EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

ENCePP Feedback from Industry

Meeting of ENCePP Steering Group with Pharmaceutical Industry

22 May 2013

Presented by: Kevin Blake

Background

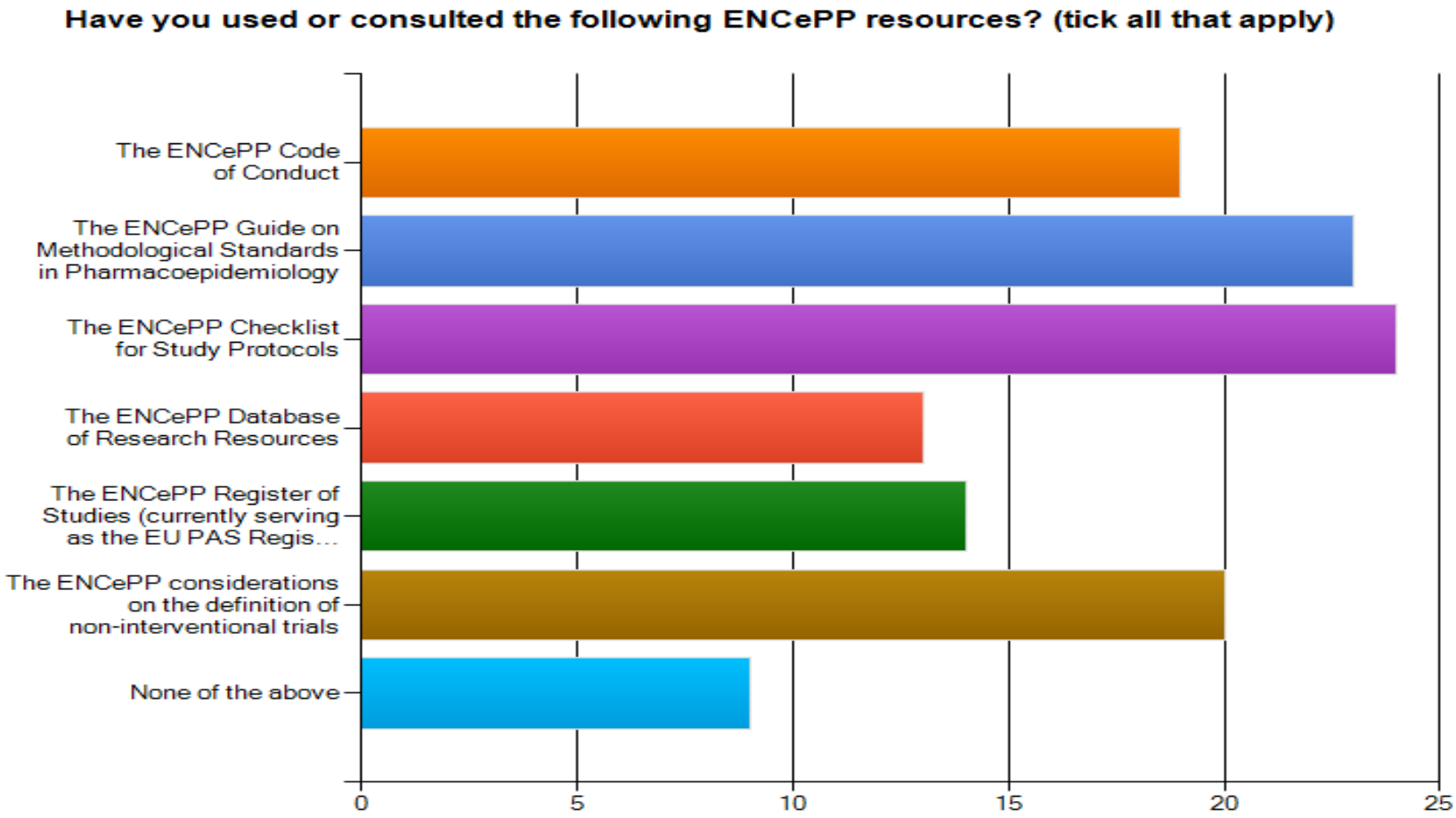
- To receive feedback from pharmaceutical industry colleagues to support discussions at a meeting at EMA in the first instance.
- Invitees: AESGP; EBE; EFPIA; EGA Generics; EUCOPE; EuropaBio; Europharm SMC; Vaccines Europe.
- Uptake of ENCePP Study Seal Concept may be considered as relatively slow (5/15 MAH funded as of 30/04/2013).
- Feedback to inform on closer collaboration.

Individuals who responded:

- Total: 49 [not all completed the survey]
  - 86% were closely involved in post-authorisation studies (PAS).
  - 39% organisations conducted 1 – 5 PAS per year (*33% >10; 16% 6 - 10*).
- Heard of ENCePP through:
  - 31% industry association, 29% work-colleagues, 18% member of ENCePP
- Had interacted with ENCePP Secretariat:
  - 6 (of 40 responses) – 4 of these in relation to registering a study
- Understanding of the objective of ENCePP*
  - 68% to facilitate the conduct of PAS in the EU,
  - 60% to develop PhEpi guidance,
  - 40% to foster collaboration within the network, and
  - 28% to serve a regulatory purpose.

**>1 may apply*

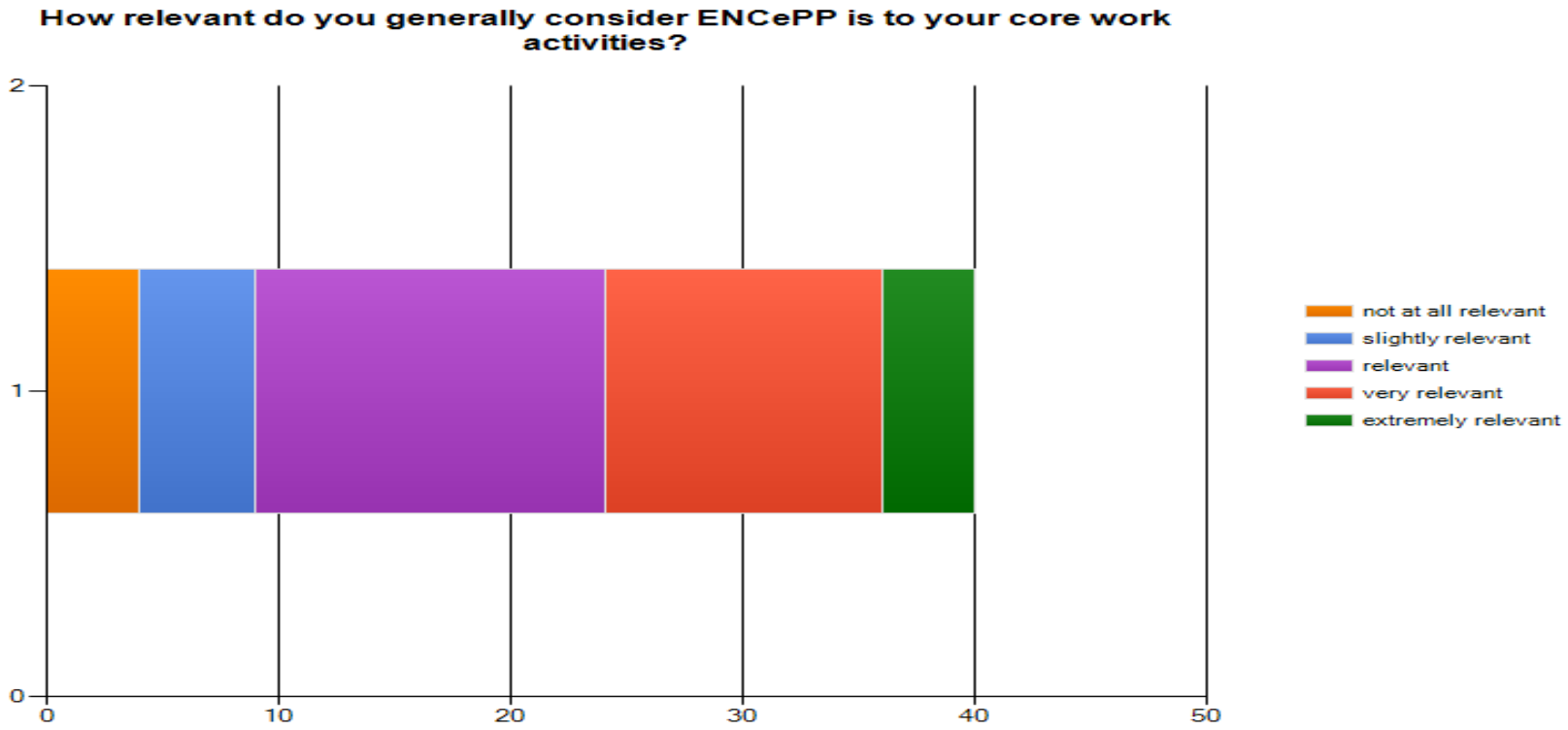
Use of ENCePP outputs



How has ENCePP helped your work

- Use of the checklists/providing guidelines/pharmacoepidemiological (external) views.
- Reinforces and adds new perspectives on best scientific methods/ practice/reminder that quality matters.
- Has supported implementation of GVP.
- It is too early to see how it has helped.
- No value added; specifically this website is not stable and fails during registration.

‘Relevance’ of ENCePP



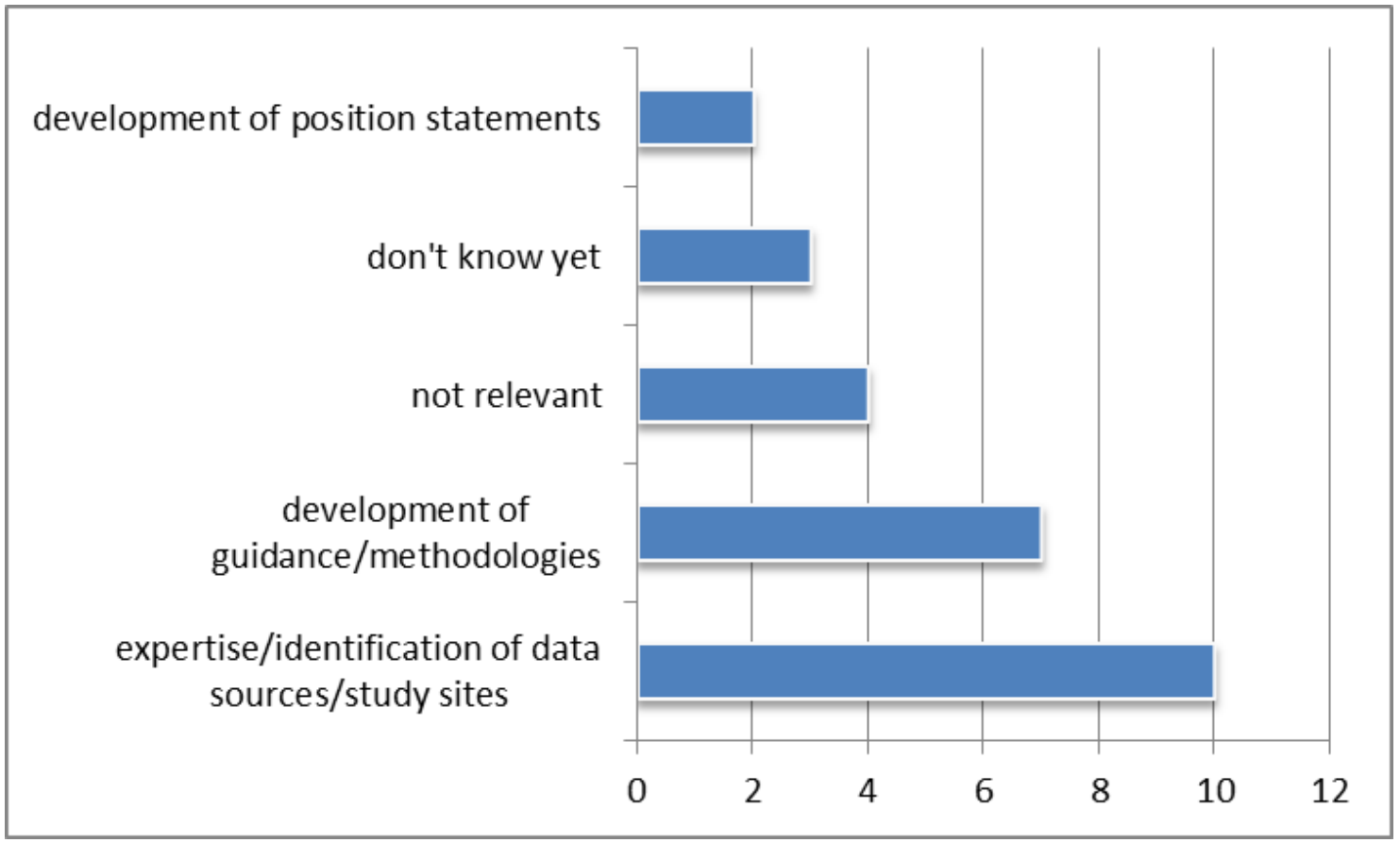
- 31 of 40 responses considered ‘relevant’ or better

ENCePP principles in PhEpi research

	not at all relevant	slightly relevant	relevant	very relevant	extremely relevant	Rating Average	Rating Count
Scientific independence to publish results	7.7% (3)	23.1% (9)	**28.2% (11)**	**28.2% (11)**	12.8% (5)	3.15	39
Transparency throughout the life-cycle of the study	7.7% (3)	7.7% (3)	**38.5% (15)**	23.1% (9)	23.1% (9)	3.46	39
Promoting best methodological practices	5.0% (2)	10.0% (4)	**30.0% (12)**	27.5% (11)	27.5% (11)	3.63	40
					answered question		**40**

- Scientific independence to publish appears as less relevant generally but also scores high on 'very relevant'

ENCePP assisting design/conduct of PAS



Barriers to applying for an ENCePP Study Seal

- ? *Any* barriers: tick-boxes 17 'no' and 15 'yes',
- Free text comments (total of 17):
  - *'Not open to industry', 'limits interaction with industry e.g. PPP'*
  - *'Collaboration hindered by ENCePP Code of Conduct': 'does not allow for commitment owners oversight'; 'the burden linked to the seal request, and the impression to have then a kind of lack of control'; 'limited added value'; 'seal not linked to quality'; 'seal should only be given to non-commercial sites;' 'difficulty in executing operationally including meeting deadlines agreed upon by MAH with regulators', 'other centres in Europe may be more scientifically appropriate'; 'not able to adequately address the need for global post approval commitments with EU, US and other sites'*
  - '*Additional training and information is required*'

Benefit to 'seal' for industry studies

- *Any* benefit: tick-boxes 20 'yes', 12 'no'
- Free text comments (total of 19):
  - *''Will reinforce scientific expertise within companies and facilitate agreement on protocol with PRAC'; 'ENCePP approval of a study ensures robust scientific and methodological approaches to PAS cross-stakeholders thus facilitates interpretation and communication of the study results'; 'Consistent with the ISPE Good PE/PV Study Standards and our company's standards for disclosure and transparency of research related to our products, including observational research'; 'Credibility with regulators'.*
  - *'No real difference between pharma-sponsored and pharma-undertaken'; 'continued use of ENCePP Study Seal should be open to pharma'.*
  - *'There will be benefits, but the barriers weigh more'.*
  - *'This would be a major breakthrough, under appropriate conditions (of transparency and scientific standards)'*
  - *'More information is required'.*

Ways to improve ENCePP

- *Any* suggestions: tick-boxes 14 'yes', 16 'no'
- Free text comments (total of 15):
  - *'Some flexibility for pharmaceutical industry-based scientists to participate as collaborators throughout the study process leading to higher scientific endeavour'; 'trust scientific integrity of epidemiology researchers in industry' '.*
  - *'Maintaining open network'; 'transparency in requirements re. partnership & access to grants' 'Extend data sources – include orphan diseases'.*
  - *'Extend scope – effectiveness research, HTA'.*
  - *'Evaluate individual centres resource capability to perform multiple studies'; 'expectation of timely delivery'.*
  - *'Use clinicaltrials.gov or EudraCT to register non-interventional trials'.*
  - *'Improve interface'.*

Key points for discussion

- Good response rate – thank you!
- Generally network and outputs in particular methodological guidances and positions well-regarded.
- Code of Conduct appears to be a particular sticking-point: *purpose, execution, role of MAH, barrier to collaboration*.
- Benefit to a seal along the lines of an ENCePP Study Seal.
- Need for further approaches to collaboration with industry researchers, enhanced transparency, extension beyond safety studies and some operational (IT) issues identified.