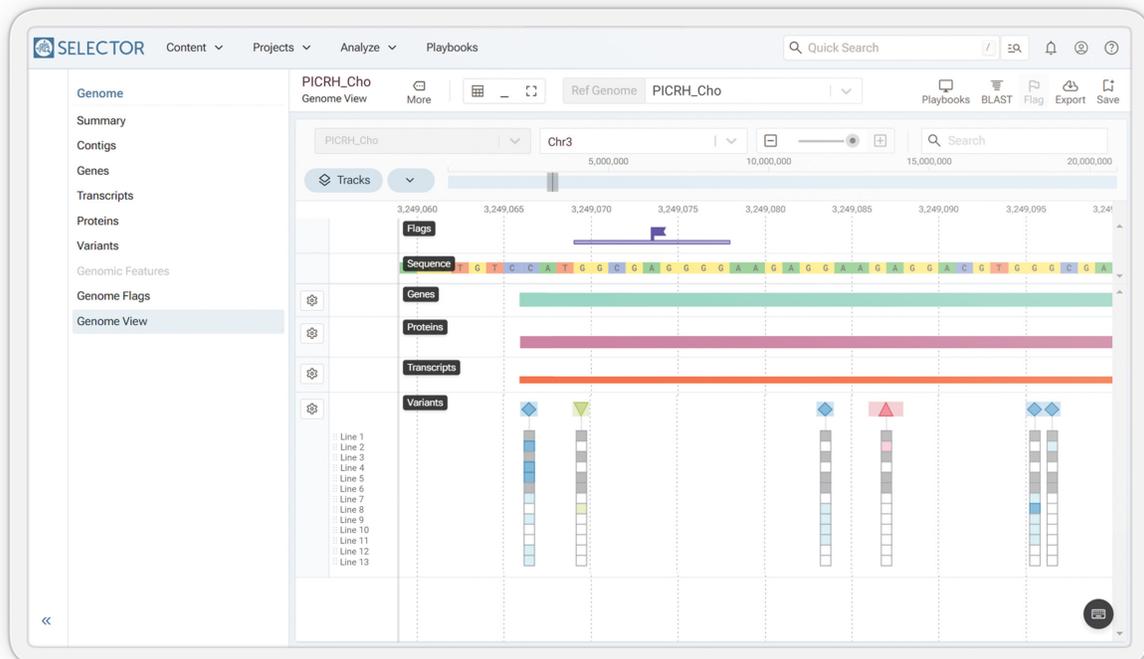


0100011101100100  
01000111011001010110111001100101

# NGS Analyses. Accessible. Limitless.



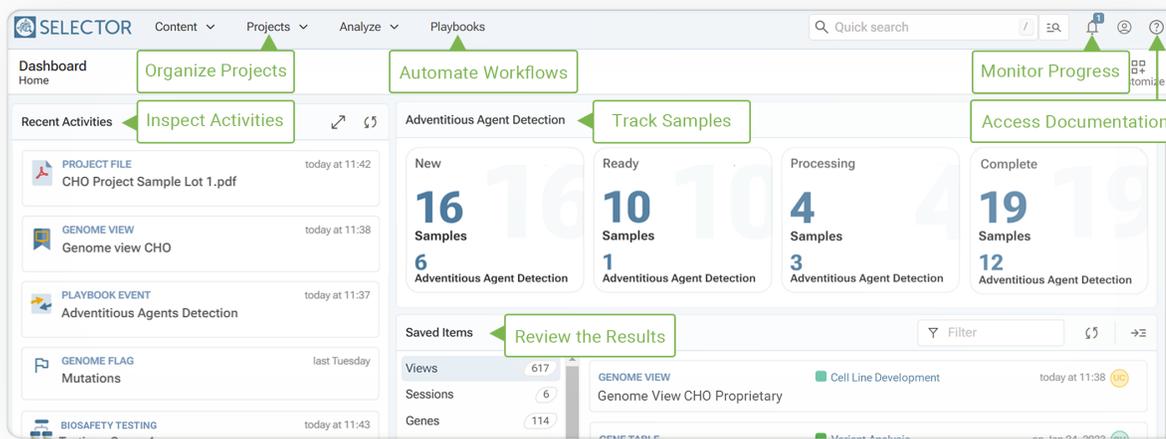
01100100011000010111010001100001  
0100011101100100

# Accelerate R&D with NGS-Driven Decisions

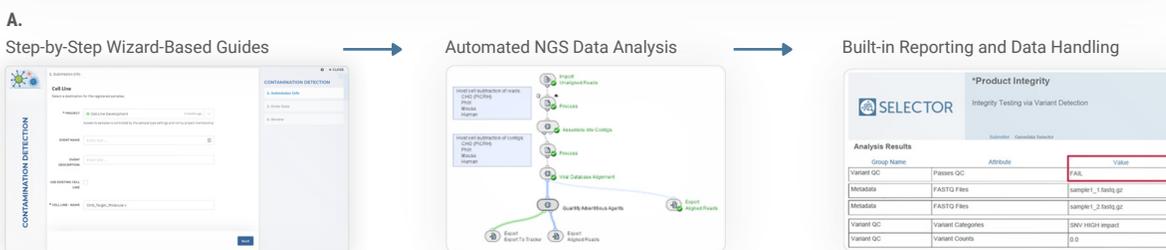
Innovative biotherapeutic and advanced therapy development is complex as these therapies are liable to contamination and modifications in identity. Next-Generation Sequencing (NGS) is a multi-attribute method that can address all your product characterization and quality control needs in just a single assay. Although NGS accelerates cell line and bioprocess development, it presents a host of IT challenges related to the integration, management, and analysis of the vast amount of data it produces.

Genedata Selector® is an end-to-end software solution for all data emerging from NGS-based assays (Fig 1). As a sequencing technology-agnostic platform, it simplifies sample and data management while enabling automated analysis, intuitive visualization, and the integration of NGS data with other data types (Fig 3). Genedata Selector is a single source of truth readily integrable into cGMP environments to provide documentation for internal assessment or submission to regulatory authorities .

**Benefit from enhanced efficiency and improved cross-team collaboration all while unlocking the full potential of NGS data analysis in-house.**



**Figure 1.** The Genedata Selector application is accessed through the web browser. The home screen is the command center allowing users to easily navigate through the platform's content and connect the dots between all NGS-based projects.



**Figure 2. A.** Customizable analysis workflows can be saved as ready-to-use Playbooks. These enable scientists to register samples, analyze, and visualize NGS as well as other omics data, and enable automated report generation. **B.** Decision-making support provided by Genedata Selector. With previously set custom go/no-go signal rules, samples that do not meet the required standards can be automatically failed.



**Figure 3.** Genedata Selector provides an end-to-end solution for NGS-based assays. Users can track and share their files, metadata, and results. Configurable pass-and-fail reports enable efficient decision-making and collaboration (next page ▶).

Sample Name	PLASMID CONTAMINATION		ADVENTITIOUS AGENTS DETECTION			FUSION DETECTION			QC CHECK	
	Passes QC	Contaminant Taxonomy	Passes QC	Virus Counts	Virus Class	Virus Taxonomy	Passes QC	Percent Fusion	Fusion Location	Master QC
AAV_batch1_sample1	Pass	ignore	Pass	0	NoHit	ignore	Pass	0	no fusions	Pass
AAV_batch1_sample2	Fail	Helper plasmid	Pass	0	NoHit	ignore	Pass	0	no fusions	Fail
AAV_batch1_sample3	Pass	ignore	Fail	7	virus	Encephalomyocarditis virus	Pass	0	no fusions	Fail
AAV_batch1_sample4	Fail	Helper plasmid	Pass	0	NoHit	ignore	Fail	0.025186785	aa_v_transfer_plasmid.1:1679...	Fail

# Leverage the Benefits of the End-to-End Platform

## Bringing Teams Closer Together for Improved Collaboration

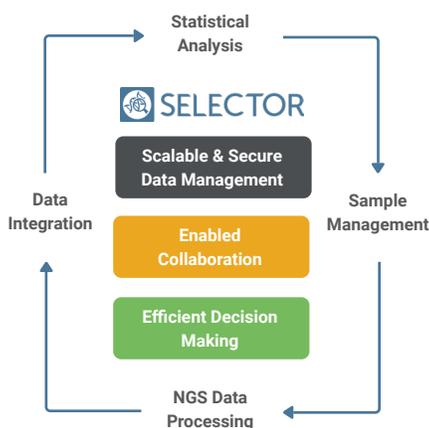
The unique powerful communication tools of Genedata Selector allow project teams to collaborate effectively. Users can always stay up to date thanks to the notifications and shared views of the software. This also applies on a cross-organizational level if your company partners with other organizations worldwide. While doing this, you can also benefit from keeping the entire experimental process in-house, so there is no need to share confidential data with third parties such as external service providers. When using Genedata Selector, IP-related proprietary data never needs to be sent away to outside vendors.

Access and share data flexibly and securely in the software whether it is genomic information, phenotype, or cross-omics data.

## Automating Workflows for Greater Reproducibility

Our software empowers users of all experience levels to perform NGS data processing and innovative analyses with integrated flexible statistical and powerful machine learning tools. Core to Selector is a workflow-based processing engine that enables tailor-made workflows by expert users for your specific data processing needs. These workflows can be saved and approved for use by other members of your team at a simple click of a button. Our diverse ready-to-use Playbooks (step-by-step wizard-based guides) can be run to register samples, execute an entire bioinformatics pipeline, and generate comprehensive reports (Figure 2A). This allows for standardized processes, greater result reproducibility, and rapid, clear insights for data-informed go/no-go decisions.

Automate routine tasks to increase productivity and reduce error-prone manual data handling.



## Maintaining Full Transparency and Simplifying Reporting

Genedata Selector provides comprehensive data traceability and transparency for all biosafety analyses performed. The sample history and comprehensive reports provide you with an overview of the underlying data processing, data analysis workflows, and the entire experimental process. With the sample-based organization, you can track and monitor all data generated by each sample. Genedata Selector is equipped for a 21 CFR Part 11 compliant environment with user data access control for enhanced security. The platform generates time-stamped reports and audit logs which provide comprehensive support for regulatory submissions.

Track your samples and data from registration through analysis and reporting for successful audits and regulatory submissions.

## Saving Time and Costs

In comparison to outsourcing the entire biosafety testing process to third-party service providers, in-house NGS-based biosafety testing with Genedata Selector is cost-efficient, fully traceable, and scalable. The platform enables efficient go/no-go decisions on biosafety, as well as the assessment of cell line stability and product integrity in one assay (Figure 2B). The automation facilitated by the software allows scientists to maximize product quality and production, enabling biopharma organizations to deliver innovative biotherapeutics to market faster. This highly efficient approach leads to reduced costs per sample, shortened development timelines, and an increased return on investment (ROI) for biopharmaceutical companies.

Unlock more time for insight generation and distribute resources efficiently.

**Scalable & Secure Data Management**

**Enabled Collaboration**

**Efficient Decision Making**

Sample Status	Passes QC
Complete	FAIL
Complete	FAIL
Complete	PASS
Complete	PASS
Complete	PASS
Complete	FAIL

# A Single Source of Truth for Broad Applications

Genedata Selector is the single source of truth that empowers scientists to integrate, analyze, and share all project-related data for improved decision-making during a range of applications.



## For Cell Line Development

The software and Genedata Selector's scientific consultants support the annotation of proprietary genomes so they can be used downstream in -omics analyses, genome editing, TLA analysis (Figure 4A), and biosafety testing. Characterizing cell line clones and confirming integration sites, stability, and integrity has never been so easy.



## For Quality Control Testing

Genedata Selector supports applications for biosafety testing with an unbiased approach of adventitious agent detection from raw materials and bulk harvest to the final product. With the platform's guided mutation profiling, you can assess the integrity and quality of your therapeutic products through variant detection (Figure 4B).



## For Cell and Gene Therapy Development

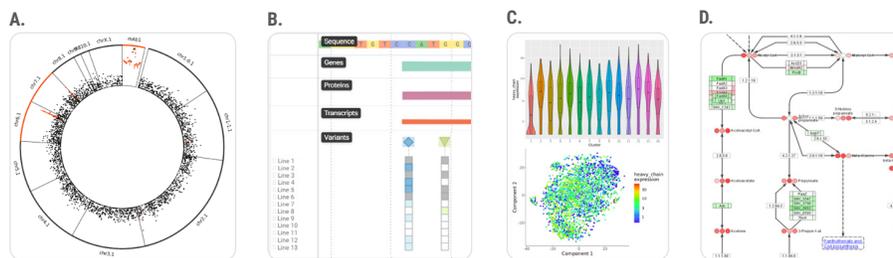
NGS provides results that correlate with current molecular assays and allows biopharma teams to assess several Critical Quality Attributes (CQAs) simultaneously by providing multiple readouts. Our platform supports the analysis and interpretation of NGS data for CQA assessment, such as confirming identity, biosafety, and potency (Figure 4C).



## For Bioprocess Development

Genedata Selector enables you to visualize your -omics data and monitor molecular pathways of cells (Figure 4D). Mutation profiling, DNA-, or RNA-seq facilitated by Genedata Selector, can rapidly determine product sequence integrity under process conditions. Supported by our platform, single-cell DNA-seq can be used to characterize cell pools or provide evidence of monoclonality for cell banks.

Leverage all these applications independently in-house and protect valuable intellectual property.



**Figure 4.** Genedata supports **A.** TLA analysis for clone selection, **B.** Safety and integrity assessment of biopharmaceuticals with mutation profiling, **C.** Measurement of gene expression in heterogeneous cell populations, and **D.** Monitoring pathways to determine potential engineering targets.



Whether you work in Quality Control, Biosafety testing, CLD, Bioprocess, or CGT development, Genedata Selector is your ideal solution to address your NGS data-related needs. As the single source of truth for all your assays, the platform brings greater efficiencies to your data analysis while allowing you to connect the dots throughout biopharma R&D. Benefit from having full control of your data in-house as well as significantly more time to focus on novel insight generation.