BaseSpace® Variant Interpreter and HIPAA

Rapidly extract biological insight from genomic data with a scalable solution.

Introduction

BaseSpace Variant Interpreter is an easy-to-use platform that enables laboratories to extract biologically relevant information from next-generation sequencing (NGS) data with efficiency and accuracy. Any platform that analyzes sensitive health information should contain features that address data security. This technical note outlines how BaseSpace Variant Interpreter addresses some of the core security requirements of the Health Insurance Portability and Accountability Act (HIPAA).

Background on HIPAA

HIPAA was enacted in the United States in 1996. After becoming law, the United States Department of Health and Human Services (HHS) implemented multiple regulations to carry out the law in practice. HHS is also the regulatory agency that oversees compliance with HIPAA. Among other things, HIPAA established national standards for the security and privacy of protected health information (PHI). HIPAA was significantly updated in 2009 when the Health Information Technology for Economic and Clinical Health Act (the HITECH Act) became law. Major provisions of HIPAA include the Security Rule, Privacy Rule, and Breach Notification Rule. Visit the HHS Health Information Privacy website[1] for more information on HIPAA, its history, and links to the specific HIPAA regulations.

BaseSpace Variant Interpreter and HIPAA

BaseSpace Variant Interpreter is designed and operated to meet requirements of the HIPAA Security Rule. The HIPAA Security Rule includes a requirement that administrative, physical, and technical safeguards be in place to ensure the confidentiality, integrity, and security of electronic protected health information (ePHI). BaseSpace Variant Interpreter has been designed with features and Illumina has implemented controls to meet the core elements of the HIPAA Security Rule (Table 1).

Administrative Safeguards

BaseSpace Variant Interpreter follows established policies, procedures and, where applicable, technical controls designed to ensure the security of data in the platform. These policies restrict access to data to a minimum set of employees, and supporting procedures address the process for access authorization, establishment, modification, and termination of access. Backup, business continuity, and incident response procedures are also documented and tested.

Table 1: Security Rule Controls

Security Control	Description
Administrative Controls	Conducting risk assessments
	Introducing a risk management policy
	Training employees to be secure
	Reporting security incidents
Physical Controls	Facility access controls must be implemented
	Policies relating to workstation use
	Policies and procedures for mobile devices
	Inventory of hardware
Technical Controls	Access control: unique user identification
	Access control: emergency access procedure
	Authentication: authentication procedures to verify user identity
	Transmission security: integrity controls
	Transmission security: encryption

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Physical Safeguards

Illumina hosts the BaseSpace Variant Interpreter platform on information technology infrastructure in secure Amazon Web Services facilities, certified under the ISO 27001 standard and meeting the control requirements of HIPAA. The facilities have built-in redundancies and strict physical access controls.

Technical Safeguards

BaseSpace Variant Interpreter implements various technical controls designed to ensure the confidentiality and integrity of the data, starting with access control. Network traffic is restricted via strict, stateful network firewalls. Administrative access to the platform is restricted and requires multifactor authentication. All access to the platform is logged and monitored. Data are further protected in transit (whenever it leaves the data center) using Transport Layer Security (TLS) protocol. Genomic data and ePHI at rest is protected using Advanced Encryption Standard (AES). BaseSpace Interpeter also undergoes vulnerability scans and penetration tests.

BaseSpace Variant Interpreter also contains security features that allow customers the ability to control and monitor access to the system and data. Access to the solution can be managed through direct authentication or via Single Sign-On with customer infrastructure. BaseSpace Variant Interpreter can be configured to lock out accounts after a configurable number of failed attempts for a configurable duration. Password complexity can also be configured to align with customer password policies. Customers can audit access to the system by account, including create, read, update, and delete of ePHI and genomic data.

Learn More

BaseSpace Variant Interpreter is available for a limited amount of time as a free trial. For more information visit www.illumina.com/variantinterpreter.

References

1. Health Information Privacy website. www.hhs.gov/hipaa. Accessed September 7, 2017.

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