

Description of the work packages (WP)

DigiMed Bayern – a pilot project for P4 Medicine

October 15, 2018

WP1 and WP2 focus on patients with coronary heart disease and carotid artery disease, which in many cases have already had a heart attack or stroke. From ten thousands of patients highly standardized clinical, phenotypic, diagnostic and therapeutic surveys are on hand. This includes imaging data, collateral diseases 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 genetically characterized.

Using the samples of these and other patients, comprehensive molecular data (genomics, transcriptomics, proteomics and metabolomics) will now be collected and correlated with the phenotypes and outcome data. A knowledge platform will be developed that will allow complex molecular data to be used efficiently for individual risk assessment and follow-up. Software modules will integrate the independent data sources (clinic, laboratory, data warehouse) and make them accessible for comprehensive analysis. The ambitions go beyond the technical solution of horizontal networking; the data will be analyzed in the context of existing knowledge.

Patients are or were mostly followed throughout the full treatment period. *DigiMed Bayern* will create a comprehensive thesaurus that allows to identify molecular patterns of high prognostic quality. Prognosis, diagnosis and therapy should be improved. An essential feature will be the accompaniment of clinical studies and the translation of the results into clinical routine. Also, 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.

The simultaneous analysis of clinical and epidemiological cohorts with the data of leading health insurances allows clinically well-characterized patient groups to be analyzed together with health care data: what is the deviation from the guideline-based therapy; what are the reasons for this and what are the consequences of a lack of adherence? The participating hospitals have large, well-characterized patient cohorts ($n > 50,000$) with a prospective follow-up of up to 10 years.

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



Deutsches Herzzentrum München
des Freistaates Bayern
Klinik an der Technischen Universität München



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

WP4 uses an existing extensive long-term epidemiological sampling of more than 18,000 people. Extensive information on risk factors, treatments and partial -omics characterization is an ideal starting point to build a digital infrastructure while completing the analyzes. This should allow to discover new cases of heart attacks and strokes and to derive innovative prediction algorithms as well as to develop and simulate individualized prevention approaches. These can then be tested in population-based observational studies and clinical trials.

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

WP6 is a central axis of *DigiMed Bayern* as a platform for the concept of data management and IT infrastructure. The goal is, in collaboration with all stakeholders, to ensure secure, compliant data access, implementation of powerful, scalable infrastructure and integration of analytical tools through to machine learning ("Artificial Intelligence") and knowledge management systems.

The ethical and legally compliant implementation in the social context is ensured by **WP7**, manned with outstanding competences. The focus is on compliance with data protection guidelines, correct but also innovative handling of patient consensus, and dialogue with society and legal bodies.

As an integrative staple, **WP8** ensures stringent management, broad public relations, close to population, cooperation with industry and for the implementation of innovation as infrastructure and economic power.