

EMA/166242/2018 ENCePP Code of Conduct Revision 4



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 declare ¹ for the purpose of conducting the study <*include here study name and identifier/registration no.*>: Risks of arrhythmias reporting with various antiepileptics including Lamotrigine: a pharmacovigilance study in VigiBase®

- 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: Dr François Montastruc

Date: 29/01/2022 (dd/mm/yyyy)

Stamp (if applicable) and signature:

S.R

Name of the coordinating study entity: François Montastruc

Address: Faculty of Medicine, Toulouse University Hospital (CHU), 37 Allées Jules Guesde,

31000, Toulouse, France.

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.

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.