ESMO Public Policy Webinar on the General Data Protection Regulation and its impact on clinical research

Friday 21 May, 2021

On Friday 21 May, the European Society for Medical Oncology (ESMO) hosted a Public Policy Webinar on the General Data Protection Regulation (GDPR) and its impact on clinical research. The webinar brought together policymakers, regulators, the research community, patient groups, industry and medical societies, among others.

Participants broadly agreed that, while protecting sensitive health data is highly important, more can be done to facilitate critical medical research: including through addressing the specificity of consent, ensuring uniform implementation of the Regulation across the Member States, and developing high-quality guidelines and codes of conduct.

Executive summary

- Institutional and non-institutional stakeholders agreed that the EU's General Data Protection Regulation (GDPR) framework on clinical research is not sufficiently clear and has been hampered by diverging and fragmented national interpretations. This undermines the ability to conduct critical research projects.
- It is important to harmonise implementation quickly, as fragmented frameworks make some Member States, and Europe more generally, less attractive for research, limiting patient access to screening, diagnosis, clinical trials and ultimately treatment.
- New legislative proposals (such as on Artificial Intelligence, the European Health Data Space, the Digital Services Act and the Data Governance Act) could create conflicting regulatory regimes for processing data for medical research, leading to further uncertainty, as is already the case for the GDPR's interaction with the Clinical Trials Regulation.
- Ultimately the impact of the GDPR on clinical research is a governance issue, it is a question of allowing the sharing of data for a legitimate purpose, while ensuring trust. Stakeholders must send a clear message to policymakers: the status-quo has its issues which hamper research and ultimately affect patients. There are technical responses that can be implemented, but these have to be done in a coordinated manner.
- Problems will not be solved overnight but timely and clear guidelines, codes of conduct, derogations (for example, one-time consent for biobanks) and consultations with medical researchers – among others – can help overcome the issues.

Perspectives of the EU bodies

During the webinar, it emerged that EU institutions and agencies, as well as healthcare professionals working on EU-backed projects, hold diverging views on the clarity and effectiveness of the framework set out by the GDPR, and its impact on clinical research.

There are indeed provisions in the GDPR to enable medical research: consent provides a legal basis for processing data (Article 9), one-time consent (Recital 33) was included to allow retrospective clinical trials, and further guidelines are being developed to reinforce provisions. However, this does not always translate into the certainty needed for researchers.

Case study: Researchers forced to "bet" on new approaches to registry building.

Professor Annalisa Trama is a Senior Researcher at the National Cancer Institute, Milan, and leads the development of the Starter Registry of EURACAN, the European Reference Network on Rare Adult Solid Cancers. The registry relies on data from different Member States, meaning that Professor Trama had to engage with several EU health systems, each with different interpretations of the GDPR and with different approaches to data protection. As a result, Professor Trama has to submit a different data protection assessment in each country – some of which were more reluctant to share data because of historical or cultural precedence. This divergence, and the need to conform to the most restrictive standards, meant that Professor Trama had to implement a far more elaborate and less well-tested 'federated' rather than a 'centralised' registry system to respect the different national circumstances.

Given the problems around pooling data from different countries, a necessity for research into rare diseases where population sizes are particularly small, Professor Trama was forced to "bet" on the innovative Federated Learning approach, which is less established and has been less tested.

Some of the issues clinical researchers face are a result of the design of the legislation. The GDPR includes provisions in Article 9.4 and Article 89 which allow Member States to further limit the processing of health data and derogations for personal data processed for scientific research, respectively. While guidelines are being drawn up to provide clarity, examples such as EURACAN highlight the impact of fragmented national interpretations and implementation, which is far from theoretical, and risks jeopardising entire research projects.

The European Parliament is acutely aware of this problem. Many MEPs have raised their concerns and consulted medical research organisations such as ESMO as the EU's institutions drafted the law. For many MEPs, the balance between protecting sensitive personal data and enabling medical breakthroughs from sources such as biobanks and retrospective clinical trials has not been correctly struck, and medical research is being made more difficult by the differing national interpretations, which undermine predictability, and raise administrative barriers such as those experienced by EURACAN. These problems will not be solved overnight, Parliamentarians acknowledge, but timely and clear guidelines *(see below)*, codes of conduct, derogations (for example, one-time consent for biobanks) and consultations with medical researchers can help overcome the issues.

Case study: European Medicine Agency Real-World Evidence network held up by lack of clarity.

As COVID-19 has highlighted, understanding the history of a disease, supporting R&D into new treatments, and leveraging already-available data to repurpose existing medicines is of enormous importance.

The Data Analytics and Real-World Interrogation Network (DARWIN EU) is a European Medicines Agency-led project to improve how Real-World Evidence (RWE) is used to assess the risks, benefits, and safety of medicines. It aims to set up a federated network and governance model for data holders to put data in a common model for analysis, facilitate studies, bring together expertise, and catalogue data partners to ensure high quality data.

However, the EMA is still drafting its Q&A on secondary use of data for medicines and public health which will underpin the formation of DARWIN. This Q&A is based on a definition of scientific research elaborated on in a European Data Protection Supervisor (EDPS) preliminary opinion, a Commission question to the European Data Protection Board (EDPB) on health research, and the EDPB's response. The EMA is still waiting for the final guidelines for ultimate clarification, risking holding up the finalisation of this crucial network.

Lack of clarity and harmonisation extends beyond *Member State implementation* of the GDPR: it also applies to how this regulation *interacts with other of legislation*. This comes at a time when the EU is bringing forward an array of new legislative proposals.

In the forthcoming proposal to create a European Health Data Space, the Commission is exploring the creation of a legal basis for access to and use of health data for research, policy-making and regulatory decision-making. The Proposal for a Regulation laying down harmonised rules on Artificial Intelligence, the Digital Services Act, and the Data Governance Act all aim to set the global standard on trust and will – in one way or another – impact how health and scientific data is governed. It is clear that the regulatory environment for medical research is becoming increasingly complex, and if the legislative framework is not developed in a coherent way, it will become even more difficult for Europe to remain a world leader in medical research, to continue to attract the best minds, and to develop projects which respond to innovations of tomorrow.

Case study: Rapid, international response to COVID-19 set back by GDPR.

Marina Garassino is the Chair of National Societies Committee at ESMO. Early in the COVID-19 pandemic, after noting that may lung cancer patients were dying from COVID-19, she worked to set up TERAVOLT (Thoracic CancERs international coVid 19 cOLlaboraTion), a worldwide clinical registry of 220 centres. During the first months of the project, through an Ethics Committee, TERAVOLT was able to release data on 200 patients. But because of the GDPR and international data sharing problems, only 100 centres were ultimately able to join the efforts.

One year after the pandemic began, the project was finally able to publish its paper. But by then, because of the fast-moving nature of the virus and policy response, the data was less important than at the onset of the outbreak. Europe was highly affected by the pandemic, but most of the centres who finally could join the registry were based in the United States. Clearly, the GDPR process set EU Member States and researchers at a disadvantage in responding to the virus.

This problem has already been seen with the Clinical Trials Regulation, where Article 28 allows for retrospective research within a clinical trial, but has been contradicted by EDPB guidelines on the GDPR, which undermines the intent of Recital 33 of the GDPR on one-time consent.

Conclusion: Unclear definitions and unharmonised implementations of the GDPR have created problems for medical research. Projects such as DARWIN can be delayed by lack of certainty, while EURACAN is already one year into implementation, and still subject to prohibitive administrative burden. Without addressing the impact of the GDPR on medical research, it is innovation, and ultimately the patient as TERAVOLT shows, which will suffer.

Further examples regarding the fragmented implementation of the GDPR

Non-institutional stakeholders echo many of the concerns raised by policymakers and regulators.

Stakeholders highlighted the sheer diversity of national approaches and procedures to data protection. From the different legal bases relied upon by biobanks in different countries (some rely on consent, other such as Belgium and Finland on a mixture between consent and national biobanking laws); to delegating competencies to regional level (17 regions in the case of Spain); and empowering ethics committees at national and regional (or even individual-clinic) level, Member States have taken varying paths to data protection.

Accommodating all the national viewpoints and interpretations is – as also acknowledged by institutional stakeholders – an administratively burdensome process for researchers, and one which reduces the time they spend on actual clinical research.

While no stakeholder claimed that there is one correct approach, there is a clear sense of urgency: fragmentation can lead to inequalities in Member States' abilities to conduct clinical research, making them less attractive for cooperation, which reduces patient access to screening, diagnosis, clinical trials and treatment. At a macro-level, this also harms Europe's attractiveness for research: one assessment by the Federation of European Academies of Medicine (FEAM) found that 40 cancer studies funded by the United States National Institute for Health (NIH) were stalled, delayed or directly affected because of the GDPR, with a particular impact felt by public sector research.

Noting that data protection measures are well-meaning, and that data should be stored safely, with processes subject to scrutiny, it was deemed important to ensure that these safeguards do not jeopardise research.

Stakeholders have proposed a host of solutions to address the problems: from guidance to researchers to navigate the different interpretations of the GDPR, to stronger legal instruments and clear codes of conduct for greater predictability, and even the creation of a 'scientific research data protection shield' – a code of conduct that is imposed on Member States.

Conclusions: Medical research is an understandable challenge for regulators. Research is driven by ingenuity, so change and novelty is to be expected, but flexibility must be built into data protection frameworks. Ultimately it is a governance issue: it is a question of allowing the sharing of data for a legitimate purpose, while ensuring trust. Stakeholders must send a clear message to policymakers: the status-quo has its issues which hamper research and ultimately affect patients. There are technical responses that can be implemented, but these have to be done in a coordinated manner.

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