

Privacy standards and compliance with Illumina Connected Software

Meeting high standards of
data privacy and protection



Introduction

Advances in next-generation sequencing (NGS) technologies have dramatically increased the amount of data generated, creating challenges in data analysis and interpretation. Illumina offers several cloud-enabled solutions for customers to manage, analyze, and interpret large volumes of genomic data in a secure, scalable, and integrated environment. Cloud-based solutions within the Illumina Connected Software portfolio include BaseSpace™ Sequence Hub, Clarity LIMS™ software, Correlation Engine, Emedgene™ software, Illumina Connected Analytics, and Illumina Connected Insights.

Illumina developed the entire bioinformatics portfolio, including cloud-based solutions, with the European Union's (EU) General Data Protection Regulation (GDPR) privacy principles in mind and a view to ensuring compliance with applicable regulations and standards around the globe. This technical note details the steps that Illumina has taken to best support customers in meeting relevant privacy standards and regulations.

Approach to data privacy and protection

Many privacy and data protection laws, including the EU's GDPR, impose obligations on entities processing "personal data" (ie, information relating to an identified individual or one who can be identified), with the aim of ensuring a high level of protection for that data. These same laws also commonly apply to the "processing" of personal data, which ranges from passive retention, hosting, or anonymization.

Privacy laws, such as GDPR, impose specific obligations on "controllers" and "processors." Controllers make crucial decisions on data processing, including the purposes for which processing takes place, decisions on which data will be processed, who it will be shared with, and how long it will be retained. Controllers are primarily responsible for compliance with applicable laws. By contrast, processors carry out processing operations on behalf of a controller. Some obligations, eg, security obligations, apply directly to processors, but a processor's obligations are primarily set out in a contract with their relevant controller.

Illumina is a processor for customers using our cloud-based software solutions, hosting and analyzing personal data provided by customers in accordance with their research use cases. The Illumina [data processing addendum](#) governs our provision of our cloud-based solutions to customers. This agreement contains specific terms required by applicable laws and, among other things, obliges Illumina to:

- Process personal data only on the customer's instructions
- Ensure that all of our staff are subject to confidentiality obligations
- Implement appropriate security measures to protect against data breaches and to notify customers of any data breaches
- Assist the customer in meeting relevant data protection obligations, eg, responding to requests from data subjects to exercise their rights and conducting data protection impact assessments
- Share data with 'subprocessors' that enter into agreements containing substantially similar terms
- Delete all data as described in the agreement with the customer
- Make information available to customers to demonstrate compliance

To make sure that Illumina can not only comply with these obligations in the context of cloud-based informatics, but also better serve our customers, we have designed and implemented a comprehensive privacy program.

Illumina privacy program

The Illumina privacy program is supported by executive sponsorship across the organization. It is developed and managed by a core cross-functional team of representatives from business functions such as commercial, information security, R&D, and human resources. This approach helps to foster a positive culture of data protection compliance.

We have implemented various internal measures to embed privacy and data protection:

- Development and implementation of a comprehensive internal data protection policy and multiple information security policies
- Designation of a full-time specialist Global Data Protection Officer (DPO), whose tasks include monitoring and advising on compliance with applicable privacy and data protection laws
- Mandatory data protection training for all employees

Illumina has received ISO 27001 security certification and ISO 27701 privacy certification for six of its solutions within the Cloud Bioinformatics Portfolio:

- BaseSpace Sequence Hub
- Clarity LIMS Enterprise
- Correlation Engine
- Emedgene software
- Illumina Connected Analytics
- Illumina Connected Insights product line

DRAGEN™ secondary analysis pipelines can be also be run within ISO 27001 certified BaseSpace Sequence Hub or Illumina Connected Analytics environments.

The ISO 27701 privacy certification, which builds on existing Illumina ISO 27001 certification, provides independent assurance on privacy and personal data protection controls and guides organizations on establishing, maintaining, and improving a Privacy Information Management System (PIMS).

Illumina ISO 27001 certification and ISO 27701 privacy extension can be accessed [here](#). Illumina will continue to pursue ISO 27001 and 27701 certifications for newly launched informatics products. We have also taken various steps to ensure that customers can comply with their substantive GDPR obligations. Illumina continues to build its privacy stance through additional certifications as well.

In 2024, our suite of informatics products also received the APEC PRP (Asia-Pacific Economic Cooperation Privacy Recognition for Processors) certification. This internationally recognized certification demonstrates Illumina's compliance with the security safeguards and accountability principles of the APEC Privacy Framework.

Illumina security measures

Security is a foundational principle of data protection laws. In addition to maintaining ISO 27001 and 27701 certifications and compliance with various global security policies, Illumina implements state-of-the-art security measures, including:

- Access control management (limited access to systems on a “need to know” and “least privilege” basis)
- Monitoring and logging
- Encryption
- Vulnerability management
- Physical controls

Privacy impact assessments

Illumina conducts privacy impact assessments on our cloud-based solutions as part of our Privacy by Design procedures. In carrying these out, we identify potential privacy risks arising from the use of these services (if any) and implement the measures necessary to mitigate those risks.

Data subjects' rights

Data protection laws, eg, the GDPR, grant individuals various rights over their personal data, such as rights to access a copy of their data and have it deleted. Illumina cloud-based solutions enable customers to manipulate their data within the defined set of pipelines or margins of the various Cloud Services, helping customers comply with their obligations in relation to data subjects' rights.

International data transfers

Illumina allows customers to choose to store their data in specific regions if they wish to do so. When providing technical support, in limited circumstances (eg, escalations that can only be handled by specific teams or in cases of out-of-hours support), Illumina may need to access personal data stored within a particular region from another country to ensure high levels of performance and security can be continuously maintained.

Most countries' data protection laws, including GDPR, do not outright prohibit companies from transferring data to different jurisdictions. Instead, data can be transferred to, or remotely accessed in, other countries where certain circumstances apply. GDPR sets out a number of such circumstances (and similar concepts also appear in other global data protection laws), including where:

- The data will be transferred to a country that the European Commission has determined provides an "adequate" level of protection for personal data (eg, the United States with respect to commercial organizations participating in the EU-US Data Privacy Framework)
- The "exporter" and "importer" put safeguards in place, such as the contractual clauses approved by the European Commission ("Standard Contractual Clauses") or Binding Corporate Rules (BCRs).

Illumina incorporates Standard Contractual Clauses (and the UK and Swiss Addenda) in its data processing addendum with customers and its intragroup agreement that applies to international data transfers between entities within the Illumina group. The Standard Contractual Clauses commit the importer to provide the level of protection for personal data as is required by the GDPR. In addition, the importer must review and challenge any requests or demands for personal data they receive from local public authorities where there are reasonable grounds to do so.

In addition, Illumina is also in progress of receiving approval of its "controller" and "processor" BCRs application, which was submitted to the Dutch data protection authority in 2021. BCRs are another approved mechanism for international transfers under the GDPR. A group of companies with approved "processor BCRs" can receive personal data from customers anywhere in the world, and further transfer the data internally, without the need for entering into the Standard Contractual Clauses.




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Finally, with regards to data transfers from the EU to the US, on 10 July 2023, the European Commission adopted its eagerly expected adequacy decision on data transfers under the EU-US Data Privacy Framework (the "EU-US DPF"). The EU-US DPF provides a new lawful basis for data transfers from data exporters in the EU to US data importers. This means that transfers covered by the scope of the EU-US DPF are permitted without further legal safeguards being necessary (ie, Standard Contractual Clauses and BCRs).

Recipients in the US that want to use the Data Privacy Framework must self-certify their adherence to the EU-US DPF Principles. Illumina has certified to the US Department of Commerce that it complies with the EU-US DPF and adheres to the EU-US DPF Principles with regards to the collection, use and retention of personal data transferred from the European Union to the US.

 [Learn more about the EU-US DPF, and view our certification](#)

Learn more

[Privacy standards and compliance with Illumina Connected Software FAQ](#)

[BaseSpace Sequence Hub](#)

[Clarity LIMS software](#)

[Illumina Connected Analytics](#)

[Illumina Connected Insights](#)

[Emedgene software](#)

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