Forum Health Region Baden-Württemberg

Roadmap Health Data Use Baden-Württemberg

March 2022

forum gesundheitsstandort BW

Baden-Württemberg

1. Opportunities and challenges of the digital use of health data

The digitalisation of the health sector and the digital collection and use of health data opens up significant opportunities for the further development of medical services. The collection of health data, the potential aggregation of different data sets into big data solutions and their digital evaluation offer completely new possibilities. This includes, for example, the possibility to detect diseases earlier, discover previously unknown patterns, advance personalised medicine and develop individualised treatments. Furthermore, transition from lab to patient is reduced, translating research into clinical practice more quickly. Medical progress will be increasingly data-driven.

The further development of medicine is therefore highly dependent on the collection, accessibility and use of data acquired in medical care, clinical research, clinical trials, in product development or by patients themselves. Likewise, access to high-quality health data is increasingly becoming a decisive location factor for the pharmaceutical industry as well as medical technology and biotechnology companies. The availability and usability of data are central to corporate research and innovation processes.[1)]

At the same time, health data is particularly sensitive and requires special protection. Patients must be confident that their data and its use are subject to strict data protection regulations and that corresponding effective measures are taken to ensure data and cyber security. The protection of individuals and ensuring patient well-being must be central to the digital use of health data. In medicine – as in other areas – it is paramount to strengthen our high European standards in data security and data protection on the global scale and to make it a success model. If we do not accomplish this task, medical progress will occur elsewhere, in places where European standards are not met.

In the context of the opportunities of medical insights offered by big data through pattern recognition from big data and artificial intelligence (AI), access to large amounts of data is necessary. Therefore, the classic principle of data minimisation can no longer be the standard. While there are understandable concerns regarding patient data confidentiality, the associated health improvements for a large number of patients should mean that a way should be found to make the data available.

The handling of health data must therefore be reassessed, with careful consideration of the associated opportunities and risks. The German Ethics Council is calling for technical, legal, political and educational efforts to ensure that progress in healthcare can continue to be made and equally, that patients have a right to informational self-determination.[2)]

As we work to reinforce the quality and attractiveness of Baden-Württemberg as a health region and to improve healthcare and performance in the state, we are grouping all these different interests under the umbrella of the Forum Health Region Baden-Württemberg and we will be promoting the targeted digital use of health data. When it comes to exploiting the potential of digitalisation, it is particularly important to create the necessary legal, technical and organisational conditions. This roadmap outlines the measures that the Forum Health Region Baden-Württemberg is already implementing and will continue to tackle in the future at state, federal and EU level.

1) German Council of Economic Experts (2020): Overcoming the Coronavirus Crisis Together: Strengthening Resilience and Growth. Annual Report 2020/21.

2) German Ethics Council (2017): Press conference on the publication of "Big Data and Health – Data Sovereignty as the Shaping of Informational Freedom"

2. What we want to achieve with the Forum Health Region Baden-Württemberg

With the coalition agreement, the Baden-Württemberg government has set itself the goal of developing a health data space that foregrounds data protection and security as well as creating attractive conditions for data use. The goal is to create efficient, coordinated and data protection-compliant digital platforms.

The Forum Health Region Baden-Württemberg promotes improved use of health data for further developing healthcare and encouraging innovation.

As a fundamental basis for all subsequent steps, efforts to advance the digital collection of health data in Baden-Württemberg are to be intensified. The Baden-Württemberg government is investing in these efforts, but funding by the federal government and the EU is also needed. The Land government of Baden-Württemberg already provides extensive funding to the state's university hospitals through various funding streams, which are also aimed at intensifying digitalisation efforts. At the same time, the funds from the federal government's Hospital Future Fund are an important instrument for establishing nationwide IT networks and ensuring the availability of qualified personnel. In addition, the Forum Health Region stakeholders see the implementation of measures set out in the roadmap as their mission for the coming years.

This document follows on from the recommendations for action published by the spokespersons of the Forum in January 2021, in particular the recommendation to further develop digitalisation in the healthcare system. These recommendations for action form the conceptual guideline for the Forum's work. Furthermore, the results from "Secure data use to improve care and reinforce the business location", an online event that took place on 2 October 2020 and was organised by the Ministry of Economic Affairs, Labour and Tourism have been incorporated into this roadmap. Following the event, a thesis paper with concrete recommendations for action was authored by representatives from science, industry, care, data protection and ethics. The statement on data generation and processing by the subworking group of the same name that is part of a working group on medicinal and medical products within the Forum Health Region Baden-Württemberg also needs to be mentioned here.

Priority 1: Promoting the harmonisation of data protection regulations

The plurality of responsible authorities and federal and state laws represent a considerable hurdle for the development of medical research projects in Germany. A large number of research projects involve partners from several federal states and therefore generate a lot of bureaucracy and uncertainty about the regulations to be applied.

The Forum Health Region Baden-Württemberg advocates further harmonisation of the legal framework and its application on health data usage. To this end, the Forum is pursuing the following measures in parallel:

- **Measure 1:** The Forum Health Region Baden-Württemberg will ask the Data Protection Conference via the State Commissioner for Data Protection and Freedom of Information (LfDI) to develop suitable procedural regulations for processing and decision-making when several

supervisory authorities are involved, as well as uniform guidelines for anonymisation and pseudonymisation of health data.

- **Measure 2:** The Forum Health Region Baden-Württemberg also advocates the establishment of a decision-making committee at federal level or a decision-making body in the event of disagreement between several supervisory authorities.

With § 287a Social Code Book V (SGB V), the German federal government has addressed the concern of harmonising the legal framework and created the necessary conditions for introducing a lead data protection supervisory authority, modelled on the General Data Protection Regulation (GDPR), for projects involving more than one federal state. However, the relevant procedures have not yet been sufficiently proven and established by the data protection authorities. In addition, no decision-making mechanism is provided for in the event of dissent between the supervisory authorities of the federal states, as foreseen in the GDPR.

Priority 2: Further standardisation of health data and access to data

The digitisation of health data implicates the potential to rapidly improve medical care through the ability to collect large amounts of data from clinics, outpatient care and research, combining different data sets and evaluating them according to certain criteria. However, the standardisation and interoperability of data sets are prerequisites for exploiting this potential for healthcare and medical research. Fundamentally, the technical prerequisites for the secure and, above all, sustainable interconnection of different IT structures in a uniform data space must first be comprehensively established in the coming years.

Inconsistent processes for applying for access to health data, which in some cases differ from institution to institution, are a big challenge for medical research. Accordingly, the Advisory Council on the Assessment of Developments in the Healthcare Sector recommends facilitating research conditions by improving and standardising application procedures in order to increase Germany's competitiveness as a centre of science.[3)]

In the Forum Health Region Baden-Württemberg, we are further developing the technical and organisational prerequisites for linking and using data across institutions and locations. The Forum is committed to simplifying access to health data for medical research.

- The Baden-Württemberg government is providing 80 million euros of funding up to and including 2022 to the Universitätsmedizin Baden-Württemberg association established by the Baden-Württemberg university hospitals and medical faculties in Freiburg, Heidelberg, Tübingen and Ulm. The association promotes the digitisation of health data for the development of new diagnostic procedures and therapies. By establishing uniform standards with regard to aggregating, making available and using health data, the amount of available data that can be used for research is growing. Standardised procedures also improve the connectivity to researching companies, most of which also operate internationally and are dependent on corresponding data preparation.

[3)] Advisory Council on the Assessment of Developments in the Healthcare Sector (2021): Digitalisierung für Gesundheit – Ziele und Rahmenbedingungen eines dynamisch lernenden Gesundheitssystems. Annualexpert report 2021, p. 237.

- As part of the AMP-KOMPASS project funded by the Baden-Württemberg Ministry of Social Affairs, Health and Integration, data on therapy and orthopaedic technical interventions as well as data from the mobile measurement sensors of smart leg prostheses are being collected in order to identify if and where prosthesis production and maintenance needs to be optimised. The transferability of personal health data to a register and to the electronic patient record (elektronische Patientenakte, ePA) is also being considered. In the long term, a customised register will be set up to identify specific needs in Baden-Württemberg and close evidence gaps on care issues. A new aspect is the linkage of the digital collection of information, especially from outpatient care focusing on the patients. This, in accordance with patient data sovereignty, is intended to ensure that the model project primarily benefits patient care.

- A digital consent management system for healthcare is being developed as part of the IDEM project (Integrated Digital Consent Management for Clinics and Research) funded by the Ministry of Economic Affairs, Labour and Tourism. Patients can consent to making their data available for use in research and development in a more user-friendly digital way.

- The TEDIAS project (Test and Development Centre for Digital Anamnesis Systems), also funded by the Ministry of Economic Affairs, is developing the first milestone of a digital hospital. The aim is to establish contactless digital patient admission in the clinical routine including the collection and integration of digital data to optimise process flows in subsequent treatment.

- At the federal level, all university hospitals in Germany, together with research institutions, companies, health insurance companies and patient representatives are working in the Medical Informatics Initiative (MII) to develop framework conditions to ensure that findings from research are directly benefiting patients. By improving the national framework conditions for data acquisition, labelling and exchange of health data, the initiative contributes to a better data exchange, networking and migration from medical research and healthcare. To this end, data standards and exchange formats are being developed, descriptive metadata is being defined via a core data set and rules of use are being established. This procedure is integrated into European and worldwide projects on the standardisation and networking of health data. Decentralised, federated data integration centres are being set up at university hospitals throughout Germany. The practical application of federated, i. e. Germany-wide, joint data collection and use is being tested and further developed on the basis of use cases for specific diseases or medical subject areas.

- The bwHealthCloud currently connects the four Centres for Personalised Medicine (ZPM) at the university hospitals of Freiburg, Heidelberg, Tübingen and Ulm in Baden-Württemberg and enables the exchange of qualityassured, standardised health data.[4)] The aim of the cloud is to create the broadest possible knowledge base for practitioners and researchers, which will allow improvements in care by finding comparable case constellations and by identifying promising or

[4)] At present, data is only collected from patients with advanced cancer. However, it is planned to expand this to other disease areas.

rather ineffective new therapeutic approaches. The bwHealthCloud is intended both to serve the quality control of new treatment concepts and to promote medical-translational research approaches. Networking with national infrastructure measures such as the Federal Ministry of Education and Research's Medical Informatics Initiative, the Federal Ministry of Health's National Strategy for Genome Medicine (genomDE) and the German Human Genome Phenome Archive (GHGA) consortium focused on the establishment of an infrastructure to store and share human omics data is already taking place. In addition, the associated introduction of comprehensive, informed patient consent (broad consent) at the university hospitals can be regarded as an important step for digitalisation in the healthcare system. With broad consent, patients can consent to the use of their treatment data for research purposes. This is the legal basis for the establishment of clinical research databases, from which findings that benefit patient care can then be derived.

- **Measure 3:** We want to expand sustainable and efficient data storage in the state through a secure cloud concept. Building on the experiences and possibilities of the bwHealthCloud, the Forum Health Region Baden-Württemberg will work with medical faculties and external economic partners to examine and promote the establishment of a coherent, secure cloud concept for the storage of health data in Baden-Württemberg.

- **Measure 4:** The Forum Health Region Baden-Württemberg will test the applicability of the Finnish one-stop shop model, managing the application for access to health and social data. Furthermore, we will initiate the introduction of a law on health data use at the federal level in conjunction with the establishment of a corresponding central point of contact.

We are working towards simplifying the structures and thus seeking to establish the model of a one-stop shop for nationwide uniform access to health data – in accordance with GDPR requirements and taking into account the Good Clinical Practice (GCP) regulations for clinical trials embedded in European law. The one-stop shop makes it possible, on the one hand, to check entitlement to data access in a uniform and transparent manner and, on the other hand, to act as a hub for available data. As a successful example of such a one-stop shop, we refer to Findata, the permit authority established in Finland in 2019 to manage access to social and health data. A one-stop shop of this kind should be established as "part of an overall research data access ecosystem" and be reflected in a Health Data Usage Act.[5)]

[5)] Specht-Riemenschneider, L. (2021): Studie zur Regulierung eines privilegierten Zugangs zu Daten für Wissenschaft und Forschung durch die regulatorische Verankerung von Forschungsklauseln in den Sektoren Gesundheit, Online-Wirtschaft, Energie und Mobilität. Study commissioned by the German Federal Ministry of Education and Research (BMBF), p. 171.

Priority 3: Strengthening the private sector's access to relevant collaborations and data for the purpose of doing research in the public interest

Under federal regulations, only publicsector institutions, e.g. selfadministration actors in the healthcare sector as well as health reporting system institutions, universities and university hospitals currently have access to health data that accrue in both clinical and outpatient care as well as scientific research, whereas research institutions and researchers in the private sector do not. In principle, the European General Data Protection Regulation stipulates equal access for profitoriented structures. In the Patient Data Protection Act (PDSG), the German federal legislator has expressly excluded industry from using data collected via electronic patient records. Any moves towards a more extensive use of data by institutions or companies that do not belong to the current group of authorised users would require changes to social security laws.

Research and development do not take place exclusively in academic structures. In Baden-Württemberg in particular, many research-based companies are active in the healthcare sector. Cross-sectoral cooperation is common and contributes to the innovative strength of the state. In the long term, a blanket denial of this data use for the purpose of private sector research activities would be to the detriment of healthcare research and further medical progress as well as to Baden-Württemberg as a healthcare location. When steps are taken to open up access to health data for private sector research, patients' right to privacy and data protection must be respected and strict criteria for use will need to be applied.

The Forum Health Region Baden-Württemberg therefore promotes access to relevant cooperations and to health data for private sector research in the public interest, while ensuring individual rights and patient welfare are protected. To this end, the following measures are being promoted:

- Model projects on joint data spaces in which research institutions and research companies cooperate in their use of information of corporate data from development, clinical trials or clinical application and follow-up will show how, and to what extent, such data can be provided for the common good.

  Data can only be used in a standardised, secure system. The results can then be transferred to care in order to achieve a solidary use of the knowledge gain (circular model). One example of such a data space is the cooperation between the Freiburg University Medical Centre and the company Roche for the further development of innovative diagnostics and therapies. As part of the cooperation, the required infrastructure is being created at the University Medical Centre to enable physical collaboration. Roche does not have access to the complete patient data sets. The first step will involve identifying a suitable data set, developing a data protection concept and putting in place the prerequisites for setting up and using a shared data space. In the future, with the help of everyday real-world data from the University Medical Centre, decision-making

processes in the Molecular Tumour Board (MTB) will be better understood, simplified and insights generated for future cases. For example, capacities could be created to enable more patients to have access to an MTB in the future.

- **Measure 5:** The Forum Health Region Baden-Württemberg will examine and develop support options, i.e. a single point of contact/service point for creating cooperation agreements between scientific institutions, university clinics and research-based companies.

Drafting cooperation agreements between scientific institutions and research companies requires either implementing a more simplified format or identifying possible support services (in the form of model agreements, contact persons for specific problems, etc.). There is currently a great deal of uncertainty on the part of the scientific community, which sometimes leads to considerable delays in implementing collaborative projects.

- **Measure 6:** The Forum Health Region Baden-Württemberg will examine the conditions under which commercial research institutions can be given access to data from the Health Data Lab and will introduce an appropriate initiative at federal level, for example in the form of a ministerial resolution or an initiative of the federal council to amend § 303 e of the German SGB V (SGB V).

When assessing the issues raised, the well-being of patients must be the decisive criterion. Requests for data access from the industry must be linked with a purpose limitation to research for the common good. Here, too, it is worth looking at the Finnish model, where the entitlement to apply for access to health data results from the intended purpose of use and not from the type of organisation applying for access. Permitted purposes are scientific research, statistics, development and innovation measures, control and monitoring by public authorities, implementation of the planning and reporting obligations of a public authority, as well as education and knowledge management.

Priority 4: Enhancing digital competence in education, training and further education in health and social care professions

Accompanying the changes taking place in the healthcare system as a result of digitalisation, the training and further education of healthcare and social care professionals must also be redesigned in line with the changes in knowledge and information. Such measures must be taken across the board so that patients are treated and informed in a competent manner.

The Forum Health Region Baden-Württemberg therefore focuses on improving the digital health skills of healthcare and social care workers by adding new education and training modules.

- In the DIKOMED-BW project, funded by the Ministry of Social Affairs through the European Social Fund, project executing organisations are developing content for medical studies and care training that will be incorporated into the curricula. The project is being undertaken by the

State Medical Chamber of Baden-Württemberg, the Association of Statutory Health Insurance Physicians and the Cooperative State University (DHBW), among others, and is coordinated by the Telemedicine Coordination Office of Baden-Württemberg (KTBW).

- The "Digital empowerment of care professionals and trainees in generic care training for the use of digital tools in acute care" project, also funded by the European Social Fund, improves the digital literacy of trainees at the Gesundheitsakademie Bodensee-Oberschwaben GmbH.[6)]

- **Measure 7:** The Forum Health Region Baden-Württembergwants to increase its efforts to qualify employees for the digital transformation through suitable support projects and new input to school and university curricula.

Priority 5: Improving citizens' digital health literacy

Due to the sensitivity, digitally processing of health data causes concern and fear among the public. There is a lack of awareness regarding the benefits of digital data, its exchange and networking in areas such as personalised medicine, diagnostics improvement, early disease detection, and the development of therapeutic options and medicines.

Empowering the public to make an informed decision is crucial, especially in the context of the introduction of the ePA and the resulting voluntary release of data by patients to the Health Data Lab.[7)] In addition to digital health applications in general, such competence development should address both the data protection aspect and the added value of health data-based research and development. The Advisory Council on the Assessment of Developments in the Healthcare Sector recommends "coordinated and targeted education on the purpose, structure and benefits, including possible risks, of an electronic patient record in order to improve its use and to enable insured people to use it in their own health interest".[8)]

The Forum Health Region Baden-Württemberg is therefore improving the digital health literacy of citizens through suitable projects and information campaigns. These are the relevant projects:

- The "Promotion of digital health literacy among patients and citizens in Baden-Württemberg" project led by the KTBW qualifies citizens to use digital health services competently both online and offline.

- The gesundaltern@bw project, which is funded by the Ministry of Social Affairs, Health and Integration as part of the digital@bw digitalisation strategy, enables older citizens to use digital applications and services in the healthcare sector.

- **Measure 8:** The Forum Health Region Baden-Württemberg is designing an information campaign for 2022 that displays the possibilities through the availability of large amounts of patient data for research and how these can help every individual. Appropriate formats are planned for the campaign.

- **Measure 9:** From the end of 2022, we will evaluate the information collected and consider further measures to strengthen the digital health literacy of citizens.

[6)] The Ministry of Social Affairs is funding five more projects to improve the digital competence of service providers through the European Social Fund (ESF) (European Social Fund in Baden-Württemberg – calls for projects and the Labour & Social Affairs funding programme (esf-bw.de)).

[7)] In the course of this, patients can provide their personal clinical and structured data (i.e. data that allow conclusions to be drawn about the patient, such as information on: name, place of residence, age, gender, etc.) either individually or collectively to the Research Data CentreHealth Data Lab (FDZ) at the Federal Institute for Drugs and Medical Devices (BfArm) in accordance with § 303d SGB V.

[8)] Advisory Council on the Assessment of Developments in the Healthcare Sector (2021), p. 321.

Imprint

The Forum Health Region Baden-Württemberg was established in 2018 on the initiative of Minister President Winfried Kretschmann to create closer links and promote networking between research, healthcare and the industry, and to develop Baden-Württemberg into a health region at the highest possible level. The Forum currently brings together more than 500 experts from hospitals and care facilities, research institutes and universities as well as biotech, pharma and medical technology companies in Baden-Württemberg.

Publisher:
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Photo credits: cover photo: © slonme/AdobeStock

Design: Designwerk Kussmaul, Weilheim an der Teck
1st edition (English), 150 copies as of: January 2023

Translation: Bachmann Consulting

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Baden-Württemberg