

# INTRODUCTION

**Paolo G. Casali, MD**

*Chair*

*ESMO European Policy Committee*



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)**



EUROPEAN PARLIAMENT

2009 - 2014

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*Plenary sitting*

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**A7-0402/2013**

21.11.2013

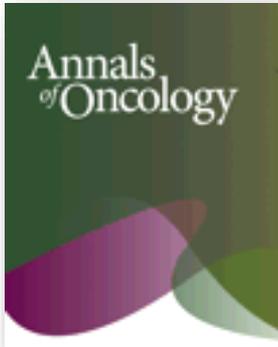
**\*\*\*I**

**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



## 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

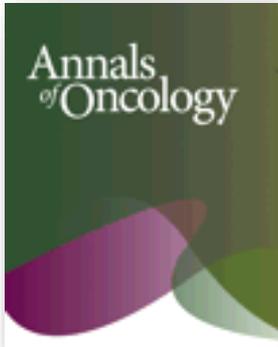


European Society for Radiotherapy & Oncology



Association of European Cancer Leagues (ECL)





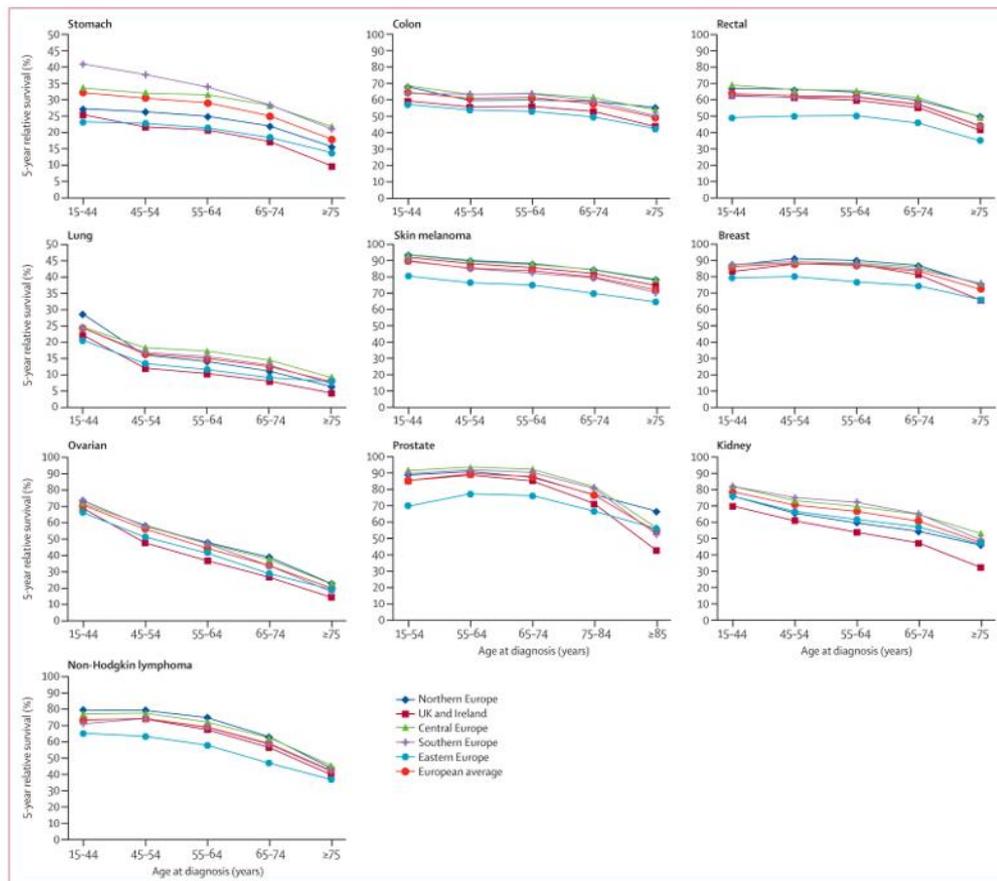
**Risks of the new EU Data protection regulation: an ESMO position paper endorsed by the European oncology community**

- **Retrospective clinical research**  
→ **one-time consent**
  
- **Biobanks**  
→ **one-time consent**
  
- **Cancer registries**  
→ **consent derogation**

# Cancer survival in Europe 1999–2007 by country and age: results of EURO CARE-5—a population-based study



Roberta De Angelis, Milena Sant, Michel P Coleman, Silvia Francisci, Paolo Baili, Daniela Pierannunzio, Annalisa Trama, Otto Visser, Hermann Brenner, Eva Ardanaz, Magdalena Bielska-Lasota, Gerda Engholm, Alice Nennecke, Sabine Siesling, Franco Berrino, Riccardo Capocaccia, and the EURO CARE-5 Working Group\*



Lancet Oncol 2014; 15: 23-34

# Cancer registration, public health and the reform of the European data protection framework: Abandoning or improving European public health research?

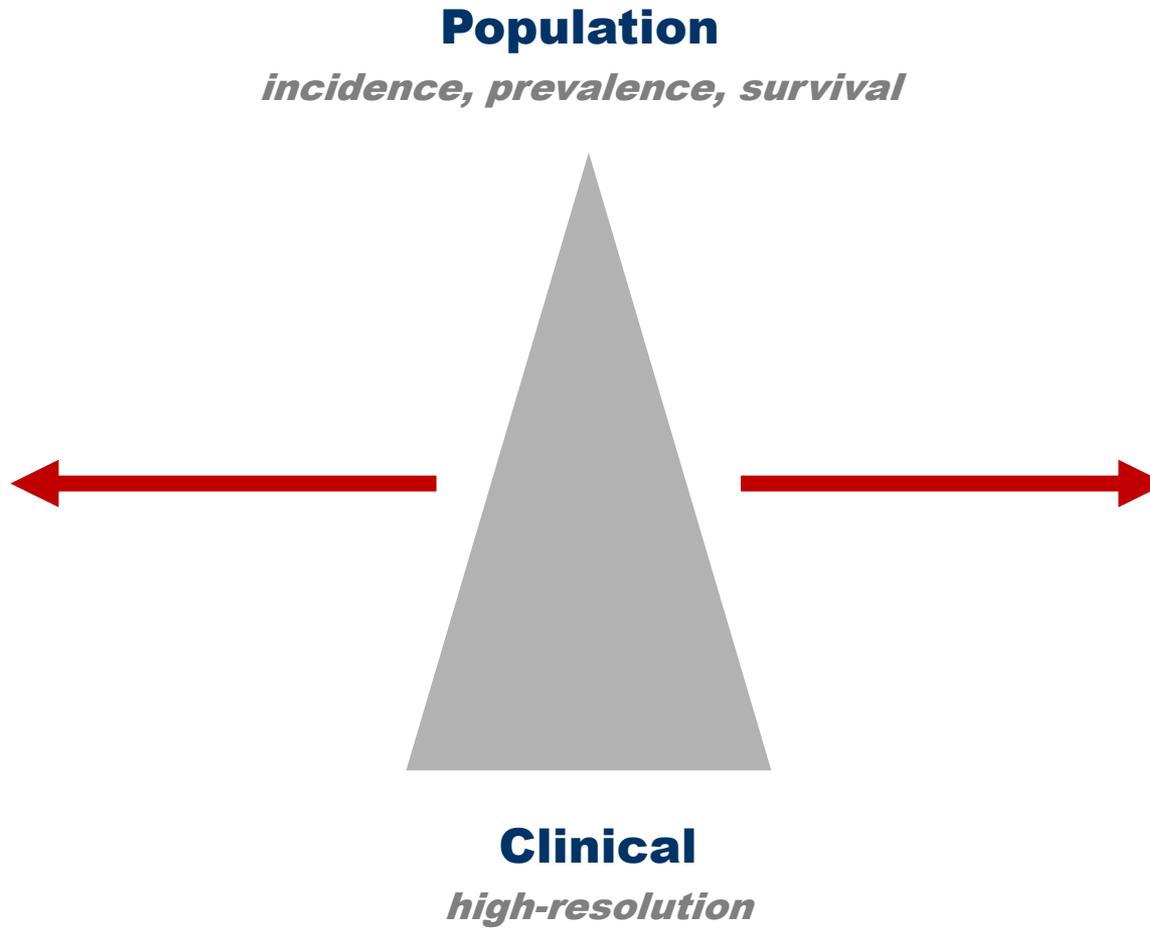
Mette Rye Andersen <sup>\*</sup>, Hans H. Storm, on behalf of the Eurocourse Work Package 2 Group

Consequences of explicit consent to register-based research [45].

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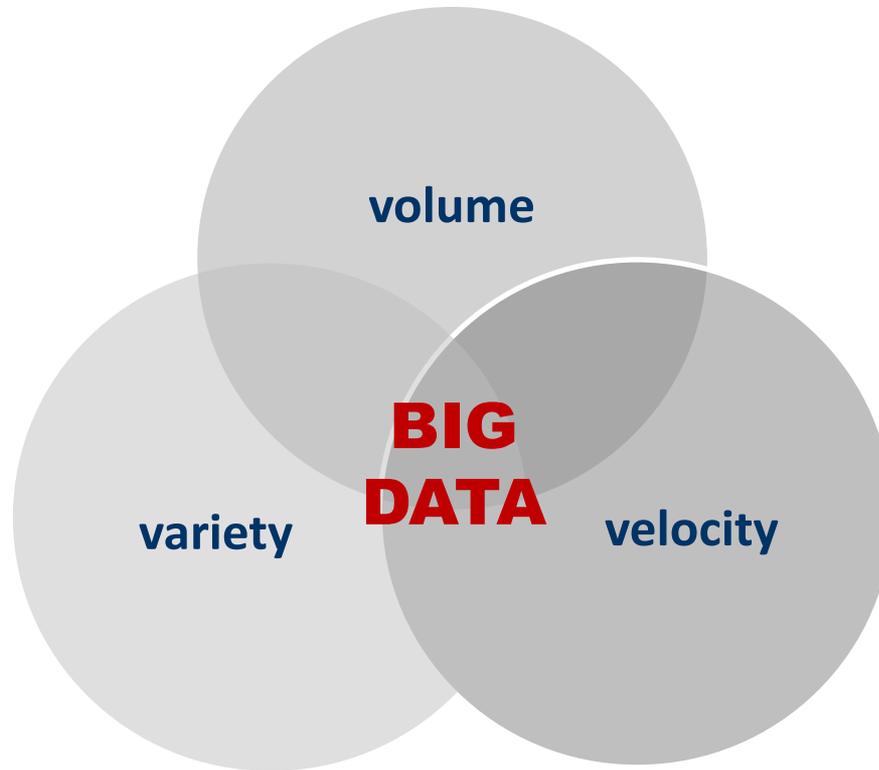
- Studies involve analysis of tens or hundreds of thousands of cases in order to gain coverage and statistical power. The practical burden of seeking consent would be disproportionate, lead to inefficient use of public funds for research and in long-term be deleterious to the public's health.
  - Exclusion of deceased data subjects introduces a significant selection bias, while inclusion cannot harm the data subject.
  - Repeated burden for patients/ relatives being asked to consent is of concern.
  - Low response rates leads to biased research results.
  - Seeking general consent imposes unacceptable work load on medical personnel and low completeness of cancer registration.
  - From a strict legal point of view, consent only remains valid for a limited period of time. Not possible to foresee future research questions.
  - Incompleteness of registration as a result of differences in the manner in which consent is sought or given invalidates international comparisons.
  - Documented differences between individuals who consent to participation in research and those who do not, entailing disastrous selection bias [40].
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# Registries



# Electronic health records





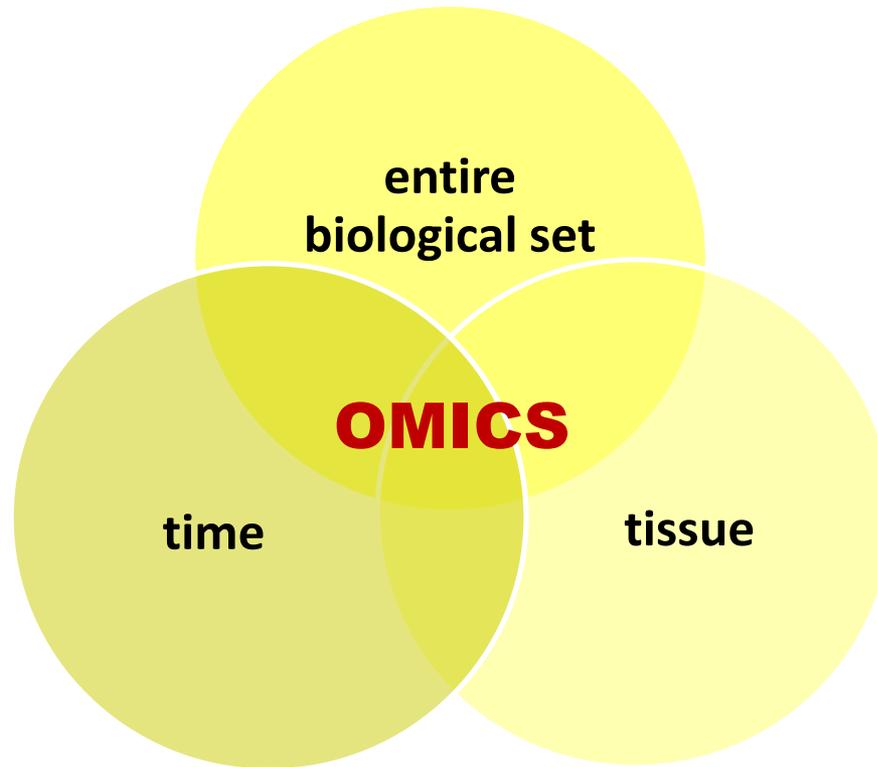


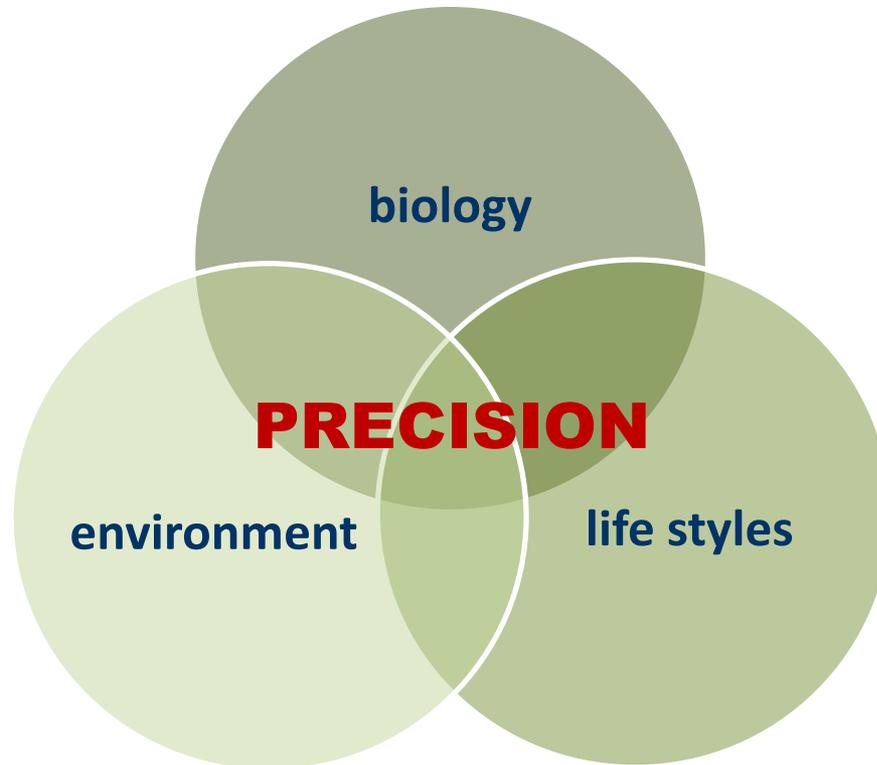
Brussels, 3.2.2021  
COM(2021) 44 final

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN  
PARLIAMENT AND THE COUNCIL**

**Europe's Beating Cancer Plan**

{SWD(2021) 13 final}





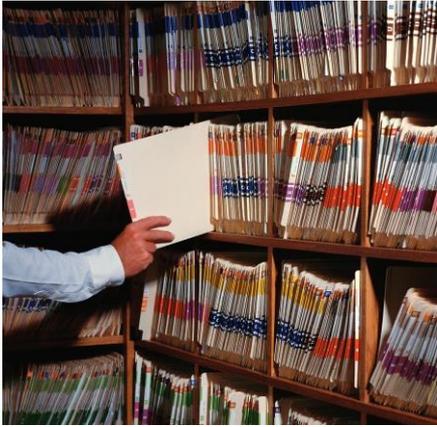
## TECHNOLOGY FEATURE

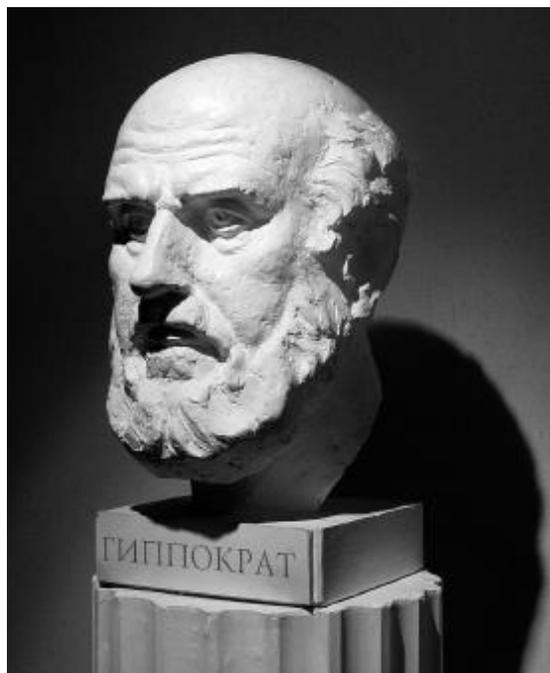
# BUILDING BETTER BIOBANKS

*High-quality, data-rich samples are essential for future research. But obtaining and storing these samples is not as straightforward as many researchers think.*

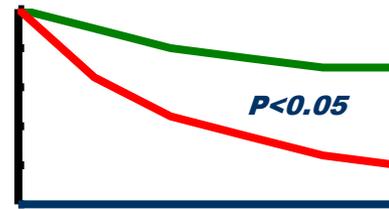
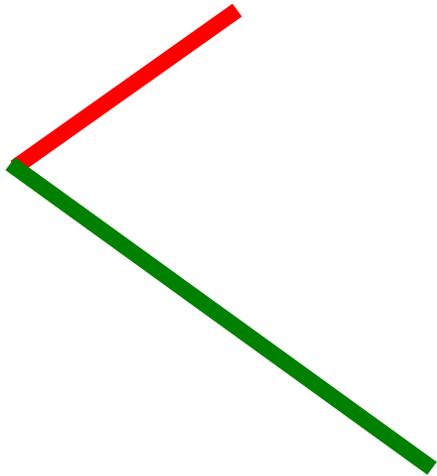


L. RUBENSTEIN/BIOPAD INST.  
Larger biobanks have invested in automated storage and retrieval systems to track samples and ensure that they are maintained at a constant temperature.





**R**



# Clinical research



**retrospective**

- **observational**



**prospective**

- **interventional**
- **observational**



**a «specific»  
re-consent?**



# **The Value of Banked Samples for Oncology Drug Discovery and Development**

Peter M. Shaw, Scott D. Patterson

**Correspondence to:** Scott D. Patterson, PhD, Medical Sciences, Amgen Inc., One Amgen Center Dr, MS 38-3-A, Thousand Oaks, CA 91320-1799 (e-mail: spatters@amgen.com).

To gain insights into human biology and pathobiology, ready access to banked human tissue samples that encompass a representative cross section of the population is required. For optimal use, the banked human tissue needs to be appropriately consented, collected, annotated, and stored. If any of these elements are missing, the studies using these samples are compromised. These elements are critical whether the research is for academic or pharmaceutical industry purposes. An additional temporal element that adds enormous value to such banked samples is treatment and outcome information from the people who donated the tissue. To achieve these aims, many different groups have to work effectively together, not least of which are the individuals who donate their tissue with appropriate consent. Such research is unlikely to benefit the donors but others who succumb to the same disease. The development of a large accessible human tissue bank resource (National Cancer Institute's Cancer HUman Biobank [caHUB]) that provides an ongoing supply of human tissue for all working toward the common goal of understanding human health and disease has a number of advantages. These include, but are not limited to, access to a broad cross section of healthy and diseased populations beyond what individual collections may achieve for understanding disease pathobiology, therapeutic target discovery, as well as a source of material for diagnostic assay validation. Models will need to be developed to enable fair access to caHUB under terms that enable appropriate intellectual property protection and ultimate data sharing to ensure that the biobank successfully distributes samples to a broad range of researchers.

J Natl Cancer Inst Monogr 2011;42:46-49

# The «one-time» consent



- **informed**
- **withdrawable**
- **patient-tailored**
- **subject to ethical scrutiny**
- **subject to any new laws/rules**
- **.....**

# REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 April 2016

on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

(Text with EEA relevance)

## One time consent

- (33) It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.

## Derogation from consent when data is being used from population-based disease registries

- (157) By coupling information from registries, researchers can obtain new knowledge of great value with regard to widespread medical conditions such as cardiovascular disease, cancer and depression. On the basis of registries, research results can be enhanced, as they draw on a larger population. Within social science, research on the basis of registries enables researchers to obtain essential knowledge about the long-term correlation of a number of social conditions such as unemployment and education with other life conditions. Research results obtained through registries provide solid, high-quality knowledge which can provide the basis for the formulation and implementation of knowledge-based policy, improve the quality of life for a number of people and improve the efficiency of social services. In order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards set out in Union or Member State law.

**REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**of 16 April 2014**  
**on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC**  
**(Text with EEA relevance)**

Whereas:

- (29) It is appropriate that universities and other research institutions, under certain circumstances that are in accordance with the applicable law on data protection, be able to collect data from clinical trials to be used for future scientific research, for example for medical, natural or social sciences research purposes. In order to collect data for such purposes it is necessary that the subject gives consent to use his or her data outside the protocol of the clinical trial and has the right to withdraw that consent at any time. It is also necessary that research projects based on such data be made subject to reviews that are appropriate for research on human data, for example on ethical aspects, before being conducted.

CHAPTER V

PROTECTION OF SUBJECTS AND INFORMED CONSENT

Article 28

General rules

2. Without prejudice to Directive 95/46/EC, the sponsor may ask the subject or, where the subject is not able to give informed consent, his or her legally designated representative at the time when the subject or the legally designated representative gives his or her informed consent to participate in the clinical trial to consent to the use of his or her data outside the protocol of the clinical trial exclusively for scientific purposes. That consent may be withdrawn at any time by the subject or his or her legally designated representative.

The scientific research making use of the data outside the protocol of the clinical trial shall be conducted in accordance with the applicable law on data protection.

**Article 29 Working Party**  
**Guidelines on consent under Regulation 2016/679**  
Adopted on 28 November 2017  
As last Revised and Adopted on 10 April 2018

Recital 33 seems to bring some flexibility to the degree of specification and granularity of consent in the context of scientific research. Recital 33 states: *"It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose."*

First, it should be noted that Recital 33 does not disapply the obligations with regard to the requirement of specific consent. This means that, in principle, scientific research projects can only include personal data on the basis of consent if they have a well-described purpose. For the cases where purposes for data processing within a scientific research project cannot be specified at the outset, Recital 33 allows as an exception that the purpose may be described at a more general level.

Considering the strict conditions stated by Article 9 GDPR regarding the processing of special categories of data, WP29 notes that when special categories of data are processed on the basis of explicit consent, applying the flexible approach of Recital 33 will be subject to a stricter interpretation and requires a high degree of scrutiny.

When regarded as a whole, the GDPR cannot be interpreted to allow for a controller to navigate around the key principle of specifying purposes for which consent of the data subject is asked.

When research purposes cannot be fully specified, a controller must seek other ways to ensure the essence of the consent requirements are served best, for example, to allow data subjects to consent for a research purpose in more general terms and for specific stages of a research project that are already known to take place at the outset. As the research advances, consent for subsequent steps in the project can be obtained before that next stage begins. Yet, such a consent should still be in line with the applicable ethical standards for scientific research.

Moreover, the controller may apply further safeguards in such cases. Article 89(1), for example, highlights the need for safeguards in data processing activities for scientific or historical or statistical purposes. These purposes *"shall be subject to appropriate safeguards, in accordance with this regulation, for the rights and freedoms of data subject."* Data minimization, anonymisation and data security are mentioned as possible safeguards.<sup>71</sup> Anonymisation is the preferred solution as soon as the purpose of the research can be achieved without the processing of personal data.

Transparency is an additional safeguard when the circumstances of the research do not allow for a specific consent. A lack of purpose specification may be offset by information on the development of the purpose being provided regularly by controllers as the research project progresses so that, over time, the consent will be as specific as possible. When doing so, the data subject has at least a basic understanding of the state of play, allowing him/her to assess whether or not to use, for example, the right to withdraw consent pursuant to Article 7(3).<sup>72</sup>

Also, having a comprehensive research plan available for data subjects to take note of, before they consent could help to compensate a lack of purpose specification.<sup>73</sup> This research plan should specify the research questions and working methods envisaged as clearly as possible. The research plan could also contribute to compliance with Article 7(1), as controllers need to show what information was available to data subjects at the time of consent in order to be able to demonstrate that consent is valid.

It is important to recall that where consent is being used as the lawful basis for processing there must be a possibility for a data subject to withdraw that consent. WP29 notes that withdrawal of consent could undermine types scientific research that require data that can be linked to individuals, however the GDPR is clear that consent can be withdrawn and controllers must act upon this – there is no exemption to this requirement for scientific research. If a controller receives a withdrawal request, it must in principle delete the personal data straight away if it wishes to continue to use the data for the purposes of the research.<sup>74</sup>

**EDITORIAL**

**Data protection and research in the European Union: a major step forward, with a step back**

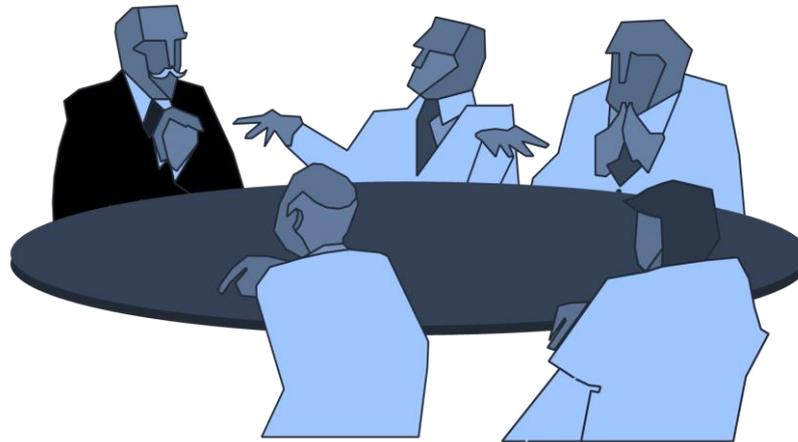
- GDPR Recital 33 should be acknowledged as a means to guarantee, in all EU Member States, that patients **have the right to provide**, if willing, **a withdrawable 'one-time consent'** to using their data and/or biological samples for future retrospective research, under the scrutiny of appropriate reviewing bodies (institutional review boards and/or ethics committees);
- GDPR Recital 157 should be acknowledged as a means to guarantee that in all EU Member States, **population-based disease registries, including cancer registries**, are allowed to operate with a **'no-consent' policy** under the supervision of relevant public health bodies;
- Recital 29 and Article 28 (2) of the CTR should be implemented across the EU 27 to give patients enrolled in a clinical trial the right to consent that their data to be used retrospectively beyond the end and scope of the trial for future research.

Endorsements	
European Organisation for Research and Treatment of Cancer	 The future of cancer therapy
European Society of Surgical Oncology	 THE EUROPEAN SOCIETY OF SURGICAL ONCOLOGY
European Society for Paediatric Oncology	 SIOP Europe The European Society for Paediatric Oncology
European Society for Radiotherapy and Oncology	
European Cancer Patient Coalition	 European Cancer Patient Coalition
Association of European Cancer Leagues (ECL)	 Association of European Cancer Leagues

# A withdrawable informed consent...



# An ethical approval of any future research...



# Available online information on future research...





# ESMO PUBLIC POLICY WEBINAR ON THE GENERAL DATA PROTECTION REGULATION AND ITS IMPACT ON CLINICAL RESEARCH

**Date:** Friday 21 May 2021  
**Time:** 13:00 – 15:30 CEST

**Moderators:** Paolo G. Casali and Rosa Giuliani



Topic	Speaker	Organization	Time
<b>Part 1: Perspectives on the GDPR and its impact on clinical research</b>			
<b>Introduction</b>	Paolo G. Casali	European Society for Medical Oncology (ESMO)	13:00 – 13:15
<b>European Commission's perspective</b>	Owe Langfeldt	European Commission	13:15 – 13:25
<b>Regulator's perspective</b>	Sabine Brosch & Orsolya Eotvos	European Medicines Agency (EMA)	13:25 – 13:35
<b>ERN EURACAN - STARTER: Starting an Adult Rare Tumor European Registry</b>	Annalisa Trama	European Reference Network on Rare Adult Solid Cancers (ERN EURACAN)	13:35 – 13:45
<b>Wrap-up</b>	Rosa Giuliani	European Society for Medical Oncology (ESMO)	13:45 – 13:55

Topic	Speaker	Organization	Time
<b>Part 2: Town Hall – Moderated by Paolo G. Casali &amp; Marina Garassino</b>			
<b>14:00 – 15:00</b>			
<b>Town Hall</b>	Marina Garassino	European Society for Medical Oncology (ESMO)	
	MEP Alessandra Moretti	European Parliament	
	MEP Peter Liese	European Parliament	
	MEP Eva Maydell	European Parliament	
	MEP Seán Kelly	European Parliament	
	MEP Tomislav Sokol	European Parliament	
	Dirk Arnold & Annalen Bleckmann	German Society for Haematology and Medical Oncology (DGHO)	
	Miguel Angel Segui-Palmer	Spanish Society of Medical Oncology (SEOM)	
	Rui Medeiros	Association of European Cancer Leagues (ECL)	
	Antonella Cardone	European Cancer Patient Coalition (EPC)	
	Michaela T. Mayrhofer	Biobanking and Biomolecular Resources Research Infrastructure – European Research Infrastructure Consortium (BBMRI-ERIC)	
	Roxanna Albu	European Organisation for Research and Treatment of Cancer (EORTC)	
	Rosa Castro	Federation of European Academies of Medicine (FEAM)	
	Denis Horgan	European Alliance for Personalised Medicine (EAPM)	
	Brendan Barnes	European Federation of Pharmaceutical Industries and Associations (EFPIA)	
<b>Discussion and Q&amp;A</b>	All		15:00 – 15:25
<b>Conclusion and closing remarks</b>	Paolo G. Casali & Marina Garassino	European Society for Medical Oncology (ESMO)	15:25 – 15:30



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