ESMO Feedback: Report on the General Data Protection Regulation (GDPR)

The European Society for Medical Oncology (ESMO) is one of the leading professional organisations for medical oncology, with more than 35,000 members from over 172 countries. ESMO is committed to preventing new cancer cases, improving the quality of cancer care and promoting equal access to optimal treatments for all cancer patients.

Throughout its advocacy and policy work on the General Data Protection Regulation (GDPR), ESMO has continuously stressed that in order for scientific research - including oncology research - to benefit from the Regulation, it needs to be interpreted and applied appropriately and in a harmonised manner across the entire EU. Clinical research, including observational retrospective clinical research, heavily relies on health data, and without access to such data this research would be negatively affected.

Since the coming into application of the legislation, challenges have arisen with the implementation and interpretation of the GDPR across EU countries. ESMO has called for a harmonious interpretation of the GDPR in all EU Member States, and has especially stressed the importance of the uniform application of the following provisions:

- The inclusion of a withdrawable 'one-time consent' from patients allowing their data and tissues to be used, subject to strict ethical standards, for future retrospective clinical research, which will also ensure the viability of biobanking (recital 33);

- The inclusion of a 'no-consent' principle to allow research based on data from population-based disease registries in line with strict ethical standards (recital 157).

In addition, based on the day-to-day experience of medical oncologists with the GDPR, ESMO urges the European Commission to address in its report the following issues:

1. **Impact on daily work:**

    - Increased difficulty to external consultations, communication between different units, electronic medical records from other healthcare regions using other EMR systems, which can impact the delivery of high-quality cancer care for patients.
    - Additional administrative burden and cost for all studies related to clinics and cancer biology.
    - Project delays and limitations of data collection - including ethnicity, origin, race, genetics, sexual orientation - which may have negative effects on the identification of health problems, including within minority groups.

2. **Impact on cancer research:**

- Significant difficulties in cross-centre data sharing (including pseudoanonymised data) and retrospective EMR-based studies.
- Difficulties in cross-country EU collaboration - Ireland, Austria and Italy - often requiring explicit consent for retrospective translational research.
- Major increase in administrative burden, impacting efficacy on research projects.

3. **Impact on cancer registries:**

- Significant delays in the conducting of studies.

4. **Impact on cross-border cancer research projects in the European Union (EU), and involving third countries:**

- Cumbersome regulatory burdens and additional financial costs, often impacting participation in critical multi-national studies (e.g., on rare cancers) – especially when non-EU countries are involved.

5. **Proposed changes:**

- Simplify and harmonise the existing rules, as well as their interpretation, to facilitate research collaboration both within and between EU and non-EU countries, while respecting ethical principles.
- Master and facilitate agreements for multiple cancer research projects by standardising procedures across countries based on good research practice and assessments of ethics committees, including for the use of anonymized aggregate genomic data to enable effective collaboration and implementation of projects.
- Integrate clinical practice and research activities, especially in the area of consent for data use for research purposes and registries to ensure comprehensive and high-quality cancer care for patients.

ESMO continues to monitor the implementation of the GDPR across the EU - and the implications for the oncology field - and highlight the need for solutions to address fragmented interpretations.

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