PM+: Consistency needed for EU clinical trials regulation to work

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Opinion Plus

The EU's new clinical trials regulation still has a few implementation challenges to overcome, says Prof. Christian Dittrich.

Ahead of the European Week Against Cancer focus later this month, I would like to reiterate ESMO's support for the adoption of the EU's clinical trials regulation.

Adopted by the three EU institutions - Council of the EU, European parliament, and European commission - back in 2014, with the aim of providing a more supportive environment for research, we are looking forward to next year, 2016, when the new regulation will finally be applied across the 28 EU member states.

This important piece of legislation contains positive developments and has tried to touch upon the main aspects that will improve the way clinical trials are conducted across the EU.
However, it still contains unresolved issues that may prove to be challenging for research in Europe and for implementation by member states.

For example, the regulation 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.

The concept provides the patients the option to 'donate' their clinical trial data beyond the end and the scope of a trial, and empowers them to continue to contribute to medical research.

I would like to congratulate the EU institutions for endorsing this critical concept which will, we believe, be a milestone for future medical research.

The inclusion of this concept is a very clear sign of respect for the patient community, as most patients enter clinical trials for more than just their own benefit.

However, the gains made in the clinical trials regulation can be over-ridden by the EU general data protection regulation yet to be voted on.

The clinical trials regulation states that "scientific research making use of the data outside the protocol of the clinical trial shall be conducted in accordance with the applicable law on data protection". It is therefore vital that there is consistency between these two pieces of legislation.

Other new items in the clinical trials regulation 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.

We in ESMO and our colleagues in the European Organisation for Research and Treatment of Cancer (EORTC) have listed the pros and cons of the clinical trials regulation in an official position paper that was recently published in ESMO's scientific journal *Annals of Oncology* [4].

As medical researchers, we would like to ensure that this regulation is seen as an opportunity to improve and harmonise the way clinical trials and medical research are conducted across Europe.

With EORTC and the European Association of 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 the relevant bodies responsible for its implementation.
I hope that the EU institutions will listen to the voice of the cancer community and will try 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.

About the author

Christian Dittrich is the group coordinator of the clinical trials faculty of the European Society for Medical Oncology (ESMO).

Tags
Digital Agenda [5]
Health [6]
Research and Innovation [7]

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Health and social care [8]
Science, technology and research [9]
Society and welfare [10]
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