



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



EMA/166242/2018
ENCEPP Code of Conduct Revision 4


European Network of Centres for
Pharmacoepidemiology and
Pharmacovigilance

Declaration of compliance with the ENCePP Code of Conduct

The (primary) lead investigator and a person authorised to sign on behalf of the coordinating study entity hereby declare¹ for the purpose of conducting the study *<include here study name and identifier/registration no.>*: Impact of EU label changes and revised pregnancy prevention programme for medicinal products containing valproate: utilisation and prescribing trends (EU PAS register number 31001)

- 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, 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:	Prof dr Olaf Klungel	Pharmacoepidemiology & Clinical Pharmacology Utrecht University Faculty of Science Dept. of Pharmaceutical Sciences PO Box 800 82 3508 TB Utrecht The Netherlands
Date:	22/08/2019 (dd/mm/yyyy)	
Stamp (if applicable) and signature:		
Name of the coordinating study entity:	Department of Pharmaceutical Sciences, Universiteit Utrecht	
Address:	P.O.Box 80082, 3508 TB Utrecht The Netherlands	
Name of person authorised to sign on behalf of the coordinating study entity [if different from (primary) lead investigator]:		
Date:	22/08/2019 (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.

¹ Complete the declaration on screen, then print and scan a signed and stamped (if applicable) copy.

² Adopted Code and any revision thereof at the time of signature of the declaration.