

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.>: Long term, prospective, observational cohort study evaluating the safety profile in patients with highly active relapsing multiple sclerosis (RMS) newly started on oral cladribine – CLARION EURAS 24484

- 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 Conduct<sup>2</sup>;
- 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:

Pasi Korhonen

Date: 19/06/2018

(dd/mm/yyyy)

Stamp (if applicable) and signature:

Name of the coordinating study entity: EPID Research

Address:

Metsänneidonkuja 12

02130 Espoo

Finland

Name of person authorised to sign on behalf of the coordinating study entity [if different from

(primary) lead investigator]: Eero Mertano, Senior Principal

Date: 19/06/2018

(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.

<sup>&</sup>lt;sup>1</sup> Complete the declaration on screen, then print and scan a signed and stamped (if applicable) copy.

<sup>&</sup>lt;sup>2</sup> Adopted Code and any revision thereof at the time of signature of the declaration.