Dear Colleague

Increasingly, translational scientists are tasked with extracting meaningful, scientifically- and commercially-relevant conclusions from large and complex multi-omic and phenotypic datasets.. Keeping up with the latest developments in this rapidly-developing field is a time-consuming task. In our series of *Insights - Genedata Profiler*™ newsletters, we aim to bring you news, viewpoints, and scientific information on genomic profiling of patients. Welcome to our first edition!

Each issue of *Insights* will feature a scientific article written by our experts. In this first issue of the series, Dr. Mark Collins and colleagues, writing from Genedata offices in Basel, Munich and Boston, address a highly topical subject: *Translational research in the era of heightened patient privacy concerns*. Providing further insights into meeting regulatory requirements for privacy and security, we are pleased to invite you to attend a live webinar later this month presented by Dr. Harri Lempiäinen - please register to be sure of your place at this event.

We also have news about Release 10.0 of Genedata Profiler, the latest version of our popular software platform that empowers translational scientists to generate deep insights from vast amounts of NGS, phenotype and related data from patients. Feel free to view and download resources such as webinars, videos, posters, and publications from our Learning Center, and if you're traveling to a conference in the next few weeks, please take the opportunity to meet Genedata experts who will be only too happy to discuss your challenges in genomic profiling.

On behalf of all the Genedata Profiler team, I hope you find *Insights - Genedata Profiler* informative and helpful. I welcome your comments and feedback at newsletter@genedata.com.

Enjoy the first issue of our series!

With best regards,

Tamas Rujan

Tamas Rujan
Head, Operations &
Marketing

HOT IN THE FIELD: FEATURED ARTICLE

Organizations are increasingly leveraging patient data obtained from clinical trials for translational research. Merging data obtained under the strict regulatory guidelines that govern clinical trials with data generated in the research environment, which is often much less regulated, raises patient privacy concerns.

Recent high profile changes to data privacy regulations, especially in Europe, for example the replacement of the US-EU Safe Harbor Framework and the new EU General Data Protection Regulation (approved only last week), further exacerbate these concerns.

In this issue's Featured Article, Translational research in the era of heightened patient privacy concerns, Dr. Mark Collins, Dr. Axel Schumacher and Tamas Rujan review this complex regulatory landscape and offer practical solutions to conducting translational research while respecting patient privacy.

Mark Collins, Ph.D.
Marketing &
Business Development

FROM OUR DEVELOPERS

Genedata Profiler 10.0 is, as the version number suggests, a major step forward, following more than ten years of development of the product line. Focusing our software development efforts over the last year on data management and safety requirements, with Genedata Profiler 10.0 we have bridged the gap between research needs and patient data safety.

Our new three-tier security architecture allows for the first time secure access to genotypic and phenotypic information across the whole enterprise, at reasonable administrative cost. The layered design allows for marrying high-throughput omic analysis capabilities with the care that needs to be taken into account for handling patient data.

Additional key components of Genedata Profiler 10.0 are the fully redesigned hardware abstraction layer and role-based study management.

Marc Flesch, Ph.D.
Head, Scientific
Software Engineering

UPCOMING WEBINAR

Patient clinical trial data represents a huge, often untapped resource for translational research. However its use poses challenges for organizations, principal among which is the need to harmonize and make actionable this complex, distributed data while addressing patient privacy and regulatory concerns.

In a live webinar entitled Ensuring patient privacy in multi-omic translational research, Dr. Harri Lempiäinen, Scientific Account Manager for Genedata Profiler in Basel, Switzerland, will demonstrate how Genedata Profiler is able to overcome these challenges and optimize the process of translational research while ensuring compliance with ever-changing patient privacy regulations.

This webinar will offer valuable insights for translational researchers, biomarker discovery scientists, research IT professionals, and bioinformaticians. If you work with data from patients, you will benefit from the insights offered by Dr. Lempiäinen in this webinar!

Harri Lempiäinen,
Ph.D.
Scientific Account
Manager

Please register to secure your participation in this important webinar.

Mark your calendar: **Tuesday, April 26**

07:00 am PDT   (San Francisco)
10:00 am EDT   (Boston)
16:00 CEST   (Berlin)

Register

LEARNING CENTER

Genedata produces scientific educational resources on the application of very large data sets to solve translational science challenges. We are pleased to make these available for download from our website. The latest additions to our Learning Center include:

Webinars

Leveraging the power of Genedata Profiler for more efficient translational research by Dr. Harri Lempiäinen, Genedata. Dr Lempiäinen demonstrates how the power of Genedata Profiler drives rapid and efficient biomarker identification and validation from raw data to results and how the platform integrates seamlessly with existing in-house platforms (e.g. the open source data warehouse tranSMART).

Molecular characterization of diseases using multidimensional big data by Dr. Harri Lempiäinen, Genedata. We address the major tasks performed by different members of an R&D team to dive deep into omics data to profile patients and compounds, applying a workflow to identify candidates for predicting response to an oncological drug.

Publications
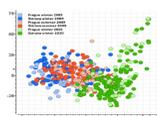
Read about a collaborative project where Genedata helped to develop new bioinformatics workflows which deliver accurate measures for inter-laboratory comparison studies.
Herwig *et al*. (2015): Inter-laboratory study of human in vitro toxicogenomics-based tests as alternative methods for evaluating chemical carcinogenicity: a bioinformatics perspective

Videos

In this short video, Optimizing the process of omics based patient profiling in translational research, we show how the latest version of Genedata Profiler (v10.0) helps global, multidisciplinary teams perform translational research while ensuring patient data privacy.

Recent Posters

A new translational research software platform for efficient patient and compound profiling. Genedata Profiler is a new translational research software platform developed in collaboration with leading pharmaceutical companies to process, manage, and analyze NGS and other omics data from patient samples, applying highest data quality and regulatory compliance standards.

Genedata Profiler - a collaborative, regulatory-compliant, integrated platform for omics-based patient and compound profiling. In this poster we discuss the key features of Genedata Profiler and illustrate the power of the platform using a case study that also demonstrates how Genedata integrates with tranSMART.

Enterprise software for efficient translational research in an increasingly complex regulatory environment.In this poster we focus on lifecycle method and data management in Genedata Profiler - critical considerations in meeting quality and compliance goals for omics-based translational research.

Featured Articles

All *Insights - Genedata Profiler* **Featured Articles** will also be available for download from the Genedata website.

Collins et al. (2016): Translational research in the era of heightened patient privacy concerns. In this paper we review the regulatory landscape and its impact on translational research, and define the key attributes of an "ideal" system to overcome the challenges of conducting translational research while respecting patient privacy.

MEET THE EXPERTS

Experts from Genedata will attend the following meetings over the next few months, where they will be delighted to discuss issues in genomic profiling of patients and characterization of diseases. Please visit our posters and ask for a demonstration of Genedata Profiler 10.0.

14th Annual Pharmaceutical IT Congress
September 28 - 29 | London, UK

BioData World Congress 2016
October 26 - 27 | Cambridge, UK

ABOUT GENEDATA PROFILER

Genedata Profiler optimizes the business process of translational research by combining high-performance raw omics data processing pipelines, sophisticated analytics, and innovative visualizations with an advanced distributed data management infrastructure. An open, interoperable enterprise software platform, Genedata Profiler empowers scientists to integrate NGS and other omics data from patients with clinical annotations, generating scientific insights while ensuring data privacy and security.

Basel | Boston | Munich | San Francisco | Tokyo
www.genedata.com