

5. Data Processing Agreement (GDPR Article 28)

Between Countagen AB (“Processor”) and the Customer identified in the applicable Order (“Controller”)

5.1 Definitions

Terms such as “personal data,” “processing,” “controller,” “processor,” “data subject,” and “personal data breach” have the meanings given in the GDPR (Regulation (EU) 2016/679).

5.2 Subject Matter and Duration

This DPA governs Countagen's processing of Personal Data on behalf of Customer in connection with the Services described in the relevant Order, for the duration of that Order plus any period necessary for data return or deletion under Clause 5.10.

5.3 Nature, Purpose, and Categories of Processing

See Annex 1 for the specific details applicable to each Order. In general: Countagen processes Sample-derived sequencing data and associated metadata for the purpose of performing targeted on-target/off-target genomic confirmation and generating the agreed Deliverables — nothing more. Countagen receives only extracted genomic DNA, its concentration, and eventually Customer-specified genomic loci coordinates for probe design — not patient names, dates of birth, medical record numbers, or procedure details; sample tracking uses only a Customer-assigned project/sample code. This DPA does not restrict Countagen's separate right, under Section 4.7A of the Master Service Terms, to generate and use aggregated, de-identified performance data across multiple customers and projects; that aggregated data does not identify Customer or any data subject and falls outside the scope of Personal Data processed under this DPA.

5.4 Processor Obligations

Countagen shall:

- Process Personal Data only on documented instructions from Customer, including regarding international transfers, unless required to do otherwise by EU or Member State law;
- Ensure that personnel authorised to process Personal Data are subject to confidentiality obligations;
- Implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk (see Annex 2);
- Not engage a sub-processor without Customer's prior general or specific written authorisation (Clause 5.5);
- Assist Customer, insofar as reasonably possible, in responding to data subject requests and in complying with obligations under GDPR Articles 32–36;
- Notify Customer without undue delay after becoming aware of a personal data breach affecting the Personal Data;

- At Customer's choice, delete or return all Personal Data at the end of the engagement, and delete existing copies unless EU or Member State law requires storage;
- Make available to Customer information necessary to demonstrate compliance with this DPA and allow for audits, including inspections, conducted by Customer or an auditor mandated by Customer.

5.5 Sub-Processors

Countagen may engage sub-processors (e.g., sequencing service providers, cloud storage/compute providers) to support delivery of the Services. Countagen will inform Customer of any intended changes concerning the addition or replacement of sub-processors, giving Customer the opportunity to object on reasonable data-protection grounds.

5.6 International Transfers

Where processing of Personal Data involves a transfer outside the European Economic Area (including to sub-processors), Countagen shall ensure the transfer is subject to appropriate safeguards under GDPR Chapter V (e.g., Standard Contractual Clauses).

5.7 Security Measures

Countagen shall implement the technical and organisational measures described in Annex 2, and review them periodically in light of the risk presented by the processing, in particular given that the data may include genetic data.

5.8 Personal Data Breach Notification

Countagen shall notify Customer without undue delay, and in any event within 48 hours of becoming aware, of any personal data breach affecting Personal Data processed under this DPA, providing information reasonably necessary for Customer to meet its own breach-notification obligations under GDPR Articles 33–34.

5.9 Assistance with Data Protection Impact Assessments

Countagen shall provide reasonable assistance to Customer in connection with data protection impact assessments and prior consultations with supervisory authorities, where required due to the nature of the processing (which may be the case given the involvement of genetic data).

5.10 Return or Deletion of Data

On completion of the Services or termination of the relevant Order, and subject to any agreed retention period for quality/regulatory purposes, Countagen shall, at Customer's election, return or securely delete all Personal Data (including Sample-derived sequencing data) in its possession, and confirm deletion in writing upon request.

5.11 Liability

Each party's liability under this DPA is subject to the limitation of liability set out in the LockSeq Master Service Terms (Section 4.12), except to the extent such limitation is not permitted under mandatory data protection law.

5.12 Term

This DPA remains in effect for as long as Countagen processes Personal Data on behalf of Customer under any Order.

Annex 1 — Details of Processing

Item	Description
Subject matter	Targeted sequencing-based confirmation of on-target and off-target gene-editing outcomes in Customer-submitted Samples
Duration	Duration of the relevant Order, plus agreed retention/deletion period
Nature of processing	Extraction/receipt of sequencing reads, target capture data analysis, variant calling, report generation
Purpose of processing	Delivery of the Deliverables (analysis report and sequencing data) to Customer
Categories of Personal Data	Genetic data derived from Samples — specifically extracted genomic DNA and its sequencing/variant-calling output at Customer-specified loci (special category under Art. 9 GDPR). Countagen additionally receives DNA concentration (non-personal, analytical metadata) and a Customer-assigned project/sample code. Countagen does not receive patient names, dates of birth, medical record numbers, editor/procedure identity, or other directly identifying information.
Categories of Data Subjects	Research subjects, patients, or research animals whose samples are submitted by Customer (human data subjects only where applicable)
Sub-processors	<ul style="list-style-type: none"> • Sequencing service: Xpress Genomics AB, EUROFINS SCIENTIFIC SE, Azenta Europe GmbH • Cloud storage and compute: Google LLC

Annex 2 — Technical and Organisational Security Measures

- Access to sequencing data and reports restricted to authorised personnel only
- Pseudonymisation/coding practices for sample identifiers, and data at rest and in transit
- Backup and disaster recovery procedures
- Physical security of lab and data storage locations (Nobels väg 16, 171 65 Solna, Sweden)
- Staff confidentiality agreements and restricted access