

GDPR & ILLUMINA PROACTIVE

Introduction

The General Data Protection Regulation (GDPR) is a European Union (EU) regulation that went into effect May 25, 2018 to establish obligations for organizations that collect or process personal data of EU citizens. This regulation is part of an evolving body of privacy laws that establish data protection rules. The basic requirement for legal protection is the existence of personal data, defined under Article 4(1) as any information related to an identified or identifiable natural person (e.g., name, address, email, etc.).

As a global leader in next-generation sequencing, Illumina handles personal data, including genetic data, which is a special category of personal data under the GDPR. At Illumina, we have measures in place to protect personal data that are outlined in our Privacy Policy. **It is important to note that the GDPR is not implicated when personal data is not involved.**

Is the data collected by Proactive subject to GDPR protection?

No. Illumina Proactive is a monitoring service in which **instrument performance data and not personal data are sent to Illumina** to enable more accurate diagnosis of failures and detection of failure risks. By activating Proactive, users **maximize instrument uptime** through preemptive detection and notification of elevated instrument risk. Direct access to the instrument through Proactive **accelerates efficient troubleshooting**.

At no point does Proactive access personal data. Illumina instruments are designed to capture *instrument* performance data, which are any metric that can characterize the operational performance of the instrument, including software logs, instrument configurations and other file types.

The instrument performance data captured by Proactive do not contain personal data. Since the GDPR applies only to personal data, it is not applicable to Proactive services.

Doesn't GDPR have different requirements for special categories of data such as the genomic data being processed by Illumina's instruments?

Yes. Under Article 9 of the GDPR, certain types of sensitive personal data require a higher level of protection because of the risk associated with processing this data. Genetic data, biometric data for the purpose of uniquely identifying a natural person, and data concerning health all fall under the GDPR's special category of personal data. Genetic data files that are processed on Illumina instruments such as fastq and BAM files may qualify as special categories of data. However, as stated above, the performance data captured and transmitted to Illumina by the Proactive service **never** contains personal data, including special categories of data. Proactive does not collect personal data or genetic data – the tool only captures instrument performance data, therefore, GDPR is not applicable.

Since Illumina is based in the United States, if Proactive is enabled, are there international data transfer terms that need to be put in place to comply with GDPR?

No. Since Proactive does not capture or transmit personal data, GDPR data transfer requirements are not an issue. Other Illumina cloud-based solutions such as BaseSpace Sequence Hub, Clarity LIMS and Illumina Connected Analytics may have data transfer implications separate from Proactive. Those solutions were developed with a Privacy by Design methodology and, where possible, limit international data transfer issues.

If Proactive is enabled on an instrument, does Illumina have access to the genomic or other personal data on that instrument?

Illumina Proactive sends instrument performance data, which includes software logs and instrument configurations (refer to Tables 8 through 13 of the [Illumina Proactive Technical Note](#) for specific data files.). Illumina Proactive does not send sequencing run data with genetic sequences (fastq files), sample sheets or personal data.

What terms govern the use of Proactive?

There are legal terms of use associated with Proactive – Instrument Performance Data Legal Terms. These terms include provisions that Illumina may collect, maintain, process, and use diagnostic, functionality, and performance related data and related information to facilitate the provision of Hardware and Software updates, product support, verification of compliance with the terms of the Software's end user license agreements and Illumina's standard Terms and Conditions applicable to this Hardware, make improvements to Illumina's products and services, and make recommendations and/or provide products or services to customers.