



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 Studies¹

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 Choice of Estrogens and Longterm Investigation of Nomegestrol Acetate - International Active Surveillance Study (CELINA).

- 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 23 / 10 / 2011;
- 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:

Jürgen Dinger, MD, PhD

Date: 25 / 1 / 12 (xx/yy/yyyy)

Stamp (if applicable) and signature:

Name of the coordinating study entity: ZEG - Berlin Center for Epidemiology and Health Research

Address:

Invalidenstrasse 115

10115 Berlin, Germany

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

Suzanne Reed, MSc, PhD

Date: 25 / 1 / 12 (xx/yy/yyyy)

Stamp (if applicable) and signature:

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

The agency is unable to accept electronic signatures and will not accept photocopies of the completed declaration and checklist.

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