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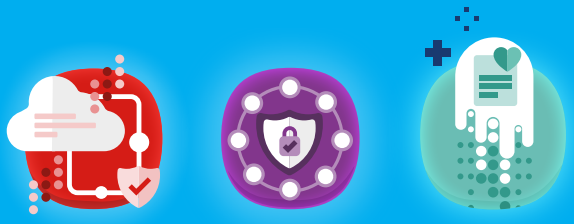
iHD

Proposal for a Societal Compact for the secondary use of health data

2023 RECOMMENDATIONS BASED ON CALLS TO ACTION ON HEALTH DATA ECOSYSTEMS



Round Table 6

Societal Compact: Developing an outline operating model

Round Table findings and recommendations based on Calls to Action on Health Data Ecosystems

This report presents the findings of two multi-stakeholder Round Table consultations that explored the concept of a Compact, proposed recommendations and created a Proposal for a Societal Compact for the secondary use of health data.

This report is a consensus of over 30 invited expert stakeholders in technology, data science, health informatics, patient representation, regulation, trade and industry representation, academia and policy-setting. The Round Tables were held on 22rd September and 13th October 2022 and this report is published in June 2023.

The two Round Tables were scoped and convened by the Digital Health Society (DHS) and The European Institute for Innovation through Health Data (i~HD) neutrally and independently from the Round Table Programme collaborators and sponsors Johnson & Johnson, Microsoft and MSD. This topic is part of a rolling programme of deeper dives drawing on 7 Calls to Action on Health Data Ecosystems that were published in 2020.

CALLS TO ACTION

1. **Raise the digital literacy & skills of all stakeholders**
2. **Generate and value trustworthy Real World Evidence**
3. **Accelerate interoperability across Europe and globally**
4. **Demonstrate benefits to society from data access, use and reuse**
5. **Adopt a risk stratification approach**
6. **Build a trustworthy framework for data access and use**
7. **Adopt a transformational approach to health data**

1 The purpose of this proposed Compact

A societal compact or social contract **(Compact)** is a voluntary agreement between a range of stakeholders to co-operate together to achieve social benefits by granting access to and reuse of health data.

This Compact is proposed to provide an assurance to all stakeholders in the health data ecosystem, and especially to the public, that organisations and individuals who reuse health data, usually to analyse it to discover new knowledge, do so in ways that are legal, ethical, secure and in society's interests.

The heart of the Compact is a set of data use commitments that adopting organisations agree to adhere to whenever they reuse health data for (secondary use) purposes that fall within the scope of this Compact. This requires complying with the principles and commitments, in full and indefinitely (unless adoption is formally withdrawn). (Its principles and commitments might also be used for purposes of use outside this scope, if agreed between data sharing parties.)

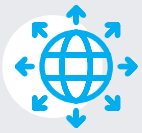
To promote visibility of this Compact and its adoption, a trust mark with a distinctive name and logo, and a formal certification scheme, will be developed later.

This document proposes those commitments, the purposes to which it should apply, and suggests an operational model for Compact adoption and oversight. It is deliberately aligned with the draft Regulation on the European Health Data Space published by the European Commission (COM 197/2022), and is proposed as a support to the implementation of its provisions for secondary data use. Endorsement of this Compact from key policy-setting bodies will be later sought.

Structure of the Compact

The core content of the Compact is envisaged as having several parts, for which draft content is proposed as below:

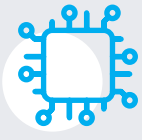
Ethical principles underpinning the Compact



The scope of applicability of the Compact

Categories of permitted and prohibited purposes for using health data

The Compact commitments a data user organisation agrees to comply with



The Compact governance rules for data user organisations

A Data Use Agreement Template that both data holders and data users agree to use as the framework of the case by case data use agreements they will sign

Standard wording for Compact adoption declarations and support statements

Context

This proposal for a Compact has been developed as part of a series jointly organised by the Digital Health Society (DHS) and the European Institute for Innovation through Health Data (I~HD) sponsored by Microsoft, Johnson & Johnson and MSD (the Sponsors). Following two Round Tables in 2020 which culminated with 7 Calls to Action on Health Data Ecosystems (read here), two further Round Tables were run in 2021 on Proposing a common basis for health data access across Europe (read here) and on Scaling up the availability and reusability of big health data (read here). This topic on a societal Compact was part of the 2022 programme of topics.

The concept of a societal Compact was originally a recommendation of **Call 6** (Build a trustworthy framework for data access and use) of the **Calls to Action**. Round Table 3 on Proposing a common basis for health data access across Europe included a working group on Societal Compact with the aim of promoting a "Data Culture for Society" extending the concept behind "Data Saves Lives".

This consultation version of the Compact was developed through multi-stakeholder consultations involving 30 experts from patient and healthcare professional organisations, academia, the pharma and ICT industry sectors, national and European level policy-makers. This proposal has been independently developed by DHS and I~HD. The Sponsors have had no influence or editorial control over the Proposal. The views and opinions of DHS and I~HD are not necessarily those of the Sponsors.

Pages 24 to 44 contain the summary notes from the Round Table Working Group meetings which contributed to the development of this Report and the Proposal for a Societal Compact.

It is now being circulated to a wider range of stakeholders and organisations in order to identify:

1. **if the approach of developing, promoting adoption of and governing a societal Compact is likely to be acceptable to most data providing, data using and data protection bodies**

2. **if declarations of adopting and complying with the terms of a societal Compact would add to public confidence in the uses being made of health data across Europe**

3. **if the Compact can be regarded as a helpful complement to the more specific data access decision making and data protection arrangements within the draft EHDS Regulation and other complementary European Regulations, especially the GDPR.**

4. **if the principles, lists of permitted and prohibited purposes, and commitments defined in this document are sufficiently clear, complete and at the right level of detail**

5. **if the proposed governance and operational provisions are likely to be workable**

Comments from individuals and organisations to each of these five questions, and on the document content, are invited to be sent by email by 30th September 2023 to info@echallliance.com after which an updated version of the Compact will be published.

June 2023

2 Ethical principles underpinning the Compact

Preamble

These principles apply to the use of health data, which may be collected through health systems (including public sector and private hospitals and clinics), by businesses (including Pharma, MedTech and technology companies) or by individuals and families about their own health and care, and health related data which may be collected outside of the health system about situations that impact on health, such as climate and housing.

These principles relate to the reuse of health and health related data for "secondary purposes", which are outside of the direct provision of health and care services to individuals or their families for which the data was initially collected. Secondary purposes are usually undertaken by analysing the health data on multiple (often large numbers of) patents in order to discover new knowledge and insights that help to improve health, health and care services or to develop new approaches and products to prevent or treat illness. (These secondary use purposes are elaborated in Section 4 of this document.)

Each person whose data is being used for secondary purposes, such as research, might be an indirect beneficiary through the results of those data uses, or might not personally benefit from those uses because the benefit will be experienced by other persons, such as other patients with a similar health condition. In these principles these secondary uses are referred to as reuses of health and health related data.

Ethical principles

1 Health and health related data must only be reused for purposes that aim to directly result in, or contribute to bringing, benefits to society in terms of improved opportunities for better health and care.

2 Health and health related data must never be reused for purposes that are unethical, violate human rights, will directly disadvantage or are very likely to directly disadvantage individuals or groups of individuals, or will exclusively further individual or organisational interests without bringing benefits to some parts of society.

3 The reuses of health and health related data must always safeguard the privacy of individuals whose data are being reused, by complying with all applicable data protection laws (such as the EU GDPR), by adopting robust information security and privacy preserving measures, and by using aggregated or anonymised data whenever possible. These limits must be balanced against benefits that may be achieved by using identifiable or pseudonymised data.

4 The reuses of health data must be respectful to the holders of the data being used, and adhere to data use terms agreed with the data holders including the purposes for which their data may be reused.

5 The results from reusing health and health related data should be published, or shared in some other way unless the results are (i) personally damaging to identifiable participants, (ii) may be used to discriminate against groups, (iii) subject to commercial use for products and services. In the latter case those products and services should be available to all possible adopters on fair terms such as fair pricing.

6 Organisations that reuse health and health related data must make every effort to be as transparent as possible to the public about their use of health data and the outcomes of each data use.

7 Bodies that make decisions to permit data access must ensure that these principles are upheld when defining decision making rules and be transparent to the public about those rules, the data access decisions that they make and the societal benefits that those data reuses have enabled.

3 Scope of applicability

This Compact is offered for adoption to any public sector, voluntary sector or private sector organisation that makes secondary use of health and/or health related data. It may be adopted for and apply to any one or more of the permitted purposes of reuse, listed in Section 4 below, made by an adopting organisation.

4 Permitted and prohibited purposes for reusing health data

Permitted purposes

An organisation adopting this Compact declares that it will abide by all of the commitments listed in Section 5 of this document when it reuses health or health related data for any of the following eight categories of purpose. These categories are identical to those listed in Article 34 of the Regulation on the European Health Data Space (COM 197/2022).

a. activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices

b. to support public sector bodies or Union institutions, agencies and bodies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates

c. to produce national, multi-national and Union level official statistics related to health or care sectors

d. education or teaching activities in health or care sectors

e. scientific research related to health or care sectors

f. development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices

g. training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices

h. providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons

A non-exhaustive list of research purposes is given below as an illustration of the interpretation of purpose e) above.

- **Epidemiology and observational research studies**
- **Disease understanding, disease burden, unmet need and stratification**
- **Outcomes research, comparative effectiveness research**
- **Predictive analytics and identify patient sub-groups that respond better to certain treatment**
- **Digital innovation: devices, sensors, apps (including understanding patient's experience and PROs)**
- **AI development conforming to the new AI Regulation**
- **Quantify deeply stratified populations, for targeted therapies and personalised medicine**
- **Biomarker discovery and validation**
- **Diagnostics development**
- **Accelerate the conduct of clinical trials**
- **New treatment indication areas**
- **Adaptive trials and licensing**
- **Patient characterization and optimal treatment sequencing**
- **Testing and improving outcome sets**
- **Assessing the feasibility of planned research and implementation**

Additional non-exhaustive illustrative lists may be compiled in the future for other categories of permitted purpose.

Prohibited purposes

An organisation adopting this Compact declares that it will not reuse health or health related data for any of the following prohibited purposes. These categories are identical to those listed in Article 35 of the Regulation on the European Health Data Space (COM 197/2022).

a. **taking decisions detrimental to a natural person based on their electronic health data; in order to qualify as "decisions", they must produce legal effects or similarly significantly affect those natural persons**

b. **taking decisions in relation to a natural person or groups of natural persons to exclude them from the benefit of an insurance contract or to modify their contributions and insurance premiums**

c. **advertising or marketing activities towards health professionals, organisations in health or natural persons**

d. **providing access to, or otherwise making available, the electronic health data to third parties not mentioned in the data permit**

e. **developing products or services that may harm individuals and societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco products, or goods or services which are designed or modified in such a way that they contravene public order or morality**

An organisation adopting this Compact additionally declares that it will not reuse health or health related data for purposes that would violate the European Convention on Human Rights.

An organisation adopting this Compact additionally declares that it will not reuse health or health related data for any of the following purposes.

- **Research uses of data that would require but have failed to apply for or obtain ethical approval**
- **Development of AI or other new technologies in ways or for uses that would not be permissible in the EU**
- **Weapons development and research, including development of biological weapons (excluding research into protection against or treatment for the effects of biological weapons)**
- **Drugs for use in capital punishment, interrogation or torture**
- **Eugenics**
- **Political projects where there is party political gain motivating the research**
- **Discrimination and profiling of persons using data to develop profiles intended for marketing, service access or financial purposes, e.g. the exclusion of guarantees from insurance contracts and the modification of insurance contributions or premiums of an individual or group of individuals presenting the same risk - unless the population profiling is solely to target appropriate therapies and to assess health risks**
- **Marketing or endorsement of an existing product**
  » the competitive promotion of the products towards health professionals or health establishments, or towards patients or the public

  » except to conduct usability testing of devices, to uncover unmet treatment needs, new or improved uses of existing diagnostics or treatments, or to provide factual education on new uses of diagnostics and treatments
- **Research where the sole outcome is a financial benefit**
- **Research which would be deemed illegal in the country in which the data user organisation is based, the country of data processing or the country from which the data originates**

5 The Compact commitments

This part of the Compact lists the set of commitments that an organisation which uses data makes regarding the way in which it will make use of data access that has been granted through this Compact. (Commitment number 5 below also applies to all data custodians.) These commitments cover adherence to the purpose of use, having a legitimate and legally compliant permission to use the data, agreeing to GDPR and other legal and regulatory requirements regarding data protection and data management, and a number of transparency commitments relating to the analysis of the data, the handling of results, and providing high-level summary information to the public. An organisation adopting this Compact must comply with to all of these commitments. An adopting organisation cannot exclude any of these from compliance. The process for investigating possible non-compliance (i.e. a breach) and the consequences of verified non-compliance are explained within the governance rules and operational workflow sections of this document.

Declared purposes

1. The organisation commits to only use health data and health related data to which access has been granted according to this Compact for one or more of the purposes listed as permitted uses. It commits never to use health data and health related data for any of the listed prohibited purposes.
2. If data access has been granted to the organisation by a data custodian (the data controller of the source data being used pursuant to this Compact) for explicitly specified purposes, the organisation commits to only use the data for those specified purposes.
3. The organisation will only permit its personnel to use data for the purposes that have been approved, and will have appropriate governance mechanisms to ensure that data are not used for non-approved or prohibited purposes.

Legal basis

4. The organisation commits to verify with the data custodian that a suitable legal basis exists for the intended data access and data use by the organisation, if the data falls under the scope of the GDPR or any other applicable data protection legislation.
5. Data custodians and data users agree that all health data sharing will comply with all European Union and Member State laws applicable to such health data sharing.

Permissions

6. The organisation commits to verify with the data custodian that where ethics committee or other research governance permissions are required for the intended data use, such permissions have been applied for or obtained. If the permission is still at the application stage and the organisation will not use the data until such permission has been granted.

7. If the data custodian has itself obtained the data from other originating data sources, the adopting data using organisation commits to verify, and may seek evidence, that the data custodian has the necessary permissions to provide the data access to the organisation for the intended purposes.

Data protection

8. The organisation commits to having suitable data protection policies and codes of practice that ensure that its personnel have sufficient knowledge of the GDPR and other data protection legislation, and know how to apply these within their job responsibilities and activities, so that they enable the organisation to meet data protection compliance obligations.

9. The organisation commits to initial training and regular update training in data protection to all staff who process personal health data as defined by the GDPR and has appointed officers who are responsible for data protection and for investigating any issues that arise with the way the data are used or misused.

Data handling

10. The organisation commits to having information security policies, and technical and organisational information security measures (including trained staff), to a level that safeguards the use of personal health data as defined by and as required by the GDPR, by relevant national Data Protection Authorities and by the data custodian.

11. The organisation commits to requiring the obligations of this Compact to be complied with by any other permitted party with which it shares the data it has been granted access to pursuant to this Compact.

12. The organisation commits to agreeing with the data custodian and specifying in the relevant Data Use Agreement provided for in this Compact, if its copy of the data must be destroyed (and when) after the permitted purpose of use has been completed.

Analysis and results

13. The organisation must state how it plans to use the findings it obtains from the data, in terms of whether the results are intended to be published as scientific findings, used to develop or validate or monitor the use of a healthcare product or service, to guide future internal strategy, to test hypotheses prior to conducting a more substantive study or any other legitimate purpose.

14. The organisation must agree with the data custodian whether any enhancements to the data that are made through the course of conducting the purpose, such as statistical data enrichment or cross mapping to additional terminology systems, will be provided back to the data custodian and under what terms, including with regard to intellectual property ownership and access.

Transparency of use

15. The organisation commits to maintaining a public inventory (possibly through its web site) of data reuses being made according to this Compact, at minimum containing the information specified by the Compact entity, and to keeping this up-to-date.

16. The inventory should specify the data sources that are intended to be used, the intended purpose, the intended time interval for undertaking that purpose, and at a high level how the findings will be used by the organisation.

Declaration of intended societal benefit and transparency

17 The organisation commits to publishing, either as part of the above public inventory or elsewhere on its web site, a brief lay summary of the intended data use and the expected eventual societal benefit from the data use and, once the intended purpose has been completed, the outcome from such data use.

Dissemination of results

18 The organisation commits to the principles of open science and to make all or some of the findings from its data use accessible to other data users, unless this will conflict with its commercial interest, in which case the intention not to publish findings but to make the findings available in some other (commercial or non-commercial) form must be explicitly declared to the data custodian before signing any data use agreement. An agreement not to publish the results of the data use, because of conflicting interests, must not detract from the obligation to enter this data reuse within the data use inventory maintained by the data user organisation.

6 The Compact governance rules

1 A data organisation signing a declaration to adopt this Compact additionally agrees to abide by the governance processes overseeing its adoption. These processes will be defined and maintained transparently, and with multi-stakeholder consultation. Governance oversight will be applied by a designated European body, referred to here as the "Compact entity". This Compact entity might be an existing organisation designated with this authority and responsibility, or a new organisation created for this purpose.

2 The Compact entity will verify the authenticity of any organisational Compact adoption declaration, and maintain a publicly visible register of adopting organisations who have signed these declarations.

3 This register will include a link to a data reuse inventory to be maintained by the data user organisation as a publicly visible transparent inventory of the uses of data being made according to the terms of this Compact.

4 The Compact entity will establish a process for being informed by data holders, members of the public or any other parties about concerns related to organisational conduct or specific data uses that might be in breach, by data holders or data users, of the commitments in this Compact. The Compact entity will have the right to contact the organisation in question, to provide details of the concern and require a rebuttal response. If the concern implies the possibility of a material breach of this Compact, then the Compact entity reserves the right to require evidence to support the rebuttal,

which will either already be held by the organisation or might need to be furnished by an independent party following an appropriately scoped investigation undertaken at the cost of the organisation.

5 The Compact entity will have the right to withdraw the name of the organisation from the register that it maintains, temporarily or permanently, if it has sufficient evidence of a material breach of this Compact.

6 The Compact entity will have the right to make public a summary of a proven material breach of this Compact.

7 The Compact entity will have the right to refer any case of material breach of this Compact or other legal or regulatory breach to other statutory bodies if necessary.

7 Data Use Agreement Template

Data custodians must agree in principle to make health data available for the permitted purposes set out in this Compact, and the data users must agree to use it in accordance with the terms of this Compact. A legal agreement to share health data is only created when a signed data use agreement has been created as provided for in the Compact, although the commitment to comply with the terms of the Compact commence when this declaration is signed.

This part of the Compact, the Data Use Agreement Template, is still to be developed. It will be completed each time new data is shared between data custodians and users. It comprises a set of headings that require parties forming a specific data use agreement to fill in and complete, with more detailed and specific provisions to assure data privacy, security, transparency, accountability and other legal compliance.

Of particular importance are headings that mirror the commitments headings in Section 5 above, providing the opportunity for an elaboration of how those commitments will be met by the data user, and if there are any complementary obligations the data custodian must fulfil to enable those (such as performing adequate anonymisation before releasing the data).

The following is a list of headings for clauses which must be contained in all Data Use Agreements created pursuant to the Compact:

- **The declared purpose(s) to use the shared health data**
- **The intended societal benefits that successful data reuse is anticipated to achieve or contribute to**
- **[Other headings applicable to all Data Use Agreements should be developed in a further Round Table or when organisations set up a Compact]**
- **Specific provisions to reflect a) the actual data being shared b) what the uses of such data will be and c) how the commitments (as set out in Section 5) will be met and other standard data sharing provisions**

The final version of the template will include standard provisions as included in any data sharing agreement, for example the parties, territory, time periods for data access, remediation, termination and governing law etc.

8 Compact Adoption declarations and Support statements

This part of the Compact, which is still to be developed, will formalise the adoption declaration wording by which an organisation agrees to adopt the Compact as a data custodian and/or data user organisation. Other wording will formalise how other kinds of organisation that support or facilitate or audit health data reuse will support and promote this Compact.

Templates should be developed in a further Round Table or when organisations set up a Compact.

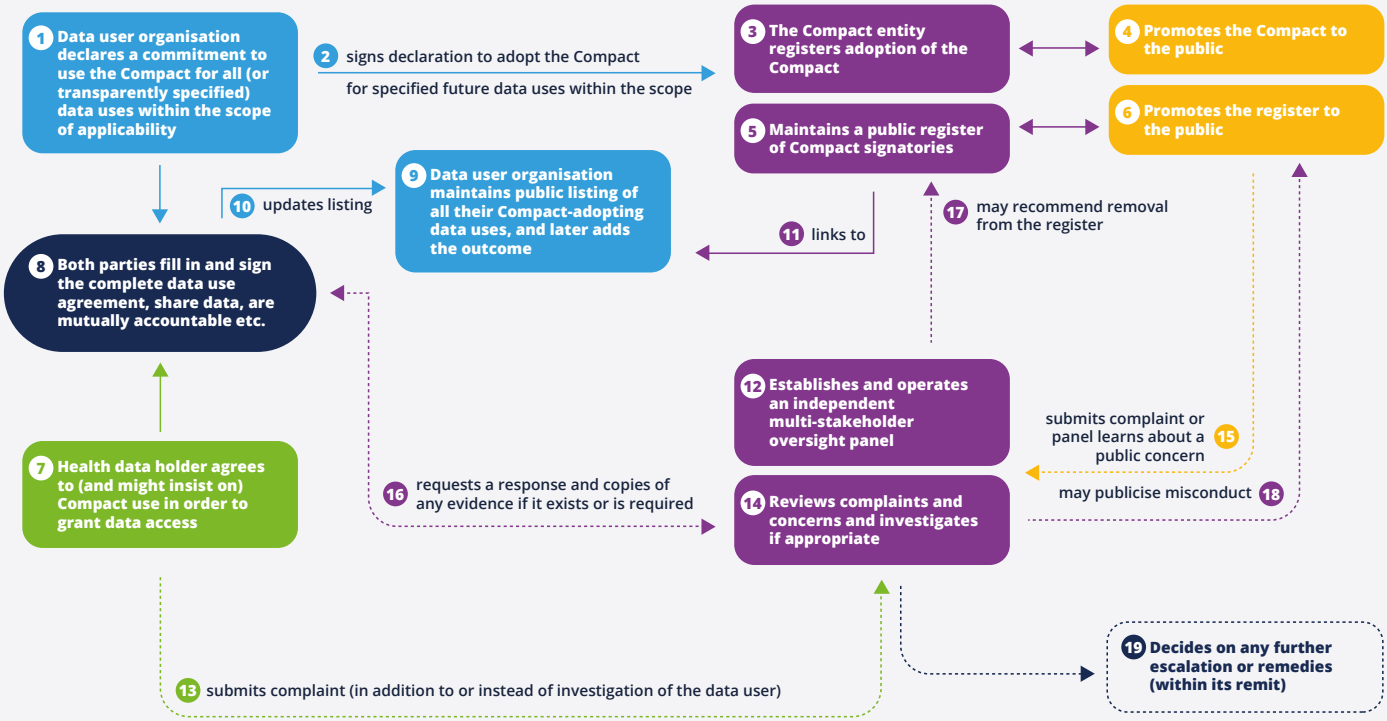
The Adoption declaration should be a simple confirmation from the relevant data holder and/or data user organisation that it agrees to comply with the terms and commitments contained in the Compact.

The Support statement should be a formal confirmation, signed by a designated organisational representative, that the relevant organisation supports the creation of the Compact, will help to communicate what it does and promote it.

9 The Compact operational workflow

This Section 9 outlines the workflow by which a societal Compact for health data reuse could be put into operation. The numbered sequence of steps in the workflow depicted in the diagram below, and then explained, is in the order to best help to convey the workflow. It does not reflect strict chronological order, because some activities, like the establishment of the Compact entity and promoting the importance of the Compact to society, could begin much earlier than when the first Compact is actually signed. Please therefore regard the sequence as facilitating understanding of the diagram and of the workflow.

The Compact operational workflow



1 Data user organisation declares a commitment to use the Compact for all (or transparently specified) data uses within the scope of applicability

The workflow for Compact adoption begins with an organisation that uses health data and a data holder that both agree to abide by the terms of the Compact in its future data uses, ideally for all of it purposes of use that fall within the scope of the Compact, but optionally to limit that scope if there are obstacles to adhering to the commitments for some of the purposes or to some scenarios of data use. The important requirement is that any restriction of scope must be transparently declared. Any number of data custodians and data users are able to adopt the Compact at any time so the model is infinitely scalable and flexible.

2 Data user organisation signs declaration to adopt the Compact for specified future data uses within the scope

Although the data user organisation may publicise its adoption of the Compact through its own website and other channels, a powerful value of adoption will be that the organisation is included in a third-party register held by the Compact entity. (The details of this entity are still to be determined). Other organisations could sign declarations to support and promote the Compact where for example they are neither data custodians or users.

3 The Compact entity registers adoption of the Compact

This Compact entity will maintain the Compact register, receive formal declarations of adoption, will require legal and compliance contact details from the signatories, and might additionally charge a registration fee (depending on the business model that is determined for this entity). The Compact entity will verify the integrity of the submitted Adoption declaration and then register this within its records.

4 Promotion of the Compact to the public

It is likely that the Compact entity, and many other governmental and public agencies and other patient/public organisations will contribute to promotion to the public and all other stakeholders of what the Compact is, what commitment to it will achieve, and why it should be considered a valuable contribution towards a trustworthy data use ecosystem and the development of the EHDS. This will be an ongoing activity for the Compact entity.

5 Compact entity maintains a public register of Compact signatories

The Compact entity will maintain a public register of the organisations that have declared adoption or support, indicating any limitation of scope if applicable, and providing a link to the web page maintained by each signatory that details the specific data uses that it makes according to the Compact. (It is not considered realistically scalable for this Compact entity to itself manage a highly detailed and high-volume inventory of data uses from all signatory organisations across Europe.)

6 Compact entity promotes the register to the public and other stakeholders

In addition to promoting the Compact itself, the Compact entity will promote the register as something that can be consulted by any interested member of the public, for personal reassurance reasons, and of course may be consulted by any data custodian that is considering or has been approached by an organisation wishing to make use of the health data it holds.

7 Health data custodian agrees to (and might insist on) Compact use in order to grant data access

It is hoped that the widespread promotion of the Compact, and its increasing adoption, will encourage data custodians to insist upon its use. Although the Compact could be used simply as a one-to-one data sharing agreement, data custodians may start to insist that any organisation they are willing to share data with must be on the Compact adoption register.

8 Both parties fill in and sign the complete data use agreement, share data, are mutually accountable etc.

The Compact Data Use Agreement template will need to be completed for any specific data access arrangement for health or health related data reuse for any of the purposes listed in Section 5. The parties will need to sign it after which it becomes a legally binding agreement. (There may still need to be other legal documents – for example model contractual clauses for data transfer outside of the EEA.) It is a bilateral matter how the data custodian wishes to monitor compliance, and what action to take should there be any concern or tangible evidence of a breach in that agreement. Each signatory may need to specify subcontractors or other data processing parties with which they contract, and who will also need to abide by the terms of the Compact and data use agreement.

9 Data user organisation maintains public listing of all of their Compact-adopting data uses, and later adds the outcome

One of the transparency commitments of the Compact will be that each data user organisation maintains a public listing, summarising the uses of health or health related data that they make under the terms of the Compact. The Compact entity is expected to define a minimum dataset (that could represent a few columns in a table) that each data user maintains on its public web page. It is intended that the level of detail is not sufficient to infringe on confidentiality or IP obligations but is sufficient to help explain to the public why and how health data is being used. Once the data use has concluded it is expected that the entry in this table is updated to summarise the outcome, which could be a high-level report of the findings, or confirmation that a product has been developed, approved, marketed or a paper published etc.

10 Data user updates listing

The data user organisation will update this listing within a reasonable period (as defined by the Compact entity) following signature of each Compact Data Use Agreement template. Arrangements will need to be defined for how this should work for groups of companies or research consortia.

11 Compact entity links to data use registers

Provided that the landing web page for each data user organisation is maintained, the link within the Compact entity register of adopting organisations will always point to an up-to-date list of actual data uses.

12 Compact entity establishes and operates an independently-appointed multi-stakeholder oversight panel to build and maintain trust

In order to fulfil its oversight function, which public surveys have indicated to be very important, the Compact entity will need a diligent (but proportional) and neutral process for appointing a multi-stakeholder panel of experts (importantly including public and patient representatives) to perform the oversight functions. That formal selection process will need to be defined, transparently publicised, as well as the membership of the panel being made public. Its terms of reference and operating procedures will also need to be defined and made public. Further details, such as whether minutes of meetings are to be made public and how confidential matters are to be documented, will need to be worked out.

13 Submission of complaints (in addition to or instead of investigation of the data user)

If the data custodian has reason to believe that the data user with whom they have signed a Compact Data Use Agreement is now in breach of that agreement, they would normally be expected to put in motion whatever remediation is specified in that agreement. This might mean a requirement for an independent audit, or some other evidence generating activity, possibly followed by legal action between the data holder and user. Irrespective of whether a formal process is instigated or not, the data custodian may choose to notify the Compact entity that the data user is in breach of the Compact.

14 Compact entity reviews complaints and concerns and investigates if appropriate

The oversight panel will receive such notifications and may determine that a notification is significant enough to require a rebuttal response from the data user organisation. The panel will have a well-defined standard operating procedure for carrying out investigations of this kind, which may vary depending on the perceived severity of the breach.

15 Other submissions of complaints or public concerns

A second channel into the oversight panel is from supporting signatories (which could include patient representative organisations) or the public, if an individual is concerned that a data breach has arisen in relation to their own data through inappropriate use by a data user. The responsibility of the oversight panel should take into account and not clash with any possible investigation that may be instigated by a Data Protection Authority. Publicised concerns in the press might also occasionally trigger the panel to investigate an organisation.

16 Oversight panel requests a response and copies of any evidence if it exists or is required

The panel will need to provide the data user with the details of the complaint or concern they have received, and may require a simple rebuttal, which it will evaluate, or may require supplementary evidence in order to make a determination of breach of the Compact.

17 Oversight panel may recommend removal from the register

If a breach of the Compact has occurred that implies an unsatisfactory organisational adherence to the Compact commitments, the panel may recommend that the organisation is removed from the register. It may instead choose to issue cautionary advice to the organisation, recommend to data custodians that access to data is suspended until remedial actions are satisfactorily implemented or make other recommendations.

18 Compact entity may publicise misconduct

The Compact entity, on the advice of the panel may decide it is appropriate to make public selected information about an established misconduct, through its register web pages. This will correspond to the "name and shame" approach that has been advocated by some patient organisations as a necessary element of governance, in order to ensure public trust in the health data use ecosystem.

19 Compact entity decides on any further escalation or remedies (within its remit)

In the event of a misconduct that is considered extreme, the Compact entity may determine that further escalation is required, such as referring the matter to a Data Protection Authority or to another regulatory body. In the future, once EHDS Data Access Bodies are well established, the Compact entity may have arrangements with such bodies about when they should be advised about proven misconduct.

Proposal for a Societal Compact for the secondary use of health data

2023 RECOMMENDATIONS BASED ON CALLS TO ACTION ON HEALTH DATA ECOSYSTEMS

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