



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



European Network of Centres for  
Pharmacoepidemiology and  
Pharmacovigilance

## Declaration on compliance with the ENCePP Code of Conduct for ENCePP Studies<sup>1</sup>

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 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

- to follow the rules and principles for the independent and transparent conduct of pharmacoepidemiological and pharmacovigilance studies of the ENCePP Code of Conduct adopted on 21 / 6 / 2010;
- to inform the ENCePP Secretariat, without delay, of any change or decision to change that constitutes a deviation from the provisions of this Code.

It is of note 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:

Nera Agabiti

Date: 21 / 6 / 2010 (xx/yy/yyyy)

Stamp (if applicable) and signature:

Name of the coordinating study entity: Department of Epidemiology Lazio Region, Italy

Address:

Via S. Costanza, 53

00198 Roma, Italy

Name of person authorised to sign on behalf of the coordinating study entity [if different from (primary) lead investigator]:

Marina Davoli

Date: 21 / 6 / 2010 (xx/yy/yyyy)

Stamp (if applicable) and signature:

DIPARTIMENTO DI EPIDEMIOLOGIA ASL ROMA E  
Il Direttore  
Dott.ssa Marina DAVOLI

The (primary) lead investigator should also complete, sign and date the Checklist of the ENCePP Code of Conduct for ENCePP Studies.

<sup>1</sup> Complete the declaration on screen, then print, stamp (if applicable) and sign.