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- GENERAL CONSIDERATIONS
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  - DATA SHARING AND INTERNATIONAL TRANSFER
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I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 April 2016

on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

(Text with EEA relevance)

GDPR. GENERAL PERSPECTIVE

(157) By coupling information from registries, researchers can obtain new knowledge of great value with regard to widespread medical conditions such as cardiovascular disease, cancer and depression. On the basis of registries, research results can be enhanced, as they draw on a larger population. Within social science, research on the basis of registries enables researchers to obtain essential knowledge about the long-term correlation of a number of social conditions such as unemployment and education with other life conditions. **Research results obtained through registries provide solid, high-quality knowledge which can provide the basis for the formulation and implementation of knowledge-based policy, improve the quality of life for a number of people and improve the efficiency of social services.** In order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards set out in Union or Member State law.

GDPR. GENERAL PERSPECTIVE

(159) Where personal data are processed for scientific research purposes, this Regulation should also apply to that processing. For the purposes of this Regulation, the processing of personal data for **scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research.** In addition, it should take into account the **Union's objective under Article 179(1) TFEU of achieving a European Research Area**.

GDPR. SUBJECT-MATTER AND OBJECTIVES

1. This Regulation lays down rules relating to the protection of natural persons with regard to the **processing of personal data** and rules relating to the **free movement of personal data**.

2. This Regulation **protects fundamental rights** and freedoms of natural persons and in particular their right to the protection of personal data. DATA SUBJECT

3. The free movement of personal data **within the Union shall be neither restricted nor prohibited** for reasons connected with the protection of natural persons with regard to the processing of personal data.

PERSONALIZED MEDICINE AS A STRATEGY IN THE EUROPEAN DIGITAL AND HEALTH SECTOR

European Commission

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Shaping Europe's digital future

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eHealth

The European Commission is working to provide citizens with access to safe and top quality digital services in health and care.

The European Commission published a Communication on the digital transformation of health and care. The Communication aims to empower citizens and to build a healthier society.

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Three priorities

The Communication on the digital transformation of health and care identifies 3 priorities:

1. **citizens' secure access to their health data, including across borders,** enabling citizens to access their health data across the EU;
2. **personalised medicine through shared European data infrastructure,** allowing researchers and other professionals to pool resources (data, expertise, computing processing and storage capacities) across the EU;
3. **citizen empowerment with digital tools for user feedback and person-centred care** using digital tools to empower people to look after their health, stimulate prevention and enable feedback and interaction between users and healthcare providers.

Furthermore, the Communication provides a concrete set of actions on how each priority can be attained.

Communication on the digital transformation of health and care >

Staff working document on the digital transformation of health and care >

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European '1+ Million Genomes' Initiative

The 1+ Million Genomes initiative has the potential to improve disease prevention, allow for more personalised treatments and provide new impactful research.

The '1+ Million Genomes' (1+MG) initiative brings together 22 EU countries, the UK and Norway with a goal to have at least 1 million sequenced genomes accessible in the EU by 2022.

What is the benefit for EU citizens?

Genomics has the potential to revolutionise healthcare in many ways. It could lead to the development of more targeted personalised medicines, therapies and interventions. It could also enable better diagnostics, boost prevention and make more efficient use of scarce resources. From cancer to rare diseases to neurodiseases and prevention, genomics can greatly improve health conditions of EU citizens.

Equally important, genomics has the potential to improve the effectiveness, accessibility, sustainability and resilience of health systems in the European Union.

What are the Signatories trying to achieve?

The Signatory countries have various objectives. Among these, are:

- ensuring that appropriate technical infrastructure is available across the EU, allowing for secure, federated access to genomic data;
- making sure that ethical and legal implications of genomics are clear and taken into account

Follow the latest progress and learn more about getting involved.

Follow the Commission's work on eHealth @eHealth_EU

Sharing data, sharing knowledge, sharing resources

GDPR TERRITORIAL SCOPE (application of all the requirements)

1.GDPR applies to the processing of personal data in the context of the activities of an establishment of a **controller or a processor in the Union**.

2.This Regulation applies to the processing of personal **data of data subjects who are in the Union** by a controller or processor not established in the Union, where the processing activities are related to:

1. the **offering of goods or services**, irrespective of whether a payment of the data subject is required, to such data subjects in the Union; or
2. the **monitoring of their behaviour** as far as their behaviour takes place within the Union.

3. This Regulation applies to the processing of personal data by a controller not established in the Union, but in a place where Member State law applies by virtue of public international law.

IN THIS CASES, ALL THE REQUIRMENTS OF THE GDPR MUST BE APPLIED

ROLES AND DATA FLOW CONTROLLER, PROCESOR

- ‘Controller’ means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data. (The research institution of the researcher would be a controller).

- ‘Processor’ means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller. (A repository that gives a service to the researcher would be a processor).

DATA TRANSFER AGREEMENT (controller/controller) or DATA PROCESSING AGREEMENT (controller/processor)

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PERSONAL DATA

‘personal data’ means any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social id.

PERSONAL DATA

‘pseudonymisation’ means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.

Pseudonymisation is a guarantee often applied in scientific research

ANONIMOUS DATA

The data can no longer be attributed to a specific data subject

- Importance of the context
- Importance of guarantees (ethics revision)
- Dinamic test

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PRINCIPLES

- Lawfulness, fairness and transparency

  1. **Consent** for one or more specific purposes
  2. Performance of a **contract** to which the data subject is party
  3. Compliance with a **legal obligation** to which the controller is subject;
  4. Protect the **vital interests** of the data subject or of another natural person;
  5. Task carried out in the **public interest** or in the exercise of official authority vested in the controller;
  6. **Legitimate interests** pursued by the controller or by a third party,

- Purpose limitation
- Data minimisation
- Accuracy
- Storage limitation
- Integrity and confidentiality (security)
- Accountability

SENSITIVE DATA

- Legal basis (art. 6) + derogation of the general prohibition (art. 9.2)

a) explicit **consent** to the processing of those personal data for one or more specified purposes

(…)

c) processing is necessary to protect the **vital interests** of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent;

(…)

h) processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, **medical diagnosis**, the provision of health or social care or treatment or the **management of health or social care systems and services** on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3;

i) processing is necessary for reasons of **public interest in the area of public health**, such as protecting against serious cross-border threats to health or **ensuring high standards of quality and safety of health care and of medicinal products or medical devices**, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy;

j) processing is necessary for archiving purposes in the public interest, **scientific or historical research purposes** or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

Article 89

Processing for archiving purposes in the public interest, **scientific** or historical research purposes or statistical purposes, shall be subject to **appropriate safeguards,** in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that **technical and organisational measures** are in place in particular in order to ensure respect for the principle of data **minimisation**. Those measures may include **pseudonymisation** provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner.

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SUBJECT RIGHTS

- Right to be informed (Possible exception art. 14)
- Right of access: confirmation as to whether or not personal data are being processed, access to the personal data and information about the circumstances of the processing (Possible exception art. 89)
- Right to rectification of inaccurate personal data (Possible exception art. 89)
- Right to obtain the erasure of personal data (Possible exception art. 17)
- Right to restrict processing: limit the way that a controller uses the data (Possible exception art. 89)
- Right to data portability: receive the personal data in a structured, commonly used and machine-readable format and to transmit those data to another controller when the processing is based on consent pursuant or on a contract pursuant; and is carried out by automated means. (Possible exception art. 89)
- Right to object to processing based on a public interest or legitimate interest (Possible exception art. 89)
- Right not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her unless (…) consent.

- + Right to return of research

- It is a duty to the controller to respond to requests for exercising the data subject's rights
- The processor assists the controller by appropriate technical and organisational measures fro the fulfilment of the controller's obligation
- Equivalents rights have to be guaranteed in the international transfer

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DATA SHARING AND INTERNATIONAL TRANSFER

"SHARING": NOT DEFINED NOR REGULATED IN THE GDPR

TRANSFER: DEFINED (By de European Data Protection Board –EDPB- AND REGULATED IN THE GDPR

- The controller or processor exporting personal data is **subject to the GDPR**
- The exporter **discloses by TRANSMISSION or otherwise makes personal data AVAILABLE** to other controller or processor (importer)

(processing: any **OPERATION** or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction): impact for the fundamental right of informational self determination

- The controller or processor **importing** the personal data is in a third country or is an international organisation

Not applicable when the data subject "gives" the data

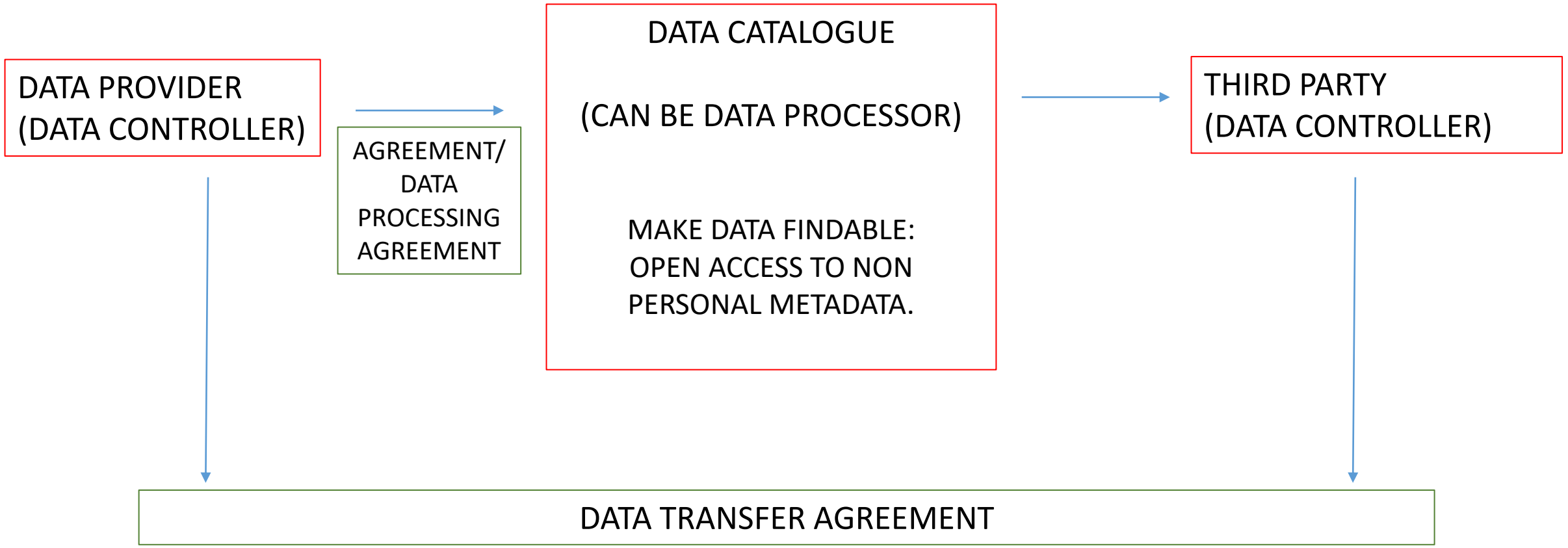
ROLES AND DATA FLOW (international) CONTROLLER, PROCESOR

- ‘Controller’ means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law;

- ‘Processor’ means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller;

DATA TRANSFER AGREEMENT (controller/controller) or DATA PROCESSING AGREEMENT (controller/processor): **INTERNATIONAL DIMENSION**

A MODEL OF FEDERATED DATA **SHARING** STRUCTURE



DATA SHARING AND INTERNATIONAL TRANSFER

Transfers of personal data to third countries (EEA) and international organisations may only be carried out:

- Controller or processor has complied with all the provisions of the GDPR. Prior to carrying out the international transfer, provisions and requirements under the GDPR must also be complied with.

- The conditions laid down in Chapter V are complied with by the controller and processor, including for onward transfers (International transfers tools ITT)

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ITT. CHAPTER V (art. 44-50

Adequacy decision (Article 45). If not:

Appropriate safeguards (Articles 46 and 47). If not:

Specific derogations (Article 49). If not:

Exceptions for one-off or infrequent transfers (second subparagraph of Article 49(1)).

Adequacy decision (art. 45)

Is an act by the Commission

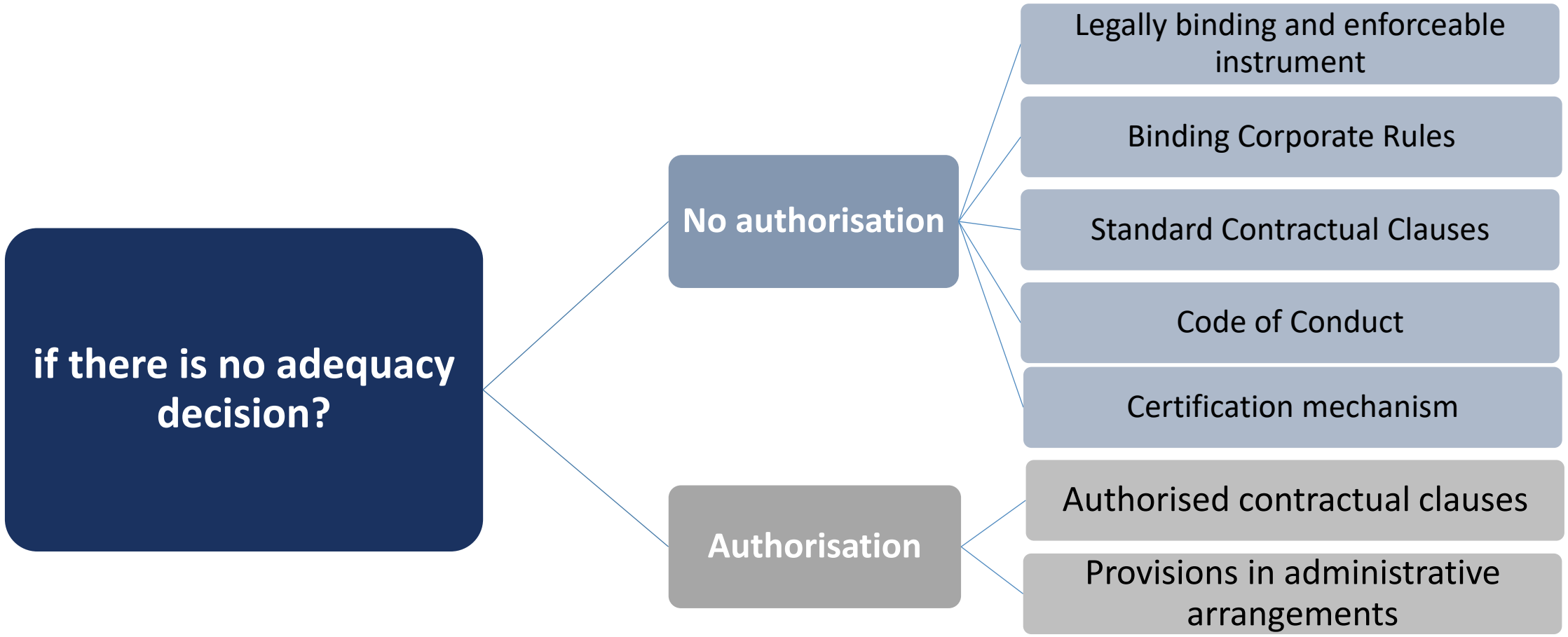
Examination procedure and subject to a periodic review

The decision can refer to a country, a territory, sector or international organization

The decisión has EU-wide effect and no authorisation will be required

Few countries: Andorra, Argentina, Canada (commercial organisations), Faroe Islands, Guernsey, Israel, Isle of Man, Japan, Jersey, New Zealand, Republic of Korea, Switzerland, the United Kingdom (under the GDPR and the Law enforcement Directive) and Uruguay

Appropriate safeguards (arts. 46 and 47)



Specific derogations (art. 49)

a. Explicit and informed consent, including the destination country (for a transfer or a group of transfers in particular)
b. Performance of a contract between the data subject and the controller;
c. Conclusion or performance of a contract concluded in the interest of the data subject between the controller and another natural or legal person
d. Important reasons of public interest (used in covid research);

EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR (February 2021) Q21. In what situations can the data controller rely on the derogation of legitimate interest in Article 49(1)(g) GDPR in the context of scientific research when transferring special categories of data to third countries? 62. A proper response to this question requires further analysis and discussion. The EDPB will elaborate on this issue in its Guidelines on the processing of personal data for scientific research purposes (currently under preparation, due in 2021).

a. Establishment, exercise or defence of legal claims;
b. Protect the vital interests of the data subject or of other persons, where the data subject is physically or legally incapable of giving consent;
c. The transfer is made from a register which according to Union or Member State law is intended to provide information to the public and which is open to consultation either by the public in general or by any person who can demonstrate a legitimate interest.

Exceptions for **one-off or infrequent transfers** (second subparagraph of Article 49(1)).

Where a transfer could not be based on the already described provisions, a transfer to a third country or an international organisation may take place only if the transfer:

- Is not repetitive,
- Concerns only a limited number of data subjects,
- Is necessary for the purposes of compelling legitimate interests pursued by the controller which are not overridden by the interests or rights and freedoms of the data subject

> For scientific or historical research purposes or statistical purposes, the legitimate expectations of society for an increase of knowledge should be taken into consideration (recital 113)

- The controller has assessed all the circumstances surrounding the data transfer and has on the basis of that assessment provided suitable safeguards with regard to the protection of personal data.

The controller shall inform the supervisory authority of the transfer. The controller shall, in addition to providing the information referred to in Articles 13 and 14, inform the data subject of the transfer and on the compelling legitimate interests pursued.

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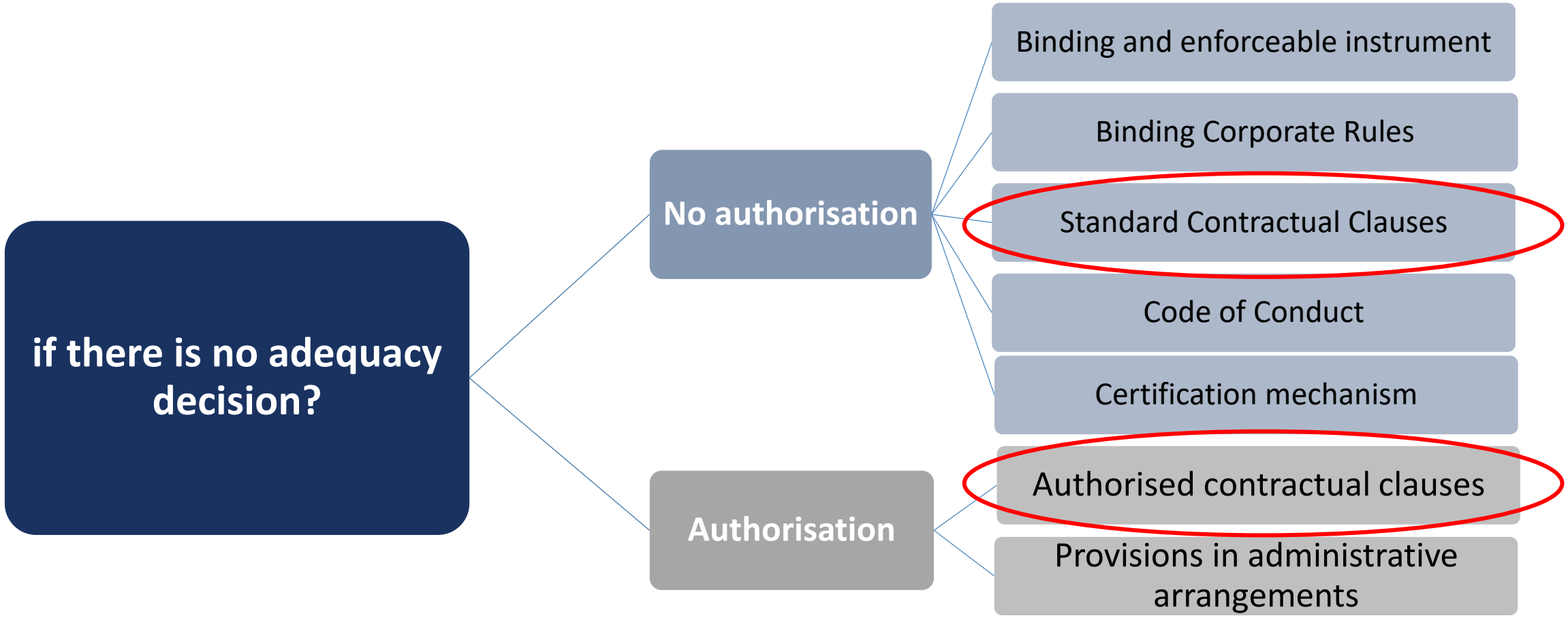
Appropriate safeguards (arts. 46 and 47)



DATA TRANSFER AGREEMENT AS AN INTERNATIONAL TRANSFER TOOL

Commission Implementing Decision (EU) 2021/914 of 4 June 2021 on standard contractual clauses for the transfer of personal data to third countries pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council. C/2021/3972. OJ L 199, 7.6.2021, p. 31–61. Available at: https://eur-lex.europa.eu/eli/dec_impl/2021/914/oj

These SCCs replace those adopted under the previous Data Protection Directive 95/46. Since 27 September 2021, it is no longer possible to conclude contracts incorporating these earlier sets of SCCs.

Until 27 December 2022, controllers and processors can continue to rely on those earlier SCCs for contracts that were concluded before 27 September 2021, provided that the processing operations that are the subject matter of the contract remain unchanged.

DATA TRANSFER AGREEMENT AS AN INTERNATIONAL TRANSFER TOOL (SCC)

SCCs remove the need for the negotiation of individual contracts

•SCCs can be added to existing contracts, not contradictory with the SCC. The clauses shall prevail in case of contradiction with related agreements between the parties

•SCCs are designed to harmonise data protection between those countries within the EEA and those without adequacy this in turn ensures that personal data is protected to a level that is acceptable under GDPR.

•The purpose of the SCC is to ensure compliance with the requirements of the GDPR

•Data subjects may invoke and enforce these Clauses, as third-party beneficiaries, against the data exporter and/or data importer.

•Interpretation of the agreement and the definitions in the light of GDPR.

DATA TRANSFER AGREEMENT AS AN INTERNATIONAL TRANSFER TOOL (SCC)

- Description of the parties

- Description of the data

- Details of the transfer(s), and in particular the categories of personal data that are transferred and the purpose(s) for which they are transferred

- Data protection safeguards: Purpose limitation; transparency; storage limitation; security; specific safeguards regarding sensitive data (pseudonymisation); no onward tranfers; each Party shall be able to demonstrate compliance.

- Use of sub-processors (Needs authorisation.Needs a written contract that provides the same data protection obligations as those binding the data importer under the clauses. The data importer shall remain fully responsible)

DATA TRANSFER AGREEMENT AS AN INTERNATIONAL TRANSFER TOOL (SCC)

• Guarantee of data subject rights. Duty to exporter and importer: assistance

• Information in a transparent and easily accessible format, through individual notice or on its website, of a contact point authorised to handle complaints

• Liability

• Supervision and jurisdiction of a data protection authority in a determinate MS

• Local laws and practices affecting compliance with the Clause: parties have no reason to believe that the laws and practices in the third country of destination applicable to the processing of the personal data by the data importer, including any requirements to disclose personal data or measures authorising access by public authorities, prevent the data importer from fulfilling its obligations under the Clauses.

•Obligations of the data importer in case of access by public authorities

• Non-compliance with the Clauses and termination.

• Governing Law (controller to controller/ controller to processor: MS)

• Choice of forum and jurisdiction (controller to controller/ controller to processor: MS)

DATA TRANSFER AGREEMENT
AS AN INTERNATIONAL TRANSFER TOOL (SCC)

ANNEX. TECHNICAL AND ORGANISATIONAL MEASURES

Described in specific (and not generic) terms

Examples:

Measures of pseudonymisation and encryption

Measures for ensuring confidentiality and integrity of processing systems and services

Measures for ensuring the ability to restore the availability and access to personal data in the event of an incident

Processes for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures

Measures for the protection of data during transmission

Measures for the protection of data during storage

Measures for ensuring physical security of locations at which personal data are processed

Measures for internal security governance and management

Measures for certification/assurance of processes and products

Measures for ensuring data minimisation

Measures for ensuring data quality

Measures for ensuring limited data retention

Measures for ensuring accountability

Measures for allowing data portability and ensuring erasure

Etc.

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CONCLUSIONS

- It is necessary to analyze the requirements for International transfers from a more general perspective of all that the GDPR: the nature of the data, minimization principle.

- It is necessary to design a Data Management Plan with the description of the data flow and the identification for the legal roles of those involved.

- Assement of legal departments and revision of ethics committees

- It is necessary to define the structure of the collaboration. Federated structures are easier to implement.

- The tool for the transfer depends on the dimension of the collaboration. Some potential useful tools are not development.

- The agreement is a good tool but requires the importer to agree to certain conditions.

- Importance of the EDPB Guidelines on the processing of personal data for scientific research purposes (currently under preparation, due in 2021)

POLICY FORUM

DATA SHARING

How to fix the GDPR's frustration of global biomedical research

Sharing of data for research beyond the EU must improve

By Jasper Bovenberg[1], David Peloquin[2], Barbara Bierer[3], Mark Barnes[2,4], Bartha Maria Knoppers[5]

Since the advent of the European Union (EU) General Data Protection Regulation (GDPR) in 2018, the biomedical research community has struggled to share data with colleagues and consortia outside the EU, as the GDPR limits international transfers of personal data. A July 2020 ruling of the Court of Justice of the European Union (CJEU) reinforced obstacles to sharing, and even data transfer to enable essential research into coronavirus disease 2019 (COVID-19) has been restricted in a recent Guidance of the European Data Protection Board (EDPB). We acknowledge the valid concerns that gave rise to the GDPR, but we are concerned that the GDPR's limitations on data transfers will hamper science globally in general and biomedical science in particular (see the text box) (*1*)—even though one stated objective of the GDPR is that processing of personal data should serve humankind, and even though the GDPR explicitly acknowledges that the right to the protection of personal data is not absolute and must be considered in relation to its function in society and be balanced against other fundamental rights. We examine whether there is room under the GDPR for EU biomedical researchers to share data from the EU with the rest of the world to facilitate biomedical research. We then propose solutions for consideration by either the EU legislature, the EU Commission, or the EDPB in its planned Guidance on the processing of health data for scientific research. Finally, we urge the EDPB to revisit its recent Guidance on COVID-19 research.

Concerns that gave rise to the GDPR include that data subjects be informed of use of their personal data and be afforded appropriate rights with respect to the use of their data, and that data users be required to follow certain standards in processing those data. But balancing these concerns against the concerns over research should be informed by the generally scientific research–friendly approach of the GDPR. Current interpretations of the GDPR fail to recognize how research uses of personal data differ from other uses, particularly because data used for research purposes are often pseudonymized, used to derive generalizable knowledge that can benefit society, and can be used in this way without identification of, or perceptible harm to, data subjects. Thus, the balance between privacy of the individual and the benefit to society in the research context is different than in other contexts, such as many commercial contexts in which data are used to construct a profile of an individual to permit targeted advertising with demonstrable impact on the individual.

GLOBAL SHARING OF RESEARCH DATA

The rationale behind the GDPR's limitations on transfers of data outside the EU is simple: When personal data are transferred to non-EU countries, the level of protection ensured in the EU should not be undermined. The limitations aim to ensure that the "GDPR travels with the data." Several routes for valid transfer of research data have been proposed, which we discuss below.

Data may be transferred on the basis of "an adequacy decision." This means that the European Commission has decided that the third country or international organization in question ensures an "adequate level of protection." Such a transnational data transfer does not require any specific authorization. However, to date, adequacy decisions are in place for only a limited number of countries worldwide: Andorra, Argentina, Canada (commercial organizations), Israel, Japan, New Zealand, Switzerland, Uruguay, and the self-governing dependencies of the Isle of Man, Guernsey, Jersey, and the Faroe Islands. The adequacy decision that was in place for the United States, the EU-U.S. "Privacy Shield" framework, was available only to for-profit organizations and today can no longer be used, as it has been invalidated by the recent decision of the CJEU (*2*).

Standard contractual clauses, which bind data transferees to comply with certain data protection standards when they receive and process personal data, are commonly used for cross-border transfer in the commercial context, but they pose particular difficulties for transfers to certain types of data recipients, including governmental agencies such as the U.S. National Institutes of Health or universities outside the EU. Such entities are often barred by their own national laws from agreeing to certain terms required to be included in the standard contractual clauses, including those specifying auditing of data systems by a foreign entity and submission to the jurisdiction of foreign courts (*3*). Many research entities that are arms of sovereign governments either lack authorization to waive their sovereign immunity or have a long-standing policy not to waive such immunity. Moreover, because the EU data transferors are often private universities or research institutes and transferees are governmental or parastatal entities, the individually negotiated interstate transfer agreements contemplated by the GDPR for transfers between two public bodies are not routinely available as an alternative to the standard contractual clauses (*4*).

Although the CJEU has upheld the validity of at least one set of the standard contractual clauses to permit cross-border data transfer, it has also ruled that a data exporter and the recipient of personal data using the clauses are required to verify, prior to any transfer, whether the level of protection required by EU law is respected in the importing country (*2*). It also made clear that recipients outside the EU must return any received data or destroy them "in their entirety" when their domestic laws no longer allow them to comply with the EU clauses (*2*). The verification must consider, as regards any access by public authorities of the importing country to the personal data transferred, the relevant aspects of the legal system of the importing country (*2*). Such an assessment on a case-by-case basis (and its monitoring on an ongoing basis) will probably be beyond the capabilities of most, if not all, EU researchers and their institutions. In essence, this requires resource-limited private parties to undertake the adequacy assessment process that would typically be done by the European Commission.

Even if researchers would somehow be able to complete such an assessment (and to monitor it on a going-forward basis), the standard contractual clauses present complications for multi-party research collaborations, when the recipient organization needs to share the data with other organizations

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GDPR and International Health Data Sharing Forum

Please find below a compendium of all of the GDPR Briefs from the Global Alliance for Genomics and Health.

GDR & International Health Data Sharing Forum: The GA4GH GDPR Forum publishes monthly "GDPR Briefs" that answer important questions about the GDPR's impact on various aspects of international health research and genomic and health-related data sharing, and that further explore the various issues raised in the GDPR Primer.

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If you have any questions or suggestions, please contact us.

International Sharing of Personal Health Data for Research

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Thanks!

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