# **About DigiMed Bayern**

The pilot P4 medicine project was launched end of 2018 with the focus on atherosclerosis. P4 medicine (predictive, preventive, personalized, participatory) is one of the world's most promising developments for holistic and efficient healthcare. Which could only be achieved by a better assessment of disease risk, disease progression and therapy success.

DigiMed Bayern combines comprehensive clinical and epidemiological datasets, enriched with state-of-the-art multi-dimensional -omics characterization (genomics, transcriptomics, proteomics and metabolomics). For the integrative analysis of the resulting "Big Data", an ethically and legally compliant and highly secure IT infrastructure will be fundamentally designed and implemented.

In addition, the infrastructure created by DigiMed Bayern will be sustainable and transferable to other institutions and disease areas. The population will benefit from concrete improvements in health management as well as the resulting advances in prediction, targeted prevention, diagnosis and therapy. The project, funded by the Bavarian State Ministry of Health and Care, is a pilot project within the Bavarian State's master plan "BAYERN DIGITAL II".



#### **Consortium Partners:**

- German Heart Centre Munich
- Bio<sup>M</sup> Biotech Cluster Development GmbH
- Department of Informatics, TUM
- Department of Sport and Health Sciences, TUM
- Department of Vascular and Endovascular Surgery, University Hospital rechts der Isar, TUM
- Institute of Bio Law, Health Law and Medicine Law, University of Augsburg
- Institute for Medical Information Processing, Biometry, and Epidemiology, LMU
- Institute for Stroke and Dementia Research, Universital Hospital, LMU
- Institute of Epidemiology, Helmholtz Center Munich
- Institute of Neurogenomics, Helmholtz Center Munich
- Institute of Human Genetics, University Hospital rechts der Isar, TUM
- Institute of Technology-Theology-Natural Sciences, LMU
- Leibniz Supercomputing Centre of the Bavarian Academy of Sciences and Humanities
- Max-Planck-Institute of Biochemistry























für die Medizin der Zukunft

www.digimed-bayern.de

# DigiMed Bayern

# Pilot Project on P4 medicine

Predictive | Preventive | Personalized | Participatory

For improved, patient-centered healthcare. For advances in digital and data-driven medicine. In focus: Atherosclerosis.



#### Work Package 1 & 2

# P4 medicine for coronary heart disease, carotid stenosis and stroke

WP1 and WP2 focus on patients with coronary heart disease and carotid artery disease, who in many cases have already experienced a heart attack or stroke. Highly standardized clinical, phenotypic, diagnostic and therapeutic data are available from about ten thousand of patients. This includes imaging data, information of comorbidities and laboratory diagnostics. Biobanks comprise biomaterials such as tissue samples from bypass surgery, carotid vessels, plaques and blood. Some of these samples have already been partially characterized on the genetic level.

These samples will be enriched with comprehensive molecular data (genomics, transcriptomics, proteomics and metabolomics), combined and analyzed in association with their phenotypes and outcome data. A knowledge platform will be developed, allowing complex molecular data to be used efficiently for individual risk assessment and follow-up. Software modules shall integrate independent data sources (clinic, laboratory, data warehouse) and make them accessible for comprehensive analyses. The ambitions go beyond the technical solution of horizontal networking: The data will be analyzed in the context of existing medical and scientific knowledge. For most of the patient cohorts, data are collected throughout the full treatment period and follow-ups. DigiMed Bayern will create a comprehensive thesaurus that allows to identify molecular patterns of high prognostic quality. An essential feature will be the accompaniment of clinical studies and the translation of the results into clinical routine. An improved understanding of causality e.g. of and in between the genes, transcripts, proteins and metabolites involved is expected as outcome. This will contribute to better predictions and new approaches to personalized prevention. Clinical and epidemiological cohorts with anonymized data of leading health insurances allows the analysis of medical care data: What is the deviation from the guideline-based therapy? What are the reasons and consequences of a lack of adherence? The participating hospitals possess large, well-characterized

patient cohorts (n> 50,000) with a prospective follow-up of up to 10 years.

It is also planned to set up an internet-based personalized prevention program. Even today, the underlying platform of the German Heart Foundation is accessed >1,000 times per day. This platform will be differentiated on an interactive basis to be able to recommend individualized advices for action. This will contribute to the prevention of cardiovascular diseases by patient-driven modification of lifestyle-associated risk factors. DigiMed Bayern accompanies the creation and scientific evaluation of the prevention program of the German Heart Foundation.

# **Work Package 3**

# P4 medicine for Familial Hypercholesterolemia

WP3 analyzes the feasibility of a population-wide screening for Familial Hypercholesterolemia. This disease is very likely to lead to early atherosclerosis, although it still remains undiagnosed in more than 95% of cases so far. The goal is an exemplary implementation of this screening approach with biochemical and molecular genetic diagnostics, as well as feedback treatment concepts. Immediate substantial improvements for affected patients are expected as outcome.

# **Work Package 4**

# The general population of Bavaria

WP4 uses an existing epidemiological sampling of the Bavarian general population from the Augsburg area of about 18,000 individuals. With additional information about heart attack and stroke cases, comprehensive and long-term data on risk factors, treatments and omics characterizations form an ideal add-on and starting point to build up a digital research infrastructure. This should allow new innovative prediction algorithms to be derived and individualized prevention approaches to be developed and simulated, which can subsequently be validated with patient data.

#### **Work Package 5**

#### Multi-omics platforms

WP5 provides platform-leading technologies and integrative expertise for multi-dimensional molecular omics analysis.

## **Work Package 6**

# IT conception and infrastructure

WP6 is a central component of DigiMed Bayern for the concept of data management and IT infrastructure. The goal is, in collaboration with all stakeholders, to ensure secure and compliant data access, implementation of powerful, scalable infrastructure and integration of analytical tools through to knowledge management systems, artificial intelligence and machine learning.

## Work Package 7

#### ELSI (Ethical, Legal and Social Implications)

WP7 addresses ethical and legal issues relating to P4 medicine and associated DigiMed Bayern work packages. The focus of the legal expertise is on the conformity with the data protection regulations, as well as the development of patient consent that combines the requirements of legal security and innovation. With regard to the ethical issues, the social implications of P4 medicine and the related developments in principles of medical ethics are in the focus.

## **Work Package 8**

# Project management und public relations

As an integrative component, WP8 supports the project with stringent project management, broad public relations, cooperation within the ecosystem and the implementation of innovation in infrastructure and economic power.

Funded by:

