



***BRACCO GROUP***  
***DATA PROTECTION POLICY***

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## 1. Introduction

In order to support our global business processes, and operations it is essential for the Bracco Group to be able to transfer information, including Personal Data, among its members and its partners. The company's international operations require complying with various legal requirements in different countries and regions. At the same time, adequate protection must be accorded to our business partners, healthcare professionals, our employees and other Data Subjects.

## 2. Objective

This Data Protection Policy defines guidelines and principles for the Processing of Personal Data within the Bracco Group in order to ensure the respect of Data Subjects' rights, fundamental freedoms and dignity, with particular regard to confidentiality, personal identity and the right to Personal Data protection.

## 3. Scope

This Data Protection Policy applies to the Processing of Personal Data of any individual whose Personal Data are processed by and on the behalf of a Bracco Group entity, including employees, customers, healthcare professionals, suppliers, other contractual partners, patients and subjects in clinical trials, and other parties, regardless of the origin of the data. The data protection and data security principles contained within this Data Protection Policy are binding upon all Bracco Group entities.

Bracco may supplement these principles through sub-policies and notices that are consistent with this Data Protection Policy.

Existing legal obligations – both national and international – shall prevail over this Data Protection Policy in countries where the collection or Processing of Personal Data occurs. Every recipient of Personal Data must therefore check whether those regulations apply in his/her field of responsibility and ensure compliance. However, where data protection requirements under national or international law applicable to Personal Data Processing are less strict than under this Data Protection Policy, this Data Protection Policy shall prevail. In certain countries, the Data Protection Authorities require Notification and/or registration from the Data Controller before any wholly or partially automated Processing of Personal Data is performed. Each Bracco Group entity is responsible for complying with any notification and registration obligations in its respective countries. The Transfer of Personal Data to government authorities and agencies is only permissible in accordance with the respective applicable national laws.

Whenever a Bracco Group entity has reason to believe that legal obligations are preventing it from fulfilling its obligations under this Data Protection Policy, it shall notify the Legal & Corporate Affairs Dept. or Global Legal Affairs Dept. ("Legal Affairs") immediately, unless prohibited from doing so by a law enforcement agency under national law.

Bracco Group entities shall then make a responsible decision on the matter in consultation with Legal Affairs and, if necessary, shall notify the respective national Data Protection Authority accordingly.

Bracco Group entities shall develop and implement policies and procedures to comply with the principles of this Data Protection Policy.

## **4. General Principles for Processing Personal Data**

### **4.1 Information to Data Subject and Consent**

The Data subject as well as any entity from whom or which Personal Data are collected shall be preliminarily informed, either orally or in writing, about the purpose of the Processing of Personal Data and the possible Transfer of Personal Data to Third Parties. Furthermore, the Processing of Personal Data is permitted only if the Data Subject has consented thereto or if permissible under applicable law at the place of Processing. The permissibility of Processing Personal Data is a prerequisite for the Transfer of Personal Data pursuant to Section 5.

If required by applicable law, Consent shall be declared in writing or by other legally permissible means. The declaration of Consent must be highlighted when included as part of other statements so as to be clear to the Data Subject.

### **4.2 Intended Purpose**

Personal Data may only be collected and processed for specified, explicit and legitimate purposes and may not be further processed contrary to such intended purposes.

When Personal Data are transferred between Bracco Group entities: (i) the discloser shall communicate to the recipient the intended purpose of the Processing and (ii) the recipient shall take in consideration the intended purpose of the Processing of Personal Data transferred when further Processing and storing this data. Changes of purpose are only permissible with the Consent of the Data Subject or if permitted by national law in the respective country from which Personal Data are transferred.

### **4.3 Data Economy**

The Processing of Personal Data must be required for the intended purpose. The time range for Processing of Personal Data should be strictly necessary to fulfill the intended purposes. Available possibilities for the Anonymization of Personal Data should be used at an early stage, as far as this is possible and the cost is appropriate to the intended protective purpose. This applies in particular with regard to the Personal Data of patients and subjects in clinical trials.

### **4.4 Data Quality & Integrity**

Personal Data must be factually correct and, as far as necessary, up-to-date. Appropriate and reasonable measures should be undertaken to correct or amend incorrect or incomplete data.

### **4.5 Data Security**

The Data Controller shall implement appropriate technical and organizational measures to protect Personal Data against accidental or unlawful destruction or accidental loss, alteration unauthorized disclosure or access. These measures refer in particular to ICT systems (i.e. server, clients, workstations, networks and communication links, operating systems, DBs, and applications). The essential measures which have been implemented within the Bracco Group to avoid the unauthorized Processing of Personal Data include, among other things, controls on:

- information security (physical and logical accesses);
- input of data into data Processing systems;
- data processing within Processing systems;

- output of data from data Processing systems; and
- data transfer among different Processing systems.

In addition, appropriate measures are adopted to protect such data against improper modification, deletion or data loss.

#### **4.6 Confidentiality of Data Processing**

Only authorized personnel, who have undertaken to observe data secrecy requirements, are allowed to be involved in the Processing of Personal Data. It is prohibited for them to use such data for their own private purposes or to make it accessible to any unauthorized person/entity. Unauthorized in this context also means the use of Personal Data by employees who do not need access to such data to fulfill their employment duties.

#### **4.7 Special Categories of Personal Data**

The collection and Processing of Sensitive Data are generally prohibited and allowed under the following circumstances:

- the individual has explicitly consented to the Processing (“opt-in”); or
- the sensitive data have manifestly been made public by the individual; or
- where necessary to comply with an obligation of employment law as authorized by national law; or
- it is necessary for the protection of a vital interest of the data subject or a Third Party, and the Data Subject is unable for physical or legal reasons to declare his/her Consent; or
- it is necessary for the exercise, enforcement or defense of legal claims and it cannot be expected that the justified interests of the Data Subject not to collect or process Personal Data prevail; or
- it is necessary for the performance of scientific research, the scientific interest in performing the research project prevails over the interests of the Data Subject not to collect or process Personal Data, and if the purpose of the research cannot be achieved otherwise or only with disproportionately high effort.

Furthermore, pharmaceutical research and development (e.g. pharmacovigilance) are subject to numerous national and international legal provisions which especially protect the personal rights of the Data Subject in respect of the Processing of Sensitive Data. Depending on the category of Sensitive Data and the risks associated with the intended use, appropriate security measures pursuant to Section 4.5 will be taken (e.g. Pseudonymization, technical security devices, encryption and limitation of physical access).

#### **4.8 Contract Data Processing**

Where Processing operations are to be carried out on behalf of a Bracco Group entity acting as Data Controller, the Data Controller shall choose a Data Processor providing sufficient guarantees to implement appropriate technical and organisational measures and procedures in such a way that the Processing will meet the requirements of any applicable Law and of this Data Protection Policy and ensure the protection of the rights of the Data Subject, in particular in respect of the technical and organizational security measures governing the Processing to be carried out and shall ensure compliance with those measures.

If the Data Processor is not a Bracco Group entity, to which this Data Protection Policy applies, such guarantees may have to be secured by obligating the Data Processor to observe the general principles of this Data Protection Policy or by applying the standard contractual clauses provided by Legal Affairs in line with European Union (EU) indications;

The carrying out of Processing by a Data Processor shall be governed by a contract or other legal act binding the Data Processor to the Data Controller and stipulating in particular that the Data Processor shall:

- (a) act only on instructions from the Data Controller, in particular, where the transfer of the Personal Data used is prohibited or subject to certain conditions;
- (b) employ only staff who have committed themselves to confidentiality or are under a statutory obligation of confidentiality;
- (c) take all required measures in order to ensure a level of security appropriate to the risks represented by the processing and the nature of the Personal Data to be protected, having regard to the state of the art and the costs of their implementation;
- (d) enlist another Data Processor only with the prior permission of the Data Controller;
- (e) insofar as this is possible given the nature of the Processing, create in agreement with the Data Controller the necessary technical and organizational requirements for the fulfillment of the Data Controller's obligation to respond to requests for exercising the Data Subject's rights described in Section 6;
- (f) assist the Data Controller in ensuring compliance with any applicable obligations on data security measures or concerning consultation with competent Data Protection Authorities;
- (g) hand over all results to the Data Controller after the end of the Processing and not process the Personal Data otherwise;
- (h) make available to the Data Controller and the competent Data Protection Authority all information necessary to control compliance with the obligations laid down in any applicable Law.

## **5. Transfer of Personal Data**

### **5.1 Transfer of Personal Data in general**

The Transfer of Personal Data across national borders is only permissible if such data are properly protected or if the Bracco Group entity that processes the data can give an adequate guarantee that the Privacy of the individuals whose data are transmitted is being protected. This Data Protection Policy is designed to ensure that all Bracco Group entities meet this requirement.

A Transfer of Personal Data within the European Union (EU) is generally permitted if Processing of the data is also permitted according to Section 4.1.

For Transfer of Personal Data within the country in which data has been collected, compliance with the existing legal requirements of the respective country must be ensured.

### **5.2 Transfer of Personal Data from the EU to Third Countries**

Based on Section 4.1 of this Data Protection Policy, the Transfer of Personal Data from an EU country to a Third Country is permitted only if:

- the Data Subject has explicitly given his/her Consent; or

- the Transfer of Personal Data is necessary for the performance of a contract between the Data Subject and the Data Controller or in order to take steps prior to entering into a contract initiated by the Data Subject; or
- the Transfer of Personal Data is necessary to complete or to fulfill a contract which was made or is to be made with a Third Party by the Data controller in the interest of the Data subject; or
- the Transfer of Personal Data is either required or prescribed by law for the protection of an important public interest or for the exercise, enforcement or defense of legal claims; or
- the Transfer of Personal Data is necessary for the protection of a vital interest of the Data Subject; or
- the transfer is carried out in response to a request for access to administrative records or for information contained in a publicly available register, list, record or document, in compliance with the provisions applying to this subject-matter; or
- a contract has been concluded between a single Bracco Group entity and the relevant Third Party or Bracco Group entity that receives the Personal Data that provides for safeguards at a similar level of protection as that provided by these rules; the contract shall conform to any model contract requirement under applicable local law; or
- the Third Party has been certified by the European Commission as providing an “adequate” level of data protection.

In any case, the Bracco Group entity that receives Personal data has to provide sufficient guarantees within the meaning of this Data Protection Policy with respect to the protection of personal rights and the exercise of rights related thereto.

If the recipient is not a Bracco Group entity, it must be ensured that this Data Protection Policy applies to the recipient accordingly. The Bracco Group entity transferring Personal Data will take appropriate measures in case of violations by the recipient.

### **5.3 Transfer of Personal Data within a Third Country or to another Third Country**

The further Transfer of Personal Data which have been transferred from the EU to a recipient within the Third Country or to another Third Country is only permitted, subject to Section 4.1, if such Third Country has an adequate data protection standard or if one of the circumstances described in Section 5.2 of this Data Protection Policy applies. In any case, the Bracco Group entity in the EU which transferred the Personal Data shall be informed prior to a further Transfer of Personal Data within the Third Country or to another Third Country.

### **5.4 Co-operation with the competent Data Protection Authorities**

A local Bracco Group entity shall respond to all requests for information from the local Data Protection Authority, to the extent such requests are consistent with applicable law and regulations and relate to compliance with this Data Protection Policy:

- in the country; or
- in relation to Personal Data exported by the entity.

A Bracco Group entity shall take into account and endeavor to comply with the advice of the Data Protection Authority in relation to the interpretation and application of the national law and shall cooperate with the Data Protection Authority to the extent consistent with applicable law or regulations and without waiving any defenses and/or rights of appeal available to the Bracco Group entity. The Bracco Group entity shall also procure that other affiliates to which the entity transfers Personal Data out of the



European Union shall take into account and endeavor to comply with such advice to the extent such advice is relevant to their Processing of Personal Data transferred.

## **6. Rights of the Data Subject**

### **6.1 Information Right**

Each Data Subject has the right to demand information about the type of Personal Data concerning him/her that is processed by a Bracco Group entity. This information will be provided irrespective of the place where the Personal Data are processed.

### **6.2 Correction Claim**

If the stored Personal Data are incorrect or incomplete, the Data Subject may request correction. Data Subjects are responsible for providing only correct Personal Data to the respective Bracco Group entity.

### **6.3 Rejection of Request for Information or Correction**

If the request for information or correction is rejected, the Data Subject will be informed about the reason for such rejection.

### **6.4 Deletion**

If the Data Subject demonstrates that the purpose for which the Personal Data are processed is no longer permissible, necessary or reasonable under the circumstances, the respective Personal Data will be deleted, subject to legal provisions to the contrary.

### **6.5 Right to Object**

Each Data Subject has a general right to object, at any time on compelling legitimate grounds relating to their particular situation, to the Processing of his/her data.

If a Data Subject objects, the Bracco Group entity shall no longer process the applicable Personal Data for the purpose for which the Data Subject objected.

## **7. Procedural Rules**

### **7.1 Implementation within the Bracco Group**

The Bracco Group entities, as Data Controllers, must ensure compliance with the principles embodied in this Data Protection Policy. In this respect, the managerial employees of the Bracco Group entities shall ensure that this Data Protection Policy is implemented, which includes in particular providing information to the employees. Information shall also include emphasizing that violation of the general principles of this Data Protection Policy may possibly entail consequences under criminal, liability or labor law.



## **7.2 Training**

A Bracco Group Data Controller shall provide or arrange appropriate training on these rules and other Privacy and data security obligations to personnel that have permanent or regular access to Personal Data, that are involved in the collection of Personal Data or in the development of tools used to process Personal Data.

## **7.3 Monitoring Compliance**

Bracco Group Corporate Headquarters (“HQ”) will evaluate, test and report on the Bracco Data Controller’s compliance with this Data Protection Policy.

Such audit must be carried out on a regular basis by the internal or external accredited audit team.

The results of all audits should be communicated to the relevant board of management.

Where any noncompliance with this Data Protection Policy is identified in such audits, the relevant business manager shall design and implement remediation measures.

## **7.4 Questions and Complaints/Remedies**

Data Subjects may contact HQ or his/her local representatives at any time with any questions and complaints regarding the Processing of Personal Data. Such questions and complaints will be treated confidentially.

If a question or complaint raised by a Data Subject relates to an alleged violation of this Data Protection Policy by a Bracco Group entity located in a country other than the country in which the Data Subject resides, the Data Subject may contact the Bracco Group entity which transferred the data. Should the alleged violation be confirmed, the Bracco Group entities affected will cooperate with the respective parties (e.g. Data Protection Authorities, other entities) in line with this Data Protection Policy and remedy such alleged violation.

## **7.5 Obligation towards Data Protection Authority**

Each Bracco Group entity shall cooperate and assist each other to handle a request or complaint from an individual or an investigation or inquiry by Data Protection Authorities.

## **7.6 Amendment of the Data Protection Policy and Continued Application**

Bracco reserves the right to amend this Data Protection Policy as necessary, for instance to comply with changes to statutes, regulations, requirements of Data Protection Authorities or internal Bracco procedures.

Should this Data Protection Policy become invalid, irrespective of the reasons or causes for such invalidity, all Bracco Group entities are bound by this Data Protection Policy with respect to Personal Data transferred prior to the date of such invalidity.

## **7.7 Transparency**

In order to make the principles accessible to Data Subjects, the current version of this Data Protection Policy shall be made available to all Data subjects in a suitable manner, e.g. via the Intranet or Internet.

## 8. Definitions

**Anonymization** is the changing of Personal data such that they can no longer be assigned to a certain or ascertainable individual.

**Bracco Group** means Bracco S.p.A. and all companies in which Bracco S.p.A., directly or indirectly, holds more than 50 % of the shares or has comparable control rights.

**Consent** is any freely given, informed declaration by the data subject that he/she accepts the Processing of his/her Personal Data. Consent may be subject to particular requirements arising from respective national laws.

**Data Controller** is the legally independent Group entity that decides the purposes and means of Processing Personal Data.

**Data Processor** is the individual or legal entity that processes Personal Data on behalf of a data controller.

**Data Protection/Privacy** is the sum of all actions taken to protect the personal rights of data subjects when handling their personal data.

**Data Protection Authorities** are the public authorities responsible for monitoring the application within its territory of the Data protection/Privacy laws.

**Data Subjects** are all individuals whose personal data are processed within the Global Business Unit Imaging, including current, future and former employees, customers, suppliers and other contractual partners, interested persons, subjects and patients in clinical trials.

**Personal Data** are any information relating to an identified or identifiable individual. An individual is identifiable if he/she can be directly or indirectly identified, e.g. by assigning a reference number.

**Processing of Personal Data/Processing** is any automated or non-automated operation or set of operations performed in respect of personal data – such as collection, recording, storage, adaptation, alteration, selection, retrieval, use, transmission, blocking, deletion or erasure. This definition will also apply to the word “processed” when used in this context.

**Pseudonymization** is the replacement of a data subject’s name and other identifiable characteristics with a label for the purpose of preventing identification of the data subject by unauthorized parties or to greatly impede such identification.

**Sensitive Data** are special categories of personal data concerning racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, health and sexual orientation.

**Third Country** is every country outside the European Union (EU).



**Third Party** is every individual or legal entity that cannot be assigned to the data controller, e.g. every external business partner but also any other company in the Group. Third parties are not the data subject himself/herself nor contract data processors within the European Union (EU).

**Transfer of Personal Data** is the forwarding of personal data, its distribution or all other forms of transfer to third parties. A transfer of personal data includes situations in which (i) Bracco discloses Personal Data to third parties (e.g., in the context of corporate due diligence); and (ii) Bracco provides remote access to Personal Data to a Third Party. This definition also applies analogously to the words “transferred” and “transferring” when used in this context.