

## Background Information

### **Genetic Information Management Suite (GIMS): A milestone in genetic diagnostics**

*Genetic diagnostic reports for physicians in an easy-to-understand format / Creating analytical reports based on current research in minutes / Personalized medicine becomes widely leverageable*

**About 15 years ago, the international Human Genome Project declared the sequence of the human genome completed. Since then, genetic diagnostics has been on the rise. With the knowledge of the human genome and the roles genes play, the amount of information about the efficacy of drugs for the treatment of diseases is also growing. However, this flood of new findings raises another problem: How can we convert the results of genetic tests and conclusions about their influence on the treatment success into reliable and clinically practicable data as quickly as possible? Or in other words: How can physicians in their practices or in hospitals easily access information helping them to find the right drugs or therapies—with the least adverse effects—for their patients? So what is the best way for bridging this “last mile?” For the first time, bio.logis GIM’s Genetic Information Management Suite (GIMS) is now offering a software solution for this problem. It automates, standardizes and simplifies the traditionally time-consuming job of manually interpreting and converting results into therapeutically useful information at the point of care, making personalized medicine a cost-efficient and wide-spread option in clinical practice. All data is pseudonymized, encrypted, stored and provided from a data center hosted by Deutsche Telekom AG.**

Your own DNA includes information about tolerance and efficacy of drugs as well as genetic dispositions for various diseases. This information and the knowledge about which individual therapies work best is constantly growing. A major reason for this enormous information gain is the increasing use of computing power, cloud computing and IT-supported analytics. This drastically cuts the costs of DNA sequencing, making genetic diagnostics available and affordable for the general public.

At the same time, interpreting the results becomes more complex. On average, a person’s genome shows about six million deviations from the human reference genome, so there is an average of six million variants of every single genome. If you were to compare the related clinical information of a person—the so called “clinical interpretome”—with the tomes of the German Brockhaus Encyclopedia, this knowledge would fill over 2,000 meters of shelf space. Even in times of digitalization, generating meaningful and sound diagnostic reports from these enormous volumes of data still takes enormous amounts of time. Given the growing diversity of the findings in genetics research and the increasing demand of genetic diagnostic analysis, the traditional generation of diagnostic reports is no longer practicable. In other words, the explosive growth of knowledge provides not only new opportunities, but also raises a new problem—the translation of analysis results into leverageable information for the treating physician.

#### **GIMS—supporting the “last mile” to the patient**

So we need manage this “last mile” better than before. However, it is not quite as easy as it sounds. Despite the use of modern technology, generating human genetic diagnostic reports still

remains a complex process, requiring great expertise, lacking standardization and therefore scalability. Furthermore, the results of genetics testing have to be translated into clinically relevant information and recommendations to make them available to physicians and patients in a clinically leverageable format.

Therefore, bio.logis Genetic Information Management GmbH has developed GIMS—a software solution supporting laboratories in the efficient and standardized preparation of genetic information and in making them available at the point of care in an easily understandable format. This is an important milestone for implementing personalized treatment concepts. GIMS is the first software solution of its kind, enabling laboratories to largely automate the translation of results from genetic testing into clinically relevant information and easily understood recommendations. Currently, GIMS is the only software suite on the market offering this type of automation quickly and cost-efficiently.

#### **Efficient information management for diagnostic reports at the click of a button**

The workflow for the treating physician could not be simpler: Just a few minutes after a laboratory has uploaded a patient's analysis results into the lab's own secured GIMS platform, the patient can use their credentials to log in and access their personalized diagnostic report. Additionally, the information includes treatment recommendations based on up-to-date research and provided by the laboratory.

Benefits at a glance:

- enormous time and cost savings from the automation of manual processes and workflows;
- automatic generation of diagnostic reports in a standardized format with consistent wording and quality;
- clinically leverageable information and recommendations for physicians and patients, accessible via a secured web portal and mobile app.

#### **Data protection—top priority**

The genetic analysis results are stored in a private data repository at a high-security data center hosted by the Deutsche Telekom. All the data are pseudonymized to protect them. The data are also encrypted so that not even the data center's administrators can read the personal data.

Therefore, only the laboratory itself can allocate a certain person's analysis results to generate a personalized diagnostic report. So this service complies with all the strict German data protection regulations.

### **The key—from analysis to interpretation**

The Genetic Information Management Suite (GIMS) is a software suite developed by a team of experienced specialists in human genetics diagnostics and bioinformatics, natural scientists and software engineers at bio.logis Genetic Information Management GmbH.

At the heart of GIMS is the dedicated Content Management System enabling laboratories to merge and maintain medical and scientific content centrally on one single digital platform. This content is used by the Diagnostic Report Module (DRM) to automatically generate diagnostic reports based on individual test results.

Since last year, the software suite's Diagnostic Report Module has been labelled with the CE mark as a Class I medical product. The module has been certified by the German trade association for Internet medicine (BiM) as an "Internet medicine quality product."

### **GIMS for use in European hospitals**

In order to drive the practical implementation of genetic knowledge to improve therapeutic decision-making, bio.logis GIM takes part in U-PGx (Ubiquitous Pharmacogenomics), a project funded by the EU's Horizon 2020 initiative. Currently GIMS is being implemented in seven selected university hospitals across Europe (the Netherlands, UK, Austria, Greece, Italy, Spain, Slovenia) for application in day-to-day clinical operations, where bio.logis GIM closely collaborates with the internationally renowned KNMP (the Royal Dutch Pharmacists Association). For this pharmacogenetic project, the participating university hospitals will analyze the blood samples of over 8,000 patients. The objective is to treat about half of the patients with an individually optimized drug therapy based on the findings of the relevant gene alterations and to compare the course of the disease with the same number of patients who were treated without using any genetic information. In this context, GIMS performs the automatic compilation of all scientific and diagnostic content for each analysis result. Based on genetic testing, personalized dosage recommendations for a total of 84 different drugs can be generated in the national language.

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**About U-PGx**

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