Studies submitted to EC az groeninge

All research* conducted in az groeninge needs to be submitted to the Ethical committee of az groeninge, with the exception of:

1) clinical trials involving a medicinal product (CTR) and/or
   Interventional (+ low-interventional) studies with a medicinal product (IMP) are covered by the law of May 7th, 2017 starting from January 31st, 2022 (CTR, see below).
2) clinical investigations involving a medical device (MDR) and/or
   Clinical investigations (prospective and retrospective) with a medical device are covered by the law of December 22th, 2020 starting from May 26th 2021 (MDR, see below). Please note that some clinical investigations involving a medical device have to be submitted to the EC of az groeninge (see below for more information).
3) clinical investigations involving an in-vitro diagnostic test (IVDR)
   Clinical investigations with an in-vitro diagnostic device are covered by the law of June 15th, 2022 starting from May 26th 2022 (IVDR, see below).

*All other prospective research (interventional studies without a medicinal product and non-interventional studies) is covered by the Belgian law of May 7th, 2004 (Experimental law). Retrospective research without a medical device is not covered by the 2004 law, but it is highly recommended to submit this retrospective study to the EC of az groeninge.

Legislation

The new European regulation No 536/2014 (Clinical Trials Regulation, CTR - Belgian law of May 7th, 2017) is applicable since January 31th, 2022. This new legislation deals with clinical trial with medicines conducted in the European Union (EU) and aims to harmonize notification and evaluation by the FAMHP and Ethics Committee. Since January 31th, 2023, the transition period has ended and every prospective interventional study with a medicinal product must now be evaluated by an independent Ethics Committee (not linked to the site where the study is taking place) using the CTIS platform. More information is available on the FAMHP website.

Since May 26th, 2021, the new European regulation No 2017/745 (Medical Devices Regulation, MDR - Belgian law of December 22th, 2020) is also in force. All clinical trials involving a medical device (interventional and non-interventional, prospective and retrospective) must be evaluated in accordance with this law. Depending on the type of investigation, a different evaluation procedure is followed (Belgian law of May 7th, 2004 - Ethics Committee linked to the site versus May 7th, 2017 - independent Ethics Committee). More info is available on the FAMHP site.

Finally, since May 26th, 2022, the new European regulation No 2017/746 (In Vitro Medical Devices, IVDR) is also in force. The IVDR introduces an update of European legislation on performance study, clinical trials with in vitro medical devices. More info is available on the FAMHP site.

The royal decree of January 9th, 2018 regulates the operation of a Biobank in the context of all operations performed with human body material (MLM) for scientific purposes. For interventional prospective clinical trials with a medicinal product (CTR), no registration in a Biobank is necessary. However, when the MLM is used for another purpose, the samples must be registered in a Biobank (cfr Compendium Biobanks 20.07.2018). More info is available on the FAMHP site.