

Data processing Policy - Clinical Products



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1. Introduction

When EPILOG (hereinafter “**EPILOG**” or the “**Processor**”) performs Services for the customer and the end-user (hereinafter collectively the “**User (s)**” or “**Controller(s)**”), it shall (i) have access to Personal Data; (ii) will have to Process Personal Data for which the Users are responsible as joint-Controllers in accordance with the applicable Privacy Legislation.

This Data Processing Policy applies to the Processing of Personal Data by EPILOG for the Customer and determines (i) how EPILOG will manage, secure and process the Personal Data, and (ii) Parties’ obligation to comply with the applicable Privacy Legislation.

The approval of the customer with this Data Processing Policy and consequently of how EPILOG processes Personal Data of Data Subjects is entailed by relying on the Services of EPILOG. The approval of the end-users with this Data Processing Policy and consequently of how EPILOG processes Personal Data of Data Subjects is entailed by checking the “*I agree with the Acceptable Use Policy, Data Processing Policy, Privacy Policy and Cookie Policy*” box.

2. Definitions

Assignment: All activities, such as but not limited to the Services, performed by EPILOG for the Users, and any other form of cooperation whereby EPILOG Processes Personal Data for Users, regardless of the legal nature of the agreement under which this Processing takes place;

Customer: every professional entity relying on the Services of EPILOG;

Data Subject: the patient and/or participant of a clinical trial or clinical research whose data is processed via the Services of EPILOG as collected by Users;

Data Processing Policy: this data processing policy;

Data Breach: Unauthorized disclosure, access, abuse, loss, theft or accidental or unlawful destruction of Personal Data, which are Processed by EPILOG on behalf of Users;

EPILOG NV: a limited liability company (“naamloze vennootschap”) incorporated and existing under the laws of Belgium, with registered office at 9000 Ghent, Vlasgaardstraat 52, Belgium, with VAT/company number BE-0664.618.462, RPR/RPM Gent, and any of its affiliates;

EPILOG CO.: a Delaware corporation, with registered office at NY 10036 New York, 1177 Avenue of the America’s (7th floor), USA, and any of its affiliates;

EPILOG: Both EPILOG NV and EPILOG CO combined;

End-User: any individual (such as but not limited to physicians or other health care professionals, researchers and/or employees of the Customer), authorized by the Customer to access and use the Platform(s) on behalf of the Customer;

Personal Data: Any information relating to an identified or identifiable natural person;

Privacy Legislation:

If the assignment is performed by EPILOG NV: (i) the Belgian Privacy Law of 30 July 2018 concerning the protection of individuals with regard to the processing of personal data, (ii) the General Data Protection Regulation 2016/679 of April 27, 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC and/or (iii) the (future) Belgian legislation regarding the implementation of the General Data Protection Regulation;

If the assignment is performed by EPILOG CO.: **(i)** the Health Insurance Portability and Accountability Act of 1996, **(ii)** the Health Information Technology for Economic and Clinical Health Act and **(iii)** all rules, regulations, and related laws and acts promulgated under and in connection therewith;

Process/Processing: Any operation or set of operation which is performed upon Personal Data or sets of Personal Data, whether or not by automated means, including, but not limited to: collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction of Personal Data;

Services: all services provided by EPILOG to Users within the framework of the Assignment, implying the Processing of Personal Data by EPILOG;

Sub-processor: Any processor engaged by EPILOG;

Overview of personal data: Overview of **(i)** the Personal Data, which parties expect to be subject of the Processing, **(ii)** the new Personal Data created during the Processing, **(iii)** the categories of Data Subjects, which Parties expect to be subject of the Processing, **(iv)** the use (i.e. the way (s) of Processing) of the Personal Data, the purpose and means of such Processing and **(v)** the term(s) during which the (different types of) Personal Data shall be stored;

Description of the technical and organizational measures: Overview and description of the security measures taken by EPILOG under this Data Processing Policy.

3. Roles of the Parties

Parties acknowledge and agree that with regard to the Processing of Personal Data, the Users shall be considered 'joint-Controllers' and EPILOG 'Processor' in accordance with the applicable Privacy Legislation.

4. Use of the Services

4.1. The Users acknowledge explicitly that:

- EPILOG purely acts as a facilitator of the Services. Hence, the Users shall be solely responsible on how and to what extent it makes use of the Services;
- The Users are solely liable for (and indemnifies EPILOG for) all acts and omissions of the people mandated by Users to make use of the Services. Users shall inform said people of the applicable Privacy Legislation, this Data Processing Policy and/or all other relevant legislation and impose compliant use;
- EPILOG bears no responsibility with regard to adjustments and/or changes made to the Personal Data on the explicit request of Users;
- Users are solely liable and responsible for the material and/or data provided by Users, as Users are solely liable for complying with the Privacy Legislation and/or any other regulations with regard to aforementioned material and/or data;
- Users are solely liable and responsible for the data and/or Personal data created by the Services of EPILOG, as Users are the Controllers of the created data and/or Personal Data and consequently solely liable for complying with the applicable Privacy Legislation and/or any other regulations with regard to aforementioned data and/or Personal Data;
- Users shall be solely responsible to comply with all laws and regulations (such as but not limited with regard to the retention period) imposed on it by making use of the Services;
- EPILOG is allowed to use in any way (Personal) Data provided by the Users as well as any and all output created via the Services of EPILOG, upon the condition that the Personal Data is anonymized, and such use is only for statistical purposes and/or to further develop and optimize the EPILOG Services and Platforms (even after termination). EPILOG shall never use said data for any other commercial purpose or detriment to the Customer. This obligation shall, however, in no event imply that EPILOG shall not be entitled to use and/or commercialize any ideas, input, feedback received from the Users, which may serve to improve and/or expand the Services.

4.2. In case of misuse by Users of the Services and/or the Personal Data that was created by the Services, Users agree that EPILOG can never be held liable in this respect nor for any damage that would occur from such misuse.

4.3. Users therefore undertakes to safeguard EPILOG when such misuse would occur as well as for any claim from a Data Subject and/or third party due to such misuse.

5. Object

5.1. Users acknowledge that as a consequence of making use of the Services of EPILOG, the latter shall Process Personal Data as collected by Users.

5.2. EPILOG shall Process the Personal Data in a proper and careful way and in accordance with the applicable Privacy Legislation and other applicable rules concerning the Processing of Personal Data.

More specifically, EPILOG shall – during the performance of the Assignment – provide all its know-how in order to perform the Assignment according to the rules of art, as it fits a specialized and ‘good’ processor (as defined in the Privacy Legislation).

5.3. Nonetheless, EPILOG shall only Process the Personal Data upon request of Users and in accordance with its instructions, as described in [Overview of personal data](#), unless any legal obligation states otherwise.

5.4. Users own and retain full control concerning (i) the Processing of Personal Data, (ii) the types of Personal Data Processed, (iii), the purpose of Processing, and (iv) the fact whether such Processing is proportionate (non-limitative).

Moreover, Users shall be solely responsible to comply with all (legal) obligations in its capacity as Controllers (such as but not limited to the retention period) and shall have the sole responsibility for the accuracy, quality, and legality of the Personal Data, disclosed to EPILOG in the performance of the Assignment, and the means by which it acquired such Personal Data. The responsibility and control concerning the Personal Data, subject to this Data Processing Policy, shall thus never be vested with EPILOG.

6. Security of processing

Taking into account the state of the art, EPILOG implements appropriate technical and organizational measures for the protection of (i) Personal Data – including protection against careless, improper, unauthorized or unlawful use and/or Processing and against accidental loss, destruction or damage – (ii) the confidentiality and integrity of Personal Data, as set forth in [Description of the technical and organizational measures](#).

7. Sub-processors

7.1. Users acknowledge and agree that EPILOG may engage third-party Sub-processors in connection with the Assignment. In such case, EPILOG shall ensure that the Sub-processors are at least bound by the same obligations by which EPILOG is bound under this Data Processing Policy.

7.2. The Processor undertakes to make a list available concerning the Sub-processors on which it appeals for the performance of the Assignment. Such list shall include the identities of those Sub-processors and their country of location. It is the Users responsibility to frequently check the list of Sub-Processors and inform EPILOG of any objections. If the Users wish to exercise its right to object, it shall notify EPILOG in writing and in a reasoned manner by the latest within thirty (30) days after the list was updated.

7.3. In the event the Users object to a new Sub-processor and such objection is not found unreasonable, EPILOG will use reasonable efforts to (i) make available to Users a change in the Services or (ii) recommend a commercially reasonable change to the Users use of the Services to avoid Processing of Personal Data by the objected new Sub-processor without unreasonably burdening the Users.

If EPILOG is, however, unable to make available such change within a reasonable period of time (which shall not exceed thirty (30) days following the objection of the Users), the Customer may terminate the Assignment / the Services, under the following conditions:

- The Services cannot be used by the Users without appealing to the objected new Sub-processor; and/or
- Such termination solely concerns the Services which cannot be provided by EPILOG without appealing to the objected new Sub-processor;

And this by providing written notice thereof to EPILOG within a reasonable time.

7.4. EPILOG shall be liable for the acts and omissions of its Sub-processors to the same extent as if it would be performing the Services itself, directly under the terms of this Data Processing Policy.

7.5 For a list of sub-processors, please refer to [List of EpiLog sub-processors](#).

8. Transfer of personal data to third countries

8.1. The Services are provided by EPILOG NV: Any transfer of personal data to a third country or international organization (which is not based on a request or instruction of the Customer) shall be subject to an adequacy decision by the Commission or the following safeguards:

- Closing a data transfer agreement with such recipient, which shall contain the standard contractual clauses, as referred to in the ‘European Commission decision of 5 February 2010 (Decision 2010/87/EC)’, or;
- Binding corporate rules, or;
- Certification mechanisms (such as but not limited to the EU-US Privacy Shield).

8.2. The Services are provided by EPILOG CO.: In compliance with the Privacy Legislation, personal data may be transferred or stored in any state of the United States.

8.3. A copy of the used safeguards can at all times be requested via [insert email].

9. Confidentiality

9.1. EPILOG shall maintain the Personal Data confidential and thus not disclose nor transfer any Personal Data to third parties, without the prior written agreement of the Users, unless when:

- Explicit written deviation;
- Such disclosure and/or announcement is required by law or by a court or other government decision (of any kind). In such case EPILOG shall, prior to any disclosure and/or announcement, discuss the scope and manner thereof with the Users.

9.2. Users acknowledge and agree that the Personal Data shall (in accordance with the Privacy Legislation) be shared with EPILOG's employees, representatives, officers, directors, agents, advisors, affiliates, subcontractors and consultants who have a need to know such Personal Data for the purposes of rendering the Services. EPILOG ensures that its employees, representatives, officers, directors, agents, advisors, affiliates, subcontractors and consultants, engaged in the performance of the Assignment, are informed of the confidential nature of the Personal Data, have received appropriate training on their responsibilities and have executed written confidentiality agreements. EPILOG ensures that such confidentiality obligations survive the termination of the employment contract.

9.3. EPILOG ensures that its access to Personal Data is limited to such personnel performing the Assignment in accordance with the Data Processing Policy.

10. Notification

10.1. EPILOG shall use its best efforts to inform Users within a reasonable term when it:

- Receives a request for information, a subpoena or a request for inspection or audit from a competent public authority in relation to the Processing of Personal Data;
- Has the intention to disclose Personal Data to a competent public authority;
- Determines or reasonably suspects a Data Breach has occurred in relation to the Personal Data.

10.2. In case of a Data Breach, EPILOG:

- Notifies the Users without undue delay after becoming aware of a Data Breach and shall provide – to the extent possible – assistance to the Users with respect to its reporting obligation under the Privacy Legislation;
- Undertakes – as soon as reasonably possible – to take appropriate remedial actions to make an end to the Data Breach and to prevent and/or limit any future Data Breach.

11. Rights of Data Subjects

11.1. If a Data Subject requests to exercise his/her rights and the Users itself – in its use of the Services – do not have the ability to correct, amend, block or delete the Personal Data (as required by Privacy Legislation), EPILOG shall – to the extent it is legally permitted to do so – comply with any commercially reasonable request by the Users to facilitate such actions.

To the extent legally permitted, the Users shall bear the responsibility for any costs arising from EPILOG provision of such assistance.

11.2. EPILOG shall, to the extent legally permitted, promptly notify the Users if it receives a request from a Data Subject for access to, correction, amendment or deletion of that Data Subject's Personal Data. EPILOG shall, however, not respond to any such Data Subject request without the Users prior written consent except to confirm that the request relates to the Users to which the Users hereby agree.

EPILOG shall provide the Users with commercially reasonable cooperation and assistance in relation to the handling of a Data Subject's request for access to that person's Personal Data, to the extent legally permitted and to the extent the Users do not have access to such Personal Data through its use of the Services.

To the extent legally permitted, the Users shall be responsible for any costs arising from EPILOG' provision of such assistance.

12. Return and deletion of Personal Data

12.1. Upon termination of the agreement between the Customer and EPILOG, the Users shall be notified by EPILOG of its possibility to export the Personal Data through the available export tools and during a six months after the termination of the aforementioned agreement.

12.2. Once the aforementioned term regarding export has passed, EPILOG shall permanently delete the Personal Data resp. anonymize it.

13. Control

13.1. EPILOG undertakes to provide the Users with all information, required by the Users to allow verification whether EPILOG complies with the provisions of this Data Processing Policy.

13.2. In this respect EPILOG shall allow the Users (or a third party on which the Customer appeals) to undertake inspections – such as but not limited to an audit – and to provide the necessary assistance thereto to the Customer or that third party.

14. Term

The Data Processing Policy lasts as long as the Assignment has not come to an end.

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