EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ENCePP Code of Conduct

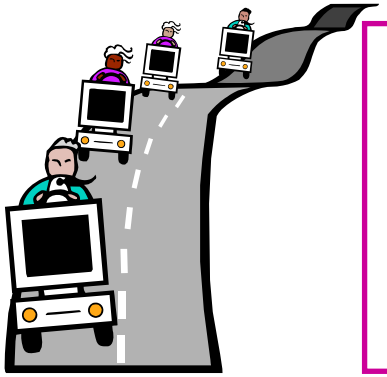
Presented by: Stefanie Prilla

ENCePP Plenary meeting, 8 June 2010

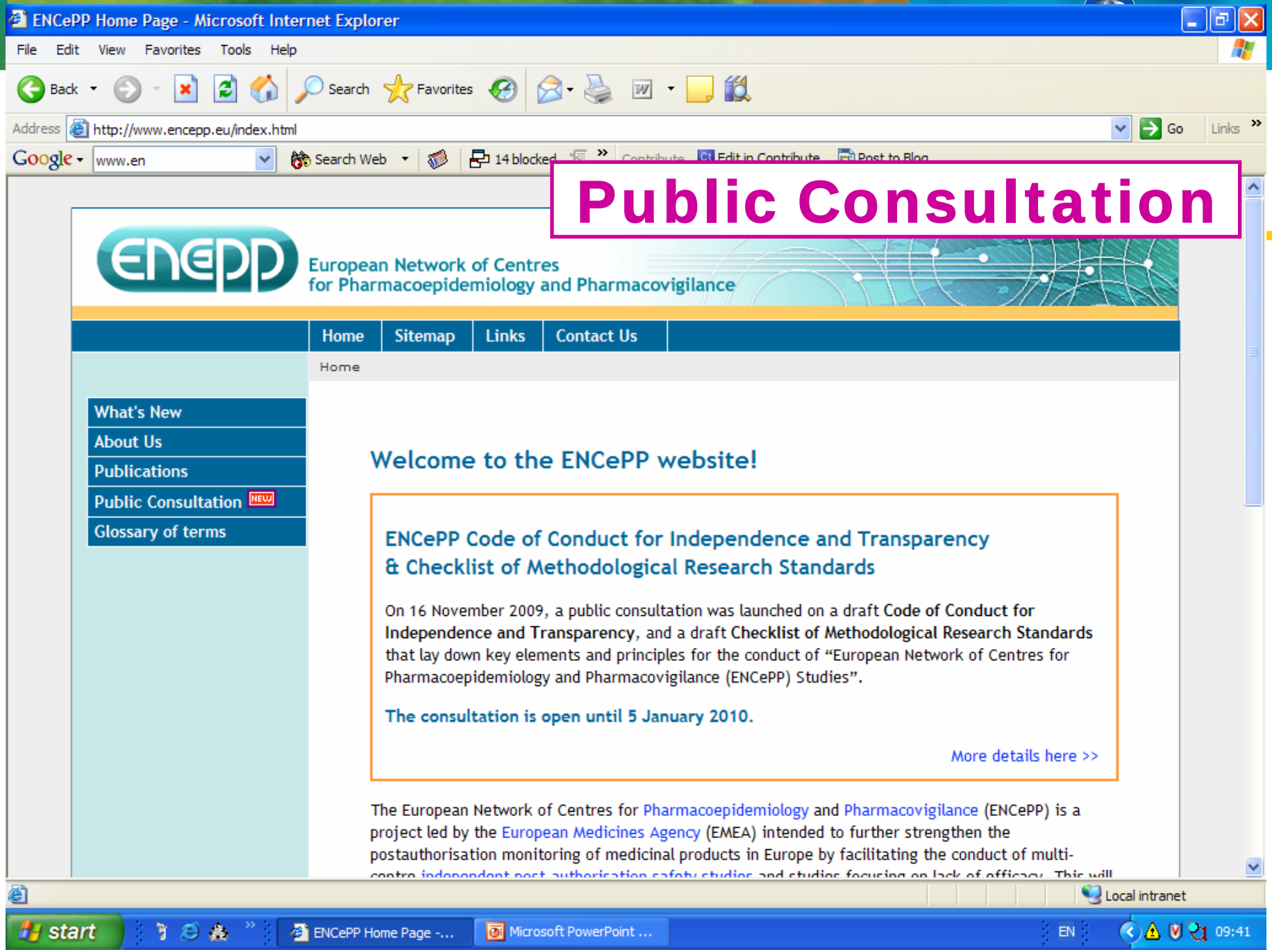
Document History - How did we get there ?

- **May 2009**: First draft prepared by Working Group *Transparency & Independence* (chair: Helen Dolk)
- **18 Sept 2009**: Core elements of the draft CoC presented to ENCePP Plenary

- **Oct 2009**: Consultation of ENCePP partnership; Adoption of revised draft by ENCIAG



- **Nov 2009 – Jan 2010**: Public Consultation
- **Jan 2010 – April 2010**: Review and implementation of comments
- **May 2010**: Adoption by Steering Group


ENCePP Home Page - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address http://www.encepp.eu/index.html
Go Links
Google www.en
Search Web 14 blocked
Edit in Contribute Post to Blog
Public Consultation
European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance
Home Sitemap Links Contact Us
Home
What's New
About Us
Publications
Public Consultation NEW
Glossary of terms
Welcome to the ENCePP website!
ENCePP Code of Conduct for Independence and Transparency
& Checklist of Methodological Research Standards
On 16 November 2009, a public consultation was launched on a draft Code of Conduct for Independence and Transparency, and a draft Checklist of Methodological Research Standards that lay down key elements and principles for the conduct of "European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Studies".
The consultation is open until 5 January 2010.
More details here >>
The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) is a project led by the European Medicines Agency (EMEA) intended to further strengthen the
Local intranet
start
ENCePP Home Page -...
Microsoft PowerPoint ...
EN
09:41

Stakeholders – who made comments ?

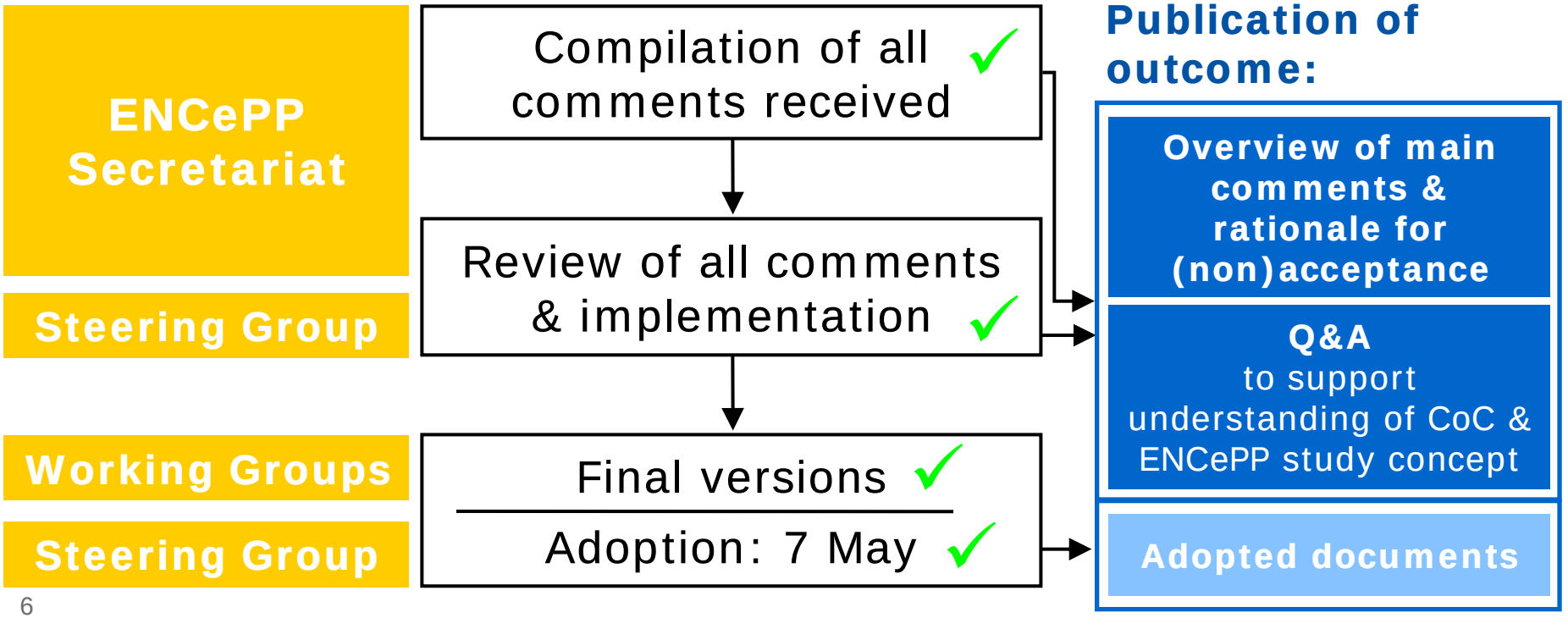
- ✓ **Regulatory Authorities** (EU and non-EU)
  - ➢ **European Medicines Agency Committees**
- ✓ **Pharmaceutical Industry**
- ✓ **Learned societies**
- ✓ **Patients**
- ✓ **Health Care Professionals**
- ✓ **ENCePP** → interested individuals in- and outside own centre

Stakeholders – who made comments ?

No.	Name of organisation or individual
1	Bayer Schering Pharma
2	European Federation of Pharmaceutical Industry and Associations (EFPIA)
3	European Parkinson's Disease Association (EPDA)
4	Fundació Institut Català de Farmacologia
5	Centre for Pharmacoepidemiology, Karolinska Institutet, Sweden
6	MHRA Pharmacoepidemiology Research Unit
7	National Institute of Statistical sciences
8	anon
9	Glaxo SmithKline (GSK)
10	Bundesverband der Pharmazeutischen Industrie e.V. (BPI)
11	International Society of Pharmacoepidemiology (ISPE)
12	Roche
13	European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
14	US Food and Drug Administration (FDA)
15	Health Search, Italian College of General Practitioners

CoC & Checklist of MRS – Public consultation

Public consultation of the CoC & the Checklist of MRS ✓



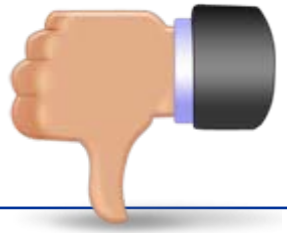
Code of Conduct

… what it is

Rules and principles as regards:

- **best practice** in the relationship between investigators and study funders, including protocol agreement and publication of results, and
- **transparency** throughout the research process,
- thereby promoting **scientific independence** of such studies.

Code of Conduct
… what it is **not**



- **"ENCePP studies"** (mandatory) ≠ OBLIGATION
- Primarily **PE and PhV studies**, with an emphasis on non-interventional Post-Authorisation Studies.
- Main focus on contract research / funded research
- No guarantee for high quality research
- No replacement of existing legislation or guidance

Code of Conduct - content

- Steps taken, adoption/revision date
- **CoC document: background, scope, ENCePP studies, provisions**
- Annex 1: Definitions
- Annex 2: Checklist for ENCePP Studies (stand-alone document)
- Annex 3: Declaration on compliance (stand-alone document)

Main issues/changes after public consultation

- Clear communication of voluntary nature of the Code and 'ENCePP studies'
- Refined scope
- Separate chapter on declaration of interest & refined provisions on (non)participation of persons with CoI
- Availability of study protocol
- Availability of study data
- Registration of studies

Review

Review either 1 year after launch or after registration of 15 ENCePP studies whichever comes earlier.

Critical areas to be actively monitored as part of the first review:

- Possible conflicts/incompatibilities:
  - Requirement to provide the study protocol before start of data collection vs. conduct of feasibility studies before actual study
  - Requirement to annex the Code (EN) to the research contract vs. possible legal requirement of the contract to be written in the local language
- Definitions: Pharmacoepidemiology, research contract, direct vs. indirect interests
- Usefulness of a model/template contract

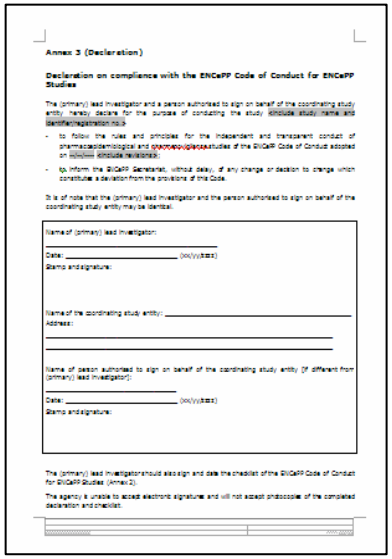
ENCePP studies

CoRe requirements

Code of Conduct

(adopted by the ENCePP Steering Group on 7 May 2010)

Declaration



- complete
- sign & stamp
- submit originals

⇨ to be uploaded on the ENCePP website / Register of Studies

Checklist