SECURITY BRIEF

Illumina Emedgene™ software

Enterprise-level, secure genomics research data platform

- Conforms with data privacy provisions and key regulations like HIPAA, GDPR, and SOC 2 Type II
- Meets global and local data privacy and requirements with ISO/IEC 27001:2022 and ISO/IEC 27701:2019, respectively; Illumina QMS meets ISO 13485:2016
- Includes compliance with administrative, physical, and technical safeguards required by HIPAA
- Provides multilayered, security-first infrastructure built with encryption, two-factor authentication, role-based management of PHI/PII data, and more

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Introduction

Analyzing, handling, and storing large-scale genomics data for a diverse range of research applications requires enterprise-level protection. To keep Illumina platforms, products, and web applications secure for everyone, we partnered with top-tier cloud providers around the globe to build Emedgene software with security at the core. Emedgene software is a customizable platform that streamlines user-defined tertiary analysis and research report generation to help labs address data interpretation bottlenecks as they bring next-generation sequencing (NGS) assays in house or scale existing workflows.

Emedgene software can integrate directly with Illumina Connected Analytics and shares enterprise-level data privacy and security standards (Table 1), empowering labs performing deep data science and supporting data sharing on a secure and compliant platform. Illumina Connected Analytics is a comprehensive, cloud-based data management and secondary analysis platform that enables researchers to manage and process large volumes of genomic data in a secure, scalable, and flexible environment.

Data within Emedgene software and Illumina Connected Analytics are hosted on Amazon Web Services (AWS) and maintains compliance with a wide variety of industry-accepted security standards using AWS Well-Architected best practices.[1] By committing to local and global security policies, Illumina aims to reduce roadblocks encountered by researchers to realize the true potential of genomics data and workflow solutions.

Key security and privacy features

Availability

In the context of cloud-computing services, internal and external availability risks exist. To address these concerns, Illumina built a business continuity and disaster recovery plan into its business process. Emedgene software is installed on a high-availability cloud infrastructure that adheres to ISO/IEC* 27001:2022 and Uptime Institute Tier III design standards to guarantee dedicated network connectivity, redundancy, uninterruptible power supply, and effective data backup strategies.

The ISO 27701 privacy 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. 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, Emedgene software, along wtih the other Illumina 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.

Record keeping and audit logs

Emedgene software allows for record keeping and audit logs, ensuring IT accountability within the platform for virtually all objects, actions, and activities, including viewing an object.

API protection

Emedgene software was built with application programming interface (API) protection in mind. All service methods require API key signatures, and service is refused to all others. Requests are monitored for abuse.

Encryption for sensitive data

Emedgene software prioritizes confidentiality of data processing activities in the cloud environment. Data uploaded from sequencing instruments undergo encryption both "in transit" and "at rest" using the AES* standard and transfer layer security (TLS 1.2 or newer).

Bring your own key (BYOK)

Emedgene supports BYOK. Users may double-encrypt data with a key that is fully controlled and managed by them. Supported BYOK functions are push, search, and read double-encrypted data on Emedgene software. Supported BYOK solutions are AWS Key Management Service (KMS) and Azure Key Vault.

* ISO, International Organization for Standardization; IEC, International Electrotechnical Commission; AES, Advanced Encryption Standard.

Table 1: Emedgene software and related Illumina company certifications and accreditations

Certification	Description
ISO/IEC 27001:2022	International standard for managing risks to the security of information; certification to ISO 27001 proves information management; the standard adopts a process-based approach for establishing, implementing, operating, monitoring, maintaining, and continually improving an ISMS
ISO/IEC 27701:2019	The ISO 27701 privacy certification provides independent assurance on privacy and personal data protection controls and guides organizations on establishing, maintaining, and improving a PIMS.
ISO 13485:2016	International quality management standard for medical devices that specifies requirements for a Quality Management System where an organization needs to demonstrate the ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.
APEC PRP	This internationally recognized certification demonstrates the compliance of Illumina with the security safeguards and accountability principles of the APEC PRP framework.
AWS standards and accreditations	
SOC 1 and 2 / SSAE 16 / ISAE 3402	An audit verifying that AWS controls to protect customer data are properly designed and that the individual controls are operating effectively.
Federal Information Security Management Act (FISMA) Moderate	An accreditation granted by the US Government to strengthen federal information system security; for reference, the NIH data centers are rated FISMA moderate

ISMS, information security management system; PIMS, privacy information management system; Asia-Pacific Economic Cooperation Privacy Recognition for Processors, APEC PRP; Service Organization Controls, SOC; SSAE, Statements on Standards for Attestation Engagements; ISAE, International Standards for Attestation Engagements; Federal Information Security Management Act, FISMA

Third-party penetration testing

Third-party penetration tests simulate an attack on a system's deployment and are a good way to actively test defenses. Illumina employs an unbiased third party to conduct penetration tests for Emedgene software cloud instances. After the vendor finishes the test, Illumina receives a comprehensive report, detailing the results (Illumina does not release the results of these penetration tests).

Data isolation

Emedgene software offers the highest degree of data isolation by implementing industry-standard data segregation techniques, including the need-to-know principle, enforced through technical and organizational measures, eg, role-based access governed by fine-grained security controls.

Data management and retention

Emedgene software is a fully automated data management platform that stores customer data synchronously across multiple availability zones within a geographic region, performs regular data integrity checks, and self-heals to protect against data loss.

Global standards and certifications

Emedgene software is ISO/IEC 27001:2022 certified by an independent auditor for the full scope of its activities, including development, management, and support of a cloud-based analysis platform.

Emedgene software was developed in accordance with the Illumina Software Life Cycle (SLC) process under the Illumina Quality Management System (QMS). Illumina operates and maintains a QMS, which complies with the requirements of ISO 13485. Also, processes within the Illumina QMS have adopted industry best practices and relevant standards, such as ISO 14971 for risk management and IE62304 for SLC.

Additionally, Emedgene software complies with DCB 0129, the UK National Health Service clinical risk management standard attained by manufacturers of health IT systems to ensure clinical safety of products.[2]

Integrity

Emedgene software uses public key infrastructure (PKI); hashing techniques ensure data flow integrity and origination across the entire solution. Customer database backup occurs up to 24 times per day to decrease the risk of data loss. In addition, the system contains logging that provides notification when data are altered. If improper alteration is detected, rolling back to a previous backed up version is available.

Login policies

Emedgene software enforces strong password requirements, a renewal period, an inactivity timeout, and the option to implement single sign-on (SSO). Individualized logins are also available, enabling multiple users to access the platform per instance.

Portability

The lack of vendor lock-in removes legal impediments to export client data only by the appropriately permissioned client.

Two-factor authentication

An authentication service is supported by Security Assertion Markup Language (SAML) 2.0 to manage institutional users and passwords (optional). Step-up authentication also ensures protection of sensitive actions. Two-factor authentication is an available configuration option enabling customers to set up their own federated access management process.

HIPAA and GDPR compliance

Emedgene software supports customers operating in regulated environments and is in accordance with current data protection laws, including General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA).†

Illumina complies with core GDPR principles and implements a Privacy by Design and by Default approach, which requires organizations to integrate data protection into processing activities and business practices. Privacy by Design ensures that the organization considers privacy and data protection issues at the design phase and then throughout the lifecycle. Privacy by Default emphasizes the need to process only the data that is necessary to achieve the intended purpose.

Illumina supports the requirements of HIPAA, including administrative, physical, and technical safeguards. Illumina facilities that process protected health information (PHI) or personally identifiable information (PII) are in compliance with HIPAA and employ industry best practices such as:

- Buildings are monitored 24 hours a day and keycard accessed
- Offices have a monitored security system
- Computers used to access or store PHI are password protected and have full-disk encryption turned on
- Any access from outside the office is via a secure virtual private network (VPN)

Role-based management of sensitive data

Emedgene software supports customers operating in regulated environments with stringent compliance requirements. Emedgene software includes fine-grained, configurable access controls that govern individual user access and management of sensitive PHI/PII data within the platform. To prevent error, data loss, or tampering, system access is restricted based on which roles require access and the tasks those roles are required to complete.

Transparency

Emedgene software complies with most data residency and privacy requirements; data center regions and providers are disclosed.

Shared responsibilities

Illumina is responsible for protecting the infrastructure that runs all services offered in the AWS Cloud. This infrastructure is composed of the hardware, software, networking, and facilities that run AWS Cloud services. Part of this responsibility requires that Illumina performs recurring security patch updates or other updates to protect the environment from emerging threats and supports iterative improvements. Illumina provides these updates during windows defined in the Emedgene software Terms and Conditions. Customers required to comply with HIPAA are responsible for ensuring that they have a HIPAA

† Contact your Illumina representative to discuss additional data center needs

compliance program in place and that they use Emedgene software in a manner to ensure their compliance.

Guaranteed data residency

Emedgene software provides data residency to address local regulatory and compliance requirements. Built with the same exceptional security and privacy features as Connected Analytics, Emedgene software employs a region-specific instance model where omics data files, metadata, and health data are stored in the region the user selects. In globally distributed, high-performance computing centers, the platform regulates access to the data; the actual omics data flow, including data download and data view, occurs between the browser and the regional web server directly. When collaborating with partners in different regions, users can implement cross-regional access, reducing latency while ensuring data residency. Data centers supporting Emedgene software include:

- US East (N. Virginia) us-east-1
- Canada (Central) ca-central-1
- UK (London) eu-west-2
- Germany (Frankfurt) eu-central-1
- Israel (Tel Aviv) il-central-1
- Japan (Tokyo) ap-northeast-1
- South Korea (Seoul) ap-northeast-2
- Middle East (UAE) me-central-1
- Australia (Sydney) ap-southeast-2

Learn more

Emedgene software

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