Genedata Biologics®

The Biopharmaceutical Workflow Platform

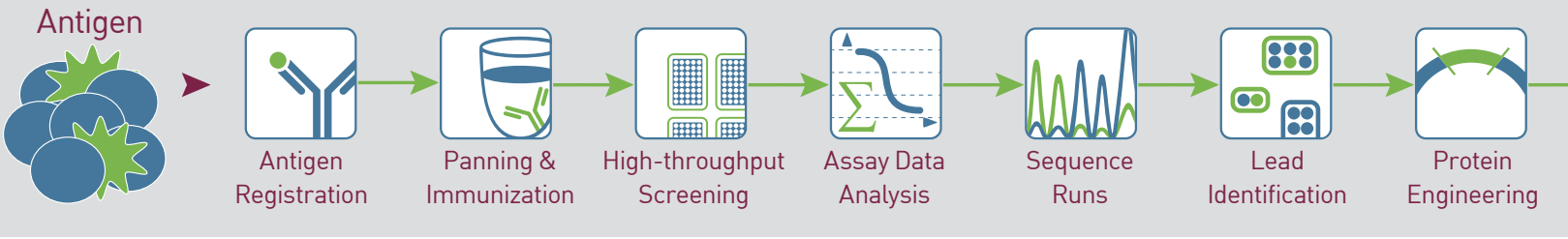
Integrating Workflows
Genedata Biologics® supports the complete large-molecule research process - from screening, protein engineering and optimization, expression, purification, analytics and QC, to candidate developability and manufacturability assessment.

Boosting Efficiency and Quality
The platform simplifies and streamlines laborious processes, such as instrument operations and reporting, which substantially increases throughput. By reducing manual processes, sample and data handling errors are avoided, and the quality of results improves dramatically.

Driving Innovation
Genedata Biologics provides native support of bispecific and next-generation antibody formats, novel scaffolds, and antibody drug conjugates.

Established Enterprise Platform
The system is an open and scalable foundation that supports hundreds of users, working in a multi-site, cross-department, and division-of-labor environment.

Genedata
solutions in silico



Antibody Discovery

Genedata Biologics analyzes data derived from diverse discovery technologies, including phage and yeast display, B-cell cloning, and hybridoma.

The platform has been designed to support fully automated, high-throughput screening of candidate molecules (e.g., Fabs, IgGs or in-format screening of bispecifics). Its built-in tools facilitate isolate tracking through integrated plate management functionalities, including plate barcoding and cherry picking.

Automatic sequence processing and integration of 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 regards 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.

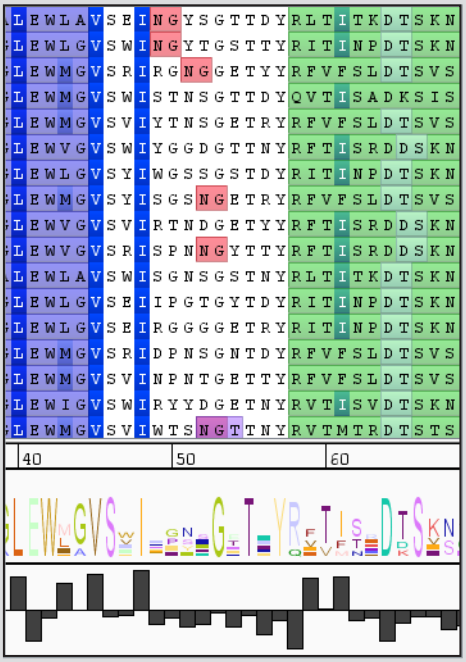
The system's *in silico* cloning engine allows highly parallelized and error-proof molecule design and validation of synthesized DNA for hundreds of molecule variants in one go. Its tools are also applicable to engineering of therapeutic proteins such as FVIII.

Production and Analytics

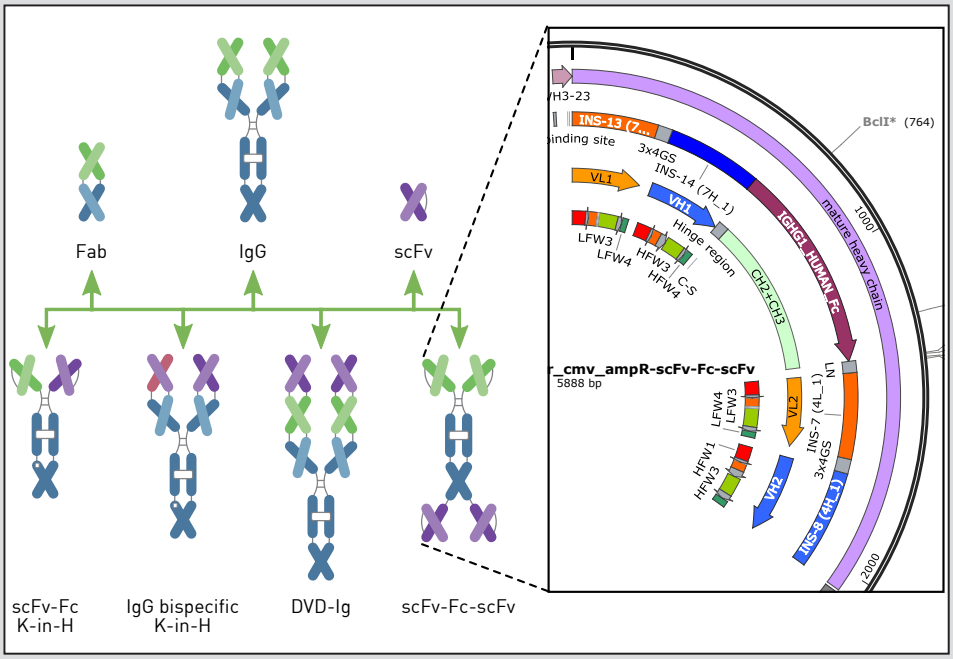
The full protein production process, from the initial definition and design of the proteins to be produced, to the final, fully characterized high-quality sample, is supported by the system.

The platform tracks and validates all protein expression and purification batches as well as all vector, plasmid, and cell line batches. Its built-in inventory management facilitates aliquot tracking.

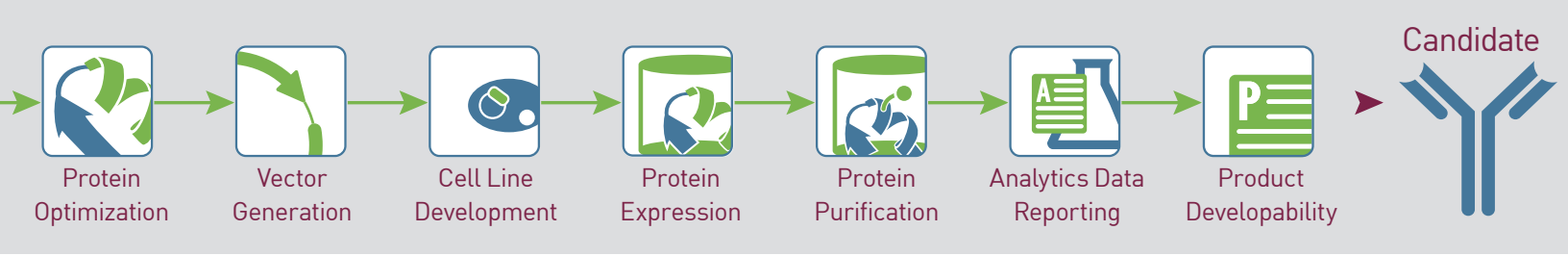
Analytical characterization and QC data such as LC-MS, SEC, HIC, endotoxin levels, glycosylation profiles, and functional data from in vivo assays are aggregated and directly linked to the respective samples, with tools automating the generation of Certificates of Analysis or other reports.



Hit selection and antibody candidate assessment by integrating assay data and sequence characteristics, such as liability motifs.



Tools for design, cloning, and testing of large panels of next-generation antibody candidates; here an auto-generated plasmid map from a bispecific scFv-Fc-scFv engineering campaign.



Next-generation Antibodies

Native support of next-generation antibody molecule formats (e.g., bi- and multi-specifics, tandem-scFv-Fc, DVD-Ig, Diabodies) and parametric variants (e.g., linkers, V-domain order, Fc) removes the bottleneck of molecular biology and cloning processes required for systematically 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 molecules, and their related samples, assays, and analytics results to allow the systematic evaluation of large panels of multi-specific antibodies.

Antibody Drug Conjugates

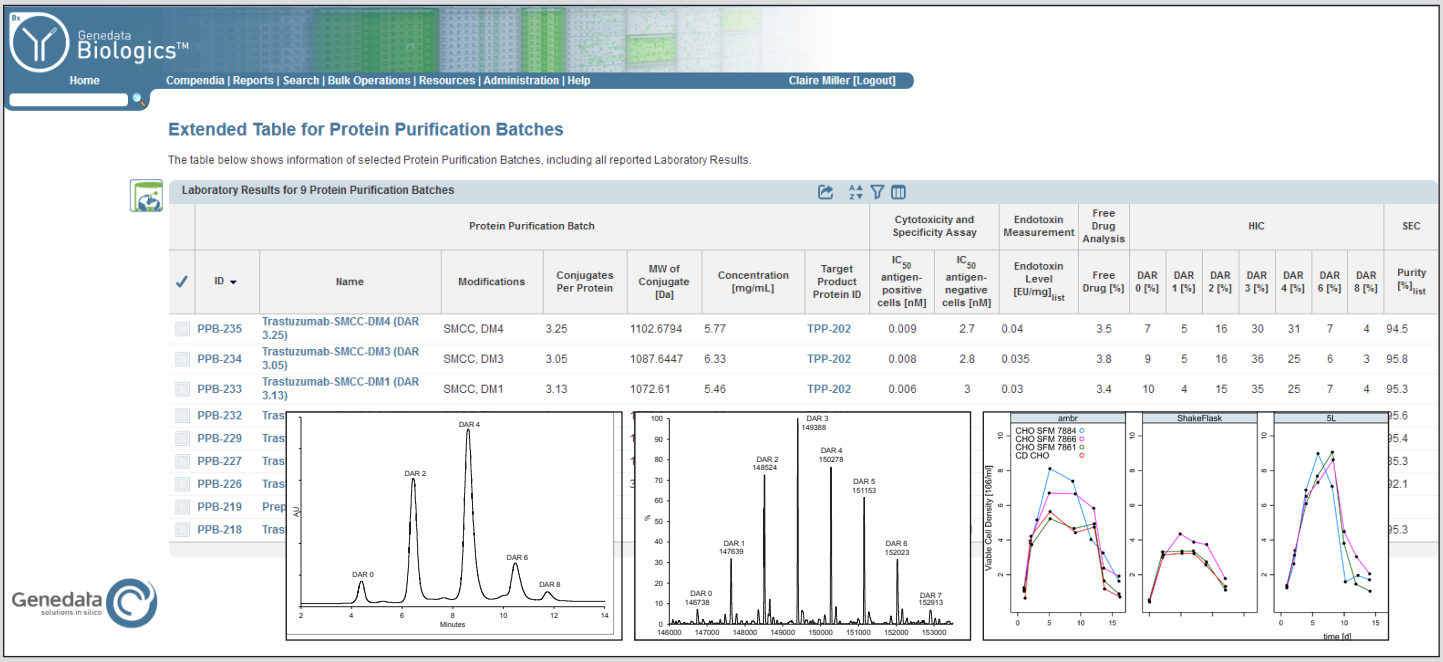
The system provides tools for the methodical design and assessment of large panels of ADC molecules that result from the complex combination of antibody leads, conjugation strategies (e.g., lysines, cysteines, Fc glycans, non-natural amino acids), linkers (e.g., cleavable, non-cleavable), and small-molecule payloads (e.g., MMAE, DM1).

The platform tracks all ADC molecules, plus all expression and purification batches, drug conjugation protocols, and ADC-specific analytics results (e.g., DAR, drug loading distribution, homogeneity). It enables a systematic identification of the most promising candidates by taking into account multiple selection criteria.

Developability Assessment

Genedata Biologics enables a systematic assessment of a candidate's developability risk profile by evaluating intrinsic molecular properties that may influence the technical development of the drug candidate. By analyzing predictive developability parameters based on molecule, sample, and analytics data collected during a candidate's life cycle, the system can identify potential problems including aggregation, formulation instability, and reduced pharmacological activity.

The resulting developability risk scoring matrix provides the necessary basis for an informed decision on the candidate molecules to transition from research to development.



Central database for all molecule, sample, and analytics and assay data; here an example of a large-scale ADC engineering campaign.

Works Out of the Box

Genedata Biologics is an established enterprise software platform based on a scalable architecture that has been designed for processing, storing, querying, and visualizing large volumes of complex data. The intuitive user interface allows flexible and interactive data registration, analysis, and reporting.

The system can be configured to support corporate-specific variants of the biologics R&D workflow, such as handling of proprietary libraries, next-generation antibody formats, special cloning strategies, or corporate sample naming nomenclatures.

Services and Support

Genedata offers a broad range of services and support, from installation, configuration, and customization to global deployment and roll-out projects, training, and workflow and IT consulting services – all tailored to the specific needs of your organization. Our consulting team of highly skilled professionals with extensive domain knowledge in biologics R&D and software technology, brings specialized know-how and experience to your organization.

Seamless Integration

As an open system, Genedata Biologics provides a rich set of public interfaces (APIs) for seamless integration with existing laboratory and corporate IT infrastructures.

Dedicated instrument adapters enable the automated, two-way integration with liquid handling robots, colony pickers, or assay data readers. The system supports fully automated and barcoded processes, eliminating laborious and error-prone manual data handling.

Transparent and flexible IT interfaces allow for straightforward integration with corporate IT systems such as LIMS or lab notebooks.

Experienced Partner

With over 20 years of experience in biopharma R&D technologies and collaboration with top global biopharmaceutical companies, Genedata is the ideal partner for advancing your biologics R&D operations. Genedata continues to invest and expand the Genedata Biologics platform to meet emerging new requirements and enable our partners to bring better medicines to the market faster.

Genedata Biologics® is part of the Genedata portfolio of advanced software solutions that serve the evolving needs of drug discovery, industrial biotechnology, and other life sciences.

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