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FEAM
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Academies of Medicine

Use of data in cross-border biomedical research: what are the challenges ahead for Europe?

Summary report of a workshop held on 20 November 2017

About FEAM, The Federation of European Academies of Medicine (www.feam.eu)

FEAM's mission is to promote cooperation between national Academies of Medicine and Medical Sections of Academies of Sciences in Europe; to provide them with a platform to formulate their collective voice on matters concerning human and animal medicine, biomedical research, education, and health with a European dimension; and to extend to the European authorities the advisory role that they exercise in their own countries on these matters.

About the FEAM European Biomedical Policy Forum

The FEAM European Biomedical Policy Forum provides a platform for discussion on key policy issues for the biomedical community.

The Forum is an initiative from the Federation of European Academies of Medicine (FEAM). It aims to bring together representatives from academia, research charities, industry, European and national trade associations and professional bodies, regulators, public health bodies, and patient and consumers groups. If you would like further information on the FEAM European Biomedical Policy Forum or becoming a partner, please contact silvia.bottaro@feam.eu

Disclaimer:

Opinions expressed in this report do not necessarily represent the views of all participants at the event, the Federation of European Academies of Medicine (FEAM) or the FEAM European Biomedical Policy Forum partners.

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All web references were accessed in December 2017

FEAM EUROPEAN BIOMEDICAL POLICY FORUM

FEAM Federation of European Academies of Medicine

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Introduction

This note summarises the key points of the Federation of European Academies of Medicine (FEAM) European Biomedical Policy Forum meeting on the use of data in cross-border biomedical research.

The workshop was organised against the backdrop of the General Data Protection Regulation (GDPR), which will come into force on 25 May 2018 and may have important consequences for cross-border biomedical research.

The aims of the meeting were to stimulate debate on the following topics:

1. What are the concerns of different stakeholders over the GDPR legislation and how will it impact cross-border biomedical research in Europe? Which solutions should be put in place?
2. What is the EU doing to support the use of personal data to advance biomedical research? What is the role of the European Commission and Member States in promoting compatibility and avoid fragmentation between national laws?

The agenda can be found at annex one along with speaker biographies (annex two) and a list of participants (annex three).

Summary

Biomedical research and healthcare are increasingly data-intensive and the potential benefits of big data are significant and varied. They include improved diagnosis and treatment, improved patient safety, better health outcomes, better performance of healthcare systems and increased efficiency and effectiveness in research and development.

If the full benefits of personal data are to be realised in European biomedical research, some fundamentally important challenges must be addressed. Chief among them is the need to balance the rights of individuals and the effectiveness of research and care systems, but there are other considerations including technical, legal and systemic challenges. The most complex challenges encompass all of these factors.

In general terms, there are some fundamental barriers to the realisation of the heralded benefits. From the point of view of the individual, rights to access personal health data are hampered by stark differences in the availability of such data in different countries. From the point of view of researchers and healthcare providers, technical barriers such as a lack of interoperability limit the flow of data between countries and systems. One of the most fundamental challenges is the need to build and maintain public trust about the responsible collection, sharing and use of personal data. At present, individuals are generally supportive of data sharing as long as they can trust that appropriate safeguards are in place. But all stakeholders must play their part in preserving public trust and demonstrating the benefits of sharing and using personal data.

A specific set of challenges arises from the European General Data Protection Regulation (GDPR). Technical challenges include ambiguity about terminology, definitions, roles and responsibilities and there are specific problems arising from inconsistencies in the treatment of consent and lack of clarity about the legal basis for the further processing of data.

These challenges are compounded by the fact that the GDPR leaves significant room for interpretation of its many provisions at the national level. This means that, unless a high degree of harmonisation is achieved in the interpretation of the GDPR, there may be a proliferation of national standards, requirements and legislation which may prove to be a significant barrier to effective cross border research in Europe. The picture is complicated still further by the existence and applicability of several other regulations, laws, conventions and codes to biomedical research.

The most likely and most costly impact is that potential benefits in diagnosis, treatment and care will be delayed or put out of reach. Implementing the GDPR within complex international systems will also mean that companies, research institutions and public healthcare providers will incur additional (potentially significant) costs for compliance.

Participants agreed that if these challenges are to be met and if the potential benefits of data-driven research and care are to be realised, there will need to be greater commonality and co-operation between EU decision makers, Member States, business and the research community. In particular, participants highlighted the importance of co-operation between European Commission DGs, clear and consistent communication of the biomedical community's concerns and priorities and

commonality (as far as possible) in Member States' approaches to interpreting the GDPR so that fragmentation and proliferation of laws and regulation is minimised.

Some specific actions were suggested by participants. These included:

- Forming a cross Directorate General (DG) multi-stakeholder group to monitor the implementation of GDPR in the field of research;
- Establishing incentives for harmonisation of national implementation measures and/or consider European Union law to produce a fully harmonised framework in some areas of research (e.g. areas of likely EU consensus);
- Issuing a call (with associated funding opportunities) to analyse whether the right balance is being struck between privacy and research interests in GDPR implementation (similar to ICREL);
- Monitoring and analysing the costs and other impacts of GDPR implementation in research.

Report

Welcome

The meeting was opened by **Prof. Bernard Charpentier, President, Federation of European Academies of Medicine (FEAM).** Prof. Charpentier welcomed speakers and other participants to the inaugural meeting of the FEAM European Biomedical Policy Forum.

Prof. Charpentier introduced the FEAM European Biomedical Policy Forum, which he described as 'a platform for discussion on key policy issues for the biomedical community.'

Session 1: Cross border biomedical research: What are the new challenges arising from the forthcoming data protection legislation?

Session 1 was chaired by **Prof. Stefan Constantinescu, Vice President, Federation of European Academies of Medicine (FEAM)** who explained that one purpose of this session was to give different stakeholders an opportunity to articulate their concerns. Speakers from the European Commission would have an opportunity to address these issues in the second session and it is hoped that, in time, problems may be turned into solutions.

The first presentation was given by **Prof. Françoise Meunier, Director of Special Projects, European Association for the Research and Treatment of Cancer (EORTC) and Vice-President, Federation of European Academies of Medicine (FEAM).** Prof. Meunier set out the case for a streamlined legal framework across Member States to help ensure European progress in medicine and to enhance EU competitiveness in health research.

Prof. Meunier began by describing some observations and considerations about the GDPR, saying that in general terms the GDPR's provisions are comprehensive meaning there ought to be little requirement for Member States to elaborate further. However, in the case of scientific research there appears to be significant room for interpretation at the national level.

For example, the existence of differing views about pseudo-anonymisation as a safeguard for the processing of personal data is a potential barrier to effective cross border research collaboration. Similarly, the possibility that Member States may maintain or introduce different approaches to the processing of genetic and other health data may impinge on developments and applications in personalised medicine.

These ambiguities and the possibility that they may be resolved in different ways in Member States pose a major threat since scientific research is most effective at a pan-European scale. This being so, it is essential that Member States work together on such important matters as pseudo-anonymisation.

Prof. Meunier also highlighted the importance of better clarifying the territorial scope of this regulation with regards to the application of the articles 9.4 and 89, specifically whether place of research or place of residence of subjects was the applicable principle. Such questions are of growing importance because of migration between Member States and because of the inherent complexity of

international research and cross-border data sharing. Prof. Meunier demonstrated the point by describing an example of a chain of custody for biological material (in which the transfer of material is not useful if not accompanied by the associated metadata) which spanned many actors in different countries, wherein different laws may apply.

The picture is complicated still further by the existence and applicability of several other regulations, laws, conventions and codes, many of which may be subject to different interpretation within the 28 Member States. Researchers must navigate and comply with all of these legal requirements and their specific (sometimes complex and different) terminology. In effect, this means that research organisations must now play multiple roles in an increasingly complex legal framework, which can be burdensome, costly and potentially risky.

To mitigate the risks and costs of these increasingly complex requirements, Prof. Meunier proposed a simplified model for pan-European research, in which each participant would observe the laws that apply in their own country. Prof. Meunier underlined the importance of such an approach by cautioning that 'Unless the law of the place of research applies, biomedical research and medical progress will stop!!'.

Prof. Kristian Hveem, Professor in Medicine and Clinical Epidemiology, Technical University of Norway (NTNU) gave an overview of key issues concerning the GDPR as they affect biobanks. GDPR affects biobanks because they include sensitive data, such as genetic and health data – indeed the value of biobanks lies in such data. Population based biobanks are large and significant resources which have provided the basis for important studies that, in some cases, have led to important new insights and improved practices.

Prof. Hveem explained that biobanks could be exempted from some of the GDPR's provisions in certain cases or under certain conditions. For example, 'the data storage principle can be modified and data can be stored for longer periods provided that they will be processed solely for scientific research purposes.' There may also be exemptions for further processing of data that was initially processed for another purpose. These exemptions are important for biobanks which can hold large and sometimes old collections of samples and data.

Biobanks can also use 'broad consent' (to some extent) under the GDPR and can process sensitive data without consent. Prof. Hveem said that biobanks should work towards a research culture in which consent is a general rule. However, in the case of historic collections, it may not be possible to seek or gain consent.

Biobanks can provide effective means of sharing data and facilitating international collaboration and Prof. Hveem outlined some important details and considerations about international transfers and collaboration. Under the new regulation, personal data may be transferred outside of the EU (to a third country). Such transfers may take place, even in spite of potential risks, if the data subject has explicitly consented to the proposed transfer and is aware of the risks concerned.

Biobanks can continue to transfer personal data to the USA but may not do so under the Safe Harbour principles. New rules (the EU-US Privacy Shield) remain subject to negotiation. However, academic and not for profit research organisations are unlikely to be eligible under these new arrangements. Although not required under the terms of the GDPR, additional contractual measures (such as a Data Transfer Agreement or Material Transfer Agreement) are recommended.

Prof. Hveem noted that different regulations apply in different countries and biobanks may also choose to work in different ways. For example, researchers can access clinical and genetic data from the UK Biobank for a fee of £250. By contrast, HUNT Biobank in Norway cannot share data in the same way. Its approach is to invite researchers to access data centres or cloud based data and to do their research 'in the data set'. This approach is used by some other institutes and in some other countries.

Johan Wisenborn, Head Data Privacy Country Operations, Novartis presented the European Federation of Pharmaceutical Industries and Association's (EFPIA's) perspective on the GDPR. Mr. Wisenborn outlined EFPIA's support for the harmonisation of data requirements for research. He said the ability to capture and share personal health data among researchers will underpin larger data sets which will help to advance the understanding of diseases (including rare diseases) and support developments in personalised medicines. He also noted that individuals are generally supportive of data sharing as long as they can trust that appropriate safeguards are in place.

EFPIA points to several other benefits of health data. Allowing re-use of data will avoid duplication of studies, guarantee the verification of clinical trials results and enable individuals who wish to, to share their data to benefit others with the same or other medical conditions. Robust and harmonised rules on the processing and use of patient data in Europe will reduce delays and duplication allowing new medicines to be developed and brought to market quickly for the benefit of patients. They will also have the added benefit of increasing R&D efficiency and effectiveness. This will lead to better outcomes for individual patients, improve population health in general, contribute to the sustainability of health systems and help to preserve the EU's place as a global centre of research.

Mr. Wisenborn stated the one of the original drivers of the GDPR was harmonisation of rules across the EU. However, the GDPR has failed to harmonise rules and, instead, allows Member States to adjust rules to local preferences. For example, there remains room for national rules to determine the consent requirements and the definition of scientific research remains unclear. This means that interested parties must now follow what happens at national level very closely if the potential benefits of harmonisation are not to be lost entirely.

EFPIA has conducted a mapping exercise and has identified the following priorities:

- Preserving the possibility of operating with broad consent;
- The importance of achieving a balance between individual rights and wider interests in advancing research (i.e. that research should not be harmed);
- Ensuring a high level of flexibility to re-use data with appropriate safeguards (noting that while there is an increased possibility of 'further use' it will be necessary to follow that this is effectively implemented at the level of individual Member States);
- Recognition of safeguards (e.g. pseudo-anonymisation)/avoidance of mandatory processing requirements (it was noted that it will be important to have the same safeguards in different countries or pan-European research will become more difficult);
- Consistent definitions of key terms.

The mapping exercise also showed that most national authorities in Member States will rely on the maintenance or development of secondary measures (such as national directives, laws or regulatory guidance) to determine the rules for research. The most complex area appears to be the legal basis

for secondary (further) use and the interaction with consent. The GDPR text suggests that secondary use for scientific research purposes is possible if the data subject is informed and if adequate safeguards are applied, also in the situation where the legal basis for the primary purpose is based on consent. However, in some countries the current national legislation proposals is not consistent with the GDPR on this matter and this requires discussion at national and European level.

As the GDPR does not itself provide for a harmonised approach, interested parties must look to the implementation of the regulation for greater harmonisation. EFPIA suggests that the EU might support greater harmonisation through dialogue with Member States, with guidance from the Article 29 Working Party and by promoting harmonised practices within research networks.

The GDPR allows for the creation of codes of conduct (such as the BBMRI code of conduct[1]). Although codes of conduct are unlikely to have precedence over national law, they may demonstrate to Member States what is possible and, in this way, may affect the implementation of national laws. A code of conduct will be of most value if Member States allow it the space to function and are not over-prescriptive in the implementation of GDPR.

EFPIA, together with other stakeholders, is developing a web-based information platform with the purpose of strengthening pro-research voices. The intended audience is researchers, physicians, healthcare providers, industry, patients, Data Protection Authorities, and policymakers. The content on the platform could be explanatory material and discussion tools around the use of health data for research and in particular mentioning successful real example use cases where for example the re-use of data has facilitated research and/or led to new therapies or products.

EFPIA says that the pharmaceutical industry and its partners recognise the need for enhanced technical safeguards and forms of accountability to those whose data they use. EFPIA calls on Member States to commit to the development of an aligned approach to these issues and to avoid undermining such efforts through an uncoordinated implementation of the research provisions of the GDPR.

Sarah Collen, Senior European Policy Manager, NHS European Office offered a perspective from a healthcare provider. She explained that a National Working Group, chaired by NHS England (including the Health Research Authority and NHS national bodies, and regulators) is preparing guidance that will be distributed to help the NHS, social care and partner organisations prepare for the GDPR when it begins in May 2018.

In addition, the Health Research Authority is leading a separate work stream on health and social care research and her presentation focused on four priorities from this stream of work.

1. Legal basis for processing personal data

- The landscape is changing and, as a result, there is uncertainty about many aspects of the GDPR, including the legal basis for processing personal data.
- The UK Information Commissioner's Office has produced a blog explaining that consent is not the 'silver bullet' to comply with the GDPR. Consent is an available legal basis for research, and is often sought for research to fulfil other legal and ethical requirements, but it is not the only (or even preferred) legal basis for complying with the GDPR.

[1] http://code-of-conduct-for-health-research.eu/

- The changes the GDPR brings in terms of requiring data controllers to know and inform the data subject (patients) about the legal basis they are relying on highlight the need for providers to understand the different legal bases for processing personal information, to be sure which one applies and to communicate this information to patients as clearly as possible. This was not necessary in the past.

- There are changes to legal bases - 'legitimate interests' of the data controller, for example is no longer available to public authorities in the performance of their tasks (in the UK this will include NHS organisations and universities). However, the 'public interest' condition, should be available to these organisations, as well as other legal channels.

2. Safeguards in UK's draft Data Protection Bill (the UK's implementation legislation of the safeguards and derogations found in the GDPR).

- Clause 18 of the draft UK Data Protection Bill addresses safeguards for the rights and freedoms of data subjects. However, as currently constituted, the draft text gives rise to concerns about its potential impact on interventional research.

3. Transparency

- Hospitals and other healthcare providers must be as transparent as possible and provide accessible information to individuals about how they intend to use their personal data in health and care settings.

- There are a variety of tools available to providers – some simple, some less so - but it is not always clear when or how to discuss these matters with patients. However, the importance of informing patients and not misleading them is clear and the guidance being developed will hopefully soon be available to assist NHS organisation to prepare for this. Robust transparency can also assist with processing of data for health and social care data for research purposes.

4. Data subject rights

- This includes consideration of data subjects' rights to access, rights to rectification, rights to erasure and rights to data portability. The right to data portability is new, and may have an impact on health research when based on consent, using automated means, such as research involving MRIs. We will need to test to see how this works out in reality. There is also some concern about the right to erasure. While health purposes receive an exemption from needing to fulfil this right, for research purposes, they have removed the condition available in the current Directive, that if erasure would involve 'disproportionate effort' it is not obligatory to comply. Now the GDPR will require that the research will be rendered impossible or seriously impaired – this is raising the bar, but to what extent is to be seen.

Panel discussion

Prof. Constantinescu began the Panel discussion by commenting on the need to balance the requirement to protect individuals' rights with the need to make data available for research. In a discussion about gaining public trust about the sharing and use of data, the Panel said that the research community must demonstrate the benefits of sharing data, for example by highlighting examples such as the role played by data sharing in the development of new medicines and how this

may benefit individuals. Codes of conduct may also serve to demonstrate what a commitment to responsible treatment of sensitive data looks like in practice.

Key concepts' definitions

A member of the audience highlighted an apparent inconsistency in the ways that articles 13 and 14 treat the issue of information about further processing of data. It was explained that, in the case of Article 13 (3), the requirement to inform data subjects in advance of further processing when data was collected from the data subject, is very likely to affect the further processing of existing data. By comparison, Article 14 says that, where data is not collected directly from the data subject, the GDPR foresees a derogation for scientific research if a disproportionate effort is required and if research were to be seriously impaired or rendered impossible (Article 14 (5)b). As the situation is not dissimilar after a sufficient time span, there was the question whether this was an oversight and whether adaptations of the law could still be envisaged.

Another issue is the important but not always clear assignment of role as data processor and data controller. The GDPR attaches different responsibilities to each role, necessitating different contractual arrangements. The assignment of responsibility for the processing and defining the means leaves scope of interpretation – a situation that is further complicated by the GDPR's introduction of joint controllers. The Article 29 Working Party has issued some general guidance but it also appears to recognise that there is some room for interpretation on this question. Another participant suggested that these ambiguities and inconsistencies may be because the regulation concerns 'general' data protection and does not specifically address matters which arise in scientific research.

The transfer of data between countries and continents

The transfer of data between countries within the EU and between Europe and the USA was discussed. It was noted that the USA has adopted a markedly different approach to rules for data transfer. The American approach is sectoral (with different rules applying to different industrial/economic sectors) while the EU has favoured a broader, general approach. Concern was expressed about the possibility that all transfer mechanisms between the USA and EU may be invalidated as a result of legal challenges to the Privacy Shield.

The transfer of data with or between national security agencies (described as 'a highly politicised issue') was touched upon. In response to a question about whether biobanks can refuse a request to access data, Prof. Hveem said that the HUNT Biobank is required to make judgements about whether or not it is appropriate to give access to data on an almost daily basis. Prof. Hveem said that, while the biobank's preference is to share data to benefit research, the biobank must always be satisfied that data can be safeguarded properly, underlining his point by saying that, in HUNT's view, the data subjects are the data owners. However, he also pointed out that, in a competitive landscape, if people or institutions are not able to acquire or access data from one source they will simply seek it from another.

The cost of research

Reflecting on the prominence of 'costs' in speakers' presentations, Prof. Meunier observed that the cost of complying with the Clinical Trials Directive had increased the cost of research without increasing its quality and expressed concern that European research would face the same situation in relation to data protection.

Implementing the GDPR within complex international systems will mean that companies, research institutions and public healthcare providers will incur additional costs for compliance. And, since interpretations of the regulation are likely to differ between Member States, it would be reasonable to assume that complexity and cost will both increase more than would have been the case if a higher degree of harmonisation had been achieved in the design of the GDPR.

The full cost of implementing the GDPR will be difficult to estimate. One reason is that other hidden costs must be taken into account. For example, the increasing complexity of consent means that consent forms are becoming more detailed and are growing in length (Prof. Meunier cited one example in which the median length of consent forms was 18 pages). One direct result is that patients require more time to digest such complex information before giving consent, which creates delays. These delays impair patient care and research, creating opportunity costs as well as financial costs. It is recommended that the costs of implementing the GDPR in the field of research be carefully monitored so that it is possible to analyse whether the GDPR achieves the right balance between privacy and research interests.

Session 2: How to facilitate the use of data in cross-border biomedical research? Cross-sectorial dialogue with policy makers.

Session 2 was chaired by Prof. Françoise Meunier, who invited **Dr. Andrzej Rys, Director, Dir B - Health systems, medical products and innovation (European Commission, DG SANTE)** to get the session underway.

Dr. Rys spoke about the benefits of big data use in healthcare, a sector which he described as a data-intensive industry and in which various types of data (clinical, genetic, behavioural and environmental) are collected from multiple sources.

The potential benefits of big data are significant and could include improved diagnosis and treatment, better predictions about the spread of disease and improved management of healthcare systems leading to improved patient safety, better health outcomes and better performance of healthcare systems.

However, these hopes are not new. Technology has not yet delivered what it has promised and there remain significant challenges to the realisation of these benefits. For example, technology driven exercises cannot take place without the input of patients and healthcare professionals. This will require healthcare professionals to gain better digital skills and a better appreciation of the value of data. Moreover, there are technical barriers such as a lack of interoperability which hinders the flow of data between countries and their various systems.

The role of the EU in overcoming these challenges and realising the benefits of big data is threefold:

- To give citizens better access to their health data everywhere in the EU;
- To connect and share health data for research, faster diagnosis and better health outcomes;
- To use digital services for citizen empowerment and person-centred care.

A European Commission public consultation on the transformation of health and care in the digital single market identified four main concerns and expectations among respondents - privacy, cybersecurity, data quality and standardisation of electronic health records.

The public consultation also revealed that the use of personal health data for research purposes was viewed positively and that almost three quarters of respondents would make their data available to progress research and innovation. The same consultation demonstrated widespread support (c. 65%) for the advancement of high performance computing, big data analytics and cloud computing for health research and personalised medicine. A similar number of respondents (c. 65%) were positive about the further development of digital infrastructure to pool health data and resources across the EU.

Dr. Rys outlined two forms of support that were being made available to support Member States and other stakeholders with the implementation of the GDPR. These were a stakeholder workshop on GDPR and health held on 23 October (co-organised by JUST, CNECT and SANTE) and a European Commission Expert Group on the GDPR (organised by JUST) which would hold an afternoon session on implementation in the health sector on 6 December.

Miguel González-Sancho, Head of Unit, Unit H3 – e-Health, Well-being and Ageing (European Commission, DG CONNECT) outlined some of the opportunities and benefits associated with big data and health. Mr González-Sancho identified some non-clinical benefits which must be kept in mind when considering public policy. These included:

- The possibility of feedback loops about interventions;
- Making health policy and interventions patient-centric (with patients playing a more active and less passive role);
- Health is not just about medicine or research. There are also important administrative and information management dimensions to effective healthcare.

Mr. González-Sancho discussed the three roles played by the EU (as described by Dr. Rys), describing them as three priorities concerning the digital transformation of health and care. He noted that while citizens in Europe have the right to access their health data there are striking differences in the availability of such data in different settings and countries. Mr González-Sancho also noted that applying big data to advance progress in medical research and personalised medicine is also hampered by technical problems concerned with and interoperability and standards.

However, the promise of big data cannot be realised by simply developing and deploying technological tools to solve technical problems. As with all forms of innovation in complex systems, technology is only one consideration. Effective innovation depends, in part, on the interplay of many important factors including technology, privacy and ethics. Health data is sensitive data and therefore, trust and security are essential for scaling up the use of digital innovations in health.

The benefits of innovation can take a long time to be realised in complex environments such as health systems so, at the EU level, the focus is on trying to ensure the existence of conditions that enable and facilitate the exchange of data and on trying to pool resources which are presently distributed across Europe. So, at EU level, the main challenges are:

- Ownership and accessibility – e.g. e-health records;
- Privacy;

- Identification and safety – How long is consent valid for? Interpretation may result in further fragmentation. How well prepared is the health sector to meet the challenges of cybersecurity?;
- Liability – e.g. in systems where Artificial Intelligence or machine learning might play an increasingly important role who is responsible for errors (this debate has some parallels with the legal and ethical debates which apply to driverless vehicles);
- Intellectual property – How can the value created by the analysis of data be protected?

Question and Answer session

The earlier observation that the new regulation is a general provision was underlined when it was noted that the motivation for the new regulation was to strengthen privacy rights and data protection in a society in which personal data is one of the most important currencies. Because the regulation was not conceived or designed with a sectoral focus, it was suggested that stakeholders should seek to resolve problems which apply in research and innovation through the implementation of the GDPR. This being so, there is a need for communication, co-operation and commonality in the implementation of the GDPR.

Co-operation between DGs

Participants highlighted the importance of co-operation between DGs, clear and consistent communication of the biomedical community's concerns and priorities and commonality (as far as possible) in Member States' approaches to interpreting the GDPR so that fragmentation and proliferation of laws and regulation is minimised.

Co-operation between DGs is especially welcome on matters where there appears to be a different understanding of key features of the GDPR. It was suggested that other DGs might signal to DG JUST when they identify or anticipate potential problems, to help smooth out problems with the GDPR in a cross-Commission approach.

Interoperability of data

The importance of commonality and co-operation between Member States was discussed in terms of interoperability of data. The significance of this issue was underlined when it was pointed out that interoperability is an issue between hospitals within countries so may well be a significant problem between Member States, and must therefore be considered a high priority.

Consultative and communication tools

Some avenues for communication and co-operation between stakeholders already exist and others may be created. For example, a DG JUST working group has been established to work with healthcare experts and to enable them to identify and discuss potential problems. But where consultative mechanisms do exist they must be monitored to ensure that they are fit for purpose. For example, some participants reported that cumbersome processes associated with some mechanisms have prevented meaningful dialogue from taking place.

Codes of conduct

In response to a question about whether the European Commission will support the development of codes of conduct, it was stated that there is some provision for stakeholders to develop codes of conduct and that resulting codes may be endorsed. It was suggested that such codes would be more

influential (i.e. they may inform legislative processes or the development of guidance within Member States) if they were practical and reflected the experiences of specific institutions, communities or professions, and were not simply abstract statements or sets of principles.

It was also suggested that there may be a role for FEAM to articulate the view of the biomedical science and research community.

Concluding remarks and next steps

Prof. George Griffin, President elect, Federation of European Academies of Medicine (FEAM) thanked the speakers, participants and organisers for an excellent meeting. He also thanked the UK Academy of Medical Science and the UK Department of Business, Energy and Industrial Strategy for their financial support of the Forum and this meeting.

Prof. Griffin identified some prominent themes for further reflection, including the status of big data as one of the main currencies in health research and the need for data sharing to be responsible.

He said that the presentations and discussion had touched on some fundamentally important issues. Healthcare is increasingly data intensive and many different benefits arise from the collection and sharing of personal data. These benefits are broadly recognised and people are supportive of their data being used to improve healthcare. However, the emphasis must be on the responsible and safe collection and use of data. The collection or strategic use of data should never harm the individual.

There are multiple pinch points for the collection and handling of data in increasingly complex international systems. If these challenges are to be met and if the potential of data-driven research and care is to be realised, there will need to be greater commonality and co-operation between EU decision makers, Member States, business and the research community.

Annex I - Agenda

20 November 2017 (12:00-16:00)

Thon Hotel EU, Rue de la Loi 75, B-1040 Brussels / room Belgium II

12:00-13:00	**Registration and lunch**
13:00-13:15	**Welcome and Introduction** • Prof. Bernard Charpentier, President, Federation of European Academies of Medicine (FEAM)
13:15-14:45	**Session 1: Cross-border biomedical research: What are the new challenges arising from the forthcoming data protection legislation?** *Chair: Prof. Stefan Constantinescu, Vice President, Federation of European Academies of Medicine (FEAM)*
13:15 - 14:15	**Presentations:** • Prof. Françoise Meunier, Director of Special Projects, European Association for the Research and Treatment of Cancer (EORTC), Vice-President, Federation of European Academies of Medicine (FEAM) • Prof. Kristian Hveem, Professor in Medicine and Clinical Epidemiology, Technical University of Norway (NTNU) • Johan Wisenborn, Head Data Privacy Country Operations, Novartis • Sarah Collen, Senior European Policy Manager, NHS European Office
14:15 - 14:45	**Panel discussion with the audience**
14:45-15:00	**Coffee break**
15:00-15:50	**Session 2: How to facilitate use of data in cross-border biomedical research? Cross-sectorial dialogue with policy-makers.** *Chair: Prof. Françoise Meunier, Director of Special Projects, European Association for the Research and Treatment of Cancer (EORTC), Vice-President, Federation of European Academies of Medicine (FEAM)*
15:00 - 15:30	**Presentations:** • Dr. Andrzej Rys, Director, Dir B - Health systems, medical products and innovation (European Commission, DG SANTE) • Miguel González-Sancho, Head of Unit, Unit H3 – e-Health, Well-being and Ageing (European Commission, DG CONNECT)
15:30 - 15:50	**Q&A**
15:50-16:00	**Concluding remarks and next steps** • Prof. George Griffin, President elect, Federation of European Academies of Medicine (FEAM)

Annex II - Speaker biographies

Prof. Bernard Charpentier
President, Federation of European Academies of Medicine (FEAM)

Prof. B. Charpentier received his MD and graduated in Nephrology from Paris University School of Medicine in 1975. He is full Professor in Medicine in Paris-Sud 11 University since 1983, medical Consultant and was Head of the Department of Nephrology, Dialysis and Transplantations in the University Hospital of Bicêtre (1992-2011). He was Director of several CNRS-INSERM-University Paris-Sud 11 research units devoted to Immunology and Immunoregulation (CNRS UPR 277-420; INSERM U542-1014). He is (co)author of more than 400 pubmed-indexed publications on Nephrology and Transplantation. He was member of several Editorial Boards of immunology and transplantation journals and of immunology, nephrology, and transplantation societies. He acts as a consultant for several International, European and National Advisory Committees. He is member of the Ethical and Sanction Committee (CODEEM) (2011-2017) of the French Pharmaceutical Companies Union (LEEM).

He was Dean of the Faculty of Medicine Paris-Sud (1998-2008), President of the French Medical Deans' Council (2003-2008), President of the French Transplant Society (1997-2000), President of the European Society for Organ Transplantation (ESOT) (2005-2007), Co-Chairman of the XVth ESOT Congress (Paris-2009). He was elected as Fellow of the French Academy of Medicine (2010), Council Member of the Federation of European Academies of Medicine (FEAM-2012), FEAM Vice-President (2014) and now FEAM President (2015). He is member of the « Science Advice for Policy by European Academies » (SAPEA) of the European Commission. He is Commandeur de la Légion d'Honneur, Officier de l'Ordre du Mérite, Chevalier des Palmes Académiques, Médaille d'Honneur du Service de Santé des Armées.
His field of interest are mainly focused in transplantation medicine, basic immunology, immunoregulation and immunosuppressive drugs.

Prof. Stefan N. Constantinescu
Vice President, Federation of European Academies of Medicine (FEAM)

Stefan N. Constantinescu is Professor of Cell and Molecular Biology at Université catholique de Louvain. He coordinates the Cell Signaling and Molecular Hematology Pole of de Duve Institute at UCL and is a Member of Ludwig Institute for Cancer Research, at the Brussels Branch. Trained as an MD at the Carol Davila University of Medicine and Pharmacy in Bucharest, he uncovered in 1989 a major pediatric AIDS outbreak in Romania that has changed blood transfusion practices and impacted the pediatric AIDS field. His PhD thesis concerned mechanisms of signaling by type I interferons. He undertook postdoctoral work with Prof. Harvey F. Lodish at Whitehead Institute at Massachusetts Institute of Technology (1995-2000) on oncogenesis via erythropoietin receptor and is an independent group leader since 2000.

His research focuses on molecular bases of blood formation and cancer, and on fundamental aspects of cytokine receptor and transmembrane protein structure and function. His laboratory at de Duve Institute (UCL) and Ludwig Cancer Research has contributed to the identification and study of the driver mutations in human myeloproliferative neoplasms Polycythemia Vera, Essential Thrombocythemia and Myelofibrosis (JAK2 V617F, W515 mutants of Tpo receptor, mechanism of oncogenesis by calreticulin mutants). He was elected to both the Royal Academy of Medicine in Belgium, and the Romanian Academy of Medical Sciences, and is Vice-President of FEAM since 2016.

Prof. Françoise Meunier
Director of Special Projects, European Association for the Research and Treatment of Cancer (EORTC), Vice-President, Federation of European Academies of Medicine (FEAM)

Since 1991, Françoise Meunier, has managed as Director General EORTC a major European organisation in oncology with a network of 2500 oncologists in 600 universities and a staff of 200 (17 nationalities). As Director Special Projects since 1st April 2015, she is now responsible for public relations, communications and survivorship program.

She is member of numerous international scientific societies and received several awards for her contribution to oncology. In 2007, she was conferred the title of Baroness by His Majesty, The King Albert II of Belgium.

She is a board member of FEAM (Federation of European Academies of Medicine) and "Centre Scientifique de Monaco", and member of ARMB (Académie Royale de Médecine de Belgique).

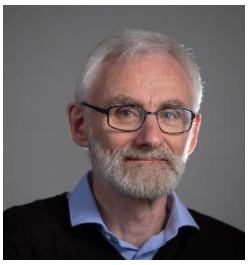
Since 2014 – she is board member of Centre Scientifique de Monaco

In 2015, she was appointed Board member of Alliance for Biomedical Research in Europe.

She was offered in July 2015, the degree of Doctor of Medical Science (Honoris Causa) by the Senate of Queen's University Belfast.

In 2016 she is active member of the Scientific Panel for Health (SPH).

Prof. Kristian Hveem
Professor in Medicine and Clinical Epidemiology, Technical University of Norway (NTNU)



Kristian Hveem is a Professor in Medicine and Clinical Epidemiology at the Faculty of Medicine and Health Sciences, the Norwegian University of Science and Technology (NTNU), and a specialist in gastroenterology and internal medicine. He is the director of HUNT Biobank (The European Biobank of the year 2013) and the national CONOR biobank in Norway. Since 2010 he has been leading the National Biobank Infrastructure, "Biobank Norway" (BBMRI.no), funded by the Research Council of Norway, and he is the Norwegian representative on the BBMRI-ERIC management committee. From 2010-2013 he served as the first director of the Danish National Biobank (DNB). He is still associated with DNB as a scientific advisor. He is also the present leader of the Nordic Biobank Network
In 2016 his research group, "HUNT genes", was appointed as a K.G. Jebsen Center for Genetic Epidemiology, a national funding scheme for advanced translational research. Prof Hveem is both leading and participate actively in a number of national and international research projects.

Johan Wisenborn
Head Data Privacy Country Operations, Novartis

Johan Wisenborn, Head Data Privacy Country Operations at Novartis, is leading a team of approximately 20 full-time data privacy lawyers working for Novartis around the globe. From 2010 to 2016, Johan was the Head of Legal and Compliance for Novartis in the Nordics. Before joining Novartis, Johan has worked for AstraZeneca and with the law firm Mannheimer Swartling.

Sarah Collen
Scientific Coordinator, NHS European Office

Sarah Collen has 17 years of experience working in Brussels on EU public affairs. She joined the NHS European Office in 2013 as Senior Policy Manager. On top of representing the NHS in negotiations on European legislation that could have an impact on the service, she has played an active role in promoting EU funding opportunities to the NHS, including EU research and innovation funding (from Horizon 2020) and funding to support public health initiatives (EU Health Programme). In terms of EU legislation, she has most recently worked on the Medical Devices Regulations and also the EU General Data Protection Regulation. She is the UK's National Focal Point for the EU Health Programme. She previously worked in the European Parliament and has also directed a Brussels based non-governmental organisation working in the field of development and human rights.

Dr. Andrzej Rys
Director, Dir B - Health systems, medical products and innovation (European Commission, DG SANTE)

- Director responsible for health systems, medical products and innovation Directorate-General for Health and Food Safety, European Commission
- Member of IMI Governing Board
- Alternate Member of the European Medicines Agency (EMA) Board
- Medical doctor specialized in radiology and public health, graduate of Jagiellonian University, Krakow (Poland).

Previous and other positions

- 2011: Director for Health Systems and Products in the Directorate-General for Health and Food Safety, European Commission
- 2006: Director for Public Health and Risk Assessment in the Directorate-General for Health and Consumers, European Commission
- 2003: Founder and Director of the Center for Innovation and Technology Transfer at Jagiellonian University (Krakow, Poland)
- 1999-2002: Deputy Minister of Health in Poland. Member of the Polish accession negotiators team
- 1997-1999: Director of Krakow's city health department
- 1991-1997: Founder and Director of the School of Public Health at the Jagiellonian University

Miguel González-Sancho
Head of Unit, Unit H3 – e-Health, Well-being and Ageing (European Commission, DG CONNECT)

Miguel González-Sancho is since 2016 Head of the Unit "eHealth, Well-Being and Ageing" at the European Commission, within the Directorate General "Communication Networks, Content and Technology" (DG CNECT, https://ec.europa.eu/digital-single-market/en/dg-connect).
Miguel previously held different positions in DG CNECT, including Head of Unit for Administration and Finance, Deputy Head of Unit for Policy Coordination as well as Deputy Head of the Unit "ICT for Inclusion". During this period, he worked on various European digital policy strategies ("e-Europe", "i2010", "Digital Agenda"), as well as policy and research projects on ICT for public services and social inclusion.
Miguel was also Member of Cabinet of the European Commission Vice-President responsible for the Digital Agenda, Neelie Kroes. He also worked as legal officer on telecommunications regulation, and as handler of antidumping investigations in DG TRADE at the European Commission.
Miguel holds university degrees in Law (UNED, Spain) and International Relations (UCL, Belgium), as well as master degrees in Business Administration, European policies, and Finance Management/ Auditing.

Prof. George Griffin
President elect, Federation of European Academies of Medicine (FEAM)

Prof. George Griffin gained BSc in Pharmacology and Molecular Biology at King's College London Sciences, where he was awarded the Delegacy Prize for Excellence in Preclinical Science. He was awarded PhD in Cell Biology/Biochemistry, University of Hull, and returned to clinical studies at St George, University of London, where he was awarded the MBBS. Professor Griffin's postgraduate training paralleled basic and clinical science. During this time, he was awarded a Harkness Fellowship of the Commonwealth Fund of New York at Harvard Medical School. On return to the UK, he continued clinical training at Royal Postgraduate Medical School where he was tutor in Medicine, and the National Hospital for Nervous Diseases. He then returned to St George's as lecturer and was awarded a Wellcome Trust Senior Lectureship and became consultant physician on the Clinical Infection Unit where he was instrumental in developing an internationally renowned research unit twinned to the Clinical Unit. He held prestigious research fellowships in the University of Michigan and National Institutes of Health.
He has chaired scientific advisory boards in major pharmaceutical industry in the USA and UK. He has been chair and member of major Wellcome, Medical Research Council and Gates Foundation committees. He was censor at the Royal College of Physicians and was made a member of the Academy of Medical Sciences in which he has been elected to become foreign secretary and council member. He was appointed to the board of Public Health England where he will help shape strategy for research and clinical development.

His research has focussed on the host response to infection at cell, molecular and whole body level. Such work involves immune and metabolic responses in vivo in humans. Furthermore cell and molecular studies include culture of human mucosal explants and definition of macrophage activation in vitro by microbial agents. A macrophage is a cell which ingests particles (microorganisms or host cells) for destruction and immune presentation. It is important in intracellular infection and also produces cytokines (a category of signaling molecules) as part of the immune response.

Professor Griffin's principal clinical contributions to knowledge have been in the characterisation of intestinal disease in HIV infection, mechanism of weight loss in HIV and definition of loss of mucosal immune response in advanced HIV infection. The dominant cell and molecular achievements have been the characterisation of NF-kBas, a crucial factor maintaining macrophage differentiation and the role this transcription factor plays during tuberculosis infection of the macrophage and the mechanism of enhanced HIV transcription in such cells. More recently he has characterised the role of co-infection of HIV infected cells with herpes virus in enhanced HIV transcription in the genital epithelium.

Annex III - Participants list

Last Name	First Name	Position	Organisation
Becker	Regina	Strategy Manager	LCSB / University of Luxembourg
Bottaro	Silvia	FEAM Forum Policy Officer	FEAM
Cattarin	Francesca	Health Policy Officer	BEUC
Charpentier	Bernard	President	FEAM
Collen	Sarah	Senior Policy Manager	NHS European Office
Constantinescu	Stefan	Vice President	FEAM
Dixon	Liberty	FORUM Policy Manager	UK Academy of Medical Sciences
Florindi	Francesco	Engagement Officer	BBMRI-ERIC
Galbraith	Heike	Director EU Government Affairs	Pfizer
Gonzalez-Sancho	Miguel	Head of Unit - Dir H, Unit 3. eHealth, Well-Being and Ageing	European Commission, DG CONNECT
Griffin	George	President elect	FEAM
Gyorffi	Miklos	Research administrator	European Parliament
Hernando	Ines	eHealth Senior Manager	COCIR
Hussain	Nasir	Government Analyst (Healthcare)	Bloomberg LP
Hveem	Kristian	Professor in Medicine and Clinical Epidemiology	Technical University of Norway
Kandel	Valentine	Assistant manager	European Federation of Pharmaceutical Industries and Associations (EFPIA)
Kipling	Jeff	Scientific Advisor	FEAM
Kuyumdzhieva	Albena	Programme Manager-Research/Ethics Review	European Commission, DG Research & Innovation
Leech	Kirk	Executive Director	EARA
Legros	Laurence	Executive Director	FEAM
Malinina	Jelena	Analyst	RPP Healthcare
McBride	Tony	Consultant	Futura Consulting
Meunier	Françoise	EORTC Director of Special Projects, FEAM Vice President	European Organisation for Research and Treatment of Cancer (EORTC) FEAM
Meyerovich	Kira	Manager Regulations and Industrial Policy	MedTech Europe
Middelveld	Roelinde	Project Manager	Karolinska Institutet
Mobasser	Hamed	Scientific Policy Officer	FEAM
Nauwelaerts	Wim	Partner	Sidley Austin LLP
Negrouk	Anastassia	Head of International Policy Office	European Organisation for Research and Treatment of Cancer (EORTC)
Oberschelp de Meneses	Anna Sophia	Associate	Convington
Olejniczak	Kacper	Officer Regulations and Industrial Policy	MedTech Europe
Rouaud	Carole	Senior policy adviser	Standing Committee of European Doctors (CPME)

Rys	Andrzej	Director, Dir B - Health systems, medical products and innovation	European Commission, DG SANTE
Simulescu	Loredana	Policy Officer	Alliance for Biomedical Research in Europe
Seebohm	Annabel	Secretary General	Standing Committee of European Doctors (CPME)
Townend	David	Professor of Health and Life Sciences Jurisprudence	Maastricht University
Verdonck	Pascal	Professor of biomedical engineering	Royal Academy of Belgium for Science and the Arts
Virgil	Ivan	Head of genetic laboratory	Personal Genetics SA
Vonck	Prof. dr. Kristl	Neurologist, Epilepsy Alliance Europe Task Force Member	International League Against Epilepsy, Ghent University Hospital Belgium
Winger	Martin	International Affairs European Science Policy	German Research Foundation
Wisenborn	Johan	Head Data Privacy Country Operations	Novartis

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