

The documentation for notification of a non-interventional study contains:

1. cover letter;
2. completed non-interventional study notification form;
3. plan of the trial;
4. approved Summary of Product Characteristics and Patient Information Leaflet;
5. positive opinion of the Ethics Committee
6. decision on issuance of marketing authorisation;
7. proof that prescribed fees have been paid to the Institute;
8. decision of the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency, if it has been involved in the decision making;
9. additional information related to health protection of the subject, at the request of the Institute.

The documentation shall be submitted both in electronic and written form.

Original documents must be submitted, or their copies verified by a notary from Montenegro or from other country having a notary service, or, in case of countries with no such service, by local authorities (for example, by court, or municipal authority).

An application with documentation for notification of a non-interventional study shall be submitted in language which is in official use in Montenegro.

The form for notification of a non-interventional study, referred to in item 2, is published on the website of the Institute in the section Legislation/Templates.