



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

Report from the Steering Group

ENCePP Plenary Meeting, 12 November 2013



Presented by: Susana Perez-Gutthann

An agency of the European Union





Key points

- Looking back: Achievements 2012-2013
- Revised mandates (SG and Plenary)
- ENCePP E-Register/EU PAS Register
- Next ENCePP plenary



Key achievements 2012 -2013

Updated Standards and Guidances

- ✓ Revisions 1 and 2 of Guide on Methodological Standards. Reference document in GVP on PASS and new sections on vaccines and comparative effectiveness
- ✓ ENCePP Checklist for Study Protocols also revised, cited in GVP on PASS and recommended for inclusion as an annex to the protocol for PASS



Key achievements 2012 - 2013

New working groups

- ✓ Establishment of HTA Working Group
- ✓ Establishment of Working Group on Data Integration
- ✓ Establishment of Pregnancy Special Interest Group
- ✓ Establishment of joint Enpr-EMA – ENCePP Working Group on paediatric pharmacovigilance



Key achievements 2012 - 2013

Increasing the reach of ENCePP outputs

- ✓ ENCePP E-Register serves as EU PAS Register referred to in GVP with increase in numbers of studies registered
- ✓ Meeting with industry representatives; survey of industry; proposal for further engagement to enhance utility of network for industry
- ✓ Publication of ENCePP survey of EU Member States' national legal requirements on data protection
- ✓ Establishment of link on [ENCePP website](#) to safety signals discussed at PRAC



Main changes - Revision of ENCePP Steering Group and Plenary mandates (full versions available online)

- Term of Steering Group increased from 2 to **3 years**
 - Candidates will no longer be able to **motivate their candidature** in person at the Plenary meeting but in writing only
-
- Working groups section updated relating to reimbursement for meetings
 - Regular (6-monthly) reports from WG Chairs to the Steering Group (**NEW**: publication of reports on website)
 - New section on Special Interest Groups



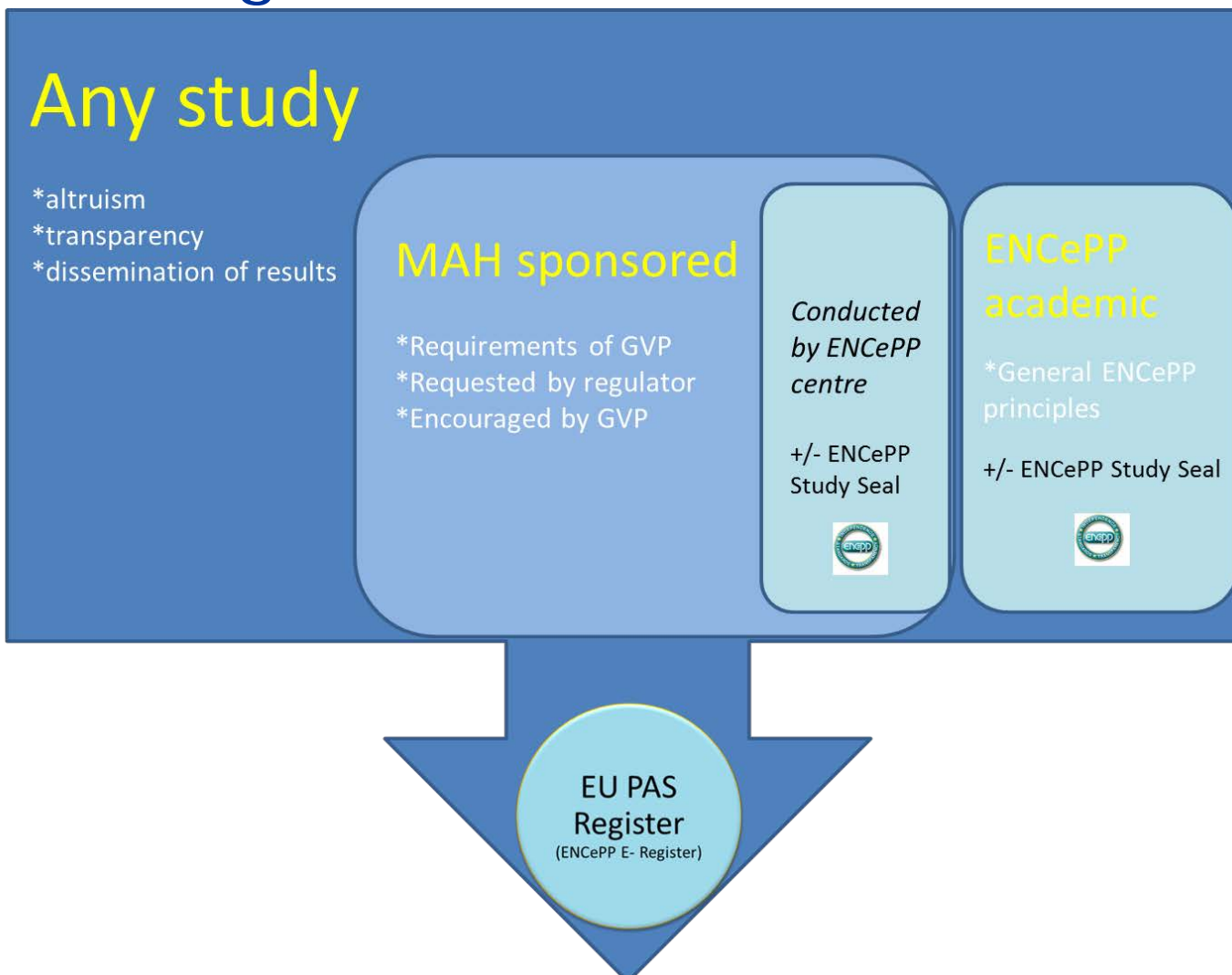
The ENCePP E-Register/EU PAS Register

A few statistics:

	06/06/2013	29/10/2013
Total no. of studies	111	165
ENCePP Seal Studies	15	20
Studies registered by ENCePP centres	52	64
Studies requested by a regulator	n/a	83



Registration of studies in the EU PAS Register / ENCePP E-Register





ENCePP Plenary meeting 2014



***2014 & foreseeable future:
Focus on working group outputs,
increased number of WG f2f meetings →
1 annual Plenary meeting only
(date tbc)***

Use of webinars under consideration