Project proposal and scoping paper on "International transfer mechanisms of data for research"

1. What policy problem is the project addressing? Why does the problem merit the attention of EASAC?

Data sharing is an essential part of modern research and, within medical research, data on individuals are often pooled to ensure sufficiently large study numbers, and to replicate findings and identify complex pathways. The EU General Data Protection Regulation 2016/679 (GDPR) has harmonised legislation on the processing of personal data within the EU (EAA), but there are still substantial challenges to sharing data with countries outside of the EEA (which, at the time of writing is expected to include the UK). In particular, a lack of non-consent based transfer mechanisms that can be used for sharing personal data with public institutions in other countries such as the USA.

These issues were discussed at a recent Biosciences Steering Panel meeting following presentations by Norwegian researchers and with attendance by FEAM. The Steering Panel agreed that it is important for academies to help intensify efforts to find solutions to enable the international sharing of health data for research, while taking account of legal and ethical issues, in particular privacy (see Appendix for summary of Steering Panel presentations and discussion).

Our Norwegian colleagues observed that the high reputation of EASAC and its manifest impact in many other policy areas encouraged the expectation that the academies could add significant value, complementary to other current initiatives exploring options to resolve the data sharing problem.

2. Is the project related to the EU agenda and EASAC's objectives? Does it fit in with the current range of advisory work? If not, is there a case for expanding that range?

EASAC has a history of interest in optimising the use of health research data, and worked together with FEAM in providing evidence on the value of research and the need for collaborative activity, in previous discussions with the European Commission and Parliament. As discussed in the Appendix, the Biosciences Steering Panel advised that the project proposal comes within the expected remit of EASAC: the project intention aims at the means to maximise the use of the scientific evidence base for policy and other societal goals in Europe (and the wider global context). Our emphasis would be on exemplifying how data sharing adds value to EU research and its translation to policy, innovation and practice, clarifying principles and options for reform, rather than being overly prescriptive on legal detail in the GDPR or other legislation.

The Steering Panel concluded that the objectives were relevant to EASAC's role in "science for policy". Clearly the project proposal does also encompass elements of "policy for science": the recommended involvement of other academy network partners (see section 8) helps to provide the resource and ambition to address these elements and, also, to capture relevant legal expertise so as to be able to proceed efficiently.

3. Is the problem such that objective scientific interest is relevant for the policy maker? If so, can EASAC secure access to that evidence?

Inherent in the project is an emphasis on the objective compilation of the science base, to make best use of that resource for policy makers and others. EASAC (and its partners) have access to the relevant evidence to illustrate the value of multinational medical research and to compare the potential of different solutions for reform.

4. Who is responsible (or should be) for the problem at the EU policy level? What might they do differently as a result of the EU project? What is the evidence that they are interested in the problem as formulated?

As noted in the Appendix, the new European Commission has expressed a priority for the "European Health Data Space" and is also currently considering ways to reform some aspects of the GDPR. Key contacts are likely to be in DG Sante and DG Connect but the issues raised may well be of interest more widely for the European Commission. There will also be advice forthcoming from the European Court of Justice (CJEU). There is significant interest in the European Parliament and successive Presidencies of the EU Council (see Appendix).

If the proposed project is successful, we would expect to raise the visibility of the public importance of medical research and help to inform the European Institutions in their reform of the GDPR so as to improve procedures for international transfer of high quality, personal research data, safely and effectively.

5. Who are the other stakeholders in the issue being addressed? Does the project proposal accommodate their concerns?

The position of other stakeholders is a major consideration. Already some NGOs have initiated examination of the GDPR by the CJEU on the grounds that it is too permissive and does not adequately protect privacy. An academies project would need to take account of these views and CJEU pronouncements.

6. What external factors influence the timing of the project, i.e. should it be completed by a certain date in order to have maximum impact?

It is anticipated that the first ECJ ruling may appear early in 2020 and that the European Commission will commence its evaluation of relevant issues for revising the GDPR in 2020. The European Commission/DG Sante is also expected to initiate its strategic work on the "European Health Data Space" during 2020. Moreover, the Croatian Presidency of EU Council is expected to have a priority on data in 2020. It is worth adding that international sharing of research data may become a particularly urgent issue for the UK and EU very soon.

Thus, if approved by Council, the recommendation is to commence the project as soon as possible for completion during 2020, with dissemination of outputs during the tenure of the German Presidency of EU Council. Contacts with policy makers and other stakeholders would be initiated from the time of project inception.

7. What work is already being done by others in this area? Have member academies already been active? Why would EASAC intervention have added value and how would it be distinctive?

Many academies are very interested in the issues for data sharing, although the particular issues raised in the project proposal do not appear to have received sufficient attention, and this omission needs to be rectified.

Researchers are acting to raise visibility of the problem within the medical research community (see Appendix) but EASAC (and its partners) can add value by drawing on a wider and interdisciplinary experience, and the evidence base across the EU, and by seeking impact using our connections with the European Institutions.

There are other relevant developments for scientific data management proposed by other stakeholder groups, e.g. as part of developing the European Open Science Cloud (www.eoscsecretariat.eu).

8. Is there a case for doing the project with anyone else?

Based on discussion at the Biosciences Steering Panel and on the previous mutual interests during the run-up to the GDPR, a very strong case can be made for proposing the project as a partnership between EASAC and FEAM.

It is also recommended that we discuss with ALLEA whether they wish to join with FEAM and EASAC in this project. ALLEA has significant general interests in sharing and using data (e.g. their report with the Royal Society in 2019 "Flourishing in a data-enabled society") and can augment project strengths across the social sciences and humanities.

9. What is the intended project deliverables?

We propose a joint Statement based on Working Group activity. It would be an early task for project partners to determine if convening a workshop would be the best way to collect evidence and share perspectives, as a basis for subsequent Working Group deliberations. As already emphasised, we would aim to keep in contact with key policy customers throughout the project.

10. What issues need to be taken into account by Council for allocation of EASAC resources? Is the topic within the competencies and interests of EASAC member academies?

This project is within the competencies of EASAC and FEAM, and the involvement of ALLEA would be helpful in disseminating interest and ensuring breadth of discussion and impact.

If Council approves the proposal, EASAC will discuss with FEAM, ALLEA and the Norwegian Academy the multidisciplinary resource needs for the Working Group (and workshop, if confirmed) and explore how best to ensure and share support for project secretariat activities.

Appendix: Project proposal from the Norwegian Academy of Science and Letters to EASAC

Presentations and discussion at EASAC Biosciences Steering Panel, 3 October 2019

Invited Norwegian guests were introduced by Rolf Reed (Steering Panel) and presentations were made by Giske Ursin (Cancer Registry of Norway), Gun Peggy Knudsen (The Norwegian Institute of Public Health), and Heidi Beate Bentzen (Centre for Medical Ethics and The Norwegian Research Center for Computers and Law, University of Oslo).

Data sharing is an essential part of modern research and, within medical research, data on individuals are often pooled to ensure sufficiently large sample size, for example to analyse associations between risk factors and disease subtypes. Multinational collaborations can efficiently address complex medical and public health questions.

Within the EU/EAA, the General Data Protection Regulation (GDPR, EU 2016/679) has harmonised legislation with regard to the processing of personal data. However, currently there are substantial challenges with sharing data outside of the EEA[1]. For example, the US National Institutes of Health cannot accept current GDPR terms[2] and the WHO International Agency on Cancer[3] has faced challenges in obtaining data from the EU/EEA post-GDPR. There is need to provide guidelines or reform transfer mechanisms so that European researchers can share their data internationally.

Examples of research needs

Among examples of research opportunities presented where collaboration for patient or other individual data sharing is essential were:

- Rare disorders, including cancer subtypes, psychiatric disorders and autism.
- Antimicrobial resistance, where data on patient flow within and between countries is needed, together with sharing for re-use of national data between countries for modelling.
- Microbiome research, where there are privacy issues because each individual's microbiome is unique.
- Genetic research, also with privacy issues. Large studies are essential to have sufficient numbers within subgroups of disease and combination of genetic variants.
- Vaccine research, particularly to support new collaborations on personal data, e.g. the NIH research network on influenza vaccines.

Current GDPR mechanisms for supporting international transfer of patient research data

- Adequacy Free movement of data from the EEA is allowed if there is an "Adequacy" decision for the recipient. This applies to some countries but, for example, for the USA it is limited to the Privacy Shield framework comprising certified companies and

[1] See chapter 5 (Articles 44-50) of GDPR for provisions for transfer of personal data to third countries or international organisations, https://gdpr-info.eu.
[2] https://epi.grants.cancer.gov/Consortia/meeting2018.html.
[3] www.iarc.fr.

not public sector researchers. Moreover, these arrangements are currently being challenged in the CJEU by NGOs, on the ground of insufficient protection of privacy.

- Standard Contractual Clauses (SCC) These arrangements are inflexible and cannot be agreed, for example, by the US NIH. Furthermore, they also are being challenged in the CJEU as not offering sufficient privacy. The European Commission stated in June 2019 that they would revise SCC but there is no information on the timetable for this (presumably awaiting CJEU judgement in early 2020).
- Codes of conduct With regard to these, no guidelines have yet been issued by the European Data Protection Board[4] relating to international transfer of data, but they are likely to be complex and, similarly to the codes of conduct within the EU, require creation of independent monitoring boards[5].
- Further transfer mechanisms as exceptions Two were discussed: (i) "If explicitly consented" but such consent must specify data transfer to a country lacking protections[6] and this detail has not usually been included in consent forms used in studies until now. (ii) "Important public interest" to be specified in law[7]. The threshold seems to be set high. For example, the Danish Data Protection Authority has suggested an outbreak of Ebola as a sufficiently important public interest.

Potential solutions: what can the academies do?

How can the data subject best be protected? According to the GDPR, this would be through an adequacy decision (Art 45) or through appropriate safeguards (Art 46). Consent should only be used as a transfer mechanism in the absence of adequacy and safeguards (Art 49) and it provides weaker protection for the individual. Hence, a transfer mechanism that provides an appropriate safeguard will best serve the data subject – and it also happens to be a more practical solution for ensuring data flow for research. However, as described above there is a lack of non-consent based transfer mechanisms that can be used for sharing personal data with US public institutions. The available transfer mechanisms can – either because of how they are designed (e.g. Privacy Shield) or due to conflicting US federal laws (e.g. Standard Contractual Clauses) – only be used by private institutions.

Given that the current transfer mechanisms are inadequate, the following priorities were emphasised in the Norwegian presentations:

- Engage in informing and influencing the European Commission revision of SCCs.
- Encourage production of the European Data Protection Board guidelines on international transfer.

[4] https://edpb.europa.eu.
[5] https://edpb.europa.eu/our-work-tools/our-documents/nasoki/guidelines-12019-codes-conduct-and-monitoring-bodies-under_en.
[6] The exact wording of the GDPR is "the data subject has explicitly consented to the proposed transfer, after having been informed of the possible risks of such transfers for the data subject due to the absence of an adequacy decision and appropriate safeguards"
[7] The GDPR wording is "recognised in Union law or in the law of the Member State"

- Increase visibility of the problem and its solutions. Although the visibility in the medical community will be raised by a forthcoming Letter to Lancet (Ursin et al on behalf of 19 authors, 16 institutions and 9 countries), European academy networks can greatly help to stimulate discussion and action by publishing a Statement explaining the value of data sharing for research and the vital importance of reliable, safe transfer mechanisms, and by engaging actively through their contacts with the European Institutions.

<u>Biosciences Steering Panel discussion of the proposal</u>

- It was agreed that research data are a public good[8] and that sharing also serves efficiency and efficacy: researchers often cannot themselves fully analyse the data they have harvested so sharing makes better use of the investment in research. The current problems in data transfer undermine the EU objectives for "Open Science".
- The issues for data generation, curation and sharing have been discussed previously by the Biosciences Steering Panel, for example in the context of Personalised Medicine and collaboration in sharing SNP data.
- There are associated issues for promoting data quality, incentivising researchers to share, and ensuring sufficient privacy guarantees. These requirements substantiate the need for good guidelines on transferring quality data, safely, among the best researchers worldwide.
- The ability of private companies to use Privacy Shield and Standard Contractual Clauses, whereas public sector researchers cannot, gives a large advantage to the private sector, often capitalising on data produced with public investment.
- It was agreed that data transfer is a growing international problem, not only an EU-US impediment. EU/EEA countries have similar challenges with sharing data with international organisations. For example, there are no obvious transfer mechanisms for sharing cancer registry data with the International Agency for Research on Cancer, the WHO cancer research organisation.
- Does the project proposal represent "science for policy" or "policy for science" (the latter would normally be considered outside the remit of EASAC)? Essentially, the project would focus on the scientific evidence base that cannot properly be used for policy or other societal goals because of the legislative impediments.
- The topic is deemed relevant, given the previous work by FEAM[9] and EASAC and in view of the imminent importance of the issues for UK-EU data sharing. It is also very timely, for engagement with the European Commission on GDPR reform (SCC and European Data Protection Board guidelines) and other shared health data issues and for the other European Institutions. There is momentum for the "European Health Data Space", raised in the recent ENVI parliamentary committee confirmation hearings of DG Sante Commissioner Kyriakides. Data protection is also likely to be a

[8] For example, A Knottnerus "Research data as a global public good" J Clin Epidemiology 2016 70, 270-271.
[9] For example, the FEAM European Biomedical Policy Forum, "Use of data in cross-border biomedical research: what are the challenges ahead for Europe?" 2017

Croatian EU Presidency priority and the very recent EPRS parliamentary report[10] noted concern about data transfer outside the EU but does not offer solutions for legislative reform.

- The Steering Panel discussed other potentially overlapping issues for quality data generation and sharing. Patrick Charnay proposed examining issues for compiling and accessing human DNA sequences, particularly in terms of the work of the European Bioinformatics Institute, together with other likely policy changes for sharing plant and animal DNA sequences (arising from proposed revision of Nagoya Protocol), and strategic challenges more generally for EU and global data infrastructure. This proposal will be presented in detail at the next Steering Panel meeting. Broader consideration of strategic data sharing issues for other disciplines and sectors warrants further examination: with a focus on principles, "advising on directions, not directing" and might examine the case for a new default position, promoting the sharing of data rather than imposing privacy where it has no value.
- These broader considerations would be deferred for subsequent discussion. The present focus is on international transfer of data for medical and public health research. The Biosciences Steering Panel agreed unanimously that the project proposal should be submitted to the next Council meeting of EASAC with a recommendation to involve FEAM and, if possible, ALLEA.

Robin Fears

30 October 2019

[10] EPRS/STOA "How the General Data Protection Regulation changes the rules for scientific research" PE 634.447 July 2019