

## Background information

### **GIMS—supporting the “last mile” of human genetic diagnostics**

*The Genetic Information Management Suite (GIMS) creates diagnostic reports and treatment recommendations for physicians and patients almost in real-time / Diagnostic Report Module and Delivery Module to bridge the “last mile”*

**GIMS is a cloud-based IT solution that was developed by a team of experienced specialists in human genetic diagnostics, scientists and IT experts at bio.logis Genetic Information Management GmbH. The aim of this unique solution is to drive the implementation of human genetic diagnostics in clinical practice. As the first product of its kind, the Genetic Information Management Suite (GIMS) largely automatically translates laboratory findings into comprehensive diagnostic reports and treatment recommendations for the treating physician. Currently, GIMS uses the two available service modules, Diagnostic Report Module (DRM) and the Delivery Module (DM), to bridge the so called “last mile” to physician and patient. An upcoming third module, the Knowledge Management Module (KMM), is planned to support the sharing of knowledge between labs and expert groups.**

A possible analysis panel for testing the thrombosis disposition of a person may contain four genes, one about nutrition may have up to 17 genes to be analyzed to detect potential risks or intolerances. Depending on the underlying analysis technology, several gigabytes of raw data will be collected and stored per patient. However, genetic diagnostics not only generates a huge amount of data; translating analysis results into clinically leverageable information and creating genetic diagnostic reports also make this process highly time-consuming.

Therefore, the bio.logis GIM’s expert team has developed a software suite using special algorithms, workflows, and modular components to enable the efficient creation of easily understood genetic diagnostic reports. GIMS only takes a few seconds to create a medically sound report. Along with the medical validation by a laboratory physician, the time needed amounts to about five minutes. As a further special feature, the creation of reports is completely standardized using text templates prepared and maintained by the laboratory. Findings and further information are very clearly presented by a Delivery Module. Additionally, web-based applications deliver the data straight to the point of care.

The GIMS IT solution complies with the strict European data privacy laws. The highly secure infrastructure is hosted by Deutsche Telekom. Since last year, the software suite’s Diagnostic Report Module has been labelled with the CE mark as a Class I medical product. Furthermore, the module has been certified by the German trade association for Internet medicine (BiM) as an “Internet medicine quality product.”

#### **bio.logis GIMS—workflow**

Currently, GIMS delivers its services via two modules, the Diagnostic Report Module (DRM) and the Delivery Module (DM). When a genetic diagnostic report is requested by a physician, the commissioned laboratory performs a DNA analysis. Now the Diagnostic Report Module gets to work: An interface with the client’s Laboratory-Information-Management-System (LIMS) feeds the DNA findings into the Genetic Report Engine, the heart of the module. The engine connects the laboratory findings with the appropriate reporting templates from the module’s Content



Management System (CMS). The process also takes into account other patient data such as existing diseases, sex, or age, to create a standardized and thorough genetic diagnostic report.

What makes GIMS so special is the fact that the information later displayed in the personalized report can be created directly by the laboratories in the software suite's Content Management System as text templates for any number of theoretically possible genetic variants. So the laboratory maintains control over the content compiled in the report while assuring that identical information is included in the report for identical gene variants. This enables a standardized and fully reliable report creation workflow. Using the Content Management System is also much more efficient than manually creating reports, because all the information is stored and managed centrally.

The second GIMS component is the Delivery Module. As soon as a sample has been analyzed, the results are compiled in a Genetic Health Record (GHR) which is then made available to the requesting physician and their patient in a clear layout via an intuitive web portal or application. Furthermore, filter functions and other genetic information and references expand the presented findings. Each laboratory decides for itself which additional information to include in the GHR and provide to the physician at the point of care.

Once the information is added to the GHR, the physician at the point of care can access the analysis results in real-time. Along with the included treatment recommendations they provide a medically sound basis for making decisions on the individual treatment of a certain patient. The Delivery Module also has an alert function for the physician about new reports, data, or other important facts.

bio.logis GIM is already working on the next expansion of the software suite, the Knowledge Management Module (KMM) currently being developed. KMM supports laboratories with the interpretation of genetic variants and other medical parameters—another unique GIMS feature. Many existing solutions merely deliver a final result with no or only some rudimentary reference data, making it impossible to tell what information the result is based on. Here, the Knowledge Management Module offers another approach: It uses clearly defined workflows to enable the structured collection, documentation, and curation of data and entire decision-making processes, providing visibility about who made a certain assessment based on certain information. Furthermore, KMM allows to gradually build a medical knowledge base.

This growing knowledge pool can also be used by laboratories to support a “collective intelligence.” In future, a laboratory could, for example, query a newly discovered genetic variant in the module to find out whether it has already been assessed by another laboratory in the network—and ideally use the available information.

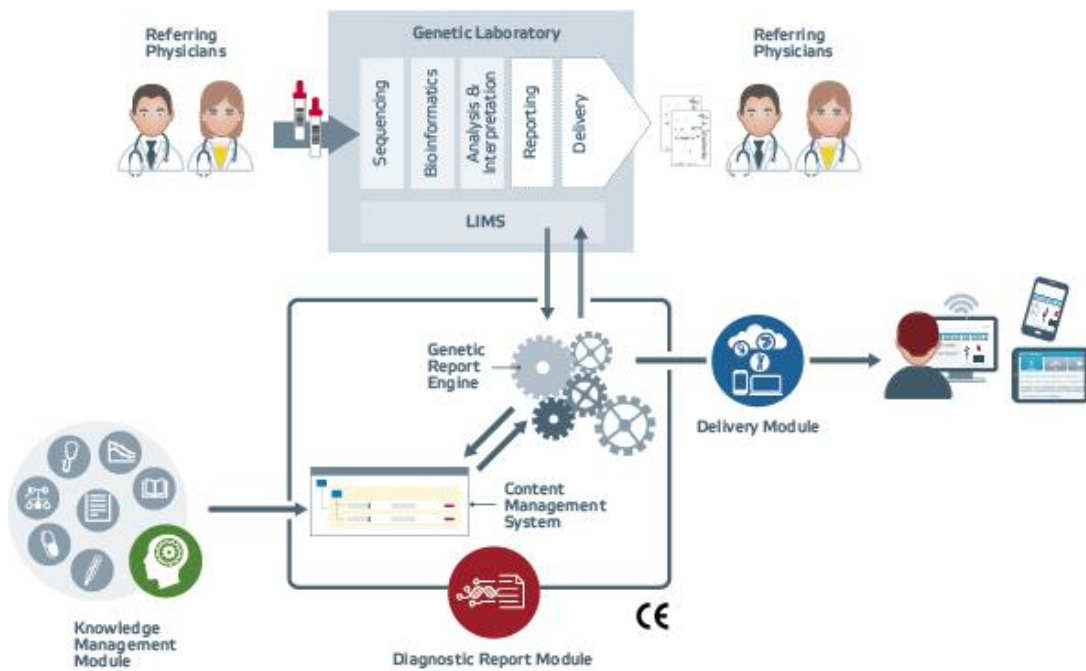
### **Conclusion—GIMS is the first software suite to enable efficient, standardized and comprehensive reporting**

The extensive automation of the assessment process saves up to 95% of time compared to manually created genetic diagnostic reports. GIMS also enables laboratories to efficiently prepare and deliver analysis results in a standardized and easily understood way. bio.logis GIM offers a

reliable first-of-a-kind IT tool to significantly accelerate and standardize scientifically sound key decision-making processes for the personalized treatment of patients.

*(about 7,600 characters)*

**Imagery:**



**Caption:** GIMS consists of three modules. The Genetic Report Engine of the Diagnostic Report Module connects the DNA information from the client’s Laboratory-Information-Management-System (LIMS) with the text templates—prepared and stored by the laboratory in the Content Management System—and combines them into a standardized genetic report. The Delivery Module converts the information provided by the Diagnostic Report Module into a clearly structured layout. The Knowledge Management Module collects data, structures decision-making processes and workflows, and optionally enables cross-laboratory knowledge management.

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