New European legislation on the way for clinical trials

November 3, 2020

Questions answers regarding. clinical trial regulation

The Clinical Trials Regulation applies to clinical trials with medicinal products in humans.

- **Should trials that are *only* to take place in Denmark (Danish mononational trials, including trials from non-commercial sponsors) be submitted through the EU portal?**
  All drug trials must be submitted through the EU portal, see, however, regarding. transition period the first year.

- **Should all submissions be made through the portal, eg annual safety reports?**
  All submissions during the life of the trial including notifications, significant changes, annual safety reports, final report and results must be made through the portal. An exception is SUSARS, which must be sent directly to the EudraVigilance database (the final solution, however, we do not yet know).

- **When will the regulation enter into force / apply?**
  The regulation will not enter into force until the EU portal, which is intended to support communication between the sponsor / applicant and the authorities, has been completed. Audit of the EU portal begins December 2020.

- **How do I submit my application after the regulation has entered into force?**
  You must submit your application for a clinical trial permit to the EU portal, which must no longer be submitted directly to the national authorities. This applies to both the application to the Danish Medicines Agency and the ethics committee. see also below regarding. transitional

arrangement the first year

- **How should ongoing national and VHP trials be handled - is there a transitional arrangement?**
  There is a transitional scheme, which means that for up to a year after the regulation has entered into force, you can still apply under the old legislation. If an ongoing trial is not completed 3 years after the entry into force of the Regulation, you must transfer your trial to the Regulation. **The European Commission has prepared a guide** on how (section 11).

- **Where can I see which documents to submit?**
  Annex 1 to the Regulation lists the documents to be submitted .

- **Will the Danish Medicines Agency inform about the specific changes in relation to applying for a permit for a clinical trial with medicines?**
  Yes, when we know more about what the EU portal will look like, we plan to hold briefings, but also provide information on our website. If there is an opportunity to practice on the EU portal, we will of course also inform about it.

- **For which trials does the new legislation apply?**
  The new legislation applies to drug trials on humans.

- **Do I still have to send my application to the Danish Medicines Agency and the Science Ethics Committee System after the regulation enters into force?**
  The clinical trial application is processed by both us and the Science Ethics Committee System by submission in the new EU portal. Therefore, applications must not be submitted directly to the Danish Medicines Agency or the ethics committee system. However, this only applies to drug trials.

- **How should I report SUSARs?**
  Under the Regulation, SUSARs are intended to be reported only to EudraVigilance and thus not simultaneously to the participating national Member States. We do not know the final solution yet

Did you get answers to your questions?

Yes	No

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