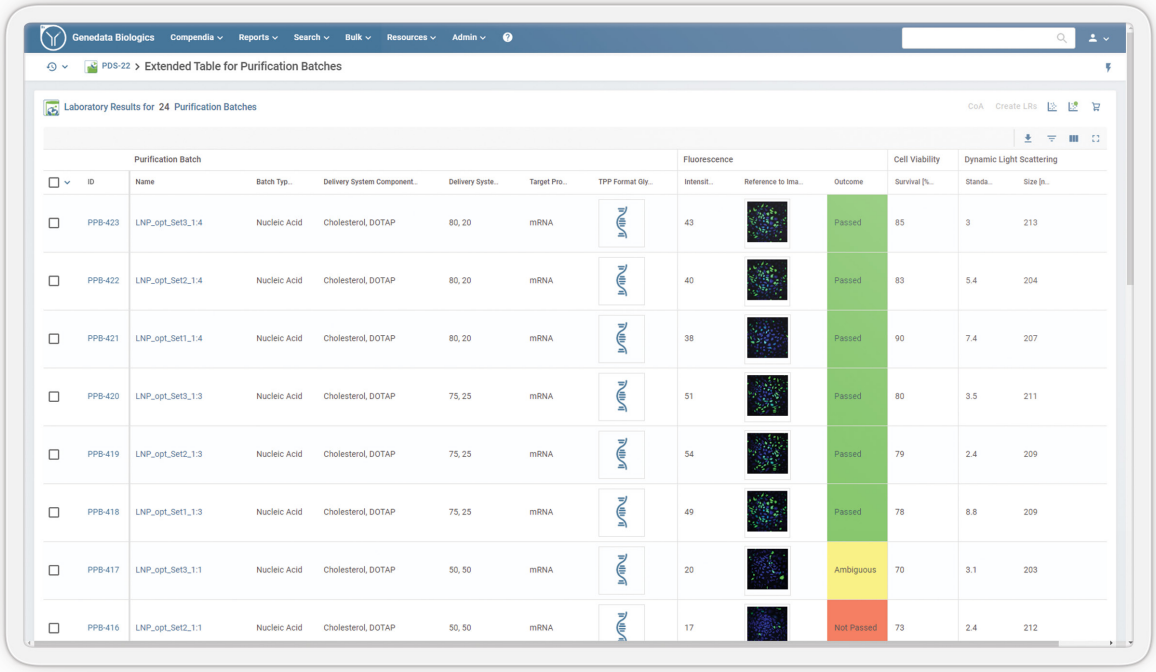
Genedata

Biotherapeutics Discovery. End-to-End.

BIOLOGICS



Why Genedata Biologics?

Built for Biologics

Accelerate research with a first-in-class platform uniquely designed from the start to digitalize biotherapeutic discovery. Genedata Biologics® facilitates complex R&D processes by designing, tracking, testing, and assessing novel biotherapeutics drugs. As a scalable and open platform, it works with any format, including antibodies, bi- or multi-specifics, ADCs, novel scaffolds, rAAVs, engineered therapeutic cell lines such as TCR-T and CAR-T cells, and RNA modalities.

A Next-Generation Platform

Acting as a central end-to-end data backbone, the platform integrates all R&D processes, from library design and immunizations, selections and panning, molecular biology, screening, protein engineering, expression, purification, and protein analytics, to candidate developability and manufacturability assessments. The intuitive user interface allows flexible data registration, analysis, and reporting. A shared platform, it manages highest data volumes and facilitates collaboration among different sites, groups, and external partners such as CROs.

Increases Automation & Drives Innovation

Genedata Biologics dramatically simplifies day-to-day laboratory activities such as cloning, screening, expression, purification, and sample management, and automates all data upload, processing, and reporting. Transparent and flexible IT interfaces allow for straightforward integration with existing laboratory and IT systems. Dedicated instrument adapters enable automated, two-way integration with instruments and robotics stations to enable true high-throughput and barcoded processes. Real-time access to structured data empowers more informed decisions and drives future discovery programs.

Increases Efficiency & Eliminates Risks

Genedata Biologics gives every R&D team access to all discovery program information for any project at any time and acts as a single source of truth across an organization. This makes it possible to simultaneously investigate across projects to track progress and optimize resource usage, which improves R&D forecasting and overall productivity as well as reduces costs. Customers report more than a 50% gain in efficiency and improved quality of results.

Operational Excellence

Genedata Biologics offers an integrated request management system that tracks requests and tasks performed by specialized groups as well as CROs and external collaborators. It streamlines and automates communication of required information and achieved results. The system tracks details of all requests and documents request fulfillment in real-time, improving operational efficiency and resource planning.

Essential for AI/ML

Well-managed data and AI/ML technologies are poised to transform decision-making and drive future innovation in biopharma R&D. Genedata Biologics provides a built-in structured data architecture across the organization, which makes it possible to use data and information for diverse AI/ML pipelines (e.g., ML approaches to prediction of physico-chemical properties of designed molecules). Programmatic access enables efficient data curation and algorithm development for AI/ML tasks.

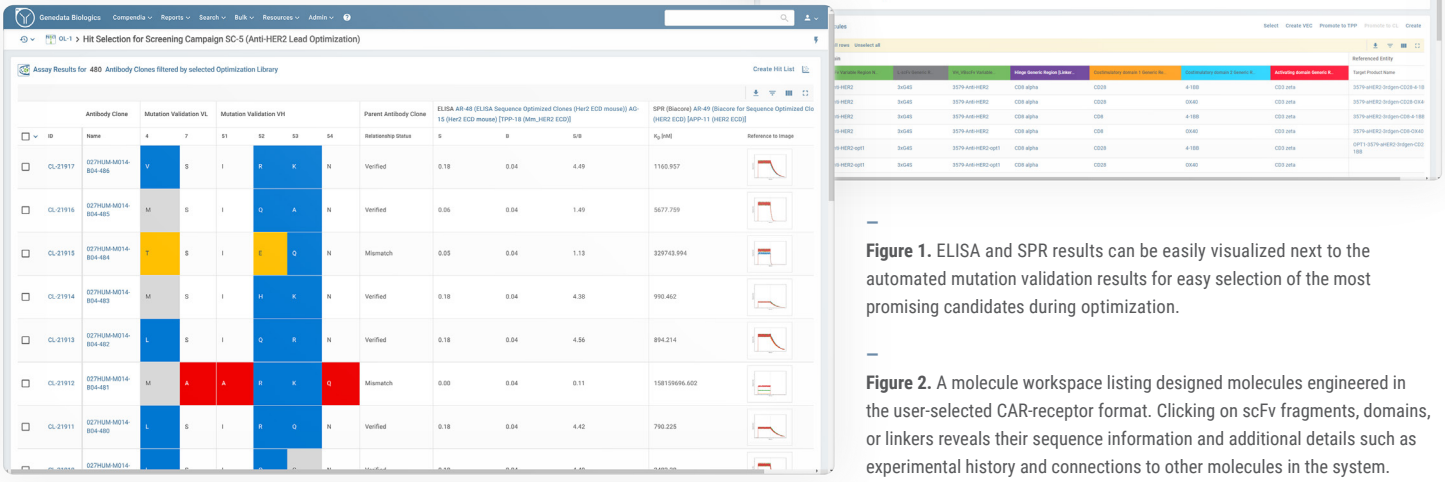
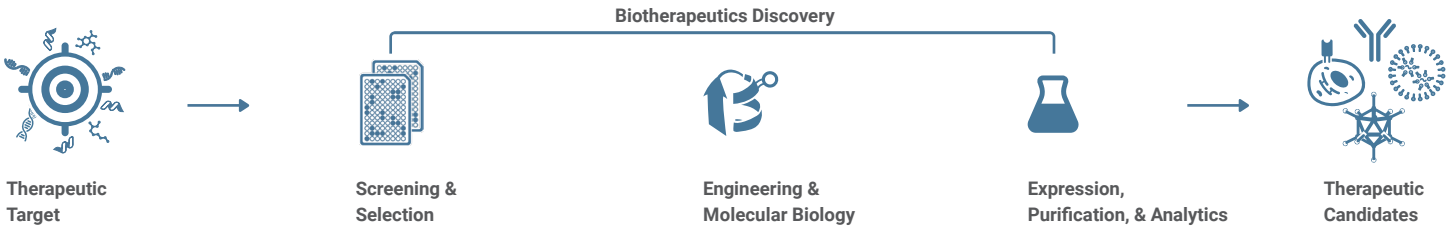


Figure 1. ELISA and SPR results can be easily visualized next to the automated mutation validation results for easy selection of the most promising candidates during optimization.

Figure 2. A molecule workspace listing designed molecules engineered in the user-selected CAR-receptor format. Clicking on scFv fragments, domains, or linkers reveals their sequence information and additional details such as experimental history and connections to other molecules in the system.



End-to-End Workflow

Biotherapeutics Discovery

Genedata Biologics has been designed to support fully automated, high-throughput screening of biotherapeutic and vaccine candidates (e.g., IgGs, bispecifics, TCRs, CARs, protein subunits, enzymes). The platform analyzes data derived from diverse discovery technologies, including phage and yeast display, B-cell cloning, and hybridoma. Its built-in tools facilitate isolate tracking through integrated plate management functionalities, including plate barcoding and cherry picking. Automatic sequence processing and integration with purification and assay data enable the identification of high-quality leads according to clear and transparent selection criteria.

Protein Engineering

Genedata Biologics supports a wealth of protein engineering techniques to simultaneously improve lead candidates with regard to binding affinity, cross-reactivity, stability, and expressibility. Advanced tools for affinity maturation, site-directed engineering, germlining, humanization, reformatting, or isotype switching enable rapid and reliable generation of superior protein variants. The in silico-cloning molecule workspace allows highly parallelized and error-proof molecule design and validation of synthesized DNA for hundreds of molecule variants in one go. Its tools are applicable to engineering of all therapeutic proteins.

Production & Analytics

The full production process, from the initial definition and design of the target to be produced (e.g., bispecific, mRNA, rAAV), to the final, fully characterized high-quality sample, is supported. The platform tracks and validates all expression and purification batches as well as all vector, plasmid, and cell line batches. Its built-in inventory management facilitates aliquot tracking. Analytical characterization and QC data such as LC-MS, SEC, HIC, endotoxin levels, glycosylation profiles, and functional data from in vivo assays are aggregated and directly linked to the respective samples, with tools automating the generation of Certificates of Analysis or other reports.

Developability Assessment

Genedata Biologics enables an early, rapid, and high-throughput assessment of a candidate's developability risk profile by evaluating intrinsic molecular properties that influence technical development. By analyzing predictive developability parameters based on molecule, sample, and analytics data collected during a candidate's life cycle, the platform can identify potential problems early, e.g., yield, stability, solubility, and specificity. The resulting developability risk scoring matrix provides the necessary basis for an informed decision on the candidate molecules to transition from research to development.

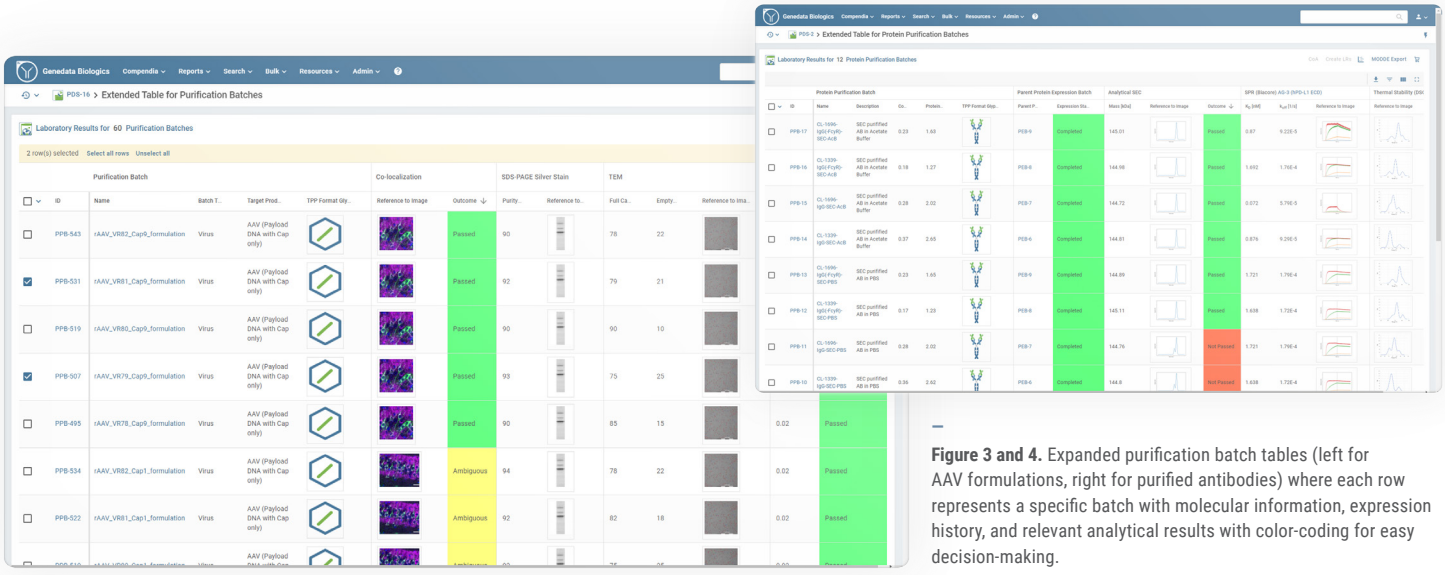


Figure 3 and 4. Expanded purification batch tables (left for AAV formulations, right for purified antibodies) where each row represents a specific batch with molecular information, expression history, and relevant analytical results with color-coding for easy decision-making.

Supports All Modalities

Next-Generation Antibodies

Native support of next-generation molecule formats (e.g., bi-and multi-specifics, ADCs, DVD-IgG, scFv-Fc) and parametric variants (e.g., linkers, V-domain order, Fc) removes the bottleneck of molecular biology and cloning processes required for generating DNA constructs to express and test the desired molecules. Genedata Biologics supports high-throughput yet flexible molecule design, DNA synthesis, and verification. It integrates designed molecules and their related samples, assays, and analytics results to allow the evaluation of large panels of protein variants to select the best format.

Cell Therapies

Genedata Biologics enables the engineering, production, and testing of adoptive cell therapies (e.g., CAR-Ts, TCR-Ts) as well as stem cells (e.g., iPS cells). Using purpose-built functionalities, the platform supports the entire E2E process, including the design and generation of viral vectors for genome modification. Automated dashboards visualize the real-time status of each cell line's production journey through research, development, and manufacturing. The platform supports development of both autologous and allogeneic cell therapies with all testing, validation, and developability and manufacturability assessments carefully tracked for transparent decision-making.

Gene Therapies

The platform increases the efficiency of gene therapy R&D and supports diverse viral delivery systems, including adeno-associated virus (AAV), adenovirus, and retrovirus vectors. It covers the entire gene therapy workflow, from serotype optimization and viral vector design to virus packaging, purification, and testing. It tracks all samples and associated information, including customized vectors and packaging plasmids, cell lysates, purified virus batches and their sequences, titers, and assay results such as empty-to-full capsid ratios. Genedata Biologics provides valuable, real-time insights leading to improved quality control, assay standardization, and more accurate viral potency assessments, putting all critical decision factors in one place to facilitate scale-up and reproducibility during vector manufacturing.

RNAs

Genedata Biologics captures design, analysis, and production data end-to-end for a variety of RNA-based therapeutics (e.g., mRNAs and RNA aptamers), and includes specialized tools and features for their in silico engineering, such as modified nucleosides and terminal modifications (e.g., 5′ cap structures). The system automatically tracks delivery systems and their composition (e.g., lipid nanoparticle components) and enables scientists to efficiently utilize all the information needed to progress new RNA-based drug candidates.

Vaccines

Genedata Biologics accelerates the discovery and development of vaccines, including the most novel mRNA and AAV-based vaccine formats. The platform is designed to increase the efficiency and quality of vaccine research from molecular biology to screening and production. Purpose-built features enable rapid screening of vaccine candidates, automation, and scale-up engineering including expression and purification. The platform integrates all lab instruments for error-proof data capture and analysis in one central location, and it facilitates a fully integrated investigation of all vaccine R&D data within and across projects, helping to bring high-quality vaccines to market sooner.

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Genedata BIOLOGICS

Genedata Biologics® is part of the Genedata portfolio of advanced software solutions, which digitalize and automate data-rich and complex biopharma R&D processes. From early discovery all the way to the clinic, Genedata solutions maximize the ROI in R&D expenditure.