BHF Response to DCMS 'Data: a new direction' Consultation

October 2021

About the BHF

The British Heart Foundation (BHF) is the largest independent funder of research into heart and circulatory disease and the third largest charitable funder of medical research in the UK. Each year, thanks to the generosity of our supporters, we are able to fund around £100 million of new research across the UK. The research we fund has helped halve the number of people dying from heart and circulatory conditions since the 1960s. Despite these breakthroughs, our work is not done as there are still more than 7 million people living with heart and circulatory diseases in the UK and these diseases cause more than a quarter of all UK deaths.

The BHF's interest in this consultation

The BHF supports an extensive portfolio of projects focused on the use of health and care data, which has grown substantially in recent years. In 2019, we announced the launch of a £10 million BHF Data Science Centre (BHF DSC) in partnership with Health Data Research UK (HDR UK). The Centre was established to work in partnership with patients, the public, the NHS, researchers and clinicians to promote the safe and ethical use of data for research into the causes, prevention and treatment of all diseases of the heart and circulation. The Centre has already risen to the many challenges of the Covid-19 pandemic and is leading several large-scale data projects that aim to better understand the relationship between Covid-19 and cardiovascular diseases. In April 2020, the BHF and the BHF DSC supported the development of a paper that fed into SAGE decision-making, which proposed a way to share data among researchers to rapidly explore the answers to Covid-19 related research questions, across the four nations, using cardiovascular disease as an exemplar.

The BHF also provides significant core funding to both HDR UK and the UK Biobank (currently £2 million and £3.2 million over five years, respectively), and has supported 12 BHF/Alan Turing Institute Cardiovascular Data Science Awards to date, at a value of over £0.5 million. This is a joint funding scheme to support collaborative research between cardiovascular investigators and data scientists seeking to generate data science solutions to key cardiovascular problems. In addition to these strategic investments, as of November 2019 we were supporting approximately £16m across other ongoing data science, machine learning and artificial intelligence research activities.

More recently, the BHF announced a £1 million fund to explore how NHS data can be harnessed to improve delivery of care and patient outcomes. The Cardiovascular Catalyst Awards will fund research into the use of advanced analytics to improve cardiovascular care in the NHS, which has suffered devastating impacts due to Covid-19. Funded research projects will utilise NHS data, e.g., clinical data and healthcare records, and researchers will be required to outline how patients and the public will be involved in shaping research and in decisions on how the data will be used.

We are privileged to work with a world-class community of researchers who utilise the considerable health data asset of the UK on a day-to-day basis. Our expert patient data panel ensures that our data and data science work is always supported by a strong patient voice, encouraging, and challenging us on matters of engagement and transparency.

As one of the largest charities in the UK and with a significant number of supporters whose generosity we rely on to carry out our lifesaving research, we have a particular interest in any changes that could affect how we engage with those supporters and raise funds. In 2019/2020, we raised £53.9 million from our supporters through fundraising activity and a further £80.8 million

through legacies. As such, we have a particular interest in any proposed changes that could allow us to use data innovatively to better engage with supporters, while maintaining the public's trust in how we and other charities use their data.

The BHF welcomes the opportunity to share our thoughts on how the Government can create an ambitious, pro-growth and innovation-friendly data protection regime that underpins the trustworthy use of data.

Our response addresses issues relating to BHF-funded research as well as the operational side of the BHF as a charity. While some topics overlap between these different facets of the BHF, some issues are more specific to one or the other, e.g., the impact of proposed changes on researchers.

We would also like to stress our role and remit in the research space. As a research funder, we do not provide support for researchers to navigate the data regulatory landscape; rather, this is the responsibility of individual research offices at the universities where our researchers work. Additionally, unlike some research funders, the BHF does not hold sensitive health data; our concerns regarding changes to data legislation centre around safe data handling and open engagement with patients and the public about how their personal health data is being used in order to build and maintain trust.

Key Points

- **EU adequacy:** In our interests both as a major medical research funder and as a large charity, we strongly believe that the Government must ensure maintenance of the UK-EU data adequacy agreement, not only in the short-term but when adequacy is being considered for renewal in 2025 – to do so will require a firm commitment to making sure that UK data laws do not diverge significantly from the EU's.
- **Public engagement, trust, and transparency:** Government must ensure that changes to the regulations that protect public rights are communicated transparently, especially as they pertain to access of health data by private companies and automated decision-making. There must be clear opportunity for input and challenge in shaping development and implementation of new regulation.
- **Clear standards for Trusted Research Environments (TRE):** Government should support NHSX ambitions to ensure that all UK TREs conform to consistent standards on access and governance so that patients, the public and health and care professionals can understand what they do and how they work, and have confidence that data is being accessed securely.
- **Education and upskilling of data researchers**: Those who are responsible for overseeing the safe use of and access to data must be confident and well informed on data protection legislation.
- **Compulsory transparency reporting on use of algorithms**: There should be a mandatory transparency obligation for UK public sector organisations that use algorithms to make decisions affecting people's lives.
- **Soft opt-in**: We strongly support proposals to extend the soft opt-in to non-commercial organisations.
- **Legitimate interest**: We support proposals that could enable legitimate interest to be used more confidently by charities to communicate with supporters.
- **Accountability framework**: We believe that Government should consider the relative risk of these changes in relation to the adequacy agreement, and potential impact on organisations that have invested in compliance with current requirements.

Protecting the EU data adequacy agreement

After more than a year of talks, EU-UK GDPR data adequacy was approved in June 2021 by the European Commission. This was a positive result as data transfers are essential for running UK-EU clinical trials as researchers need to routinely send patient data and test results across international borders. The BHF also welcomed the news, as around 19% of our collaborators are based in the EU.

The adequacy decision is valid for four years, but includes an obligation on the EU Commission to monitor developments with UK data protection laws and revise or revoke the adequacy agreement if the UK system is seen to have diverged from the required standard. If adequacy is not maintained, UK-based researchers involved in UK-EU clinical trials, for example, would have to arrange alternative mechanisms to share personal data with their EU-based partners.

These alternative data transfer mechanisms would increase the cost of research through added complexity and legal fees, which could deter EU research studies from involving UK-based research and, in turn, reduce patients' access to life-saving research. Investigations by the University College London European Institute and British think-tank, the New Economics Foundation, found that it could cost medical-research institutions £50,000 to £100,000 to negotiate a data-sharing agreement with an institution in another country. As stressed by many in the research sector, it is in the best interests of all patients that UK and EU researchers be allowed to continue exchanging data - an essential part of collaborative research.

Similar concerns have been raised across the charity sector, notably in events hosted by sector experts such as the Data and Marketing Association and the Chartered Institute of Fundraising. The ability to freely transfer data from the EU to the UK is crucial for charities to maintain supporter databases and fundraise effectively without the need for costly and bureaucratic alternative mechanisms such as Standard Contractual Clauses, or the need to find alternate suppliers with servers based in the UK.

We note the impact assessment of changes to the UK's adequacy status in the accompanying 'Analysis of expected impact' document (beginning at paragraph 68). However, given the breadth and importance of this issue, we would argue that a more thorough and up-to-date impact assessment should be carried out prior to any changes being implemented as a result of this consultation to better understand the impact on different businesses and sectors. This should include a fresh look at the cost implications for organisations, building on the data used for this analysis. Considering the significant risk that this poses, far beyond the research sector and indeed for the entire UK economy, it was concerning to see this issue only make up a small section of the consultation.

We strongly recommend that the final report includes detail on the steps being taken to ensure that any legislative changes do not threaten the EU data adequacy agreement.

Research and innovation considerations

The BHF is committed to realising the potential that comprehensive, nationwide, representative data has in this exciting era of personalised medicine and digital innovation. We therefore support the Government's ambition outlined in this consultation to improve researchers' access to data and to provide greater clarity on the aspects of the legislation relating to research.

While we have not provided specific answers to questions in this section, as many were out of our scope and legal expertise, we outline four principles that we believe should be upheld during any proposed legal changes to the research and innovation system:

1. Public engagement, trust, and transparency

Analysis from Understanding Patient data (UPD) shows that people are generally comfortable with anonymised data from medical records being used in research provided there is a public benefit. Crucially, the more informed the public feels, the more likely they are to support the use of their data for health research purposes. Many however, are uncomfortable with the idea of companies accessing their health data, and there are particular concerns about information being passed on for marketing or insurance purposes.

The impact of underestimating the importance of public trust for patient data sharing initiatives was recently demonstrated by the unexpected backlash to changes proposed around the GP Data for Planning and Research (GPDPR) programme. After more than 1 million people opted out of the scheme, the programme launch had to be paused pending it meeting specific criteria, including improved communication with patients and the public. It is disappointing that this issue was not given more consideration in this consultation.

Along with the Association of Medical Research Charities (AMRC) and Cancer Research UK (CRUK), we call on Government to ensure that any changes to the regulations that protect the public's rights are communicated transparently, especially around issues we know are of public concern, such as increased access to health data by private companies and non-human methods of processing sensitive data e.g., automated decision-making.

In addition, we recommend that any future reforms to reduce barriers to innovation include a public engagement plan that reaches an audience that accurately reflects the demographics of the population and that represents voices from patients and the public. For any new data protection legislation, engagement with the public should address the following key questions:

- **How will patient data be shared, with whom and for what purpose?**
- **What are the measures in place to protect against misuse of patient data, and the penalties for breaches of data laws?**
- **Where can the public access trusted, clear information about the use of their health data and how can they raise any question they might have?**

Facilitating an open conversation with the public on this issue would help to build trust and public understanding on this topic. It would also allow Government to monitor public attitudes about health data and quickly address concerns that come to light.

2. Clear standards for Trusted Research Environments

Researchers must be able to access data for research in a responsible way with appropriate consent mechanisms and data protection. Trusted Research Environments (TREs) allow researchers to do this, bringing improvements in data quality, security, transparency and privacy. These features make them crucial in building and maintaining public trust in data-driven planning, research and innovation. However, a current limitation of TREs is the lack of official governance standards, leading to a divergence between some TREs in their governance and technical implementation (including interoperability).

Providing standards for the technical design and deployment of TREs is essential to ensuring interoperability across environments. Being clear on where standardisation is needed and where there is room for flexibility will also allow for innovation between different TREs and ensure that collectively, they meet a range of user needs.

We support the ambitions that NHSX has outlined with regards to TREs:

- **A minimum technical specification for TREs** which covers core areas such as interoperability, cybersecurity and use of privacy enhancing technologies.
- **TRE standards and policy** should be developed alongside creating new governance standards and enhancing any relevant existing ones. Policy and best practice guidance for TREs should include when their use will be mandatory and any legitimate exceptions.
- **An accreditation framework** should be put in place which details the specifications and standards that TREs must adhere to, and how adherence will be assessed and monitored.

In addition to standardising the way that TREs operate, the high levels of data security that TREs provide should be explained to the public in clear language. This will help to reassure the public that appropriate measures are in place to ensure that their private health data is handled in a secure and highly regulated way.

3. Education and upskilling of data researchers

The consultation poses questions about whether aspects of data privacy create a barrier for researchers. The BHF would like to stress that data privacy is not a barrier for research; rather, it is a fundamental control element and encourages appropriate discipline in the application for, and use of, personal data. It can cause difficulties, however, when processes surrounding data handling and collection are not communicated clearly with researchers. Clearer guidance and accessible learning resources for researchers on how to safely handle sensitive data would help to build confidence and would also improve data security.

We recommend that any changes to data laws are communicated clearly with the research community. This should include clarity around applicable regulation, the sharing of practical resources, and strong case studies. We also support AMRC and CRUK in calling for improved guidance from regulators and greater focus on education and upskilling of data custodians, researchers, and host organisations on data protection legislation.

4. Compulsory transparency reporting on use of algorithms

Algorithms and artificial intelligence are powerful tools which can help to make great progress in health research and patient outcomes. However, if unregulated, biases in algorithmic decision-making reflect wider inequalities in society which in turn exacerbates existing health and research inequalities. For example, a 2019 study by Obermeyer et al found that use of a widely used commercial prediction algorithm for cardiovascular care resulted in significant racial bias in predicting outcomes. Specifically, the algorithm identified White patients to have higher risk scores and were more often selected to receive additional care than Black patients who were equally as sick.

To address this serious issue, we support the establishment of mandatory transparency obligation for UK public sector organisations that use algorithms to make decisions affecting people's lives, as advised by the Centre for Data Ethics and Innovation (CDEI). For example, public bodies such as Office of Health Improvement and Disparities (OHID) and Office for National Statistics should be required to publish information on how and why the decision to use an algorithm was made, the type of algorithm used, how it was used, and the steps taken to ensure fair treatment/exclusion of bias.

Compulsory transparency reporting on the use of algorithms by the public sector would be a positive step towards improving public trust. The current accountability and decision-making processes surrounding algorithms are opaque which can lead to mistrust from the public as well as the spread of misinformation. **We recommend that there should be compulsory transparency reporting on the use of algorithms in decision-making for public authorities, government departments and**

government contractors using public data and that this should include standards around reporting in which ensure that it is communicated in clear language. We also recommend that there should be ongoing testing, and reporting, for bias in these algorithms to avoid perpetuating cross-cutting inequalities.

Transparency will not only help to build public trust in algorithms and the use of their health data, but it could also help to increase public understanding and literacy in this area and evidence a commitment to real engagement between technicians and the public to help develop algorithms that more accurately reflect the real world, without bias.

Further operational considerations

An essential part of maintaining the trust of our supporters and raising funds is by ensuring that members of the public can be confident in how we and other charities are using their data. In addition to the principles outlined in the previous section to ensure the continued innovative and responsible use of data in the UK's research and innovation ecosystem, we have also identified several areas that could impact on the wider activities of the BHF. These changes could help to clarify when we can use legitimate interest as a legal basis for contacting our supporters, and how we contact them through using electronic communications using the soft opt-in. Proposed changes could also impact on our own internal data management structures.

Below, we answer specific questions within the consultation as opposed to the above approach because these pertain to activities that directly impact the BHF's operations as a charity.

Q1.4.1 To what extent do you agree with the proposal to create a limited, exhaustive list of legitimate interests for which organisations can use personal data without applying the balancing test?

The BHF agrees with the principle of introducing an exhaustive list of legitimate interests for which organisations can use personal data without the need for the balancing test. We believe that doing so would provide clarity on the rules for the activities included in the final list and enable organisations to move away from an over-reliance on consent (as noted in paragraph 57 of the consultation document) as their basis for processing data. Furthermore, producing such a list would not only help organisations to have more confidence in using legitimate interest as a legal basis for activities identified on the list, but would also minimise the risks currently associated with using that basis.

However, while we agree with the thrust of this change, there are several areas of risk to be considered. First, the activities outlined on the list need to be set out in more detail, perhaps through additional guidance. As with any exhaustive list, there will always be activities that fall into a 'grey area', so clarity on where the boundaries lie will be essential to ensure that organisations do not inadvertently break the law. Likewise, there will be a need for very tight parameters to be put in place through guidance, detailing if and when activities cease to be a legitimate interest (for example, due to frequency of marketing) to ensure that the system is not abused.

Secondly, an unintended consequence of this change could be to create confusion about whether legitimate interest remains a valid basis on which to process data for activities not on the list. The Government and ICO would, therefore, need to ensure that it was clear to organisations that other activities not on the list can still be carried out using legitimate interest as a basis, provided the balancing test is applied.

Please note that our agreement with the creation of the exhaustive list is predicated on the activities that it includes, as outlined in our response to Q1.4.2 (below).

Q1.4.2 To what extent do you agree with the suggested list of activities where the legitimate interests balancing test would not be required? Please explain your answer, indicating whether and why you would remove any activities listed above or add further activities to this list.

The BHF agrees with the activities that are currently included on the list. However, we would argue that there is a strong case to include direct marketing (which includes fundraising) in this list to further remove ambiguities and ensure that organisations can use legitimate interest confidently.

Recital 47 of the GDPR explicitly references direct marketing as an activity that may be carried out under the legitimate interest basis. We feel that the current approach to the use of legitimate interest as a result of existing regulatory guidance has resulted in the intention of this recital not being fully realised in practice, with organisations still unnecessarily relying on consent in many cases.

Adding direct marketing to this list would help to give charities more confidence in using legitimate interest as a basis for making contact and building a relationship with supporters. This would be in line with the general approach of this consultation as it seeks to foster a more innovative approach to the use of data by organisations while maintaining the data rights of individuals. We believe that the number of safeguards already in place, as outlined in our response to Q1.4.3, will ensure that appropriate and responsible use of data will be maintained if direct marketing is added to this list.

Q1.4.3. What, if any, additional safeguards do you think would need to be put in place?

Existing data protection legislation already contains significant safeguarding measures, and requires organisations to implement internal systems, checks and balances to ensure that their use of data is responsible and in line with the expectations of data subjects. Amendments arising from this consultation will need to ensure that those safeguards are maintained. This will be a key element not only in ensuring the integrity of the UK's own data protection system but also in maintaining data sharing agreements with other jurisdictions, including the EU. As noted in our response to Q1.4.1, a key element will be clear guidance on where the boundaries of activities on the list begin and end to mitigate the possibility of organisations unintentionally breaching the law, or abusing the new system.

In relation to our call for direct marketing to be added to the aforementioned list, it is also worth noting the range of additional safeguards that already exist within the charity sector. The Code of Fundraising Practice, for example, provides data protection standards over and above the requirements of the law. Furthermore, it also provides more general principles to guide charities on how they interact with donors, such as avoiding fundraising in a way that is 'an unreasonable intrusion on a person's privacy, is unreasonably persistent or places undue pressure on a person to donate'. Many of the requirements of the Code stem from charity law, while others are professional standards developed within the industry over the course of the past thirty years with the aim of maintaining best practice in the sector. These requirements are well-established within the sector and serve as an additional safeguard against abuse of the system. The Data and Marketing Association's (DMA's) Code provides a further safeguard, setting out the standards for those operating in the wider Direct Marketing industry to adhere to. This Code also sets out standards over and above the requirements of the law to ensure that activity of this type is carried out in an appropriate way.

The Fundraising Preference Service (FPS) provides an additional safeguard. This service is funded by charities and enables members of the public to opt-out of receiving communications from charities, whether they have been contacted by them or not. This means that the charity sector is the only sector in the UK with a specific opt-out mechanism, enforced through regulation, to enable members of the public to stop fundraising approaches through multiple channels.

These additional safeguards already in place demonstrate that there are existing standards and mechanisms to ensure that direct marketing activities by charities will continue to be carried out in an appropriate and responsible way if a less restrictive use of legitimate interest is applied.

Views on Section 2.2: Reform of Accountability Framework

While the BHF supports the thrust of the Government's proposals to remove some of the more prescriptive elements of current legislation and enable organisations to implement a 'more flexible and risk-based' approach dependent upon the activities they are carrying out, we question the benefit of the proposed changes when considered against the potential risks posed.

Large charities, including the BHF, have embedded current requirements into their ways of working, having invested significantly in this in the lead-up to, and since, GDPR and the Data Protection Act 2018 came into effect. While the current system is somewhat prescriptive, it removes any element of doubt in what is required of organisations that may arise if the system is replaced by something more open to interpretation, as proposed.

We note the proposals to remove the requirements for, for example, Data Protection Officers (DPOs) and data protection impact assessments (DPIAs) and to replace them with a more flexible Privacy Management Programme (PMP). However, it is not clear in the proposals that there would be any real change from what is currently required beyond the names of the requirements. In this sense, it looks to be a case of changing the requirements, but not the standards.

This proposal is unlikely to change anything significantly within our own structures and systems. However, there would be costs arising from any changes that are required as legal advice would be needed to ensure that our processes meet the new requirements, if some small changes were required there would be development costs to update systems, and staff would need training in any new systems. This has been echoed by other large charities and sector organisations with whom we have engaged, as well as through communications from some law firms, such as Linklaters.

For example, requirements for a named individual to be responsible for the PMP, to implement impact assessment and monitoring systems, and to ensure adequate reporting would in practice almost mirror current requirements – the BHF would comply by using broadly the same systems we currently have in place, albeit with some superficial changes depending what the final requirements arising from this consultation are. The GDPR already contains sufficient flexibility for smaller businesses to accommodate its requirements without unnecessary complexity. **What is lacking is the understanding of that flexibility and how it can be applied, and this could be clarified more easily and without cost for organisations who have already implemented current requirements through targeted guidance and training.**

Although we would not foresee any significant changes as a result of these proposals, we question the need for these changes and whether it is worth imposing a superficially less onerous system with the significant risk of being perceived to have deviated too far from alignment and adequacy with the EU. On that basis, we would recommend that Government does not proceed in implementing these changes.

Q2.4.9. To what extent do you agree that the soft opt-in should be extended to non-commercial organisations? Please explain your answer, and provide supporting evidence where possible.

The BHF strongly agrees with the proposal to extend the application of the soft opt-in to non-commercial organisations.

Under the Data Protection Act 2018 (DPA), charities are required to seek explicit opt-in consent to contact a donor after they have made a donation because donations and sale of goods or services by charities are not currently counted as a commercial transaction. **As a result, around 34% of**

donors on our databases cannot be contacted using electronic means, despite clearly supporting the BHF.

The DPA enshrines rules from GDPR and The Privacy and Electronic Communications Regulations (PECR) in UK law. Under PECR, the soft opt-in enables commercial organisations to email or use other electronic means (which are more cost effective than hard copy methods) to contact individuals who negotiated (unsuccessfully) or bought one of their products until they explicitly opt-out. Charities are not able to do this because the PECR soft opt-in does not extend to them, which means more expensive methods have to be used, such as direct mail, which increases costs thereby reducing income available for charitable purposes. For these other, more expensive, forms of marketing such as direct mail, both commercial and non-commercial entities can contact individuals under the rules in GDPR using legitimate interest (subject to carrying out the balancing test), which demonstrates that the rules are inconsistent especially in how they apply to charities.

Widening the applicability of the soft opt-in would level the playing field between charities and commercial organisations and enable charities to cost effectively keep in touch and build a relationship with supporters who have made donations or bought goods/services. As it currently stands, not only can we not ask for future donations but we cannot build a relationship and share the work we are doing with the money they donated. Allowing charities to use the soft opt-in would enable us to do this, building a stronger and more meaningful connection to our cause. We believe this to be in line with the intent of the PECR but has unfortunately not been applied in current legislation.

The consultation document notes under this proposal at paragraph 210 that the soft opt-in will be extended to 'organisations other than businesses where they have previously formed a relationship with the person, perhaps as a result of membership or subscription'. We feel that 'donations' should be explicitly referenced here to ensure that there is no unintended consequence whereby donations continue to be omitted from using this basis for further contact. This would ensure that one-off donations are captured and remove any doubt around recurring donations, providing much needed clarity in language and how regulations are put into practice.

Safeguards already exist for charities to ensure that the soft opt-in would be applied correctly if it were extended to fundraising. The Code of Fundraising Practice already stipulates that people must be given the option to opt-out when their data is first collected, and in every subsequent communication that the charity sends. This is in line with the safeguard outlined in paragraph 211 of the consultation document. This demonstrates that charities will not only already be bound to meet the requirements of marketing using the soft opt-in basis, but that this would be at a level consistent with the public's expectation as set by other methods of marketing by commercial organisations using the soft opt-in basis.