UK BioIndustry Association Summary of roundtable discussion on Data: A New Direction consultation

November 2021

Government Proposals

The Government is proposing changing Data legislation to "create an ambitious, pro-growth and innovation-friendly data protection regime that underpins the trustworthy use of data." The consultation contains five chapters covering a broad range of areas. We were particularly interested in chapter one "Reducing barriers to responsible innovation" given our sector. This chapter sets out to clarify and improve aspects of data regulation that are seen as barriers to research and innovation. A roundtable discussion was held on 5 November to address these points.

Key points from discussion:

- Consent is not the recommended legal basis under GDPR for research, and therefore the proposed changes would not address barriers faced by those accessing health data for research, which is also subject to common law.
- The development of a cohesive and joined up approach to the use of health data in research should consider the law of confidentially.
- Any changes to UK GDPR should not take us out of step with the EU GDPR, in order to maintain data adequacy.
- The Government should further consider the process of anonymising health data for research and how this can be done in the patient's best interest.
- Industry specific guidance is needed to address the use of genomic data and where this falls in terms of reidentification risk.
- The Government should be doing more to facilitate the creation of anonymised data by clarifying governance in this area.
- The Government should think about the governance of data intermediaries which hold valuable public data assets such as health data, in order to avoid oligopolies.

Session Structure

The session was attended by representatives from DCMS, BIA members, legal experts from Bird & Bird and representatives from the Health Research Authority (see Attendee list at end). In the session we covered the following areas:

1. **Re-use of data/Consent**

The Consultation proposes confirming that consent to broad areas of scientific research under GDPR is acceptable when it is not possible to fully identify the purpose of personal data processing at the time of data collection. To facilitate the re-use of data for research the proposal suggests confirming that scientific research is always compatible with the original purpose and doesn't need a different legal basis.

2. Medical confidentiality

In the UK, data protection law relies on consent, scientific research or legitimate interest as the legal basis for processing data. The common law duty of confidence, however, means that confidential information (such as health data) should only be used for the purpose for which it was provided (direct care). The consultation does not address this.

3. Anonymisation

Anonymous data is not subject to GDPR and there is no statutory definition of "anonymous data". Various guidance on anonymisation exists including in GDPR recitals. The consultation asks if a better definition of anonymous data would help facilitate research and if so, what test or definition should be used.

4. Data intermediaries

The Government wants to encourage the development and use of data intermediaries. These are third parties which have custodianship over data and facilitate sharing and access. The consultation seeks advice on what the Government can do to support the uptake of data intermediaries.

Key points from the discussion:

Re-use of Data and Consent

"…*I would think that if patients would want further research then that research should be allowable…it's the tensions between [GDPR and common law] that's difficult to manage*…"

Attendees highlighted that combining disparate data for causal data research is important and therefore getting consent and rules on data re-use right is important. Attendees discussed challenges they had faced with getting the right sort of consent for the research they were conducting. One cited a case in which all data had to be destroyed and recollected under the right consent. However, this was not due to the GDPR, but rather UK common law which should be followed in this circumstance. The barriers attendees faced were therefore because of decisions made by Research Ethics Committees (RECs): "*But the REC don't like open ended approaches…. their interpretation was extremely restrictive in our view and of the clinicians and the third sector partners."* Some attendees felt that the GDPR should take precedence over REC committees. In contrast, others voiced a need for some degree of independent oversight to preserve public trust, which they saw as critical: *"… there needs to be a level of scrutiny [on data access and use] that's independent to the outcome that's actually protecting the patients' rights…"*

- Consent is not the recommended legal basis for research under GDPR, and therefore the proposed changes would not address barriers faced by those accessing health data for research, which is also subject to common law.

Medical confidentiality

"Thinking about NHS data …the reason we need consent is more of a systems issue, it's to do with not handling data in the right way to protect people's confidentiality"
The law of confidence was discussed and how this places a higher bar on data protection than GDPR. In addition, it was suggested that this law is not well understood, and the Government would be better placed

in addressing this rather than other suggestions made in the consultation. Attendees referenced the Health Insurance Portability and Accountability Act (HIPAA) in the United States and how this is well understood, adopted, and enacted across US healthcare and research. In contrast, UK law covering the use of health data is very fragmented, devolved and data protection law and common law confidentiality are overlapping in application.

- The development of a cohesive and joined up approach to the use of health data in research should consider the law of confidentially.

The attendees were concerned with losing data adequacy with the EU, adding: "*anything that moves away from a common understanding of GDPR between ourselves and the EU is not a good thing in my mind either, so whatever changes we're thinking of, for a company like us it would be very important to stay in step with European legislation"* Data adequacy with the EU was seen as vital for research, which often relies on international collaboration. It was felt that SMEs in particular would suffer if data adequacy was lost as they don't have access to the legal resource that larger pharma companies have. One attendee clarified that the perception of shared legislation was more important than the reality.
In addition, attendees reflected that devolution of practice in the UK has resulted in a preference for working with more nationalized frameworks. For example, setting up a clinical trial in a European country where agreement from a single national region was preferred to multiple heterogeneous authorities.

- Any changes to UK GDPR should not take us out of step with the EU GDPR, in order to maintain data adequacy.

Anonymisation

"…the elephant in the room here is genomic data…"

Attendees were particularly concerned with the use of genomic data, particularly whole genome and genotype data, and the inability to render this anonymous with current technologies. One attendee cited a very rare circumstance of being able to identify a patient in a population by his genome. It was thought that changes to legislation would not help with this.

- Industry specific guidance is needed to address the use of genomic data and where this falls in terms of reidentification risk.

The Government could be doing more to facilitate the creation of anonymised data, by clarifying that the processing of data to anonymise it is permissible. UK complexities were further discussed in the context of generating deidentified data. The processing of data to make it deidentified needs to be done by a member of the patient's care team. This creates a barrier in terms of capacity within a care team, but also in the ambiguity surrounding the definition of "care team". Furthermore, each care provider's data controller has a different understanding of data protection which therefore impacts their actions. The resulting variation in approaches and interpretation of "care team" is seen as creating barriers to research whilst also not protecting the public's best interests.

- The Government should further consider the process of anonymising health data obtained for primary care for subsequent research and how this can be done in the patient's best interest.
- The Government should be doing more to facilitate the creation of anonymised data by clarifying governance in this area.

Data intermediaries

"*Encourage the development of Data Trusts/Exchanges as long as they're transparent, accountable and do not create an oligopoly created by academic universities, or their spinouts*"

Attendees were generally in favour of the use of data intermediaries for research. Caveats were discussed such as the issues around the Royal Free's data sharing with DeepMind, which was seen to have had the potential of leaving DeepMind in control of NHS data. This incident had an important impact on public trust. Attendees were also concerned that in this case, Google would have had insight into the research being performed by other researchers, and potentially rivals. The intermediaries were therefore seen as potentially having power over others in the system and attendees were keen for them to be used responsibly. Respondents also voices concerns that data intermediaries would be managed exclusively by universities, therefore giving the public sector exclusive control over decisions regarding research access to health data. In general, the best way to help the establishment of data intermediaries was seen as addressing the points highlighted above.

- The Government should think about the governance of data intermediaries which hold valuable public data assets such as health data, in order to avoid oligopolies.

The BioIndustry Association

1. The BioIndustry Association (BIA) is the trade association for innovative life sciences in the UK. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.
2. Our members include:
    - Start-ups, biotechnology and innovative life science companies
    - Pharmaceutical and technological companies
    - Universities, research centres, tech transfer offices, incubators and accelerators
    - A wide range of life science service providers: investors, lawyers, IP consultants, and communications agencies
3. The BIA's members are at the forefront of innovative scientific developments targeting areas of unmet medical need. This innovation leads to better outcomes for patients, to the development of the knowledge-based economy and to economic growth. Many of our members are small, pre-revenue companies operating at the translation interface between academia and commercialisation.
4. We have a growing number of members working at the interface of patient and health data and innovation, including using analytic models, machine learning and AI. Access to good quality, standardised linked clinical, genomic and cohort data is a key issue for these companies.

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