

*Health data drives innovation*



# *Digital Health Society Summit 2023*

How to facilitate more access  
to Health Data for research?

Introducing the Societal  
Compact

# Health system sustainability and resilience

## Economic context:

- Legacy of the crisis: high debts and deficits
- Continued increases in public health spending anticipated
- Concerns about how this will be paid for (sustainability of public finances)

## Population health:

- Ageing and rising levels of chronic disease and comorbidity
- Public health problems and inequalities

## Health systems:

- Challenge of responding to changing population needs
- Need for structural reforms – e.g. integrated care, eHealth
- Evidence of marked variation in clinical practices and significant levels of 'waste'



# The spectrum of learning from health data: from care to research

## Individual level health data

### Used for:

- Health and outcomes monitoring
- Care pathways and continuity of care
- Telehealth, personal health
- Personalised medicine
- Prevention
- Reimbursement

## Population level health data

### Reused for:

- Health services and resource planning
- Quality and safety monitoring, pharmacovigilance
- Public health surveillance
- Public health services and strategy

## Large scale health data

### Reused for:

- Disease understanding and stratification
- Personalised medicine and bio-marker research
- Drug and vaccine development
- Digital innovation: devices, sensors, apps, AI

# The challenge with gaining public acceptance of health data reuse

**Individual level  
health data**

**Population level  
health data**

**Large scale  
health data**

**Decreasing public understanding of why and how data are used**

**Increasingly unfamiliar data users**

**Increasing time from data use to demonstrated value**

**Increasing distance of data results from the patient**

**Perceived lessening choice and greater cybersecurity risk = harder to trust**

# How do we reach societal acceptability?

- Data protection regulations prioritise the **rights of the individual**
  - Clinical research can bring important benefits **to society**
  - Many surveys indicate **patients are in favour** of their data being re-used for research
  - The data ecosystem needs to **give societal commitments** that data will only be used to bring health and care benefits, by bona fide organisations
  - The public need **greater transparency** about why and how health data are used, safeguarded, and the benefits of that use
- We need to find the right balance between the rights of the individual and the benefits for society**

## Data Protection



GDPR



## Data Altruism



Data Governance Act

- Public preferences respected
- Societally acceptable data uses
- Agreed minimum safeguards
- Codes of data conduct widely upheld
- Accountability for use
- Public involvement and transparency
- Visible societal benefits



The public and decision makers need a way of determining who to trust with health data, and why

*Bona fide* organisations need a way of demonstrating they are trustworthy

Everyone needs transparency

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

2023 RECOMMENDATIONS BASED ON  
CALLS TO ACTION ON HEALTH DATA  
ECOSYSTEMS



# A societal compact (or social contract)

- A voluntary agreement between a range of stakeholders
  - who co-operate to achieve social benefits by granting access to and reuse of health data
- The Compact
  - aims to provide an assurance to all stakeholders in the health data ecosystem, especially the public
  - that organisations and individuals reuse health data in legal, ethical and secure ways
  - that they use data in society's interests



# Compact development process

- Developed through a multi-stakeholder expert group in late 2022
  - building on >15 years of prior work on principles, codes of practice etc.
  - developed as part of a programme of health data topics arising from a Calls to Action report published by i~HD and DHS in 2020
- Refined through wider consultation in early 2023
- Published now as a proposal draft, for further consultation
  - National feedback is especially invited on its potential global suitability and expressions of interest to help develop it further

# Main components of the Compact

- Ethical principles
- Permitted and prohibited purposes for reusing health data
  - Mirroring the EHDS regulation
  - Adding details and examples
- Data use commitments
- Governance and operational models

# Ethical principles for health data reuse



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 disadvantage or are very likely to 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.**

# Ethical principles for health data reuse



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.

# EHDS permitted and prohibited purposes for secondary health data use

## Public interests for public and occupational health

- cross-border threats to health
- public health surveillance
- healthcare quality
- safety of medicines and devices

Support of public body mandates e.g. regulators

Statistics related to health and care

Education or teaching in health and care

## Scientific research related to health or care

- product and service innovation (e.g. medicines, devices)
- training, testing and evaluating of algorithms

Providing personalised healthcare

## Developing products or services that may harm individuals and societies

- illicit drugs, alcoholic beverages, tobacco products
- goods or services that contravene public order or morality

Decisions with legal or equivalent effects detrimental to a person based on their electronic health data

Decisions that exclude persons or groups from the benefit of insurance or modify their contributions

Advertising or marketing activities towards health professionals

Providing data to third parties not specified in a data access permit



# Expansion of research purposes (examples)

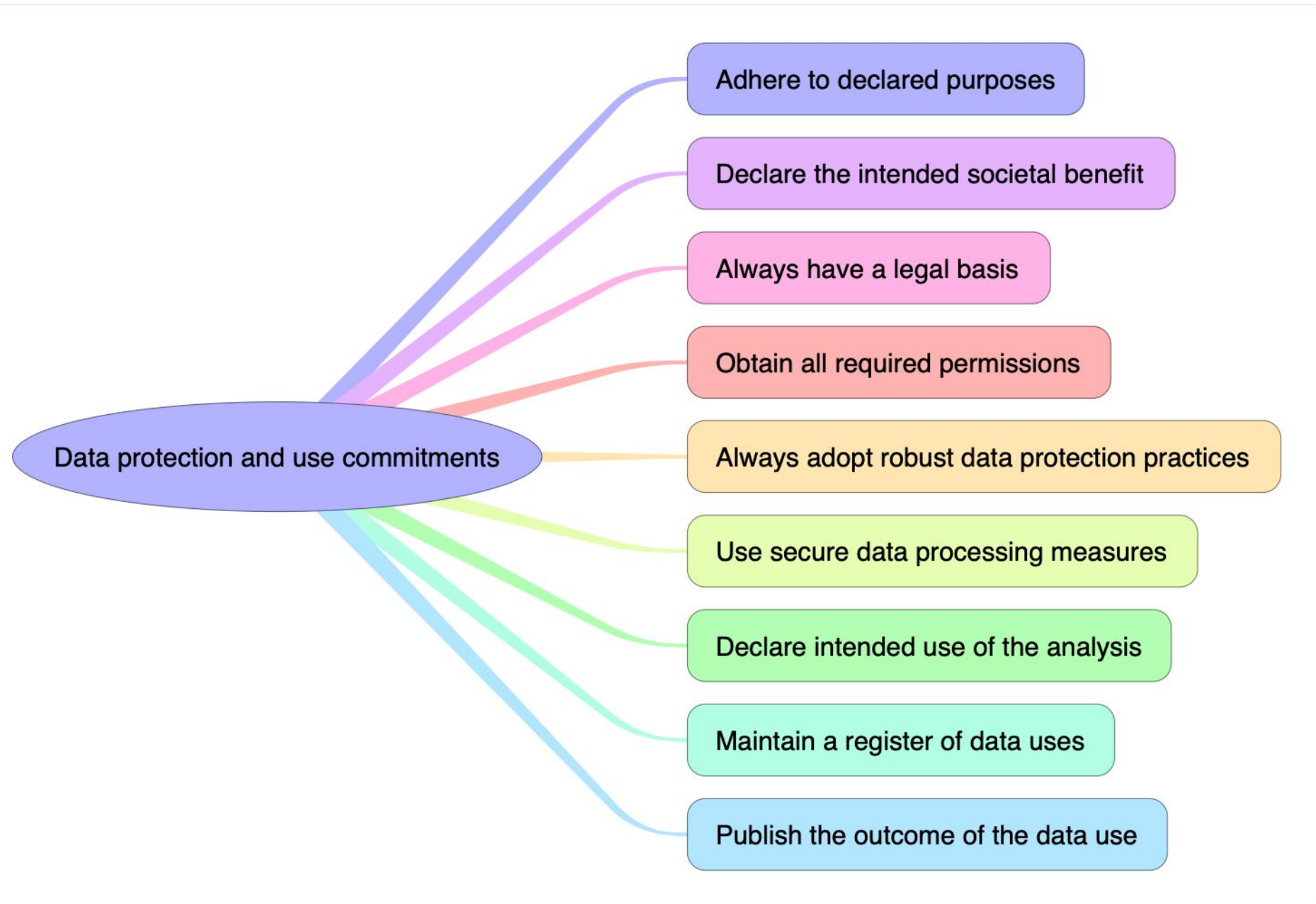
- Epidemiology and observational research studies
- Disease understanding, disease burden, unmet need and stratification
- Outcomes research, comparative effectiveness research
- Predictive analytics and identify patient sub-groups that respond better to certain treatment
- Digital innovation: devices, sensors, apps (including understanding patient 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 characterisation and optimal treatment sequencing
- Testing and improving outcome sets
- Assessing the feasibility of planned research and implementation



# Extending the EHDS prohibited purposes

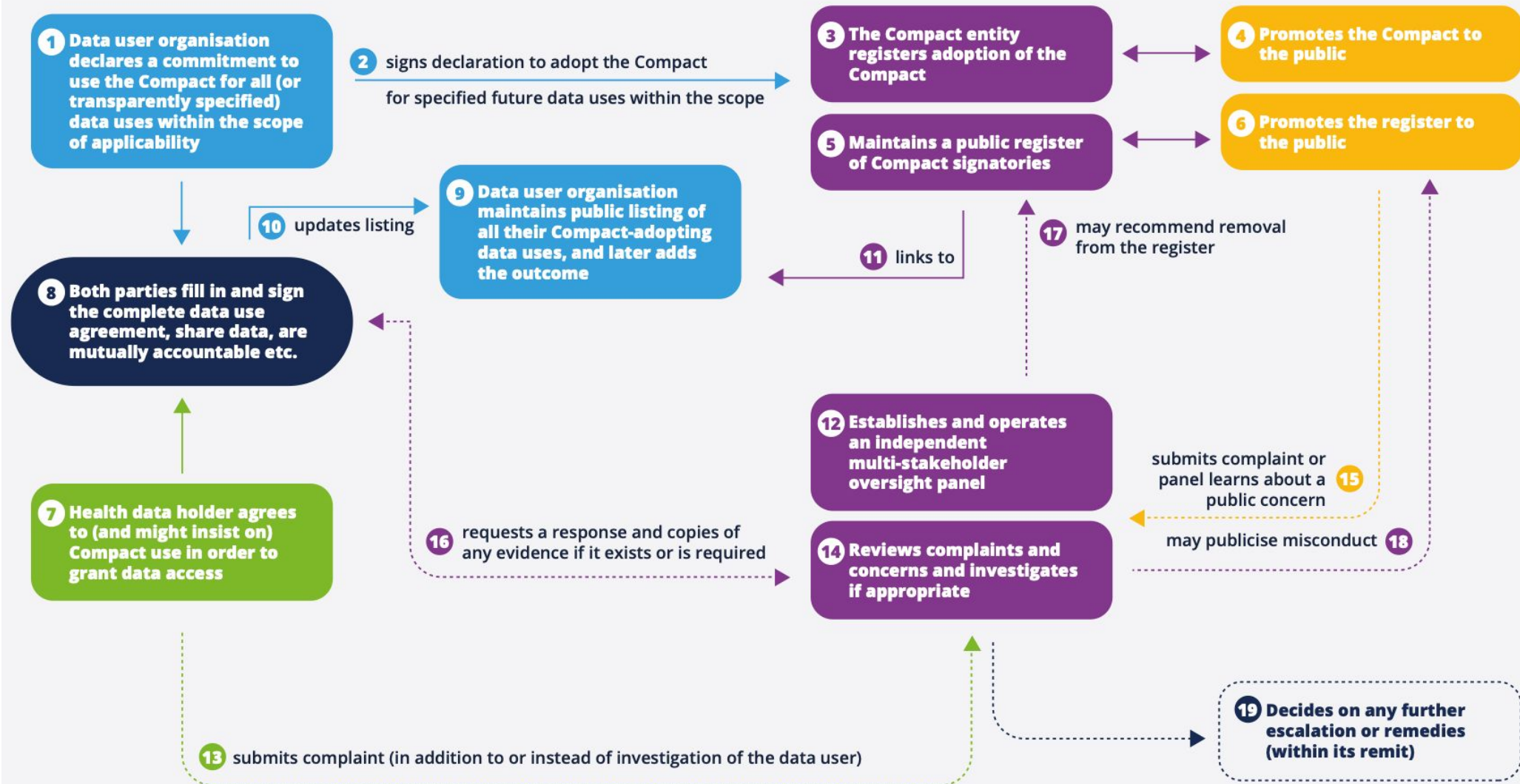
An organisation adopting this Compact declares that it will not reuse health or health related data for purposes that would **violate the European Convention on Human Rights**.

- Research uses of data that would require but have failed to apply for or obtain ethical approval
- Development and uses of new technologies 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
- Direct marketing or endorsement of products e.g. medicines
- 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



Details of these commitments are given in the Compact document

# The Compact operational workflow



# We invite feedback on its suitability

- We are keen to broaden the countries across the world whose data is used for research, to reduce the country bias we have today in health data sets
- We invite ministries and DPAs to review this proposal and to give us feedback on its potential usefulness and practical adoption in your country
- We will be happy to support countries that wish to be early adopter pilots of putting this Compact into practice

## Download link

<https://echalliance.com/news/round-table-6-proposal-for-a-societal-compact-for-the-secondary-use-of-health-data/>

## Recent news article from France

<https://www.healthhub.hr/heads-up-proposal-for-a-societal-compact-for-the-secondary-use-of-health-data/>

## Contacts

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