

Low-intervention clinical trial

A low-intervention clinical trial studies an authorised medicine. Its use according to the trial protocol follows the terms of the marketing authorisation, or published scientific evidence on safety and efficacy. Any additional procedures must not pose more than minimal additional risk or burden to the safety of the participants compared to normal local clinical practice. Low-intervention clinical trials are used for example to investigate safety and efficacy questions that have arisen since authorisation.

Refer to Regulation 2014/536 for more information.