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# Genedata Selector for Cell Line & Bioprocess Development

## INDUSTRY

Biopharmaceutical R&D

## APPLICATION

Host Cell Line Engineering  
Clone Selection  
Cell Line Stability

## KEY CHALLENGE

Improve Product Quality  
and Productivity with NGS

## SUMMARY

Genedata Selector  
Automates NGS-Based  
Cell Line and Bioprocess  
Development

## GENEDATA SOLUTION



With the rising number of innovative and complex biotherapeutics emerging from discovery to the development phase, biopharma organizations are facing challenges optimizing cell line and bioprocess development to deliver biotherapeutics to the market rapidly and cost-effectively. Next-generation sequencing (NGS) has become a key technology in the field. It will continue having a tremendous impact as it delivers experimental results faster and more cost-efficiently than traditional assays. For example, NGS-based assays enable the refinement of host cell lines, confirmation of clone identity, as well as the verification of product stability, integrity, and purity with significant time and cost savings. Although NGS accelerates cell line and bioprocess development, it also comes with a host of IT challenges related to the integration, management, and analysis of data it produces. An effective software solution is required that streamlines the underlying data-related processes and delivers high-quality results for efficient decision-making.

[Genedata Selector](#)<sup>®</sup> is an end-to-end software solution that integrates and analyses NGS and other omics-based assay data in a central database enabling scientists to collaborate and efficiently share data with full transparency and traceability (Figure 1). By automating the management and analysis of raw NGS data, Genedata Selector harmonizes data processes across organizations improving the reproducibility of results. Due to the project-centric focus of the software, improved collaboration across teams is facilitated. The customizable reports of Genedata Selector simplify internal reporting and submission to regulatory agencies. This enables a rapid turnaround delivering cell line and bioprocess development projects faster to the Investigational New Drug (IND) application stage. By facilitating integrative analyses, the

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software provides scientists with an in-depth understanding of host cell lines, [engineering targets, and quality assessments](#) in the development of next-generation therapeutics (Figure 2).

## Challenges

### Easy Access to All Host and Production Cell Line Information

The development of advanced biotherapeutics requires easy access to all omics and phenotypic data related to the development of the production cell line for efficient decision-making. However, the lack of a centralized database results in data silos preventing easy and efficient access to data for analysis.

### Effective Refinement of Host Cell Lines

Innovative NGS or multi-omics approaches support the identification of undesirable phenotypes for correction for

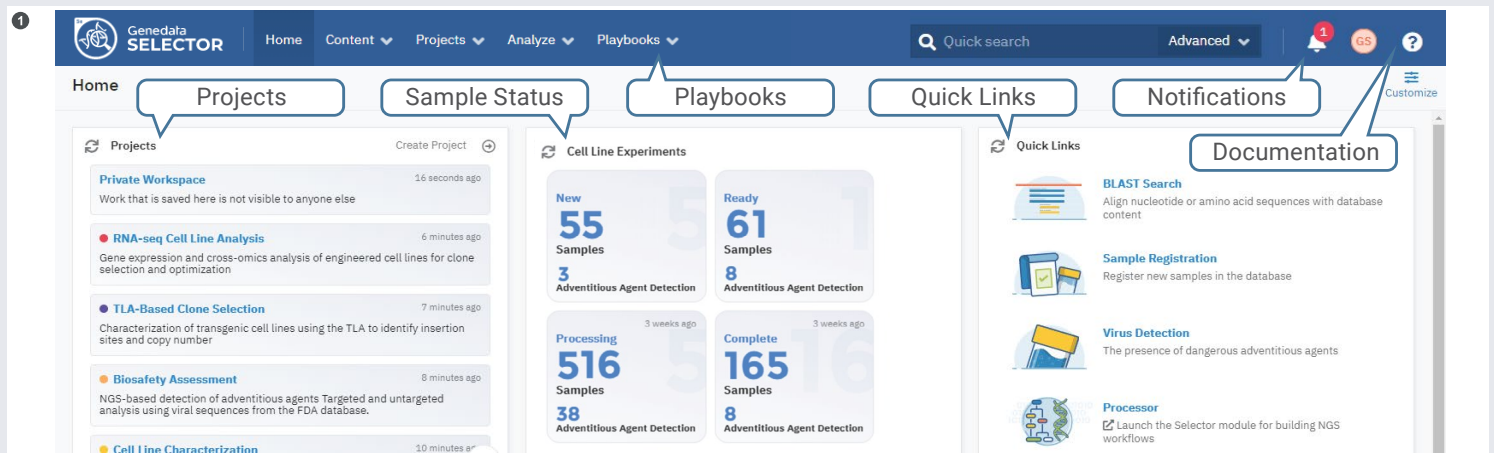
example by applying gene editing approaches. However, this involves integrating and analyzing large, complex multi-dimensional datasets. This integrated approach would provide an improved biological view and understanding of molecular pathways underlying cell behavior and characteristics. To avoid time-consuming data analysis, efficient multi-omics data integration, as well as sophisticated statistical and visualization algorithms, are required.

### Efficient Clone Selection and Identity Confirmation

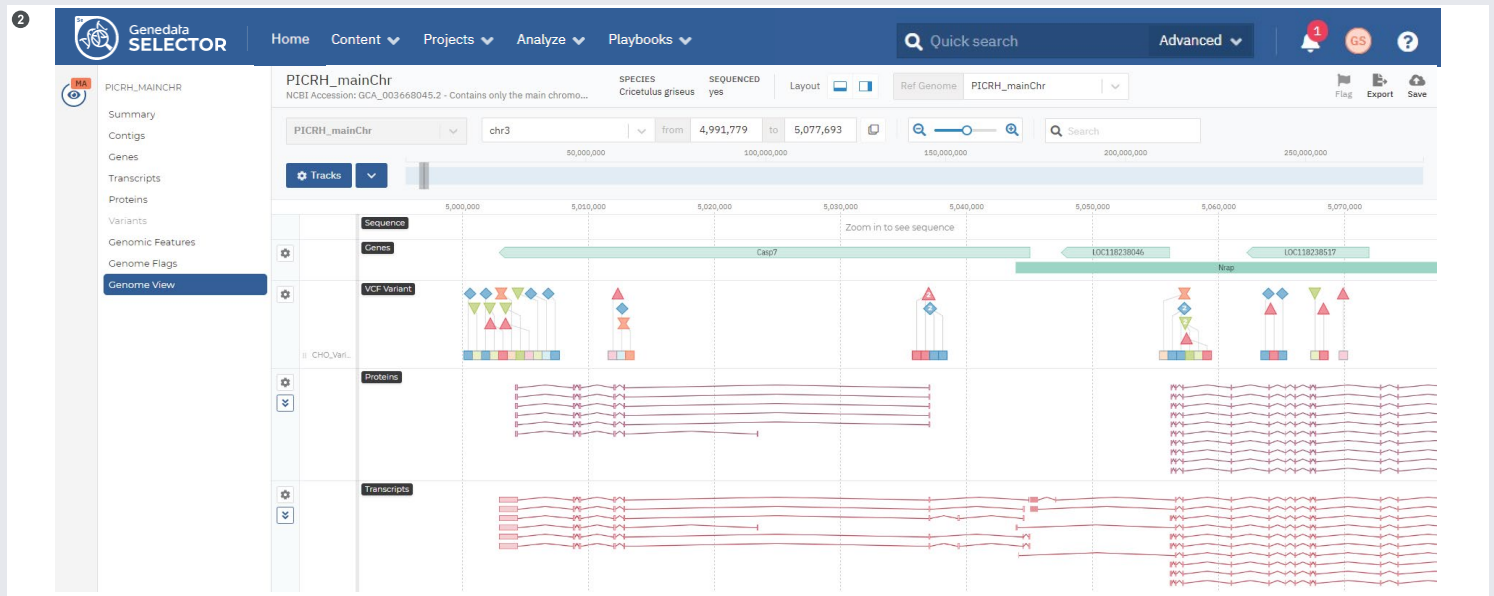
Determining integration sites or confirming clone identity, e.g., with targeted locus amplification (TLA) technology or long-read sequencing, can be time-consuming, and error-prone if dependent on manual data handling.

### Ensuring Clone Stability During Upscaling

Early in-house detection of unstable clones prevents the



1 Genedata Selector Home Screen



2 Genedata Selector Genome View

development of heterogenous cell banks and products with undesired quality attributes that can lead to high costs. Identifying critical sequence and structural variants using mutation profiling or variations in cell populations with single-cell RNA seq requires the processing and investigation of large quantities of complex data.

## Solution

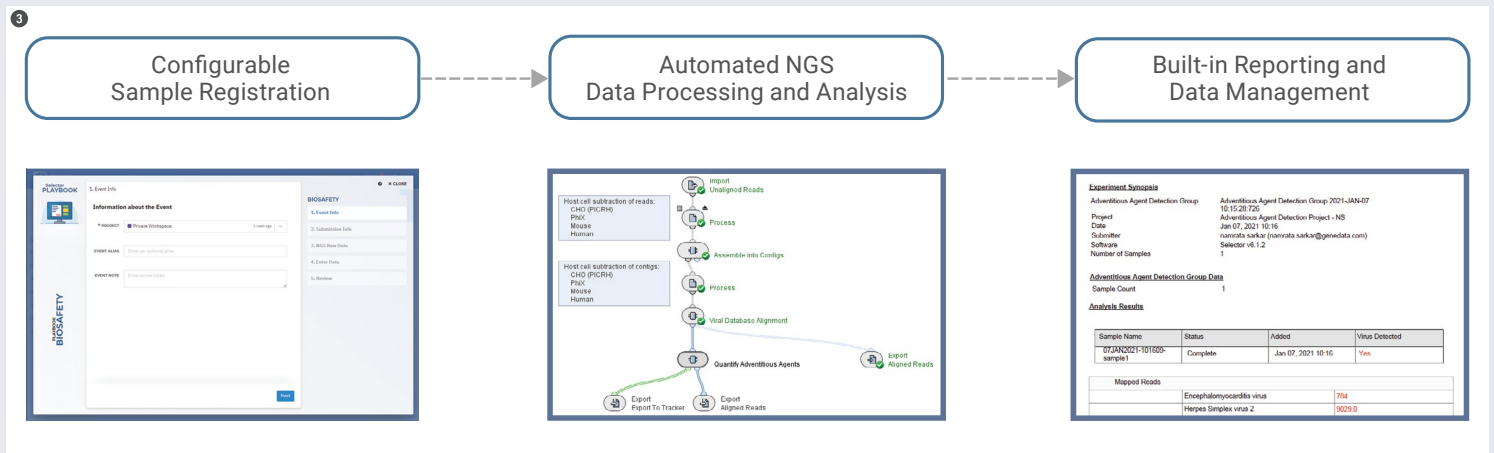
### A Single Source of Truth

[Genedata Selector](#) enables scientists to work collaboratively on cell line development projects, easily and rapidly access all data related to host and production cell lines, and perform accurate and efficient data analysis. The software includes out-of-the-box yet customizable analysis workflows and easy-to-use guides ([Playbooks](#)) which enable scientists to process, analyze, and visualize NGS and other omics data independent of their level of bioinformatics experience

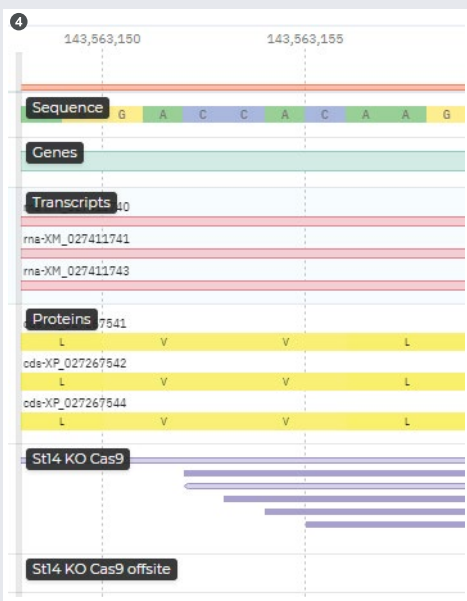
(Figure 3). Beyond software, Genedata’s scientific consultants provide support in various areas from building new analysis workflows to performing complex analysis. For example, consolidating proprietary genomes and multi-omics data in Genedata Selector.

### Support for Planning Precise CRISPR Experiments

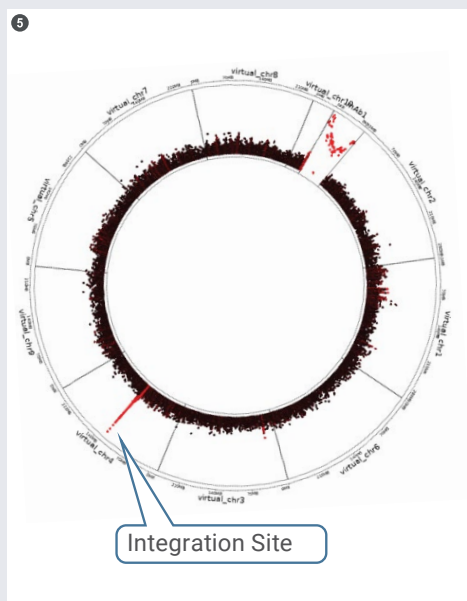
Genedata Selector offers a wide range of analysis and visualization options to identify gene editing targets based on genotype-phenotype relationships and cross-omics analyses. The software includes a [gRNA prediction tool](#) that uses the proprietary host cell genome as a reference (Figure 4). This results in the accurate prediction of quality-controlled, off-target tested gRNAs for genetic engineering. In addition, the software provides valuable information such as specificity scores, potential off-target binding sites, and a list of primer sequences ready-to-order for validation experiments.



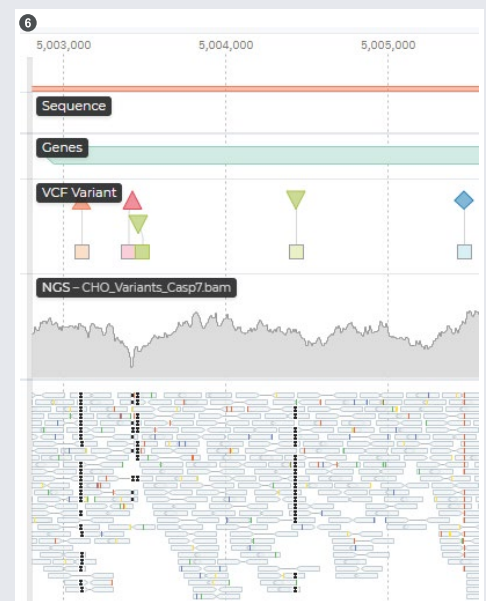
3 Workflow automation with Playbooks including sample registration, data analysis, management and reporting



4 gRNA prediction



5 Clone Selection



6 Mutation Profiling

### Automated Clone Selection and Identity Confirmation

Using [TLA analysis](#) or long-read sequencing technologies together with Genedata Selector, scientists can confirm gene editing events, accurately confirm or track transgene integration sites and select stable clones for production (Figure 5). The inbuilt user-friendly and [easy-to-use Playbooks](#), automate different clone selection workflows allowing to increase throughput, from data entry to report generation avoiding errors due to manual data handling.

### Cell Line Stability Assessment with Mutation Profiling

Genedata Selector allows cell characterization and the identification of variants throughout bioprocess development (Figure 6). This enables scientists to rapidly assess the performance and stability of their cell lines and accelerate decisions regarding process format adaptation from a small to large scale. For example, RNA-Seq provides insights on the performance of a cell line and enables mutation profiling to track stability and product integrity. Whereas single-cell RNA-Seq analysis provides cell line and bioprocess development teams with information for proof of clonality or heterogeneity of cell populations for earlier decision-making.

## Benefits

### Enhanced Collaboration Across Multidisciplinary Teams

Genedata Selector enables project teams to collaborate effectively through interactive communication via notifications and shared views in the software. It maintains a chain of custody for all genome data and data-related activities providing a single source of truth that teams can easily access on-demand. With Genedata Selector, teams can easily share knowledge with other teams or partnering organizations.

### Scientists Empowered to Perform NGS Data Analysis

The enterprise software equips scientists to analyze the vast amounts of data gained through NGS experiments without the need for bioinformatics expertise. From within the laboratory, scientists can run workflows independently using proprietary host cell line genomes, enhanced data-

bases for adventitious agent detection, or cloning vector information as a reference. This allows teams to make fast, accurate decisions during [gene editing](#), clone selection, bioprocess development, and [biosafety testing](#) processes, improving the accuracy and success rate of experiments.

### Automation of Routine Tasks

Automating standardized tasks using Genedata Selector increases productivity and reduces error-prone manual data handling. For example, easy access to results and reports in the software facilitates faster clone selection and efficient, routine biosafety testing. In addition, the playbooks generate customizable reports containing the molecular history of clones simplifying submissions to regulatory authorities.

### Saving Time and Costs

Rather than outsourcing data analysis, Genedata Selector enables in-house NGS data processing, analysis, interpretation, and reporting accelerating process optimization timelines while protecting valuable intellectual property. The automation facilitated by the software for cell line monitoring activities leads to the manufacturing of high-quality products. Detecting unstable clones with undesirable traits using Genedata Selector for automated NGS data analysis allows scientists to maximize product quality and production.

## Summary

[Genedata Selector](#) is the solution of choice to process and integrate NGS with all omics data during cell line and bioprocess development. It provides a single source of truth empowering scientists to efficiently engineer host cell lines and to make data-driven decisions on the stability, integrity, and [biosafety](#) of master cell banks, and biological products. While equipping scientists with full control and flexibility, the software streamlines and automates complex analysis workflows and simplifies reporting. Ultimately, Genedata Selector accelerates cell line & bioprocess development and enables biopharma organizations to deliver innovative biotherapeutics to market faster and more cost-efficiently.

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