



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
Safety Evaluation of Adverse Reactions in Diabetes - Drug utilisation studies (ENCEPP/SDPP/4364)

- 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 / 11 / 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:

Miriam C. J. M. Sturkenboom

Date: 15 / 8 / 2013 (xx/yy/yyyy)

Stamp (if applicable) and signature:

Erasmus MC
Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam

Name of the coordinating study entity: Erasmus University Medical Center

Address:

Department of Medical Informatics

Dr. Molewaterplein 50

PO Box 2040

3000 CA Rotterdam

The Netherlands

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

Date: 15 / 8 / 2013 (xx/yy/yyyy)

Stamp (if applicable) and signature:

Erasmus MC
Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



**European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance**

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.

(Faint, mirrored text and signature, likely bleed-through from the reverse side of the page)

(Faint, mirrored text and signature, likely bleed-through from the reverse side of the page)