Material on clinical trials to be submitted to Fimea electronically as of 1 January 2020

Fimea's new Administrative Regulation 8/2019 will enter into force on 1 January 2020, following which all material related to clinical trials shall be submitted to Fimea electronically.

There are no changes concerning the documents to be submitted to Fimea as compared to the previous regulation, only the method of submission will change. In other words, it is no longer necessary to submit hardcopy documents.

The documents may have an electronic signature, or the material may include a scanned hand-written signature.

Electronic material

Any electronic material submitted to Fimea must be in PDF format (with the exception of the EudraCT form .xml file). To facilitate processing, longer documents should include bookmarks.

The names of electronic documents shall indicate the document and version number and/or date, and non-ASCII characters may not be used in the names. As a rule, different documents may not be saved in the same document file (single PDF file); for example, the trial protocol and trial subject information leaflet may not be combined in the same file.

Each consignment must be accompanied by a covering letter stating its essential details.

The material being submitted must be compressed (in zip format), and all the documents included in the same consignment must be sent at the same time.

Electronic materials must be submitted without password protection.

Submitting materials

Either CESP (Common European Submission Portal, commercial operators) or Fimea's Secure Mail Service (academic operators) shall be used as the submission channel for electronic material.

The CESP is a portal maintained by the Heads of Medicines Agencies (HMA) intended for the encrypted submission of materials to authorities. You must first register before gaining access to the portal. The parties maintaining the portal provide plenty of training on the use of the portal. Applicants are requested to always choose “Clinical Trial” under “Regulatory Activity Type” in the CESP submission details so that the report will be directed to Fimea’s clinical trials division. In the comment field, enter the EudraCT number and briefly describe (on heading level) what kind of material the consignment consists of.

Or you can register with the Fimea Secure Mail Service. The recipient of clinical trial materials is the service mailbox FI-CTA@fimea.fi. In the subject field, enter the EudraCT number and briefly state the nature of the material. Further information about the Secure Mail Service is available on the Fimea website at https://www.fimea.fi/web/en/about_us/contact_information/secure-mail