

Challenges ahead for European clinical trials

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The European Society for Medical Oncology (ESMO), in collaboration with the European Organisation for Research and Treatment of Cancer (EORTC), expressed their views on the EU Clinical Trials Regulation in an official position paper recently published in *Annals of Oncology*.

"The Clinical Trials Regulation (CTR) represents one of the most important changes in the field of clinical trials in the last decade, however it still contains unresolved issues that may prove to be challenging for research in Europe and for implementation by Member States," says Prof. Christian Dittich, Coordinator of the ESMO Faculty for Principles of Clinical Trials and Systemic Therapy.

Adopted by the EU institutions back in 2014, the new Regulation will come into force and become law across the 28 EU Member States in 2016.

Although still work in progress, the new EU CTR is definitely an opportunity to facilitate [clinical cancer research](#) in Europe and reduce some of the burdens that have proven so costly in the past.

For example, the CTR includes the concept of a one-time-consent for patient data and tissue to be used beyond the end and the scope of a clinical trial. This provides patients with the option to 'donate' their [clinical trial data](#) and empowers them to continue to contribute to medical research.

Other new items in the CTR include the creation of a single registration

portal, a new category of studies (called 'low intervention clinical trials') and data transparency. These, combined with the more procedural items, will require additional efforts to ensure that they are correctly transposed at EU Member State level.

Gains made in the CTR in terms of usage of patient data and tissue through the provision of a 'one-time consent' needs to be consistent with the EU General Data Protection Regulation, which has yet to be voted on.

"It is vital that there is consistency between these two pieces of legislation," says Paolo G. Casali, Chair of the ESMO Public Policy Committee.

"The Regulation is indeed an opportunity to improve and harmonise the way [clinical trials](#) and medical research are conducted across Europe," continues Casali, "However to guarantee future success, it is essential that this important Regulation is evenly implemented across all European countries, as some stages of the regulatory pathway for new studies will fall within the national domain, for example ethical approval".

With EORTC and the European Association for Cancer Research (EACR), ESMO has formed a European Clinical Cancer Research Forum. "Together with EU cooperative research groups we will monitor the implementation of the Clinical Trials Regulation and provide constructive input and feedback to all the relevant bodies responsible," states Casali.

We hope that the EU institutions will listen to the voice of the [cancer](#) community and will be ready to address any potential discrepancies in the implementation of this Regulation across the EU 28, so that the much needed research in cancer can continue to improve the outcomes of patients in Europe and beyond," says Casali.

More information: "An ESMO-EORTC position paper on the EU Clinical Trials Regulation and EMA's Transparency Policy: Making European research more competitive again"

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