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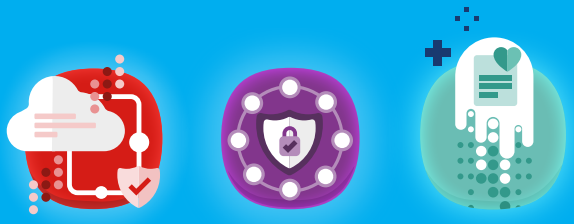
iHD

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.)

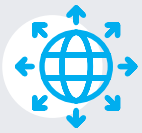
To promote visibility of this Compact and its adoption, a trust mark with a distinctive name and logo, and a formal certification scheme, will be developed later.

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:

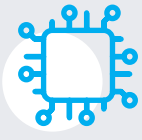
Ethical principles underpinning the Compact



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.

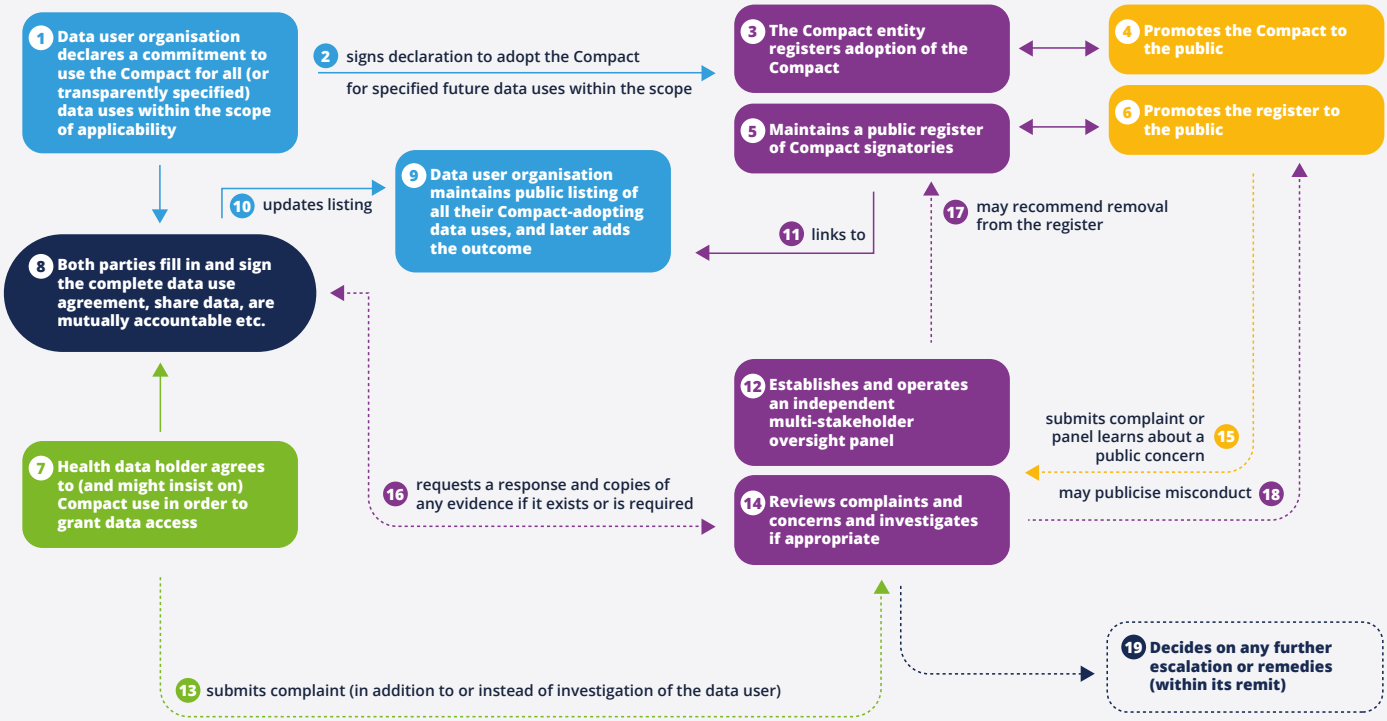
The Adoption declaration should be a simple confirmation from the relevant data holder and/or data user organisation that it agrees to comply with the terms and commitments contained in the Compact.

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.

RT6 Societal Compact: Developing an outline operating model

Working Group 1 breakout group meeting notes

22nd September 2022
Moderators: Dipak Kalra, Maria Christofidou

WG participants	
Dipak Kalra	Marc Lange
Maria Christofidou	Katrina Lowes
George Crooks	Oliver Maassen
Javier Rinćon Cruz	Nicola Perry
Sarah Daveney	Tudor Pitulac
Elina Drakvik	Bojan Raičkovi
Clayton Hamilton	Michel Silvestri
Thomas Hellebrand	Tjade Stroband
	Michel Van Speybroek

The following are the main topics under which the details of a Compact is being discussed in this WG.

- **Scope: organisations, sectors, data sources, purposes**
- **Commitments: good practices that will be adopted**
- **Adoption model**
- **Governance arrangements**

During the first breakout meeting the scope was discussed in detail, the purposes at a high level. The latter two topics can be discussed at the second Round Table session.

Scoping the Compact

Which data using organisations, innovation sectors and data sources should the Compact initially be targeted for?

Organisations

There was rich discussion about the categories of organisation that should be invited to sign a Compact, and if the Compact should be developed with particular organisation-types in mind (e.g. industry). The EHDS grants greater public body access to data, more forcefully, and it may make sense to ensure applicability of the Compact to industry to help present the commitments of industry as data users.

The strong consensus of WG participants was that there would be value and send a strong signal of alignment if public and private bodies could sign the same Compact (i.e. adopt the same data governance standards). A further argument was that it may at times be hard to differentiate public and private users, especially if they are working in collaboration e.g. in a research consortium such as IMI/IHI projects. Building on the COVID experience, there is likely to be even more collaboration between public bodies, academia and industry. There may be added value in showing the public and other stakeholders that a diversity of public and private organisations can co-operate with using data whilst conforming to the same standards.

We should future proof the work of developing the Compact, since it will be challenging to design and gain consensus on it. It may be best to start with a brief listing of the principles for using health data (like a declaration, charter, but more detailed).

It should be designed from the outset to be as widely applicable as possible. Health and care data must be used and deliver value to citizens as much as possible. There is a risk that the pandemic is strongly influencing how the EHDS is being interpreted and might be implemented. It has the opportunity to offer so much more.

The understanding about having a social or societal Compact or contract, and what it should be, is not as mature across stakeholders as it should be. All stakeholders in society should be involved in its design and acceptance. Public trust in public and private organisations is not equal, and a charter like document will not in itself create confidence - that will depend on demonstrating what is done in practice with the data.

Innovation sectors

There was also consensus that the Compact should be developed to cover all innovation sectors. It may be unhelpful to suggest that any one sector is more important or can make better use of data than others. It is better to consider all data innovation sectors equally and in an inclusive way when developing the Compact and encouraging its adoption. We should design the Compact comprehensively, but accept that adoption will be incremental and may be what happens. Staggered adoption might prove necessary for operational reasons, perhaps particular purposes might be early adopters, but not by particular organisations or sectors. Cell and gene therapies are an example of very high cost novel therapies where there is a clear and urgent need for data to evidence their value.

Data sources

The Compact should not specify particular data sources since a wide (and widening) range of data is proving to be useful to health related research. There was consensus that it should cover all health data, but also wellness data, social determinants of health, environmental data. The scope could be “data about health or relevant to health”, irrespective of the source. It was noted that the scope of the EHDS proposal is also very wide. The greatest concern of individuals is about how their data may be used, especially if that use might be discriminatory. It is therefore better for the scope to be wide so bias in data sources is less likely.

Permitted and prohibited data use purposes

There was support for aligning with the list of permitted secondary use purposes in the EHDS, which will scope a lot of future secondary data uses across Europe:

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 more detailed list of research uses has been developed through previous Round Tables, copied below, and could be used as a supplementary illustrative list (since item (e) above is quite imprecise) to help broaden public understanding about the possible spectrum of research uses.

- **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**

The EHDS Regulation also includes a list of prohibited uses.

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

A previous Round Table report included a longer list of misuse purposes, also intended to be illustrative and not complete.

- **Research uses of data that would require but have failed to achieve ethical approval**
- **AI development that would not be permissible in the EU**
- **Weapons development and research, including development of biological weapons (but OK for research into treatments following biological attack)**
- **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

  » (but OK to carry out population profiling to target appropriate therapies and to assess health risks)
- **Marketing or endorsement of an existing product**

  » the promotion of the products … towards health professionals or health establishments, or towards patients or the public

  » (but OK to conduct usability testing of devices, uncover unmet treatment needs)
- **Research where the sole outcome is a financial interest**
- **Research which would be deemed illegal in this country**
- **Business models that build on selling or reselling the accessed data**

For public communications, it will be much easier to develop and present a list of misuses that would be forbidden. It is probably harder to develop a list of all of the possible positive uses. This is a vast and complex area, harder to explain and harder to maintain, as data use will sometimes be for novel purposes that are not in any existing list. However it is worth communicating the beneficial purposes of health data (but not as a closed list) to help the public to understand the benefits of using data.

Making the misuse (prohibited) list explicit will be very important. It will need to be monitored and regularly updated. A list of misuse purposes that would be prohibited can have powerful assurance and connivence building impact.

The preserving of human rights should be better emphasised in it, especially in advocacy messages, as it is going to be missed if not explicitly stated. There are 4 treaties that could be considered as relevant: The Universal Declaration of Human Rights, the European Convention on Human Rights and the Convention for the protection of Human Rights and Fundamental Freedoms and the EU Charter of Fundamental Rights. However, it would take a broader round of thinking to really understand in any meaningful way, what would constitute compliance with these treaties in any given circumstance of data use.

In summary, the Compact should include examples of permitted purposes to illustrate the range of beneficial purposes, but the list of misuses to be prohibited will be important to declare explicitly. This misuse list might be layered into a short core list (e.g. the EHDS prohibited list) with links to the more detailed list. GDPR compliance is another assurance that has to be specified. The communications can be tailored, but all of the details must be in the Compact.

The Compact needs to adopt a principles-based approach, which gives rise to the misuse list. The principles should come first, before the misuse details.

Commitments that signatories of a Compact should abide by

The following list of commitments was considered to be the vital practical (tangible) content that the Compact must contain. This content felt "familiar" and achievable to the working group members, as it resembles the principles of the GDPR, and other codes of practice that organisations may already adopt. This list does not introduce a new way of working or unfamiliar demands or expectations.

- **Purpose of use:** the organisation conducting the analysis must only permit its staff to use data for purposes that have been approved, such as a particular area of research, and commit not to use data for prohibited purposes.
- **Legal basis:** the organisation conducting the analysis must check that its planned use of the data complies with one of the set legal bases for data use, defined by the GDPR. (This is not required if the data have been anonymised.)
- **Permissions:** if the data have come from another source, such as from a hospital, the organisation conducting the analysis must also confirm that it has permission from the source to use the data for the planned study. This might include approval from a research ethics committee.
- **Data handling:** the organisation conducting the analysis must agree with the data source how it must safeguard the data it accesses or receives, if it is permitted to

share it with other collaborating organisations, and if its copy of the data must be destroyed soon (and how soon) after the study has been completed.

- **Data protection:** the organisation and its staff must have policies, commit to staff training and refreshers, and appointed officers who will be responsible for data protection and for investigating any issues that arise with the way the data are used or misused.
- **Analysis results:** the organisation conducting the analysis must state how it plans to use the results, and if the results will be published or used to develop or improve a healthcare product or service.
- **Transparency:** the organisation maintains a public inventory of data uses being made, at a high level, including sources, permissions and intended outcome (updated later with actual outcome)
- **Declaration of intended societal benefit?** (accepting that research might not in practice be able to achieve this)
- **Declaration of intended quid quo pro?** (or is it better to promote standardised ways in which data access fees should be calculated?)

Working Group 1 breakout group meeting notes

13th October 2022
Moderator: Dipak Kalra

WG participants	
Dipak Kalra	Marc Lange
Javier Rinćon Cruz	Oliver Maassen
Sarah Daveney	Tudor Pitulac
Elina Drakvik	Tjade Stroband
	Michel Van Speybroek

Summary of consensus from the previous WG1 breakout

The second WG1 breakout started with a recap of the consensus that had been agreed at the first WG1 breakout, which the participants reaffirmed.

The scope of applicability

One Compact should be promoted and adoption encouraged across all organisations that use health data, especially to ensure both public and private organisation use, to demonstrate that the commitments for trustworthy data use are aligned between them and because they often collaborate on innovation initiatives anyway.

The Compact should be developed and promoted for adoption across all innovation sectors from the outset (i.e. not singling out any innovation sector such as AI development), to avoid any implication that some sectors are more important, more risky or less societally acceptable.

The Compact should not be restricted to any particular data sources (such as EHR data), since a widening range of data is proving to be useful to health related research. The scope of applicability should be specified at a high level, possibly "data about health or relevant to health".

Purposes for using health data

Specifying the permitted and prohibited purposes for using health data was considered in both WG1 meetings to be very important. It contributes to defining the scope of applicability of the Compact, indicating what areas of data use activity within a large and complex organisation it covers, and by implication which is does not. However, even more importantly, specifying the permitted purposes, and even more so the prohibited purposes, communicates to the public how their health data may be used and promises how it will not be used.

It was agreed that alignment with the EHDS Regulation is important, and that the primary list of permitted purposes should be identical to those in the Regulation. However, especially since scientific research is not spelled out in the Regulation, the Compact should offer a more detailed information layer to illustrate research uses, using list from our previous Round Table (reproduced earlier in this WG report). A

nominated curator organisation should maintain the layered list as illustrative of the purposes, as it could never be complete or future proof.

It was similarly felt that the Compact should align with the EHDS list of prohibited misuse purposes. However, it should add as a misuse any purpose that violates the declaration of human rights. A more detailed information layer of prohibited misuse examples should be included, from our previous Round Table (reproduced earlier in this WG report). This list should also be maintained, in the light of experience.

There was no time for discussion of this in the meeting, but there was agreement that we must consider how to present these purposes as part of a principles-based approach.

Discussion of the commitments

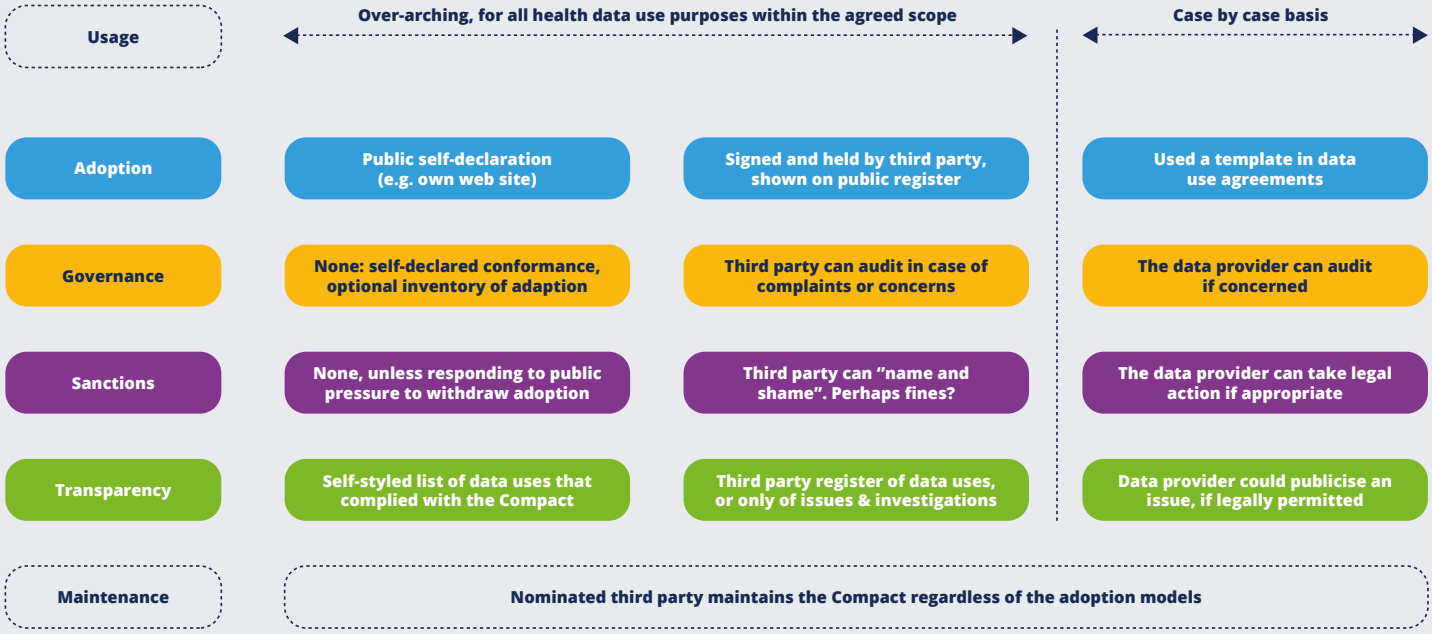
A list of areas of commitment to good practice in managing, protecting and using data and the results arising from data use had been briefly discussed at the first WG meeting. It was not feasible to critique these in detail, but it was agreed that the approach of listing these areas, and of describing what good practice entails at a high level, was right. The presented slides, reproduced earlier in this report, were not considered detailed enough, but it was also agreed that the Compact should not itself seek to provide a detailed code of practice in any of the areas.

It was agreed that the Compact should require transparency about how health data has been used and especially what has been achieved through the agreed data use. Case study examples from Data Saves Lives and i~HD could be illustrations of what level of detail is desirable, although a less detailed summary might be pragmatic and acceptable. A high-level summary is unlikely to raise intellectual property protection and commercial confidentiality concerns. A commitment to dissemination is starting to be included in research proposals. This is important to include in the Compact: dissemination of the research question as well as the findings and outcome, perhaps in a dissemination section in the commitments in addition to the section on transparency.

On data protection, policies and procedures should be compliant with the GDPR and other legislation. Great detail should be avoided, so the text is understandable to most members of the public.

It was felt that each heading should be expanded to approximately a paragraph, so it avoids duplicating more detailed instruments like codes of practice. However, the commitments should be specific enough to be actionable and auditable. Additional details could be added on an interactive step by step approach as the Compact is living. The starting point should be a level of detail that many organisations would be ready to sign.

Adoption and governance model options



It was agreed that this diagram needs to be complemented by an explanation of how adoption would work from a process and operational point of view.

The case by case model would be for implementation between data providers and data users. The Compact would serve as a standard form of words (a template) to be customised to each specific data use, and then embedded within a data access agreement and enforceable in the case of breach by the data provider. The case by case model might be challenging to enforce for breach of contract if the data provider is a much smaller organisation than the data user, with a lower budget to take on a litigation case.

The self declaration adoption and conformance model, on the other hand, might be so weak (watered down) that it fails to provide the public assurance that is needed.

The over-arching organisation wide commitment model was regarded as being better suited to assuring the public. It would offer assurance of commitments for all future data uses, hopefully giving confidence to the public to make their data available for future uses. (Compact-derived wording details could still additionally be included in specific agreements.)

A third party would provide the independent oversight that some public surveys have suggested to be important. A light form of third party, more of an independent "broker" for the Compact and observing compliance to it, but not an auditor, might be preferable, at least initially.

There was discussion about the positioning of consent in the process. Consent may be the legal basis by which the data provider or data intermediary makes data available to a data user. It would be the legal obligation of the data

provider to ensure they have a GDPR compliant legal basis for sharing data or granting data access to another organisation. However the Compact should include a commitment by data users to verify that a legal basis exists (and other permissions such as ethics committee approval, if relevant) before they use the data.

A data intermediary would probably not be a Compact signatory in the over-arching adoption model, but could agree with their data donors (patients, public) to only share data with organisations that have signed up to the Compact. In the case by case adoption model they could only sign agreements that included Compact wording. This could be included within the wording of the consent they obtain from their data donors.

Initial plenary discussion on the adoption and governance model option

Our ultimate aim is to help people to be better assured, and therefore more confident, to allow their health data to be used. It is important to recognise that the Compact will be one element of a more holistic environment of trust that needs to be created in order for citizens to gain that confidence and be willing to make their data available for different purposes. The Compact wording itself must be therefore clearly communicated and highly visible to the public, and so must the way it is operationalised. It will be more difficult to win public confidence if its adoption is more private between specific parties.

In order to encourage organisational commitment it will be important to consider the cost benefit to the organisation implementing compliance. If the Compact requires well recognised practices that a good data using organisation is already likely to have, and is expressed as a high enough level that organisation-specific policies and procedures will usually not need to be changed, then wide-scale adoption will be easier to achieve. It will also encourage adoption if the scope of applicability is precisely defined, enabling large and complex organisations with a diverse portfolio of business activities to delineate the areas of activity to which it should apply.

The involvement of a third-party providing independent oversight of adoption and compliance aligns well with requests for independent stewardship and oversight of health data use that has arisen in public consultations and surveys. Having such a body with a formally designated role would help assure the public that they can have trust in the system.

It was noted that giving the third-party the power to "name and shame" in the event of breach will only be effective if the organisation concerned cares about being named. It is hoped that an organisation that cares about being included in a register would also care if they were shamed via the register, but this assumption needs to be tested through experience. (As a counter example, some organisations have seemingly been shameless about tax avoidance strategies.) Widespread trust in the register might influence committed organisations to ensuring their registration remains valid, for example if a data user's presence on the register becomes a widely required precondition for sharing data with them.

It was considered important that the operational model and governance model of a Compact should align with the way in which the EHDS seeks to operationalise and govern data sharing. It should support the implementation of the EHDS and definitely not compete with it - help create the conditions for the EHDS to

thrive. The presence of a Compact might encourage industry and other organisations that have useful health data to contribute their data into the EHDS, and become more active users of it. There was some discussion about the role of Data Access Bodies regarding the Compact. These bodies could incorporate some wording from the Compact in data access agreements that they sign with data using organisations and thereby help to enforce the case-by-case model of adoption. However, it does not appear that they would have a role as the third-party envisaged on the diagram to collect prospective organisational commitments for intended future health data uses, nor to maintain a register of signatory organisations. Data Access Bodies would presumably only investigate and audit suspected breaches in the case of data use agreements that they had approved.

Communicating the contents of the Compact should be relatively easy to most professional and technical stakeholders, but will be much more challenging to the public whose assurance and support is most needed. So, apart from direct public communication, it will be important that governmental and respected public sector and professional organisations can openly endorse the Compact, since their endorsement will carry weight with public opinion. Support from individual professionals, especially health professionals, will also have a big impact on public trust, since many patients will trust the opinion of health professionals whom they trust. In this regard, it will be important to have a Compact that says the right things and a mechanism that demonstrates convincingly that the Compact is being observed. Data intermediaries and co-operatives are not normally data users, so would not naturally be Compact signatories, but might insist on only sharing their donors' data with organisations that have signed it.

Organisations that champion trustworthy health data use and promote the value of healthy to society, such as Data Saves Lives, can play an important role in endorsing and promoting the Compact, to encourage its adoption by data users, to encourage data providers to insist on it, and to encourage the public to have confidence in it - if it is operating effectively. They might help with stakeholder consultations and feedback during its development. These organisations could also help the European Commission to find an appropriate fit for the Compact within the EHDS governance model.

If a third party model is pursued we will need to consider the practical implications of audit. It would not be realistic for a single third-party to maintain a register of actual data uses, which would need to be maintained openly by each data using organisation. It would also be very expensive if that third-party require the resources to conduct investigations into suspected breaches or areas of concern. Perhaps the third-party would not actually conduct these investigations but require that an independent investigation is conducted and funded by a data user when a breach is strongly suspected, and the report provided to the third party to review. A sustainable business model for the third party needs to be worked out, in particular who should fund its activities.

Any suspected breach will need to take into account that a data user might have legitimate access to certain health data sets through a different role relationship with a data provider organisation, for example by providing clinical or technical services to the organisation, which might lead to some staff having similar data on the same individuals under different terms and for different purposes.

The obligations in respect to GDPR compliance, and the adherence to permitted purposes for use according to the GDPR would depend on whether the data that is made available is anonymised, pseudonymised or fully identified. However, many patient surveys and citizens juries have shown that members of the public want to be certain that their health data will be used for ethical purposes, purposes that contribute to better health, irrespective of whether their identity has been removed or not. The compact might differentiate a few aspects of its commitments between these different categories of data, but many of its commitments might apply equally to all three categories. It can be difficult to guarantee the robustness of anonymisation, so anonymised data should be within the scope of the commitments in the Compact.

We should develop some example scenarios of how the Compact could be put into practice, to help explain the concept and help to identify any gaps in our consensus on how it should work.

Views on the name Compact (combining plenary and WG1 inputs)

It was noted that the word "Compact" is not well understood by many people, and most meeting participants had needed to look it up. This word will especially be challenging to convey when considering the diversity of Europe's population, the majority of whom will not have English as a first or strong language. This word might raise confusion, and was not favoured by patients and the public during consultations in the north of England.

It was noted that a charter or declaration often contains rather high level statements that would be difficult to demonstrate conformance to. A code of conduct is, on the other hand, quite detailed, specifies instructions to an organisation and its personnel, and might be too sector or use case specific. Best practice and guidance implies that it is optional.

The word "Commitment" was favoured.

Working Group (WG) 2 breakout group meeting notes

22nd September & 13th October 2022
Moderators: Bleddyn Rees & Carina Dantas

1. Only first meeting
2. Only second meeting

WG participants	
Bleddyn Rees	Nathan Lee 1
Carina Dantas	Jelena Malinina 1
Nicola Bedlington	Daniel Nadal
Angela Bradshaw 2	Danny Van Roijen
Catherine Cronaki	Jamie Roots
Elina Drakvik 1	Dr Ligia Kornowska 1
Elisabetta Gatti	
Adrian Jonas	

Introductory Information

1. **It was noted that Round Table 3 and its report on a Compact provided clarity on:**

- **What a Societal Compact is**
- **Guiding Principles for any Compact**
- **Possible type of stakeholders who could be signatories to a Compact**

And accordingly, these did not need to be discussed further. Also discussing returning value for data access and use was out of scope for this Round Table.

2. **The following are the main topics relating to the Compact being discussed in this WG.**

- **Specific societal benefits and purposes**
- **Access terms to health data**
- **Governance arrangements and structure**
- **What adherence and monitoring arrangements are needed?**
- **Annual reporting of activities, societal benefits achieved & compliance with Guiding Principles**

Throughout the discussions and indeed in the Plenary session the importance of trust and existing concerns of European citizens was raised. The scale of the challenge facing access and use of health data and EHDS is illustrated by the Survey of 35,000 European Citizens undertaken in 2020 by the EU Agency for Fundamental Rights which found that "between 1 in 4 and 1 in 5 people in the EU don't trust sharing of data of any kind with public authorities".

In contrast, since Round Table 3 was held the pandemic has raised the profile of health data with citizens and its importance in managing society's wellbeing. So, there is a real window of opportunity to engage citizens and industry on health data sharing and this requires absolutely clear communication of the benefits citizens and society as a whole will receive and collaborating with initiatives like Data Saves Lives to explain and win trust. In any event, independent bodies who are honest brokers are key to communicating the benefits of health data access and use in order to overcome the obvious public anxiety and increase the number of people and organisations prepared to sign a Compact.

When considering the issues in this paper it is worth distinguishing between personal, anonymised and pseudonymised data which can create different issues rather than just considering generic health data. In relation to personal or pseudonymised data citizens and patients could decide on a case by case basis whether to provide all their data or exclude certain information on a request by request basis.

Components of Societal Benefits & Purposes

Benefits need to be clear and explicit and perhaps SMART (Specific, measurable, achievable, relevant and timebound). This is critical to enabling trust and agreement to give access to/sharing health data. They should focus on four categories: inputs, processing, outputs and outcomes.

The WG discussed and reached a consensus on the following:

- **Benefits should not be prescriptive in scope but flexible to adapt to new technologies and population/citizen needs**
- **Tangible relationships between types of data and its use makes practical sense e.g. cancer data and cancer research**
- **Compacts should enable and not compete with EHDS. Compacts as contractual arrangements could be created relatively quickly and so in the next five years champion the aims of EHDS by facilitating health data access and use.**
- **There needs to be tangible direct or indirect benefit to society and/or groups of citizens and/or patients and these benefits could include promoting equity, diversity and inclusion**
- **Benefits should also include and be transparent about any "disbenefits or negative consequences for society e.g., in experiences or outcomes. In this respect it is about transparency about the balance of benefits v disbenefits.**
- **Clear and simple communications of all benefits including purpose, aims, how data will be used and results.**
- **Minimum communication of uses is essential including at the end of research projects and in annual reporting of all Compacts.**

Clarity about the benefits from data access and use is also essential in the first case to encourage organisations to become signatories to a Compact to either provide health data and or use it.

Purposes & uses of health Data

The list below is illustrative and not intended to be exhaustive and in no particular order.

- **Improving health outcomes of patients and the wellbeing of citizens**
- **Improving care service models (patient convenience and efficiency)**
- **Research into:**
  - » data bias and scientific methods to reduce or eliminate bias in health data
  - » comparative outcomes and improving healthcare outcomes
  - » the cost effectiveness of prevention, treatments, and outcomes and wider health economic analysis and the means to achieve these benefits
  - » value based healthcare
- **Public Health:**
  - » data bias and scientific methods to reduce or eliminate bias in health data
  - » comparative outcomes and improving healthcare outcomes
  - » the cost effectiveness of prevention, treatments, and outcomes and wider health economic analysis and the means to achieve these benefits
- **Developing new drugs and devices and accelerating the time to develop**
- **Training and education e.g., training data for machine learning and AI**
- **Increasing the use of evidence-based decisions developing new treatments and policies e.g. to underpin decision making on the development, authorisation and supervision of medicines**
- **Greater availability and use of Real-World Data and decision making, including the volume and quality of health data.**
- **Research into the wellbeing of Health and Care professionals and ways to retain and recruit staff.**
- **Scientific Methods to improve the quality of existing health data**
- **Furthering the Quadruple Aim (reducing costs, improving population health, improving patient experience and improving health team wellbeing)**
- **A more generic approach would be to simply adopt the uses in Article 34 of the draft EHDS Regulation (permitted purposes for secondary use processing)**

The other side of the coin are purposes which should never be allowed and should again be explicitly stated in the Compact. In Round Table 3 a list was generated, and this was supported and for convenience is set out below:

- **Uses that require but have failed ethical approval**
- **AI development that would not be permissible in the EU**
- **Weapons development and research including biological weapons**
- **Drugs for use in capital punishment, interrogation, or torture**
- **Eugenics**
- **Discrimination and profiling persons**
- **Marketing or endorsement of an existing product**
- **Research where the sole outcome is a financial interest of business**
- **Article 35 of the draft EHDS Regulation has a more general approach that health data cannot be used to "develop products or services that may harm individuals or society at large or good or services that contravene public order or morality" as well as a specific list of prohibited uses which could again be adopted (e.g., taking decisions detrimental to a natural person based on their EHR data or excluding them from an insurance contract benefit)**

The consensus opinion was that uses should avoid controversial purposes or issues and in the early years focus on widely supported uses to nurture and develop the necessary and essential trust in the access and use of health data. Explaining the benefits clearly and simply will assist recruiting signatories especially of individuals.

There is no need for a Compact to be limited in geographic scope so health data holder or user could be from outside the EU provided they adhered to the Compact terms and compliance. This would allow organisation like WHO to potentially become involved.

Access terms to health data

The access terms should be contained in the Compact written in clear, simple and transparent terms. The Compact should explicitly require:

- **Compliance with all applicable national and European laws (e.g.GDPR,DGA) to ensure data privacy, good data management and governance**
- **Possibly compliance with Human Rights such as the European Convention on Human Rights (but further work would be needed to understand the implications and which human rights treaties to adhere to)**
- **Compliance with and use of FAIR guiding principles for scientific data management**
- **All uses of health data must be guided by best practice in ethical principles and guidelines for example the French Presidency European Ethical Principles for Digital Health (and benchmark from ALTI and adapt to the specific uses proposed)**
- **All requests for data access must be in writing specifying the exact purpose, aims [SMART], how the data will be used and agree to publish the results of the use. Requests would need to follow best practice as the EC develop templates for data access requests under Article 45(6) of the EHDS Regulation**
- **Fair and equitable value exchange between the signatories, those sharing data and those using that data (what is fair was beyond the scope of this Round Table).**

Governance arrangements, structure, compliance & monitoring

Round Table 3 did not propose that the Compact would involve the creation of a legal entity which would receive from signatories' health data and share that health data with other signatories (and providing ancillary services like a platform hosting). Instead, the Compact would allow direct sharing of health data between two or more signatories on the agreed terms contained in the signed Compact agreement. The Compact agreement in effect creating bilateral or multilateral arrangements in relation to specific data sets and from time to time.

The compact is not intended create either a data altruism organisation or data cooperative within the meaning or scope of the Data Governance Act. It is essential to the concept of a Compact and to promote its broad uptake that it is not led by any one stakeholder group and instead is co-created between stakeholders.

Fundamental to the Compact success is trust and that any data provider must be assured that the Compact terms and conditions for access and use of that health data have been complied with and been seen to be complied with. It was recognised that the global medical device, technology, and pharmaceutical companies are complex organisations both organisationally and geographically and creating processes to assure compliance takes time. Indeed, adherence to Compact terms will help prepare those organisations for EHDS compliance.

There was very strong support for an independent panel to be appointed to carry out the required compliance oversight. Whilst a Compact could be self-regulated it must not be totally self-regulated, and the independent oversight panel would meet this requirement. By independent we mean the panel members would not be employees or contractors or otherwise associated with any of the signatories.

A number of operational questions were discussed including:

- **Who, on behalf of the Compact, would supervise compliance and any enforcement?**
- **Would the Compact create posts such as Chair, Vice Chair or Compliance Officer?**
- **What enforcement mechanics would exist (e.g., warning notice to comply, requirement to stop using the data shared and ultimately expulsion form the Compact for non-compliance. How proactive should the compliance checking be?**
- **How would any decisions about operating the Compact work? Would it be simple majority, unanimity, or specific voting percentages for certain decisions (e.g., new organisations joining)**
- **The Compact must be transparent so information about it must be in the public domain such as its scope, identity of the signatories, results of the use of any data and its annual activities. To publish this information the Compact might create a website and operate in similar ways to EU funded projects (roles, operational management, and website)**

It was acknowledged that the exact operational details may vary depending on what types of data might be shared and the identity of the signatories. Indeed, some maybe 'nice to have" and others essential. This level of detail would need to be agreed at the point a group or organisations and individuals wish to create a Compact.

The practical requirements should avoid reinventing the wheel and adopt good or best practices established in EU projects or Member States for example governance arrangements in the 100M Genome Project, data transfer arrangements in [EHDEN.]and patient data transfers using a mobile app from the Interoperate project.

However, for the Compact to work it will incur operating cost and expenses which need to be met (such as creating the Compact agreement (including communication campaigns to promote it and recruit signatories see section 7 from WG 2 of Round Table 3), running the Compact (requests for data access) creating the oversight panel and) publishing reports on its work and results. These costs could be met by membership fees from industry signatories (which could be tiered) and/or fees paid for data access by signatories or sponsorship or grants.

Annual reporting of activities, benefits achieved and compliance

It was agreed that annual reporting was required to provide transparency about the activities of the Compact. This should include clear and simple information about data access provided from whom to who, for what purposes, aims, how it was used, and all results achieved (respecting any commercially sensitive confidential information). Results should include any identified disbenefits and any data privacy or security breaches and steps taken to resolve or mitigate any effects.

The reporting of benefits and the wider impact of a Compact needs a robust evaluation process which should be embedded in the Compact agreement.

How could a Compact compliment and enable the EHDS?

A Compact would not compete with the EHDS in any way but on the contrary make a contribution to fulfilling its purpose and specifically:

1. **Strategically a Compact could assist EHDS with;**

- Data sharing by industry and the voluntary sectors to enhance health data sharing conceptually by all stakeholders not just the public sector.
- In the next five years helping to create the conditions for the EHDS to thrive and **contributing to building the necessary citizen, patient, and industry trust** essential to making the EHDS a success especially by focussing on non-controversial purposes and uses and providing tangible evidence of benefits.
- Making a wider contribution with multi-stakeholders to establishing a "Data Culture for Society" building on "Data Saves Lives".
- Conversely EHDS would in turn assist any Compact operate by providing data sharing infrastructure for data sharing and patient access to their EHRs and the ability to transfer that data.

2. **The Compact terms should explicitly reference the draft EHDS draft regulation by;**

- Sign posting future compliance requirements and adopting them now such as the purposes for which health data can be processed for secondary use (Article 34) and the prohibited secondary uses of health data (Article 35). The work of the RT3 included greater detail on both the permitted uses and prohibited uses and these could be used to provide greater clarity and certainty.
- Including in the Compact terms a provision confirming that Articles 31 (types of data), 46 (templates for data access requests), 67 (interoperability requirements), 52 (terms to access my HealthData@EU) will automatically apply as and when the European Commission exercise their enabling powers

3. **It would be advantageous in the consultation process to create the first Compact to engage with both the Commission and some Member States especially those with advanced data use and sharing arrangements or plans and to liaise with EUREGHA.**

4. **Both this report and if a Compact(s) is used in the next few years would provide very practical experience for the European Commission of sharing health data (e.g., templates for access requests and results reporting) and data flows to inform its use of the implementing powers it has. The EC has extensive implementing powers to enable the EHDS which will take some time to prepare and publish so the practical experiences of any Compact in the meantime would offer valuable experiences and insight.**

Feedback on the discussions in the first Plenary of the meeting on 13th October

There was agreement that existing terms like Declaration, Code and Guidance have for some stakeholders particular meanings which are not always consistent, suggest voluntary obligations and do not easily fit with the concept of "giving "for the common good of society which is the essence of a Compact (which also explains why commitments is not the right term either). Whilst it is acknowledged that a Compact will not be a familiar term for most people with effective communication this concern could be overcome and such communication is essential in order to create trust and ensure organisations sign up.

The WG supported the signed adoption model for a compact as originally discussed in Round Table 3. In addition, it was recognised that some organisations might not be capable of signing a Compact for example they are not legal entities or are not data holders or data users but should be encouraged to support the formation of Compacts as "supporters" for example Data Saves Lifes {mou] Signature should be flexible to allow organisations to sign as supporting signatories without any legal obligations.

Possible Recommendations to develop a Compact operational model

1. **EC to invest substantial funding in building trust in health data access and use by for example surveys and communication campaigns.**

2. **The EC should convene multi stakeholder meetings to discuss how with Member States a) address misinformation, disinformation, and no information challenges around health data and b) to promote a cultural change to data trust and create a "Data Culture for Society"**

3. **Communication, consultation and socialising the Compact with a wide large selection of all stakeholders (including TEHDAS and the French Data Hub) when creating the first Compact(s) will be critical.**

4. **The concept of a "supporter" needs to be developed. Allowing the active involvement of stakeholders who are neither data holders or users as "supporters" will be important to winning widespread trust and especially from civil society. Creating a supporting role will need further work to be developed into a practical range of meaningful involvements. Important potential supporters such as Data Saves Lives, professional clinical bodies, citizens and patient representatives bodies would be able to offer extremely valuable help in promoting the Compact.**

5. **It would be advantageous in the consultation process to create the first Compact to engage specifically with both the Commission and some Member States (especially those with advanced data use and sharing arrangements or plans) and liaise with EUREGHA.**

6. **As part of any communication about a Compact perhaps 3 specific hypothetical examples of data sharing, use and benefits should be created demonstrating different practical purposes and scale to make the concept real for all stakeholders. This should include data flows from multiple data holders to data users in simple visual form.**

Glossary

API	Application programming Interface
Compact or Societal Compact	is a voluntary agreement between a range of multiple stakeholders to co-operate to achieve declared social/societal benefits
DGA	The EU Data Governance Act (COM/2020/767)
DHS	The Digital Health Society
EHDS	The European Health Data Space
EU	European Union
GDPR	The EU General Data Protection Regulation (2016/679)
HL7	Health Level 7 refers to a set of international standards for the transfer of health and administrative data.
I~HD	The European Institute for Innovation through Health Data
PROs	Patient Reported Outcomes
Regulation on EHDS	EU Draft Regulation (COM197/2022)
SDO	Standard Development Organisations
TEHDAS	Towards the European Health Data Space An EU Joint Action to develop European principles for the secondary use of health data
WHO	World Health Organisation

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2023 RECOMMENDATIONS BASED ON CALLS TO ACTION ON HEALTH DATA ECOSYSTEMS

THIS INITIATIVE IS SUPPORTED BY