Forum Östergötland

a support function for clinical and translational research at Linköping University and Region Östergötland

https://liu.se/organisation/liu/medfak/fo
forumo@regionostergotland.se

Scientific, regulatory and statistic counselling

Help with essential documents (study protocol, etc.) for MPA applications

Clinical trial facility with research nurses

Setting up electronic data collection tool

Courses, ISO 14155

Randomization Monitoring

LINKÖPINGS UNIVERSITET

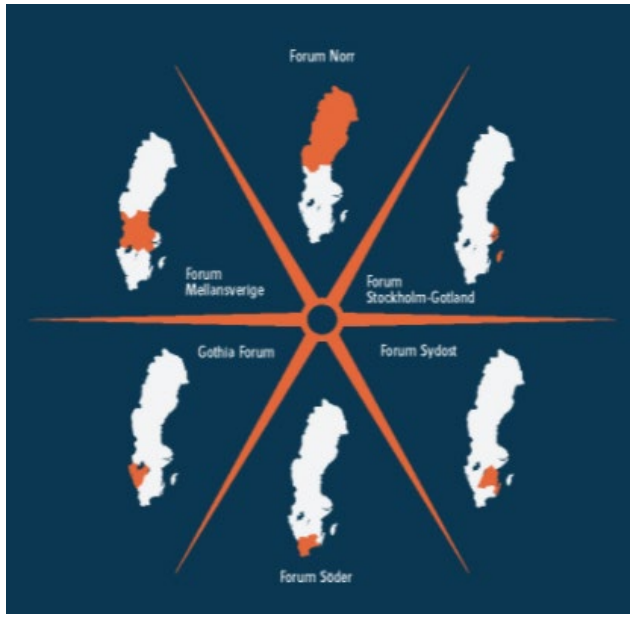
Region Östergötland

Forum Sydost

- Forum Östergötland is a part of the regional node Forum Southeast

in the national collaboration Clinical Studies Sweden.

Six regional nodes in Sweden
www.kliniskastudier.se



New European legislation
EU Medical Device Regulation 2017/745 (**MDR**)

All clinical <u>investigations</u> of medical devices in Sweden have to be submitted to the Swedish Medical Product Agency **MPA**/Läkemedelsverket.

This includes those clinical investigations for which an ethics approval previously was sufficient.

What is a medical device?

Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for medical purpose

Other products without medical purposes (eg cosmetic eye lenses) can also be included in the definition and is listed in the Annex XVI in the MDR.

The complete definition can be found in the MDR article 2.

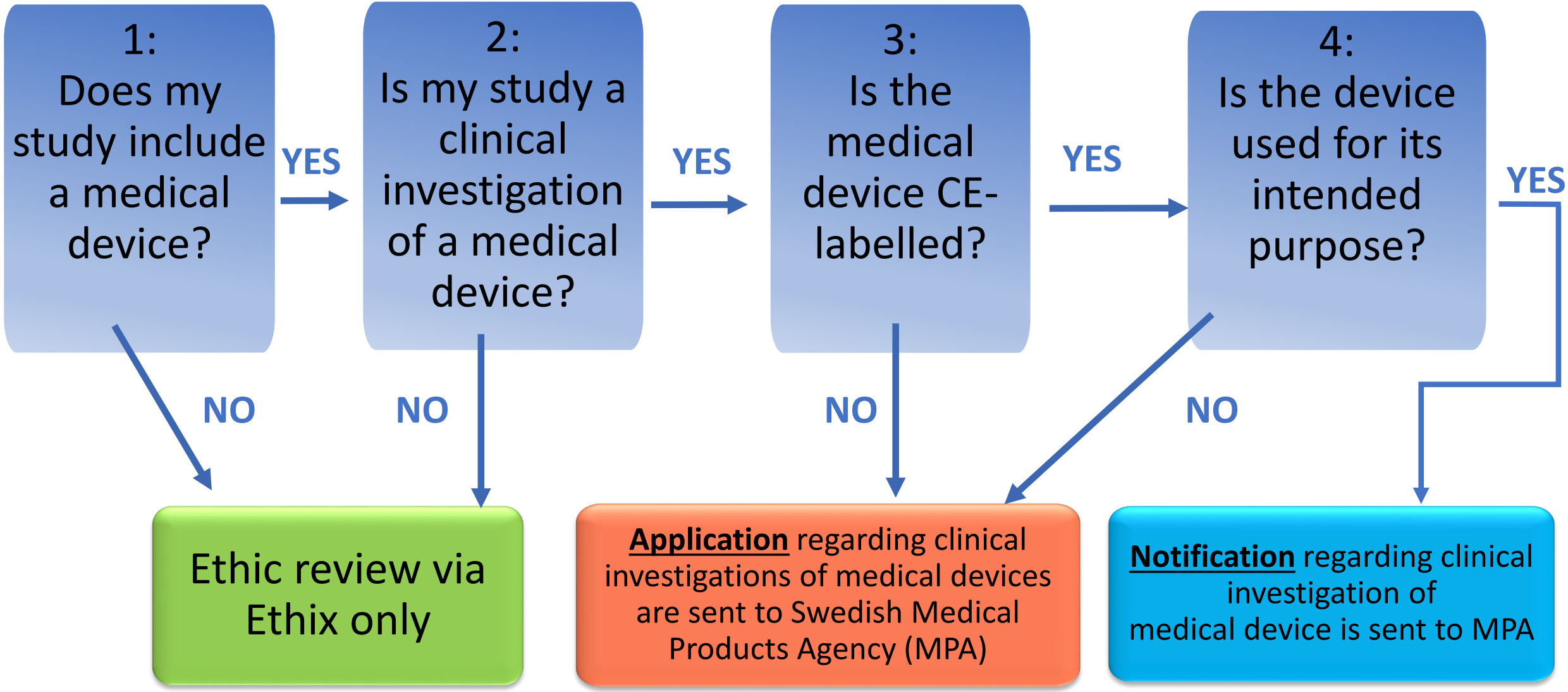
What is a clinical investigation of a medical device?

A clinical investigation is a **systematic** investigation involving one or more **human subjects**, undertaken to assess the **safety** or **performance** of a device.

How to conduct a clinical investigation of a medical device?

Clinical investigations of medical devices should be carried out in accordance with **Good Clinical Practice**, as described in the international standard **ISO 14155**

Does the MDR regulation apply to my clinical study?



What do the different options mean?

Ethic review via Ethix only

- Ethics review for clinical research as usual for research that does not follow MDR.
- The entity responsible for the research is the main applicant and the prinicipal investigator.

Application regarding clinical investigations of medical devices are sent to Swedish Medical Products Agency (MPA)

Notification regarding clinical investigation of medical device is sent to MPA

- According to MDR and national law
- Ethics review is part of the process within the application to MPA.
- Sponsor (not the researcher or the entity responsible for the research) is the main applicant

Contact information

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