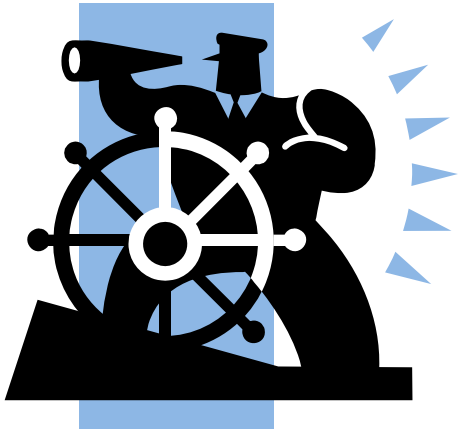
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

Report from the Steering Group: Reflections

Presented by: Ingemar Persson, ENCePP Steering Group

London, 23 November 2011



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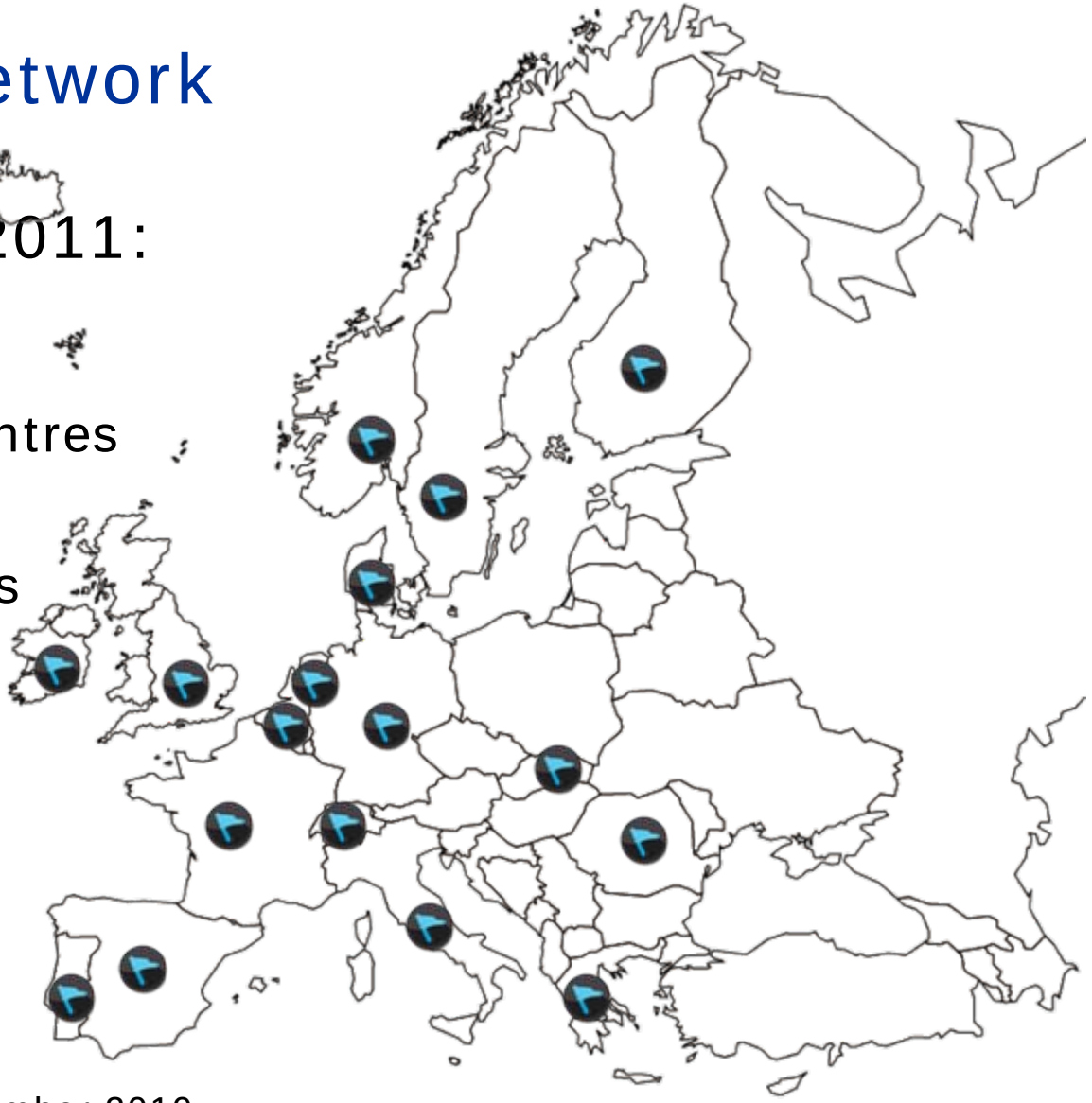
Jim Slattery	EMA – Statistical Advisor

Chronology

11 Dec 2009	• SG Election & start of 2-year mandate
2010	• No. of meetings: 7 (2 face-to-face)
	• 1st DIA ENCePP Info Day
2011	• No. of meetings: 6 (2 face-to-face)
	• 1st Journal Editors Workshop
	• 2nd DIA ENCePP Info Day
23 Nov 2011	• End of mandate

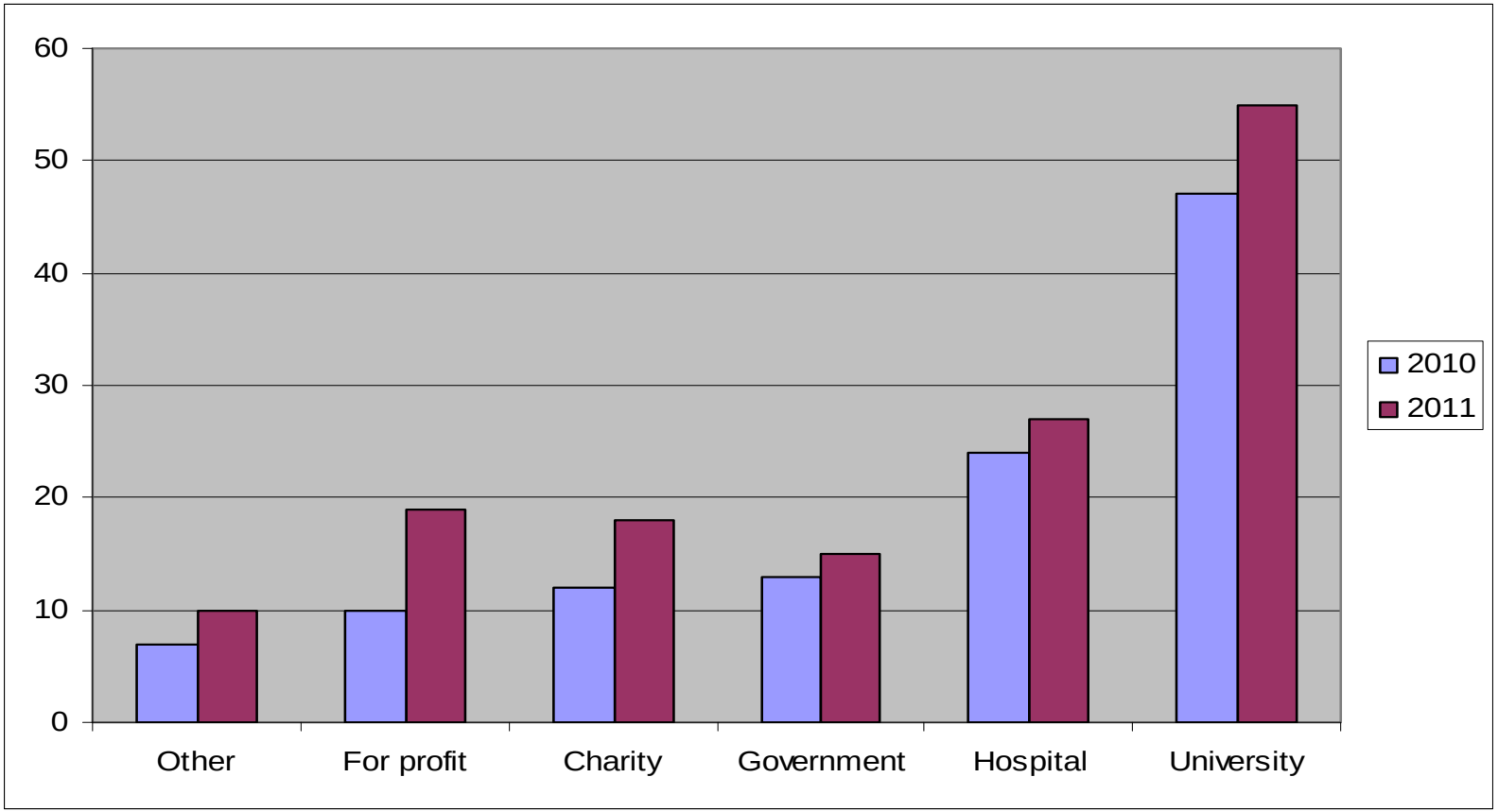
Growth of the network

- As of 18 October 2011:
  - 96 (*75*) research centres
  - 13 (*11*) networks
  - 18 (*11*) data sources

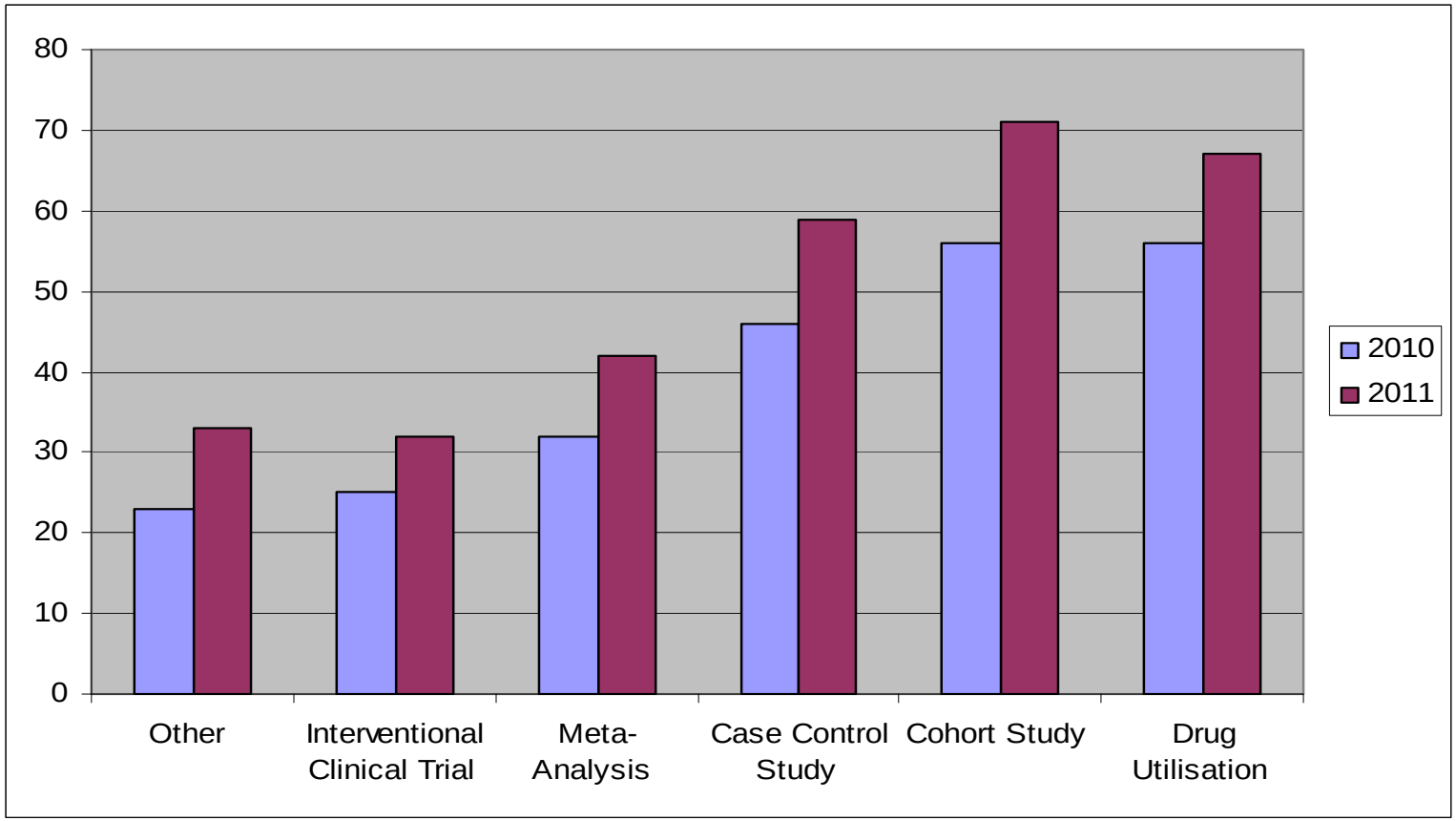


- from across EU
- numbers in *italics* from November 2010

Classification of centres



Experience with study designs



Increase in capacity across study design

Work Plans: shift in focus

- Adoption ENCePP Work Plans 2010 and 2011-2012 and publication on ENCePP website

- 2010: to have in place by the end of the year a high-quality, *self-sustainable network* in the field of independent post-authorisation monitoring of medicinal products in the EU

- 2011-2012: Building on the initial phase of establishment, the priority is to *consolidate ENCePP* as an important and internationally renowned resource in the field of pharmacovigilance and pharmacoepidemiology that delivers for health protection and promotion.

Key Milestones in terms of the network itself

- Establishment of ENCePP Steering Group (SG) in January 2010.
- Launch of ENCePP Database of Research Resources (centres and networks) on 31 January 2010 (http://www.encepp.eu/encepp/resourcesDatabase.jsp)
- Launch of Database of data sources in April 2010 (http://www.encepp.eu/encepp/resourcesDatabase.jsp)
- Launch of Members Forum on ENCePP Website in April 2010 (http://www.encepp.eu/jforum/forums/list.page)

Major outputs: Standards

- Adoption of *Checklist* of Methodological Standards for ENCePP Study Protocols March 2010
  - Adoption of Revision1: ENCePP Checklist for Study Protocols Jun 2010 (renamed to reflect broader update outside ENCePP studies e.g. also in risk management planning, regulatory agencies assessment of protocols)

- Adoption of ENCePP *Guide* on Methodological Standards in Pharmacoepidemiology (following public consultation) May 2011

Major outputs: Independence

- Adoption of ENCePP *Code* of Conduct (May 2010)
  - Adoption of Revisions 1 (September 2010) and 2 of Code (October 2011)

- Development and launch of *ENCePP study concept*, including the “ENCePP seal” June 2010 (development of a communication package consisting of leaflet, press release, publication on EMA public website)

- Adoption by the SG of *‘access to data’ policy* and implementing rules in relation to ENCePP study data (September 2010) – now included in Revision 2

Major outputs: Transparency

• Creation of a fully functional *database of post-authorisation studies*. The ENCePP e-register of studies was launched to the public during the ENCePP Plenary meeting on 18 November 2010 (http://www.encepp.eu/encepp/studiesDatabase.jsp).

• Liaison with EUNetHA and EnprEMA initiated to potentially broaden the scope of the network to further cover *health outcome research and paediatric research*.

• Exploration of the merits of developing an *accreditation system* and its features has started.

Increasing visibility of the network

• *Workshop with Medical Journals Editors* June 2011 on the aims of ENCePP as regards independency and transparency in research and to increase the visibility of the network to the broader scientific community.

- Reassurance given that posting results will not impact negatively in terms of subsequent publication

• Pharmacoepidemiology and Drug Safety (Nov 2011): *author guidelines* modified

- to encourage authors to release results of public health importance
- to recommend posting protocols in the ENCePP register

Promotion of ENCePP

- Promotion of ENCePP at a number of *international conferences and symposia.*
- Organisation of the two "*ENCePP Information days*" in collaboration with DIA November 2010 and November 2011 targeted at pharmaceutical industry staff.
- Continued contact with international initiatives with complementary objectives including *FDA and Health Canada* activities to exchange information and consider complementarity

Interaction with Third parties

• Adoption of ENCePP Linking Policy re. placing announcements on the *ENCePP website* October 2011

• *Guidance* on Third Party announcements finalised November 2011: allows for industry to post announcements including, for example, requests for collaboration in the conduct of studies in the ENCePP Partners Forum

- Presented to DIA at 2nd Infoday and to PhVWP Nov 2011
- Well received
- For further announcement/dissemination

Other achievements

- ENCePP response to public consultation on *personal data protection in the EU* (SG sponsors: M. Sturkenboom & C. de Vries)
  - Follow-up visit to DG Justice
- ENCePP response to the public consultation on revision of the *Clinical Trials Directive*
- Adoption of strategy for *impact evaluation* of ENCePP
- ENCePP partners *survey*

ENCePP Studies

4 Studies found

Status	Official Title	Lead Investigator	Last Updated
Ongoing	International Active Surveillance study - Folate and Oral Contraceptive Utilization Study	Dr Juergen Dinger	03/01/2011
Planned	Impact of risk minimisation in patients treated with rosiglitazone-containing products	Professor Henrik Toft Sørensen	15/02/2011
Planned	International Active Surveillance Study of Women Taking Dienogest for Endometriosis: Visanne Post-approval Observational Study	Dr Juergen Dinger	03/01/2011
Planned	Long-term outcomes and adverse events of therapy with inhaled corticosteroids, long-acting beta-2-agonists and anticholinergic drugs in hospitalised patients with Chronic Obstructive Pulmonary Disease (COPD) - a cohort study based on health information systems in three Italian regions.	Dr Nera Agabiti	27/10/2010

Small numbers but early days yet and a lot has been learned

Essential ongoing deliverables

• Development of approaches to facilitate the conduct of multi-national studies in light of existing differences in *data privacy laws across the EU*, in collaboration with Working Group 3.

• Further defining the role of ENCePP as regards its *interaction with regulatory decision-making* and in light of the changes introduced by the new Pharmacovigilance legislation.

• Ensuring that the *ENCePP Studies database* feeds in, as appropriate, to any international discussions on standardisation of data fields, including WHO platform and ISO.

Personal reflection

We, especially regulators, came from *the need* to create better resources for Pharmacovigilance and Risk Management in the EU.

Now we have a network *system in place* with competence centres, data resources and rules for conduct – offered to all stakeholders to the best of collaboration and interactions.

The ENCePP system has the *potential* to meet challenges of modern pharmacovigilance and requirements of the new legislation.

It is time for ENCePP to be increasingly *recognized and used*. Its *promotion and faclitatation* will be important tasks over the next years.