



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ENCePP Code of Conduct

Presented by: Stefanie Prilla

ENCePP Plenary meeting, 8 June 2010



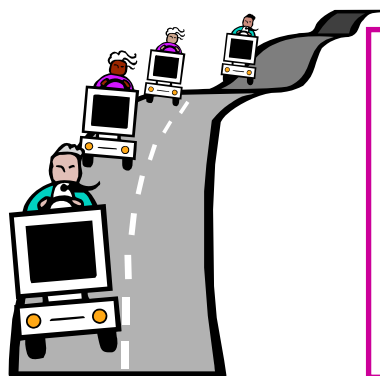
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Document History - How did we get there ?

- **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

Public Consultation



European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

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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](#) (EMA) intended to further strengthen the postauthorisation monitoring of medicinal products in Europe by facilitating the conduct of multi-centre independent post-authorisation safety studies and studies focusing on lack of efficacy. This will



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





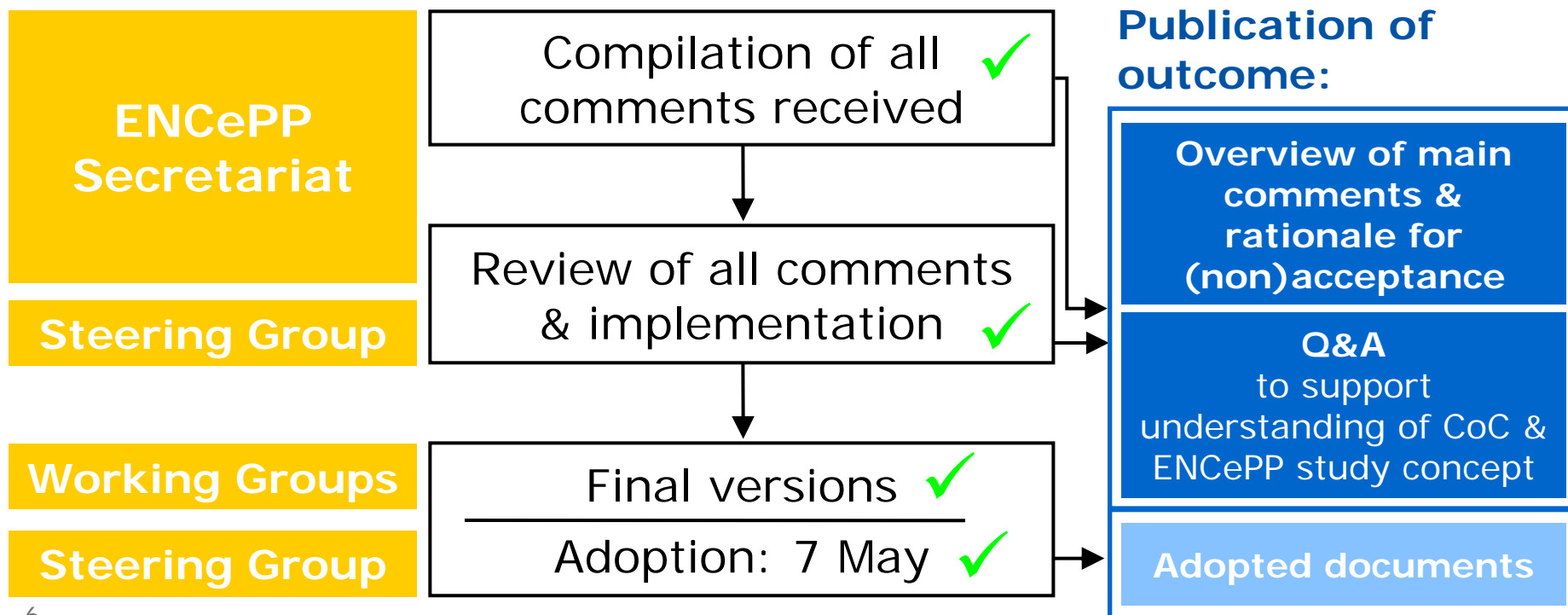
Stakeholders – who made comments ?

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

Annex 3 (Declaration)

Declaration on compliance with the ENCePP Code of Conduct for ENCePP Studies

The (primary) lead investigator and a person authorised to sign on behalf of the coordinating study entity hereby declare for the purpose of conducting the study (ENCePP Study) (hereinafter referred to as the "Study"):

- to follow the rules and principles for the independent and transparent conduct of pre-clinical, toxicological and clinical studies of the ENCePP Code of Conduct as set out in Annex 3 (ENCePP Code of Conduct);
- to inform the ENCePP Secretariat, without delay, of any change or decision to change which constitute a deviation from the provisions of the Code.

It is to be noted that the (primary) lead investigator and the person authorised to sign on behalf of the coordinating study entity may be identical.

Name of (primary) lead investigator: _____
 Date: _____ (dd/mm/yyyy)
 Stamp and signature: _____

Name of the coordinating study entity: _____
 Address: _____

Name of person authorised to sign on behalf of the coordinating study entity (if different from (primary) lead investigator): _____
 Date: _____ (dd/mm/yyyy)
 Stamp and signature: _____

The (primary) lead investigator should also sign and date the checklist of the ENCePP Code of Conduct for ENCePP Studies (Annex 2).
 The agency is unable to accept electronic signature and will not accept photocopies of the completed declaration and checklist.

Checklist

Annex 2 (Checklist)

Checklist of the ENCePP Code of Conduct for ENCePP Studies

The purpose of this checklist is to emphasise the core elements of the ENCePP Code of Conduct which are relevant at the time of study start. The act of completing the checklist confirms that the study for which the ENCePP Study is applied for complies with the requirements of the Code. If, upon completion of the checklist, the study does not meet the requirements of the ENCePP Code of Conduct, the sponsor must address the deficiencies of the provisions of the Code.

The checklist must be completed by the (primary) lead investigator of the study for which the ENCePP Study is applied for. The (primary) lead investigator must:

- Tick all boxes of the checklist thereby confirming compliance of the study with core requirements of the Code.
- If additional or other additional information is requested.
- Sign the checklist.

The undersigned declare upon honouring the following on behalf of the organisation that he/she represents: (signature should read the (primary) lead investigator)

1. General	Check
The study has been designed	
<ul style="list-style-type: none"> in line with the general principles outlined in the Code (see chapter 3 of the Code); and according to a maximum level of transparency (see chapter 4 of the Code). 	<input type="checkbox"/>
2. Research contract	Check
A research contract between the (primary) lead investigator and the coordinating study entity and the study sponsor has been concluded prior to study start.	<input type="checkbox"/>
The statement that parties to the Agreement and individuals acting on their behalf hereby commit to adhere to the rules of the ENCePP Code of Conduct (their entity) is included in the research contract and the latest version of the Code at the time of the signature of the contract is attached.	<input type="checkbox"/>
The contract includes the following information:	
<ul style="list-style-type: none"> The main objectives and a brief description of the intended method of the research as well as a clear assignment of tasks and responsibilities; The procedure for solving agreement on the study protocol as well as the involvement of the sponsor in the development of the protocol; The amount of the financial support and the payment schedule. 	<input type="checkbox"/>

- complete
- sign & stamp
- submit originals

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