THE EU CLINICAL TRIALS REGULATION AND ITS IMPACT ON ONCOLOGY

Setting the scene

Rosa Giuliani
Director of Public Policy, European Society for Medical Oncology
OVERVIEW

Introduction to the European Society for Medical Oncology (ESMO)

Setting the scene and key elements of the Clinical Trials Regulation

The importance of the Clinical Trials Regulation and its impact on oncology
ESMO IN A NUTSHELL

The European Society for Medical Oncology (ESMO) is the leading professional organisation for medical oncology.

Driven by a shared determination to secure the best possible outcomes for patients, ESMO is committed to caring for the carers who are engaged in action against cancer in their communities.
ESMO MISSION

- Improve quality of prevention, diagnosis, treatment and care
- Educate and train oncology professionals
- Advance the art and practice of oncology
- Ensure a high standard of qualification
- Promote equal access to optimal cancer care
- Disseminate knowledge to cancer patients and the public
ESMO MEMBERS
A global community

North America 9%
South America 7%
Europe 54%
Africa 5%
Asia-Pacific 25%

> 25,000 members
> 160 countries
Reciprocity agreements with 44 national oncology societies
ESMO CONGRESS 2021

- Registrants: +22,700
- Countries: 143
- Abstracts presented: 1,989
- Late-breaking abstracts: 68
- Abstracts selected for Presidential symposia: 11
- Mini orals: 130
- Proffered papers: 115
- e-Posters: 1,744
- Speakers: +450
- Sessions: +170
BEYOND EDUCATING AND TRAINING
Tools, partnerships and collaborations across the oncology community

ESMO SCALE FOR CLINICAL ACTIONABILITY OF MOLECULAR TARGETS (ESCAT)

ESMO CLINICAL PRACTICE GUIDELINES

ESMO PATIENT GUIDES

ESMO GLOBAL CURRICULUM

ESMO DESIGNATED CENTRES OF INTEGRATED ONCOLOGY AND PALLIATIVE CARE PROGRAMME

Rare Cancers Europe
ESMO WELCOMES THE CLINICAL TRIALS REGULATION

And aims to work towards

Ensuring that medical oncologists are well informed about the implications of the new Regulation

Raising awareness of the need to implement the legislation in a consistent manner in all 27 EU Member States (once applicable)

Addressing the need to rationalise administrative and bureaucratic hurdles associated with clinical research
Recap of the EU Clinical Trials Regulation No 536/2014

**Timeline for application of CTR nationally**

1. **Before go live**
   - Any CTA submitted at this time is still governed by the old Directive

2. **Initial 12 months**
   - A CTA may still be submitted in EudraCT and governed by the old Directive
   - A CTA may be submitted in the new EU portal and governed by the CTR

3. **Next 24 months**
   - All initial CTAs must be submitted in the new EU portal and governed by the new Regulation

4. **From 3 years after go live**
   - All CTAs are governed by the new Regulation, regardless of their date of submission
MAIN CHARACTERISTICS OF THE CLINICAL TRIALS REGULATION

- Involvement of Ethics Committees in assessment procedure
- Strictly defined deadlines
- Coordinated assessment
- Single set of documents
- Single entry point: CTIS
- Increased legal certainty
- Simplified reporting procedures
- Increased transparency
- Union control in MS and third countries re: clinical trials
- EU standards applied to all clinical trials referred to in EU clinical trial applications
EU CLINICAL TRIALS REGULATION NO 536/2014
Interaction with the General Data Protection Regulation 2016/679

Article 28
2) Without prejudice to Directive 95/46/EC, the sponsor may ask the subject or, where the subject is not able to give informed consent, his or her legally designated representative at the time when the subject or the legally designated representative gives his or her informed consent to participate in the clinical trial to consent to the use of his or her data outside the protocol of the clinical trial exclusively for scientific purposes. That consent may be withdrawn at any time by the subject or his or her legally designated representative. The 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.

3) Any subject, or, where the subject is not able to give informed consent, his or legally designated representative, may, without any resulting detriment and without having to provide any justification, withdraw from the clinical at any time by revoking his or her informed consent. Without prejudice to Directive 95/46/EC, the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal.

Recital 33
It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.

Recital 157
By coupling information from registries, researchers can obtain new knowledge of great value with regard to widespread medical conditions such as cardiovascular disease, cancer and depression. On the basis of registries, research results can be enhanced, as they draw on a larger population. Within social science, research on the basis of registries enables researchers to obtain essential knowledge about the long-term correlation of a number of social conditions such as unemployment and education with other life conditions. Research results obtained through registries provide solid, high-quality knowledge which can provide the basis for the formulation and implementation of knowledge-based policy, improve the quality of life for a number of people and improve the efficiency of social services. In order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards set out in Union or Member State law.

Recital 161
For the purpose of consenting to the participation in scientific research activities in clinical trials, the relevant provisions of Regulation (EU) No 536/2014 of the European Parliament and of the Council (15) should apply.
EU CLINICAL TRIALS REGULATION NO 536/2014
Recap of key points for oncologists

1. EMA has developed an EU portal with a database of clinical trials to increase transparency.
2. CTR discusses the concept of non-commercial clinical trials without providing a definition, and encourages Member States to adopt measures to encourage them (i.e. exemption from inspection fees and lower authorisation fees).
3. CTR introduces the concept of low-intervention clinical trials including provisions for a risk proportionate approach for safety reporting, monitoring and insurance coverage.
4. CTR also introduces the concept of co-sponsorship.
5. When collecting data, the provisions surrounding consent in the CTR will apply, but for any processing of this data, the GDPR will apply.

⇒ ESMO is currently developing a policy guide on CTR for oncologists
TWO ESMO WEBINARS ON THE CLINICAL TRIALS REGULATION

The Clinical Trials Regulation and its impact on oncology

Tuesday 12 October from 13:00-14:00 CEST

The Clinical Trials Regulation - Challenges and burdens affecting non-commercial research

Thursday 28 October from 13:00-14:00 CEST
ESMO PUBLIC POLICY WEBINAR
ON THE CLINICAL TRIALS
REGULATION AND ITS IMPACT
ON ONCOLOGY

Date: Tuesday 12 October 2021
Time: 13:00 – 14:00 CEST

Moderator: Rosa Giuliani, ESMO Director of Public Policy

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<tr>
<td>Setting the scene</td>
<td>Rosa Giuliani</td>
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<td>Regulatory perspective</td>
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<td>Clinical research perspective</td>
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<td>European Society for Medical Oncology (ESMO)</td>
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Please note that all questions need to be asked via the Q&A box.

Please do not use the raise hand function to ask your questions.

For technical issues, please send an email to: publicpolicy@esmo.org.
THANK YOU