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European Society for Medical Oncology

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One-time Consent: A Necessity for Pan-European Research

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ESMO: About Us

Europe's leading medical oncology society

Providing a professional network for our members & working with national societies across Europe & the world

Our motto:

Good science, better medicine, best practice

Best practice knows no borders:

Supporting & promoting excellence throughout our field for the benefit of our patients

Why have we followed the GDPR?

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REPORT

on the proposal for a regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) (COM(2012)0011 – C7-0025/2012 – 2012/0011(COD))

Committee on Civil Liberties, Justice and Home Affairs

Rapporteur: Jan Philipp Albrecht

- **Fragmented implementation of 1995 Directive across EU MS**
- **Horizontal Regulation touching across different sectors**

Result: Potential unintended consequences on medical research

Importance of Medical Research

1. **Retrospective clinical research**

   Recalling data about past patients (how they did, etc)

   Consent currently needed or not (divergent approach across EU MS)

2. **Biobanks**

   Large repositories of biological samples, including tissues and blood, used purely for research purposes

   Consent usually foreseen (data protected with strict safeguards)

3. **Epidemiological research (population-based disease registries)**

   Epidemiological research helps us to understand how many people have a disease or disorder, if those numbers are changing, and how the disorder behaves (survival, etc).

   Consent impossible

The text approved by the EU Parliament: Art 81

*1b. Where the data subject's consent is required for the processing of medical data exclusively for public health purposes of scientific research, **the consent may be given for one or more specific and similar researches**. However, the data subject may withdraw the consent at any time.*

*2a. **Member States law may provide for exceptions to the requirement of consent for research**, as referred to in paragraph 2, with regard to research that serves a **high public interest**, if that research cannot possibly be carried out otherwise.*

*The data in question shall be anonymised, or if that is not possible for the research purposes, pseudonymised under the highest technical standards, and all necessary measures shall be taken to prevent unwarranted re-identification of the data subjects. However, the data subject shall have the **right to object** at any time in accordance with Article 19.*

Limitations of EP text

1. **“specific consent” required every single time new research is carried out on existing patient data**
   - **Impact**: researchers will have to re-consent a patient every single time they use patient data for research purposes, putting at stake retrospective clinical research and biobanking; expensive, burdensome, intrusive for patients, in practice unfeasible, especially for academic research.

2. **“right to object”:**
   - **Impact**: As population-based disease registries work on the basis that the data has to be ‘all inclusive’, the opt-out option being made available to the patient will put the survival of the vital repositories of data in jeopardy.

3. **“high public interest”**
   - **Impact**: MS may derogate from the consent provisions only if the “research serves a high public interest”. How do you define high public interests? The lack of a definition will lead to a fragmented implementation of the Regulation.

Solution: one-time consent

One-time consent is an **informed consent** that aims to provide the patient with the **option of donating their data** exclusively for health research, **protected by strict ethical safeguards,** along with the option to **withdraw their consent** at any time and possibly also to narrow their consent if they will

Concept endorsed by leading cancer organisations, patient Organisations, scientific organisations

Concept already present in Clinical Trials Regulation

Need for Harmonization between the two

Consent and medical research: What we need in the GDPR (Council Position)

Retrospective clinical research (recital 25aa)

→ *one-time consent ("donation" of data)*

Biobanks (recital 25aa)

→ *one-time consent ("donation" of tissues)*

Epidemiological research (Cancer Registries) (125aa)

→ *derogation from consent obligation*

*Recitals 25aa and 125aa are crucial as **they offer clarifications** for those MS with restrictive interpretations of the GDPR – specifically on health Research*

IMPACT: Harmonious interpretation of GDPR across all EU Member States

Risks of the new EU Data protection regulation: an ESMO position paper endorsed by the European oncology community

recommendations

In summary, patients should have the right to 'donate' their data and tissues to health research. Patient consent for use of data or tissue for health research should be a fully informed, withdrawable, more or less broad, 'one-time' process, which truly implements the patients' rights, rather than creating burdensome, possibly harmful consequences to the patients' community. The patient shall retain access to the tissue and data donated, hence ensuring him/her to obtain relevant information related to his/her condition. On the contrary, denial of this right would make patients less free, because they would be denied a civil right, i.e. to contribute to research, which advances knowledge and leads to new ways of improving their health and that of other patients. There need to be put in place legal provisions to protect data confidentiality, reviewing mechanisms to oversee retrospective researches and biobanks, and a system allowing full transparency of research processes and storage of patient tissue in biobanks. Cancer registries should be able to register cancer cases and patient data without the requirement of patient consent, in order to provide society and health administrators with exhaustive health data for public health policy decisions.

The European cancer community urges all EU decision makers to save research, as well as to protect the right of patients to donate their data and tissues to advance research and find cures. EU decision makers are urged to change the European Parliament Amendments 191 and 194 to Articles 81 and 83, as they would impair public health research within and across EU Member States. A balance between the right to privacy and the right to health can be achieved by reasonably addressing all concerns, while fully complying with those relating to confidentiality and ethical use of personal health data.

endorsements

This ESMO position paper on the EU General Data Protection Regulation is endorsed by the following organisations, and under review for endorsement by additional organisations:

European Organization for Research and Treatment of Cancer

European, Middle Eastern & African Society for Biopreservation and Biobanking

Eurocan Platform

European Society of Surgical Oncology

European Society of Pediatric Oncology

European CanCer Organisation

European Cancer Patient Coalition

European SocieTy for Radiotherapy & Oncology

Association of European Cancer Leagues (ECL)

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Thank you!

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