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Clinical cancer research across Europe: Do we need to change tracks?

What does a better future for European clinical cancer research look like? For a clearer picture of what is needed, Europe's cancer research community needs to work together to define patient-relevant outcomes that are agreed by payers and regulators – then push for the best research to deliver them.

Exchanges in this session built on the report of the European Organisation for Research and Treatment of Cancer (EORTC): Manifesto for a new approach for better medicine in Europe. The widely endorsed manifesto presents key recommendations for reforming the treatment research paradigm in Europe, including a much-needed refocusing of attention to post-market approval research, including via use of real world evidence.

Panel members discussed the key role that access to data has in driving change in research and looked at obstacles to the open exchange of results for cancer research initiatives. They also considered how Europe's clinical cancer research models can better integrate the expertise of stakeholder groups such as patients and healthcare professionals.

The EORTC Treatment Optimisation manifesto was developed in consultation with cancer stakeholder group and is actively supported by a number of MEPs. It calls for reform of the current system to use a true patient-centred approach. Research design and execution need to respond directly to patients' real-world situations – for example: by comparing and sharing data on the effectiveness of treatment options and setting processes for long-term drug safety monitoring.

KEY MESSAGE

Treatment optimisation is a key research topic that the Manifesto's authors say should be included in the upcoming Horizon Europe Research Mission.

This thinking places treatment optimisation at the core of the drug development process, and the Manifesto's authors recommend that the treatment optimisation agenda form a part of the EU's Cancer Mission.

Along with the technical and scientific complexity of cancer research, programmes also need to respond to an ever-changing epidemiological situation. For example, lessons from the tuberculosis (TB) research community's response to drug resistance hold useful lessons for their cancer colleagues.

TB's public-private-partnerships deliver combined therapies to respond rapidly to resistance. A 'PPP' approach for cancer research can look beyond one-drug and condition to bring a 360 view of the problem – speeding innovation, as data is shared by clinicians, drug developers, diagnostics specialists, patients and healthcare professionals.

Developers' future research approaches, presented by the European Federation of Pharmaceutical Industries & Associations (EFPIA), are considering four strategies:

- » Data strategy to understand and support decisions across the healthcare value chain.
- » Digital strategy to increase speed of interaction, learning and communication across stakeholder groups.
- » Deeper patient engagement, to ensure that science and development questions are seen through the patients' eyes from the outset.
- » Increased collaborative research on common topics, where developers find ways to cooperate in a non-conflictual space.

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Dr Denis Lacombe, Director General, European Organisation for Research and Treatment of Cancer (EORTC): Potential approaches for bringing new therapeutic strategies into being; proposed reforms to existing processes in Europe's regulatory environment

Dr Magda Chlebus, Executive Director of Science Policy, European Federation of Pharmaceutical Industries and Associations (EFPIA): What is required to make treatment optimisation a reality

Dr Ralf Herold, Scientific Officer, European Medicines Agency (EMA): EMA's response to evolving debates on new endpoints, continuing controversies and potential misunderstandings in this area

Panel perspectives:

Marcus Guardian, Chief Operating Officer, European Network for Health Technology Assessment (EUnetHTA)

Jo de Cock, Chief Executive Officer, National Institute of Health and Disability Insurance, Belgium

Moderators:

Dr Denis Lacombe

Roger Wilson, sarcoma survivor and patient advocate

*Dr Denis Lacombe,
Director General, European
Organisation for Research and
Treatment of Cancer (EORTC)*



The European Medicines Agency (EMA) presentation emphasised some of the possibilities that come from sharing of trial results and data. Overall, the Agency seeks to be supportive of treatment optimisation through activities it conducts in respect to post-market authorisation requirements. This means building learning processes into trial design, and encouraging research teams to rapidly capture and share their data to the benefit of all. For this sharing to work at scale, across dozens of concurrent trials in Europe, an integrated research data infrastructure is needed. However, many participants cautioned that sadly such an infrastructure remains quite lacking and that this should be addressed.

Data sharing issues sparked a lively exchange with the audience, on how to best manage data, who owns and curates it so that it is future-safe and accessible. Some suggested a European initiative, possibly linked to the European Reference Networks. Others felt that 'society' should be responsible for product and public registries of drug development data. But how to manage this? Is there an ISO standard for medical research data? These are all-important questions for the von der Leyen Commission, which has set data infrastructure for all economic sectors as a priority.

Manifesto for a new approach for better medicine in Europe. <http://bit.ly/33fiscO>

