Up the Stairs
to Your Success in Digital Competence for Better Health Care and Research

The HiGHmed Teaching Program for Health Professionals

www.highmed.org
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Welcome Note

With the aim of improving digitalization, German university hospitals are required to strengthen the digital talent pool and continuously train health professionals within their organizations. However, a rapid adaptation of university teaching to the challenges of educating students and staff necessitates a concerted effort to qualify medical students and physicians for the medicine of the future.

The HiGHmed consortium addresses this by bringing together outstanding expertise in the teaching and training of medical informatics. The participating university hospitals contribute to a long tradition in shaping this scientific discipline, with Heidelberg/Heilbronn representing the oldest medical informatics curriculum in Germany and Göttingen having the first internationally accredited program in Germany. Excellent academic and innovative private partners contributing to the HiGHmed curriculum will further support the HiGHmed program to sustainably strengthen medical informatics in both research and clinical care.

The development of medicine resulting from novel information technologies and data-rich medicine also creates new roles in clinic technology, such as data stewardship, that require the implementation of new learning modules. The training of physicians to deal with data-driven research methods, the continuing education of senior health professionals, and health care management will be of major importance for the connection between informatics and medicine.

In this brochure, HiGHmed is pleased to introduce the activities undertaken within our consortium on the topic of teaching and strengthening medical informatics to you. The HiGHmed partners present their expertise and participation as part of a fantastic joint teaching project preparing health professionals for the implementation of digital health.

Prof. Dr. Roland Eils
Coordinator of HiGHmed
Medical Informatics Initiative Germany
Greetings

Physicians in Germany perceive the digital transformation of medicine as an ongoing fundamental change regarding many aspects of their work in patient care – they understand that it is much more than just digitization of technical processes. The transformation still focuses on technology and how it can provide improvements of complex administrative processes, with less focus on supporting the key activities of physicians. In the next decade, Germany will have to invest billions in new digital support technologies – however, it is even more important to invest in developing the key qualifications of all professionals to enable them to make use of the new options!

By starting the medical informatics initiative, the German federal government has taken an important step to concretize this urgent need as they requested the consortia to address the topic of teaching. Only by coaching, enabling and teaching can we empower physicians to shape the transformation process following their system of values.

The key to a successful future of medicine is not only the qualification of physicians but of all health professionals – in particular health care management – based on a sustainable forward-looking strategical teaching and training concept along with a digital agenda. Many players will be active in this field. They should work together to achieve maximum efficiency with limited resources. Digital competencies will be needed more and more – especially with the growing complexity of an ever more precise medicine. Thus, specialists in all areas of health care have the right of access to learning modules they can utilize at home or in their offices combined with up-to-date training courses. Blended learning strategies are necessary and must be manageable in the daily lives of health professionals.

I welcome the HiGHmed teaching and training program and wish the team success and many cooperating partners and followers. The German Medical Association (Bundesärztekammer) supports the project.

Dr. Franz Joseph Bartmann

Long-standing President of the State Chamber of Physicians of Schleswig-Holstein and Board Member of the German Medical Association
The HiGHmed Strategy to Empower Health Professionals for Digital Health

Serving urgent needs in accordance with the Digital Agenda of the German Government

The digital transformation of medicine is speeding up. Fifty percent of patients consult the internet before they go to the doctor. Precision medicine comprises complicated medical knowledge, which nobody can learn the traditional way anymore. Systems medicine identifies new rare constellations of factors causing diseases, which can be targeted with a growing range of interventions.

Everything is changing – is it possible to prepare professionals and patients for the winds of change?
The Digital Agenda of the German Government has been addressing this issue for some years. Many workshops have identified the issue that adaptation of the learning and teaching processes and structures in Germany is the key to successfully moving the country back to the top level of economic, scientific, and democratic performance in an ever more digitalized global environment.

Empowering capable actors
Germany started to develop curricula in medical informatics rather early; internationally, Heidelberg/Heilbronn (1972) and Hanover/Brunswick (1974) were among the first. In 2012, Göttingen received the first international accreditation in Germany by the International Medical Informatics Association. Many other existing curricula and educational models can be used and enhanced to address new target groups and attract higher numbers of students and lifelong learners. The HiGHmed consortium started with the three units mentioned above and wants to include as many players as possible. Currently, 14 sites are already collaborating (see map) – several others are interested.

Geographical dissemination of the HiGHmed teaching program in Germany in late 2018, 14 digital health training instructors started in 2017/18. The group is open for further partners if they support the strategy.
Using standardized infrastructures for blended learning – the only way possible

During the last 15 years many well-known institutions and innovative projects have tested digital learning formats. From these early players we know, that only blended learning formats with sustainable infrastructures and teams that are able to work in compliance with legal regulations have the chance to be successful. Therefore, the HiGHmed teaching program is utilizing the national IT infrastructures which have been set up in Germany during the last 20 years.

Exploring new regulations to enable blended lifelong learning

Nevertheless, the optimistic HiGHmed teaching approach requires hard basic work and long-term planning to be successful. The following aspects are of key importance:

- modern embedded learning concepts
- a wide range of target groups
- realistic use of existing technical standards and infrastructures
- inclusion of a growing number of partners
- a realistic long-term financial planning including “crowd-funding” options, and
- a consequent process of adapting regulatory aspects of teaching and learning.

It will take a decade to move ahead and establish a wide range of teaching modules and formats for many target groups within this digital change – however, with the tailwind of the digital agenda of the German science and education policy there is a realistic chance of success!

Focusing on main components of the HiGHmed program

The HiGHmed approach is a gradual one: start with familiar topics, build up the teams, and then address new topics and challenges. Therefore, the 1st generation of online modules comes from the strong participating curricular teams. This range of topics will be integrated into the existing curricula.

Hands-on training modules with industrial partners and HiGHmed Schools, e.g. of the working group Promotion of Women, are already in preparation and their establishment will follow the first step.

All this will need to be integrated conceptually to be able to deliver HiGHmed certificates. Only after these steps, we will expand the range of partners and modules and address long-term operational and functional sustainability.

Providing professional recognition of HiGHmed certificates

HiGHmed certificates will document that a health professional has undergone a set of blended learning modules within the HiGHmed program.
Recognitionally, the certificates shall be designed in a transparent and standardized manner so that participants get positive professional acceptance from their employers or within existing traditional curricula.

Recognition of credits earned in all participating curricula will be addressed by a specialized working group Curricular Integration, which will deal with this complex issue – it may well be that different solutions have to be found in different federal states.

**Being aware of lessons from history**

The use of digital computers in medicine and health care was initiated in the 1950s driven by the hope, that this new technical option to handle increasing amounts of data and patient measurements could be helpful in diagnostics and treatment. At the same time, it became generally accepted that only regulated clinical trials can validate innovative research results. Internationally many top universities, military organizations, industrial companies, and health care organizations invested in digital machinery to build up working groups. 30 years later, the results were rather poor, but the complexity of the matter was much better understood. Many professorships of pioneers in this field ended without succession. The number of experts who knew about positive options and about the complexity and long-term costs of necessary infrastructures remained limited – with few national and organizational exceptions.

When at the end of the last century in the field of medical informatics – as it was called internationally by then – the new generation of small personal computers and networks emerged, no larger number of highly trained experts was available. Especially the top health care management was not pleased with new requested for funds. The legal constructions of the health care systems had only been adapted to the demands of data protection but had totally neglected the option that the digital transformation might change everything – as it was already happening in parts of the industry or the military. Now we know that digitalization does change everything – thus every person, patient, and professional has a need and a right to learn, so that they can participate and win in the long lasting digital transformation process of medicine and health care.

**Program Initiators:**
Prof. Dr. Otto Rienhoff, Prof. Dr. Petra Knaup-Gregori and Prof. Dr. Dr. Michael Marschollek

**Program Coordinator:**
Dr. Inga Kraus
In Germany, education is under the authority of the sixteen individual states forming the Federal Republic of Germany. Hence, there are different regulatory frameworks in all these states. In addition, the curriculum at all participating universities has been accredited without the option of online courses, which are provided by other universities within the HiGHmed consortium.

Although digital teaching and training formats were introduced more than two decades ago and many players have tried experimental blended learning approaches internationally, the regulatory systems of the German federal states do not allow such formats. If they have not been claimed already for accreditation and there are no uniform regulations for different universities or federal states. There is almost no common regulation. This reduces the sustainability of online e-learning modules. This HiGHmed working group aims at ensuring that HiGHmed online teaching modules are recognized with credit points in the curricula of the participating universities and universities of applied sciences. Furthermore, a mechanism must be found, for utilizing modules from certain universities in the teaching of other universities.

The HiGHmed teaching approach must address these issues if it wants to be a growing and financially feasible teaching infrastructure in Germany addressing the digital transformation in curative medicine, predictive healthcare, and (bio-)medical research. Furthermore, a special concept must be developed to bundle the HiGHmed e-modules into a uniform HiGHmed e-learning program that finally leads to the HiGHmed Certificate.

Therefore, the working group Curricular Integration is composed of representatives of partners from different states and types of educational systems (universities as well as universities of applied sciences). This working group started its work in 2018 and will pursue its main activities in 2019 and 2020, when the sustainability of the HiGHmed program must be stabilized. As the regulatory complexity mentioned above is also addressed by other organizations in Germany, this working group must identify appropriate allies in this difficult and complex field.

Team:
Prof. Dr. Thomas M. Deserno, Prof. Dr. Peter Heuschmann, Prof. Dr. Petra Knaup-Gregori, Prof. Dr. Andreas Mayer and Prof. Dr. Sylvia Thun
Working Group Marketing and Public Relations

Promotion of the curricular recognition of the HiGHmed digital teaching modules and the establishment of the HiGHmed certificates

When the first blended learning products become available it will be extremely important to have a marketing strategy in place that is geared to the target groups, professionally designed, and already in operation. Therefore, in 2018 the HiGHmed teaching team started the working group Public Relations and sought for appropriate consultations.

The following targets must be analyzed and mapped in marketing strategies, which will be discussed and finalized by the marketing board of the HiGHmed teaching program:

- **Target groups:** governance of ministries/universities, researchers, care personal, students
- **Motivation:** test, use, pass the modules
- **Explained easily:** benefit of the modules to the participants’ own advantage
- **Value adding:** HiGHmed certificates
- **Easy to use:** modules for your own work environment

Due to the wide range of the continuing education topics and the different backgrounds of the employees within the Medical Informatics Initiative (MII), a high degree of individualization is necessary, so that interested person can select topics that are tailored to their current challenges and their previous knowledge.

In some years, the main result of HiGHmed teaching will be a variety of mostly digital teaching modules in the field of medical informatics, which can be used across curricula and regardless of location. They will meet high demands on training and continuing education due to the new possibilities offered by digitalization in medicine and the results of the Medical Informatics Initiative (MII). Marketing will remain a long-lasting necessary component of this activity and thus needs sustainable financing.

**Team:**
Prof. Dr. Thomas M. Deserno, Prof. Dr. Mark Hastenteufel, Prof. Dr. Christoph Russmann and Prof. Dr. Bernd Stock
Working Group Didactic Strategy

Development of a uniform didactic course concept for a consistent structure of the different online modules

The central aim of the working group is the development of a uniform e-learning course concept for all teaching and learning modules produced by the different academic project partners in HiGHmed. The concept shall lead to a comparable and thus recognizable, didactic structure of the different online modules.

By consolidating the competencies of the partners and using digital teaching formats, different target groups for the Medical Informatics contents shall be addressed. These target groups range from senior medical professionals and scientists, who have job specific training needs, through to students in existing Mi-curricula which will be expanded by the HiGHmed modules. Any participant who completes a certain set of modules shall be able to obtain a HiGHmed certificate, suited to their profession. Later, also patients and other non professionals shall be addressed.

When implementing the modules at different locations, different technical preconditions also must be taken into account. For instance, the participating institutions use three distinct learning management systems, which are to be integrated in a way that allows learners to navigate seamlessly between the modules. While learning in more than one module, not only technical aspects should be harmonized, but also the methodological and medial elements. These elements should stimulate communication and interaction. Constructive feedback and cooperation with others as well as constant support by the teachers are essential aspects for an optimized learning progress in an online focused learning environment.

Therefore, the working group Didactic Strategy developed an online course model (see fig.) that includes all teaching phases from welcoming participants to iteratively teaching course contents and summative assessments to course evaluation and completion. This phase model especially takes into account communicative and constructive processes and the activation of participants.

Finally, to ensure standardized access to the online modules, taking into account the different target groups and application scenarios, the working group has developed a navigation concept. This allows various user respectively target groups to find their own individual learning path and to finally gain a HiGHmed certificate.

Team:
Dr. Marianne Behrends, Nils-Hendrik Benning,
Prof. Dr. Oliver J. Bott, Ina Hoffmann and Marie-Louise Witte

Didactically motivated 5 phase model of online based teaching in HiGHmed

|-----------------------------|-------------------------------------|-------------------------------|------------------------|-----------------------------|
| • Introduction of the teacher and the module topics | • Learning goals | • Provide knowledge and offer learning materials for online learning | • Assessments are important - for motivational reasons, - to evaluate student progress, - for issuing module completion certificate | • Anonymous surveys for module evaluation |}

The 5 phases of online teaching of the HiGHmed modules
Working Group
Technical Infrastructure

Technical strategies for cross-organizational online courses in Germany

During the developmental phase of the teaching module it is of utmost importance to harmonize work- and production flows, terminology, infrastructure, processes, etc. However, in a heterogeneous consortium like HiGHmed various individual learning management systems (LMS) to organize teaching are used at each partner site e.g. Stud.IP, Moodle, and ILIAS. In this context an appropriate cross-organizational solution is crucial to make content available to all learners, students, as well as employees in continuing vocational education and training.

To implement a suitable technical solution, requirements are analyzed to support innovative e-learning concepts with a strong focus on sustainability and expandability. The evaluation process of the technical solutions is based on the generally accepted quality criteria of reliability, costs, and functional suitability, as defined in the ISO/IEC 25010 standard.

Based on the assessment of available technology and organizational structures, the working group recommends a federated and integrative approach for the technical infrastructure to enable a unified user experience for participants as defined by the common didactic concept. All learning content and courses that are part of the program will be centrally presented at a dedicated web portal. Identity management systems from partner sites will be integrated into a federated authentication and authorization infrastructure, allowing trusted cross-organizational identification of participants. Authenticated users will be able to access existing LMS and e-learning platforms of partner sites and may enroll in courses designated for HiGHmed teaching and training. The existing federated authentication infrastructure operated by the German National Research and Education Network (DFN) will be leveraged for identity management, the web portal and central e-learning platform will be collaboratively operated by the project group.

Team:
Dennis Bode, Andrea Essenwanger, Prof. Dr. Andreas Mayer, Susanne Steuer, Markus Suhr, Joana M. Warnecke and Maximilian Westers

Schematic representation of the potential technical infrastructure for cross-organizational online courses in HiGHmed. Existing on-site e-learning platforms of partner organizations are connected with shared infrastructure services by way of a federated authentication and authorization framework.
Working Group
Promotion of Women

Steps to success – Strengthening women in medicine and medical informatics

In Germany, more women than men of the same age qualify for university admission. Also regarding the completion of university studies, women are more successful than men. However, despite their promising entry into professional life, women are still underrepresented in leadership positions. Often differences in the choice of subject are cited as an argument for female career options. Nevertheless, as a comparison of medicine and computer science shows, an increase in the proportion of women in certain subjects does not lead to an increase in the number of women in research and management positions. Women make up 21% of the students in computer science. In contrast, the proportion of women in medicine is 63%. Despite these differences, both in medicine and computer science fewer women than men hold management positions and pursue a scientific career. The reasons for this are, among others, missing career networks and a lack of opportunities to reconcile family and career. Additional assistance should be offered to women in medicine and computer science right from the beginning of their career to counteract this situation.

Against this background, it is one of the aims of HiGHmed to design support concepts that promote women in their personal development, create networking opportunities for women and point out career paths to women. With the goal to attract more women to research and science at the interface between medicine and medical informatics, HiGHmed seeks the exchange with existing networks of women in this field and initiates the promotion and exchange of women in a summer school.

The first summer school “Women in Health and Computer Science (WinHaCS)” in 2019 will present exciting career-related topics on the role of women in management positions especially in the digital world. Together with various female scientists and experts, WinHaCS offers workshops and podcasts. To reach graduates and young scientists from different fields of research, the workshops will take place at the three locations Technical University Braunschweig, Hannover Medical School and Hannover University of Applied Sciences and Arts. The podcasts are intended to create public awareness, for example by interviews conducted with successful female academics, managers and founders to highlight outstanding career paths. The workshops support the acquisition of competencies by covering the topics “Deal or no Deal – Negotiating Is Always Worthwhile”, “Working in a Team and Leadership Qualities” and “Elevator Pitch – Self Presentation for Women”.

Team:
Dr. Marianne Behrends, Andrea Essenwanger, Ina Hoffmann, Joana M. Warnecke and Marie-Louise Witte
Today, medical imaging science (e.g. radiology, photonics) is a dynamic, evolving field generating a wealth of data in medicine. Major trends are functional, multimodal, molecular and intra-operative imaging. Advanced algorithms and image analysis methods can be used to enhance images and extract novel information for medical diagnosis and therapy. When used in clinical decisions, the generation of the images, their strengths and limitations must be understood.

**Target Group:** The module is oriented to bachelor level. The course is aimed at bachelor’s students of medical engineering, medical informatics as well as IT-savvy physicians and medical students. Basic knowledge in applied mathematics, engineering, and applied computer science, e.g. programming knowledge, is required.

**Learning Objectives:** The course offers its participants an introduction to the methodology of processing and analyzing medical image data using computer-aided methods with the focus on imaging modalities, image representation and storage, image preprocessing and enhancement, image segmentation, feature detection, and basic classification. Additionally, the consideration of quality measures including sensitivity and the specification of image-based diagnostic testing form an essential part of the course. Practical exercises and interactive examples are provided to deepen the knowledge in individual and group work, using common software tools and libraries.

**Embedding:** The scope of the module comprises 6 credit points at HAWK. The module serves as a foundation for the understanding of advanced image processing concepts such as classification and object recognition, e.g. methods based on machine learning covered by other modules.

**HAWK – Faculty of Natural Sciences and Technology** in Göttingen offers bachelor’s and master’s programs in the field of engineering sciences. In 2016, the Gesundheitscampus Göttingen was established as a joint activity of HAWK and the University Medical Center Göttingen. The campus offers courses in the field of medical engineering, physiotherapy, nursing science and speech therapy.

[www.hawk.de](http://www.hawk.de)
Secure SW-Development for Medical Devices

Cybersecurity for connected medical devices and medical device software

Heilbronn University of Applied Sciences (HHN), Faculty of Computer Science

Nowadays, more and more diagnostic and therapeutic functionality are realized “in silico”: software becomes a medical device. Medical devices are regulated worldwide in order to ensure safety, reliability and effectiveness. Another big trend is interconnectivity of medical devices. Unfortunately, this gives attackers the opportunity to exploit existing vulnerabilities. Therefore, regulatory agencies worldwide consider security more and more as an integral part of the product lifecycle. Many software-based medical devices do not have adequate security precautions, e.g. implantable pacemakers and insulin pumps. This module addresses these shortcomings and enables learners to build secure software for medical devices.

Target Group: Master’s students in medical informatics and medical engineering.

Learning Objectives: The module is split into two sub-modules. First, the regulatory background regarding “Software as a medical device” is covered. Learners will be able to decide whether a software is considered a medical device and which laws and standards are applicable. Topics covered are:

• Medical Device Regulation (MDR) regarding “Software as a medical device”
• Software development lifecycle for medical devices (IEC 62304), usability of medical devices (IEC 62366)
• Risk assessment for medical devices (ISO 14971), including cybersecurity (AAMI TR57)
• Quality management system for medical devices (ISO 13485)
• Technical documentation and post-market management

In the second sub-module learners will be able to setup and implement a secure software development lifecycle for medical device software. Topics covered are:

• Secure SW-development lifecycle
• Risk-based specifications of security requirements, threat modelling, and addressing threats
• How to incorporate security into planning, requirements, design and at code level
• Common vulnerabilities, security design principles, security best practices and security testing
• Secure SW delivery and post-market security

Embedding: The module is embedded in the cooperative “medical informatics master’s” program, jointly realized by Heilbronn University of Applied Sciences and Heidelberg University started in 1972 and having more than 1,800 alumni.

www.hs-heilbronn.de/mim

HiGHmed teaching team and its Dean at HHN: Prof. Dr. Rolf Bendl (Dean), Prof. Dr. Andreas Mayer, Prof. Dr. Mark Hastenteufel, Susanne Steuer and Maximilian Westers (from left to right)
Advanced Concepts of Data Analytics and Curation

Business intelligence, data warehousing and data mining in health care and research

Hochschule Hannover (HsH) – University of Applied Sciences and Arts Faculty III – Media, Information and Design

Competencies in data analytics and curation has become a key success factor for all research and care processes in medicine.

Target Group: Master’s students in health information management or medical informatics and scientists/executives, that need further training in data integration, curation and analytics in the context of medical research.

Learning Objectives: The course introduces concepts and methods of (clinical) data warehouses, data mining and machine learning. The contents of the module are data warehouse conceptual modeling techniques, resulting multidimensional data models and corresponding data analysis operations as well as the basic principles of data mining respectively machine learning algorithms. The module is intended to enable the participants to use these methods and technologies in their own scientific work. The following competencies are taught in detail:

• Participants know and understand basic concepts and application scenarios of data warehouses and data mining analysis procedures in the context of business intelligence (BI) and knowledge discovery.
• Participants know typical application scenarios of data warehouses in medicine and clinical research and are aware of data quality and curation issues in these fields.
• Participants understand the use and creation of multidimensional data models and the concept of data cubes. They are able to implement Online Analytical Processing (OLAP) methodologies.
• Participants know typical cases of use and the limitations of machine and statistical learning. They can apply these methods and algorithms in typical application scenarios in medicine and clinical research.

Embedding: Being part of the HiGHmed module network, the module of the HsH follows those modules, which relate to data collection topics such as medical image processing and assistive health technologies as well as image and signal-based assistance systems. The HsH module focuses on the integration and consolidation of data from different sources and on useful methods and tools to extract, transform and load the data into a format usable for sophisticated statistical analysis and machine learning methods. The module concludes with topics on how to proceed with the analyzed data, including the reliable use of data in research and care, patient-centered information management and medical decision support.

Hochschule Hannover (HsH) – the University of Applied Sciences and Arts in Hannover focuses on teaching and research, practice orientation, and internationality. With nearly 10,000 students it is the second largest university in Hannover and was established in 1971. www.hs-hannover.de
Modern epidemiological research is increasingly working with data from new mobile technical tools or sensor data. This indicates a change in the assessment of the trustworthiness of data sources. Now not only researchers or medical devices collect data, but the user also contributes with patient-reported outcomes or with automatically generated data outside the direct doctor-patient contact. This leads to limitations on the internal validity of such data. It is crucial to clean the data sets systematically and transparently, to apply feature engineering and to evaluate the data quality (DQ) prospectively. Only after that e.g. machine-learning (ML) algorithms should be applied to draw conclusions about biomedical hypothesis.

Target Group: The blended course is designed for bachelor’s, master’s or PhD students, with a background in information technology, computer science or life science. MD-students are also invited. Basic knowledge in medical terminology and experience in data analysis is recommended.

Learning Objectives: Within HiGHmed, the HZI is responsible for the development of algorithms to detect outbreaks and infection clusters in German hospitals. Subsequently, the course focuses on three relevant topics:

Module I: Evaluation of Data Quality (starting in January 2019)
Module II: Methods of Statistical Learning (starting at the end of 2019)
Module III: Signal Detection (starting at the end of 2020)

Module I provides insights into the process of exploratory data mining with the application of the respective methods for the evaluation of DQ. Data completeness, data accuracy, and data currency will be explored within variables, observations, and time constructs. The students will combine all assessed DQ conflicts to develop a DQ report. This is a crucial step for feedback to stakeholders to give them the opportunity to improve their DQ. With the newly gained knowledge on data analysis and research communication, Module II explores ML-methods. Students learn methods of statistical learning to make predictions or to “uncover hidden insights” in the data. In Module III knowledge acquired in Modules I and II is applied to outbreak detection. Students will explore surveillance systems, methods to detect outbreaks or perform network analyses within hospitals.

Embedding: The physical presence of students in the classroom is required, materials are provided via an online platform. The course is taught in English. It is integrated in the PhD-Program Epidemiology of the HBRS and the HZI.

www.helmholtz-hzi.de/en/career/phd_programme_epidemiology/objectives

HiGHmed teaching team and Director at HZI: Dr. Tobias Kerrinnes, Dr. Stefanie Castell, Prof. Dr. Gérard Krause, Dr. Stephan Glöckner, Prof. Dr. Dirk Heinz (Scientific Director HZI) (from left to right)
Reliable Use of Data in Medical Research

Competencies for the use of medical data in clinical research and health care

Hannover Medical School (MHH)

Advanced information infrastructure concepts to share medical data along with advancements in data analytics such as machine learning and data mining offer new opportunities and challenges for the reuse of medical data in clinical research. Against this background, combined with the wish for a learning health care system that incorporates translation of results from research back to medical practice, the module provides medical students with the necessary data literacy for their scientific development.

Target Group: The module is aimed at medical students between their third and fifth study year and is designed as a blended learning course. Three classroom lectures (at the beginning, in the middle and at the end of the course) are complemented by five collaborative e-learning lectures. To make the above-mentioned topics more interesting and attractive, the basic material, which has been developed by experts in medicine and medical informatics, is presented in different forms, e.g. videos, scientific papers, manuals or games. Furthermore, the applied learning tasks will make the learners a part of a community of inquiry.

Learning Objectives: The structure of the module is based on the five main topics of data literacy, defining the competencies which are required for successful and secure working with data. Starting with realistic examples of the use of medical data, a conceptual framework with relevant terms and concepts will be defined and discussed. In the part data collection, different sources of medical data such as registries, wearables, omics databases, etc. are identified. The students measure their own activity data with sensors and gather more experience concerning potential problems while measuring and documenting. Requirements (e.g. FAIR data principles, guidelines for the management of research data) and principles of medical data management during a data lifecycle are introduced. Furthermore, the students receive information about the functionalities of a data warehouse and the tasks of a data integration center and they learn approaches for data modeling. The section about data evaluation delivers insight into different computerized data analyses as well as visualization and classification approaches combined with practical exercises. Data appliance needs to consider some administrative tasks, e.g. students prepare an application for ethical approval (including a clinical study protocol and a process description). In this context, aspects of data privacy and protection will also be discussed.

Embedding: The elective module “Reliable Use of Data in Medical Research” comprising a learning unit of 28 hours is integrated in the model study program Hannibal (“Hannover integrated adaptive practice-related learning concept”). Hannibal was established at the Hannover Medical School in 2005. Its main characteristics are early patient contacts for practical skills and patient communication as well as the imparting of profound knowledge with a focus on scientific work and research.

www.plri.de/forschung/projekte/highmed-lehre/highmed-lehre-mhh

HiGHmed teaching team and its Dean at MHH:
Prof. Dr. Ingo Just (Dean), Ina Hoffmann, Dr. Marianne Behrends, and Prof. Dr. Dr. Michael Marschollek (from left to right)
Health-Enabling Technologies and Data

Reliability of data analytics for low quality recordings of diverse sensors

TU Braunschweig (TU BS), Carl-Friedrich-Gauß-Faculty

The use of health-enabling technologies (HET) at home, in the vehicle or worn on the human body generates signal measurements and image data with poor signal quality, shifting offsets and recording gaps. The data quality is much lower as compared to clinical data, but a big data volume is recorded continuously and needs real-time analysis to predict or alarm adverse events. Hence, HET yields novel challenges in signal processing and data analytics, for instance, reliable collection and semantic integration of this data with the electronic health records of the subjects. In addition, the automatic understanding of measurements requires robust algorithms for analysis, such as deep learning.

Target Group: The target group is master’s students of computer science, medical informatics, and related study courses. In this module, students learn to understand and solve challenges and difficulties in biomedical image and signal processing of HET data and their integration into health records. Students also know and understand the basics of semantic interoperability. Besides, students can actively apply and analyze signal and image processing methods, both in theory and in practice with the open source software program. Students learn how to deal with linear and non-linear noise and to evaluate the suitability of methods for processing or preprocessing HET data as well as to work out proposals for suitable methods. The module is to be embedded in the master’s program in computer science, business informatics, and comparable master’s programs in the elective field of medical informatics.

Learning Objectives: The module covers HET data management from its creation via recording and storing to analysis. The students are encouraged to record medical and non-medical data at the PLRI living lab, in the car, or on their own body by using the open source software program, all methods are also applied practically. Furthermore, the basics of semantic interoperability, the determination of a reliable ground truth for the evaluation of algorithms and the model-based methodology for real-time monitoring, event prediction and emergency detection are covered.

Embedding: The module is to be integrated into the curriculum of the Carl-Friedrich-Gauß-Faculty of TU Braunschweig.

www.plri.de/forschung/projekte/highmed-lehre/highmed-lehre-tubs
Patient participation and shared decision making is a highly topical issue in modern medicine: Medical staff must deal with patients who regularly consult “Dr. Google”, who bring their own measurements generated by M-Health devices and want to understand the background of their treatment. At the same time, new data and knowledge sources are available, artificial intelligence will influence our daily work, results from big data analytics must be interpreted and omics data will lead to precision medicine. Their influence must always be transparent to physicians and patients. Most of the current professionals have undergone an education that did not involve these innovations.

The teaching module on participatory information management utilizes the approach of research-based learning. The learners go through all the steps of the research life cycle: Learners will start by analyzing the current situation for modern participatory technologies such as patient portals. They generate research questions and select scientific methods to answer them. They create a research design and do the research. Results will be presented orally and their work will be critically reflected.

**Target Group:** The main target group is bachelor’s and master’s students in medical informatics as potential designers of innovative participatory solutions. The target group also includes medical students and practicing physicians since they are the potential users of these systems and should learn how to contribute to their design.

**Learning Objectives:** Successful learners will be able to deliver applications that support the capture and visualization of patient-generated data. They can prepare medical knowledge in a way that is understandable to laypersons. To enhance scientific skills, learners are enabled to develop research hypotheses, select and apply methods and present their results.

**Embedding:** Our Medical Informatics program started in 1972 as a joint program of the University of Heidelberg and University of Applied Sciences Heilbronn. It is one of the oldest informatics programs in Germany and one of the oldest medical informatics programs worldwide offering a bachelor and a master program, with high number of influential alumni who still play a major role in this field.

[www.klinikum.uni-heidelberg.de/mi](http://www.klinikum.uni-heidelberg.de/mi)
Decision Support in Medical Care

How to access knowledge for clinical decision support

University Medical Center Göttingen (UMG)

Data-intensive personalized medicine as well as optimized health care strategies for patients with comorbidities make clinical decisions much more complicated than the usual level taught at medical schools. This has a massive impact on the need for support, documentation and the realization of studies. Additionally, this complexity hampers the communication between the physicians involved in decision-making, as well as the patients’ participation in these processes. Students and personnel in medical care must be prepared for such situations and they need to learn problem-solving strategies. Furthermore, they must know about the options, strengths, and weaknesses of digital systems for decision support in medical care and practice working with such systems.

Target Group: The module is designed as an elective module for several branches of study. It is primarily aimed at students of medicine and medical informatics as well as physicians in postgraduate training or continuing medical education. It is also open to other students in the field of medical care and people working in medical care who meet the entry requirements.

Learning Objectives: Based on the clinical use cases of HiGHmed and the experiences gained in the HiGHmed MeDICs, the participants at various career levels will get prepared to use complex and heterogeneous health care-related data for clinical decisions. In this context, the collaboration with Ada Health supports the realization of a teaching demonstrator to support patient-oriented decision-making, which will be focused on the clinical use case of “cardiology”. Additionally, the analogous approach with Siemens Healthineers must be realized and focused on the long-term handling of data collected by patients in a participative manner. Besides questions of data safety, quality management and risks of misinterpretation, also aspects like heterogeneity of health care data and gender impact on clinical disease characteristics are addressed. It imparts key competencies concerning the general handling and the limitations of decision support systems in medical care. The module will be developed and provided in close cooperation with the German Medical Association and the industrial partners Ada Health GmbH and Siemens Healthineers.

Embedding: The Göttingen curriculum of Medical Informatics has been designed by the Department of Medical Informatics at the UMG and is offered at the Faculty of Mathematics and Computer Science of Georg-August-University Göttingen. The Göttingen curriculum has been internationally accredited by the International Medical Informatics Association (IMIA) since 2012.

www.mi.med.uni-goettingen.de

HiGHmed teaching team and its Dean at UMG:
Prof. Dr. Heyo Kroemer (Dean), Christoph Jensen, Dr. Inga Kraus, Markus Suhr and Prof. Dr. Otto Rienhoff (from left to right)
Terminologies and Ontologies in Health Care

Utilization of standardized terms as a prerequisite for digital health

Charité-Universitätsmedizin Berlin, Berlin Institute of Health (BIH)

E-health applications are changing the paradigm of medical documentation and data analysis: Structured documentation should, in the broadest sense, facilitate a communication between health care workers and researchers rather than be used for statistical and administrative processes and billing. Instead, the data should be incorporated into the overall patient record and its accompanying applications, such as the recording of patient registration data, the reporting system or external and internal quality assurance. Data must be recorded consistently, clearly, precisely, and in a standardized manner.

**Target Group:** Health professionals and students in the health sector from the fields of medicine, medical informatics, computer science, public health, biometrics, bioinformatics, epidemiology, care, therapy, medical controlling.

**Learning Objectives:** Participants learn about the purpose, requirements and application scenarios of medical documentation using terminology and ontologies. The importance of structured data collection for scientific and administrative purposes is described. In the Terminology and Ontologies module, they learn about the most important regulatory and documentation systems of the health care sector. Learners understand and apply the formal and substantive documentation requirements in health care. This course describes the requirements for modern medical terminology systems, such as the SNOMED CT, LOINC, IDMP, OMICS terminology, ICHI for mapping treatment procedures, and the International Statistical Classification of Diseases and Related Health Problems in the 11th International Revision “ICD-11” for mapping diagnoses in the e-health context. Moreover, they will learn how these terminologies are bound to information models such as HL7 FHIR.

Participants acquire the ability to independently derive a formally correct procedure, using conventional methods of documentation, transmission and analysis of the structured and annotated data. Students are enabled to adequately deal with the various documentation systems and the terminology lists and ontologies involved. They apply the learned systems in the right context and support the underlying workflows and systems.

**Embedding:** The educational goal of the Berlin Institute of Health (BIH) is to support a new generation of translationally trained researchers in their scientific and clinical research with an integrative, translational and entrepreneurial approach. It aims to provide research solutions enabling the transformation of medical care into a value-based model from the 21st century.

www.bihealth.org

Charité is internationally renowned for its excellence in teaching and training. Having marked its 300-year anniversary in 2010, Charité is now one of the largest employers in Berlin.

www.charite.de

HiGHmed teaching team and its Dean at BIH:
Prof. Dr. Axel Radlach Pries (Dean), Prof. Dr. Sylvia Thun and Andrea Essenwanger (from left to right)
Sources of Medical Knowledge

Use the innovative services from ZB MED

Cologne University, Medical Faculty and ZB MED

The Medical Faculty of the Cologne University joined the HiGHmed consortium in 2018. The collaboration with the faculty enhances the strategic plan to make better use of the biomedical scientific literature and to increase data availability and data literacy to life science researchers in Germany. Specific modules will be provided by academic staff of the German Central Library of Medicine (ZB MED) which is situated in Cologne and closely aligned to the Medical Faculty.

HiGHmed partners in Cologne will provide a blended learning module on how to use the innovative services from ZB MED.

**Target Group:** The module is designed as an elective module for different types of students and health professionals, i. e. students of medicine, medical professionals and physicians in postgraduate training or continuing medical education. It is also open to other students in the field of medical care, bioinformatics research, librarians in the life sciences and people working in medical care when meeting the entry requirements.

**Learning Objectives:** The digital module will explain the services of the library and its relevance for finding up-to-date data and knowledge including basic data transformation (called “data literacy”, also covering hands-on experience). These elements will be linked with curricular elements in the HiGHmed approach, which describe more details of literature and data management in modern medical research and patient care.

**Embedding:** The library in Cologne is in an annual exchange with the National Library of Medicine in Washington regarding the latest developments in the field of information exchange in medicine. This important collaboration and exchange guarantees that the Cologne modules will also deal with the most recent developments in publishing and the reliable and evaluable presentation of results.

www.zbmed.de and https://medfak.uni-koeln.de

Two-person-managerial-team at ZB MED: Prof. Dr. Dietrich Rebholz-Schuhmann and Gabriele Herrmann-Krotz
Clinical Studies
From design to successful implementation

Julius-Maximilians-University Würzburg (JMU), Faculty of Medicine, Institute for Clinical Epidemiology and Biometry

Modern clinical studies often generate large amounts of data by using new technologies in the health sector and they must adhere to rigorous quality criteria. Knowledge about the ethical, legal and regulatory requirements regarding planning, performing and analyzing this type of studies is essential for successful research.

Target Group: The course is aimed at senior medical students as well as physicians or medical scientists involved in the implementation and conduct of clinical studies.

Learning Objectives: The participants in this course will work on practical issues regarding the development and implementation of study designs. They will acquire knowledge in protocol development, trial documents, ethical issues, patient information, data management and establishing trial procedures in multi-center clinical studies. They will learn the general principles of trial conduct in accordance with Good Clinical Practice and legal requirements (e.g., drug law, medical product law). Podcasts and video lectures on special topics will complement the curriculum. Real-world examples from recent trials will be included as case studies via the online platform CaseTrain. In addition, the participants will acquire special knowledge of design aspects, e.g., sample size calculation.

Embedding: This course will be run in cooperation with the new study program and master’s program “Translational Medicine” (www.med.uni-wuerzburg.de/studium/tmed) at Julius-Maximilians-University Würzburg supported by the Elite Network of Bavaria.
Semantic Analyses of Medical Data Models

Understanding semantic interoperability and generation of common data elements in medicine

Faculty of Medicine, University of Münster (WWU)

Missing semantic annotations and heterogeneous data definitions impede cross-institutional data integration both for research and routine care applications. Participants of this module will acquire skills to identify and tackle current semantic challenges in medical data integration and will develop competencies to analyze existing medical data models for the generation of interoperable common data elements or core data sets within any disease domain. To achieve this, organizational and technical aspects of implementing core data will be covered by illustrating real-world implementations of hospital information systems.

Target Group: Medical students (writing their MD thesis), physicians (continuing education) as well as post-graduate students of medical informatics who are interested in obtaining skills in the generation of harmonized and efficient data models for electronic data capture in research registers or clinical routine documentation.

Learning Objectives: Developing practical skills for semantic analyses of medical data models and the generation of common data elements in different disease domains. The module will cover the concepts of semantic interoperability, research data standards such as the Operational Data Model by the Clinical Data Interchange Standards Consortium (CDISC ODM), metadata standards such as the ISO 11179. In addition, practical skills for using medical terminology systems such as the Unified Medical Language System, medical coding principles and semantic analyses using well-established tools (Varghese et al., 2018) will be acquired. Based on the FAIR (Findable, Accessible, Interoperable, Reusable) guiding principles for scientific data management, the participants will be familiarized with a metadata platform for finding, accessing, creating interoperable and re-useable medical data models to generate harmonized data elements.

Embedding: The Institute of Medical Informatics at the University of Münster has long-standing experience in teaching medical students as well as informatics students at graduate and post-graduate level. Curricular courses in medical informatics are provided for the medical school and the doctoral program (Dr. rer. medic.) of the Faculty of Medicine in Münster since 2005. In addition, teaching of medical informatics is provided for business informatics students and for computer science students.

Faculty/Curriculum:
www.medizin.uni-muenster.de/imi/studium

HiGHmed teaching team and its Dean at WWU:
Prof. Dr. Mathias Herrmann (Dean), Prof. Dr. Martin Dugas and Dr. Julian Varghese (from left to right)
Artificial intelligence (AI) based diagnostic decision support systems (DDSSs) have achieved sufficient quality to support doctors in their daily work and to advise patients on their health concerns. Advances in DDSSs represent some of the most promising developments in today’s medical computer science.

Ada Health GmbH AI-based products combine the latest reasoning technologies with expert medical knowledge curated by Ada’s physicians over the past 7 years. An interdisciplinary and international team of over 120 professionals consisting of doctors, scientists, and engineers collectively work on bridging gaps between state-of-the-art technology and clinical practice. With over 1,000 diseases and 5,000 symptoms, Ada covers a wide range of medical knowledge for patients and doctors. Results are graphically enhanced and underlying probabilities are depicted in an intuitive manner, providing interpretability and transparency.

While the Ada app focuses on patient empowerment, Ada offers a professional DDSSs tailored to the needs of medical professionals. Benefits of the professional DDSSs not only include improved diagnostic accuracy, but also reduced cost and time investments. Aside from its clinical usages, the professional DDSSs are likely to play a prominent role in the future of medical education. For instance, the professional DDSSs can assist in teaching students’ diagnostic skills, improve their efficiency in selecting testing procedures, and supplement knowledge of less common but clinically significant symptom patterns. Therefore, it is paramount to integrate these technologies into university-level medical curricula.

For these reasons, Ada will create a dedicated module on the applications of DDSSs in clinical care. This module will focus on the following aspects:

- Introducing the basic theoretical background of model-based DDSSs
- Teaching how to use and interact with DDSSs in an informed manner
- Understanding and assessing complex cases by practicing with real clinical case data
- Testing/training diagnostic skills with the help of diagnostic decision support

Member(s) of the project team at Ada Health: Henry Hoffmann, Dr. Martin C. Hirsch and Sabrina Golde

www.ada.com
Siemens Healthineers supports HiGHmed blended learning with reality lab

Siemens Healthineers

Siemens is a partner in HiGHmed involved in the use cases and supporting the teaching program. Siemens is an internationally leading player in the utilization of digital means to develop new and better diagnostic tools for many disciplines in clinical diagnostics and care. Siemens has been supportive to all those activities in the past, that helped physicians and health professionals to make use of all these new technologies that enable physicians to remain in the driving seat regarding such revolutionary developments.

However, digitalization has such a massive impact on how diagnostic measurements and therapeutic decisions are handled that there is an urgent need to constantly update all levels in health care regarding all these new options – their potential and also their risks. As it would be extremely helpful to have a blended learning environment in Germany to facilitate this approach, Siemens is supporting the HiGHmed teaching program with the establishment of a demonstration and training lab, which can be utilized by all users of digital modules to get hands-on experience with new technological approaches.

The idea is that universities deal with new digital developments in the health sector in an interlinked world of digital modules which explain options, strengths and weaknesses, costs and maintenance, quality management and research options of innovative digital tools. After getting the relevant background information, participants can get realistic hands-on experience in the Siemens lab – including discussions with senior developers about options, risks, and perspectives.

The design of the lab will make use of experience gathered at other places e.g. in Biel/Bern, where one of the most advanced teaching labs has been installed and successfully evaluated. The organization of booking and participation processes, the didactic concept, optional examination modules, as well as sustainable management of costs will be part of the HiGHmed approach, which looks for long-term stability of such blended learning options and not for short-term show cases.

The blended learning modules of HiGHmed will include the labs for practical training.

Member of the project team at Siemens Healthineers:
Volker Lang
www.siemens-healthineers.com
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