



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 <include here study name and identifier/reg.no.>

WWE117397: Post-authorization safety Electronic Medical Records database retrospective cohort ...

- to follow the rules and principles for the independent and transparent conduct of pharmacoepidemiological and pharmacovigilance studies of the current version of the ENCePP Code of Conduct²;
- 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:

Date: (dd/mm/yyyy)

Stamp (if applicable) 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 (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.

Electronic signatures or photocopies of the completed declaration and checklist will not be accepted.

¹ Complete the declaration on screen, then print, stamp (if applicable) and sign.
² Adopted Code and any revision thereof at the time of signature of the declaration.

