BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

‘Data for Health and Science’ Seminar

16 June 2015, Brussels

ISC
Intelligence in Science

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1. INTRODUCTION

On the occasion of the Day of Action on Data for Health and Science on 16 June 2015, led by BBMRI-ERIC (Biobanking and BioMolecular resources Research Infrastructure), BBMRI-ERIC hosted a seminar entitled 'Data for Health and Science' to explain the reasons why personal data is necessary to scientific research, including medical research, and how the EU General Data Protection Regulation could ensure access to data in scientific research whilst protecting the privacy and rights of data subjects through ethical, legal, and technical measures.

In 2012, the European Commission proposed a reform of the EU's 1995 data protection rules in view of strengthening individual rights to their personal data in light of the increasing availability of personal data in the digital economy. The European Parliament adopted its amended draft at first reading in plenary on 12 March 2014 by 621 votes to 10 with 22 abstentions.

BBMRI-ERIC, which is one of the largest health research infrastructures in Europe today, primarily aims at establishing, operating, and developing a pan-European distributed research infrastructure of biobanks and biomolecular resources, supporting high-quality biomolecular and medical research. Based on its deep knowledge of this research context, BBMRI-ERIC has been pushing for a balance between the protection of personal data and facilitating scientific research to enable innovation in our data driven knowledge and economy.

On 28 January 2015, BBMRI-ERIC held a roundtable where representatives of patient advocacy groups, biobanks, research infrastructures, the European Commission, the Joint Research Centre, and other stakeholders discussed concerns about several developments in relation to the proposed General Data Protection Regulation. In relation to health research, the stakeholders present acknowledged the value and importance of enabling fair access to personal data in creating knowledge and breakthroughs benefiting patients, citizens, and society at large. Among the main concerns raised was the potential harm to patients in the event of unwarranted restrictions to health research. There is a risk that the European Union will lose its competitiveness in research and innovation. It was also thought that the important existing role of ethics committees and technical safeguards in protecting personal data has not been sufficiently taken into account or understood.

The roundtable participants agreed about the need to show that the current proposed versions of the General Data Protection Regulation would discourage certain valuable research in the European Union and hamper Horizon 2020's aims of securing Europe's global competitiveness, producing world-class science, and removing barriers to innovation.

The 'Data for Health and Science' seminar picked up from the roundtable, and speakers explained the EU data protection reform and its implications for research, presented relevant case studies, and put forward recommendations to a wider audience, including research organisations, patients, policy-makers, and EU citizens.

2. SEMINAR 'DATA PROTECTION FOR HEALTH AND SCIENCE'

2.1. Professor Jan-Eric Litton (Chair), Director General, BBMRI-ERIC (Biobanking and BioMolecular resources Research Infrastructure)

Professor Jan-Eric Litton began by stating that BBMRI-ERIC acknowledges and embraces the GDPR's potential for the European Research Area (ERA). In relation to health research, Professor Litton said it could become a major tool for allowing simplified transnational research and cross-border exchange of data for the benefit of European citizens.

Subsequently, Professor Litton introduced BBMRI-ERIC, which has been awarded the European Research Infrastructure Consortium (ERIC) legal status. The specific legal form is designed both to facilitate the joint establishment and operation of research infrastructures of European interest and to provide expertise and consulting opportunities with other European and non-European organisations concerned with its activities and related fields in the building of an ERA.

BBMRI-ERIC is the largest health oriented Research Infrastructure ever to be launched in Europe. BBMRI-ERIC members and official observers include 17 European countries and the World Health Organization's International Agency for Research on Cancer (IARC). The research infrastructure facilitates access to high quality human biological samples and associated data; provides access to high quality biomolecular resources; includes a central catalogue of European biobanks and samples; and aims to ensure scientific excellence, quality of samples as well as ethical and legal compliance. The founding members of BBMRI are Austria, Belgium, Czech Republic, Estonia, Finland, France, Germany, Greece, Italy, Malta, Netherlands, Sweden, and the United Kingdom, which joined recently. Official Observers of BBMRI-ERIC include Norway, Poland, Switzerland, Turkey, and IARC.

Professor Litton went on to describe some of the issues pertaining to the European Research Area, such as limited competence of the EU legislator in the area of research and the risk of a persisting scattered legal landscape, even with a regulation on data protection in place. Professor Litton also emphasised that administrative cooperation is necessary but difficult to achieve without a clear legal basis to enact legislation. In this context, Professor Litton explained the need for a Day of Action to alert policy-makers of potential harmful impacts of the General Data Protection Regulation on health and science research. Professor Litton pointed out that the Justice and Home Affairs Council's General Approach on the entire Data Protection Regulation, agreed on 15 June, is much more positive for research than the Parliament's position.

To show the magnitude of existing samples in Europe, Professor Litton estimated that there are 1692 million tissue samples in Europe, stressing that a requirement for re-consent for the use of biomolecular resources and associated data could stifle biobanks.

2.2. Dr Erik Briers, Board Member, EPPOSI /Chair, BBMRI-ERIC stakeholder forum

Dr Erik Briers offered his point of view as a cancer patient and began by highlighting the importance of biobanking as a custodian of valuable data which provides access, protections and restrictions. Dr Briers explained that patients may want to donate their tissue to research

which may benefit them as well as future patients. Dr Briers stated that X-rays, laboratory results, and samples generate useful data, but that other information such as lifestyle, diet, and age is also needed to study the causes of a disease. Dr Briers reminded that we do not always know what data will be useful in the future and also highlighted the importance of dead patients' data, which are necessary to prognostics.

Dr Briers' message was that patients want their data to be protected but are not concerned about how it is done and that policy-makers should remember that the objective is to improve conditions for future patients.

2.3. Jasper Bovenberg, Lawyer, BBMRI-ERIC Dutch Node

Jasper Bovenberg discussed the potential impact of the European Parliament's position on the Data Protection Regulation on medical research in the Netherlands.

Mr. Bovenberg showed that broad consent is currently used in medical research on clinical data, medical registries, cohorts and population biobanks, and clinical trials in the Netherlands, which is at odds with the European Parliament's requirement for opt in consent for specific or similar research with the only possible exemption for research that serves a high public interest. In the Netherlands, an opt-out exists for use of clinical data and data from medical registries.

Mr. Bovenberg also argued that medical research is not within the EU's competence since medical care is not and medical research is a part of medical care, concluding that medical care research should be exempt from the Regulation. Mr. Bovenberg equally argued that according to the subsidiarity principle, the Netherlands should retain the competence in medical care research as it is sufficiently legislated and regulated.

Mr. Bovenberg explained a set of reasons why there should not be a requirement for specific consent in research:

- Finding medical links requires linking medical data from multiple sources, such as hospital records, pathology archives, biobanks, registries, and clinical trials
- Asking individuals' informed consent for every link will limit linkage, because it is time consuming, ineffective, and unscientific. It is ineffective because consent requests are perceived as span and unscientific because it creates a bias
- EU (H2020) and national funders require researchers to share their data. Subjecting such sharing to specific informed consent (to share) would limit opportunities for funding
- Introducing the requirement of specific consent would frustrate BBMRI-ERIC and other ERICs' goal to enable cross border research.

Mr. Bovenberg made the point that the EU Charter of Fundamental Rights allows for data processing on the basis of consent or 'some other legitimate basis laid down by law' and that research can constitute a legitimate basis. Mr. Bovenberg equally recommended that the Regulation should be aligned with the option for broad consent in the EU Clinical Trials Regulation, which states that 'the sponsor may ask the subject…to consent to the use of his or her data outside the protocol of the clinical trial exclusively for scientific purposes.' Mr.

Bovenberg then argued in favour of allowing the 1995 Directive to apply to existing registries, archives, and biobanks.

His next recommendation was to implement the EP's Committee on Industry, Research and Energy Amendment 37 for recital 53(a) new, which was supported by the following justification: 'Broad consent is a necessity for conducting research in fields of medicine that rely on biobanks and tissue banks among other forms. Biobanks are collections of biological samples and data, accumulated over a period of time, used for medical research and diagnostic purposes. These repositories store data from millions of data subjects, which is used by scientists to perform research. The option of broad consent given to a data subject at their first encounter with a doctor allows the researchers to use this data without having to go back to the data subject for every minor research they are conducting and is thus a necessary and practical solution for protecting and fostering public health research.' Mr. Bovenberg subsequently recommended implementing the EP's Committee on Industry, Research and Energy Amendment 37 for recital 53(a) new: 'A data subject should always have the option to give broad consent for his or her data to be used for historical, statistical or scientific research purposes, and to withdraw consent at any time.'

Overall, Mr. Bovenberg stressed the need to allow research to continue working on the basis of its current best practice, subject to proportionate measures, including pseudonimisation, research protocol, approval by a Data Access Committee, organisational and technical measures, and standard contractual clauses securing data subject jurisdiction and collective action.

2.4. Paulo Silva, Legal Officer, DG Justice, European Commission

Paulo Silva provided an overview of the new European data protection framework and compared it to the 1995 EU data protection Directive.

Mr. Silva affirmed that the proposed Regulation maintains the aims of the 1995 Directive, which are to protect the right to personal data protection and to guarantee the free flow of personal data between Member States. However, the Regulation tries to adapt the rules to new challenges, namely the challenge of technology, globalisation and societal change. These include electronic health records and biometric and genetic data.

The Regulation aims to address Europeans' lack of trust in the online environment as evidenced by a Eurobarometer survey which found that 75% of respondents feel they have only partial or no control of their data online and 2 of 3 citizens say they are concerned about this. Data subjects have found it difficult to exercise the following data protection rights: the right of access to one's personal data, the right to have one's data deleted, the right of access to effective remedies, and the right to withdraw and transfer personal data from an application or service. Mr. Silva pointed to a Mobiquity study which shows a lack of trust in the health sector, illustrated by the fact that the main obstacle blocking the adoption of mobile health and fitness applications is privacy concerns.

The new legal base for the right to protection of personal data is the Lisbon Treaty's Treaty on the Functioning of the EU Article 16, and some of the general objectives of the proposal for a General Data Protection Regulation are to:

- strengthen data protection rights and to ensure that all individuals in the EU have the same data protection rights
- ensure data protection rules fit for the digital single market
- put individuals in control of their personal data
- strike the right balance between data protection rights and the need to support public health and medical research objectives

To put individuals in control of their data, the proposed Regulation introduces the following changes:

- Better information to individuals about data processing
- Consent to be given explicitly, whenever this may be required
- Enhance "right to be forgotten"
- Clearer rights of access to individuals
- Generalise data breach notifications
- Reinforced data security obligations on controllers
- Strengthened national DPAs
- Enhanced and dissuasive administrative and judicial remedies for breaches of DP rights

To adapt data protection rules to the digital single market, the proposed Regulation delivers the following changes:

- The Regulation is directly applicable and removes legal fragmentation
- Cutting red tape (e.g. abolishing notifications to process the data)
- One-stop shop system for data protection in the EU: only one DPA checks compliance of a business, regardless of how many MS the business may be active in
- Better enforcement and governance and more level playing field through stronger national DPAs

The main innovations introduced regarding processing of personal data relating to health and processing for research purposes are:

- Definition of data concerning health (and biometric and genetic data) introduced
- Better harmonisation of legal provisions on Data Protection
- Conditions for processing of "sensitive data" including data concerning health (Articles 9, 81)
- Specific Health Article introduced – Article 81 for processing of health data, including processing without consent
- Targeted approach to Right to be Forgotten for health data
- Introduction of specific research article – Article 83, ensures complete harmonisation of data protection safeguards
- Possibility for delegated acts specifying elements of Articles 81 and 83

Mr. Silva clarified that consent in the proposed Regulation is one of various legal grounds for processing data, explaining that although generally sensitive data cannot be processed without explicit consent, there are other legal grounds provided by the Regulation, including:

- Legitimate activities by associations or foundations that permit the exercise of fundamental freedoms;
- By a law, and subject to suitable safeguards;
- Grounds of public interest particularly for health purposes, including public health, social protection and the management of health-care services,
- For procedures settling claims for benefits and services in health insurance
- For historical, statistical and scientific research purposes

The proposed Regulation introduces a specific research article, namely Art 83, which ensures harmonisation of data protection safeguards. It allows processing for research purposes, within limits of Regulation, if purposes cannot be achieved by anonymised or pseudonymised data.

As for further processing, processing of personal data for other purposes is only allowed where the processing is compatible with those purposes for which the data have been initially collected. Where not compatible, consent is required, or another legitimate ground for lawful processing.

Mr. Silva added that the proposed Regulation enhances responsibilities (and liability) for the controller.

Other aspects of the reform which aim to facilitate health data processing and build trust are:

- Mandatory appointment of independent Data Protection Officers (large undertakings)
- Obligation for data controllers to carry out a data protection impact assessment in specific cases
- Concept of "Data protection by design and by default"
- Encouragement of self-regulatory initiatives, including the active promotion of Codes of Conduct.

Mr. Silva indicated that the trilogue would begin in June, following the General Approach adopted by the Council on 15 June. Mr. Silva suggested that there would be an agreement by the end of the year and reminded that the Regulation will be enforceable in all Member States two years after it has been adopted.

2.5. Professor Jane Reichel, Member, Centre for Research Ethics & Bioethics, Uppsala University

Professor Jane Reichel showed how data in medical research is strongly guarded by a robust legal and ethical framework. With informed consent, use of data and samples in medical research is approved by national research ethics committees.

Professor Reichel evoked the issue of choosing between a strict common rule and individual exceptions for the Member States and the constitutional issue whereby the European Union has the competence to fund medical research but not to regulate medical research.

Finally, Professor Reichel concluded that a common rule for exceptions from data privacy would facilitate cross-border biobanking and recommended the adoption of complementary soft law and governance tools to handle samples and research. To exemplify such tools, Professor Reichel suggested ethical requirements in Horizon 2020 and EU funded self-regulatory projects for a bottoms-up approach to ensure data protection.

2.6. Jacques Demotes-Mainard, Director General, European Clinical Research Infrastructure Network (ECRIN)

Jacques Demotes-Mainard described the work and benefits of the European Clinical Research Infrastructure Network (ECRIN) and showed how the European Parliament's version of the GDPR would affect ECRIN.

Mr. Demotes-Mainard began by introducing ECRIN, which is an infrastructure for multinational independent clinical trials, funded by the EU's Seventh Framework Programme from 2012-2015 and awarded the EU legal ERIC status in 2013.

Mr. Demotes-Mainard then explained how ECRIN supports multinational trials on questions ranging from regulatory ethical requirements to data management.

To be eligible to join ECRIN, the rules for transparency are:

- Commitment to register the trial in a public register before inclusion of the first participant, for example on www.clinicaltrials.gov
- Commitment to publish results irrespective of findings
- Commitment to make raw anonymised data sets available to the scientific community upon request to the sponsor or principal investigator one year after the trial is completed (last follow up of the last patient) or, for registration trials, when registration is completed or the development is discontinued

To access patient data of all clinical trials, the procedure includes:

- personal data protection
- anonymisation
- restricted access
- access procedure
- contracting with dataset users
- informed consent

Mr. Demotes-Mainard underlined the importance of access to clinical trial data in optimising use of the data, pooling results from multiple trials to promote evidence-based medical practice, and increasing the robustness of results by re-analysing the data. Due to the value of facilitating access to clinical trial data, Mr Demotes-Mainard warned against locking access for re-use of data and emphasised that « specific, informed and explicit consent » is difficult

to achieve for secondary use of clinical trial data. He then recommended allowing for the possibility of broad consent, which is possible in the Clinical Trial Regulation 536/2014.

2.7. Paul Jackson, Managing Director, CESSDA

Paul Jackson pointed to the differences between non-invasive research and research which poses a threat to data subjects and therefore requires regulatory control, explaining that research which does not conflict with the interests of data subjects and which satisfies certain conditions should be subject to less stringent rules.

Mr. Jackson began by introducing CESSDA's strategic mission, which is 'To provide a comprehensive, distributed and integrated social science data research infrastructure, facilitating access to social science data resources for researchers regardless of the location of either researcher or data' and is influenced by Public Policies and Private lives and Privacy By Design.

Mr. Jackson brought attention to the non-invasive nature of social science research and affirmed that regulatory controls should be about ensuring the non-invasive effect we have on individuals as well as our positive effect for an inclusive, reflective and innovative society right across the ERA.

Mr. Jackson equally emphasised that achieving an inclusive, reflective and innovative society needs many actors to work together and that statisticians, scientists, economists, historians, involved in this purpose have the same non-invasive philosophy. Mr. Jackson recommended basing regulatory requirements on the invasiveness of the research rather than on the disciplinary or research area. This would include separating invasive scientific and medical purposes from non-invasive scientific and medical purposes.

Mr. Jackson noted that private consent may not be necessary to uphold data protection rights where there is clear public consensus for a non-invasive purpose.

2.8. Robert Frost, Policy Director, Medical Policy, Office of the Chief Medical Officer, GlaxoSmithKline, UK

Robert Frost presented the main safeguards for industry and academic research use of data and reminded that medical research delivers important benefits by helping to understand the causes of disease, develop new treatments, and ensure the effective and safe use of medicines.

Mr. Frost stated that the legislation must recognise existing safeguards in place to protect the use of data in medical research and not restrict research in the best interest of society and current and future patients. Mr. Frost went on to elaborate on the safeguards in place in interventional clinical trials and observational research.

For interventional clinical trials, there is a Clinical Trials Regulation, which covers the approval, conduct and safety of trials. Data is collected from data subjects with their informed consent and has to undergo ethics approval. The data used is then key-coded, and data-use is regulated by Declaration of Helsinki ethical principles as wel as the ICH Good Clinical Practice, which covers the ethical and scientific conduct of a trial. Regarding re-use of data, permission for re-use is provided in the original informed consent form, and re-use may be

broadly defined to facilitate further research and maximise benefit. Principles adhered in research include placing the interests of the subjects above other interests (CTR) and only allowing research to be conducted by individuals with appropriate ethics and scientific education, training and qualification (DoH).

As for observational research, approval for data-use requires broad consent for data collection or ethics approval where consent is not possible. Data access is subject to important requirements. Rules which govern research conduct include using coded or anonymised data, technical safeguards, and contractual measures such as using data for agreed purposes. Re-use of data is either defined in the initial consent or approved by an access/ethics committee.

Interventional clinical trial studies are well defined and detailed. Broad consent for re-use of data is given for further research such as research on the medicine or disease. With observational research, it is not possible to describe all potential uses of data in detail at the time of data collection. Therfore, broad consent or alternatives to consent, such as ethics approval, is given.

Mr. Frost asserted that appropriate access to data is crucial for public health, patient welfare and the development of new medicines and treatments and reiterated the importance of having the GDPR recognise existing safeguards for medical research to support research in the best interests of society and current and future patients.

2.9. Catherine Guinard, Public Affairs Manager, Cancer Research UK

Catherine Guinard illustrated the use and benefits of personal data in health research with a case study and explained why a requirement for specific consent would hinder research to the detriment of patients.

The case study presented was the European Prospective Investigation into Cancer and Nutrition (EPIC), which investigates the relationships between diet and other lifestyle factors and cancer risk, involving over half a million men and women from ten European countries.

The prospective investigation has led to a better grasp of the pre/post-menopausal breast cancer as well as dietary factors affecting colon cancer. The EPIC centre in Oxford is now looking at the effect of diet on obesity and how nutritional and lifestyle factors affect the risk of bone fractures.

To show what the European Parliament's General Data Protection Regulation position would mean for EPIC, Ms. Guinard explained that is no guarantee the study would meet the tough requirements set for the use of pseudonymous data without consent. In addition, Ms. Guinard explained that the study's success also relies on using identifiable data to build its dataset by linking its own findings with data from other sources like cancer registries, which is why re-use of available data should be permitted. EPIC Participants have given broad, not specific, consent for this linkage. The European Parliament's position would require going back to each participant in the study to ask for their specific consent, which would be incredibly burdensome in terms of time and cost, and this extra burden could delay the study or even prevent it from happening.

2.10. Dr Beth Thompson, Policy Adviser, Wellcome Trust

Dr Beth Thompson presented a set of proposed solutions, widely accepted in the research community, to the General Data Protection Regulation in order to ensure a balance between protecting the privacy of data subjects and enabling research.

The first solution proposed was to maintain the privileged position of research in the current Data Protection Directive. The Commission's proposal and the Council's position include important research exemptions, while the European Parliament's text tightly restricts these exemptions. Dr Thompson stressed that in order to prevent severe unintended consequences for research, the final text of the Regulation will need to include the exemptions provided in the Commission's and the Council's texts.

The second solution proposed was to ensure robust, proportionate safeguards. In research, there are important ethical and governance currently in place to ensure that data subjects and their privacy are protected. Many in the research community appreciate the European Parliament's concern that the Commission's proposal does not adequately reflect the importance of such safeguards and welcome the emphasis on appropriate safeguards in the Council's position. Dr Thompson added that proportionate safeguards should be included in the text of the Regulation to ensure personal data are used safely and securely in research, and prevent misuse of research exemptions.

Finally, Dr Thompson proposed balancing harmonisation and flexibility for Member States. Dr Thompson reminded that the Parliament and Council have both delegated some research provisions to Member States, which would lead to fragmentation. Dr Thompson highlighted that harmonisation of appropriate standards would be ideal to promote research collaboration, but recognised the challenge of doing so due to national differences. To avoid the risk of compromising exemptions for research, Dr Thompson explained that the final text may need to allow flexibility to allow Member States to implement culturally and socially acceptable rules.

3. CONCLUSIONS

It is expected that the trialogue negotiations on Chapter IX, which deals with the articles relevant to health data and research, will take place in November 2015.

BBMRI-ERIC aims to continue to raise awareness on the implications of the Regulation for biobanks and health research leading up to the trialogue in November and beyond.

The speakers' PowerPoint Presentations from the 'Data for Health and Science' seminar can be found at: http://www.iscintelligence.com/event.php?id=262

4. NEXT STEPS

- A Day of Action position paper on the General Data Protection Regulation will be published in the summer of 2015
- BBMRI-ERIC will prepare a BBMRI-ERIC statement on the General Data Protection Regulation
- Engagement with EU policy-makers and other stakeholders will continue until the adoption of the Regulation, expected by the end of 2015

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