

Resetting Data Governance: Authorized Public Purpose Access and Society Criteria for Implementation of APPA Principles

WHITE PAPER
APRIL 2021



Contents

Executive summary	3
1 Current issues in data sharing and use	4
1.1 Developing ways of protecting individual rights not solely based on consent	4
1.2 Are “data holders” the enemy?	4
1.3 How to understand “public interest”	5
1.4 APPA: a new data governance model	5
2 APPA deployment principles	7
2.1 Achievement of true public interest	8
2.2 Reasonable means	9
2.3 Social agreement	10
3 APPA application criteria assessment and questionnaires	11
4 APPA governance implementation methods	14
4.1 Who uses APPA application criteria	14
4.2 The third-party approach	15
4.3 Ethical review for medical research and APPA	16
4.4 Next steps	16
Conclusion	18
Contributors	19
Acknowledgements	20
Law guidelines	21
Endnotes	22

Executive summary

Data governance is the most pressing challenge of the Fourth Industrial Revolution. In the field of healthcare, issues related to data governance, such as privacy, consent and the at times conflicting needs of individuals and society, are particularly acute. It is for this reason that the World Economic Forum has chosen healthcare as an entry point for

addressing major issues on data governance: What is the desirable governance model for extracting value from personal information while handling that information with sufficient care? Establishing a data governance system for public health crises, including pandemics, could save lives while enhancing public trust in the use of data to further the public good.

Authorized Public Purpose Access (APPA)

As of April 2021, the coronavirus (COVID-19) continues to spread around the world, with the number of infections and deaths still increasing¹. Strict curbs on travel and other public activity imposed immediately after the pandemic began helped to slow spread of the virus, allowing economic activity to resume. But the renewed activity soon led to a resurgence of infections, demonstrating the difficulty of managing the pandemic. Our team believes that a systematic and cross-national approach to handling personal information such as location and medical data is essential, not only to address the current crisis but to prepare for the next one. The approach will have to be widely trusted to ensure participation and compliance. Therefore, it is necessary to develop a data governance model that balances individual rights with the interests of data holders and the public interest.

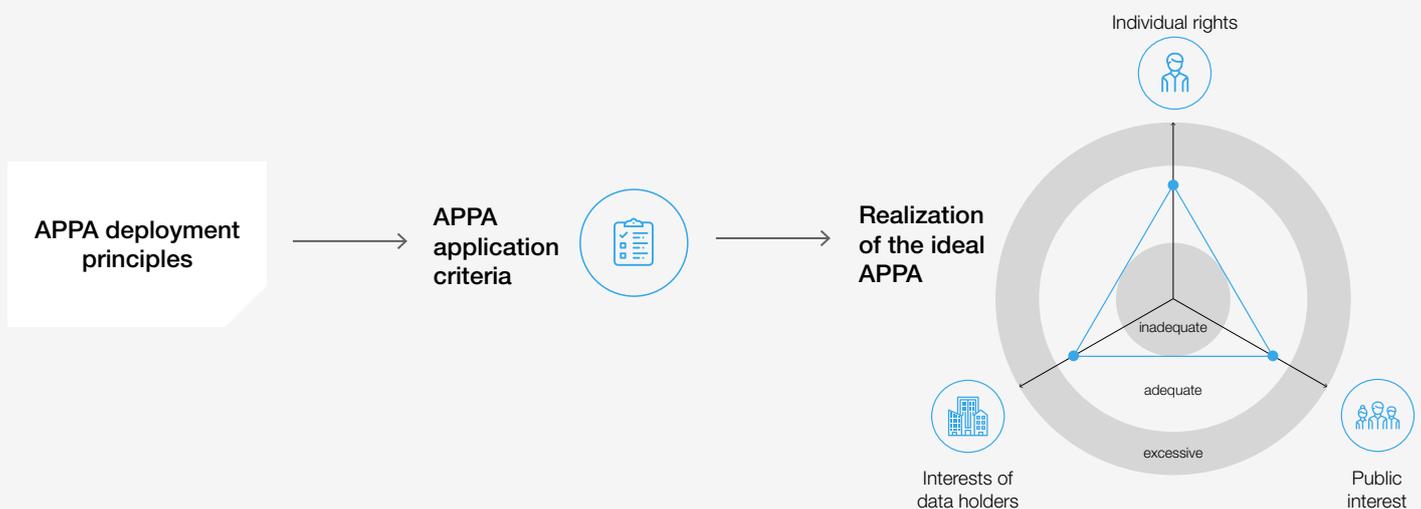
[A first white paper published in January 2020](#) presented the Authorized Public Purpose Access (APPA) data governance model.² APPA postulates that data must be connected in order to create value. Current data governance models do not

sufficiently facilitate the sharing and pooling of data contained in numerous databases, in individual countries or globally, with the result that much of the potential value of data is wasted. Current governance models are designed in ways that give precedence to protecting the legal interests of one of three key constituents: individual data subjects, data holders or the public at large.

The use of personal data for public-health purposes, including for fighting pandemics, should be subject to appropriate and balanced governance mechanisms such as those proposed by the APPA approach. The same approach could be extended to the use of data for non-medical public-interest purposes, such as the achievement of the United Nations Sustainable Development Goals (SDGs).

This white paper proposes a systematic approach to implementing APPA and pursuing public-interest goals through data use. The approach values practicality, broad social agreement on appropriate goals and methods, and the valid interests of all stakeholders.

FIGURE 1 Toward implementation of the APPA concept



1

Current issues in data sharing and use

1.1 Developing ways of protecting individual rights based not solely on consent

- Giving data subjects the right to make decisions regarding personal data is an important factor in protecting privacy and autonomy. Consent is not always required, but it is often over-relied upon as the default option.
 - Experts have suggested that consent is not necessarily an essential element for respecting autonomy, but rather a means of preventing improper handling of personal data and its disadvantageous consequences.³
 - While some jurisdictions have adopted alternative methods such as comprehensive consent, opt-out and even data use without consent in certain cases, these approaches require appropriate operations from the perspective of respecting human rights and autonomy.
 - In some cases, such as in those of minors and elderly people with dementia, data subjects may not have sufficient decision-making ability, making it difficult to obtain appropriate consent.
 - Since the decision-making ability required to provide appropriate consent varies depending on the complexity and risk of the decision, even healthy adults may not fully understand the meaning of a consent decision nor have sufficient ability to make such a decision.⁴
 - Consent-based data collection and use increase the time and cost required for data collection, thereby reducing the volume of data that can be collected. There are cases in which data collection is not practically feasible under a consent-based model.
 - If informed consent is required each time data are collected, the result can be “consent fatigue,” which can potentially lead to inappropriate judgement due to the burden of reading and understanding many informed-consent documents.
 - Although “nudging” may reduce decision-making costs, such approaches require that nudgers (data holders, etc.) are trusted.
- In light of this context, it is necessary to introduce a mechanism to supplement the conventional notification/consent mechanism.

1.2 Are "data holders" the enemy?

- The advent of extremely large data holders such as platform providers has created power gaps in information and negotiation. For this reason, regulations are necessary to protect privacy, to ensure fair competition.
- Platformers such as Apple and Google may not own data but they control it in practice. This fact has a tremendous impact on the development and dissemination of contact tracing apps used against COVID-19.
- Excessive control by the state over the private sector may conceal opportunities for democratic data use and, as the result, for value realization to benefit society.^{5,6}
- Constraining data holders may threaten not only economic development, but also lead to the loss of their cooperation in achieving the originally expected public interest.
- Given these circumstances, data governance should flexibly shape data use to bring data holders on board.

1.3 How to understand "public interest"

- The realization of "public interest" is an important mission of states and international organizations.
- Regarding the use of data for lawful purposes including the public interest, states often provide special regulations in their data protection legislation. For example, GDPR⁷ reserves Article 6 (1) (d), (e), (f) and Article 9 (2) (g), (h), (i), (j) as disciplines concerned with "public interest". In Japan, the Act on the Protection of Personal Information, Article 23⁸, Paragraph 1, Items 3 and 4, states that a person's consent is not required for the provision of information to a third party if the information is of high public interest for certain situations. Even though such explicit provisions for data use have been introduced, they are too ambiguous to be useful in assessing existing examples.
- The power of data use by national governments has been evident in responses to COVID-19 in several Asian countries. At the same time, they risk excessive state surveillance and infringement of personal rights in the name of the "public interest". In order to promote the public interest, it is necessary to clarify what kind of individual rights and corporate rights can be restricted.
- Current data-governance regimes may in practice underestimate potential benefits, not only for society as a whole but also for individuals. In the EU, the European Data Protection Board (EDPB) has issued a statement to ensure the GDPR does not interfere with COVID-19 countermeasures⁹. Yet, to cite just one example, the attitude towards the use of mobile phone location information for COVID-19 responses varies from country to country, including outside the EU.
- The rule of law should be abided (SDG target 16.3¹⁰). National activities in the public interest, such as disaster countermeasures and public health, usually fall under laws apart from data protection legislation. However, the development of law sometimes falls behind social change, making it difficult to rely on them alone.
- Pandemics like COVID-19 reaffirm that "public interest" challenges such as to public health are not exclusive to any one nation. The "public interest" requires the cooperation of multiple countries, international organizations and stakeholders.

For these reasons, it is necessary to develop international regulations and corresponding operating models that prevent the "public interest" from being used unconditionally and without limitation by companies and nations as the basis for data use. At the same time, it is necessary to clarify which data use in the public interest is allowed, to prevent inappropriate data use, including by sovereign states.

1.4 APPA: a new data governance model

- Unlike in the past, when personal data was assumed to be under the exclusive control of a specific subject, personal data controlled by a large number of parties can be used in non-rival ways to create new value. In terms of data use, it is necessary to consider a governance model that unlocks the social value of data while guaranteeing human rights.
- The World Economic Forum Centre for the Fourth Industrial Revolution Japan has proposed a new data governance concept called Authorized Public Purpose Access (APPA), defined as "a model for realizing value by permitting access to data for specific, agreed public purposes, such as the development of medical care and the improvement of public health, through processes that do not rely exclusively on explicit, individual consent as a means of protecting human rights".¹¹
- [In the white paper published in January 2020](#), data governance models were analysed from the point of view of individual rights, the interests of data holders and the public interest. It was found that in many cases, they fail to generate sufficient social value because they are biased toward one of these three elements. The APPA data governance model aims to create new social value by balancing, or at least appropriately managing, the three elements.
- The following three points are the key issues to data governance for healthcare and to data governance in other fields as well.
 1. Guarantees of individual rights (not limited to privacy rights) regarding data use should be shaped appropriately to each specific case and can be achieved through a range of methods including, but not limited to, Notice and Consent.
 2. Businesses and nations are not free to use anonymized personal data. It is always necessary to consider the impact of using the data on individuals and society.

3. To date, there is no consensus on the definition of "public interest". However, it may be possible to reach a consensus over public interest goals in specific situations. For example, the international community agrees on SDGs related to health and well-being, and that data use should be promoted to achieve these goals.
- The objectives of this white paper are, therefore, to make the APPA concept applicable to the public interest in the healthcare field (protecting life, ensuring public health), and particularly, to promote understanding in both the public and private sectors of data use for public interest purposes.
 - Points 1 and 2 above will be further examined in another white paper.

The January 2020 white paper on APPA provided examples of factors to consider in terms of individual rights, interests of data holders and the public interest.

Other issues, such as building an economically sustainable governance model, were also raised. This white paper shares the current state of discussion on some of these issues and important issues exposed by COVID-19.

To implement APPA in the real world, it is necessary to rethink current governance mechanisms. This process was analysed in Rebuilding Trust and

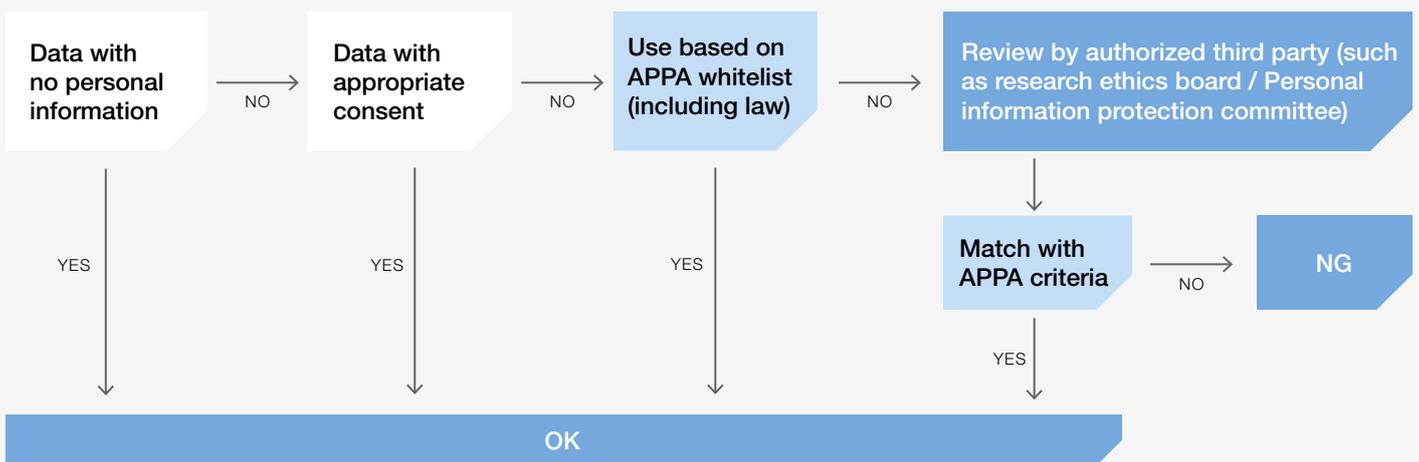
Governance: Towards Data Free Flow with Trust (DFFT)¹², released by the World Economic Forum in March 2021. The "Trust Governance Framework" proposed there can be explained in terms of APPA. The principles presented in this white paper serve as norms for the "Governance of Governance" concept in the Trust Governance Framework. In other words, these principles are proposed as guidelines for rule-making by states or platformers, and for formal objections by third-party organizations or individuals who monitor how companies or states handle personal data. Therefore, we aim to clarify what cannot be done by combining current principles, then present an evaluation standard that builds on current discussions without conflicting with existing principles.

The APPA application criteria are derived from current laws and guidelines governing personal data, as well as the definition of APPA itself, assuming implementation in data use cases mentioned in the first white paper. They are intended to secure the trustworthiness of actual data use within the Trust Governance Framework.

In addition, in the field of medical research and advanced medical care, governance has been conducted by third-party organizations (ethics committees), yet issues related to data use have emerged in recent years. The APPA criteria may offer ways for the committees to resolve these concerns.

How data use should be governed based on APPA is shown below.

FIGURE 2 The APPA-based approval process



Whether the data contains no personal information or whether there is appropriate consent remains for further examination. This paper mainly discusses the following points:

- What kind of data use should be included in the APPA whitelist?

- What are the criteria for appropriate data use based on APPA principles?

These principles and evaluation standards will assist companies and researchers who want to use data when they assess whether their use is appropriate.

2

APPA deployment principles

APPA is based on the four principles of bioethics (respect for autonomy, non-harm, good conduct, justice) and other established principles in medicine and healthcare, such as the Declaration of Helsinki¹³ and the Declaration of Taipei¹⁴. The APPA concept is at the core of current initiatives such as disaster countermeasures, or genomic information sharing and cancer registration in the healthcare field.

References in this paper are broadened to include major international laws and guidelines related to a range of personal data beyond the healthcare field¹⁵. On this basis, the principles that shape the APPA concept have been further developed and a set of application criteria developed as well as other points to consider when implementing APPA.

The validity of APPA principles has been reviewed in multiple cases^{16,17,18} and it is our hope that they continue to be examined as relevant cases are developed.

As a trust governance framework, APPA also emphasizes the importance of establishing trust anchors with efforts from multistakeholders, to ensure the trustworthiness of these principles.

The following three principles are central to APPA-based data governance.

1. Achievement of true public interest. APPA does not aim to include all forms of public interest at once. The true public interest should be

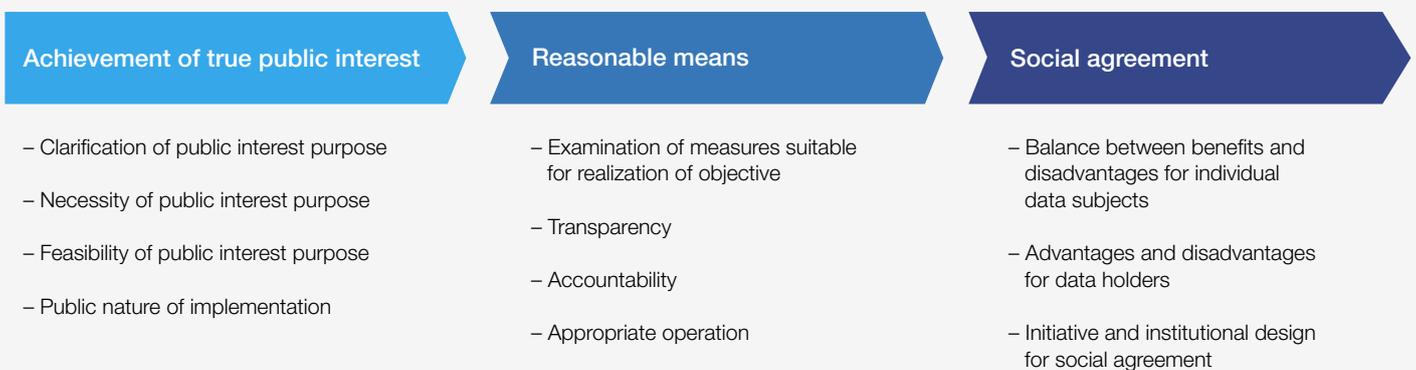
achieved through a process of clearly defining expected benefits, assessing their necessity in each specific case, considering the validity of implementation by verifying feasibility and examining benefits and disadvantages, and guaranteeing the public nature of implementation in other cases to gain a common understanding of the newly created social value.

2. Reasonable means. This refers to requirements for the achievement of public interest objectives. Public confidence in data governance can be built only if society deems the methods, as well as the goals, to be fair and reasonable.
3. Social agreement. A sound data-governance regime requires clearly defined processes for securing public support for both the goals and means of data use. A democratic process is crucial to ensuring that the proposed public interest purpose is legitimate and that the data in question are handled responsibly.

For each of these principles, we have identified more specific points of focus, shown in the table below. Confirmation of the applicability of the three major principles should be carried out in this order: 1. Achievement of true public interest - 2. Reasonable means - 3. Social agreement over implementation.

Data use without conforming to these principles should not be allowed according to APPA.

FIGURE 3 APPA deployment principles



What is the “public interest” in APPA? Is the interest of states or public institutions truly “public interest”, while the interest of companies (corporations) is separate from that of individuals? Could it be considered as the benefit for humankind or the global environment at large? Should it be centered on human beings, as to maximize the diverse advantages and minimize the disadvantages of each individual?

To demonstrate current public interest purposes, we may refer to several examples, such as the development of medicine and public healthcare, disaster management, hunger relief and poverty eradication. In short, the achievement of the SDGs.

As presented in the January 2020 white paper, public interest goals should be limited to specific purposes that have been defined through a process of broad public agreement, critique and verification, respecting the human rights of minorities and not favouring the interests of particular groups or states.

As such, some data subjects may oppose certain public interest uses of data.

Article 23 (1) (2) of Japan's Act on the Protection of Personal Information¹⁹ provides for “Protection of life benefits,” which can allow data to be used against a

person’s will, in order to protect certain crucial rights and benefits. This white paper is also concerned with such “public purposes”. Likewise, the purpose of academic research and education, which were not always discussed as public interest categories in the past, should be covered by APPA as well.

The public interest may put data holders at a disadvantage. For example, the patent system to protect the interests of private companies may hinder access to healthcare in some countries, which is an increasingly serious issue not only in the treatment of AIDS and but also COVID-19 vaccination. The pursuit of public interest sometimes becomes a disadvantage to data holders. Therefore, data subjects and data holders should be enabled to anticipate data use without difficulty, to prevent the risk of human rights violations due to states expanding their interpretation.

The following items should therefore be carefully considered, given the difficulty of determining what explicitly counts as a legitimate public interest goal, to what extent the purpose should be clarified and how public interest initiatives should be assessed when they overlap with other goals (commercial or military, for instance).

2.1 Achievement of true public interest

Clarification of public interest purpose

The OECD Eight Principles²⁰ are a touchstone in the field of privacy protection. Sound data-governance regimes should comply with the OECD’s Clarification of Objectives²¹ in order to prevent unrestricted data collection, sharing and use, and enhance the social acceptability of data use. The OECD principles take more concrete form in the domestic privacy laws of individual countries, their essence is carried over to multilateral rules such as the EU’s General Data Protection Regulation (GDPR).

There have been related discussions on how to clarify the purpose of use for “broad consent” in the healthcare field. While consent for a broad purpose such as “the development of medical treatment”

sometimes aligns with the intention of the individual, the related data use may not always occur as individuals expect. Some have proposed to clarify the purpose as much as possible when obtaining consent, then confirm it again each time the data is used (Dynamic Consent), but the problem of cost and consent fatigue persists.

APPA does not suggest a backdoor to such efforts to obtain consent. Rather, it aims to make undiluted efforts in clarifying purposes and permits data use without confirming people’s will at specific moments, and only for certain democratically authorized purposes.

Necessity of public interest purpose

Any entity that intends to use data without explicit consent in order to achieve a public-interest objective must satisfactorily show that this manner of access and use is truly necessary. Even if the goal has been clearly defined as being in the public interest, it is

important to ask whether the data must be accessed in this way, on this occasion. This requirement is stated in legal systems related to personal data such as GDPR, Japan’s Personal Information Protection Law, and other legal grounds.

Feasibility of public interest purpose

Is there a clear public interest purpose? If it is necessary to achieve the goal in question, is it per se a feasible goal? Public purposes, according to APPA, should never lack broad public agreement. Societies are composed of many interrelated people and groups with diverse values. The principle of the "public interest," at its root, requires sincere acknowledgment of parties who are likely to suffer disadvantages.

The achievement of a public interest goal should generate social value that exceeds the cost of the

related data use. Assessment requires estimating that value in quantitative and qualitative terms, determining the social cost of the required data use required, and understanding any restrictions placed on the individual rights of relevant parties.

Data users will always be able to argue for the feasibility and necessity of their endeavours. To ensure an objective assessment, it is necessary to always allow criticism from other parties.

Public nature of implementation

One goal of APPA-based data governance is to encourage standardization and interconnectivity among systems so that data can be used in a way that ensures scalability and contributes to the

development of society and its infrastructure more quickly and safely. It is important to consider making more data widely accessible in the first place by defining it as "public goods."

2.2 Reasonable means

In terms of the "Access" in APPA: Data is often intangible, replicable and can be easily disseminated. Thus, the provision of open data sources (after anonymization if necessary, depending on the content) to facilitate data distribution is crucial to ensuring the public interest. On the other hand,

granting access rights only to specific parties permits individual rights to be protected during personal data use without anonymization or consent. Therefore, it is necessary to show whether the means are appropriate and rational to enable appropriate data use, to build trust in the society of data governance.

Examination of measures suitable for realization of objectives

Even where social agreement has been obtained to access data for a certain purpose, there should be limits to how and to what extent the data is used. Data users need to perform a reasonable evaluation of their methods, including the systems used for data processing and analysis and other technical

considerations, such as data minimization, secure computing and methods to allow appropriate and limited access to the relevant data (instead of turning over the data itself). The goal should be to ensure that the means of data use are in line with the ends.

Transparency

At each stage of data collection, sharing, processing use and use, it should be shown that the data are being used in accordance with the clearly defined objectives. Methods should also be disclosed in sufficient detail to allow for reasonable evaluation

and oversight. Data subjects should retain access to their data and have the right to challenge its use. Maximum effort should be made to explain even the most opaque processes, such as the workings of artificial intelligence and machine-learning algorithms.

Accountability

Given the importance of fully protecting privacy, it is vital that data users collect and process data in accordance with laws and regulations in effect. In addition to the transparency described in 2.2, it is

necessary to clarify who bears ultimate responsibility for the use of the data in question. If data is used improperly, action must be taken promptly in accordance with laws and regulations.

Appropriate operation

In addition to the above conditions for proper implementation, security measures must be taken such as leakage risk assessments, technical security

assessments, screening of people who process the data, development of technical requirements for processing or use, and establishment of restrictions.

2.3 Social agreement

In terms of the "Authorized" in APPA. Being authorized is essential to show the procedural legitimacy of data use. This calls not only for the establishment of certain formal rules, it means that their implementation should be consistent with the constitution in constitutional states.

In the healthcare field, Collaborative Partnership (collaboration with communities) is a specific ethical requirement defined by the National Institutes of Health (NIH)²². Under an APPA-based governance model, it is important to clarify the principles on which the agreement process functions, so that stakeholders can understand the public-interest objective, respect one another's points of view, and share any mutual benefits. It is also important gain the understanding, inasmuch as possible, of any party who will be disadvantaged.

It is a tough challenge to balance these three main elements, especially when they conflict with one another. Although there is no proposal for how to coordinate between all the rights and interests involved in every specific case, we believe that overlooking any of these three elements is fatal. This balance, at the same time, should not be confused with securing them in an equal manner.

Balance between benefits and disadvantages from the perspective of individual data subjects

The social agreement in question must meet APPA standards. For this reason, it is necessary

to thoroughly discuss and clarify what kinds of benefits are generated from the use of the data for individuals who are data subjects, along with risk assessment, to minimize any disadvantages.

Advantages and disadvantages from the perspective of data holders

Data holders need incentives to participate in public-interest projects. These incentives may be either direct or indirect: there may be cases where, even if no direct benefit is to be derived from the project itself, working for the public good will result in the accumulation of innovation know-how within the organization, or enhanced social reputation. By the same token, if citizens are not convinced of the merits of or rationale for a project, data holders may hesitate to move forward due to reputational risk. Therefore, it is necessary to consider how to mitigate such risks and to develop a mechanism for profit-sharing when a project generates monetary value.

Initiative and institutional design for social agreement

Leadership is important. A workable governance system needs actors whose task is to identify stakeholders, take the initiative in discussions and coordinate interests among stakeholders. There is a need for agile system design in which social agreements have a certain degree of legal force and enable data distribution. It should also be noted that the validity of the "social agreement" is under historical assessment.

3

APPA application criteria assessment and questionnaires

The following application criteria are deduced from the APPA principles, with reference to the OECD’s Eight Core Principles on Privacy Protection, the ethical requirements of NIH clinical studies, the data protection impact assessment of the EU Data Protection Commission, and other sources.²³

These application criteria indicate how governance ensures trustworthiness in individual cases of data use. Also, they are to be examined and used for further international rule-making by neutral third-party organizations in the future. In terms of operation, they can be presumed to form a basis for judgements made by each data user. Therefore, each item was scrutinized in terms of cases where data is used for public interest purposes in the healthcare field, including in controversial cases.

In line with the trust-building mechanism of the Trust Governance Framework²⁴:

The APPA application criteria aim to ensure that the data subject (individual X1 in the Framework schematic) and the data holder (X2) trust the data use (Z) performed by the user (Y) according to APPA principles. They present standards to secure the Trustworthiness of Z. The rules for the stated purpose (M) are presented according to the following criteria categories: A) Achievement of true public interest; B) Reasonable means (the guideline to evaluate act Z) and C) Social Agreement. Social agreement criteria should refer to evidence (P), and consideration should be made as to whether governance is designed to secure Trustworthiness (Trustworthiness by design) as a whole.

APPA Deployment Principles	Sub-items	Criteria
Achievement of true public interest	Clarification of purpose of public interest	What is the expected public interest benefit?
Achievement of true public interest	Necessity of public interest purpose	Why is it essential to use data in the manner proposed to achieve the public interest purpose in the case in question?
Achievement of true public interest	Feasibility of public interest purpose	(a) Is the project feasible from institutional and technical perspectives, and under resource constraints such as time and budgets? How is it better compared to alternative approaches?
Achievement of true public interest	Feasibility of public interest purpose	(b) Has the public purpose been clarified to all parties concerned and made available for verification? Has the group has reached a consensus on the issue (unanimity is not required)?
Achievement of true public interest	Public nature of implementation	(c) Is it possible to reasonably achieve standardization and interconnectivity among systems so that data can be used more quickly and safely while ensuring scalability to contribute to the development of society as a whole?

Achievement of true public interest	Public nature of implementation	(b) Is the implementation assessment/social consensus building process in APPA widely shared as examples for data use?
Achievement of true public interest	Public nature of implementation	(c) Are initiatives to define data as "public goods", including opening up data, ensuring transferability and disclosing the results, being sufficiently considered (to the best endeavours)?
Reasonable means	Examination of measures suitable for realization of objectives	Is the system for data processing/analysis inspected to enable data users to adjust their approach to data use and meet their goals? Are rational evaluations conducted about technology, user requirements and other issues?
Reasonable means	Transparency	(a) Has it been clearly shown that the data will be used in accordance with the clarified objectives at each stage of data collection, sharing, processing and use? Have enough details on data-use methods been disclosed to allow for reasonable evaluation and oversight?
Reasonable means	Transparency	(b) Does the data owner have the right to monitor and control the process of data distribution and how their data is shared and used?
Reasonable means	Accountability	(a) Is it clear that data collection, processing and use comply with laws and regulations in such a way that privacy is fully protected and data are acquired by appropriate methods? Is the locus of responsibility for data use clear?
Reasonable means	Accountability	(b) Is there a system in place to promptly respond to data misuse in accordance with laws and regulations?
Reasonable means	Appropriate operation	Are appropriate security measures in place, such as leakage risk assessment, technology security assessment, screening of persons who process or use the data, technical requirements for processing or using the data, and establishment of relevant restrictions?
Social agreement	Balance between benefits and harms from the perspective of individual data subjects	For individuals who are data subjects, risk assessment (who and what rights might be infringed) and what kind of profit (public interest) is generated by data use are clarified, and any disadvantages minimized. Is debate about the conversion exhausted?
Social agreement	Advantages and harms from the perspective of data holders	(a) Is there a risk of abuse due to the superior position of data holders? (Have differences in negotiating power between individuals and data holders been taken into consideration?) Do data holders avoid exploiting individual interests and incorporate profit returns to individuals?

Social agreement	Advantages and disadvantages from the perspective of data holders	(b) Are there potential benefits for data holders? Is there a balance between the burden on data holders and the public interest? Do data holders concur with the overall initiative?
Social agreement	Initiative and institutional design for social agreement	(a) Are actors in place to identify stakeholders, take the initiative in discussions, and coordinate interests among stakeholders?
Social agreement	Initiative and institutional design for social agreement	(b) Does the social consensus have a legal aspect? Or is there an appropriate governance design such as the establishment of a third-party committee that enables convincing data distribution?
Social agreement	Initiative and institutional design for social agreement	(c) Is it possible to constantly take the suitability of the above items, along with the organizations that adopt the APPA framework, into critical consideration?

4

APPA governance implementation methods

4.1 Who uses APPA application criteria

APPA is a governance model that seeks to balance the legal interests of individuals, companies and governments. Bringing it into real-world settings requires active promotion. Since APPA is not a fixed, one-size-fits-all solution, actual governance based on APPA is sometimes best shaped according to each purpose (disaster countermeasures, pandemics, etc.), by applying its foundational principles in a flexible manner.

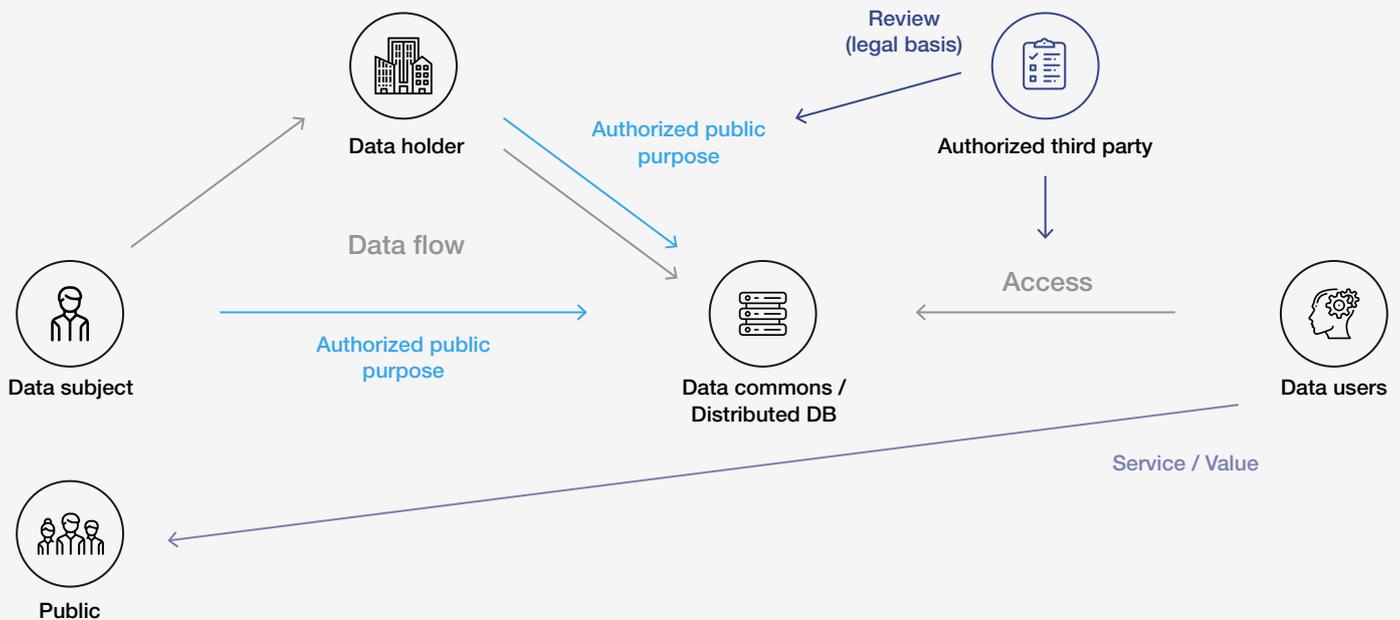
Just as the United Nations took the initiative to set common international Sustainable Development Goals (SDGs), it could be meaningful to pursue some degree of international standardization for APPA, along the lines of the International Organization for Standardization (ISO) or the Institute of Electrical and Electronics Engineers (IEEE).

In a world changed by the Fourth Industrial Revolution, "governance is thus implemented by different entities at multiple levels. In order for these multiple layers of governance to work organically with each other and contribute to building trust in society as a whole, mutual coordination and collaboration are essential."¹¹

The implementation of APPA also demands a mechanism for mutual coordination and cooperation by multiple stakeholders rather than governance solely by law or the outsourcing of all responsibility to a neutral third party.

The figure below illustrates the sort of data flow and governance architecture envisioned

FIGURE 4 APPA governance structure



Data can be provided by data subjects or data holders, and it can be used by third parties (who are then also considered data holders). Data processors, who do not own the data but create value through data analysis and AI learning, can also access data.

Taking cues from medical research, our team considers it necessary to set up third-party institutions

to audit data use according to APPA principles and criteria described above. However, that does not mean we recommend completely relying on this third-party organization and neglecting social monitoring. The framework must also manage tense relationships among stakeholders, including individuals, data holders, data users and states, and make it possible to assess data use historically.

4.2 The third-party approach

The most appropriate governance method depends on the value generated by using data and the scale of the public interest.

On the other hand, depending on the identified "public interest", referencing current schemes could be a realistic approach to implementation.

Therefore, an ideal third-party organization is envisioned in the following three scenarios.

- 1. Governance by international organizations based on guidelines, alliances and other instruments.** In the case of data distribution in a coordinated effort to contain a global pandemic, our team proposes that international organizations such as the United Nations and the World Health Organization (WHO) should play a role in reviewing data use according to the stated purpose while building and standardizing an international data infrastructure. It is also necessary to create a distributed information-sharing infrastructure or Data Commons, a place for open data use, to encourage the participation of data holders, guarantee the rights of individuals and generate benefits for society²⁵. For example, GA4GH is leading in the genome area, and cross-border data access to promote "data visiting" through international alliances may be possible.
- 2. State-controlled governance based on legislation.** The principles for domestic governance are based on legislation. For example, South Korea addressed a SARS public health emergency in 2015 with a legal amendment²⁶. Another example is the "Act on the Secondary Use of Health and Social Welfare Data"²⁷ in Finland. FINDATA²⁸, a data permit authority, was recently established under the Finnish Institute for Health and Welfare (THL) to deal with the secondary use of anonymized healthcare data for academic research and statistical purposes and R&D, and the innovative activities of corporations. In recent years, there has been a growing need to improve safety and quality in healthcare, and demands for secondary use of health and social-welfare data

are increasing. In addition to Nordic countries such as Finland, the development of national databases and secondary-use mechanisms has been promoted in Asian countries such as Thailand and Japan. While such data use, if in line with the APPA principles, can be tolerated by APPA, it is desirable that an independent organization, such as a privacy commission, be able to intervene with a certain level of authority.

- 3. Agile governance capable of responding quickly to technological developments.** Self-imposed standards by the private sector and industry have traditionally served as effective governance in national and international organizations and other areas where technological innovation is rapid. In recent years, with the need for more flexible regulations in conjunction with technological innovation, developments such as joint regulations provide a certain level of legal basis for self-imposed standards, solutions to regulation-related issues (for example, by implementing automated regulations) using technology and RegTech. The latter is an attempt to create a regulatory system and organizational structure that enable the regulatory authorities to monitor the market more efficiently while complying with the regulations more efficiently, taking into account the technologies that can be used by private companies. In addition to such architectures with appropriate governance by design, it is important to build consensus among stakeholders for governance by multiple stakeholders rather than by a single entity.²⁹

These methods need to be employed according to defined public purposes, and their effectiveness is guaranteed only when a third-party organization has the appropriate authority. Granting authority to a third party should not generate another institutional subordination similar to that of states. In addition, because conducting examinations based on individual cases may place excessive burden on third-party organizations, the decision may be made as automated as possible to reduce the burden. In that case, it is also necessary to allow an objection from the disadvantaged party.

4.3 Ethical review for medical research and APPA

In terms of how to use APPA application criteria, governance in healthcare heavily depends on states and international organizations like the WHO. While achieving the public interest of protecting life is a core mission of these public institutions, the COVID-19 pandemic has also cast doubt on the advisability of leaving governance solely to these institutions.

For medical research and advanced medical care, third-party organizations (ethics committees) also participate in governance, supplementing laws and guidelines set by the state to avoid serious human rights violations such as human experimentation in the past.

Ethics committees have recently faced several issues:

- It is unclear what should be examined and what criteria should be used for ethics review. In particular, there is a lack of frameworks and experts to review data handling.
- As the scope of medical research and medical care subject to examination expands, decision-making also involves business factors.
- There is no agreement on how to obtain consent or informed consent in order to protect individual rights. (To what extent is broad consent allowed? What conditions are required to permit opt-out?)
- Trust in the ethics review committee is not secured. (The committee may not function as a trust anchor. From which committee should one obtain approval?)

Along with highlighting issues of concern in the use of ethics committees, the APPA criteria can also serve as guidelines when assessing whether an activity is carried out to in effect achieve genuine public interest goals, even when the activity is not subject to ethics review.

For example, in a case where a company proposes to conduct a study on people's behavioural

changes in response to “nudging,” to encourage people to get vaccinated: Given that the safety and efficacy of vaccines are verified academically, we may expect a certain public interest benefit from encouraging vaccination. However, some citizens resist vaccination, and vaccines are not entirely free from side effects. In such a case, should this nudging activity and related research be accepted?

The APPA framework for such assessment does not answer all of the concerns related to this activity. Some need to be verified separately from the framework, including the effects of vaccination.

The criteria presented here are intended to assess the situation as a whole: in order to evaluate the effectiveness and validity of nudging and its contribution to future vaccine administration (the public purpose), when using data on behavioural change (as a means of data use), what kind of data can be used, and what kind of process is required? (Is there social agreement on the issue?).

Judgement in conventional ethics reviews is often made only by confirming how research is conducted, by looking at factors such as whether participants were given explanations, whether they granted their consent, or whether the collected data were anonymized. We hope to form judgement by taking a closer look at how data is used, after examining whether there is a true public interest, whether the means that will be used to achieve the public purpose is rational, and whether there is social consensus.

In the example above, obtaining consent from participants prior to nudging them could affect the evaluation of the nudge effectiveness. Where there is social agreement, it may be acceptable to collect data first, then analyse it after obtaining consent from participants. Also, completely anonymizing data may prevent governments from providing more precise vaccine support. Therefore, considerations should be reserved for certain standards regarding such data usage, to determine necessary conditions for data analysis without anonymization.

4.4 Next steps

The APPA criteria will go beyond a framework for case-by-case assessment and provide suggestions on how to design medical and healthcare databases. Shared databases have been constructed and used all around the world, in the public and private sectors including academic societies. But even those databases that have made a verified

contribution to controlling infectious disease still have a long way to go in terms of rule-making.

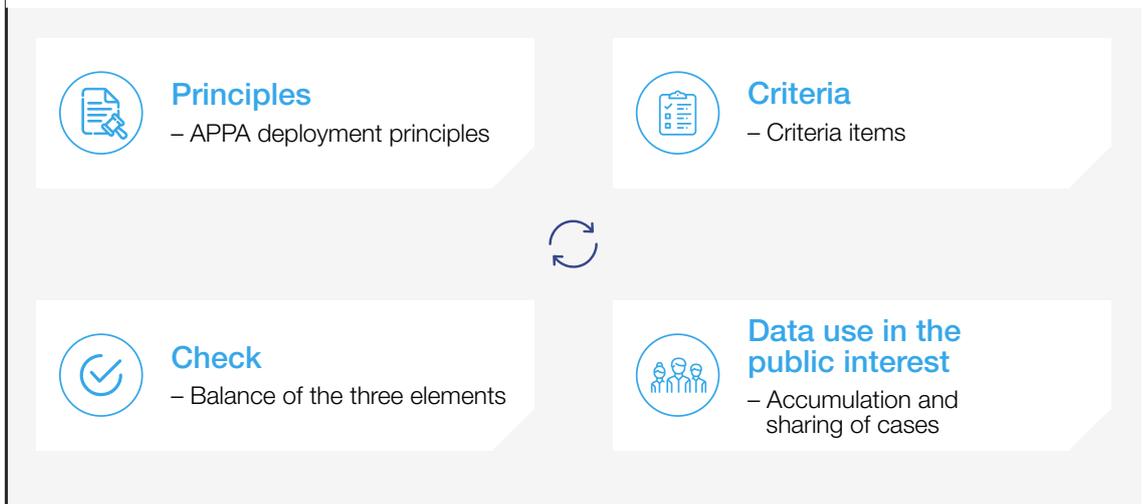
For example, consent may not be required to make decentralized data linkable, if care has been taken to keep data access to the minimum necessary level for the given purpose, transparency has been

ensured and data are being used for goals for which there is sufficient social agreement. When broad consent is obtained first, the use of data should not be allowed after confirming that it is within the scope of the consent, but rather after the assessment using APPA criteria.

In Japan, regulations regarding the secondary use of healthcare data without consent have been developed based on the law in several areas, such as information on cancer or medical fees and information on elderly care. Legislation has been enacted to allow the use of anonymized healthcare data when there is considerable public interest^{30,31}, and guidelines are being considered regarding the disclosure of non-anonymized personal information to third parties without consent due to exceptions such as public health.

In anticipation of such developments, as shown in the figure below, it is important to accumulate examples of how the APPA principles and APPA criteria summarized in this paper are used in practice to govern data use, and to share these examples with stakeholders in each APPA constituency (individuals, businesses and governments). It will also be necessary to monitor over time whether the human rights of individuals, the interests of data holders and the public interest remain balanced in the long run under a given model. The goal is to expand recognition of APPA principles and criteria, gain acceptance by society and improve the real-world functioning of APPA-based systems.

FIGURE 5 Social implementation of the APPA concept



Conclusion

In order to socially implement the concept of Authorized Public Purpose Access (APPA) in the field of healthcare, this white paper presents the APPA principles, judgement criteria and governance methods.

In response to COVID-19, both the public and private sectors have undertaken a range of initiatives that depend on the use of data. While some show how states could take powerful steps with data use, others reaffirm the importance of the private sector, as platformers employ their know-how in collaboration with governments to develop technology and address the pandemic³². Still, many countries remain hesitant to use data due to concerns about human rights and privacy.

APPA deals with individual rights, including the right to privacy, on the premise of a new governance framework for the Fourth Industrial Revolution. A proposed "specific, agreed public purpose" related to COVID-19 might be "the administrative agency responsible for protecting citizens actively uses the data it needs in order to impose/ease restrictions on citizens' activities". Should that be allowed?

Such decision-making is possible only with the involvement of multiple stakeholders, in a process in which public institutions such as international organizations play an important role. International organizations such as the WHO are required to exercise leadership while respecting the judgement of each country. With

the spread of the open-governance movement in the 2010s, there was a trend toward the use of data for public purposes in a range of countries. On the other hand, there is also a great temptation to lock in data (data localization) and conceal or falsify unfavourable data.

Global crises like the COVID-19 pandemic are likely to occur again in the future³³, demanding the development of internationally trusted infrastructure and international regulations for data use. Consideration for individual rights is essential when using mechanisms such as Data Commons and decentralized data architectures. We cannot build trust by using pro forma consent to dodge the guarantee of individual rights.

As of April 2021, the world is still gripped by the COVID-19 pandemic. This devastating crisis may have silver linings in the form of the reaffirmed necessity of data use for the public interest, as well as radical technological innovation. As the situation changes over time, we would like to encourage stakeholders to implement the APPA principles, judgement criteria and governance methods presented here, first within the healthcare field, then expanding to more diverse target areas in the future, in order to develop common assets for all humankind. The use of data for COVID-19 countermeasures has unleashed both great expectations and anxieties. It is hoped that this white paper will serve as a reference for international rule-making.

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Acknowledgements

We wish to express our sincere appreciation to the following for their valuable opinions in the preparation of this white paper.

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Takeda Pharmaceutical

Law guidelines

Law/Guideline	Organization	Category	Reference
OECD Privacy Principles	OECD	International organization	http://www.oecdprivacy.org/
APEC Privacy Framework	APEC	International organization	https://www.apec.org/Publications/2017/08/APEC-Privacy-Framework-(2015)
8 Ethical Requirements	Emanuel, NIH	Academic Society	The Journal of Infectious Diseases, Volume 189, Issue 5, 1 March 2004, Pages 930 – 937, https://doi.org/10.1086/381709 https://www.bioethics.nih.gov/slides/10-29-03-Emmanuel.pdf
Ethically Aligned Design	IEEE	Academic Society	https://standards.ieee.org/content/dam/ieee-standards/standards/web/documents/other/ead1e.pdf
Act on the Protection of Personal Information	Japan	Governance	http://www.japaneselawtranslation.go.jp/law/detail/?id=2781&vm=04&re=01
General Data Protection Regulation (GDPR)	European Commission	Governance	https://gdpr-info.eu/
California Consumer Privacy Act (CCPA)	California, United States	Governance	https://ccpa-info.com/wp-content/uploads/2019/08/bclp-practical-guide-to-the-ccpa-august-2019.pdf
Data Protection Act 2018	United Kingdom	Academic Society	https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted
Consumer Data Privacy in a Networked World	United States	Governance	https://www.ntia.doc.gov/files/ntia/apf_submission_on_us_privacy_white_paper.pdf
Approved Infection Sharing Agreement (New Zealand case)	New Zealand	Governance	https://www.privacy.org.nz/privacy-act-2020/information-sharing/approved-information-sharing-agreements/
Trusted Exchange Framework and Common Agreement (TEFCA)	Office of the National Coordinator for Health IT	Governance	https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf

Endnotes

1. <https://covid19.who.int/>
2. APPA – Authorized Public Purpose Access: Building Trust into Data Flows for Well-being and Innovation <https://www.weforum.org/whitepapers/appa-authorized-public-purpose-access-building-trust-into-data-flows-for-well-being-and-innovation>
3. Solove, “Introduction: Privacy self-management and the consent dilemma”, Harvard Literary Review, vol.126, 2012, pp.1880–1903.
4. Benoli and Becher, “The duty to read the unreadable”, Boston College Law Review, vol. 60, 11 January 2019.
5. “Proposal of the Anti-Monopoly Act concerning the abuse of a dominant position in transactions between digital platform players and consumers providing personal information” [Translated from Japanese], Japan Fair Trade Commission, 29 August 2019: https://www.jftc.go.jp/houdou/pressrelease/2019/aug/190829_dpfp2.pdf (link as of 18/11/20).
6. <https://judiciary.house.gov/news/documentsingle.aspx?DocumentID=3436>
7. Art. 6 GDPR – Lawfulness of processing | General Data Protection Regulation (GDPR) (gdpr-info.eu)
8. <https://elaws.e-gov.go.jp/document?lawid=415AC0000000057>
9. European Data Protection Board, Statement on the processing of personal data in the context of the COVID-19 outbreak https://edpb.europa.eu/our-work-tools/our-documents/statements/statement-processing-personal-data-context-covid-19-outbreak_en
10. <https://sdgs.un.org/goals/goal16>
11. APPA – Authorized Public Purpose Access: Building Trust into Data Flows for Well-being and Innovation <https://www.weforum.org/whitepapers/appa-authorized-public-purpose-access-building-trust-into-data-flows-for-well-being-and-innovation>
12. http://www3.weforum.org/docs/WEF_rebuilding_trust_and_Governance_2021.pdf
13. <https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/>
14. <https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/>
15. see to Law/Guideline Table in Endnotes
16. <http://www.jacr.info/eng/index.html>
17. https://www.city.kakogawa.lg.jp/kurashi/bosai_bohan/ICT/16516.html
18. <https://www.tracetgether.gov.sg/>
19. <http://www.japaneselawtranslation.go.jp/law/detail/?id=2781&vm=04&re=01>
20. <http://www.oecdprivacy.org/>
21. <http://www.oecdprivacy.org/#purpose>
22. <https://academic.oup.com/jid/article/189/5/930/810459>
23. [https://www.dataprotection.ie/sites/default/files/uploads/2019-10/Guide%20to%20Data%20Protection%20Impact%20Assessments%20\(DPIAs\)_Oct19.pdf](https://www.dataprotection.ie/sites/default/files/uploads/2019-10/Guide%20to%20Data%20Protection%20Impact%20Assessments%20(DPIAs)_Oct19.pdf)
24. http://www3.weforum.org/docs/WEF_rebuilding_trust_and_Governance_2021.pdf
25. <https://healthcommonsproject.org/> <https://www.people-tonomachi.com/>
26. http://elaw.klri.re.kr/eng_service/lawView.do?hseq=29132&lang=ENG%20%20https://www.loc.gov/law/help/health-emergencies/southkorea.php#_ftn32
27. <https://stm.fi/en/secondary-use-of-health-and-social-data>
28. <https://www.findata.fi/en>
29. http://www3.weforum.org/docs/WEF_rebuilding_trust_and_Governance_2021.pdf
30. Act on Anonymized Medical Data That Are Meant to Contribute to Research and Development in the Medical Field https://elaws.e-gov.go.jp/document?lawid=429AC0000000028_20201212_502AC0000000044&keyword
31. Act Partially Amending the Health Insurance Act Encouraging Appropriate and Efficient Operation of the Medical Insurance System <https://hourei.ndl.go.jp/simple/detail?lawid=0000148434¤t=-1>
32. https://phii.org/sites/default/files/DT4CT%20White%20Paper_6.30.20-v2.pdf
33. <https://www.theguardian.com/commentisfree/2021/mar/24/covid-pandemic-prepared-investment-science>



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