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POLICY DEPARTMENT **A**
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Data Saves Lives: The Impact of the Data Protection Regulation on Personal Data Use in Cancer Research

Study for the ENVI Committee

Data Saves Lives: The Impact of the Data Protection Regulation on Personal Data Use in Cancer Research

DIRECTORATE GENERAL FOR INTERNAL POLICIES
POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY

WORKSHOP

Data Saves Lives: The Impact of the Data Protection Regulation on Personal Data Use in Cancer Research

Brussels, 19 November 2015

PROCEEDINGS

Abstract

This report summarises the presentations and discussions of the workshop on data saves lives, held at the European Parliament in Brussels on Thursday 19 November 2015. The aim of the workshop was to provide background information and advice regarding the proposed General Data Protection Regulation and the impact it may have on the use of personal health data in cancer research.

During the first part of the workshop the policy context and state of play of the proposed new Regulation were presented. An update on the Trilogue discussions and latest amendments to the text of the Regulation were given; obstacles and opportunities for harmonisation of cancer data were also discussed.

The second part of the workshop focused on the impact of the proposed Regulation on cancer research. Access to data, ethical standards, data storage, and a European project on cancer survival were covered during this session. All presentations highlighted the need for a broad consent (a one-time consent given by data subjects to allow the use of their data for a variety of research studies which are subject to strict criteria) in order to make cancer research possible.

Finally, future developments based on the experience of healthcare providers, patients and the industries were discussed. Possible practical solutions were given that could solve the obstacles of the proposed Regulation faced by the cancer research community.

This workshop and the respective document were prepared by Policy Department A at the request of the Committee on Environment, Public Health and Food Safety.

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LIST OF ABBREVIATIONS

BBMRI	Biobanking and BioMolecular resources Research Infrastructure
BBMRI-ERIC	Biobanking and BioMolecular resources Research Infrastructure – European Research Infrastructure Consortium
BD4BO	Big Data for Better Outcomes project
CIOMS	Council for International Organizations of Medical Sciences
DG ENVI	Directorate General for the Environment
DG SANTE	Directorate General for Health and Food Safety
DPA	Data Protection Authority
EC	European Commission
ECIS	European Cancer Information System
ECO	European Cancer Observatory
EFPIA	European Federation of Pharmaceutical Industries and Associations
ENCCA	European Network for Cancer Research in Children and Adolescents
ENCR	European Network of Cancer Registries
EORTC	European Organisation for Research and Treatment of Cancer
ERA	European Research Area
ESMO	European Society for Medical Oncology
EU	European Union
EUPID	European Unified Patient Identity
EUROCARE	European cancer registry based study on survival and care of cancer patients
ExPO-r-Net	Paediatric Oncology European Reference Network
IACR	International Association for Cryptologic Research
IARC	International Agency for Research on Cancer
IEA	International Epidemiological Association
IHCP	Institute for Health and Consumer Protection

- IT** Information Technology
- JRC** Joint Research Centre
- MEP** Member of European Parliament
- RARECARE** Surveillance of Rare Cancers in Europe
- SIOPE** European Society for Paediatric Oncology
- WHO** World Health Organisation

EXECUTIVE SUMMARY

On 19 November 2015 the Committee on the Environment, Public Health and Food and Safety (ENVI) of the European Parliament held a workshop on “Data saves lives: The impact of the Data Protection Regulation on personal data use in cancer research”. The workshop was hosted by Mr Alojz PETERLE (MEP), co-chair of the Health Working Group within the European Parliament’s Committee on Environment, Public Health and Food Safety (ENVI).

Mr PETERLE opened by saying that the aim of the workshop was to provide an update on the process of the Trilogue negotiations on the proposed General Data Protection Regulation and to discuss how personal data are used in health research.

In the first part of the workshop, Ms LAURISTIN (MEP), shadow rapporteur of the General Data Protection Regulation, presented the main outcomes of the Trilogue negotiation, which is nearing conclusion. She explained that the current text of the Regulation includes provisions from the existing Directive (95/46/EC) and ensures a good balance between the protection of individual data and restrictions in the work of medical professionals and medical science. She stressed the importance of informing data subjects and of having strict safeguards, including technological safeguards, regarding archiving personal data.

Dr CROCETTI from the Institute for Health and Consumer Protection at JRC explained that cancer researchers often link personal data to the patients sharing their data (data subjects) to ensure high data quality, for example, to avoid duplication. He is in favour of an improved Data Protection Regulation, as it will lead to common rules and will harmonise procedure across Member States. However, he also expressed his concerns regarding the provisions on the ‘explicit patient consent’ and ‘pseudonymisation’ which will affect the use of historical data and potentially limit retrospective and epidemiological studies.

During the second part of the workshop, challenges and options based on the perspectives of scientific researchers were discussed. According to Dr STORM (Danish Cancer Society) access to data for health research is already heavily regulated to guarantee secrecy and confidentiality. He was also against the ‘explicit patient consent’ for the use of personal data for every new study as proposed by the new Regulation: asking permission from several hundred thousand patients to use their data would be unmanageable and expensive. Also, explicit consent would lead to an unrepresentative group of study subjects, as cancer patients are more likely to share their data than non-patients.

Prof. REICHEL, representing BBMRI-ERIC, described how personal data are stored in bio banks in Europe and how bio banks in different Member States are connected to each other to facilitate cooperation in research. According to Prof. REICHEL there is a need for updated and coherent rules on data protection in Europe that could facilitate cross-border research within the European Research Area. However, she also stressed the need for proportionate and well-defined exemptions to allow researchers to (re-)use data over time.

Dr GATTA presented experiences from EUROCARE’s research projects. She presented the large disparity in cancer survival rates in Europe, which could be reduced thanks to more cancer research. She also expressed her worries that the proposed Regulation might impede population-based research and suggested an exemption from patient consent to permit the collection of complete, accurate, and high quality data.

The third part of the workshop focused on the experiences of healthcare providers, patients and the industry. Prof. LADENSTEIN presented the work of the European Reference Network for Paediatric Oncology, an experts' network aiming to reduce inequalities in childhood cancer survival and healthcare capabilities in Europe. Prof. LADENSTEIN stressed that much is already being done to protect the safety and privacy of personal data and that it can be further improved with the use of new technology.

Mr STEPHENS, a cancer survivor, presented the views of patients. He explained that generally cancer patients are very willing to take part in research and donate their data, not only because it helps improve their own and other patients' cancer survival rates, but also because their data can be used in future studies. Further, he believed cancer patients should be actively involved in decisions regarding the use of their personal data.

According to Mr BARNES, representing the pharmaceutical industry (EFPIA), the use of health data is critical for the industry to gain a better understanding of cancer and ultimately improve prevention, diagnosis and intervention. He also cited a research project EFPIA was involved in that investigates how the industry can use big data to improve outcomes for patients. The project looks at whether additional factors such as whether a medicine has to be placed on the market, how much the medicine is worth, and whether the medicine is effective, should all be regulated in one single framework.

The last speaker, Dr CASALI (ESMO), acknowledged the importance of safeguards regarding personal data and proposed a 'one-time consent' for cancer research so that data can be used beyond the scope of the research without strict limitation and costly administrative burdens.

During the question and answer session, the topic was heavily debated although most of the participants shared the speakers' concerns regarding 'explicit patient consent'. MEP SCHALDEMOSE and Ms LADENSTEIN questioned whether the current draft of the Regulation still requires citizens and patients to give consent for each new study as in the original proposal. Ms LAURISTIN answered that this will not be the case for medical research; once the data subject gives consent, the personal data can be used for wider research and across borders. However, she also stressed that data subjects have to be well informed about the storage and data processing, in the name of public interest.

In his closing remarks, Mr PETERLE expressed contentment that the Regulation seems to be balanced regarding data protection and medical research. He agreed that everything should be done in the public interest, especially engaging the participation of patients and citizens. Now that the Trilogue is coming to an end, Mr PETERLE is optimistic that the Regulation will benefit all patients, researchers and professionals.

1. LEGAL AND POLICY BACKGROUND

The principal EU legal instrument concerning data protection is Directive 95/46/EC¹ on the protection of individuals with regard to the processing of personal data and on the free movement of such data (*Data Protection Directive*). In the context of this Directive, personal data refers to “any information relating to an identified or identifiable natural person (*‘data subject’*); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity”.

Article 8 of the General Data Protection Directive lists special categories of data that Member States should prohibit to process as a rule. This provides data subjects the right to private and family life. One of the categories is “*data concerning health*”. Exceptions to the general prohibition include consent from the patient and cases where “*processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services*” and is processed by a health professional or by another person also subject to an obligation of secrecy.

In 2012, in light of globalisation and the rapid technological changes, the European Commission (DG Justice and Consumers in lead) proposed a new General Data Protection Regulation (5853/12)² with the aim of modernising and replacing the current legal framework by enhancing the level of personal data protection for individuals and by increasing business opportunities in the digital single market. In parallel with the proposal for a General Data Protection Regulation, the Commission adopted a policy communication setting out the Commission's objectives (5852/12)³ and a Directive on data processing for law enforcement purposes (5833/12)⁴.

In March 2014, the European Parliament adopted a legislative Resolution⁵ on the Commission's proposal for a Regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data, in which it proposed various amendments. On 15 June 2015, the Council reached a general approach on the proposal by the European Commission, and Trilogue negotiations with the European

¹ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, L 281, 23/11/1995. Available at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML>.

² European Commission (2012), 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), available at:

<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:52012PC0011>.

³ European Commission (2012), Safeguarding privacy in a connected world. A European data protection framework for the 21st century, available at:

<http://register.consilium.europa.eu/doc/srv?!=EN&f=ST%205852%202012%20INIT>.

⁴ European Commission (2012), Directive of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and the free movement of such data. Available at:

<http://register.consilium.europa.eu/doc/srv?!=EN&f=ST%205833%202012%20INIT>.

⁵ European Parliament, Legislative resolution of 12 March 2014 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, 12 March 2014, available at:

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2014-0212+0+DOC+XML+V0//EN>.

Parliament started on 24 June 2015 with a view to reaching overall agreement on new EU data protection rules by the end of 2015 or early 2016⁶.

The proposal for the new Regulation has triggered a lot of responses from a range of stakeholders, including those working in the area of cancer research. Cancer is the second highest cause of death in the EU-28⁷, and has a long research tradition in Europe⁸. There are over 200 cancer registries⁹ that collect and analyse data of people diagnosed with cancer. Data of these registries are collectively collected in the European Network of Cancer Registries (ENCR)¹⁰, which is part of the International Association of Cancer Registries (IARC)¹¹. These registries provide a tool to evaluate the effectiveness of health policies and to compare practices. Furthermore, the Commission's Joint Research Centre, DG SANTE, the IARC, the ENCR and the European Partnership for Action Against Cancer (EPAAC)¹² are developing a European Cancer Information System (ECIS)¹³, which will include all institutions, persons, procedures, and resources dealing with cancer information and data in Europe. The ECIS will provide a framework to assess and control the impact of cancer in the community, and will monitor the direct effects and benefits of cancer prevention and control activities in Europe. Additionally, EUROCARE¹⁴, the European Cancer Observatory (ECO)¹⁵ and EUROSTAT¹⁶ collect further data and information with regard to cancer in Europe.

There is thus a wealth of data available in the area of cancer research, and the adoption of a new Regulation has raised various ethical questions in relation to the cross-border exchange of samples and the security of data transfers. For cancer patients, the amendments of the new Regulation will further strengthen the protection of their data as patients will have more control over and easier access to their personal data, and will be better informed about what will happen with their personal data once they have decided to share it. On the other hand, concerns exist among cancer researchers¹⁷, the pharmaceutical industry¹⁸, and cancer patient organisations¹⁹ regarding the option for individuals to 'opt out' of a study and not share their personal health data. This is expected to make it more difficult to collect and access data for research purposes. Researchers are also concerned that this 'power' of individuals will reduce the strength of

⁶ EUR-Lex - EDPS recommendations on the EU's options for data protection reform. [http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1444660587291&uri=CELEX:52015XX0912\(01\)#ntr3-C_2015301EN.01000101-E0003](http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1444660587291&uri=CELEX:52015XX0912(01)#ntr3-C_2015301EN.01000101-E0003).

⁷ Eurostat, 2012, Cause of death – standardised death rate, 2012. Available at: [http://ec.europa.eu/eurostat/statistics-explained/index.php/File:Causes_of_death_%E2%80%94_standardised_death_rate,_2012_\(per_100_000_inhabitants\)_YB15.png](http://ec.europa.eu/eurostat/statistics-explained/index.php/File:Causes_of_death_%E2%80%94_standardised_death_rate,_2012_(per_100_000_inhabitants)_YB15.png).

⁸ Weinstein I. & Case K. (2008), The History of Cancer Research: Introducing an AACR Centennial Series. *Cancer Research* 68. Available at: <http://cancerres.aacrjournals.org/content/68/17/6861>.

⁹ Cancer registration is defined as the process of continuing and systematic collection, storage, analysis, interpretation of data on persons with cancer. The population-based cancer registries collect data on every person with cancer in a defined population, usually comprising people resident in a well-defined geographical region.

¹⁰ Website of ENCR: <http://www.enrcr.eu/index.php/who-we-are/about-us>.

¹¹ Website of IARC: <http://www.iarc.fr/>.

¹² Website of EPAAC: <http://www.epaac.eu/>.

¹³ The deliverable of EPAAC WP9, including a summary of the ECIS proposal, is available at: <http://www.epaac.eu/news/149-the-proposal-for-european-cancer-information-system-ecis>.

¹⁴ Website of EUROCOURSE: <http://www.eurocare.it/>.

¹⁵ Website ECO: <http://eco.iarc.fr/>.

¹⁶ Website EUROSTAT: <http://ec.europa.eu/eurostat>.

¹⁷ Casali P. (2014), Risks of the new EU Data protection regulation: an ESMO position paper endorsed by the European oncology community. *Annals of Oncology* 25(8), pp 1458-1461. Available at: <http://annonc.oxfordjournals.org/content/25/8/1458.full>.

¹⁸ EFPIA (2015), General approach to data protection reform is a step in the right direction, available at: <http://www.efpia.eu/mediaroom/272/43/General-Approach-to-Data-Protection-Reform-Is-a-Step-in-the-Right-Direction>.

¹⁹ European Cancer Patient Coalition (n.a.), General Data Protection Regulation, available at: <http://www.ecpc.org/activities/policy-and-advocacy/eu-legislations/237-general-data-protection-regulation>.

research results, as it will be based on less data. Furthermore, there are concerns that the amendment made in the new Regulation restricts retrospective research²⁰.

Outstanding experts in the field were invited to discuss the challenges and future perspectives of a potential future General Data Protection Regulation (5853/11) which could influence the use of personal data in cancer research.

²⁰ Nyrén O., Stenbeck M. & Grönberg H. (2014), The European Parliament proposal for the new EU General Data Protection Regulation may severely restrict European epidemiological research. *European Journal of Epidemiology* 29, pp. 227-230. Available at: <http://link.springer.com/article/10.1007/s10654-014-9909-0>.

PROCEEDINGS OF THE WORKSHOP

1.1. Introduction

1.1.1. Welcome and opening

MEP Mr Alojz PETERLE, Co-Chair, ENVI Health Working Group

During the introduction Mr PETERLE mentioned that, while many people in the field of cancer research are aware of what is at stake with the General Data Protection Regulation (hereinafter referred as the Regulation), it is now important to have an update on the process of the Trilogue. Furthermore, he believed that creating awareness about the future Regulation would help the Trilogue become a success.

1.2. Part I: Policy context and state of play of the proposed general Data protection regulation

1.2.1. The Data Protection Regulation – appropriate safeguards to protect data subjects

MEP Ms Marju LAURISTIN, shadow rapporteur of the Data Protection Regulation (Committee on Civil Liberties, Justice and Home Affairs)

Ms LAURISTIN presented the main outcomes of the Trilogue and expressed her gratitude for the so far enlightening and fruitful discussions within her team and the medical community. The general public awareness about the impact that data protection regimes have on medical research have stimulated the Trilogue's discussion.

Ms Lauristin explained that the current text of the Regulation includes provisions from the existing Data Protection Directive (95/46/EC)²¹ and ensures a good balance between the protection of individual data and restrictions in the work of medical professionals and medical science. In the current situation, health data are available to those involved in medical research and services and is related to professional rules/codes and ethical agreements which are working well in the medical community. Articles 5 and 6 of the future Regulation will include different implementation rules for medical and public health purposes (as well as scientific research in general) concerning purpose limitation²² when processing health data.

Ms Lauristin specified that the principle of purpose limitation is not applicable if data are processed purely for scientific research or for medical practices. Thus, broad consent will be applicable for research and public health services. This means that a one-time consent is given by data subjects to allow the use of their data for a variety of research studies which are subject to strict criteria. In the medical and scientific areas, freedom of research should not be limited, so broader and more flexible activities can be undertaken. However, data subjects always have to be protected and informed.

Ms Lauristin stressed the importance of archiving personal data in the public interest for scientific purposes. However, she highlighted that it has to be done with all organisational and technological safeguards (e.g. using pseudonymous data). For

²¹ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML>.

²² Purpose limitations are rules regarding the use of data: the purpose of the use of personal data has to be specified and this data cannot be used for any other purposes than stated. This involves asking for a specific (or narrow, explicit) consent from data subjects regarding the use of their data, thus, limiting the use of data for further and wider research.

example, to protect the identity of the data subject, pseudonymous personal data cannot be accessed by people who have no direct right. She also highlighted that safeguards have to be controlled and monitored and all data breaches should be reported immediately. To highlight the need for good institutional safeguards, she mentioned the case from her home country, Estonia. Data from one cancer patient were transferred from a registry to a public health institute after the patient gave her consent. However, the patient raised a complaint because all people in the institute had access to her name and her personal data, which were not anonymous anymore, and her data were even leaked to the media without protecting her privacy.

Ms Lauristin concluded her presentation by stating that negotiations have reached reasonable balance: on the one hand, privacy of patients is protected, on the other hand, no unnecessary restrictions to medical research exist. This will allow developing better services and new ways of diagnostics and curing. As the Regulation only provides general rules based on high public interest in public health, Member States have to include specific provisions and rules in their own legislation.

1.2.2. Flexibility and harmonisation of cancer data: obstacles and opportunities

Dr Emanuele CROCETTI, Institute for Health and Consumer Protection (IHCP), JRC

Dr CROCETTI started his presentation by stating that cancer research needs more flexibility and fewer obstacles. He then underlined the important role of population-based cancer registries in providing reliable population-based information on cancer (e.g. indicators at population level on incidence, prevalence, survival, and time trends). A population-based cancer registry includes different sources of personal information linked and matched with a specific person (these are defined 'linkages'). For this reason it is necessary to have a strong identifier (the direct personal ID of the data subject, e.g. name) to avoid duplication of records, which is misleading in terms of quantity and quality of the information. Dr Crocetti assured the audience that the purpose of linkage is not for disclosing the identity of the patients, but for producing high quality data.

The Joint Research Centre (JRC) collaborates with the cancer registries by providing common rules and procedures to guarantee high quality research and to make the available data comparable. In the EU there are 113 population-based cancer registries (covering around 70 % of the EU-28 population) coordinated by the European Network of Cancer Registries. Dr Crocetti explained that each Member State has its own rules regarding the application of privacy regulations to cancer registries. Recent evidence²³ showed that an increasing number of registries must operate under privacy regulations that govern the confidentiality of all patient-level data they handle. Such regulations may result in difficulties with data collection and data transfers within the research community. Dr Crocetti stressed that the implementation of Directive 95/46/EC²⁴ is under different national laws which results in different interpretation by States and will have an impact on the availability and quality of data. Moreover, it may cause a major problem for comparability of data which needs to be addressed in the new Regulation by common rules and standards across Member States.

²³ Forman et al. (2014), Chapter 2: Registration techniques. In: Forman D, Bray F, Brewster DH, Gombe Mbalawa C, Kohler B, Piñeros M, Steliarova-Foucher E, Swaminathan R and Ferlay J, editors Cancer Incidence in Five Continents, Vol. X. Lyon: International Agency for Research on Cancer. Available at: <http://www.iarc.fr/en/publications/pdfs-online/epi/sp164/C15volX-02.pdf>.

²⁴ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML>.

Dr Crocetti then moved on to list four potential critical drawbacks of the new proposed Regulation²⁵. First, biological, pragmatic, economical and ethical reasons make the collection of explicit patient consent undoable. Second, on average 20-25% of cancer patients die during the first 12 months (the statistics are even worse for some types of cancers) so it is practically impossible to contact all of them in a short time frame. He expects 2,700,000 new cases in the 28 EU Member States and he stressed that it is not easy to collect, store and handle all information properly. Third, Dr Crocetti highlighted a need for a broad consent to avoid contacting patients repeatedly. The last drawback was related to pseudonymisation. He stressed that most data are used in a pseudonymous way. However, in order to know about the outcome of a study (e.g. survival, recurrences), pseudonymisation needs to be reversible, in order to go back to the original identifier.

Dr Crocetti then gave several examples of research that might be at risk with the proposed Regulation. For example, to measure the efficacy of vaccination programmes, a linkage between vaccinated files and cancer registries is needed; to measure the impact of cancer screening programmes, a linkage between invitation and participation files is needed; also, to test hypotheses related to cancer (cancer has a long latency from exposure to onset) – there are two options: (1) start now to collect data or ask for consent for each individual and wait for decades or, (2) use available data and derive results in a short time.

Dr Crocetti concluded his presentation by stating that the individual right to data protection should not harm the population's right to health and urged the new Regulation to harmonise the rules for making cancer research not only possible, but as effective as possible.

1.2.3. Questions & Answers

MEP Ms SCHALDEMOSE asked Ms Lauristin whether the updated Regulation would still require researchers to ask data subjects for their informed consent for every new study where their data will be used. Ms Lauristin recognised that it is impossible to ask consent from every study subject for every new research. She specified that for medical activities there will be a provision in the Regulation that data can be used beyond their initial purpose without asking consent, if the interest of the data controller and expectation of the data subject are legitimate. She continued by saying that in medical and health areas it is important that people are well informed: e.g. a person providing data for a registry should be informed that the registry will be used for medical research purposes and should be informed about the logic and purpose of data processing, which could involve profiling of data.

Ms Schaldemose also asked whether data from different registries (e.g. social security number registries) can be used without asking consent from every study subject each time. Ms Lauristin answered that the cross-use of registries and further processing for scientific research should not be limited. It is free for the researchers to (re-)use and cross-use data inside the medical research area. Ms Lauristin added that when research makes use of a large range of data subjects, data subjects can be informed via public information.

²⁵ European Commission (2012), 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), available at: <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:52012PC0011>.

Prof. LADENSTEIN (SIOPE) questioned whether the wording of the 'specific and explicit consent' as it was in the previous draft of the Regulation is still in the text or it has been changed into the requirement for a 'broader consent'. Ms Lauristin responded that for medical health data, in the context of research and the development of medical services, consent is not for one specific purpose and data can be used for the whole range of research. Prof. Ladenstein wondered whether this would also be the case for retrospective research as long as patients are well informed. Ms Lauristin said that, as long as patients are broadly informed (e.g. if their data are stored, it can be used again for other research that is in the public interest and related to the health of other people), it can also be used for this type of research. Ms Lauristin also mentioned that despite the clear general framework and rules of the future EU Regulation, legislation in Member States can further specify the rules and safeguards regarding registries. However, Member States cannot set rules that are 'lower' than the Regulation.

Prof. REICHEL (BBMRI) expressed the researchers' concerns about pseudonymisation which is one of the most promoted technical safeguards. She explained that pseudonymisation of data in registries, especially in bio banks where data are identifiable, would hamper the continuation of ongoing future studies or retrospective studies making use of bio banks. Moreover, studies that make use of electronic health and/or medical records also face difficulties with pseudonymisation. Ms Lauristin responded that pseudonymisation aims to both protect the data subjects and to assure quality of research and that it is a particular issue to be regulated by the Member States' technological and institutional implementation rules.

Dr STORM (Danish Cancer Society) wondered whether the Regulation states that when pseudonymous data are handed to a third party, these data are anonymous for the receiving party. In the Nordic countries it is the case that all pseudonymous data are individual data that can be re-identified. Ms Lauristin said that the Regulation makes a difference between anonymous and pseudonymous data. Anonymous data are data that cannot be identified and pseudonymous data can be identified (e.g. by coding). However, they must not be accessible or usable for persons who do not have the right to use them.

Ms NEGROUK (EORTC) mentioned that research on rare cancers and rare diseases is often international research and, in order to transfer data between countries, different entities have to be contacted. She questioned whether the Regulation included a provision that would make international data transfers easier. Ms Lauristin understood her point and also referred to the EU e-health policy that deals with the same issue. She said that the Regulation does not cover this part and only sets a standard. The definition of institutional and technological implementation details is at the discretion of the Member States, provided their specific provisions comply with the general standards and framework set by the Regulation.

Prof. Ladenstein responded that too much flexibility for Member States regarding the technical and institutional implementation could lead to fragmentation, because one Member State could implement a higher explicit informed consent than another State. She asked whether the Regulation takes this into account. Ms Lauristin replied that the principle of consent is very clearly defined in the Regulation and that Member States cannot introduce another dissimilar principle. However, she encouraged Member States to create common rules to facilitate cross-national research.

Further, Ms Lauristin informed that the Trilogue discussions are likely to end before Christmas. In January the Regulation will pass to the legal services to go through all legal checks. It is expected to be adopted in spring 2016.

1.3. Part II: Challenges and options based on the perspectives of scientific researchers

1.3.1. Access to data and ethical standards for scientific research in the health context

Dr Hans STORM, Medical Director, Danish Cancer Society

Dr Storm started his presentation by explaining the importance of having individual data linked to each person as it enables them to monitor and describe what happens to a single patient. It is important in the process to move from a descriptive epidemiology across analytical cancer epidemiology to a more comprehensive cancer control. According to Dr Storm, data can save lives only if it is of high quality (i.e. valid, complete, unbiased and relevant), correctly analysed, and adheres to ethical standards for the research.

Dr Storm clarified the different types of permissions and terms to access data for health research. Health registries, such as cancer registries, contain personal data and are subjected to data inspection. In most countries, health registries operate under ethical committee systems that oblige them to operate in secrecy and confidentiality as stated by law. The International epidemiological association (IEA),²⁶ the Council for International Organizations of Medical Sciences (CIOMS),²⁷ the European network of Cancer Registries,²⁸ and the International Association for Cryptologic Research (IACR)²⁹ are examples of organisations that check upon ethical standards of health registries. Furthermore, specific legislation exists for hospital records and bio banks. Dr Storm stressed out that this shows that cancer research is already a heavily regulated area and there is no need for more regulation.

To reinforce this argument, Dr Storm also explained that the process of clinical research, trials and testing new drugs involves doctor-patient relationships which are subject to health declarations; only after obtaining the informed consent of the patient, prospective studies can be carried out and there is, therefore, no violation to patient's privacy. On the other hand, the research process of register based/public health studies requires data collection of individuals for administration or monitoring purposes. This collection is continuous and ongoing for decades, for example to study survival rates of cancer. Moreover, there are research questions that sometimes need 20 years to be explored, because of long induction periods for cancer to develop (e.g. asbestos, radiation exposure).

Dr Storm compared two options to solve the issues related to register based studies. The first option is to form a cohort of exposed and unexposed healthy individuals (age and sex will be matched so data are comparable), obtain individual consent and follow them for 20 years. The second option is to find, for example, company rosters of exposed workers and to identify workers with cancer (dead and alive) and compare cancer incidence among workers to the general population. The first option would take about 20-24 years; the second option would only take 2-3 years. Dr Storm highlighted that option 1, the one with individual consent for each research purpose, would lead to a delay in research and the loss of many lives, and thus the second option is preferable.

For a public health / registry based study where the second option is applied, safeguards are applied and the researcher is responsible in all phases. For example, necessary data variables must be specified in the research protocol, and clearance is needed from Data Protection Authorities (DPA) and Scientific Ethical Committees. Further, the researcher

²⁶ International Epidemiological Association website: <http://ieaweb.org/>.

²⁷ Council for International Organizations of Medical Sciences website: <http://www.cioms.ch/>.

²⁸ European Network of Cancer Registries website: <http://www.enrcr.eu/>.

²⁹ International Association for Cryptologic Research website: <https://www.iacr.org/>.

needs to guarantee the correctness of data linkages on each person and adequate security measures, depending on the study type, should be taken (e.g. pseudonymisation/anonymisation, avoid unintended access/disclosure). Also, the researcher should adhere to the terms given by the DPA and ethics committee. Finally, when studies are published, there must be no stigmatisation of patients and no possibility of identifying individual persons.

Dr Storm reiterated that a narrow consent is unnecessary in public health research. Asking permission from several hundred thousand data subjects is impossible and an expensive task bound to be biased because cancer patients are more likely to provide their data than the general population. He also mentioned quality issues as a counterargument. An error in a linkage can occur which means that researchers lose track of data. Furthermore, the involvement of a third party to deal with linkages would increase time and costs of research.

Dr Storm concluded his presentation by stating that all cancer studies are at risk if the proposed Data Protection Regulation will remain in its proposal text regarding the informed consent and other obstacles to research. Research on health data can be done in an unethical and low quality way which should be avoided. At the same time, failure to do health research is unethical and devastating for public health.

1.3.2. Data protection and the storage of personal data in bio banks

Prof. Jane REICHEL, Representative BBMRI-ERIC

Prof. REICHEL represented the Biobanking and BioMolecular resources Research Infrastructure – European Research Infrastructure Consortium (BBMRI-ERIC)³⁰, the largest health infrastructure in Europe. BBMRI-ERIC has 14 founding Member States together with three official observers, including the International Agency for Research on Cancer (IARC/WHO). The aim of BBMRI-ERIC is to establish, operate and develop a Pan-European distributed research infrastructure in order to facilitate the access to biological resources and facilities and to support high quality biomolecular and biomedical research as a part of the European Research Area (ERA).

While explaining how BBMRI-ERIC tries to achieve the aim, Prof. Reichel mentioned several activities, for example, networking between bio banks and cohorts of 17 European countries and the IARC/WHO, facilitating access to high quality human biological samples and associated data, and creating a central catalogue of European bio banks/samples. BBMRI-ERIC also offers common services for ethical, legal and societal issues and information technology (IT), and long-term sustainability of research results.

Prof. Reichel then mentioned the 'ADOPT BBMRI-ERIC' project that aims to boost and accelerate the implementation of BBMRI-ERIC and its services³¹. As part of this project, BBMRI-ERIC selected, as a pilot study, colorectal cancer, a sufficiently common cancer in Europe. BBMRI-ERIC collected 10,000 biological samples from 17 Member States and used 10,000 medical records using text-mining. Despite lots of successful research that has been done and funded by the EU, Prof. Reichel is concerned that nobody will continue the work on research (e.g. collecting of samples) after the project has ended.

Prof. Reichel mentioned that the basic principle of BBMRI-ERIC is to build a research infrastructure and collect samples and data for future use. She recognised the need for updated and coherent rules on data protection for Europe. According to her, absence of

³⁰ BBMRI-ERIC website: <http://bbmri-eric.eu/>.

³¹ ADOPPT BBMRI-ERIC project website: <http://bbmri-eric.eu/adopt-bbmri-eric>.

rules to approve research means absence of research. Nevertheless, as research is already conducted within a highly controlled environment, it should not be overdone.

Prof. Reichel also acknowledged the need for proportionate and well defined exemptions to allow researchers to use and re-use data over time and for unspecified purposes. However, she also pointed out the question whether 'customised' national exemptions or harmonised EU exemptions are better for researchers. In general, national researchers prefer specified and customised national exemptions in order to safeguard research that is already conducted and to avoid big changes in the status quo. However, for international research, especially within BBMRI-ERIC, a fragmented legal landscape has its costs. Therefore, she recommended setting up common rules that would facilitate cross-border research within the ERA.

1.3.3. Experiences from EUROCORE – cancer survival in Europe

Dr Gemma GATTA, EUROCORE co-leader, RARECARE and RARECARENET leader and partner of EPAAC

Dr GATTA presented some results and experiences of the EUROCORE research project³² whose first data were published in the IARC scientific publication in 1995. Over the years, the participation of European cancer registries in the project has increased. Currently, 31 European countries (117 registries, 50 percent of the European population) are included in the project and more than 20 million cancer cases are documented in the database. There is also a uniform data collection protocol and statistical analyses.

One of the major results of the EUROCORE project is that it provides data that differentiate outcomes between populations based on age groups, sex, socioeconomic status and between rare and common cancers. Dr Gatta then showed some graphs on cancer survival time trends in Europe (2000-2007) from the EUROCORE-5 data³³. These data show large variations across Europe: the situation in Northern and Central Europe is usually better than in Eastern Europe. Several factors are related to the variations across countries and regions in cancer survival: for example there are differences in cancer biology and in diagnostic intensity and screening leading to earlier stage diagnosis in some Member States. Also, the availability of effective treatments in Member States differs as there are socioeconomic, lifestyle, and general health differences between populations. Dr Gatta stressed the importance of further investigations on better tumour characterisation, co-morbidity and its influence on the prognosis, survivorship, cancer costs and organisation of care.

According to Dr Gatta, data are important for concluding and explaining diagnosis, but they have to be accurate, complete and unbiased. She also underlined that exemption from patient consent is necessary to permit the collection of those data to develop evidence-based policy decisions and measure their effectiveness. Further, Dr Gatta highlighted the importance of having population-based cancer registries that include all cases, reach more sources of data, as well as data available in a timely manner, and that have access to clinical information (e.g. diagnosis, process and treatment). To conclude, in order to continue with studies such as EUROCORE, an essential precondition for population-based cancer registries is to avoid asking for informed consent.

³² EUROCORE website: <http://www.eurocore.it/>.

³³ EUROCORE 5 publications available at: <http://www.eurocore.it/Publications/tabid/61/Default.aspx>.

1.4. Part III: Future development based on the experience of healthcare providers, patients, and the industry

1.4.1. The processing of personal data from patients to healthcare provider

Prof. Ruth LADENSTEIN, SIOPE Board Member (St. Anna Children's Hospital)

Prof. Ladenstein presented the situation of inequalities in childhood cancer survival rates across Europe by showing some graphs from the study EURO CARE-5³⁴: every year there are 35,000 new cancer cases in children and young people in Europe. Furthermore, 300,000 children in Europe are surviving and about 80% are disease free after five years. Nevertheless, 10-20% of children still die from curable forms of cancer because treatment is not equally accessible or provided to all of them. The Paediatric Oncology European Reference Network (ExPO-r-Net)³⁵, composed of members from thirty-one countries, is a three year project that aims to reduce these inequalities between EU Member States. The network will enhance cross-border healthcare, for example by linking centres of expertise with tumour boards. Moreover, it will identify target groups such as children with special diagnostic and therapeutic needs.

The basis for ExPOR-r-Net is telemedicine, i.e. IT solutions and tools that enable to connect data. However, the processing of patients' personal data between healthcare providers across countries, in particular when it is processed across borders, is problematic. For example, virtual clinical and tumour boards make use of case histories and images which need to be pseudonymous as data travels across borders. However, it is difficult for healthcare professionals to use pseudonyms when a case is discussed. Moreover, when data are not correctly linked, errors in studies may occur.

Prof. Ladenstein explained that childhood cancers are rare and the incidence of specific types of childhood cancers is very low. ExPOR-r-Net started to research some of these rare tumours; however, it is complicated as all Member States have some knowledge but there is no central advisory system to coordinate the expert centres in each Member State. Prof. Ladenstein highlighted the need for an international consultation platform that stores all the information and where all European experts could collaborate and capture patients' data.

An example that could stimulate cancer survival rates, but requires personal data to travel across borders, is the Survivor Passport³⁶, a product developed by a European Network for Cancer Research in Children and Adolescents (ENCCA), an EU funded project. It is a document that will be given to a patient after therapy and contains data on cancer history, therapy information, and clinical recommendations for EU care. The Survivor Passport uses a traffic light coding system that will guide healthcare professionals with clinical recommendations regarding cancer care follow up. It has been integrated and will be put into practice under the Austrian Cancer Plan³⁷. However, the cross-border dimension is a challenge because the Passport contains condensed data and has to travel safely with the patient.

³⁴ Gatta et al. (2013), Childhood cancer survival in Europe 1999–2007: results of EURO CARE-5—a population-based study, available at: [http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(13\)70548-5/abstract](http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(13)70548-5/abstract).

³⁵ ExPO-r-Net website: <http://www.expornet.eu/>.

³⁶ SIOPE (2014), A Passport to the future: Improving life for survivors of childhood cancer, available at: <http://www.siope.eu/2014/05/02/passport-future-improving-life-survivors-childhood-cancer/>.

³⁷ Austrian Federal Ministry of Health (2014), Austrian Cancer Plan (*Krebsrahmenprogramm Österreich*), available at: <http://www.bmg.gv.at/cms/home/attachments/2/7/0/CH1480/CMS1412233312313/krebsrahmenprogramm.pdf>.

Another ENCCA outcome is the creation of a European Unified Patient Identity (EUPID), which aims to fulfil the requirements for identity management of data linkages, re-identification, and the use of different pseudonyms in different contexts. For example, EUPID uses separate pseudonyms for bio banks and clinical trials, and a third pseudonym for the so called 'virtual patient' which includes data from both bio banks and clinical trials. This involves a lot of complexity but connects the healthcare sector with the research sector and allows re-identification of the patient which is needed for the future (e.g. survival studies, Survivor Passport).

Finally, Prof. Ladenstein mentioned the importance of using secondary data in cancer research, which involves linkages, new technologies and new data sets, she was happy to hear from Ms Lauristin that there is no need for an explicit and specific consent in the future for the use of secondary data and retrospective research. In this way there will be no limitation regarding data linkages in cancer research in the future.

1.4.2. Providing personal data and cancer survival – the rights of patients

Mr Richard STEPHENS, cancer survivor

Mr STEPHENS took the floor to represent the voice of cancer patients. He started by presenting the reasons why cancer patients are very willing to donate their data. First, they want to help themselves; once people are diagnosed with cancer they will give their doctor all the information they need to receive the right treatment. Secondly, data can benefit other patients as well. Third, patients are willing to provide their data for future uses, because they want to leave a better world, especially those who have children.

He continued by mentioning the new five-year Cancer Strategy³⁸ in England. Mr Stephens was part of the consultations and met over 100 cancer patients and received written representations from around 300 more cancer patients. He noticed that many cancer patients felt that data and information was not being used as efficiently as it should be. Mr Stephens also informed that over 6,000 people signed a petition³⁹ to the European Parliament which asked to maintain exemptions for research that uses personal data in the new Regulation. He pointed out that patients care more about the right to donate their data and about their data being used, than the right to privacy.

Furthermore, Mr Stephens observed that patients would like to be active citizens and be involved in decisions about using their data. Patients want to know which data are used, whether they are pseudonymous and/or anonymous, as well as what type of consent can be given. Moreover, they want to know who holds their data, who wants their data, and what they want it for. In general, patients agree that their data are used when it is for the benefit of public health or other cancer patients and when data users can be trusted. Mr Stephens compared the donation of personal medical data with an Oxfam shop, where clothes are donated, so they can benefit other people.

Mr Stephens also gave an example from his own experience to demonstrate that patients primarily donate their data for their own benefits (e.g. they look at their own treatments and their long term prospects). Mr Stephens knew that high blood pressure runs in his family which gives him a higher risk of heart disease. He also knew that chemotherapy could damage his heart muscle and he was a smoker at the time of the diagnosis. He did not have a problem sharing this information with the doctor. After experiencing chest

³⁸ Independent Cancer Taskforce (2015), Cancer strategy England, available at: http://www.cancerresearchuk.org/sites/default/files/achieving_world-class_cancer_outcomes_-_a_strategy_for_england_2015-2020.pdf.

³⁹ Petition to urge the European institutions (Council, Parliament and Commission) to maintain exemptions for research in the Trilogues on the new Data Protection Regulation, available at: <http://www.euroscience.org/news/sign-petition-to-keep-ethical-responsible-research-using-personal-data/>.

pains, he came to the right conclusions with his doctor and he was referred straight away to the hospital, which saved his life.

Mr Stephens reported that patients believe existing laws and regulations are good enough and there is no need for tighter or more legislation. More education for patients and the public would be a better option to make sure people know what they are doing. Also, patients could be involved in data access committees, funding committees, management bodies, regulatory bodies, and trial management groups for research to make them an equal partner in the process. This way a patient can have a say in how data are used and who is using it.

Mr Stephens concluded his presentation with the motto of the patient charter of England's National Health Service⁴⁰: "No decision about me, without me", which also applies to the use of personal data. Patients understand the use of data and they want their data to flow. Therefore, patients should be at the heart of the matter, they should be empowered as active citizens across Europe, and the EU can have a large role to help cancer patients in the future.

1.4.3. Cancer data used in the industry

Mr Brendan BARNES, European Federation of Pharmaceutical Industries and Associations (EFPIA)

Mr BARNES (EFPIA) presented a wide range of data that is used by the industry, such as clinical trial data, bio bank data, health system data (e.g. transactions and records), pharmacovigilance data and medical records. The patient is right at the centre of all this data. This raises questions as to the role of the patient which is usually both an individual generator of data as well as someone who benefits from the accumulation of data.

A better understanding of cancer is possible if data are shared and used. It can improve prevention, diagnosis and intervention that will expand cancer treatment outcomes and sustain health systems. Mr Barnes pointed out that the sustainability of health systems in Europe is a challenge as many health system interventions and drugs do not work as effectively as they are expected to work.

He then cited the Big Data for Better Outcomes project (BD4BO)⁴¹ which is part of the Innovative Medicines Initiative programme⁴² and looks at how to use big data to improve outcomes for patients. The project looks for a more integrated regulatory approach. For example, it also looks at whether additional factors such as whether a medicine has to be placed on the market, how much the medicine is worth, and whether the medicine is effective, should all be regulated in one single framework. Another way to increase the sustainability of health systems is to use a more targeted population for testing medicines, for example by monitoring the use of medicines in real populations and real situations rather than in clinical trials.

According to Mr Barnes the ideal situation would be to move data between institutions and across borders for legitimate research purposes, while assuring security and accountability. Issues such as data ownership, standards and interoperability, and data responsibility all trade-off with each other and should be regarded in isolation. A

⁴⁰ NHS (2010), Equity and excellence: Liberating the NHS, available at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213823/dh_117794.pdf.

⁴¹ EFPIA (2015), Consultation paper. Big data for better outcomes - concept for an IMI2 programme. Available at: http://www.imi.europa.eu/sites/default/files/uploads/documents/Events/SF%202015/BigData_Concept_29May2015.pdf.

⁴² Innovative Medicines Initiative programme website: <http://www.imi.europa.eu/>.

particular data protection technology should take all these issues into account, otherwise it will not be an adequate way to protect data.

Mr Barnes pointed out that the industry shares the concerns of patients and healthcare systems about a restriction on the use of data, overregulation and costs of access to data as stated in the proposed Regulation. Such hurdles to reuse data could result in research taking place elsewhere. Mr Barnes mentioned that there should be a balance between harmonisation and fragmentation and proposed to have a platform to continue a dialogue between all stakeholders. The proposed Regulation surprised many people in the research area because it is already a highly regulated area. Mr Barnes believed that it is important to communicate and share information with people and engage people in a dialogue to find the appropriate balance between research needs and regulation.

1.4.4. Improving survival with cancer data

Dr Paolo CASALI, Chair of ESMO's Public Policy Committee and a Board Member

Similarly to the previous speakers, Dr CASALI expressed the worries of the cancer community, and the medical community in general, regarding the specificity of consent as stated in the proposed Regulation. He argued that the right to donate data or not to donate data is a matter of freedom. The consent rules in the proposed Regulation would have a negative effect on population based cancer: if one patient would deny access to his data, the registry will be biased by definition. Therefore, Dr Casali stressed the need for cases to be registered without any kind of consent, while keeping all safeguards in place.

The European Society for Medical Oncology (ESMO) published a consensus paper⁴³ in 2014 signed by the European cancer community urging that derogation from the consent requirement (as stated in the proposed Data Protection Regulation) is needed for cancer registries. Furthermore, Dr Casali recommended a 'one-time consent' for retrospective research and bio banks, which means patients allow their data and tissues to be used for future research. Such one-time consent does not necessarily have to be a broad consent, for example it can be specified that data are only used for particular studies. At the same time, he also underlined that it is important that patients are well informed and that they have the option to withdraw their consent.

Furthermore, Dr Casali clarified that any research is subject to ethical scrutiny and that law, rules and regulations assure that data are stored in the best way possible. Moreover, one-time consent is already incorporated in the Clinical Trial Regulation⁴⁴, which states that the patient should give his consent whether or not to use his data after the end and beyond the scope of the clinical trial.

To demonstrate the importance of a one-time consent for bio banks and retrospective clinical research and derogation from consent for cancer registries and disease registries, Dr Casali mentioned three examples. The first one was a retrospective study⁴⁵ that used data stored in hospitals. The study found that a specific chemotherapy makes a

⁴³ Casali (2014), Risks of the new EU Data protection regulation: an ESMO position paper endorsed by the European oncology community. *Annals of Oncology* 25(8), pp. 1458-1461. Available at: <http://annonc.oxfordjournals.org/content/25/8/1458.full>.

⁴⁴ 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. Available at: http://ec.europa.eu/health/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf.

⁴⁵ Rosen et al. (2006), Disease-free survival in children with Ewing's sarcoma treated with radiation therapy and adjuvant four-drug sequential chemotherapy. *Cancer* 33(2), pp. 384-393. Available at: [http://onlinelibrary.wiley.com/doi/10.1002/1097-0142\(197402\)33:2%3C384::AID-CNCR2820330213%3E3.0.CO;2-T/pdf](http://onlinelibrary.wiley.com/doi/10.1002/1097-0142(197402)33:2%3C384::AID-CNCR2820330213%3E3.0.CO;2-T/pdf).

difference in a particular type of paediatric sarcoma. This research allowed the sarcoma community to not use randomised trials anymore for this specific cancer type. The second example was a Japanese study that used data from a tissue bank to study treatment for gastro-intestinal stromal tumours (GIST)⁴⁶. The results of the study led to successful treatment of GIST. The third example was a study of EUROCARE⁴⁷ on survival rates of cancer patients, which used data from cancer registries in Europe. Survival studies are important to see if a health system works or not, depending on whether survival rates increase or reduce. All these examples showed that the use of historical personal data is essential to improve cancer treatment outcomes.

Dr Casali looked forward to seeing the final text of the Regulation which hopefully will incorporate the concepts of one-time consent and consent derogation for cancer (and medical) research.

1.4.5. Questions & Answers

During the second question and answer session, Ms KEENAN (Cancer Research UK) asked whether it is appropriate to differentiate the level of consent for different purposes, i.e. the one-time consent for bio banks and clinical research and the consent derogation for cancer registries specifically. She also wondered whether the same would apply to areas of health other than cancer. Dr Casali clarified that the topic of the workshop was cancer data and therefore the focus went to cancer registries. However, the proposed consent would apply to any kind of population based diseases registry. Further, Dr Casali thought that the one-time consent is a reasonable compromise.

Dr Storm acknowledged the need for long term data linkages; however, he also questioned the long term effects of data sharing and learning from data from childhood cancer patients. The EUPID is an excellent data management tool for research; however, using data from childhood cancer patients for long term studies on the side effects of their treatments, might not be useful anymore when they have grown up. Moreover, a probability of 1-3% of an error rate when you link data can be a problem for research findings. Prof. Ladenstein responded that managing data linkages in the future involves a good management of cancer registries in general. She mentioned that the use of full names and birth dates is not an option in research, even if this would prevent errors. Therefore, the use of pseudonyms could create a system that minimises the risk of data errors and data linkage. Dr Storm added that there will be a problem with the accuracy of data linkages in the future, unless Europe implements a personal identifier for each person. Prof Ladenstein mentioned that this is the aim within paediatric oncology and that the EUPID is a pilot project; however, it could be expanded.

Ms Negrouk (EORTC) was interested in a multi-stakeholder platform, as mentioned by Mr Barnes. She has been involved in an international research project where data subjects were informed (as required by the Clinical Trial Regulation) about the fact that their data will be shared with other researchers. However, some national ethical committees asked to further specify with which researchers the data are shared. A platform would help to avoid confusion between researchers and all ethical committees in Europe. She asked Mr Barnes for his vision on such a platform. Mr Barnes responded that the Data Protection Regulation is a general legislation and will require a lot of implementation efforts in order to cover every issue of research. A platform can be seen as a societal endeavour with patients, academic researcher, industrial researchers, as well as people who run health

⁴⁶ Hirota et al. (1998), Gain-of-function mutations of c-kit in human gastrointestinal stromal tumors. *Science* 279(5350), pp. 577-580, Available at: <http://www.sciencemag.org/content/279/5350/577.long>.

⁴⁷ Sant et al. (2009), EUROCARE-4, Survival of cancer patients diagnosed in 1995-1999. Results and commentary, available at: <http://www.sciencedirect.com/science/article/pii/S095980490800926X>.

services, taking part in it. Such an extended network can find solutions to particular problems that have not been addressed in the Regulation. Mr Barnes also acknowledged that the way ethical approval is structured in Europe is complex and ethical committees provide different answers although they address the same question and have the same ethical responsibility. A platform could provide concrete solutions and come up with proposals on how the European Commission could take further action in order to transfer and share data securely and efficiently across borders in Europe. Also, Mr Barnes appreciated the enormous work already done by BBMRI; however, he believed that the discussion on governance of health data at a higher level needs to continue.

Ms RESENDES (EFPIA) asked for views on the concept of high public interest since she understood that it will be used as criteria to allow exemption from medical research. She also wondered how this will apply to exploratory research (e.g. epidemiological research). Dr Casali assumed that epidemiological research also has a high public interest (e.g. outbreak of an infection). However, he believed that the public interest can differ between countries and it is a risk to use this kind of condition to allow something that will be regulated at European level. Prof Ladenstein added that she felt reassured that the medical field will somehow be exempted from the General Regulation. She believed that research will be regarded as a public interest and thus will be used as a concept, rather than criteria.

1.4.6. Closing remarks by the Chair

Although the final text is not yet known, Mr Peterle expressed that, according to Ms Lauristin's presentation, the overall spirit seems to be balanced. He continued saying that the topic remains sensitive. He was critical of the previous position of the European Parliament regarding the Regulation because it focused on individual rights rather than the public interest. Although the Regulation cannot satisfy everyone, he believed that the aim of the ongoing negotiations and discussions is to have a Regulation that benefits equally patients, researchers, medical doctors as well as the industry and MEPs.

ANNEX 1: PROGRAMME

WORKSHOP

Data Saves Lives: The Impact of the Data Protection Regulation on Personal Data Use in Cancer Research

19 November 2015 from 09.30 to 12.30
European Parliament, Paul-Henri Spaak 4B001, Brussels

**Organised by the Policy Department A-Economy & Science
for the Committee on the Environment, Public Health and Food Safety (ENVI)**

AGENDA

09.30 - 09.40

Opening and welcome

MEP Mr Alojz PETERLE, co-Chair ENVI Health Working Group

Part 1

**Policy context and state of play of the proposed General Data Protection
Regulation**

09:40 -09:50

**The Data Protection Regulation – appropriate safeguards to protect data
subjects**

MEP Ms Marju LAURISTIN, shadow rapporteur of the Data Protection Regulation

09:50 – 10:00

Flexibility and harmonisation of cancer data: obstacles and opportunities

Dr Emanuele CROCETTI, Institute for Health and Consumer Protection (IHCP),
JRC

10:00 – 10:20

Questions & Answers

Part 2

Challenges and options based on the perspectives of scientific researchers

10:20 – 10:30

Access to data and ethical standards for scientific research in the health context

Dr Hans STORM, Medical Director, Danish Cancer Society, DK

10:30 – 10:40

Data protection and the storage of personal data in bio banks

Prof. Jane REICHEL, Representative BBMRI-ERIC

10:40 – 10:50

Experiences from EUROCARE – cancer survival in Europe

Dr Gemma GATTA, EUROCARE co-leader, RARECARE and RARECARENET leader and partner of EPAAC

10:50 – 11:10

Questions & Answers

Part 3

Future development based on the experience of healthcare providers, patients and the industry

11:10 – 11:20

The processing of personal data from patients to healthcare provider

Prof. Ruth LADENSTEIN, SIOPE Board Member (St. Anna Children's Hospital), AT

11:20 – 11:30

Providing personal data and cancer survival – the rights of patients

Mr Richard STEPHENS, cancer survivor, UK

11:30 – 11:40

Cancer data used in the industry

Mr Brendan BARNES, European Federation of Pharmaceutical Industries and Associations (EFPIA)

11:40 – 11:50

Improving survival with cancer data

Dr Paolo CASALI, Chair of ESMO's Public Policy Committee and a Board Member, IT

11:50 – 12:20

Questions & Answers

12:20 – 12:30

Closing remarks by the Chair

ANNEX 2: SHORT BIOGRAPHIES OF EXPERTS

Dr Emanuele Crocetti

Emanuele Crocetti is currently employed by the European Commission at the Institute for Health and Consumer Protection in the Joint Research Centre, Ispra (Italy) where he has joined the Public Health and Policy Support Unit in developing a European Cancer Information System. He has gained a longstanding experience in cancer epidemiology and registration working for 23 years in the Tuscany region cancer registry (Italy), which he directed for several years. He is currently the Chairman of the Italian network of cancer registries (Airtum) and he has been appointed as the next President of the Group for cancer epidemiology and registration in Latin language countries (Grell). He served for six years the European Network of Cancer Registries (ENCR) as a member of the Steering Committee. He holds two specialisations, Public Health and Health Statistics. He is adjunct Professor in Health Statistics at the University of Milan, in Italy.

Dr Hans Storm

Hans Henrik Storm, MD, Medical Director (Vice CEO) Danish Cancer Society, former Director of Cancer Prevention and Documentation (1997-2014) and was Director of the Danish Cancer Registry 1985-1997.

H. H. Storm graduated in medicine in 1976 from the University of Copenhagen and was trained in surgery, internal medicine and haematology. He started as a medical supervisor and coder at the Danish cancer registry in 1977 and was appointed as a full time researcher at the cancer registry in 1981. From 1988 to 1991 he was head of Cancer Registration and from 1991 to 1996 Acting Director for the division for Cancer Epidemiology. In 2000 he was appointed director of the Department for Cancer Prevention and Documentation at the Danish Cancer Society. He has been a board member of the ENCR, chairman of the IARC/IACR/ENCR working group on Confidentiality Guidelines for Cancer Registries 1995, 2002, and the ENCR/EUROCOURSE revision in 2012.

In 1990 he was elected as a reg.Rep. for the European of the International Association of Cancer Registries (IACR), and was General Secretary between 1996-2000 and President between 2000-2004. He is co-author of the European Cancer Code (2003) and appointed as a WHO cancer expert for a decade. He has served for the Danish Data Protection Council since 2000. Since 1985 he has been a board member of the Association of Nordic Cancer Registries (president 1994-95 and 1999-2000) and a Member of the International Agency for Research on Cancer Ethics Committee (IEC) in 2014-16. H. H. Storm has been the course director of the Nordic Summer School in Cancer Epidemiology since 1993, and initiated the NORDCAN collaboration and software.

Honors: William Rudder Fellow 1996. H. H. Storm has published over 346 publications (103 as 1st author) in cancer epidemiology, descriptive and analytical, since 1980 including routine monitoring of cancer incidence, mapping, survival, and data linkage. Main areas for analytical studies are radiation, cytotoxic agents, immunosuppression, multiple primary cancers, and evaluation of cancer control.

Prof. Jane Reichel

Jane Reichel received her Master degree in law in 1997 at Stockholm University and worked as a clerk at the Administrative Court in Stockholm from 1998 to 2001. Jane defended her doctoral thesis on European administrative law at Stockholm University in 2006. She then worked as a project manager at the Swedish Agency for Public Management. In 2009 she was appointed associate professor in public law. Since 2011 she is a senior lecturer in administrative law at the Faculty of Law, Uppsala University. In the same year she also became part of the Centre for Research Ethics & Bioethics, Uppsala University. In 2014 she was appointed as professor of administrative law at Uppsala University.

At the moment she is the chairman of the research committee at the Faculty of Law and the vice dean. Jane's current research focuses on processes of globalisation and Europeanisation of administrative law, especially within the area of administrative cooperation within research and biobanking, transparency and data protection. Her research is mainly conducted within the BBMRI.se infrastructure, in collaboration with BBMRI-ERIC. She is also a member of WP 1 of the BioBankCloud project (FP7) and leader of WP 1 of the BioBankBridgeAfrica project (Horizon 2020).

Dr Gemma Gatta

Dr Gemma Gatta has been a medical doctor since 1980 and was employed from 1978 to 1981 as a Researcher at the Epidemiology Unit of the National Institute of Tumours (Istituto Nazionale dei Tumori), Milan, Italy. From 1991 to 2005 she was a research assistant at the same Epidemiology Unit. Since 2005 she has been Head of Unit at Evaluative Epidemiology Unit - Department of Preventive and Predictive Medicine.

Dr Gatta is involved in a wide range of research programmes such as the Italian Cancer Registries and methodology of case-control studies for screening evaluation. She was part of the coordinating and analysis group and steering group of the European cancer registries based study of cancer patient's survival and care (EUROCARE) and of the European cancer registries study of cancer patients prevalence (EUROPREVAL). Furthermore, she was a member of the steering group in the CONCORD project, a cancer survival in five continents study up to 2009.

She is also editor of a special issue on childhood cancer survival in Europe for the European Journal of Cancer (2001) and of the IARC technical report 'Evaluation of clinical care by cancer registry' (2003). She participated in several national and European founded cancer-related projects and is currently project leader of two DG SANTE projects on rare cancers. Throughout her career she has published more than one hundred papers.

Prof. Ruth Ladenstein

Prof. Ruth Ladenstein is a professor in Paediatrics and Senior Consultant in Paediatric Oncology. She is Head of the Clinical Trials Unit S2IRP (Studies & Statistics for Integrated Research and Projects) at the Children's Cancer Research Institute (CCRI) of the St. Kinderkrebsforschung e.V.

She has coordinated the EU FP7 funded Network of Excellence: "EUROPEAN NETWORK for CANCER research in CHILDREN and ADOLESCENCE" (ENCCA), the EU funded network: ExPO-r-NeT "European Expert Paediatric Oncology Research Network for

Diagnostics and Treatment” and the Austrian Medicine for Children Research Network OKIDS.

Prof. Ladenstein is a board member of SIOPE EUROPE. She was SIOPE president between September 2009 and October 2012 and has been chair of the SIOPE European Paediatric Research Council since 2012. Since May 2011 she has been an advisory board member of the SIOPE Europe Neuroblastoma Group and was SIOPE president from May 2007 to May 2011. Since 2002 Prof. Landestein is a Principle Coordinating Investigator of SIOPE High Risk Neuroblastoma Trials.

Furthermore, she has been an advisory board member of the German Paediatric Oncology Group (GPOH) since 2012 and since 2013 a member of the Oncology Advisory Board of the Ministry of Health of Austria. She also chairs the Austrian Group for Paediatric Haematology-Oncology.

Mr Richard Stephens

Richard is a survivor of two cancers, Hodgkin’s Lymphoma and basal cell carcinoma. Along the way he has also had a stent fitted during a coronary emergency, temporary blindness in one eye during ophthalmic shingles, surgery for two benign tumours and several other treatments for co-morbidities and late effects.

He has had x-ray, ultrasound, CT, MRI and PET scans, and chemotherapy, surgery and a stem cell harvest, delivered over seventeen years and six different hospitals/centres. He has been a participant in four clinical trials himself, and several observational studies.

Richard is one of the consumers who designed and introduced the questions on research awareness and participation for the National Cancer Patient Experience Survey. Richard supplied the slogan, “It’s OK To Ask”, used for the annual UK-wide campaign promoting clinical research, including data-sharing.

As a cancer patient and trial participant he is one of the key supporters of the AllTrials campaign and petition, calling for greater transparency in clinical trial registration and reporting, and for the sharing of data for legitimate medical research. He is the co-chair of the NIHR Dissemination Centre’s Advisory group, sits on the ethics advisory committee for Genomics England, and is the public representative on Genomics England’s Data Access Committee for the 100,000 Genomes project.

Richard is Chair of NCRI’s Consumer Forum and the NCRI Consumer Lead. He serves on several UK strategic groups for NCRI, NIHR, NCIN, RfPB, HTA and the MRC CTU. He was the patient representative on the Independent Cancer Taskforce that produced the 2015 national Cancer Strategy for England, *Achieving World Class Cancer Outcomes*.

Mr Brendan Barnes

Brendan Barnes, Director IP and Global Health at EFPIA, joined EFPIA in 2002 to work on the alignment of national laws in new Member States during the enlargement of 2004. Subsequently, he has been involved in EFPIA’s work on multilateral trade and intellectual property issues, including the EU’s legislation on product diversion and compulsory licensing and on issues relating to access to medicines. More recently, he has been involved in the development of new business models in the areas of neglected disease and infection. He previously worked in the pharmaceutical industry for 11 years, in a range of roles including Finance, Strategic Planning and Public Affairs, among other things coordinating work on the Montreal Protocol phase-out of CFC’s. In the course of his career he has also worked in a number of other industries in a range of finance roles. He has degrees in Psychology and Business.

Dr Paolo Casali

Paolo G. Casali, MD, is the Director of the Medical Oncology Unit for Adult mesenchymal tumours and Rare cancer networking at the National Institute of Tumours (Istituto Nazionale Tumori), Milan, Italy, where he also serves as Secretary of the Ethics Committee. He is a member of the Executive Board of ESMO (European Society for Medical Oncology), as Chair of the Public Policy Committee, and a member of the Board of Directors of ECCO (European Cancer Organization).

His clinical and research activities focus on sarcomas, mainly adult soft tissue sarcomas and gastrointestinal stromal tumours (GIST). He is Secretary of the Italian Sarcoma Group and a member of the Soft Tissue & Bone Sarcoma Group of EORTC (European Organisation for Research and Treatment of Cancer). He is an Editor-in-chief of Clinical Sarcoma Research, an open-access journal on sarcoma, and a member of the ESMO Sarcoma Faculty.

In the area of rare cancers, he founded and chairs the Italian Rare Cancer Network, a collaborative effort among Italian cancer centres exploiting distant patient sharing to improve quality of care and diminish health migration. He coordinates Rare Cancers Europe, an ESMO-launched multi stakeholder initiative to address the many issues posed by rare cancers.

ANNEX 3: PRESENTATIONS

Presentation by Dr Emanuele Crocetti



Flexibility and harmonization of cancer data: obstacles and opportunities

Workshop: Data saves lives: the impact of the data protection regulation on personal data use in cancer research

Brussels 19 Nov 2015

Emanuele Crocetti
**Cancer Information Group,
Public Health Policy Support Unit, JRC - Institute for Health and Consumer Protection**

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JOINT RESEARCH CENTRE

Provides scientific and technical support to the Commission
In this context it supplies DG SANTE with health indicators and in particular with information on cancer

Building blocks: Population-based cancer registries
Provide reliable indicators at a population level on:
**Incidence (new cases), Prevalence (cases), Survival,
Time trends, etc.**
(high quality: complete, valid, comparable)

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How does a population-based cancer registry work?

using many routinely available sources of information

None of them is sufficient

- hospital discharge notes
- pathology reports
- death certificates
- outpatient clinic visits and exams
- drugs
- ...
- resident population

LINKAGE!
Not for disclosing the identity of the patients but for the quality of the data

But all of them are useful

Joint Research Centre

Source: The author with permission and citation of IT Healthcare Data Research Center, an initiative of the European Commission

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European Network of Cancer Registries : HARMONIZATION



eco.iarc.fr

113 population-based CRs in EU-28 (20 national 93 regional)
Around 70% of the EU28 population

Austria	Y
Austria, Tyrol	N
Austria, Vorarlberg	Y
Belarus	N
Belgium	Y
Bulgaria	Y
Croatia	Y
Cyprus	Y
Czech Republic	Y
Denmark	Y
Estonia	Y
Finland	N
France, Bas-Rhin	NA
France, Calvados	Y
France, Doubs	Y
France, Haut-Rhin	Y
France, Hérault	Y
France, Isère	NA
France, Loire-Atlantique	NA
France, Manche	NA
France, Somme	Y
France, Tarn	Y
France, Vendée	NA
Germany, Brandenburg	Y
Germany, Bremen	Y
Germany, Free State of Saxony	Y
Germany, Hamburg	Y
Germany, Mecklenburg-Western Pomerania	Y
Germany, Munich	Y
Germany, North Rhine-Westphalia	Y
Germany, Saarland	Y
Germany, Schleswig-Holstein	Y
Iceland	N
Ireland	Y

From CI5C-10 Background information CR modified

Privacy regulations apply (yes or no): An increasing number of registries must operate under privacy regulations that govern the confidentiality of all patient-level data they handle. Such regulations may affect both the ease with which registries can collect data and their ability to share their data with the research community.





The implementation of the 95/46/EC Directive is under different national laws. Heterogeneity.

- Misinterpretation of DP by Cancer registries
- Misinterpretation of DP by data providers
- Complexity of different DP regimens in different MS
- Different impact on availability, quality and comparability of data

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PROs &



CONs

Advantage: Chance to harmonise procedures across MS and greater clarity

Potential critical drawbacks:

- Explicit Patient Consent
biological reasons, epidemiological research, pragmatic reasons and cost, ethical reasons
- Explicit Time Limits
Epidemiological data have permanent life-frame, long-lasting latencies
- Strict restriction to pre-defined analysis
ok for a specific study, impediment for other possible studies
- Pseudonymisation considered as personal data
reversibility, linkage (quality of data), update (survival, recurrences, second line treatment, etc.), checking hypothesis

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Some specific examples of what may be at risk

- Measuring the efficacy of vaccination programmes (e.g. HPV, *linkage between vaccinated files with cancer registries*)
- Measuring the impact of cancer screening programs (*linkage between invitation and participation files for screening with cancer registries*)
- Measuring efficacy of treatment (*also Health Technology Assessment*)
- *Testing* of hypotheses (cancer has a long latency from exposure to onset).

Options: (1) *start now and wait for decades*

or (2) *use available CR data and deriving results in a short time (linking exposed persons to cancer registries)*

- Measuring long-term drug's usage and risk of cancer, but also real world effectiveness (*linking medication to cancer registries*)
- Immediate testing of new biomarkers (*using cancer registries for retrieving pathologic specimens*) *Biobanks!*
- *Omics (genomics, proteomics, epigenomics, etc.)*



*The individual right to DP
should not harm
the population right to health . . .*

*Important that regulation harmonizes the
rules for making cancer research not only
possible but as effective as possible.*



Presentation by Dr Hans Henrik Storm

Data saves lives

Challenges and options based on the perspective of scientific researchers

Access to data and ethical standards for scientific research in the health context

Hans Henrik Storm, MD,
Medical Director (Vice CEO) Danish Cancer Society
Member of: Danish Data Protection Council, IARC Internat. Ethics Committee

ENVI – Data saves lives



Cancer Registration & Cancer Mortality

The basic building block's for:

- Descriptive cancer epidemiology
- Analytical cancer epidemiology
- Comprehensive Cancer Control



Data may save lives – if:

- Of high quality
- Valid
- Complete
- Unbiased
- Relevant
- Pertain to one person - unequivocally
- With no loss in follow-up
- Correctly analysed
- Flawless reported
- Adhering to ethical standards for the research

ENVI – Data saves lives



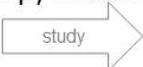
Data access for health research – permissions and terms

- Registries (health) e.g. Cancer registries (personal data)
 - Data Inspection - terms, usage, inspection
 - Ethical committee systems – relevance, methods
 - Oath of secrecy/confidentiality (e.g. medical, lawyer)
 - IEA – good epidemiological practise (Helsinki, CIOMS, ENCR, IACR)
- Hospital records
 - The above plus
 - Health law
- Biobanks
 - The above plus
 - biobank legislation

ENVI – Data saves lives



Data saves lives – the research process - 1

- Clinical research, trials – testing new drugs etc.
 - Doctor–patient relationship, Helsinki/CIOMS declarations
 - Prospective studies - ?   result
 - Informed consent
- Register based studies/ Public health
 - Data collection on individuals (administration, monitoring)
 - Continuous ongoing for decades for original purpose (million of persons e.g. with cancer on file dead or alive)
 - Research question appear 20 years after first registration – long term effect of possible carcinogenic exposure (asbestos, radiation etc.)?
 - How can we answer this question?

ENVI – Data saves lives



Data saves lives – the research process -2

- Option 1:
 - Form a cohort of exposed and unexposed still healthy individuals (age sex matched), obtain individual consent and follow for 20 years.
- Option 2:
 - Find company rosters of exposed workers
 - Identify workers with cancer (dead and alive)
 - Compare cancer incidence among workers to the general population (dose response, unbiased, strength).
- Option 1 ~ 20-24 years, Option 2 ~ 2-3 years
- How many lives are lost by delayed regulation of exposure by informed consent (Option 1)?

ENVI – Data saves lives



Requirements for option 2 – Public health / registry based studies

- Researcher is responsible in all phases
 - Protocol (necessary data variables specified)
 - Clearance by Data Protection Authorities
 - Clearance by Scientific Ethical Committee
 - Correctness of data linkages on each person on file
 - Adequate security measures pending study type
 - Pseudonymisation/anonymization when analytical data file is ready
 - Other security measures to avoid unintended access/disclosure
 - Adherence to terms given by DPA/Ethics committee
 - Publication – no stigmatisation, no possibility of identifying individual persons.

ENVI – Data saves lives



Public Health, Registry linkage studies

- Why not informed consent?
 - No contact to individuals – the personal data will be grouped and presented in summary tables/graphs
 - Asking permission from several hundred thousands – for deceased next of kin – impossible and expensive task bound to be biased (cancer patients more likely to respond ~ less than 50% of the general population)
 - Consent and research specific terms are given by DPA and Ethics
 - IEA Research ethics, ENCR/IACR confidentiality guidelines apply for cancer
 - Violation of privacy  out of business

ENVI – Data saves lives



Why not TTP in registries - encryption

- Uncertainty about linkages
- Errors in ID may radically change "ID"
- Researchers lose track of data and responsibility for key variables "ID"
- Third party increase time costs and uncertainty on the linked data
- At the outset Public Health researchers are considered criminal or careless neglecting existing law.

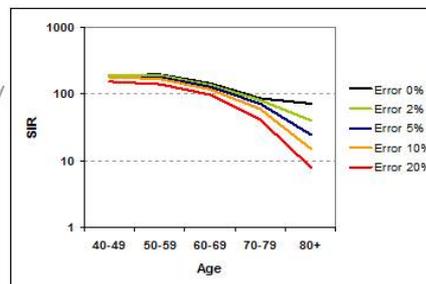
ENVI - Data saves lives



What if we miss a link!

Influence of missed link to mortality - by error proportion

(E. Pukkala)



Germany NRW cancer registry linkage study 150000 records
Pseudonyms: 1% linked wrongly 2% Not linked at all

Leukaemia risk in airline pilots - Denmark:
5 cases - significant increased risk
4 cases - no significant risk - but elevated SIR

ENVI - Data saves lives



Biobanks -what is the use and outcome?

- **Biomarkers**
 - Large number of samples needed
 - Tens or hundred thousand individuals needed
 - Identification of activated genes in a disease
- Looking for known genetic disorders (BRCA1 or 2)
- Association of genotypic with phenotypic data.

- **Prerequisite** – to **link individual biological data to other data on the individual** e.g. the information of disease, exposures, lifestyle etc. and cancer or other disease registries.

ENVI – Data saves lives



Public health studies under threat

Explicit consent difficult to obtain

- **Audit**
 - cancer screening programmes
 - HPV vaccination programmes
 - Survival & outcome research
- **Occupational hazards and cancer**
 - Nuclear power and other radiation
 - EMF – mobile phone's etc.
- **Environment**
 - Social inequality
 - Risk factors identified in large groups



Freedom of Research and Ethics

- No research without ethics
- Without research no ethics

- Ethics is about the good life (Aristoteles)

- Research contributes by promoting and creating the basis for the good life

(E.Tiedeman, previous Chair of the Natl. Ethics Committee of Denmark)



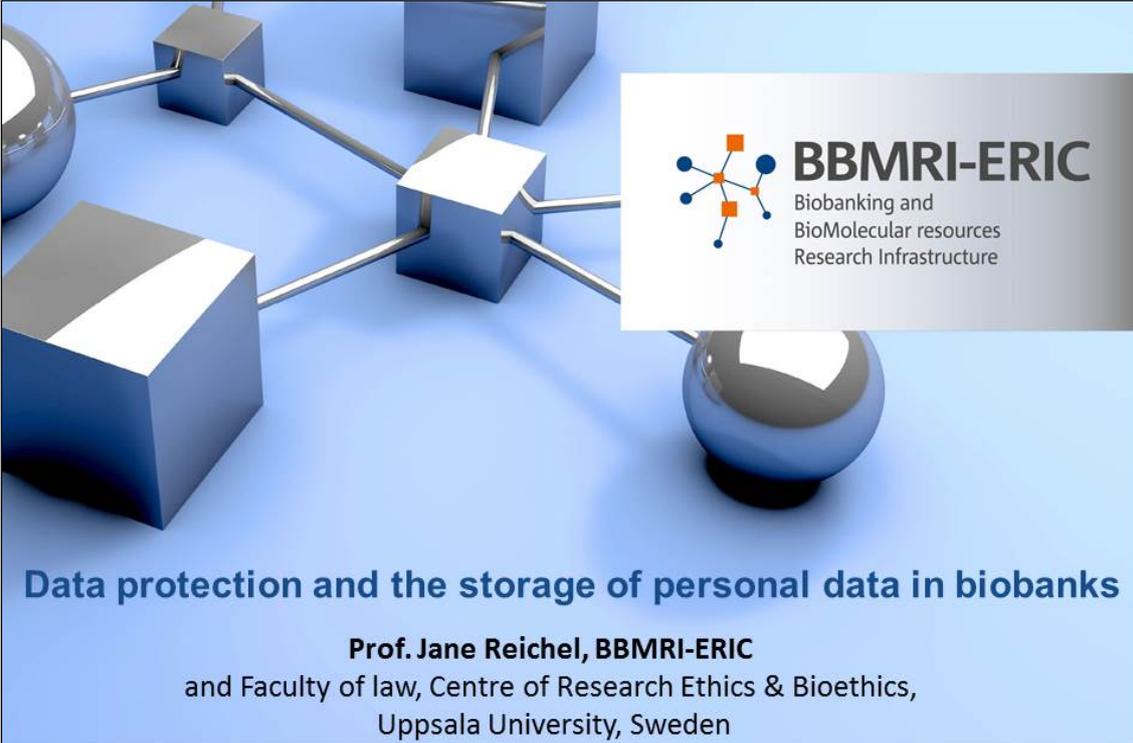
- Research on health data can be done in an unethical way – which should be avoided

- Research on data of low or uncertain quality should also be avoided

- Failure to do health research is also unethical – and devastating for public health



Presentation by Prof. Jane Reichel



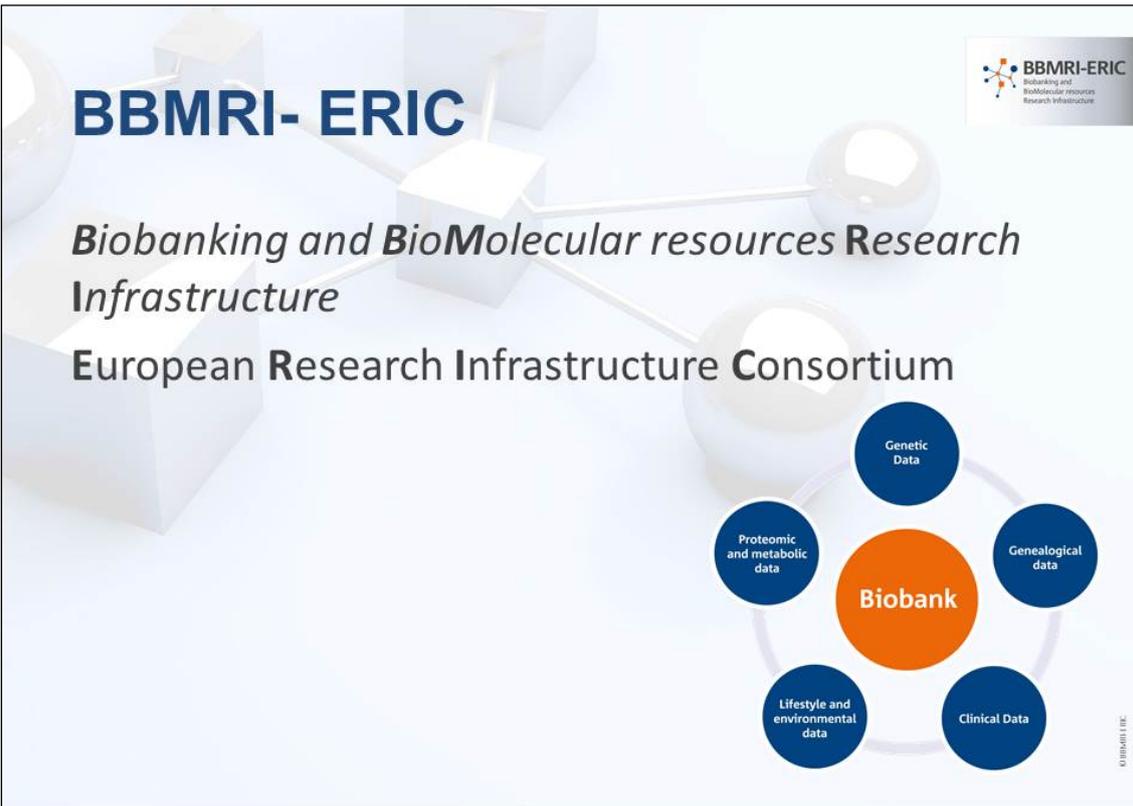
 **BBMRI-ERIC**
Biobanking and
BioMolecular resources
Research Infrastructure

Data protection and the storage of personal data in biobanks

Prof. Jane Reichel, BBMRI-ERIC
and Faculty of law, Centre of Research Ethics & Bioethics,
Uppsala University, Sweden

www.bbmri-eric.eu

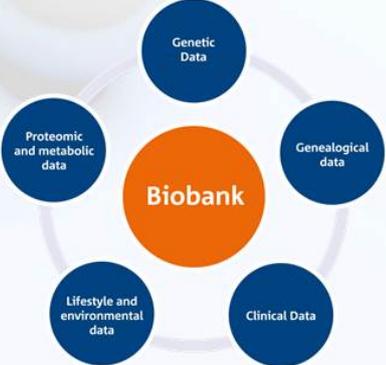
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Biobanking and BioMolecular resources Research Infrastructure

European Research Infrastructure Consortium



Biobank

- Genetic Data
- Genealogical data
- Clinical Data
- Lifestyle and environmental data
- Proteomic and metabolic data

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2

BBMRI-ERIC
Biobanking and
Biomolecular resources
Research Infrastructure

BBMRI-ERIC - largest infrastructure in health in Europe

Founding Members of BBMRI-ERIC

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- France
- Germany
- Greece
- Italy
- Malta
- Netherlands
- Norway
- Sweden
- United Kingdom

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- Poland
- Switzerland
- Turkey
- IARC



MEMBERS
OBSERVERS

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3

BBMRI-ERIC
Biobanking and
Biomolecular resources
Research Infrastructure

Aim

... to establish, operate and develop a Pan-European distributed research infrastructure in order to facilitate the access to biological resources as well as facilities and to support high quality biomolecular and biomedical research as a part of the European Research Area (ERA).



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4

Way

- **Networking biobanks and cohorts of 17 European countries and IARC/WHO**
- **Facilitating access to high quality human biological samples and associated data**
- **Creating a central catalogue of European biobanks/samples**
- **Offering common services for ethical, legal and societal issues (ELSI) and IT**
- **Long-term sustainability of research results**



www.bbmri-eric.eu

5

ADOPT BBMRI-ERIC

In the context of ADOPT BBMRI-ERIC, colorectal cancer has been selected as a pilot study. Both genes and environmental factors are known to contribute to the etiology of colorectal cancer.

- **Collect 10.000 biological samples from 17 Member States**
- **Collect 10.000 medical records using text-mining**

Colon cancer is a sufficiently common cancer Europe to constitute a significant public health problem.

12/11/2015

6



Data protection

Computers and the Internet are among the most important inventions of our time. Questions on privacy and considerations what constitutes personal information become more pertinent in the in the information age when the immense possibilities of sharing information that come along with technical possibilities, which create chances, risks and expectations.

- **Informed consent**
- **Purpose**
- **Retention periods**



12/11/2015 7



General Data Protection Regulation

There is a need for updated and coherent rules on data protection for Europe

- **Absence of rules to approve research means absence of research**

Don't overdo it!

- **Research is conducted within a highly controlled environment, via research funders, ethical review boards, academic peer review, etc**

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General Data Protection Regulation



There is a need for proportionate and well defined exemptions to allow researchers to use and re-use data over time, for unspecified purposes

- Recital 126 European Parliament and Council version acknowledges the difference between data processing in research and in other forms
- Recital 25 aa, Art 9.2 (I) and 83 of the Council version enables research without re-consent

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9

General Data Protection Regulation



Exemption via EU or Member State law?

- Delicate question if 'accustomed' national exemptions or harmonized EU exemptions are better for researchers
- Common rules facilitates cross-border research within the ERA

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10



Thank you!

Jane.reichel@jur.uu.se

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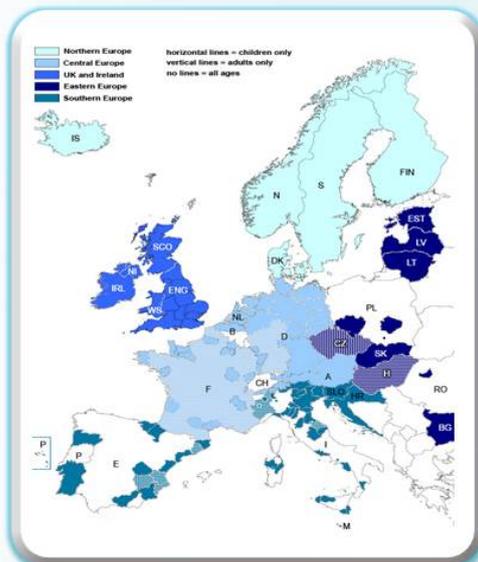
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Presentation by Dr Gemma Gatta

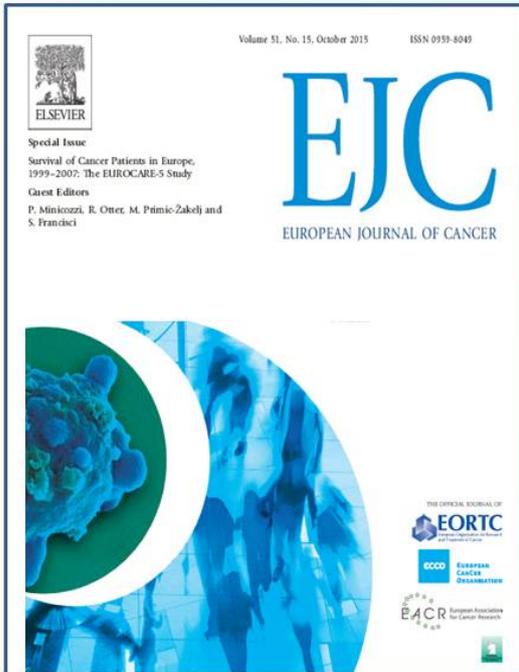
EXPERIENCES FROM EUROCARE CANCER SURVIVAL IN EUROPE

Gemma Gatta and Milena Sant



- 31 countries (117 registries, 20 national)
- Increased coverage in countries with regional registries
- 50% European population
- Overall >20 million cancer cases
- Adult patients (age 15+)
- 45 major cancer sites
- Diagnosis 1999-2007
- Follow-up 2008 or later
- Uniform data collection protocol and statistical analyses





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EJC
EUROPEAN JOURNAL OF CANCER

Special Issue
Survival of Cancer Patients in Europe,
1999-2007: The EUROCARE-5 Study

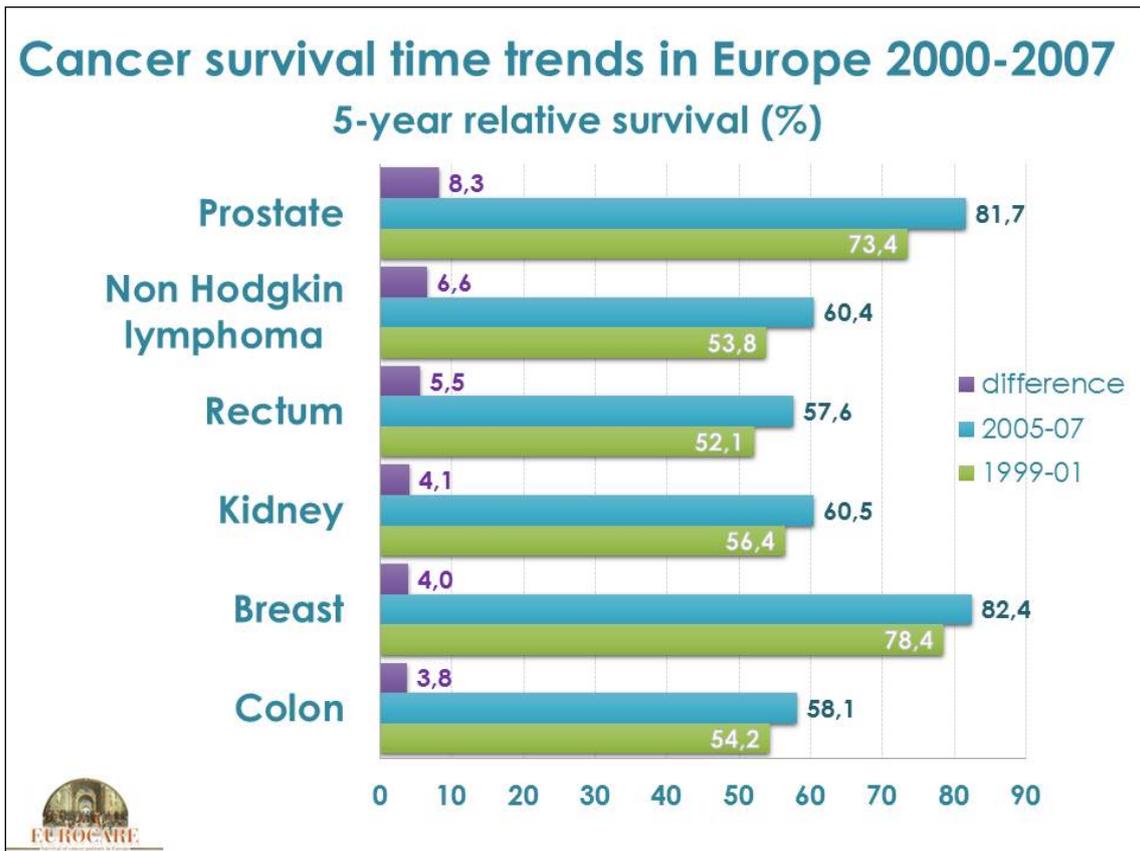
Guest Editors
P. Minicozzi, R. Otter, M. Primic-Zakelj and
S. Francisci

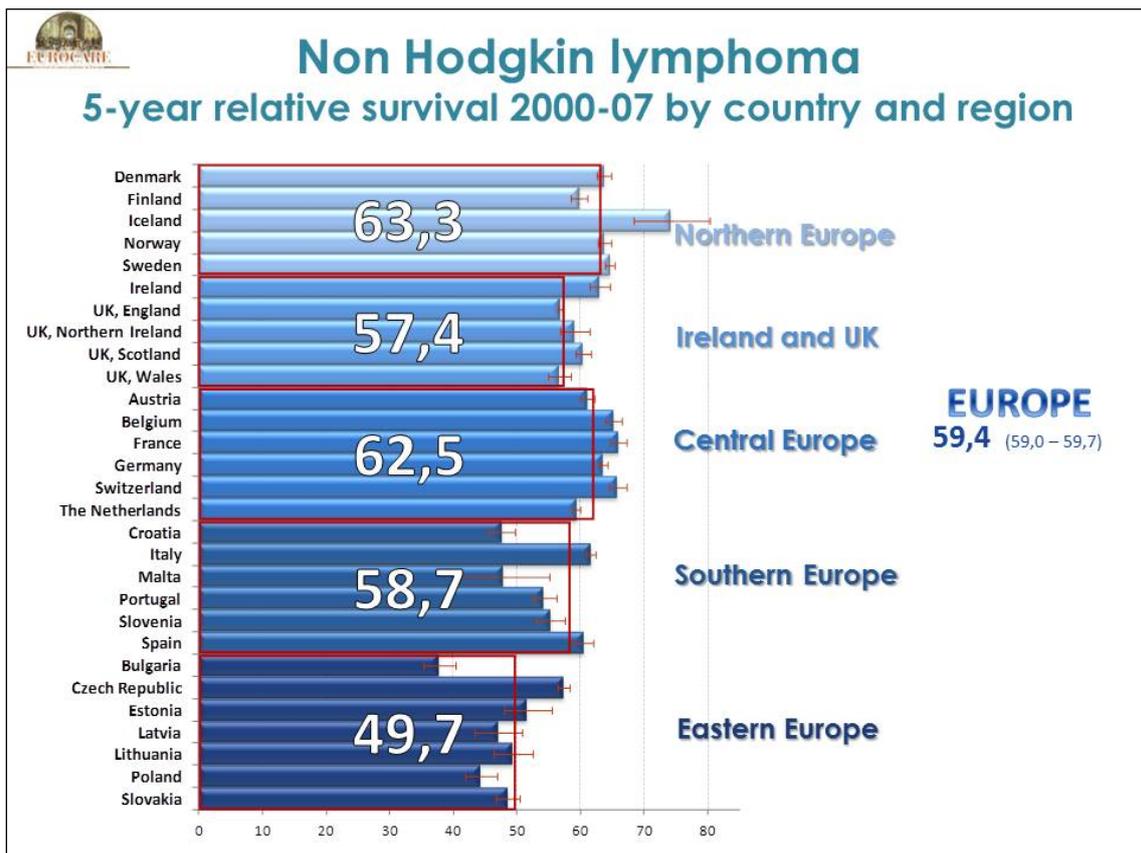
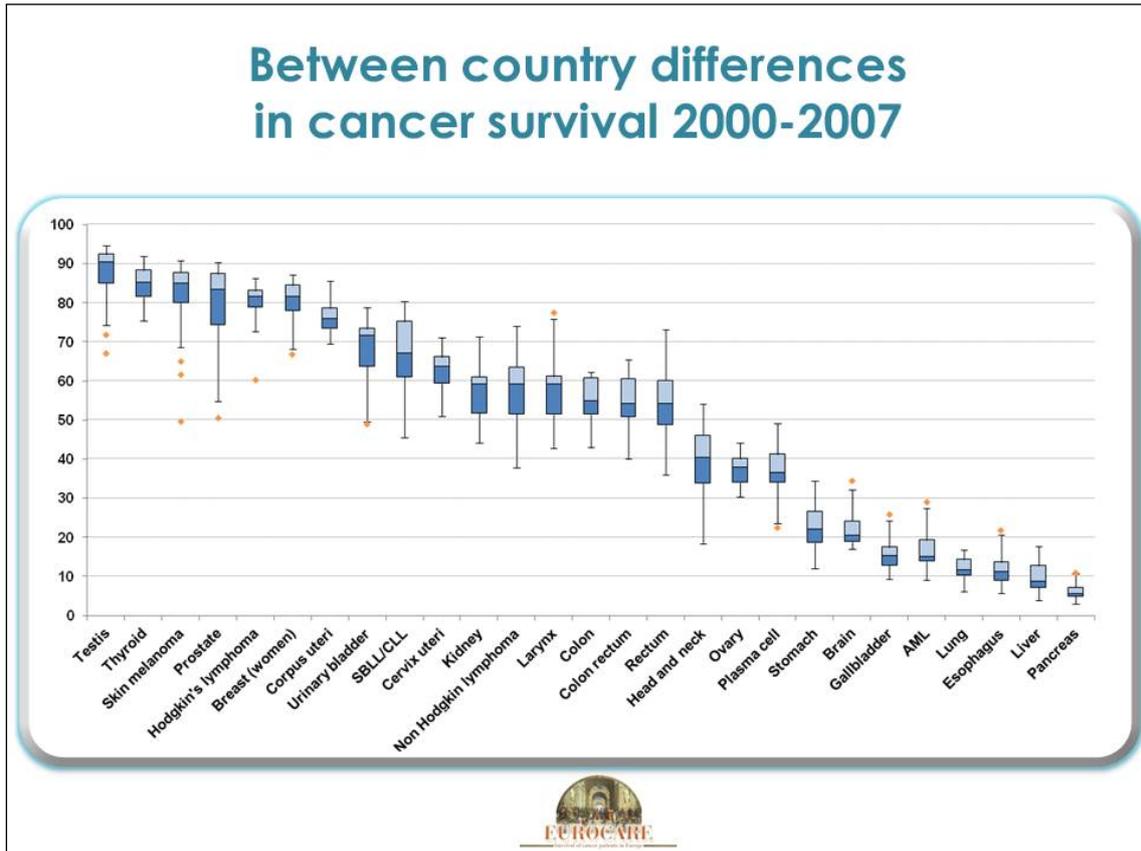
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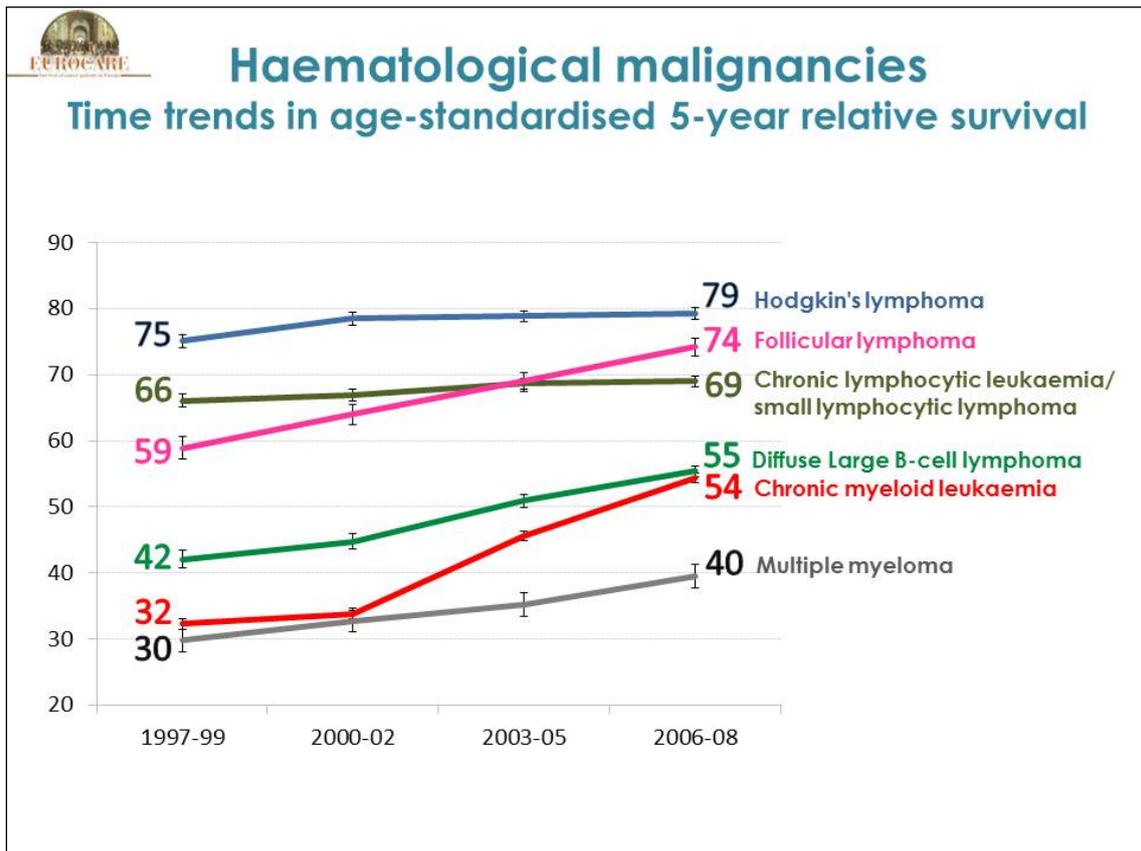
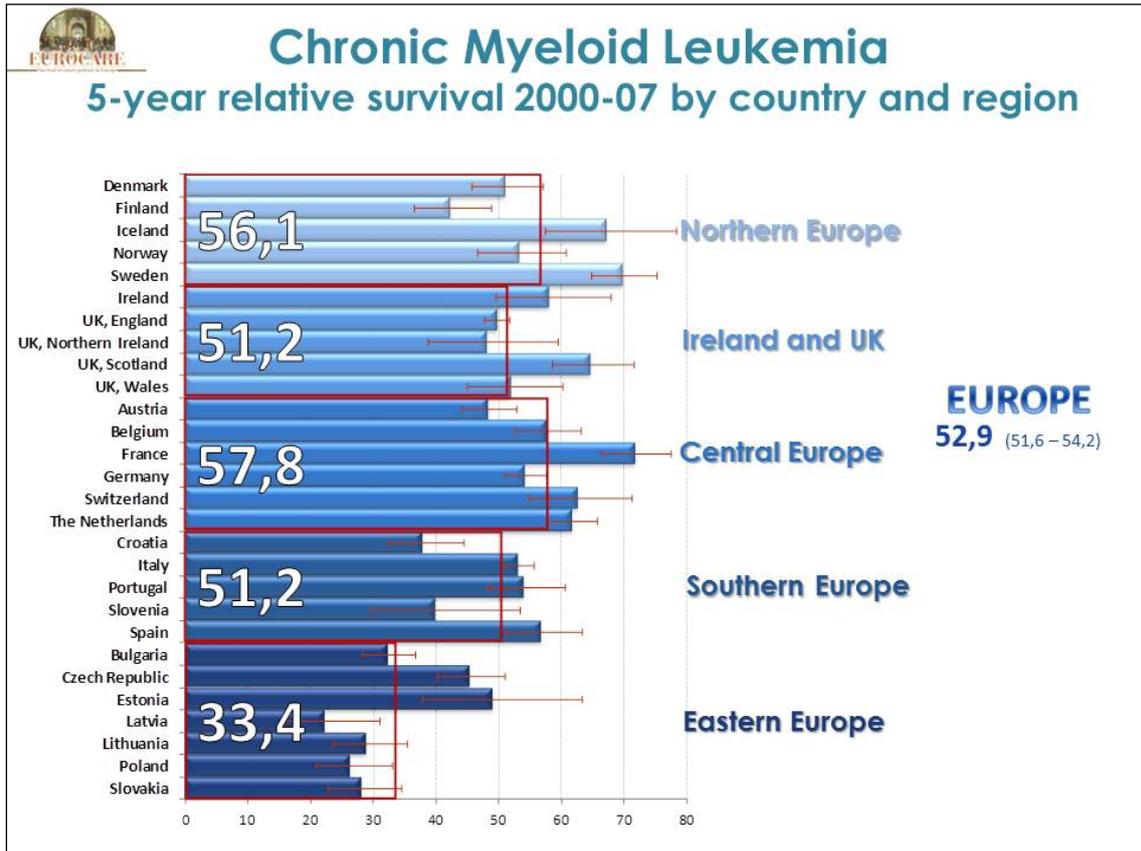
ECCO EUROPEAN CANCER ORGANIZATION

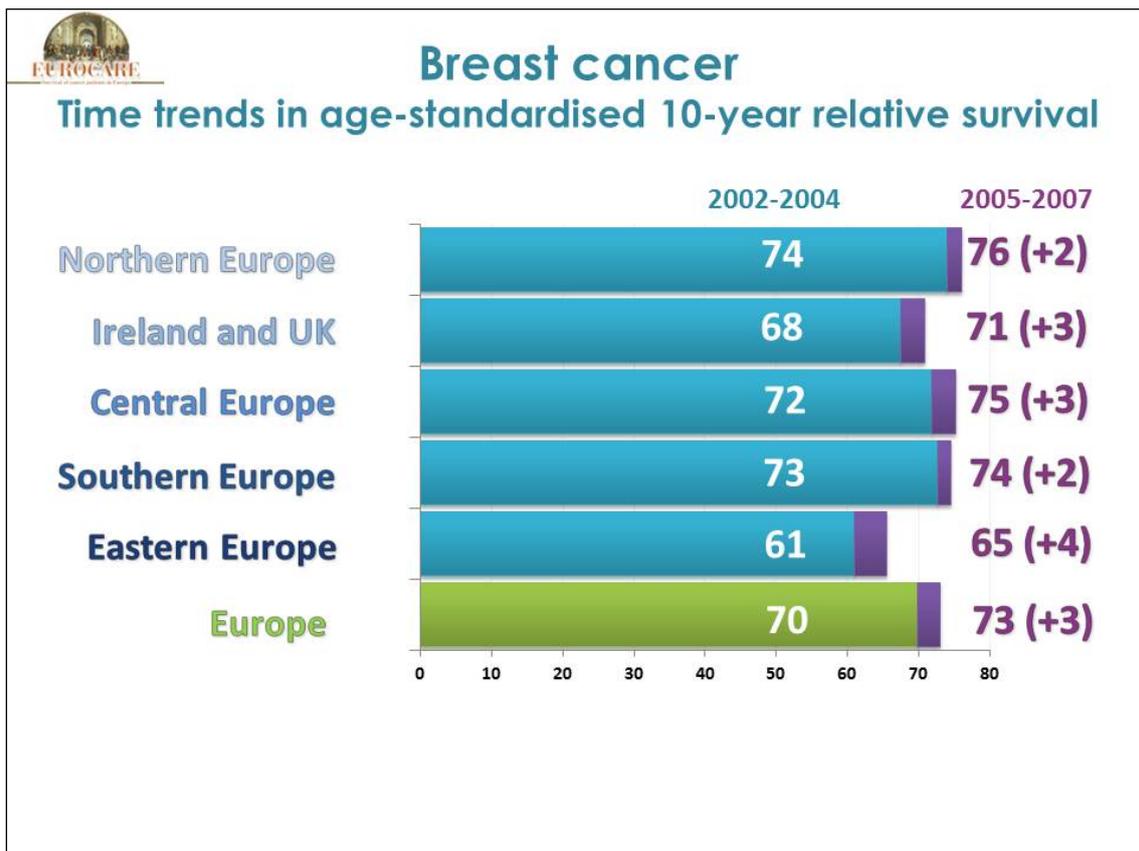
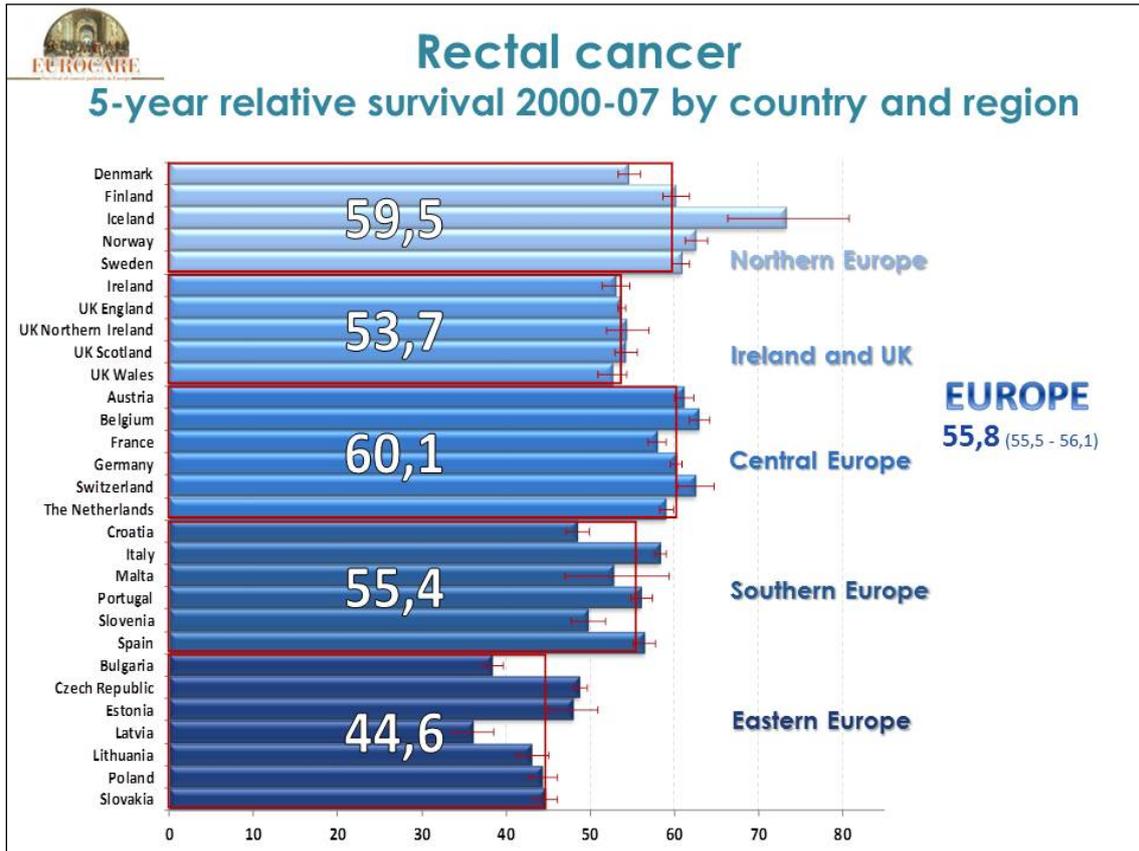
EACR EUROPEAN ASSOCIATION FOR CANCER RESEARCH

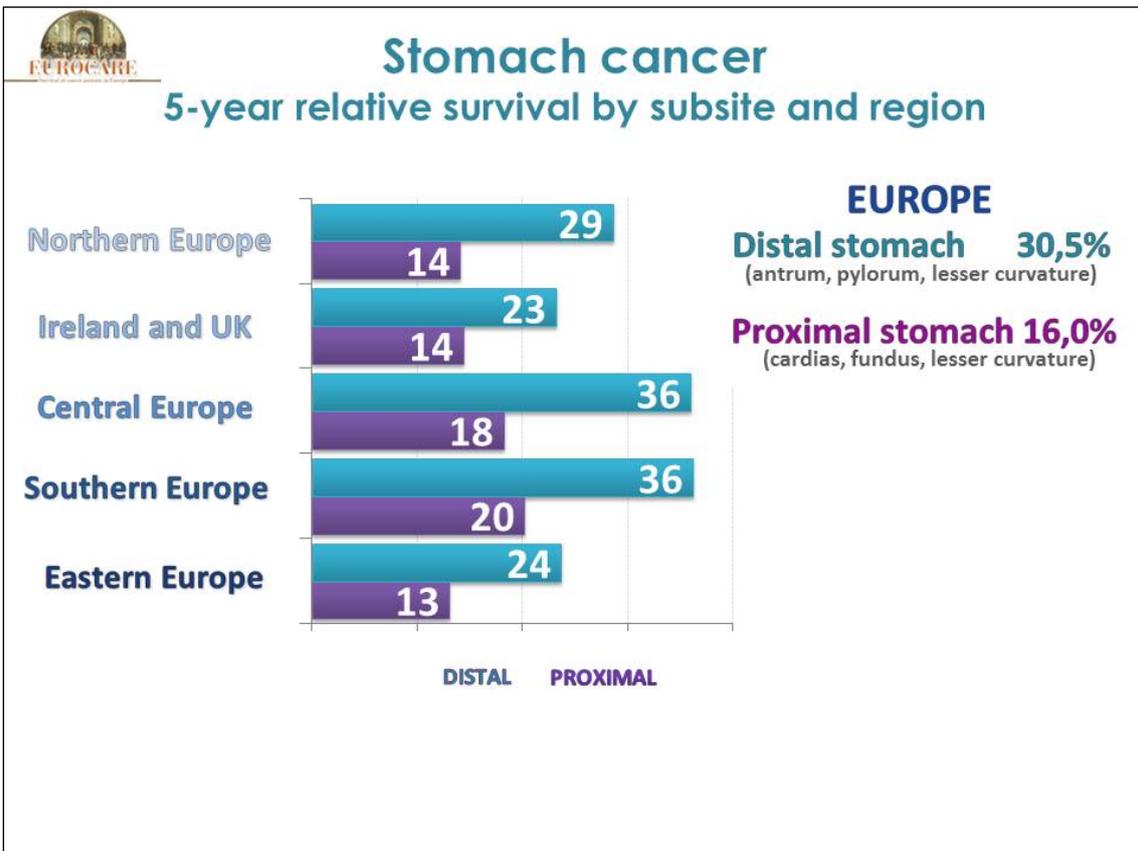
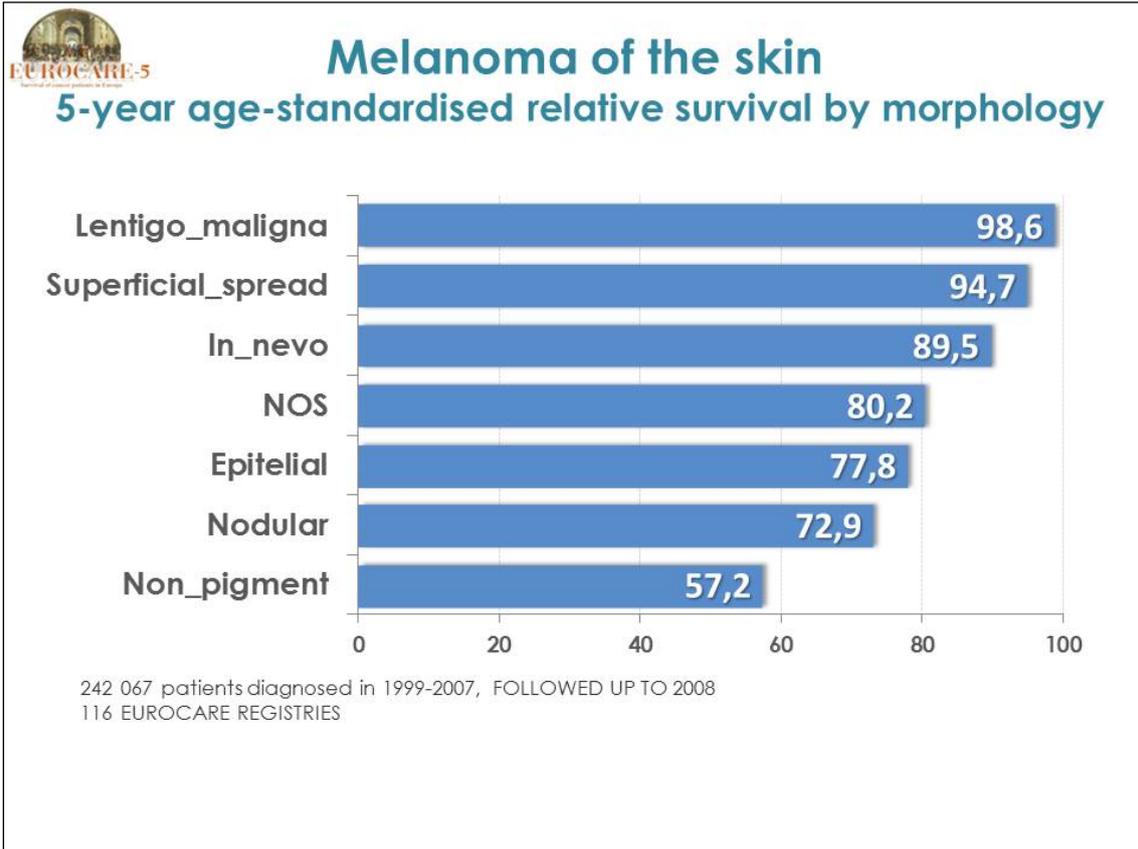
- 13 scientific articles
- Country-specific survival
- Adult patients (age 15+)
- Survival by cancer site or system
- Analyses by subsite, tumour morphology, stage
- Time trends incidence and survival
- Statistical methodology

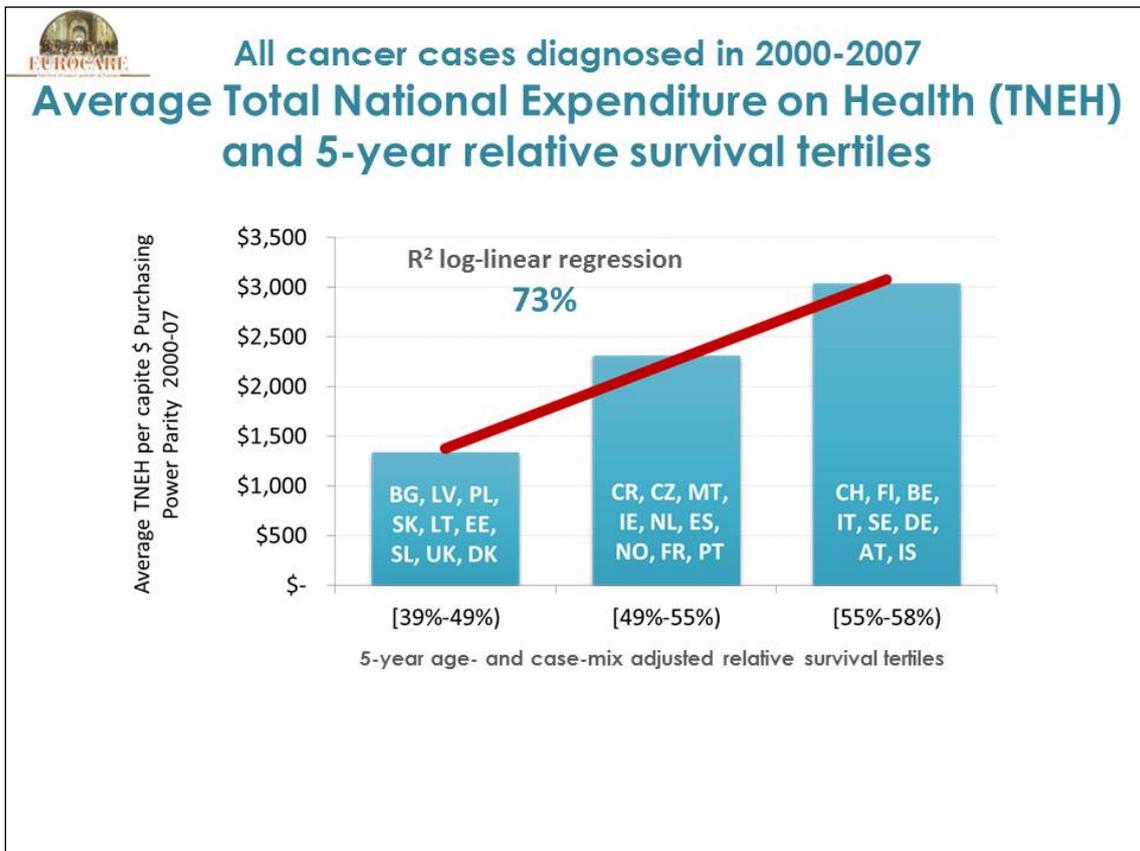
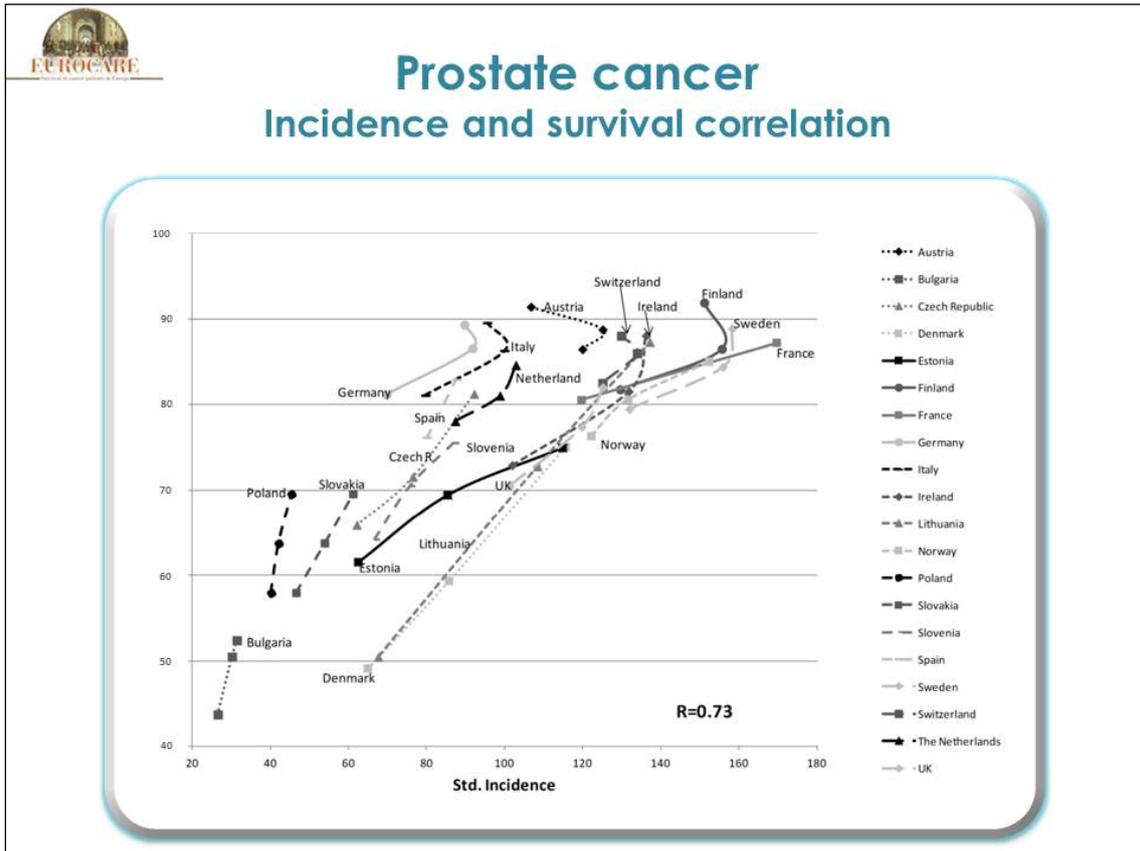












EUROCARE -5 KEY MESSAGES

Improvements in cancer survival over time, but persisting variations across countries and regions point inequalities in cancer care

Related to:

- **differences in cancer biology** (stomach, head & neck)
- **diagnostic intensity and screening, leading to earlier stage at diagnosis** (breast, colorectal, prostate)
- **effective treatments** (NHL and CML)
- **socioeconomic status, lifestyle and general health differences between populations**

Further investigations needed on:

- **tumour characterisation**
- **co-morbidity and its influence on the prognosis**
- **survivorship**
- **cancer costs and organisation of care**









To help reduce survival inequalities & improve cancer care

- Reduction in the fragmentation of care services
- Promotion of comprehensive multidisciplinary cancer care centres
- Better organisation and funding of health care systems
- Promotion and funding outcome research
- Alliance between patients, physicians and researchers














**Research based on population-based disease registries,
shall not be impeded by the proposal on the
General Data Protection Regulation**

**exemption from patient consent is necessary,
to permit the collection of**

complete, accurate, high quality data

needed to

↳ develop evidence-based policy decisions
↳ measure their effectiveness

Examples of projects dealing with big data on health, which were funded by the EU Commission

Horizon 2020 ICT-16 Big Data

European Commission
Digital Agenda for Europe
A Europe 2020 Initiative

European Commission > Digital Agenda for Europe > What big data can do for you

Home | Digital for Europe | Digital society | **Digital economy** | Access and connectivity | Research and innovation

Digital economy
Startup Europe
Data
Big Data strategy
What big data can do for you
Data Public-Private Partnership
Open Data
EU investments
Language Technologies
Big Data
Automated Translation
EU investments
Cloud Computing
Future Internet
Digitising Industry
Advisors

What can big data do for you ?

Big data presents great opportunities as they help us develop new creative products and services, for example apps on mobile phones or business intelligence products for companies. It can boost growth and jobs in Europe, but also improve the quality of life of Europeans.

Here are some examples of research projects that can help you in your daily life.

Healthcare: saving lives with better diagnosis

A widespread use of big data in the health sector can help doctors make the right choices more quickly, on the basis of information collected by other medical staff. Patients can benefit from more timely and appropriate treatments and be better informed about health care providers. An increased use of data analysis in the health sector can also lead to enormous cost savings through a more precise identification of unnecessary procedures or duplication of tests. The analysis of large clinical datasets can result in the optimisation of the clinical and cost effectiveness of new drugs and treatments.

Projects:

- EU-funded ICT tool to help patients with brain trauma (TBICARE)
- A healthier daily life with the DAPHNE platform (DAPHNE)
- Advancing medical research through cutting edge technologies (Linked2Safety)

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We encourage the removal of barriers to #OpenScience & #openinnovation @medias bit.ly/1KogDc #ICT2015 pic.twitter.com/z6y98Wku

Presentation by Prof. Ruth Ladenstein



SIOP Europe
The European Society for Paediatric Oncology

The processing of personal data from patients to healthcare provider

Prof. Ruth Ladenstein (Vienna, AT)
St. Anna Children's Hospital and Cancer Research Institute

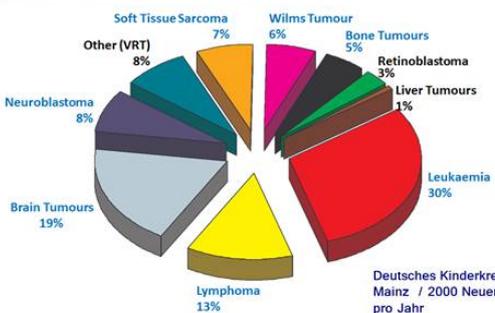


Paediatric Cancer is a public health challenge

- 6,000 children and young people die of cancer in Europe each year
- The quality and availability of paediatric cancer care widely varies across Europe
- 10% to 20% of them die from curable forms of cancer where quality care is not easily accessible.
- The outcome gap is even larger for paediatric cancers with poor outcomes

Childhood Cancer

- Rare Disease Definition: 1 in 2000 www.eurordis.org
- Childhood (< 15 years) Cancer Incidence in Europe: 1 in 6250
Kleinman et al. Cancer Treat Rev. 2010; 36(4):277-83. Epidemiology of childhood cancer.



Cancer Type	Percentage
Leukaemia	30%
Brain Tumours	19%
Lymphoma	13%
Neuroblastoma	8%
Other (VRT)	8%
Soft Tissue Sarcoma	7%
Wilms Tumour	6%
Bone Tumours	5%
Retinoblastoma	3%
Liver Tumours	1%

Deutsches Kinderkrebsregister Mainz / 2000 Neuerkrankungen pro Jahr

2

The Problem

Inequalities across Europe

Childhood Cancer Survival in Europe: 1999-2007
Results of the EUROCARE 5
A population based study

Figure 3. 5-year survival for all cancers combined (ICM tumours excluded) diagnosed in 2000-07 in children, by country. Includes data for 52 000 cases. Data adjusted for age, sex, cancer, and period of diagnosis. *Country-weighted.

**Childhood cancer survival in Europe
1999-2007: results of EUROCARE-5—a population-based study**
EUROCARE Working Group
Lancet Oncology
Volume 10, Number 12, December 2009

Survival in paediatric acute leukemia is correlated with Economic Health Care Expenditures

Childhood cancer survival in Europe 1999-2007: results of EUROCARE-5—a population-based study. Lancet Oncology, Volume 10, Number 12, December 2009.

5-year survival for acute lymphoid leukaemia diagnosed in 2000-07 in European children by country. Includes data for 15 860 cases. Data adjusted by age, sex, and period of diagnosis. *Country-weighted.

Proposed Solutions

EUROPEAN REFERENCE NETWORKS

- ExPO-r-Net is a 3-year project to build a European Reference Network (ERN) for Paediatric Oncology.
- ExPO-r-Net aims to reduce the current inequalities in childhood cancer survival and healthcare capabilities in different EU Member States
 - ✘ Support cooperation on cross-border healthcare and mobility of patients, health-care professionals and information
 - ✘ Innovate healthcare delivery

This Project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101019719.

The Paediatric Oncology European Reference Network

- will improve the standards of care across Europe
- will let children and young people with cancer benefit from high-quality, accessible and cost-effective healthcare
- <http://www.expornet.eu>



ExPO-r-Net





Co-funded by
the Health Programme
of the European Union

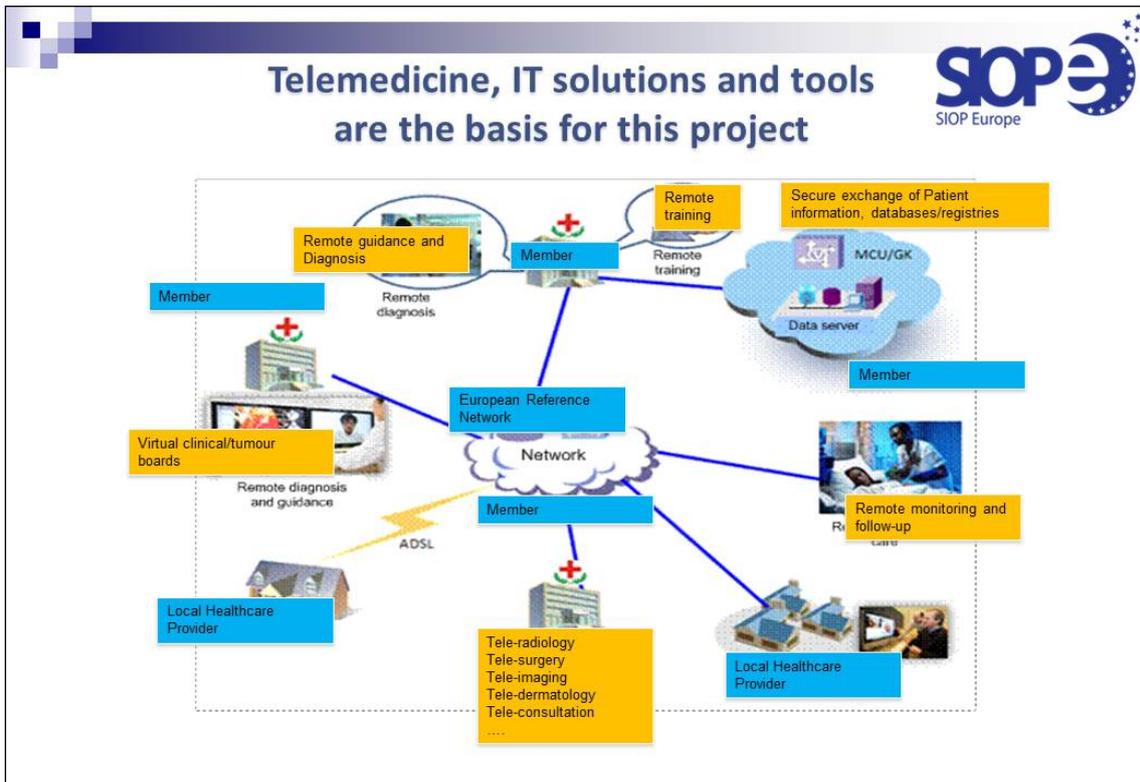
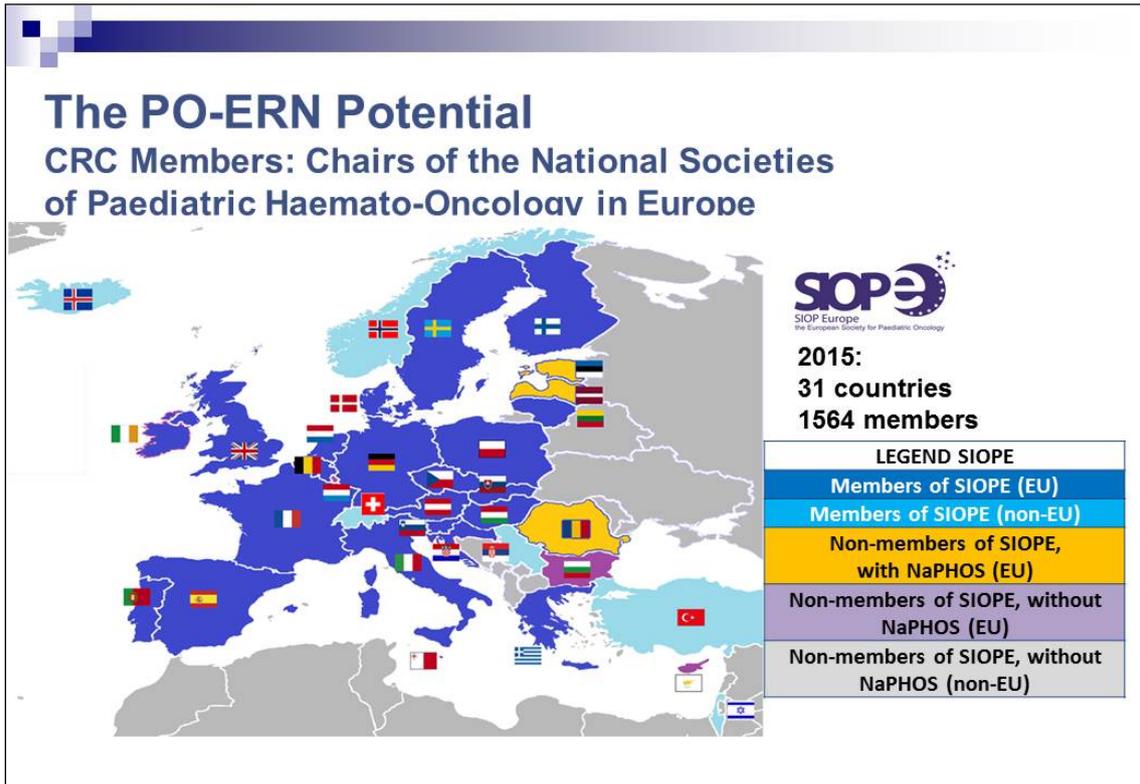
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The Paediatric Oncology European Reference Network

- **Will enhance 'Cross-border healthcare'**
 - **Linking pre-existing reference centres with tumour boards to provide cross border advice.**
 - **Identification of the target groups** : children with special diagnostic and therapeutic needs requiring a particular concentration of resources or expertise.
 - **Improving access to high-quality health care** for children with cancer whose conditions require specialised resources or expertise not widely available due to low case volumes and lack of local resource.
 - **Provision of healthcare** to children and young people with cancer in a Member State other than the Member State of affiliation.



SIOPE
SIOPE Europe





2 sides of the coin:

**PROCESSING OF PATIENTS' PERSONAL DATA
BETWEEN HEALTH CARE PROVIDERS**

**CREATING AN INFORMATIVE RESEARCH
KNOWLEDGE DATA BASE IN RARE DISEASE TO
CREATE EVIDENCE**



•Clinical and Tumour Boards are recognized as an **essential component of excellence in cancer care and complex diseases.**

•They **bring together a range of medical disciplines** for discussions on how to best care for the patient.

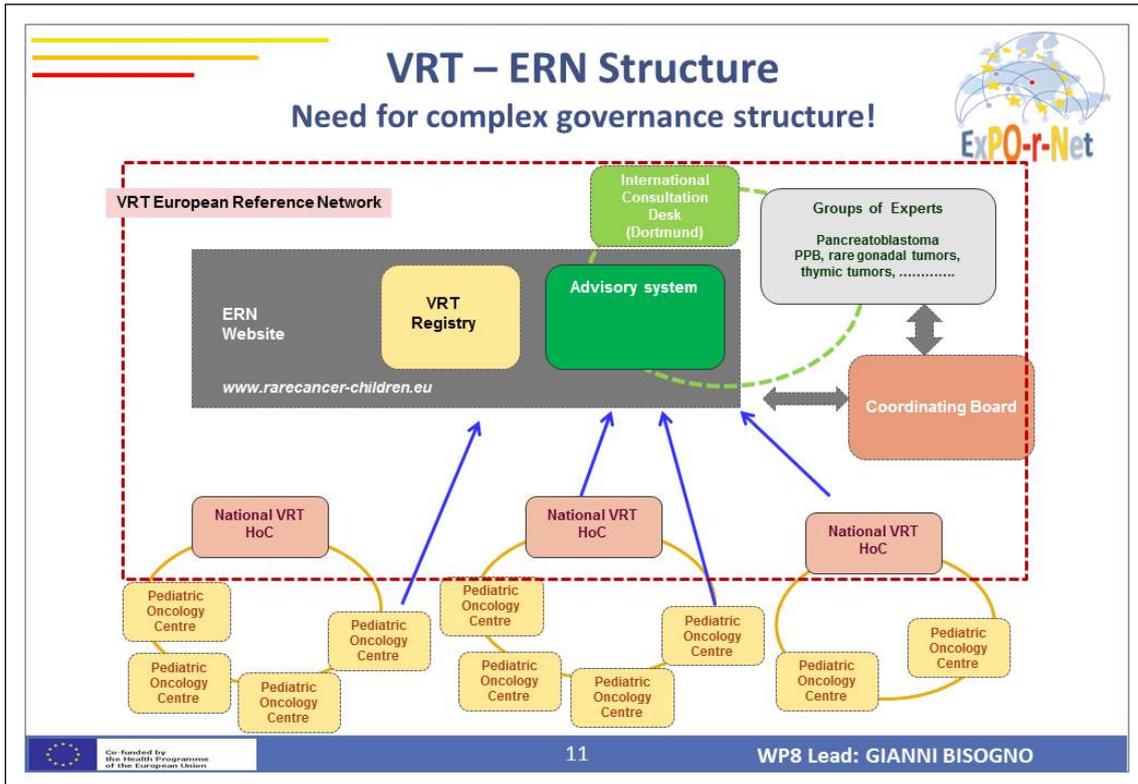
•Using **eHealth & telemedicine technology**, teams of specialists of the **Members of the future NETWORKS across the EU would meet in videoconferences** called "Virtual Clinical or Tumour Boards" to share medical information and agree on treatment options.

•**Personal data needs to travel cross-border!**

Virtual clinical and tumor boards

Health and Consumers





Survivorship Passport The International Prototype Development

- A document to be given to the patient after therapy containing cancer history, therapy information and clinical recommendations for FU care
- Use common nomenclature
 - Tumor (ICCC-3 and ICD-O)
 - Chemotherapy + Immunotherapy (ATC)
 - Surgery (ICD-9-CM)
 - Radiotherapy (New numerical coding system!)
 - “Translation” into lay language of some medical terms
 - Online tool for data entry and passport creation
 - Linkage with clinical trials data bases and health records
 - Data security and privacy issues
 - Linkage with guidelines for follow-up



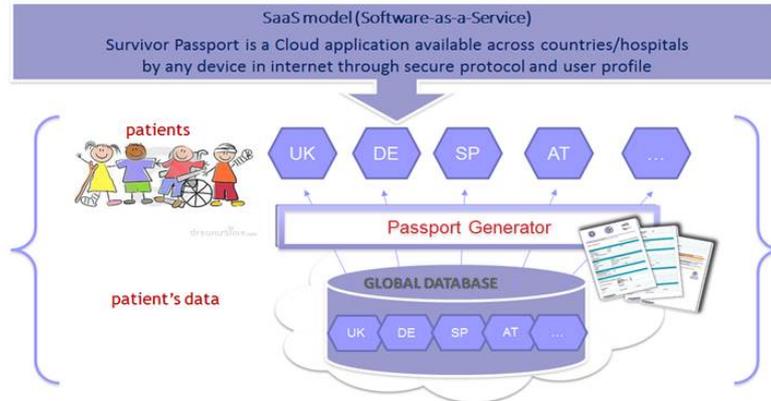
How can the Survivor Passport be deployed ?

The **cross border** dimension of long term follow up of childhood cancer survivors in Europe: the Survivor Passport as an instrument for crucial treatment and follow up data

Marisa De Rosa
Eugenia Rinaldi
Davide Saraceno



How can the Survivor Passport be deployed ?

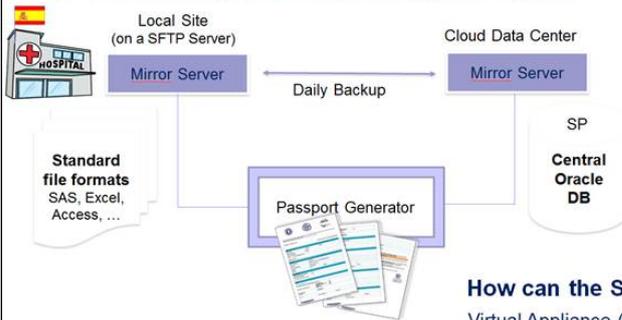


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SaaS model (Software-as-a-Service)

Data transfer to local site (database mirroring)

To give the possibility to have a copy of the data at hospital/country level



How can the Survivor Passport be deployed ?

Virtual Appliance (future possibility)



In this scenario, local users need a local IT infrastructure including Quality and Security procedures in data management.

Possible Solutions

EUROPEAN UNIFIED PATIENT IDENTITY (EUPID)

Some Technical Challenges

- solvable to protect patients' privacy:

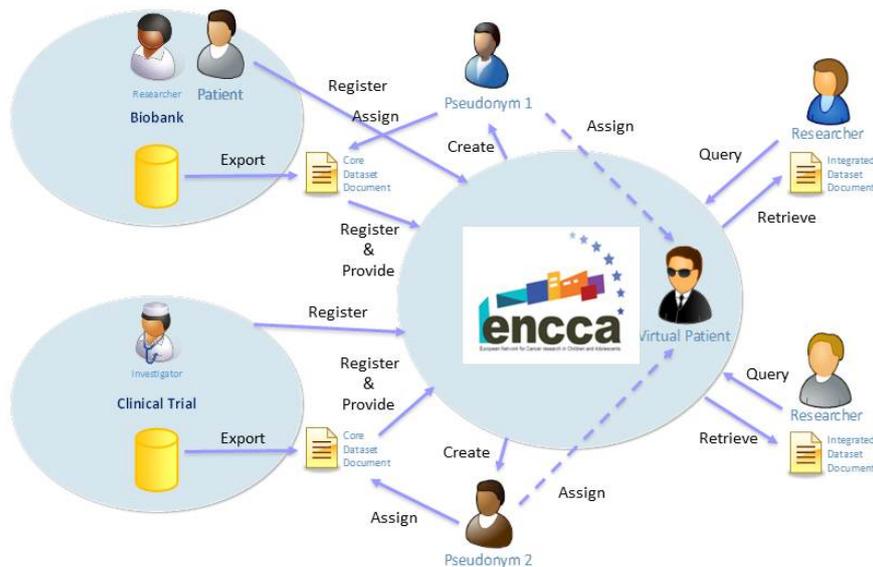
European Unified Patient IDentity (EUPID)

■ Basic requirements for Identity Management

- Preserve the possibility for re-identification by a trusted third party
- Use different pseudonyms for different contexts
- Provide a method to link the different pseudonyms in the background
- Avoid creating a transparent universal patient ID
- Prevent duplicate registration of patients
- Must be feasible in a distributed computing environment, including the Cloud



EUPID based Identity Management





Example SECONDARY USE OF DATA

A Case for International Collaboration !

International Neuroblastoma Risk Group (INRG) Data

- Cancer of the sympathetic nervous system
- 50% before the age of 2 years and wide spread dissemination at diagnosis
- It is a disease exhibiting extreme heterogeneity – Biology is key!

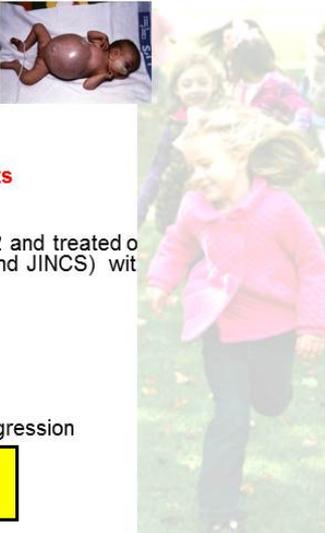
2004: INRG Task Force (52 investigators from US, Europe, Japan, Australia)

Aim: Consensus approach to *pre-treatment* risk stratification

- **“Double Pseudonymisation” of Clinical Trials and Research Data Sets** (via a honest broker = trusted third party)
- **Data collected on 8,800 unique patients** diagnosed between 1990-2002 and treated o trials of international cooperative groups (COG, SIOPE, GPOH, JANB and JINCS) wit follow-up to 2004
 - Demographics
 - 36 prognostic markers (Genetic markers: 1p, 11q, MYCN, ploidy)
 - Treatment
 - Outcome (EFS, OS)

Factors prognostic of event-free survival were identified using survival tree regression

Will we need to go back to every single patient/parent for „specific“ and „explicit“ consent in the future ?





Benefits of Secondary Use of Data

“The INRG Classification System”

- **7 factors identified that were highly statistically significant and also considered clinically relevant**
 - Non 4S **Metastatic Disease**
 - **New Age Cut Point:** < 18 months vs. ≥18 months]
 - **Histological Category** – Ganglioneuroma, ganglioneuroblastoma – intermixed vs. neuroblastoma, ganglioneuroblastoma – nodular
 - **Grade of Tumour Differentiation** differentiating vs. undifferentiated or poorly differentiated
 - **3 Biological Factors**
 - **MYCN status**
 - Presence/absence of 11q aberration
 - Ploidy (≤ 1.0 versus >1.0)

Such efforts rely on a „ broad“ **One-Time Only Consent !**

- Trying to trace back patients absorbs enormous time and resources
- Likely to result in loss of data or abandoned research





Evolution of Techniques

New datasets, using new technologies, have been generated!

Technique	N° of features
MLPA	100 loci (Androsch et al 2013)
aCGH	4k – 1000k
SNP (SNP6, cytoscanner)	> 1 Mio
Sequencing data	Coding sequence
	Whole exome
	Whole genome

The future potential of biomarker and mode of actions discovery rely on **Data Linkage and Patient Tracability !**
Does not work with anonymised data sets !



Continued Need for Secondary Use of Data and Follow UP!

Limitations of original INRG Data

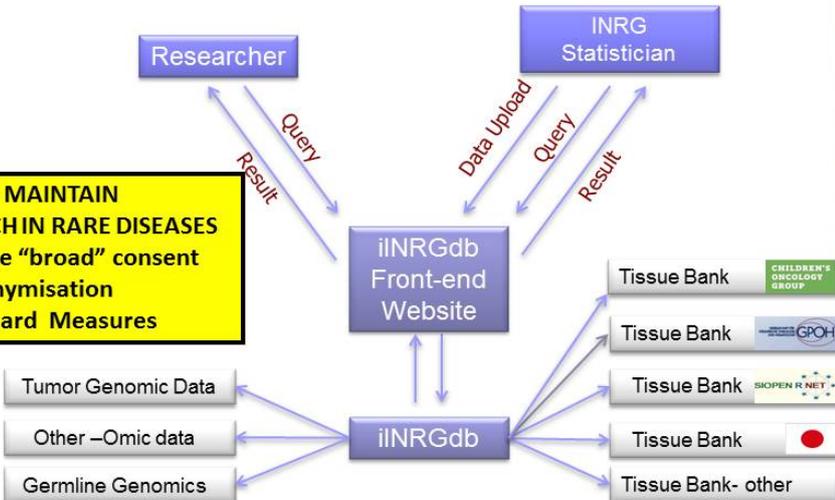
- **Original INRG Data Base outdated!**
 - Consists of prognostic factors identified > 30 years ago
 - More recent whole genome data generated by labs around the world are not included in the database (GWAS, array cGH, omic signatures, NGS)

The Need: Large Scale Data Integration in Rare Diseases

“An Interactive iINRGdb” – under construction

- Fostering research in Biomarker Discovery & Mode of Actions
- Basis for Innovative Drug Development
- Basis for “Personalized Medicine” approaches in Rare Diseases

NEED TO MAINTAIN RESEARCH IN RARE DISEASES
-One-time “broad” consent
-Pseudonymisation
-Safe- Guard Measures






Benefits of Secondary Use of Data

The INRG Classification System

- Ensures that children diagnosed with neuroblastoma in any country are stratified into homogenous pre-treatment groups
- Facilitates the comparison of risk-based clinical trials conducted in different regions of the world
- Enhances our ability to develop international collaborative studies

Thanks to
All European Collaborators
Funding Organisms of EU Projects



This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under the project ENCCA, grant agreement no HEALTH-F2-2011-261474



ExPO-r-Net project has received funding from the European Union in the framework of the Health Programme (2008-2013), grant agreement nr. 2013 12 07.



Presentation by Mr Richard Stephens

* Providing Personal Data and Cancer Survival – The Rights of Patients

Why do we donate our data?

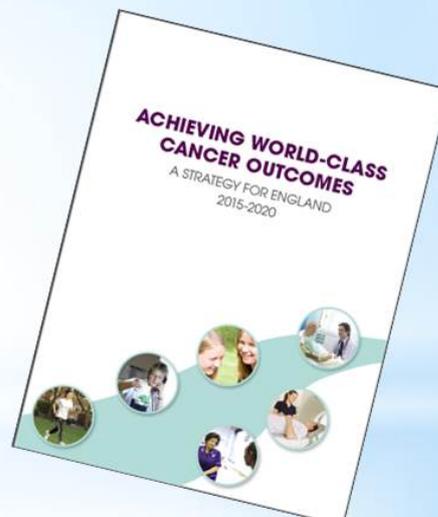
(Why do we take part in research?)

- ✓ To help ourselves (it's our illness and our treatment)
- ✓ To help others (because others have helped others)
- ✓ To make a better world (especially for our children)

* use MY data

* ACHIEVING WORLD-CLASS CANCER OUTCOMES: A STRATEGY FOR ENGLAND 2015-2020 – July 2015

“An inability to link data sets and make these available to providers, commissioners and researchers sustains the provision of sub-standard care. There is extensive evidence that cancer patients want their data to be used for research and to improve care. We must harness their support, ensuring cancer patients are placed at the heart of strengthening our cancer data intelligence.”



* use MY data

* Providing Personal Data and Cancer Survival – The Rights of Patients. We Have The Right ...

- ✓ To require that our data is used for our own benefit.
(We expect our clinicians and our hospitals to do that.)
- ✓ To require that our data is used to benefit other patients.
(We expect researchers and the medical world to do that.)
- ✓ To be involved in decisions about us, our data and using it:
 - What data? (Anonymised or pseudonimised? Consent?)
 - Who holds it? (Safety/confidentiality? Shared access?)
 - Who wants it? (Access or takeaway? All or part?)
 - What for? (Regulated medical research? Improving services? Increasing our understanding?)

* use MY data

* Providing Personal Data and Cancer Survival – The Rights of Patients; Let Us Donate Our Data



* use MY data

* Providing Personal Data and Cancer Survival – The Rights of Patients; Give Us The Tools!

- 😊 Use existing laws and regulations to protect us – they are enough
 - ✓ Take advice from Wellcome Trust, Cancer Research UK et al

- 😊 Awareness/Education Programmes for Patients and Public
 - ✓ Our rights and our opportunities as empowered citizens (Eupati)

- 😊 Patient/Citizen Involvement
 - ✓ Data Access Committees
 - ✓ Funding Committees, Management Bodies, Regulators
 - ✓ Research – Trial Management Groups, Data/Safety Committee

* use MY data

* Providing Personal Data and Cancer Survival – The Rights of Patients - And Active Citizens!

- 😊 *No decision about me without me.* (NHS England patient charter)
There is no data about us without us, so use our data to help us –
and all the other patients who will be coming in the future.

- 😊 Put patients at the heart of the matter; empower us as active
citizens. It's our data and we want to share it; so let us share in
making the decisions about who gets it and why.

- 😊 This is an area where the EU can do a lot to help millions of its
citizens. Data improves services and develops new treatments;
data adds to knowledge and understanding; data saves lives.

Use our data!

* use MY data

Presentation by Mr Brendan Barnes



DATA SAVES LIVES: THE IMPACT OF THE DATA PROTECTION REGULATION ON PERSONAL DATA USE IN CANCER RESEARCH

Author: Brendan Barnes * Date: 15/11/2105 * Version: X



Cancer Data used in the industry

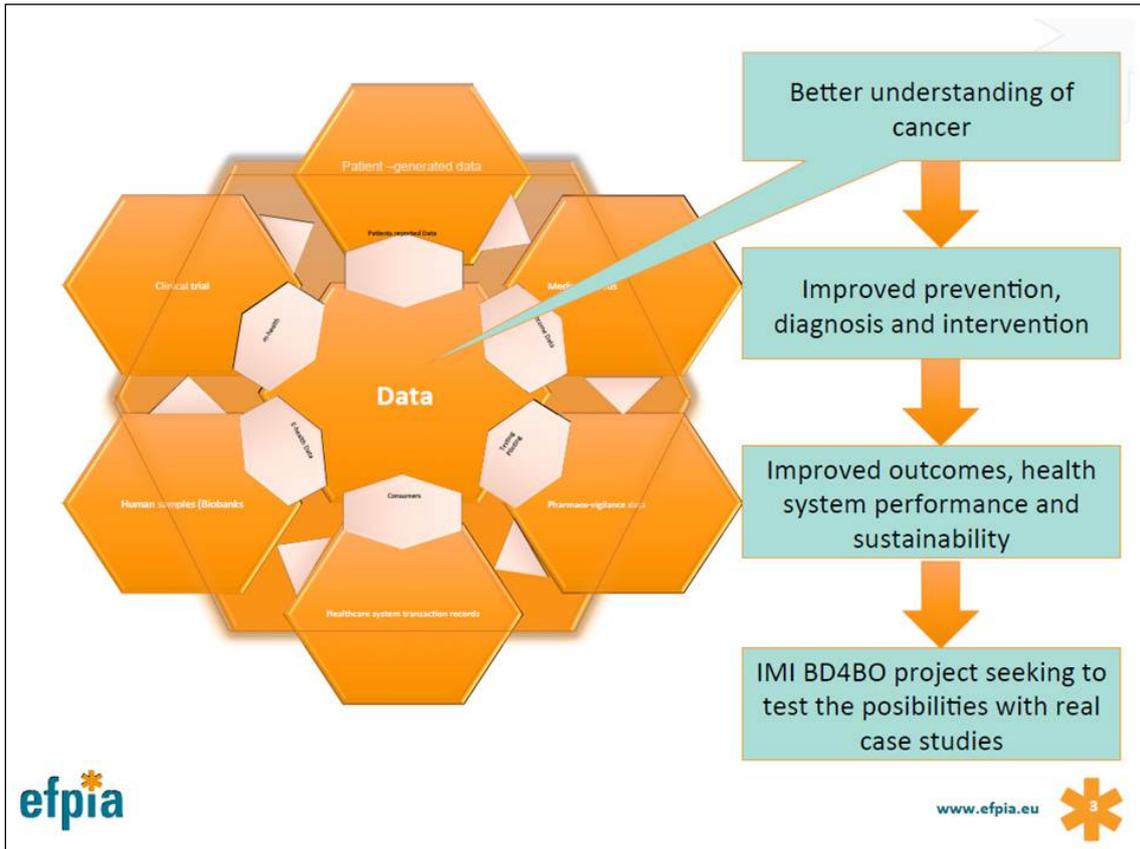
www.efpia.eu



- What data are we discussing?
- Why is it important?
- What is the impact on pharma?
- Is the GDPR going to help or hinder?



www.efpia.eu



The EU data architecture for health research needs to be operate seamlessly across borders and institutions and offer high levels of security and accountability. Many of the issues below need to be approached in a joined-up way



General Data Protection Regulation

- A missed opportunity (for patients, healthcare systems and EU industry)
- Areas of concern:
 - Restrictions on use of e-health records and other patient data to improve outcomes and healthcare delivery
 - Over-regulation and cost of access and sharing data
 - Continuation/exacerbation of fragmented EU approach to regulation
 - Restrictive approach to consent for secondary use of data
- Looking forward
 - Ensure that the Regulation does not foreclose opportunities for Europe
 - A mechanism to progress harmonisation, recognising the existing member state research infrastructures
 - A platform for continuing dialogue between stakeholders



www.efpia.eu



Conclusions

- EFPIA members are at the centre of managing the multi-stakeholder use of confidential patient data
- Big Data applied to healthcare can provide a huge societal benefit,
- Its use in Europe may be heavily-affected by the proposed data protection Regulation, as currently-drafted
- The public interest in advances in medical sciences warrants consistent data protection rules on the collection and use of personal data for medical research.
- How do we build on what we have now to construct a regulatory framework which enables research and preserves public trust?



6

Presentation by Dr Paolo Casali



IMPROVING SURVIVAL WITH CANCER DATA

Paolo G. Casali

Chair
ESMO Public Policy Committee

Director
Medical Oncology Unit 2 (Adult mesenchymal tumours and Rare cancers)
Istituto Nazionale Tumori, Milano, Italy



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

Plenary sitting

21.11.2013

A7-0402/2013

*****|**
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)60/11 – C7-0025/2012 – 2012/0011(COD))

Committee on Civil Liberties, Justice and Home Affairs

Rapporteur: Jan Philipp Albrecht



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.



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

Mette Rye Andersen *, Hans H. Storm, on behalf of the Eurocourse Work Package 2 Group

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

- 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].

Eur J Cancer 2015;51:1028





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 
- European 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) 

Ann Oncol 2014;25:1458




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



The «one-time» consent



- **informed**
- **withdrawable**
- **subjected to ethical scrutiny**
- **subjected to any additional current laws and rules**
-

ESMO

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

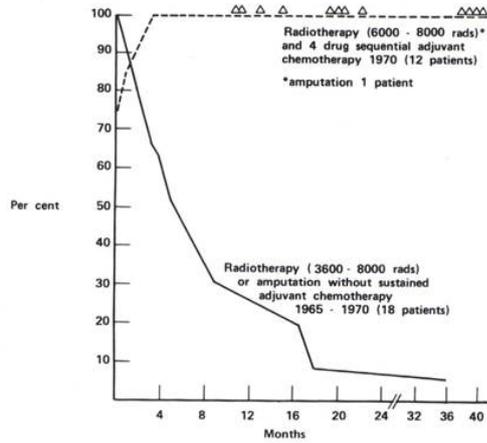
2. Without prejudice to Directive 95/46/EC, **the sponsor may ask the subject** or, where the subject is not able to give informed consent, his or her legally designated representative at the time when the subject or the legally designated representative gives his or her informed consent to participate 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.

ESMO

DISEASE-FREE SURVIVAL IN CHILDREN WITH EWING'S SARCOMA TREATED WITH RADIATION THERAPY AND ADJUVANT FOUR-DRUG SEQUENTIAL CHEMOTHERAPY

G. ROSEN, MD,* N. WOLLNER, MD,[†] C. TAN, MD,[‡] S. J. WU, MD,[§] S. I. HAJDU, MD,[¶] W. CHAM, MD,** G. J. D'ANGIO, MD,^{††} AND M. L. MURPHY, MD^{‡‡}



Cancer 1974;33:384



Gain-of-Function Mutations of *c-kit* in Human Gastrointestinal Stromal Tumors

Seiichi Hirota,* Koji Isozaki,* Yasuhiro Moriyama, Koji Hashimoto, Toshiro Nishida, Shingo Ishiguro, Kiyoshi Kawano, Masato Hanada, Akihiko Kurata, Masashi Takeda, Ghulam Muhammad Tunio, Yuji Matsuzawa, Yuzuru Kanakura, Yasuhisa Shinomura, Yukihiko Kitamura[†]

Gastrointestinal stromal tumors (GISTs) are the most common mesenchymal tumors in the human digestive tract, but their molecular etiology and cellular origin are unknown. Sequencing of *c-kit* complementary DNA, which encodes a proto-oncogenic receptor tyrosine kinase (KIT), from five GISTs revealed mutations in the region between the transmembrane and tyrosine kinase domains. All of the corresponding mutant KIT proteins were constitutively activated without the KIT ligand, stem cell factor (SCF). Stable transfection of the mutant *c-kit* complementary DNAs induced malignant transformation of Ba/F3 murine lymphoid cells, suggesting that the mutations contribute to tumor development. GISTs may originate from the interstitial cells of Cajal (ICCs) because the development of ICCs is dependent on the SCF-KIT interaction and because, like GISTs, these cells express both KIT and CD34.

We collected 58 mesenchymal tumors that developed in the GI wall (4 in the esophagus, 36 in the stomach, 14 in the small intestine, and 4 in the large intestine). KIT expression was examined by immunohistochemistry (8). Eight authentic leiomyomas and an authentic schwannoma did not express KIT. The remaining 49 mesenchymal tumors were diagnosed as gastrointestinal stromal tumors (GISTs), and 94% (46/49) of these expressed KIT. Examination of these tumors for expression of CD34, which is a reliable marker for GISTs (9), revealed that 82% (40/49) were CD34-positive, and 78% (38/49) were positive for both KIT and CD34 (Fig. 1, A to D). Three of five KIT-negative GISTs were also CD34-negative.

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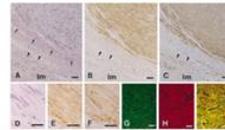


Fig. 1. Coexpression of KIT and CD34 in human GISTs. A, C, D. Some sections of a tumor that contained the majority of the interstitial cells of Cajal (ICC) were immunopositive for both KIT and CD34. B. Some sections of the same tumor were immunopositive for KIT but not for CD34. A, C, and D are stained with anti-KIT and anti-CD34 antibodies, respectively. B is stained with anti-KIT antibody and a control mouse antibody. The reactions in the tumor are displayed in brown (KIT) and green (CD34). C, D. Coexpression of KIT and CD34 in another GIST, also from the stomach. Immunohistochemical staining for KIT and CD34 is displayed in brown and green, respectively. B, C. Staining of control ICCs in human colon immunopositive for KIT, which are present within the mucosal lamina propria, and the control mouse antibody, which is immunopositive for CD34, are shown in brown (KIT) and green (CD34), respectively. A, B. Staining of control ICCs in human colon immunopositive for KIT and CD34 is shown and labeled. Scale bar is 0.2 mm. A, B, 100 \times ; C, D, 400 \times .

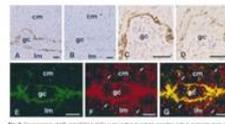


Fig. 2. Coexpression of KIT and CD34 in GISTs. Immunohistochemical staining for KIT and CD34 is displayed in brown and green, respectively. A, B. Coexpression of KIT and CD34 in a GIST from the stomach. C, D. Coexpression of KIT and CD34 in a GIST from the small intestine. Scale bar is 0.2 mm. A, B, 100 \times ; C, D, 400 \times .

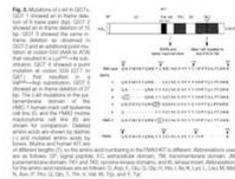


Fig. 3. Molecular analysis of *c-kit* in GISTs. **A.** Schematic representation of the *c-kit* gene structure. **B.** PCR products of the mutant *c-kit* complementary DNAs from GISTs. **C.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **D.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **E.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **F.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **G.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **H.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **I.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **J.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **K.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **L.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **M.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **N.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **O.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **P.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **Q.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **R.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **S.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **T.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **U.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **V.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **W.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **X.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **Y.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows. **Z.** Sequence alignment of the mutant *c-kit* complementary DNAs. The mutations are indicated by arrows.

EUROCARE-4. Survival of cancer patients diagnosed in 1995–1999. Results and commentary

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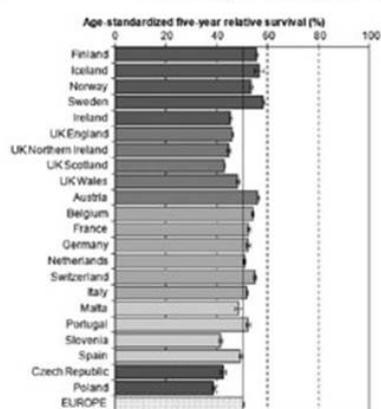
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EUROPE, adults diagnosed 1995-99

COUNTRY	Coverage %	Number of cases		
		Men	Women	Persons
Finland	100	42,345	43,273	85,618
Iceland	100	2,274	2,181	4,455
Norway	100	43,098	41,012	84,110
Sweden	100	85,619	83,209	168,828
Ireland	100	30,544	28,705	59,249
UK England	100	462,051	466,782	928,833
UK Northern Ireland	100	14,218	15,323	29,541
UK Scotland	100	56,727	59,693	116,420
UK Wales	100	28,178	28,289	56,447
Austria	100	73,962	72,239	146,201
Belgium	58	43,233	36,379	79,612
France	11	40,062	31,576	71,638
Germany	1	12,557	12,136	24,693
Netherlands	34	54,122	52,151	106,273
Switzerland	27	18,047	16,448	34,495
Italy	25	194,733	169,935	364,668
Malta	100	2,846	2,911	5,757
Portugal	43	17,385	14,184	31,569
Slovenia	100	16,308	15,524	31,832
Spain	12	50,550	35,061	85,611
Czech Republic	8	8,894	8,048	16,942
Poland	6	18,476	21,180	39,656
TOTAL		1,316,229	1,256,199	2,572,428

All malignant neoplasms



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