The EU Clinical Trials Regulation and its much-anticipated benefits:

Foreword from the European Medicines Agency

Morgane Colin de Verdiere, Catriona Ester
EMA

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Correspondence to:
morgane.deverdiere@ema.europa.eu

The year 2022 signalled the beginning of a new way of handling clinical trials in Europe, with the implementation of the EU Clinical Trials Regulation 536/2014 (CTR).[1] This eagerly awaited regulation came into application at the end of January 2022 with a three-year transition period. The new regulation will facilitate sponsors' clinical trial applications in the EU, while streamlining the assessment and supervision processes for regulatory authorities. This will make it easier to carry out larger clinical trials in multiple EU member states, which in turn should foster further innovation and research in the EU.

Moving from the old Clinical Trials Directive to the EU CTR is not without challenges and involves far-reaching changes to how medicines developers, EMA, and EU member states operate. During the transition period, EMA is therefore working closely with users to provide training and support and to address technical difficulties. Ultimately, however, the EU CTR should benefit all those involved, especially patients, through increased transparency of clinical trial data and stronger patient involvement.

As part of the new regulation, EMA has developed the Clinical Trials Information System (CTIS), which will replace the EudraCT database and become mandatory for all new clinical trial applications as of January 2023. By January 31, 2025, all ongoing trials approved under the old Clinical Trials Directive will be governed by the new regulation and must have been transitioned to CTIS. CTIS provides a single-entry point for clinical trial sponsors and regulators through which to submit and assess clinical trial data. To make information about each clinical trial more accessible to a wider audience, it also includes a searchable database for healthcare professionals, patients and the general public, available at euclinicaltrials.eu.[2] This database will prospectively contain detailed information on all clinical trials authorised through the system, including their outcomes. With this in mind, sponsors are encouraged to present data in a user-friendly, searchable format.

As part of the continuing drive to better inform and involve patients, sponsors now also need to submit a lay summary, together with the Summary of Clinical Trial Results, within 12 months of the end of most clinical trials. This lay summary should offer patients and the public an unprecedented chance to understand what is going on in medical research, while also allowing sponsors the opportunity to communicate their results in a more harmonised way. This new requirement reflects ongoing efforts to increase transparency and acknowledges the important contribution patients make to the advancement of medical research.

Patient engagement is at the heart of all that EMA does. For many years now, EMA has itself provided lay language summaries of authorised medicines, drafted in consultation with patient representatives. These summaries, known as medicine overviews, are the landing page of any medicine authorised by EMA and include a plain-language explanation of the assessment of the clinical trial data that underpinned EMA's decision. As such, EMA's medical writers know better than most the challenges of writing a summary in lay language. It is a fine balancing act, ensuring that the language is simple, without

Author information

Morgane Colin de Verdiere is Head of Medical and the Health Information Service, Stakeholders and Communication Division, EMA.

Catriona Ester is a Scientific Communication Specialist, Medical and Health Information Service, Stakeholders and Communication Division, EMA.

compromising the accuracy of the information provided. As new clinical trials come to a close, the medical writers' community at large will find itself facing similar issues. To support medical writers in preparing and writing a good lay summary, the European Commission has issued guidance on good lay summary practice,[3] which includes recommendations on patient involvement, presenting data, and the use of lay language. Medical writers may also be interested in EMA's medical terms simplifier,[4] a glossary of lay-language terms commonly used in EMA's communications for the public.

EMA is committed to stimulating innovative clinical research in the EU, while also maintaining protection of trial participants, and guaranteeing data robustness and transparency that EU citizens expect. Although very welcome, the greater transparency offered by CTIS and EU CTR requires a stringent approach to protection of personal data and commercially confidential information (CCI). A range of measures have been put in place to ensure this is achieved. Key considerations are outlined in a draft EMA guidance[5] on the protection of personal data and CCI in documents to be published in CTIS. EMA is also closely monitoring the implementation of the CTR within the context of Accelerating Clinical Trials-EU (ACT-EU), an initiative seeking to transform how clinical trials are designed and run, with monthly metric reports on progress.[6]

It is clear that it is more important than ever to empower EU citizens and patients so that they can make informed decisions about their healthcare. These far-reaching changes to the clinical trials regulatory landscape in the EU are important steps towards strengthening patient involvement in clinical trials and boosting their understanding of research and study outcomes. In turn, this will have a positive effect on the overall EU regulatory system for medicines, reinforcing public confidence in authorised medicines and contributing to a more conducive environment for future research.

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