Dear Sirs,

As president of "EVITA Association – Hereditary Cancer", ePAG at ERN GENTURIS and patient expert in hereditary cancer and a representative of families living with inherited cancer risk, I welcome the EDPB's efforts to clarify the GDPR provisions on scientific research. These Guidelines are essential to ensure that personal data, especially genetic and health data, are processed with respect for fundamental rights. At the same time, they must enable the type of research that **saves lives**, particularly in the field of hereditary cancer, where early detection and prevention are uniquely effective.

Hereditary cancer syndromes such as Lynch syndrome and BRCA-related cancers are **predictable, preventable, and treatable**, but only when data can be used to identify risk, guide surveillance, and support research. Restrictive or fragmented interpretations of the GDPR have already delayed research, limited cross-border collaboration, and hindered the development of evidence-based prevention pathways.

Below I outline key points where the Guidelines could better support responsible, high-value data use for hereditary cancer research, while maintaining strong safeguards.

1. Recognise hereditary cancer research as a high-public-interest domain

Hereditary cancer is one of the clearest examples of research that directly prevents disease, reduces mortality, and benefits entire families and populations. The Guidelines should explicitly acknowledge that:

- Research on hereditary cancer **meets the criteria of genuine scientific research** as defined in the six key-indicative factors.
- Processing genetic and health data for hereditary cancer research is **inherently in the public interest**, given its proven impact on early detection and prevention.
- Public-interest legal bases (Article 6(1)(e)) and Article 9(2)(i)/(j) derogations should be interpreted in a way that **facilitates cross-border research** and registry-based studies.

This would help reduce the current uncertainty faced by researchers, ethics committees, and patient organisations.

2. Strengthen the Guidelines' support for long-term, multi-generational data use

Hereditary cancer research requires **longitudinal data**, often across decades and generations. The Guidelines already recognise that storage limitation can be adapted for scientific research, but they should go further by:

- Explicitly acknowledging that **multi-generational data retention** is necessary for hereditary cancer research.

Avenida António Augusto Aguiar, 15-3º Esq • 1050-012 Lisboa • T +351 935 049 027 • info@evitacancro.org

- Clarifying that long-term storage is justified when it enables **cascade testing**, **risk prediction**, and **evaluation of surveillance outcomes**.
- Encouraging Member States to adopt harmonised rules for long-term retention of genetic and clinical data in hereditary cancer registries.

This aligns with the EDPB's own statement that research registries "improve the quality of life for a number of people".

3. Support responsible data sharing across borders and infrastructures

Hereditary cancer families often span multiple countries. Research consortia such as ERN GENTURIS, PREDI-LYNCH, DISARM and SHIELD depend on **cross-border data flows**, yet inconsistent interpretations of GDPR provisions create barriers.

The Guidelines should:

- Encourage **interoperable, secure research infrastructures** for genetic and clinical data.
- Clarify that pseudonymised genetic data can be shared for scientific research under Article 89(1) with appropriate safeguards.
- Promote **federated data access models** that protect privacy while enabling analysis.
- Emphasise that controllers should not default to restrictive interpretations that block collaboration.

This would support the European Research Area and the goals of the Cancer Mission.

4. Clarify the role of broad and dynamic consent in hereditary cancer research

Families affected by hereditary cancer overwhelmingly support research participation. Broad and dynamic consent are essential tools for enabling this participation while respecting autonomy.

The Guidelines should:

- Affirm that **broad consent** is appropriate when research evolves over time (e.g., new biomarkers, AI-based risk models).
- Encourage **dynamic consent** as a patient-empowering mechanism that increases transparency and trust.
- Recognise that hereditary cancer research often involves **multiple related studies**, making rigid purpose specification impractical.

This aligns with ethical standards and with the lived experience of families who want their data to contribute to prevention.

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5. Address the family dimension of genetic data more explicitly

Genetic data is unique because it affects not only individuals but also their biological relatives. The Guidelines should:

- Acknowledge that hereditary cancer research requires **family-based data structures**.
- Encourage controllers to adopt transparent communication strategies that explain familial implications.
- Support ethical frameworks for **recontact**, **cascade testing**, and **family-centred prevention**.

This would help align data protection with public health and clinical genetics practice.

6. Promote harmonisation to reduce fragmentation across Member States

Currently, divergent national rules on genetic data, biobanks, and research derogations create uncertainty and slow down scientific progress. The Guidelines should:

- Encourage Member States to adopt **consistent interpretations** of Articles 6 and 9 for scientific research.
- Highlight the need for **harmonised safeguards** for genetic data processing.
- Support alignment with the European Health Data Space (EHDS) to avoid parallel, conflicting regimes.

This would significantly improve the feasibility of EU-wide hereditary cancer research.

Conclusion: A call for balanced, enabling, and protective guidance

Families affected by hereditary cancer want their data to be used responsibly but they also want it to be used **effectively**. The GDPR already provides a robust framework for protecting rights. The EDPB Guidelines should ensure that this framework is applied in a way that **enables life-saving research**, rather than unintentionally restricting it.

By strengthening support for long-term data use, cross-border collaboration, broad and dynamic consent, and family-centred approaches, the EDPB can help Europe lead the world in hereditary cancer prevention and early detection.

Date and Signature:
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Tamara M. Milagre