



Service Definition Document Geneyx

Contents

1. SERVICE OVERVIEW	2
2. SERVICE SPECIFICATIONS	3
2.1. Service Levels	3
2.2 Customer Support Post Sales.....	3
2.3 On- and Offboarding Support.....	3
2.4 Data Access after Contract Termination	3
2.5 Incident Management & Incident Response Times	3
2.6 Change Management Process Including Product Enhancements	4
2.7 Service Constraints & Maintenance Windows	4
2.8 Levels of Customisation.....	4
2.9 Service Level Performance	4
2.10 Outage Management & Maintenance	5
2.11. Hosting Options & Locations	5
2.12. Business Continuity & Disaster Recovery Plans	5
2.13. Data Backup & Restore.....	5
2.14. Technical Requirements	5
3. COMPLIANCE	5



1. SERVICE OVERVIEW

Geneyx Analysis is a cloud-based next-generation sequencing data analysis and interpretation Software-as-a-Service platform. It facilitates standardised variant interpretation and offers AI-driven automated analyses workflows for a wide range of sequencing approaches to support users in rapidly identifying underlying causes in individuals with genetic diseases.

UNIQUE FEATURES

- Standardised, automated and robust data analysis, variant annotation, filtering and reporting with options for secondary & tertiary analysis, or tertiary analysis only
- Scalable cloud infrastructure and sample throughput
- Analysis options for a wide range of sequencing approaches including gene panels, exomes (WES) and whole genomes (WGS)
- Compatibility with short and long-read next-generation sequencing data
- AI-driven variant prioritisation
- Multi-omic integration (DNA, gene expression, methylation) in one single platform
- Coverage of a wide range of application areas including rare & inherited disorders, somatic & inherited oncology, Pharmacogenomics (PGX) and population screening including newborn and carrier screening
- LIMS and other information system integration
- Clinical Interpretation Service for variant interpretation support

BENEFITS

- Operational efficiency and cost-effectiveness through automated workflows reducing burden on specialist staff, minimising turnaround times and maximising case throughput
- Seamless workflow adaptations when adjustments to varying laboratory analysis and throughput needs are required
- Evidence-based, AI-driven decision support with option of automated integration of user-curated knowledgebases to support robust and objective decision-making
- Variant interpretation support via the Clinical Interpretation Service to help with difficult to interpret cases, clear backlog or support staff training and education
- Easy set-up and establishment of data import/export processes via LIMS to seamlessly integrate with laboratory workflows



2. SERVICE SPECIFICATIONS

2.1. Service Levels

Customers can access Support either via email or through the website. During business hours (Mon-Fri 9am-5pm) an initial email response will be provided within 24 hours of the enquiry being received. For enquiries submitted outside of business hours or on weekends or bank holidays, an initial response will be provided on the next business day. Case handling will be prioritised based on the priority order classification of the enquiry.

2.2 Customer Support Post Sales

Users will have access to a dedicated Field Application Specialist (FAS) who will provide in-depth, customised training, help with general enquiries, support through software improvements and addition of new features and acts generally as the first point of contact. In addition, users can contact the Customer Support team via email or through the website as required.

2.3 On- and Offboarding Support

Onboarding: Geneyx provides a customer-tailored onboarding journey consisting of an initial demonstration of the software, followed by an evaluation (trial) period. During this time users are provided with in-depth online training and relevant user documentation supported by a dedicated Field Application Specialist (FAS). Upon purchase, a detailed online training will be provided by an FAS, who will also be the first point of contact for any further queries.

Offboarding: Depending on the customer, offboarding is self-managed, but can be supported by the Geneyx Support Team if required.

2.4 Data Access after Contract Termination

At end of contract, users can download their data files via an API or the graphical user interface either on their own, or with assistance by the Geneyx Support team. Files available for download include .vcf files, .tsv files for variant calls and annotation, Users can obtain case report files in .pdf, .json or .csv format as well as case QC files in .csv format. Download needs to be completed within 3 months of end of contract.

2.5 Incident Management & Incident Response Times

Our incident process is part of the ISO27001 process which covers security, data loss and any related type of incident. Incidents, including those raised by customers to Customer Support, are reported to the CISO and CTO. They are logged and categorised according to industry standards. Queries are classified based on the following priority order:



- *P1 – Critical: System failure or significant impact on business operations*
 - Response time: Within 2 hours
 - Resolution time: Within 24 hours or as mutually agreed upon based on the nature of the issue
- *P2 – High: Major issue affecting system functionality or performance*
 - Response time: Within 4 hours
 - Resolution time: Within 48 hours or as mutually agreed upon based on the nature of the issue
- *P3 – Medium: Issue causing moderate impact on system functionality or performance*
 - Response time: Within 8 hours
 - Resolution time: Within 5 business days or as mutually agreed upon based on the nature of the issue
- *P4 – Low: Minor issue or general enquiry*
 - Response time: Within 24 hours
 - Resolution time: Within 10 business days or as mutually agreed upon based on the nature of the issue

2.6 Change Management Process Including Product Enhancements

We are working closely with our users to identify and prioritise areas of improvement and product enhancement. Our change management process in general follows ISO13485/ISO27001 requirements and includes planning, implementation, change monitoring, impact/risk assessments for product safety (ISO13485) and security (ISO27001) and product release stages.

2.7 Service Constraints & Maintenance Windows

The service is available to users at all times throughout the year (24/7) apart from scheduled downtimes for service upgrades. Service upgrade downtimes will be communicated at least 2 weeks in advance for customers to make appropriate arrangements.

2.8 Levels of Customisation

Geneyx Analysis can be customised in a variety of ways. Users can customise analysis protocols and filter settings based on role-based permissions. In addition, report templates for automated reporting can be customised including the integration of customer logos, report introduction sections, methodology descriptions, assay limitation descriptions and signature fields. Users can also choose which information fields to incorporate into the report, or create their own reporting templates entirely.

2.9 Service Level Performance

The uptime of Geneyx Analysis is historically 99.9% 24 hours a day, 365 days a year apart from essential maintenance.



2.10 Outage Management & Maintenance

Service upgrade downtimes will be communicated at least 2 weeks in advance for customers to make appropriate arrangements.

2.11. Hosting Options & Locations

Geneyx Analysis is located on the Azure cloud. All data is stored and processed in Azure / AWS data centres within the European Economic Area.

2.12. Business Continuity & Disaster Recovery Plans

Geneyx ensures that data is held in multiple availability zones, ensuring data redundancy and high availability. This provides an additional layer of protection for user files against potential failures or outages. Furthermore, full disaster recovery and business continuity plans are in place as part of the ISO27001 certification.

2.13. Data Backup & Restore

The Geneyx Analysis database is hosted in Azure's Netherlands data centre. The database is equipped with built-in resilience measures, including seven days' worth of restore points to ensure that the database can be restored to a previous state within the specified timeframe.

2.14. Technical Requirements

Geneyx Analysis is a cloud-based Software-as-a-Service platform. It requires an internet connection of at least 100Mbit DL/UL. Users should have access to a modern web browser (Chrome, Edge, Firefox) and ideally use Windows/MAC/Linux 64bit PCs with a minimum disk space of 500 Gb and 16Gb of memory.

3. COMPLIANCE

- ISO13485:2016, ISO27001:2022, ISO27799:2016 certified
- CE-IVDR/DTAC ready – certification process ongoing
- Hosting on secure Azure and AWS clouds both of which comply with CSA CCM v4.0
- HIPAA and GDPR compliant
- 99.99% historical uptime
- Protection of data at rest compliant with CSA CCM v4.0
- Protection of data in transit TLS1.3 compliant