The application process

Prior to beginning the application process it is important to find answers to the following questions:

- Is the product studied a medicine, a medical device, an in vitro diagnostic device and/or a device subject to pharmaceutical legislation?
- Is this a clinical drug trial, a clinical device trial and/or a performance study?

The application process proceeds based on the product under study in accordance with the following processes.

Clinical drug trial authorisation process

If the product studied is a medicine or a device-based medicine (MDR, Article 1(8) or 1(9) second subsection), or if a medicine and a device are examined in the same study, proceed in accordance with the authorisation process of a drug trial.

- Submit the drug trial application (or change notification) to Fimea and Tukija via the CTIS portal.
- Submit separate device documents simultaneously either directly to Tukija or via the CTIS portal (see Tukija for more information).
- The application is processed in accordance with the schedules specified in the Clinical Trials Decree (2014/536).
- Fimea and Tukija will issue their decisions simultaneously. The Tukija statement on the device part of the combined study is included in the assessment report of Part II of the clinical trial.
- If a medicine and a medical device are studied simultaneously (i.e. a combined study), the process will proceed to the clinical device trial authorisation process.

Clinical device trial (MD/IVD) authorisation process

If the product studied is a medical device, an in vitro diagnostic medical device or a device incorporating or administering a medicine (MDR, Articles 1(8) and 1(9) first subsection), proceed in accordance with the authorisation process for a clinical device trial.

- Submit the device trial application (or change notification) to the regional ethics committee.
- After the regional ethics committee has issued its opinion, submit the trial application or change notification to Fimea via secure mail (secmail.fimea.fi) to laitetutkimus@fimea.fi.
- The application is processed in accordance with the schedules specified in the MDR, the IVDR or the national Medical Devices Act (719/2021).
- Fimea issues its decision.