	25.0%	17	19%	38
Government based	13.2%	9	9%	19
Charity or non-profit organisation	26.5%	18	12%	24
For profit organisation	19.1%	13	16%	32
Other (please specify)		1	7%	14
answered question		68		
skipped question		3		

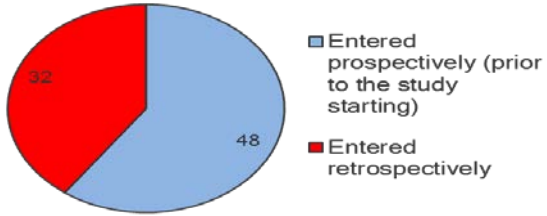


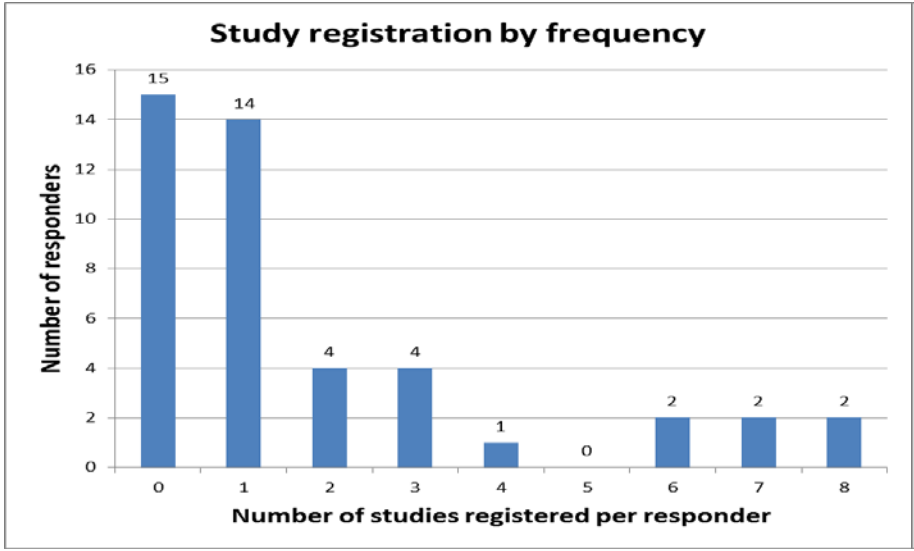
Number of PhEpi or PhV studies Centres had started in the past 4 years

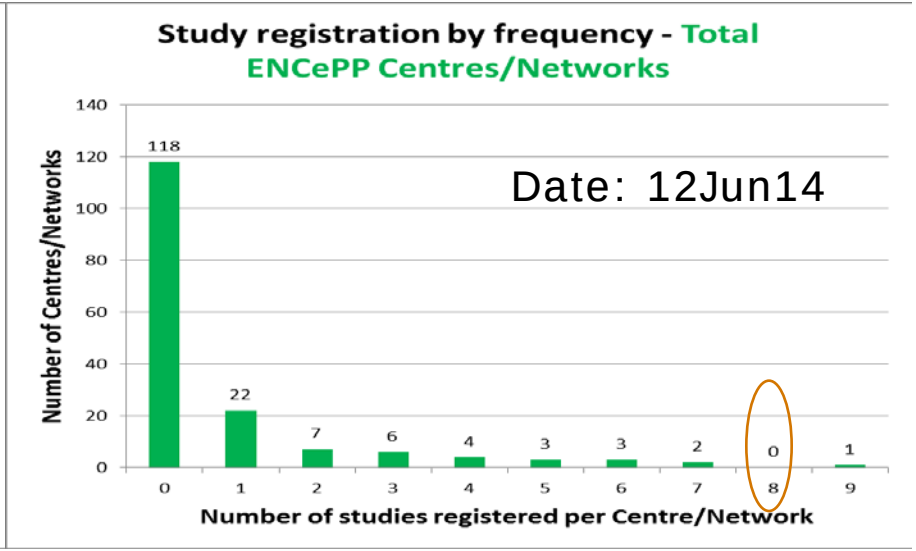
- Overall count: ~1,500 studies
- For how many of these studies were you the primary (lead) investigator or your centre the lead: ~410
- How many of these have been entered in the E-Register: 80

How many of these studies have been entered in the E-Register (n=80)?

How many of these studies have been entered on the ENCePP E-Register of Studies?		
Answer Options	**Response Total**	**Response Count**
Entered prospectively (prior to the study starting)	48	39
Entered retrospectively	32	39
	answered question	44
	skipped question	27



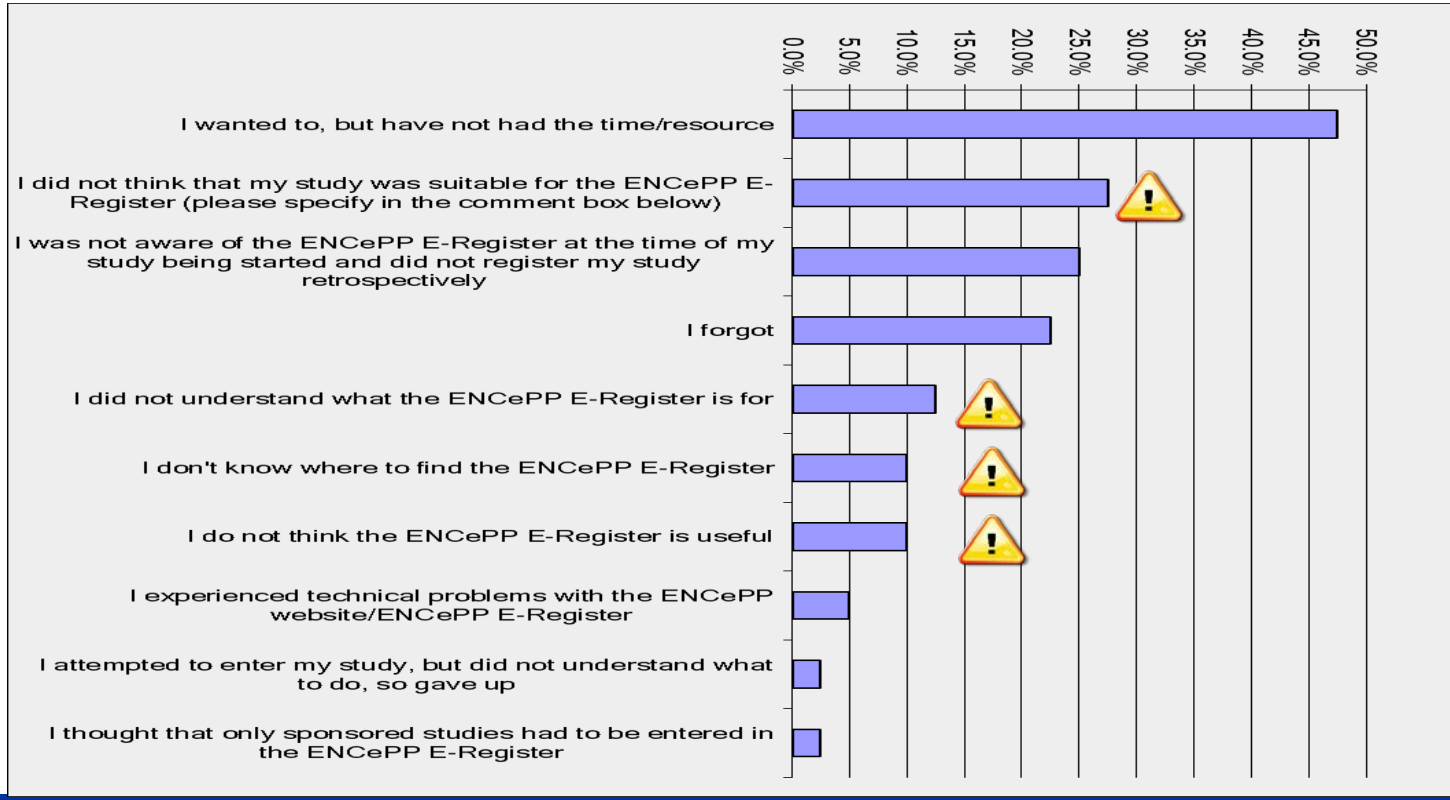




Reasons for studies NOT being entered in the E-Register (multiple answers possible):

answered question: 40

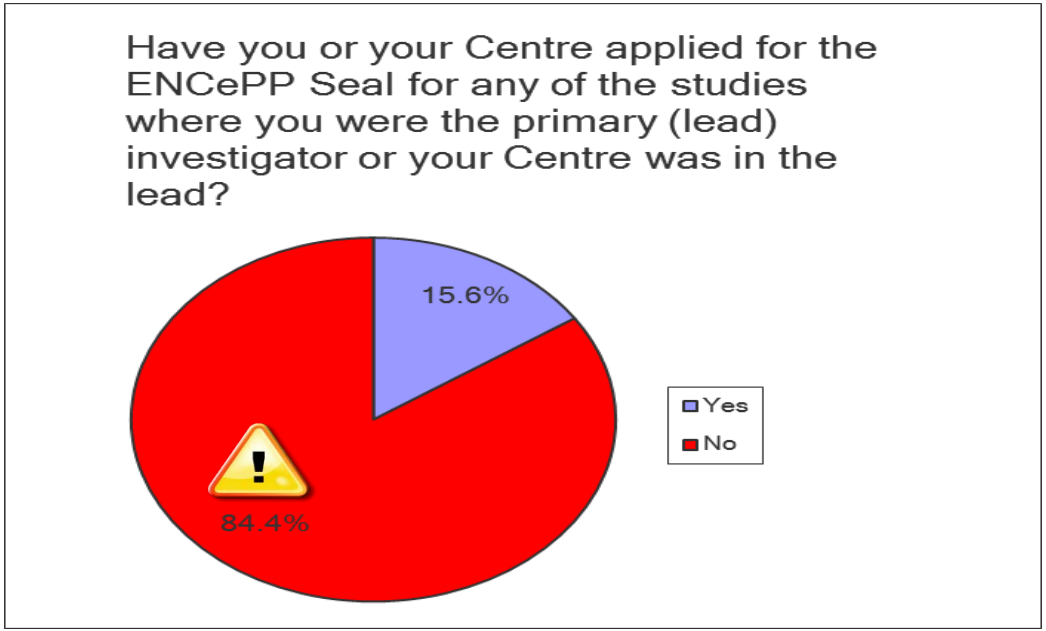
skipped question: 31



Comments/feedback on experience with the E-Register

- Lack of time/resources to register studies;
- Study sponsor/funder decision whether to register study or not;
- Unclear as to suitability of the study for registration;
- Translation of documentation/protocols into English;
- Many sponsors prefer to enter non-EU studies in clinicaltrials.gov or sponsor specific websites;
- Did not know studies could be registered retrospectively;
- Did not know that the ENCePP register exist;

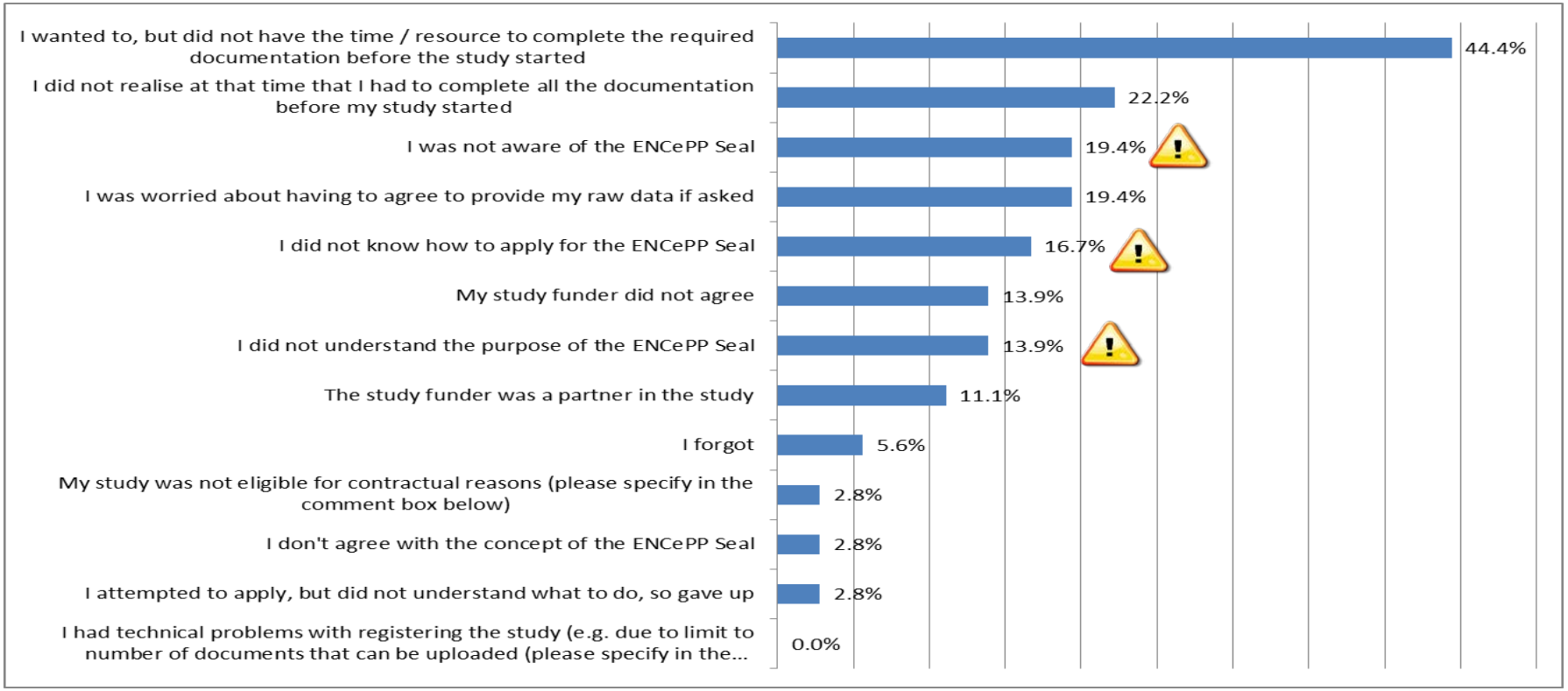
Seal applications for any of the studies where you or your Centre was PLI



answered question: 45

skipped question: 26

Reasons for NOT applying for the Seal



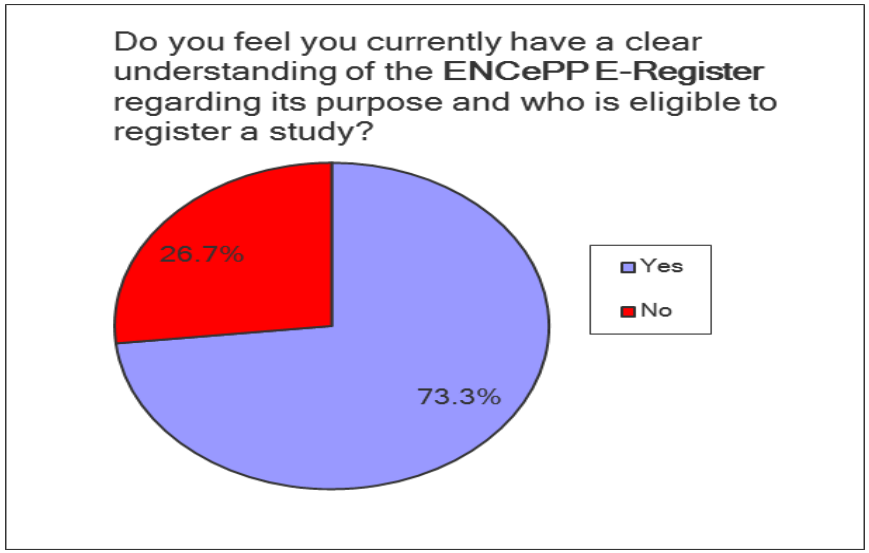
Feedback on experience with the Seal

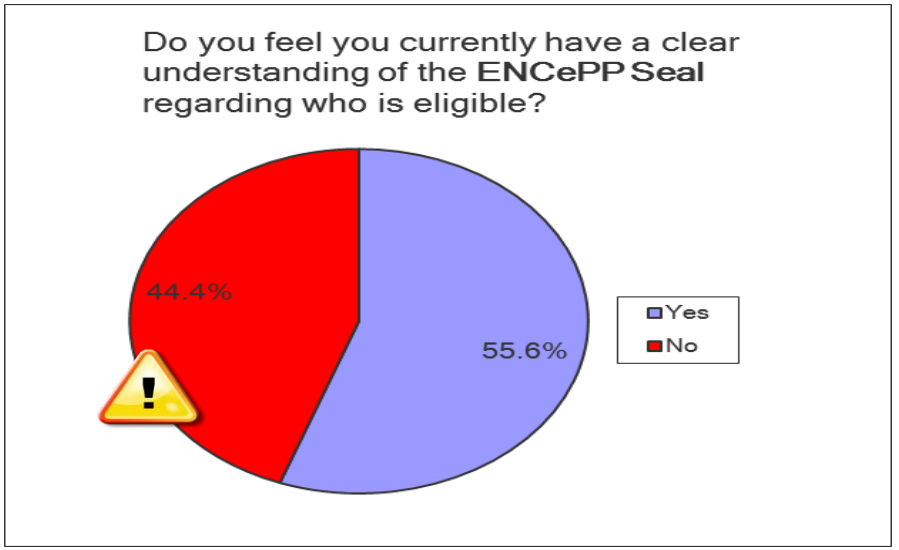
- I don't see its usefulness as it is not a requirement for any research activity;
- I do not see the added value of this seal; it seems to me more bureaucracy;
- I could not clarify if I had the right to provide raw data;
- We are solely doing sponsored studies and the study seal was not addressed/discussed with our clients. But reading all these questions, I get the impression that the definition of the study lead/lead primary investigator in sponsored studies is not clear to me. From a contracting perspective the main responsibility is with the scientific person at the sponsor side who also signs the protocol. I am sure that it is not only us that are not clear.
- Should become standard for all new studies;

Feedback on experience with the Seal (cont.)

- A large proportion of our studies have been conducted within the Statistics Denmark system that does not allow inspection of data from third parties;
- In general we are very short in time to do it prospectively;
- The seal does not seem appropriate for non-commercial studies and we rarely do commercial studies;
- Also, some research partners did not agree with some of the CoC requirements. Sponsors are still unclear about the benefits of the Seal;
- We work often in multicentre studies. It is difficult to reach agreement at the beginning of the study on the ENCePP seal;

Understanding of the purpose of the ENCePP E-Register and who is eligible?





Have you read the information on the ENCePP website?

Have you read the information on the ENCePP website?		
Answer Options	**Response Percent**	**Response Count**
Yes	66.7%	14
No	33.3%	7
answered question		21
skipped question		50

Feedback on how helpful the ENCePP website is:

- The webpage is helpful in terms of the register. However, the ENCePP concept is still confusing for us.
- Medium.
- Generally very helpful.
- Very helpful.
- The guidance is very helpful. If you are working in a profit organisation (a CRO) we use sometime different terminology. But I understand that we may not be the target audience.
- I have not noticed that there were changes & updates - the website was earlier much less informative.
- Helpful since we looked into the homepage and found a lot of useful information.
- Not very.

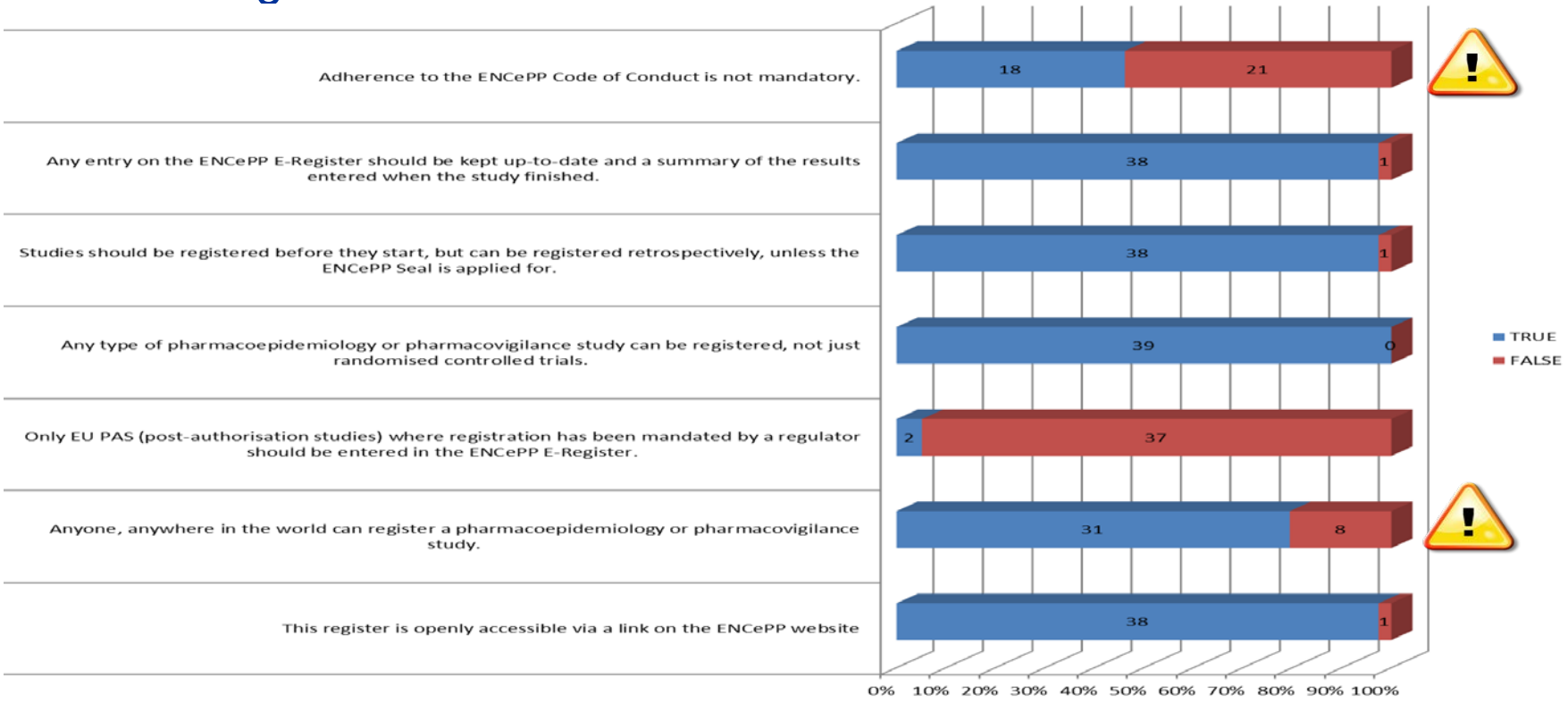
Aspects of the E-Register and/or Seal which were NOT understood

- It's not a problem of understanding technical aspects but of understanding its usefulness
- The ENCePP Seal - it is not clear what additional benefits to be gained from this (other than you have the seal of approval from ENCePP). What has put me off this is the procedures and time involved in applying when analyses are conducted on an on-going basis and this would provide an additional barrier to complete on time.
- We understand the ENCePP Register and ENCePP Seal. It may lack on the implementation into internal processes and SOPs. So far we only register studies that should have been registered with the EU PAS register.
- For the studies that are PASS or PAES: everything is clear. For the other ones that are not required mandatory to be registered, I would like to convince the client to register them however I do not clearly know what are the obligations once the studies are registered.
- Benefits of ENCePP Seal versus simple registration.

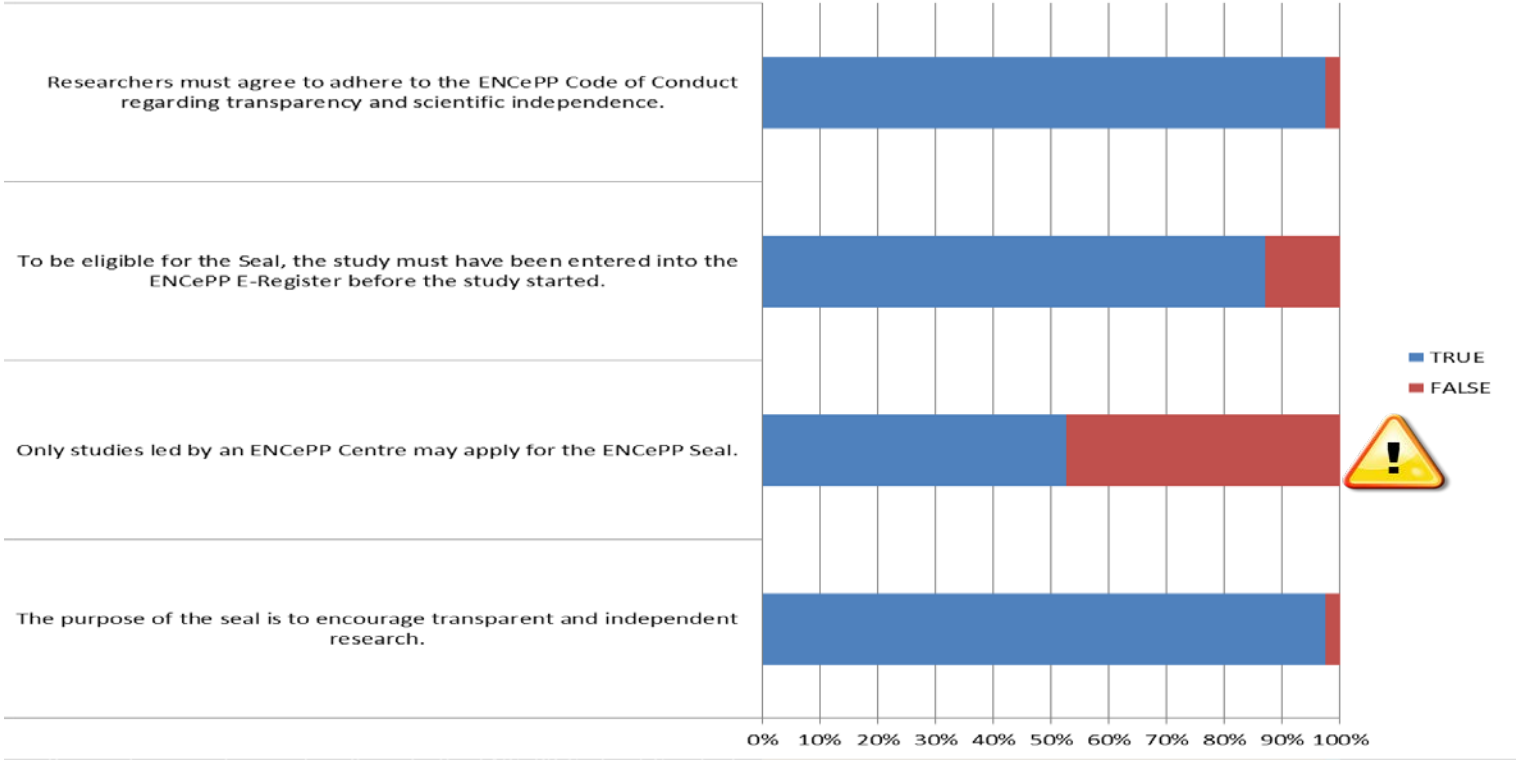
Suggestions how information about the E-Register and/or Seal could be improved

- I don't think the information given is a problem, it's more a question of its usefulness from my point of view;
- The problem is finding the time to do all this;
- Making the process as streamlined as possible so it is not seen as a barrier to implement, but rather an essential part of any pharmacoepidemiological analysis;
- A standard slide presentation (.ppt) could be helpful for educating our clients;
- The ENCePP Steering Group could read each study purpose and decide if the study could apply to the ENCePP Seal/ENCePP E-Register;
- Need support to become involved;
- Newsletters via e-mail;
- To better explain the advantages of the ENCePP Seal and reassurance about the potential constraints;

Please answer TRUE or FALSE to the following in relation to the ENCePP E-Register of Studies.

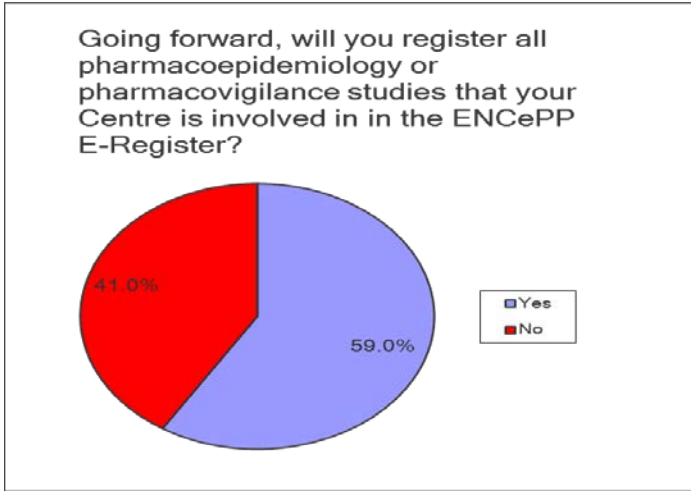


Please answer TRUE or FALSE to the following in relation to the ENCePP Seal



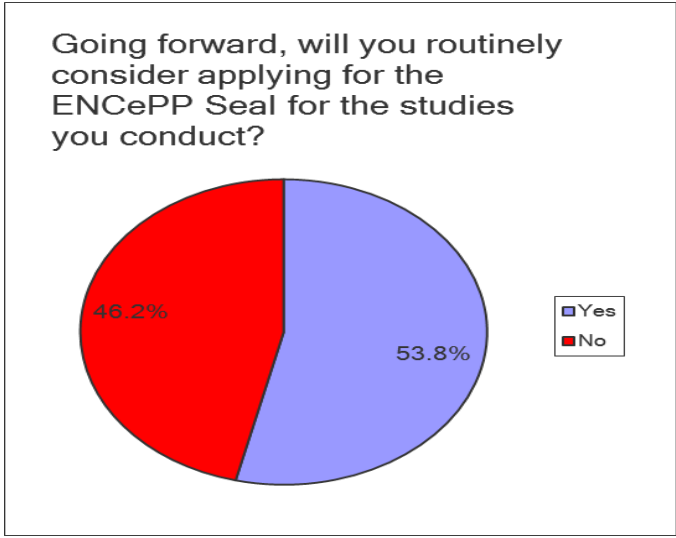
Going forward considering the E-Register

- We are currently in the process of retrospectively entering our studies in the E-Register;
- Studies, purely scientific and not in collaboration with industry, are too complex as data sources are added constantly.
- Too time consuming. We will do only if demanded by industry partners;
- The decision shall be made by the funder. We always encourage them to register;
- Maybe, if we realize the importance of the E-Register;
- Some studies are only used for education purpose;
- This will be a decision of the centre responsible;
- I plan to do so but need resources;
- Registration is lot of work for not easily identifiable benefit;
- We can only commit to compliance with CoC regarding transparency and scientific independence if:
    - we are the Principal Investigators
    - the study is under SCREN (Spanish Clinical Research Network) platform



Going forward considering the Seal

- Too much administration kills research though I can see the point for having a seal;
- Not until we fully understand its meaning and the benefits;
- We will evaluate the application for each future study;
- Maybe, if we realize the importance of the ENCePP E-Seal;
- We are sometimes not able to make study documents publicly available;
- Although we would like to, applying for the ENCePP Seal is time and resource consuming.
- It can not be done for studies in statistics in Denmark;
- Maybe for some studies, but routinely I do not know;
- It depends on the delay the committee takes to answer;
- Because it adds little value to the study and sponsors do not feel obliged to fully adhere to the CoC;
- Not unless all research partners and sponsor do support;
- Regardless of CoC independent publication is a requirement in our contracts.
- Balance between usefulness and workload to apply is not favourable;



Key issues identified

E-Register	Seal
• Awareness/knowledge/understanding of concepts and website contents	
• Time/resource constraints for entering/maintaining study records	
• Added value/benefits	• Added value/benefits for sponsors
• Web location and how to register	• Timely provision of Seal docs
• Preference: clinicaltrials.gov	• Translation issues
	• Doubts on access to raw data

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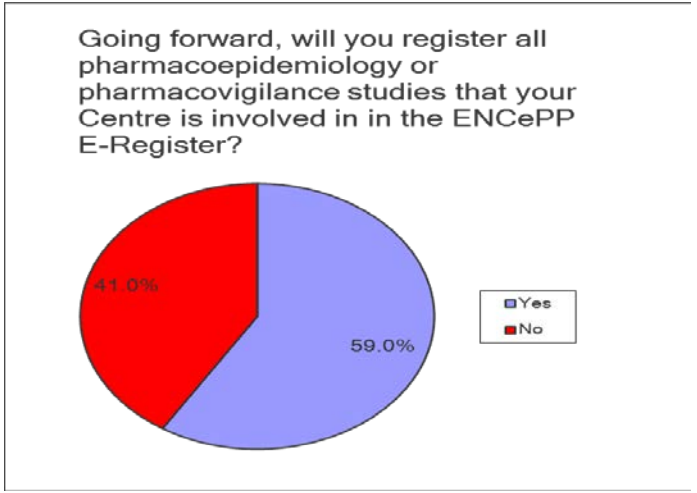

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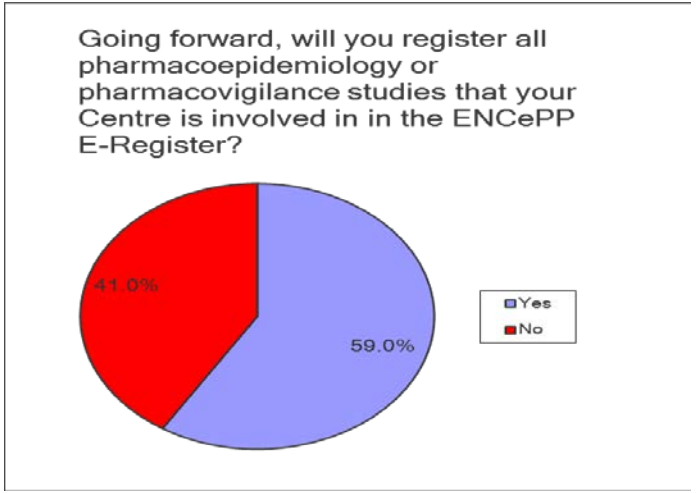

WP: Promote the ENCePP guiding principles of Scientific Independence and Transparency

- Revision of Q&A to address issues raised by survey e.g.
  - → ENCePP Seal is NOT a quality hallmark
  - → anyone conducting PhEpi or PhV research for 3rd parties can request an ENCePP seal
- Liaison with Journal Editors (either through workshop or letter) to promote uptake of the Code following publication of revision 3 (to be aligned with ENCePP communication plan)
- Concept paper on incentives for ENCePP network (e.g. promotion of Seal studies via newsletter, reimbursement of ENCePP plenary attendance only for centres publishing research in the EU PAS Register)
- Dissemination of the Code through existing research infrastructure

WP: Assess the need for supplemental tools

- Assessment of the need to supplement the Code with additional tools to support good governance e.g. joint PASS, joint registries, other partnerships.
    - Concept paper on research funding route for industry with focus on pregnancy
    - Paper on potential governance models taking account of the survey of ENCePP centres and of other developments (e.g. ADVANCE)
- Technical upgrade of E-Register (study entry)
- Disentangle E-Register and EU PAS register at entry point;

WP: Review of the ENCePP Seal concept

- Concept paper to open the ‘Seal’ to non-ENCePP Centre studies and beyond EU
- Refocus the “Seal” concept on Scientific Independence and Transparency away from its current connotation of quality seal;
- Explain the importance of Independence and Transparency as key research attributes (to be informed by results from ADVANCE surveys of stakeholders and public)
- Develop investigator’s statement for verification of adherence to Seal requirements → paper submitted to SG