

Science Summit at the United Nations General Assembly (UNGA78)



Proposal for a Societal Compact on the reuse of health data for research

iHD The European Institute for Innovation through Health Data

 the digital health **society**
The data arm of ECHAlliance Group

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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)

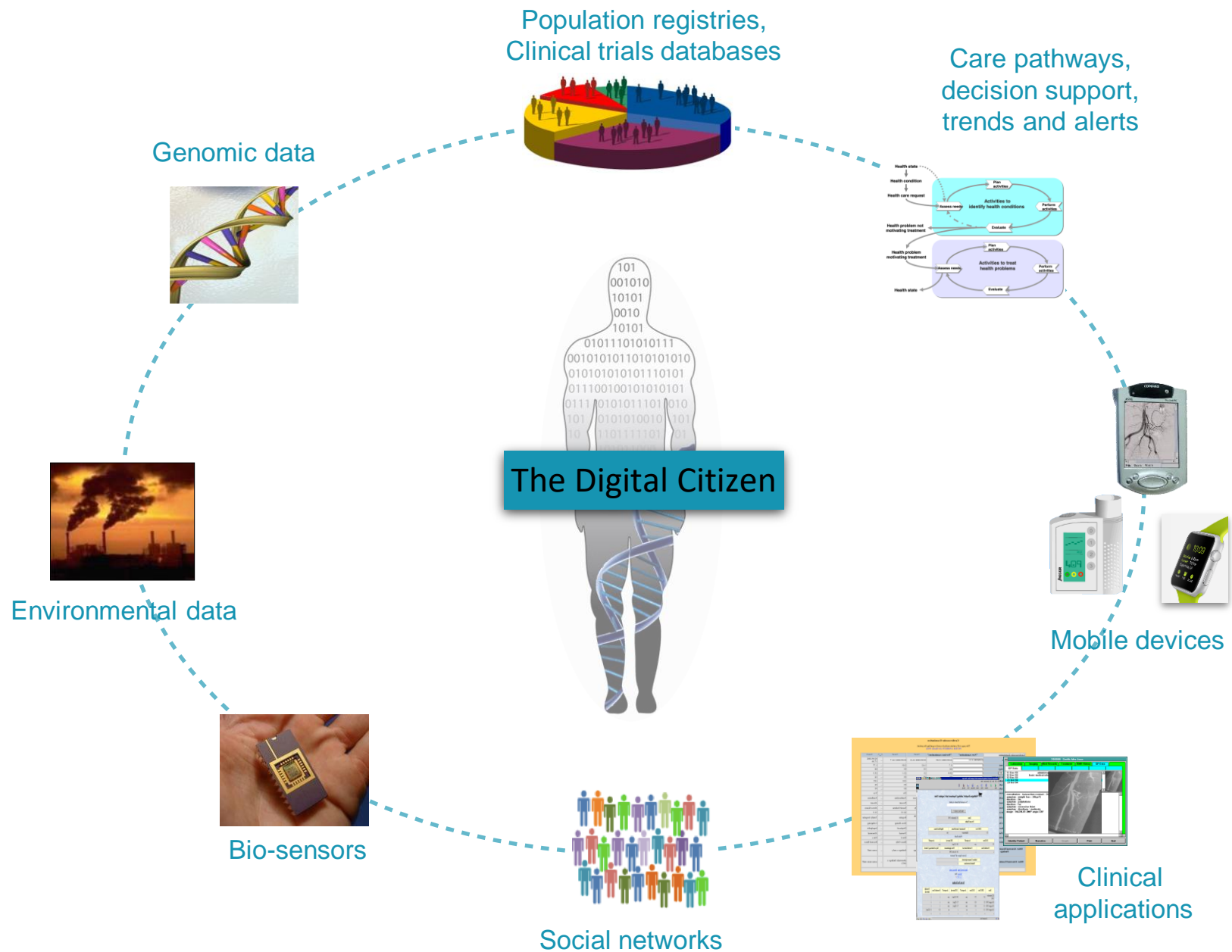
Population health:

- 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 Digital Citizen

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

Patient studies have highlighted...



...that the public are concerned about the use of health data even if their identify is not exposed

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
 - UN member country 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
- 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.

Permitted purposes for the secondary use of health data (Mirroring the EC draft Regulation for a European Health Data Space)

- 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

The Compact includes examples of research, to illustrate purpose e)

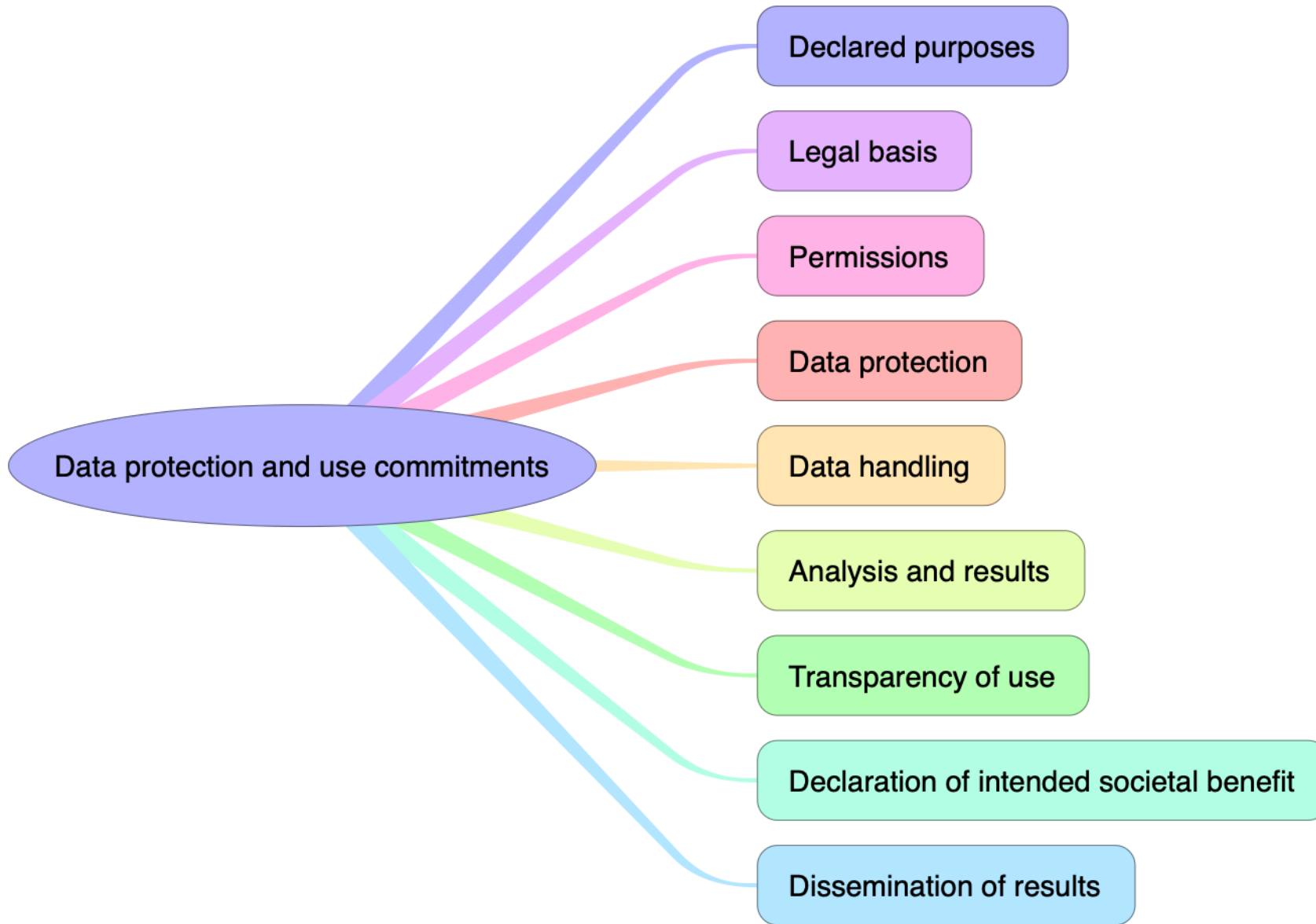
Prohibited secondary uses of health data

- 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.**

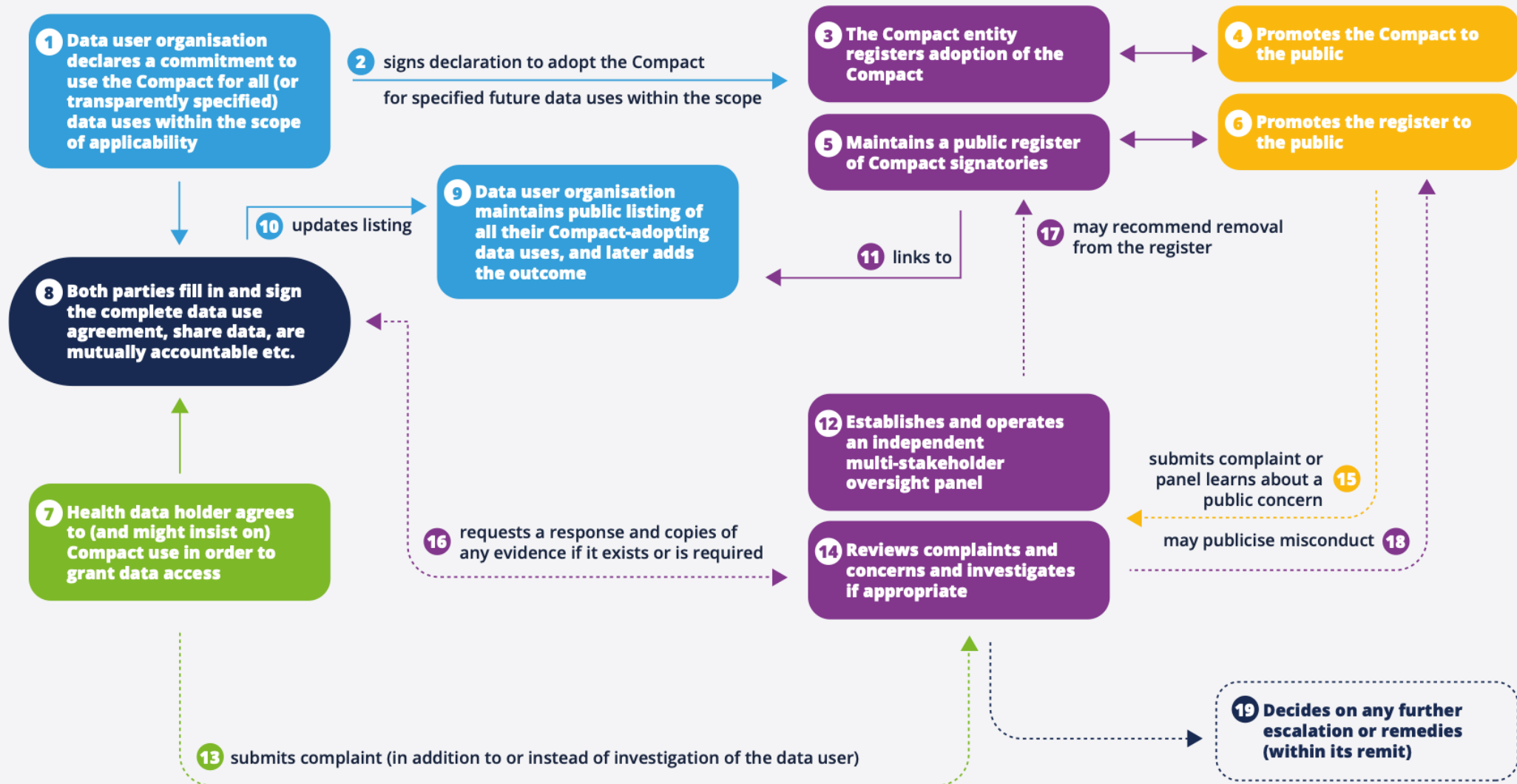
Further prohibited purposes

- 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 UN member feedback on its potential global 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 in UN countries 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
- We request the UN Science Committee to allocate agenda time in 2024 to discuss the feedback from countries, including early adopter experience, and to discuss how this compact, or a revised version of it, could be adopted and promoted by the UN

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/>

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