European Health Union: new rules to improve clinical trials in the EU

Brussels, 28 January 2022

As of Monday 31 January, the assessment and supervision of clinical trials throughout the EU will be harmonised, notably via a Clinical Trials Information System (CTIS) run by the European Medicines Agency. On this date the Regulation on Clinical Trials will enter into application. This Regulation will improve conducting clinical trials in the EU, with the highest standards of safety for participants and increased transparency of trial information.

Welcoming this important step, European Commissioner for Health and Food Safety, Stella **Kyriakides**, made the following statement:

"The Clinical Trials Regulation marks an important and positive step for European patients and brings us closer to a stronger European Health Union. It will allow us to have swifter authorisation of clinical trials across our Member States, thus improving the efficiency of clinical research as a whole. At the same time, the high quality and safety standards already set for such trials will be upheld. While almost 4000 clinical trials are already carried out each year in the EU, the Regulation will make vital research even more beneficial to the researchers and patients who depend on fast and reliable trials the most.

Over the coming years, the Regulation will create a framework for a more agile clinical trial approval process that will bring Member States closer together in the area of clinical trials. In turn, this will inspire further confidence and trust among citizens, who are at the centre of clinical research. This is why the Regulation is based on the key principle of transparency, allowing for public scrutiny at every step of the way.

I thank the Member States and the stakeholders who all worked closely with us to implement the new regulatory framework for clinical trials in Europe. I am also grateful to the European Medicines Agency, for not only their work on the Regulation, but also for their support in setting up the Clinical Trials Information System that will represent a single entry point for submitting clinical trial information in the EU."

For More Information

Questions and answers on the Regulation

EMA website

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