Enterprise software for efficient translational research in an increasingly complex regulatory environment

Genedata
solutions in silico

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Enabling Technology. Leveraging Data. Transforming Medicine.

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Abstract

Achieving the vision of precision medicine is reliant to a large degree on translational research activities that require researchers to characterize and profile patients in order to understand their response to new therapies, stratify patients for trials or search for new disease biomarkers.

The process of translational research poses significant challenges for organizations, ranging from federation of large volumes of disparate genomic and phenotypic data, through generating meaningful conclusions from such data, to collaborating across global locations. Furthermore, as researchers leverage confidential patient data (medical records, genetic information, etc.), organizations have to respect an often confusing and complex regulatory landscape. Genedata Profiler™ is a new translational research software platform developed in collaboration with leading pharmaceutical companies to effectively process, manage, and analyze omic and phenotypic data to the highest data quality and regulatory compliance standards.

In this poster we will focus on Genedata Profiler's lifecycle method and data management - a critical consideration in meeting quality and compliance goals for omics-based translational research.
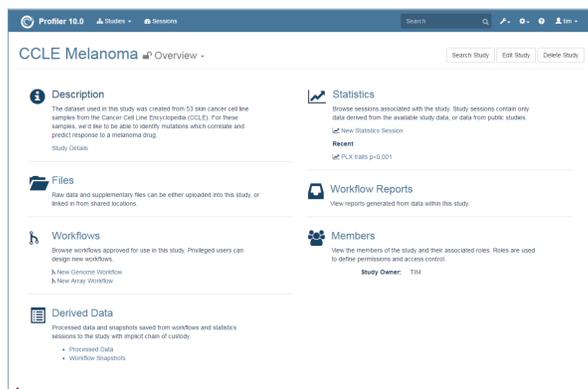
The challenges of translational research

Translational researchers face major challenges in drawing meaningful conclusions from the very large volumes of data they generate in order to deliver maximum value to the stakeholders in their organizations:

- Infrastructure challenge – federating globally distributed NGS and related data;
- Regulatory challenge – working with data from human samples in research environments;
- Data challenge – efficiently managing, processing, and analyzing omic and other data.

Genedata Profiler—a platform for translational research

Genedata Profiler provides a comprehensive and scalable translational research eco-system that addresses the infrastructure, regulatory and data challenges associated with patient profiling processes to accelerate translational research activities.


Key functionalities include:

- Secure, collaborative and regulatory-compliant data management infrastructure;
- Standardized NGS, microarray, qPCR, and MS raw data processing pipelines;
- Comprehensive, advanced statistical analysis and reporting;
- Integration with internal, external and public genotype-phenotype data.

Study-centric, role-based web UI facilitates collaboration, data, method, and results sharing.

Ensure compliance using comprehensive data access controls

Genedata Profiler comes with a rich set of enterprise-wide data and user management functionalities to help researchers overcome the infrastructure challenges associated with translational research, and enables:

- Collaboration between different user roles throughout a global organization using comprehensive role-based access controls;
- Integration, federation and curation of the wide variety of omic, phenotypic and patient data from internal (e.g. tranSMART), external and public data sources;
- Sharing of data, methods and results.
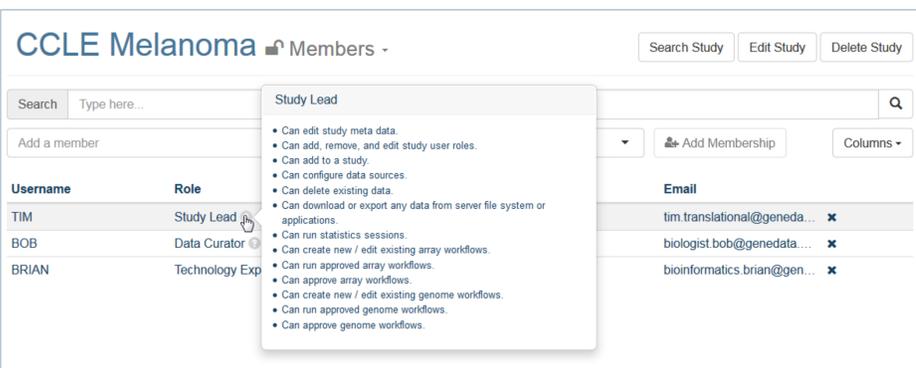
Comprehensive, flexible role-based access controls support collaboration while maintaining regulatory compliance

Ensure data quality with method lifecyle management

The global, interdisciplinary nature of translational research poses challenges to organizations to ensure that decisions are based on high quality data. Genedata Profiler provides comprehensive method management and quality reporting.

- Build processing and analysis workflows from raw data to results;
- Standardize workflows throughout an organization with full approval, versioning and access controls;
- Maintain quality and auditability with detailed quality reports and metrics.

Workflow settings can be locked down, allowing standardization of methods and use by non-experts

Configurable and dynamic quality metric plots illustrate information about NGS reads e.g. sample & mapping statistics, coverage, mapping quality, read length, insert size, base quality, sequence- or GC-content

Genedata Profiler offers a fully automatable graphical workflow system, a comprehensive reporting infrastructure, and support for all major schedulers of computing clusters. Approved workflows can be run by users with appropriate permissions

Ensure compliance with data lifecycle management

The impact of GxP regulations on translational research is ever-changing and cannot be ignored. Data in such systems is considered to be electronic records; Genedata Profiler offers a robust approach to lifecycle data management of these records via:

- Maintaining data provenance – which data is being used and from where;
- Chain of custody of data – who operated on the data, when and how;
- Audit trails – document changes to data, by whom, when and reasons for change.
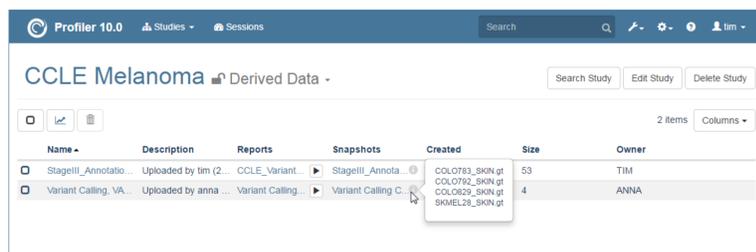
Genedata Profiler ensures GxP compliance by maintaining a link between raw data, analyses, derived data, and results on a per study basis.

Drive scientific insights

While quality data that conforms to the criteria mentioned above is the foundation of an effective and efficient translational research process, scientific insights are the outcome. Genedata Profiler empowers researchers to make discoveries with peer-reviewed methods and algorithms, interactive data analysis tools, and intuitive visualizations, and facilitates:

- A wide range of data analyses by use of a rich and growing statistical toolbox, including external algorithms as plug-ins;
- Out-of-the-box integration with public data repositories;
- Scientific insights through powerful intuitive visualizations.
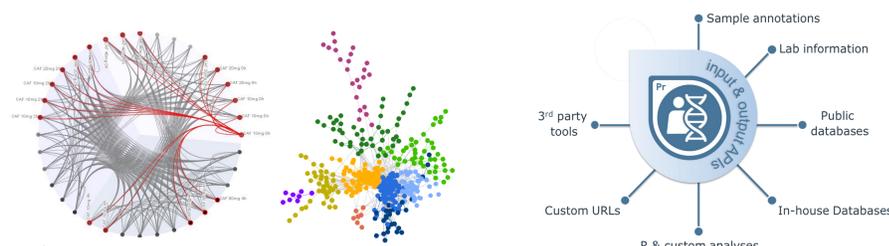
Integrating disease and genomic information from different studies allows innovative integrative data analyses, significantly reducing time and cost of omic data analysis
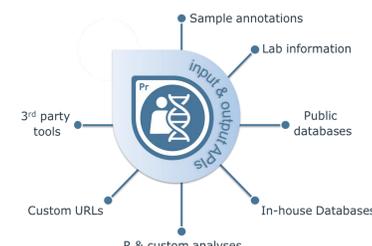
A sophisticated Shell API (with out-of-the-box cluster support) allows easy inclusion of external programs (e.g. R) as plugin activities

Summary

Genedata Profiler optimizes the business process of translational research by combining high-performance raw omics data processing pipelines, sophisticated data analyses, and unparalleled data visualizations with an advanced distributed data management infrastructure. It helps organizations comply with regulatory data retention and privacy policies through method and data management throughout the entire data lifecycle.