The Complete Solution for Genomic Security and Compliance

DNAnexus is the global leader in genome informatics and data management, providing the industry’s most comprehensive security and privacy framework. Learn why the FDA, top pharmaceutical companies, global diagnostic test providers, genome centers and sequencing service providers have trusted DNAnexus to support their global genomics programs.

WHAT SETS DNANEXUS APART

DNAnexus offers layers of platform features and accreditation to support an exceptionally strong security and compliance profile. DNAnexus is continually audited and certified by an independent 3rd party for compliance with ISO 27001, an internationally recognized Information Security Management System and accompanying controls, enabling DNAnexus to address a broad range of global compliance regimes.

Diagram Key

<table>
<thead>
<tr>
<th>Customer Compliance</th>
<th>EU-US Privacy Shield</th>
<th>CAP / CLIA</th>
<th>HIPAA / BAA</th>
<th>FedRAMP</th>
<th>GCP &amp; GLP</th>
<th>dbGaP</th>
</tr>
</thead>
<tbody>
<tr>
<td>DNAnexus Compliance</td>
<td>ISO 27001</td>
<td>FedRAMP ATO</td>
<td>BAA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monitoring</td>
<td>Threat Management</td>
<td>Access Controls</td>
<td>Logging</td>
<td>Chain of Provenance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Immutable Data</td>
<td>Complete Encryption</td>
<td>Single Sign-On</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Multi-Factor Auth</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cloud Compliance</td>
<td>FISMA</td>
<td>HIPAA</td>
<td>FedRAMP</td>
<td>SOC 1,3</td>
<td>ISO 27001</td>
<td>ISO 9001</td>
</tr>
</tbody>
</table>

Diagram Key

**BAA** - Business Associate Agreements to comply with HIPAA regulations

**CAP** - The College of American Pathologists comprehensive set of accreditation guidelines for laboratory quality assurance

**CLIA** - Clinical Laboratory Improvement Amendments of 1988 established quality standards for all laboratory testing to ensure the validity, reliability and timeliness of laboratory examinations and procedures, handling of specimens, and reporting of results

**dbGaP** - Security best-practices established by the NCBI for datasets included in its Database of Genotypes and Phenotypes (dbGaP), such as TCGA or ICGC

**EU-US Privacy Shield** - New privacy and data transfers pact which supersedes the former Safe Harbour framework

**FedRAMP** - Government-wide program that provides a standardized approach to security assessment, authorization, and continuous monitoring for cloud products and services

**FISMA** - Federal Information Security Management Act

**GCP/GLP** - Good Clinical Practices (GCP), Good Laboratory Practices (GLP), and 21 C.F.R. Part 11 are required by organizations that submit genomic data to the United States Food and Drug Administration

**HIPAA** - U.S. Health Insurance Portability and Accountability Act

**ISO 9001** - Internationally recognized Quality Management System

**ISO 27001** - Internationally recognized Information Security Management System that provides a comprehensive framework for security and compliance

**SOC 1, 3** - Service Organization Controls report
**DNANEXUS SECURITY ARCHITECTURE**

**Platform Security Architecture** - DNAnexus restricts user data to high-security facilities with SAS 70/SSAE 16, PCI Level 1, and FISMA Moderate certifications. All data are encrypted when in transit (SSL/TLS) and at rest (AES 256).

**Access Control** - Administrator controls restrict users and organizations with whom to share information, allowing granular privilege levels to be specified on groups of data and application resources. “Copy Not Allowed” functionality prevents the movement of data to other projects. Two-factor authentication, password complexity and change requirements, and session timeout features also protect against unauthorized access to confidential data.

**Consistency of Results** - Preconfigured pipelines allow bioinformaticians to preset parameters, thereby ensuring consistent analysis of samples. These pipelines can be packaged as separate apps for “Point and Click” functionality. All data, tools, and workflows are tracked and version controlled in order to ensure auditability and reproducibility. DNAnexus provides runtime consistency enabling all users to work within a common operating environment.

**Auditability** - DNAnexus provides comprehensive features that provide audit trails necessary to document compliance. All uploads are logged and “hashed” to verify integrity and audit logs are maintained for six years. DNAnexus users have complete control over record retention and destruction. Project administrators can lock projects to prevent accidental deletion of any files.

**Availability** - All user data is redundantly stored on multiple devices across multiple facilities to provide 99.999999999% durability with 99.99% access availability. Consistent with ISO 27002 controls, disaster recovery and incident response plans are in place to ensure that appropriate recovery steps are followed including stakeholder notification.

**Consent** - Under DNAnexus Privacy Policy, users are responsible for ensuring patients or donors of genomic samples have provided informed consent. DNAnexus has helped many customers adhere to data compliance in accordance to specific privacy laws and regulations.

**Compliance & Assessment** - DNAnexus performs regular reviews of security controls and a formal annual assessment of its entire security management system. DNAnexus utilizes independent 3rd parties for vulnerability scanning and network/application penetration testing. External audit by an independent third-party (BSI) has certified DNAnexus to be ISO 27001 compliant.

---

**HOW DNANEXUS CAN HELP**

Complying with security standards and privacy regulations is an increasingly complex job. DNAnexus cloud-based platform simplifies security and compliance for critical business operations so your company can focus on what matters, the science. Leverage a team of bioinformatics and cloud computing experts for a security strategy that meets your business needs.

For a detailed overview of the DNanexus approach to security and privacy, email us at info@dnanexus.com.