GOOD SCIENCE
BETTER MEDICINE
BEST PRACTICE

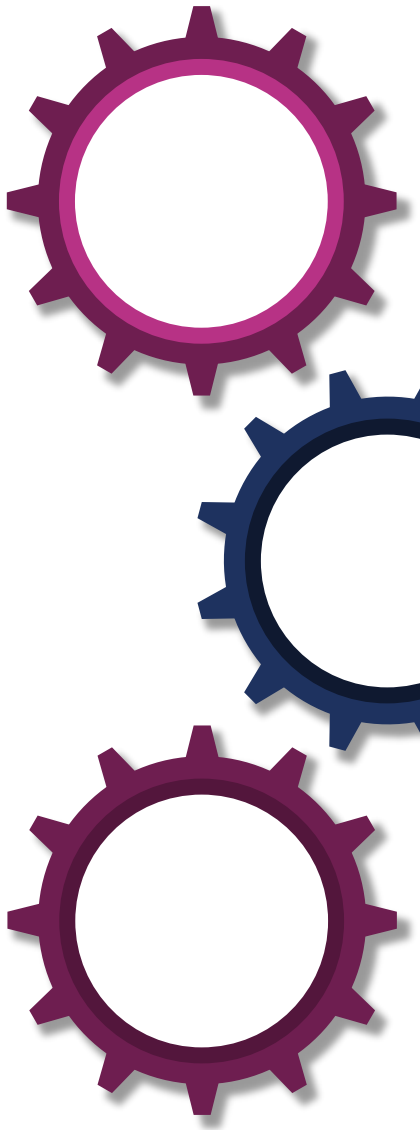
THE EU CLINICAL TRIALS REGULATION AND ITS IMPACT ON ONCOLOGY

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.

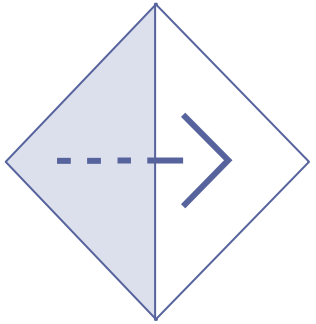
Driven by a shared determination to secure the best possible outcomes for patients,

ESMO is committed to caring for the carers

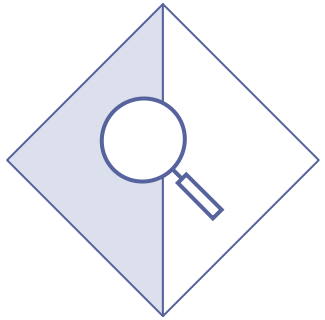
who are engaged in action against cancer in their communities.

ESMO MISSION

Improve
quality of prevention,
diagnosis, treatment and care

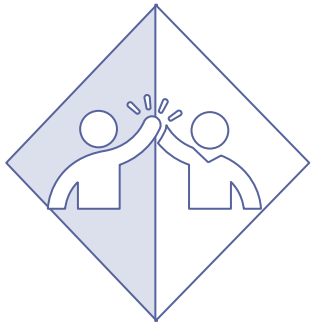


Advance
the art and practice
of oncology

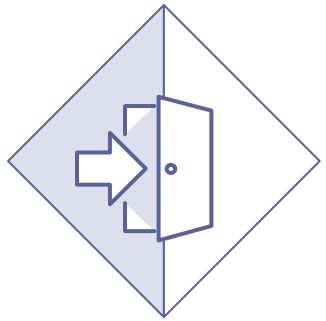


Disseminate
knowledge to cancer
patients and the public

Educate and train
oncology
professionals



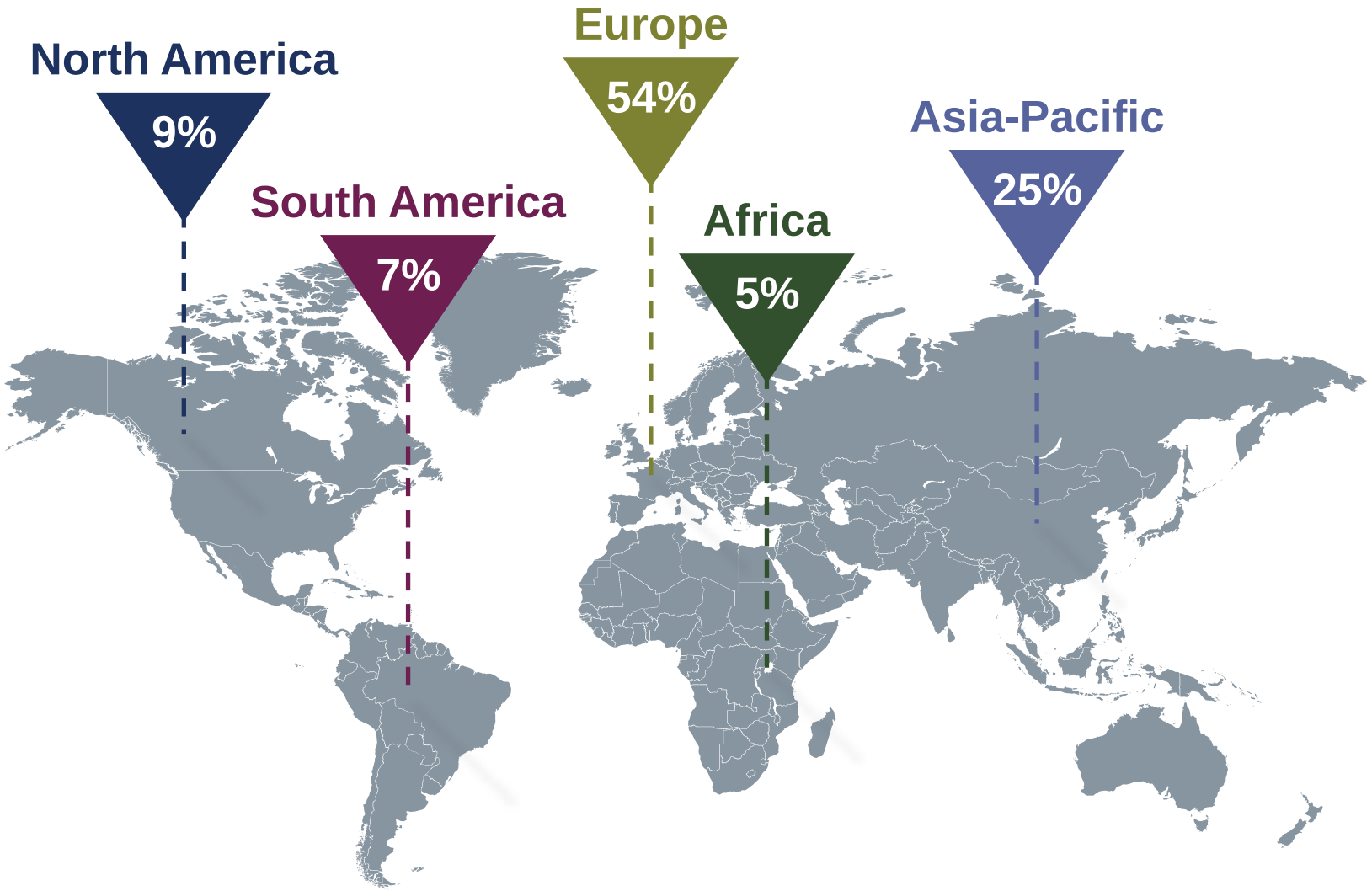
Ensure
a high standard of
qualification



Promote
equal access to
optimal cancer care

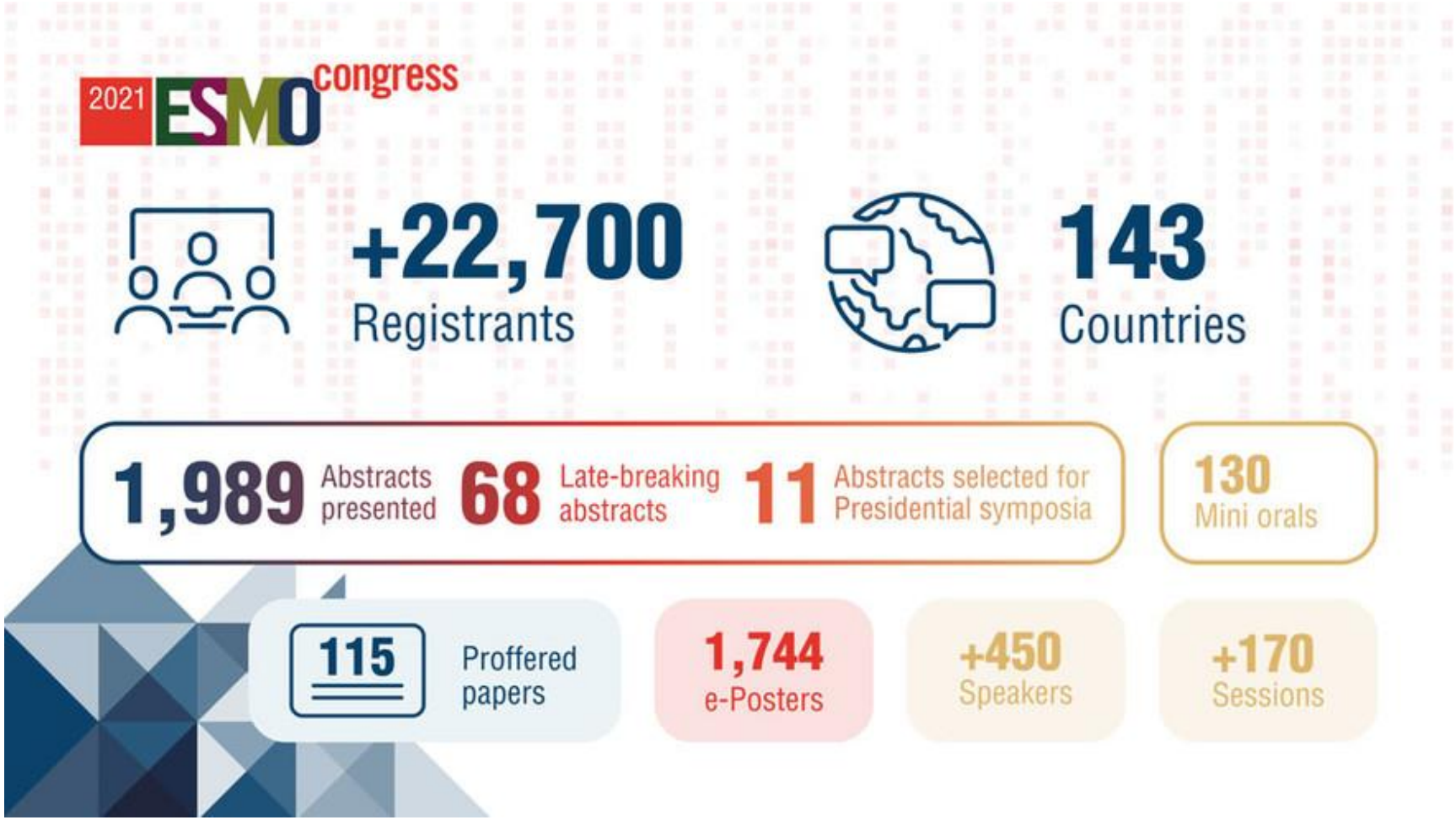
ESMO MEMBERS

A global community



- > 25,000 members
- > 160 countries
- Reciprocity agreements with 44 national oncology societies

ESMO CONGRESS 2021



BEYOND EDUCATING AND TRAINING

Tools, partnerships and collaborations across the oncology community

ESMO SCALE FOR CLINICAL ACTIONABILITY OF MOLECULAR TARGETS (ESCAT)

ESMO DESIGNATED CENTRES OF INTEGRATED ONCOLOGY AND PALLIATIVE CARE PROGRAMME

ESMO CLINICAL PRACTICE GUIDELINES

ESMO PATIENT GUIDES

ESMO GLOBAL CURRICULUM

Rare Cancers Europe

RARE CANCERS EUROPE

World Health Organization

International Agency for Research on Cancer

World Health Organization

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Decide
Health Decision Hub

ECOSOC
United Nations

ESMO

ESMO WELCOMES THE CLINICAL TRIALS REGULATION

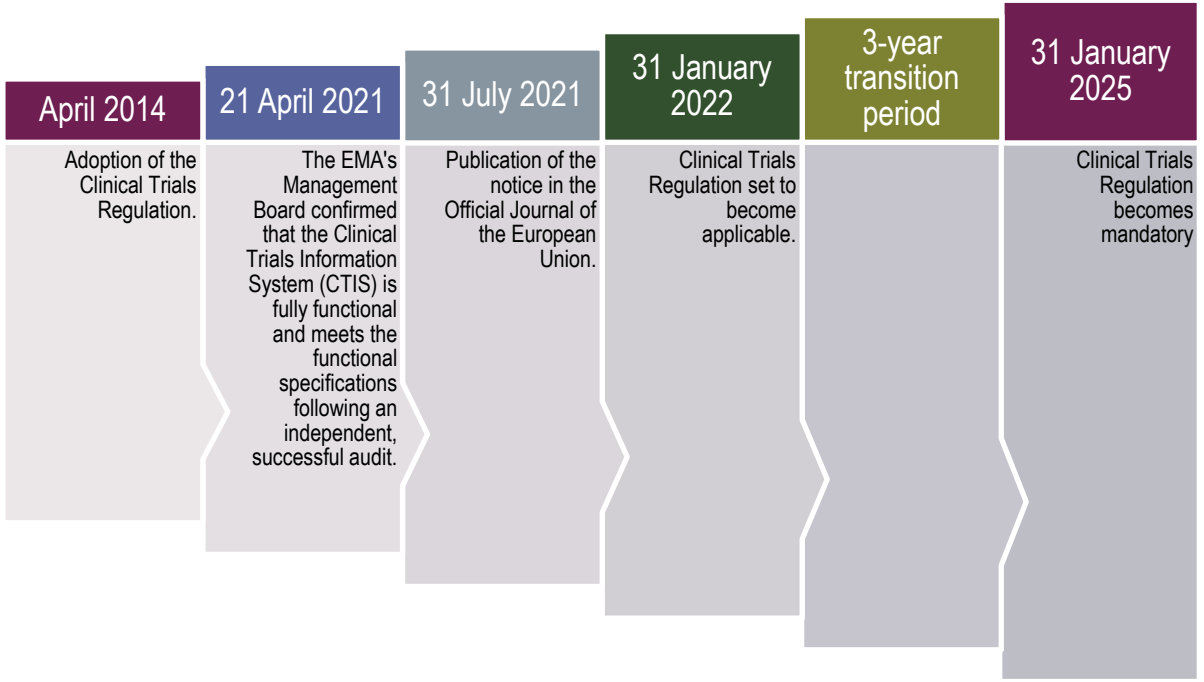
And aims to work towards

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

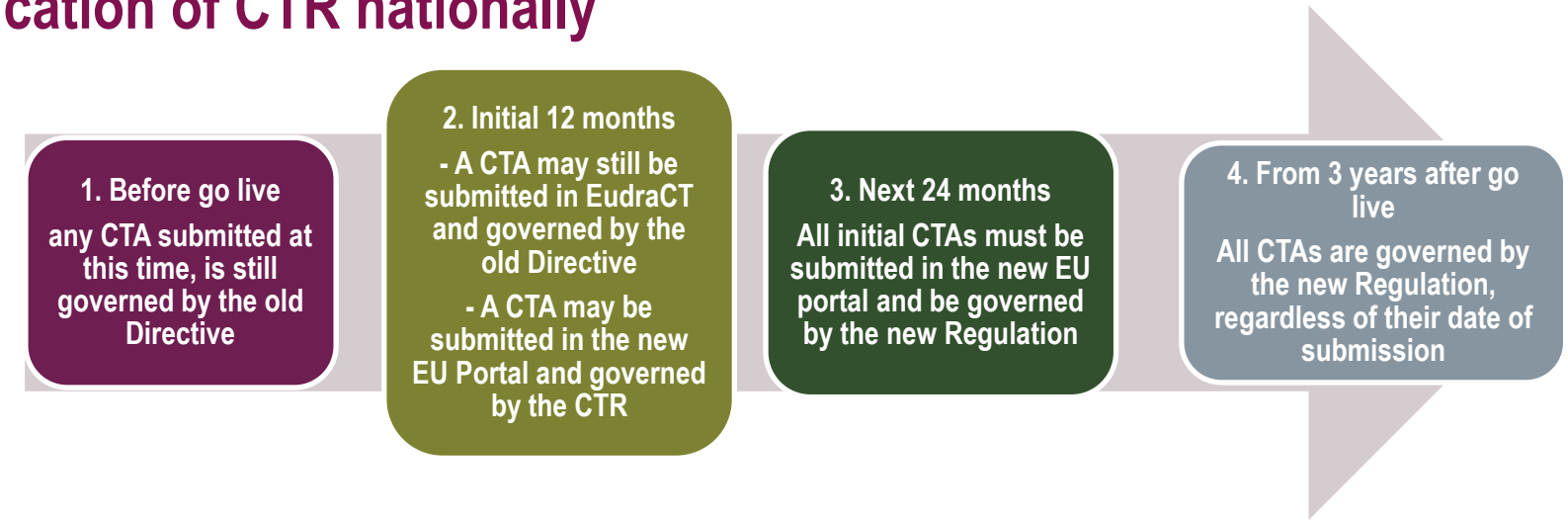
Raising awareness of the need to implement the legislation in a consistent manner in all 27 EU Member States (once applicable)

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



MAIN CHARACTERISTICS OF THE CLINICAL TRIALS REGULATION

EU CLINICAL TRIALS REGULATION NO 536/2014

Interaction with the General Data Protection Regulation 2016/679

https://www.annalsofoncology.org/action/showPdf?pii=S0923-7534%2820%2942964-3

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

Topic	Speaker	Organization	Time
Setting the scene	Rosa Giuliani	European Society for Medical Oncology (ESMO)	13:00 – 13:10
Regulatory perspective	Peter Arlett	European Medicines Agency (EMA)	13:10 – 13:20
Clinical research perspective	Stéphanie Kromar	European Organisation for Research and Treatment of Cancer (EORTC)	13:20 – 13:30
Patient perspective	Jan Geissler	CML Advocates Network & Workgroup of European Cancer Patient Advocacy Networks (WECAN)	13:30 – 13:40
Discussion and Q&A	All		13:40 – 13:55
Conclusion and closing remarks	Rosa Giuliani	European Society for Medical Oncology (ESMO)	13:55 – 14:00

HOUSE RULES

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