

# **Genetic Information Management Suite**

# Efficient translation of genetic data into clinical practice

bio.logis Genetic Information Management GmbH



### bio.logis Genetic Information Management GmbH

Founded	2013 Spin-off from the bio.logis Center for Human Genetic	S
Location	Frankfurt Innovation Center for Biotechnology Frankfurt, Germany	
Employees	25 employees Highly qualified teams in IT–/Bioinformatics and Human Genetics	BUNE
Core Business	Software and services for diagnostic laboratories	

### Participation in EU-Projects within Horizon 2020 program

- Genetics Clinic of the Future
- Ubiquitous Pharmacogenomics











**Our goal:** Support and drive the adoption of human genetic diagnostics into clinical practice

#### **Our offer:**

Innovative IT-tools and services, supporting genetic laboratories in translating genetic test results into clinical insights and recommendations

Our dedicated Genetic Information Management Suite (GIMS) focuses on process steps which are currently facing an unmet need, such as

*Efficient content management* 

High throughput production of diagnostic reports

Delivery of results and information to the point of care

### **Process chain genetic diagnostics**



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### Problem:

Translation of genetic testing results into clinically actionable information and recommendations for personalized treatment

### Why?

- Non-standardized process
- Manual work, time consuming
- Requires rare specially trained experts



Expensive, non scalable

### **Process chain genetic diagnostics**



### Problem:

Delivery of results & perception at Point of Care

## Why?

- Traditional DX-Reports no longer adequate to transport all necessary and relevant information resulting from multi-gene analyses
- DX-Reports only use fractions of data resulting from a genetic test
- Remaining data not available for subsequent clinical questions

## **GIMS®: Genetic Information Management Suite**



# bio.logis GIMS® The solution for Genetic Labs

- Efficient management of diagnostic content
- Automated production of diagnostic reports
- Structured documentation and sharing of assessments, decisions and reference information
- Delivery and presentation of genetic test results through web-based applications at *Point of Care*
- Developed by highly experienced team of geneticists and bioinformatics experts

### GIMS<sup>®</sup>-Modules

Diagnostic Report Module	<ul> <li>Efficient management of diagnostic content (interpretations, descriptions, graphs, etc.)</li> <li>Automated production of diagnostic reports <i>C Certified as</i> <i>Medical Device Class I</i> </li> </ul>
<b>Knowledge Management</b> Module	<ul> <li>Structured documentation and sharing of variant assessments, decisions and reference information</li> <li>Decision support for diagnostic reporting</li> </ul>
Delivery Module	<ul> <li>Delivery and presentation of genetic test results through web-based applications at Point of Care</li> </ul>

### **GIMS Integration**







### Value drivers costs + turnaround time

### Cost structure lab process human genetic test









### How it works

### 1. Import of lab results:

 Clinical data (variants, gender, medication, symptoms, etc.) imported into customer-specific GIMS-instance through standard interfaces

### 2. Report compilation:



- Report Engine allocates content (text elements, graphs, etc.) from content management system based on incoming clinical data
- Automated compilation of appropriate content into clinical report
- **3.** Provision of diagnostic report for medical validation
  - Re-import into clients LIMS as structured data or ready to use text/pdf-document using proprietary Report Layout Engine



### Where's the value?

- Automated production of diagnostic reports
  - Significant time savings through automation of manual work steps
- Fully functional Content Management System
  - Compilation and management of diagnostic content in one central entity with clear-cut workflows
  - Every user has access to the same, up-to-date contents standardized format, wording, quality for diagnostic reports
  - Preservation of Know-How in case of personnel turnover
- Compliance with international data security regulations
  - Hosting in high security health care data center of Deutsche Telekom
  - CE-Certification as Medical Device Class I



# Content Management System – Key Features

- Individual workflows for different diagnostic reports
- Free grouping of parameters in decision trees
- Parameters (e.g. genotypes) can be defined or imported
- Version control of content modifications
- Similar text elements displayed in real-time during editing: reduction of redundancies
- Full text search
- Comment function and discussions within system
- Individual literature references for every text element
- User rights, roles, functions fully editable
- Full UTF-8 Support



For converting diagnostic report content into ready to use documents

- Converts structured report data delivered by Diagnostic Report Module into ready to use documents (PDF, ODT)
- Layout and editing based on customerdefined templates
- Define and use your own branding, themes, styles and structure for diagnostic reports
- Templates easily manageable within the system no programming required
- Usable in combination with Diagnostic Report Module or as stand-alone reporting tool















# **Knowledge Management Module**

### How it works

- Step-wise guidance through variant assessment process
- Structured documentation of variant information, assessments, decisions, reference information, etc.
- Automated notifications when content is outdated and needs to be re-assessed
- Direct interface to Diagnostic Report Module
- Sharing function for information and content





# **Knowledge Management Module**

## Where's the value?

- Structured documentation process with clear-cut workflows for review and approval
- Makes decision process transparent and reproducible – ideal for QA and audit purposes
- Provides curated information for diagnostic decision support
- Supports automated report production through direct interface to Diagnostic Report Module
- Sharing of medical content and knowledge within a growing network of genetic laboratories, institutions and expert groups











### How it works

- Compilation of test results in patient-specific
   Genetic Health Record (GHR)
- Labs can provide referring physicians and patients access to a patient's GHR via branded web portal or mobile app
- Secure user interface for patients and physicians
- Data hosted within customer specific GIMS-entity, accessible via VPN





### Where's the value?

- Supports customer retention by providing results in an easily accessible way
- Real-time generation of Diagnostic Reports within Genetic Health Record
  - Reports always up-to-date
- Alert function when new reports, information, etc. are available
- Include important medical information, knowledge, references, etc.
  - Portal contents customizable to customers requirements
- Direct integration into EHRs possible







Fully automated report generation for selected diagnostic areas with well established panels

Medications & Therapy

Family Planning & Pregnancy

**Prevention & Nutrition** 

### **GIMS®** Infrastructure



## **GIMS® Infrastructure**

#### GIMS hosted in high security Healthcare Data Center of Deutsche Telekom

- No public cloud!
- Customer-specific, locked GIMS-entity
- Secure user access via VPN-connection
- No third-party access to customer data
- Compliant with EU data protection regulations

#### Easily integrated in every laboratory IT infrastructure

- Connection to customer's LIMS or bioinformatic platform
- GIMS supports all standard interfaces (HL7, Json, etc.)



### Benefits at a glance



- Automated production of diagnostic reports
  - Significant time savings through automation of manual work steps
- Fully functional Content Management System
  - Compilation and management of diagnostic content in one central entity with clear-cut workflows
- Structured documentation process with clear-cut workflows
  - $\circ~$  Makes decision process transparent and reproducible
- Enhanced delivery of results and clinical information at *Point of Care* 
  - Secured user access for patient and physician through customer-branded web-portal



- EU-funded project within the Horizon 2020 program
- Aiming to support the implementation of pharmacogenomics in clinical practice
- bio.logis GIM responsible for implementing GIMS at 7 selected hospitals across Europe



Horizon 2020 European Union funding for Research & Innovation





Univerza v Ljubljani



Servicio Andaluz de Salud CONSEJERÍA DE SALUD







Leids Universitair Medisch Centrum

# U-PGx | Ubiquitous Pharmacogenomics

### Project Outline

- KNMP, Netherlands provides a list of medications which are known to be influenced by genetic variations along with the appropriate genes/variants and recommendations
- Patients who are intended to receive one of the predefined medications are recruited in 7 project sites across Europe and genotyped with a standard PGxpanel
  - Leiden University Medical Center
  - University of Liverpool
  - Medical University of Vienna
  - National Cancer Centre Aviano
  - San Cecilio University Hospital Granada
  - University of Patras
  - University of Ljubljana
- GIMS will be implemented at the 7 project sites and will be used for
  - translating the KNMP recommendations into the local languages
  - o automatically generating PGx-reports based on found variants
  - Delivering results to patients

U-PGx | Ubiquitous Pharmacogenomics



### translating DNA into health

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