March 2023

DIGITAL TOGETHER

Germany's Digitalisation Strategy for Health and Care

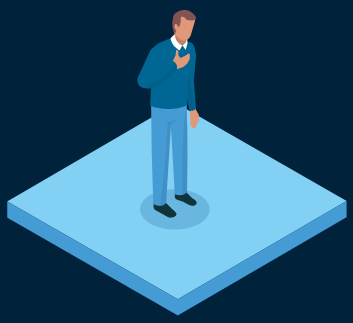
Federal Ministry of Health

The Digitalisation Strategy for Health and Care – Tangible Benefits and Opportunities

REDUCED MORTALITY

Cardiac insufficiency is the most frequent reason for inpatient hospitalisation

Telemonitoring reduces rehospitalisation and mortality rates among cardiac insufficiency patients.



REDUCED BUREAUCRATIC EFFORT

90 percent of nursing staff feel overburdened with bureaucracy

Electronic documentation simplifies work and saves time, such as when interconnected monitoring systems document vital parameters.

REDUCING MISMEDICATION

30 to 40 percent of people over the age of 65 take at least four types of medication per day; from age 75 one in three takes at least eight different types of medication

Data from the electronic patient record (elektronische Patientenakte – ePA) can assist automated medication checks and help detect medication-related risks.

EARLIER DETECTION OF COMPLICATIONS

High blood sugar levels and high blood pressure can cause kidney damage

Digitalisation helps to detect the risk of kidney damage in diabetics at an early stage.

Figure 1: *The Added Value of Digitalisation for Patients and Providers: Examples*

FASTER DETECTION OF RISKS

During pregnancy, gestational diabetes is diagnosed in approximately 5 of 100 women

Through digitalisation available data can be used to ensure that gestational diabetes is treated earlier, benefitting both mother and child.

MINIMISING EXPOSURE TO RADIATION

Cardiologists working in interventional medicine have a greater risk of cancer from heightened exposure to radiation

Robot-assisted coronary intervention systems can result in a 95.2 percent reduction in cardiologists' exposure to radiation when performing surgical operations.

RELIEVING THE BURDEN ON FAMILY CARERS

78 percent of family carers who care for people with dementia are overburdened both physically and in terms of time

Digital applications can provide support in the home for the purposes of entertainment, monitoring and reminders.

MORE TIME FOR PATIENTS

55 percent of speech therapist practices with therapeutic staff complain about a shortage of skilled workers

The time saved in using teleconsultations enables more patients to be seen.

The Strategy's Core Components – An Overview

Further development of the **telematics infrastructure** (TI) and especially the **electronic patient record** (ePA) to create an **individual healthcare platform** for insurance holders. To enable the "ePA for all", an **opt-out principle** is being introduced. This means that unless they object, all insurance holders will receive an ePA.

"By 2025, 80 percent of statutory insurance holders will have an electronic patient record (ePA)."

Telemedicine will be expanded to enable low-threshold access to healthcare. For this purpose, **specialist-assisted telemedicine services** will be introduced which can be taken up, for example, in **pharmacies and health kiosk (Gesundheitskioske)**. In addition, the existing 30 percent restriction on telemedicine services for physicians and general practitioners will be lifted.

"By 2026 there will be an assisted telemedicine access point in at least 60 percent of regions with insufficient access to general practitioners."

Digital transformation and urgently needed relief of long-term care and nursing staff is being stepped up. For this purpose, a **Competence Centre for Digitalisation and Care** will be set up and nation-wide establishment of digitally-assisted, **interoperable care documentation** accelerated.

Focus will be placed on **digital transformation of healthcare processes** rather than on simple digitalisation of documents. As part of this process, indication-related, **digitally assisted and digitalised disease management programmes** (dDMPs) will be established. In addition, information will be shared via secure digital communication channels using the TI.

"In 2026, 80 percent of communication processes in healthcare will be paperless."

Gematik GmbH will be transformed into a **digital health agency** which prioritises user orientation: The digital health agency will be responsible for digitalisation of end-to-end processes and charged with drawing up comprehensive **interoperability** requirements. Positive user experience with TI applications will be a prerequisite for the approval of such applications. In addition, the agency's **autonomy** will be strengthened by reorganising the governance structure.

The **research data landscape will be underpinned with healthcare data** – the linkage of existing data silos will be enabled by successive introduction of a research pseudonym. This opens the door to all kinds of research for the benefit of both patients and the common good.

"By the end of 2026, no less than 300 research projects will be conducted or initiated using data from the Health Data Lab (FDZ)."

Dear Reader,

When it comes to health and care in Germany, digitalisation carries huge potential that has hardly been used to date. This is why digitalisation is a key issue in this current legislative period. The COVID-19 pandemic has shown that digitalisation offers tangible benefit that enables successful, effective transformation: For example, during that time, the number of video consultations held increased significantly, while long-term care counselling and advice was digitalised and provided online. With the Corona-Warn-App (CWA) and the digital vaccination certificate, vast numbers of people used a health app on their smartphones for the first time.

The Digitalisation Strategy is to be seen as a compass to guide the actions performed by all stakeholders right now as well as in the upcoming years. Against this backdrop, it sets out short-term, medium-term and long-term measures for three separate fields of action. It also helps in striking a reasonable balance between value-generating use of health and care data and compliance with data privacy and data protection provisions.

Three examples:

- In many cases, the type of healthcare a person receives is still too often a matter of chance. If more digitally assisted healthcare programmes were available to offer patients guidance and orientation, healthcare provision could be made more personalised as well as its quality improved. Accordingly, for example, in rural regions telemedicine and digitalised disease management programmes will provide better access to better quality healthcare.
- Use of health and care data enables significant improvements in healthcare and research. For this reason, health and care data will be removed from existing data silos and linked to form a new health data space for research.
- The electronic patient record (ePA) will evolve into a digital healthcare platform. As a central application, it connects all relevant stakeholders in everyday healthcare provision. This ensures optimal flow of information between the various healthcare providers and patients, and the secure use of innovative technologies such as artificial intelligence and digital twins.

This Digitalisation Strategy for Health and Care was developed in collaboration with numerous representatives from the medical and pharmaceutical community, the healthcare, nursing and long-term care system, patients, people in need of long-term care, health insurance and long-term care insurance funds and other cost carriers, science and research, and the industrial healthcare economy. Rather than being simply a programme devised by the Federal Ministry of Health (BMG), it is designed as a guide for the joint effort of all stakeholders concerned. So now, with all of this in mind, let us get to work!

Prof. Dr. Karl Lauterbach
Federal Health Minister

CONTENTS

ILLUSTRATIONS

1. Our Vision and Aim

Digitalisation in health and care enables healthier and longer lives for all. It also improves the quality of healthcare, making it more efficient.

Digitalisation is essential in improving health and care. Given the right conditions, it provides for better quality in preventive healthcare, diagnostics, medical treatment and care, therapy and support. It enables more flexible provision of healthcare and long-term care for all, independent of geographical location, and relieves the bureaucratic burden placed on medical and nursing staff in their daily work.

In combination with the German Federal Government's National Digitalisation Strategy, the Digitalisation Strategy for Health and Care plots a clear course of action. It sets out a vision of a resilient, future-proof, sustainable and digitally assisted health and care system, and provides guidelines on how to achieve it. The Strategy provides all stakeholders with a transparent guideline. It contains verifiable goals and objectives, will be evaluated regularly, and updated continuously.
Digital transformation of health and care serves in enabling people in Germany to lead healthy, good and long lives. In doing so, an eye is kept to the European dimension of cross-border healthcare provision.
The aim is to achieve the best-possible mix of digital and analogue components of people-centric healthcare:

- Stakeholders are closely interconnected and interact via beneficial digital technologies and applications. In a digital healthcare ecosystem, healthcare providers, health insurance funds, long-term care insurance funds and other cost carriers as well as the industrial healthcare economy work hand in hand, exchanging health information and data as part of the healthcare process. Digital connectivity is closely related with increasing institutional connectivity between the various stakeholders in health and care. It, thereby, enables partnership-based cooperation across healthcare sectors and professions.
- As a learning system, the health and care system will be developed involving active use of healthcare data, thereby enabling optimal use of digitalisation potential. In addition to providing the best-possible treatment and medical aftercare, preventive health maintenance and preventing the need for long-term care are of vital importance.
- Patients can easily access and understand health related information, enabling them to better avoid illness and its consequences, and thus make informed decisions about treatment.
- Patients' health and care data should be able to be used for health policy management and research purposes, thereby serving further improvement of healthcare.
- Innovative, secure technologies can give rise to rapid, widespread benefits in the health and care context. Healthcare provision and administration processes as well as their associated structures will be continuously transformed in line with available digital solutions.
- The healthcare provision process should be seamlessly structured for patients and for healthcare and social welfare professions. The relevant data and information are available, thereby generating added value in healthcare provision.

Vision 2030:
The Digital Health Ecosystem

Figure 2: *Vison 2030: A People-Centric Digital Ecosystem for Health and Care*

Digitalisation should also contribute to greater economic, environmental and social sustainability in health and care.

The Digitalisation Strategy creates the conditions for consistently people-centric, digitally assisted healthcare, nursing and long-term care provision that offers noticeable benefit. Strengthening the digital health literacy and skills of all stakeholders is thus a key prerequisite in ensuring that digital services and applications are used.

Depending on their situation, people adopt various roles: as healthy or sick individuals, as persons in need of long-term care, family members, or representatives from healthcare and social welfare professions, such as doctors, nurses or midwives.

The Strategy thus has the following overarching goals and objectives:

CONSEQUENT FOCUS ON PEOPLE, PATIENT SOVEREIGNTY AND ENTHUSIASM

We focus on peoples' needs by:

- Using digitalisation to enable equitable, comprehensive, non-discriminatory and affordable access to healthcare, nursing and long-term care provision for all.
- Making health and care data available as the basis for timely and tailored provision of services and treatment, also making data directly available to patients to allow them to take self-determined, informed decisions on the treatment they receive. This is a key component in strengthening patient sovereignty.
- Using digitalisation to provide the best-possible treatment and care in all healthcare situations, thereby focusing on individual needs to enable participation for all.
- Using digitalisation to create both better regulatory and working conditions for healthcare, nursing and long-term care employees, thereby relieving their everyday burden and saving time that can be used for patient care. This helps to make healthcare and social welfare professions a more attractive employment choice.
- Taking a benefit-oriented approach to digital transformation, creating tangible added value for stakeholders and fostering greater enthusiasm and acceptance.

96%

(N=394)

The most important aim of the Digitalisation Strategy is to **ensure digitally assisted healthcare focuses consistently on people**. In an online survey conducted when developing the Strategy, 96 percent of respondents said they believed this was important.

IMPROVING THE QUALITY OF HEALTHCARE

The Digitalisation Strategy makes a key contribution towards improving the quality of healthcare:

- Diagnostics, treatment, health and care are improved via consistent use of data and digitally optimised processes, and needs-based use of digital applications.
- Diseases, their effects and the need (or an increased need) for long-term care are detected earlier and largely prevented by means of timely intervention.
- The provision of high-quality and needs-based healthcare is promoted and guaranteed – both in urban centres and rural regions.
- The potential for general and personalised health and care risks can be identified more quickly, allowing timely action to be taken, for example with targeted treatment of diseases such as cancer and in combating pandemic disease.
- Healthcare data is made more accessible for and used in research to improve prevention, healthcare, nursing and long-term care, and also after-care provision.

For 94 percent of respondents in the online survey, it is important that the Digitalisation Strategy leads to **higher quality outcomes** in healthcare.

94% (N=395)

INCREASED COST-EFFECTIVENESS AND EFFICIENCY

Digitalisation can make health and care more cost-effective and efficient by:

- Using high-quality health and care data facilitates the development of more efficient, more customised and more integrated healthcare provision and management programmes.
- Preventing diseases, their effects and the need (or an increased need) for long-term care as well as avoiding associated costs.
- Relieving the burden on medical and nursing staff in their everyday work, thereby improving the working conditions.
- Simplifying and accelerating seamless administrative processes by means of automation, access to relevant data, and cross-sectoral networking and interconnection.

(N=394)

85%

More than 85 percent of respondents in the online survey see increased **cost-effectiveness and efficiency** in healthcare as an important objective for the Digitalisation Strategy.

To achieve these goals, when designing the digital transformation of the health and care system, three central fields of action were identified as equally important:

1. Establishment of people-centric, digitally assisted cross-sectoral and cross-professional healthcare processes
2. Generation and use of high-quality data for better healthcare and research
3. Use of benefit-oriented technologies and applications

The fields of action are described in more detail in Section 2. Achieving these goals and implementing the measures in the respective fields of action depend on:

- Greater patient sovereignty that enables informed, self-determined action and decision-making for all patients and their relatives, and also takes account of healthcare service providers' needs.
- A suitable regulatory framework.
- A transparent, clear division of responsibilities and roles, as well as the provision of an adequate governance framework for strategy implementation.
- Strict implementation management that includes all relevant stakeholders.

These issues are addressed in more detail in Sections 3 and 6. Figure 3 gives an overview of the Digitalisation Strategy's components.

"Digitalisation in health and care enables healthier and longer lives for all. It also improves the quality of healthcare, making it more efficient."

Consequent focus on people, patient sovereignty and enthusiasm

Improving the quality of healthcare

Increased cost-effectiveness and efficiency

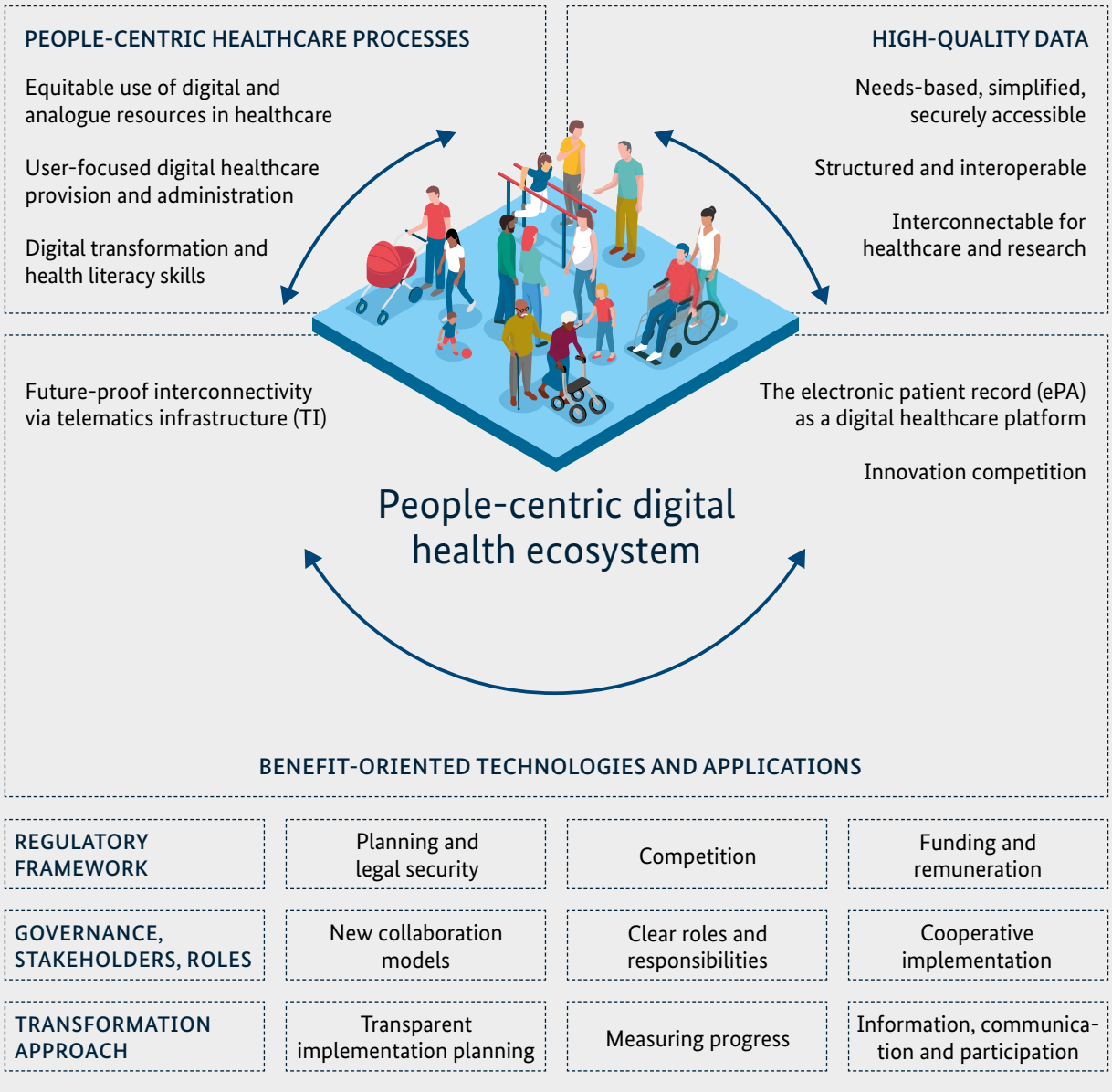


Figure 3: *Objectives of the Digitalisation Strategy for Health and Care*

2. Strategic Fields of Action

To achieve the digital transformation of health and care, new approaches are needed in healthcare processes along with the generation and use of health and care data, and use of innovative digital technologies and applications. This section sets out goals and objectives, strategic guidelines and short-term, mid-term and long-term measures for those fields of action. These serve as a compass to provide guidance for all stakeholders in health and care. They also plot the course in designing the digital transformation.

2.1 Establishment of people-centric, digitally assisted, cross-sectoral and cross-professional **healthcare processes**

I. INTRODUCTION AND OBJECTIVES

Through wider use of digital resources, healthcare provision and management processes are improved and redesigned. Against this backdrop, the aim of the Digitalisation Strategy is to establish needs-based, efficient processes which ensure optimal digital assistance and support. To ensure that the regulatory framework does not hinder good new processes, suitable mechanisms will be developed for use in process transformation.

Process Transformation Driven by Digitalisation

	EXAMPLES
NEEDS-BASED ESTABLISHMENT OF FULLY-DIGITAL PROCESSES INSTEAD OF ANALOGUE APPROACHES	▪ Electronic communication replaces paper-based exchange ▪ Previously analogue medical care can be provided in digital form (such as via telemedicine)
CERTAIN PROCESS STEPS ARE NO LONGER NEEDED AS DIGITALISATION MAKES THEM OBSOLETE	▪ Control check-ups in medical practices can focus on diagnosis and treatment as health-related data can be collected separately and in the patient's home with the use of wearables
NEW PROCESS STEPS ARE ADDED WHEN USING NEW TECHNOLOGIES AND DATA	▪ Numerous new processes created in self-directed health management in the home setting ▪ Telemonitoring of chronically ill patients and people in need of long-term care
FUNDAMENTAL PROCESS TRANSFORMATION AS DIGITALISATION ENABLES NEW HEALTHCARE APPROACHES	▪ Piloting and information services for citizens ▪ Online case conferences or remote collaboration during surgical operations ▪ Overarching resource and capacity management for service providers
GUIDELINE-BASED SUPPORT IN HEALTHCARE PROCESSES	▪ Automated recommendations for measures based on medical and care diagnoses ▪ Digital support for guidelines-based treatment pathways

Figure 4: *Healthcare Process Changes Driven by Digitalisation*

This leads to the following objectives:

1. Digitally assisted and purely analogue healthcare processes should initially be used on an equal footing if they are equally suitable and produce equivalent results. Duplication is to be avoided. The principle of cost-effectiveness must be taken into account.
2. Healthcare provision and administration processes will be digitalised. In all life situations, patients should benefit from digitally assisted healthcare provision and administration processes, including where they have only limited digital literacy skills. Appropriate arrangements will be made for insurance holders with special needs.
3. Healthcare processes should be planned from the perspective of the recipient. The needs of the provider (in terms of user-friendliness and data security, for example) must also be taken into account. Digitally assisted processes should be developed with the participation of both groups.
4. To ensure optimal use of digital solutions, digital healthcare and digital transformation literacy of all stakeholders will be enhanced and the necessary training and instruction provided.

II. STRATEGIC GUIDELINES

To ensure that transformation is designed with those affected in mind, digitalisation measures taken in health and care will follow the guidelines listed below:

- Existing processes will be reviewed for their digitalisation potential and adapted if needed. In transformation management, the practice perspective plays an important role. Available resources and capacities will be considered and prioritised.
- In designing the digital transformation, standardised mechanisms should be developed and implemented to enable digitally assisted healthcare provision, including across national borders and between healthcare sectors, and thus eliminate duplicate structures.
- In implementing the transformation, knowledge must be promoted among all stakeholders through wide-ranging healthcare communication measures. This applies in particular to reliable information on the benefits of digitalisation and self-determined use of the resources it provides. As part of that process, both citizens' and service providers' digital health literacy is to be enhanced.
- Processes are to be updated and redesigned where needed, to better utilise the potential offered by digitalisation – not least to improve the underlying processes for the benefit of those involved. Where digitalisation effects a change in existing processes, which can add value for those involved or for healthcare provision, those changes should be implemented. Merely transferring analogue processes or paper forms into digital formats is not sufficient.

Process transformation – examples

- Cross-sectoral medication management through use of e-prescriptions, electronic patient records and standardised labelling for greater medical safety and reduced expense.
- Piloting and search functions for insurance holders that provide an overview of available treatment and care capacities as well as simplified use of healthcare services.
- Hybrid healthcare processes in which digital healthcare and long-term care applications (DiGAs/DiPAs) are part of guideline-based healthcare provision and combined with analogue interventions.
- Data and AI-based identification of health risks and automatic notification of insurance holders and, if applicable, their general practitioner with a recommendation to see a doctor.

TIMELINE

Implementation of the **short-term** measures begins in 2023. For the mid-2020s, **medium-term** measures follow which will later be supplemented and enhanced by **long-term** measures (from the end of the 2020s).

III. MEASURES

Short-term

- Design of model digitally assisted healthcare processes (starting with disease management programmes, DMPs) with integral digital components such as digital health applications (DiGAs) and electronic patient records (ePAs).
- In the second quarter of 2023, a messenger service will be launched for communication between service providers. A service for communication between service providers and insurance holders will follow in 2024.
- Planning of a digitally assisted medication management system: By the end of 2025, 80 percent of ePA users who take at least one type of medication will have a digital medication overview.
- Low-threshold telemedicine services will be made available to insurance holders. Their take-up by users and their provision by non-medical health professionals, for example in pharmacies and health kiosks (Gesundheitskioske) will be assisted. By 2026, at least 60 percent of regions with insufficient access to general practitioners will have an assisted telemedicine access point.
- To improve usability of potential digital solutions in long-term care, a Competence Centre Digitalisation and Care will be established to identify and spread the potential for improving and strengthening long-term care provision for patients and carers. Funding provisions for long-term care facilities will be expanded to promote implementation of digital solutions.
- To simplify the search for the right long-term care programmes along with support and advisory services, a dedicated information portal for long-term care and support services will be set up and operated to serve those in need of care, family caregivers, family members, social welfare staff in hospitals, and in counselling and advice centres.

Medium-term

- Other digitally assisted healthcare processes will be successively developed and gradually rolled out. In 2026, 80 percent of communication processes in health and care will be paperless.
- For routine treatment of complex health issues, the relevant core information from the ePA will be made available in the form of customised “partial summaries” (such as a summary for diabetes or an oncological summary).
- The messenger service will be enabled to transmit structured information (such as for ordering follow-on prescriptions).
- Data for the ePA and the electronic medication plan (eMP) will be provided via the e-prescription service.
- The aim is that by the third quarter of 2026, 60 percent of public health service offices funded by the Federal Government under the “Pact for the Public Health Service” improve their digital maturity by at least two levels in at least three categories (in line with the digital maturity model for public health offices).
- The aim is that by the end of 2025, 50 percent of hospitals funded under the Krankenhauszukunftsfonds (Future Hospitals Fund) improve their digital maturity by at least two levels in at least two categories (in line with the DigitalRadar maturity model).
- Use of electronic real-time reporting processes by all medical facilities and by public health authorities will be mandatory.
- Work towards establishing suitable continuous training programmes along with opportunities for dialogue and exchange, especially for healthcare providers. In the course of vocational training reforms for healthcare professions, acquisition of digital skills will continue to receive consideration.

Long-term

- Healthcare, nursing and long-term care is increasingly based on digital data and its provision is personalised and tailored. On the basis of a population-based data analysis, personalised preventive healthcare programmes will be made available.

96% (N=448)

96 percent of respondents in the online survey see the **"processes"** action area as very or quite relevant. On the topic of processes, respondents see the greatest potential for digitalisation in enabling **better coordination of healthcare and greater cross-profession collaboration.** (N=447)

Digitally assisted healthcare processes for chronic illnesses such as diabetes and coronary disease – a proposal from the forum on healthcare and long-term care processes

Treatment and care of chronically ill patients should be improved by means of digitally transformed healthcare processes. In other words, measurable patient-specific end points should be achieved – such as greater longevity, fewer side-effects and better quality of life. As a prerequisite, healthcare processes must be tailored to patients' needs and newly designed if needed, while services in outpatient, inpatient, nursing and long-term care as well as digital healthcare should be combined. Using low-threshold services, chronically ill patients are supported and guided by their personal healthcare management plan. Patients receive automated information and reminders, for example concerning prescriptions, medication and appointments. For brief or minor queries, service providers can be contacted via messenger, eliminating the need to visit a medical practice. A network of outpatient and inpatient service providers accompanies patients and makes joint decisions about further treatment, for example by offering online video consultations.

Small changes can make daily life easier and reduce risk for patients and carers: Some examples

In residential care homes, nursing staff is often faced with the challenge of not allowing elderly residents at risk of falling to get out of bed on their own. By the time they have reached the light switch to go to the toilet, they could already have tripped and hurt themselves. One care home has developed a system which is designed to minimise this risk in a simplistic, easy to implement way. Movement sensors recognise when a resident sits up in bed. When this happens, a night light turns on. The sensors are also used to transmit information when a resident leaves his or her room. This can be especially useful when the person concerned has dementia. If they leave their room unnoticed, there is a risk that they could become confused and hurt themselves. The signal sent by the sensors alerts nursing staff who can help the person right away.

2.2 Generation and use of high-quality **data** for better healthcare provision and research

I. INTRODUCTION AND OBJECTIVES

With new treatment opportunities and technologies, a vast amount of health and care data has been generated in the course of healthcare provision over the past years. Digital applications should make the data more usable to enable personalised decisions concerning healthcare provision, increase patient safety, ensure people are better informed, drive data-based healthcare policy-making and generate new knowledge from research to improve healthcare. In turn, new research results should be incorporated into healthcare provision in a timely manner as part of a learning system. The Digitalisation Strategy forms the basis for connecting the German healthcare and long-term care system to the future European Health Data Space (EHDS) and enabling cross-border healthcare and research.

In the data field of action, the following and objectives apply:

1. The quality of health and care data generated during treatment and care should be successively improved, and the use of data facilitated.
2. Provide insurance holders with direct, secure access to their personal health and care data and also use it in a low-threshold manner to support and improve personalised treatment and care. This includes the right of patients to easily view their personal data, including with help from others.
3. Each and every individual has the opportunity to decide independently and without restriction on how their personal treatment, health and care data is used. This also enables informed decision-making about non-use and its consequences, for example in the context of the electronic patient record (ePA).
4. Ensure the availability and possible linkage of data from various sources. This includes billing data, healthcare data from the ePA as well as study-related, genomic and/or registry data. It also fosters acquisition of knowledge on combating health risks such as pandemics, enables preventive and predictive action by means of personalised medical treatment and care, and takes the research data landscape to a new level. This increases patient safety, the quality of treatment and care, and also efficiency in the use of resources in healthcare, nursing and long-term care as well as the public health service. By facilitating secure access to data for research in both the public and private sector, Germany's role as a leading science and industry will be further consolidated.
5. Promote the provision of representative data for research and the development and use of data-driven technologies to provide more targeted support for provision and administration processes in health and care, and place greater focus on people in research, development and application. For example, personalised treatment and care is facilitated by using AI to assist early detection of disease and, through early identification of complications in the course of healthcare, nursing and long-term care.

II. STRATEGIC GUIDELINES

To achieve these objectives, all action taken will comply with the guidelines set out below:

- Promote acceptance of and awareness for healthcare data use and improve data literacy skills among doctors, other healthcare providers and patients.
- Work towards harmonised interpretation of national and EU data protection legislation for the healthcare sector, and borrow from best practices implemented in other EU Member States. With regard to provisions on data use, data privacy and data protection, strike a balance between the various interests and work towards harmonised design and application of data protection law to ensure data protection practice that enables appropriate data use. This includes balancing the state's responsibility to protect its citizens with citizens' self-responsibility and patients' sovereignty.
- All insurance holders receive an electronic patient record (ePA) which accompanies them throughout their lives. Its voluntary use is ensured by an opt-out provision and clause. When providing treatment and care, the health and care data stored in the ePA is accessed, relevant new data is added with minimum effort, and – unless the patient has used the opt-out clause – is made available for research in a data protection-compliant form via the Health Data Lab (FDZ).
- For patients, the ePA will become the central platform for matters concerning their health, treatment and care. They receive information related to their personal data, such as details of diagnoses and treatment options, and associated reminders and medical advice. Data concerning treatments and the use of digital healthcare and long-term care apps (DiGAs/DiPAs) is automatically transferred to the ePA and subsequently made available for research.
- For healthcare providers, the ePA will become an essential component of healthcare processes. It contains reliable information and assists in the provision of treatment and care – for example, relevant data is highlighted and can be called up in a targeted search.

- For the benefit of patients, as part of the model project on genome sequencing under Article 64e of Book V of the German Social Code, genomic medicine will be strengthened as a knowledge-generating form of healthcare. Data should be easily accessible and reusable, ideally in real time. There is no maximum storage period for data in cases where longer storage periods make sense in relation to medical treatment and care, and/or are required for research. The availability of structured data in the healthcare process will be continuously improved.
- In compliance with FAIR principles, the availability of structured health and care data will be ensured for use in the ePA and for systemic improvements through research.
- Lasting structures for medical registers will be promoted to facilitate better availability of register data for healthcare provision and research, and for linkage with other data. Existing initiatives on specific illnesses and healthcare-related medical registers, such as the establishment of a German Implant Register (IRD) will continue.
- Data infrastructures will be harmonised and interfaced by means of binding interoperability requirements and via the use of internationally recognised standards. Data from healthcare, from registers and studies will be combined via an interconnected healthcare data infrastructure, enabling overarching, cross-source analyses. Transparency regarding data storage sites will be ensured and duplicate structures eliminated. The data will be made accessible on the basis of purpose and need via secure data processing environments.
- The definition of datasets and data models takes requirements for uniform, unbureaucratic medical and care documentation into account. Duplicate documentation is avoided.
- The creation of test and training datasets for algorithms (e.g. AI) is facilitated so they can be used for the respective target groups in a non-discriminatory way. Potential areas of application include interpreting medical images (such as X-rays and CT scans), observation of the human body and physiological processes for the purpose of early detection and monitoring of disease, after-care following surgical interventions, identifying similarly complex cases in large datasets (especially using genomic data and in personalised medicine), and the detection of epidemiological risks (such as the occurrence and development of pandemics).
- All service providers and their contracted software providers supply data in standardised, structured and interoperable form in accordance with internationally accepted standards and nationally defined specifications. This also applies for all other institutions that generate healthcare and long-term care data.
- Connectivity with projects and programmes in other government departments (such as the Federal Government's Data Strategy) and within the EU is ensured (primary and secondary data use in the EHDS).

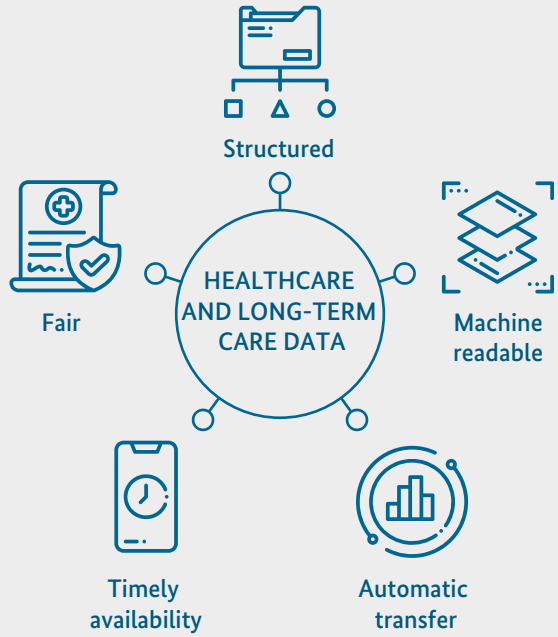


Figure 5: *Quality criteria for data*

III. MEASURES

Short-term

- The research data landscape will be underpinned by the gradual introduction of a research pseudonym in healthcare-related registers as well as routine and study-specific data to enable linkage between health and care research. In the medium-term, the research pseudonym should also enable linkage with electronic patient record (ePA) data.
- To improve public health and public health research, a Federal Institute of Public Health (Bundesinstitut für Öffentliche Gesundheit) will be established. The Institute will receive access to public health-related data from the various interconnected data sources, thereby making an important contribution to data-based decision-making on health policy concerns.
- Standardised and transparent division of responsibilities and roles in respect of interoperability issues in health and care. Moving away from system- and sector-specific rules and regulations for interoperability and standardisation.
- A right to interoperability and data portability will be enshrined in law and gradually implemented into practice.
- Implementation of medical information objects (MIOs) which generate valuable healthcare benefits for a large section of the population (e.g. medication data) will be prioritised, thereby creating the foundation for harmonised availability and usability in practice. In both the short-term and medium-term, DMP datasets will be developed and established as MIOs (see the processes field of action).
- Initiate a paradigm shift towards enabling access to data via secure processing environments for specifically defined purposes, especially for medical science research, as data access authorisation criteria.
- Improve opportunities for health and long-term care insurance funds and other cost carriers, and also associations of SHI physicians to use – in the interests of insurance holders – available health and care data to identify regional healthcare needs and deficits, design demand-based provision and conduct accompanying research.
- With further development of the leading data protection supervisory authority, a standardised data protection supervision practice in health and care will be promoted – with the goal of making use of data for healthcare research purposes safe and applicable.
- Working towards standardisation of digital documentation in care (SGB XI). An assessment will also be made to see if the interoperability of care documentation can be improved (syntactically and semantically interoperable data formats) and to identify the conditions that would need to be put in place (such as standardised healthcare terminology and classification systems).
- For the benefit of patients, initially those with oncological and rare diseases, and as part of the model project on genome sequencing according to Article 64e SGB V, enable genomic medicine as a knowledge-generating form of healthcare and evaluate its use/benefits in practice. Monitor connectivity with relevant registers, the ePA, EU initiatives (1+ million genomes/Genomic Data Infrastructure) and the interface with the European Health Data Space (EHDS).
- The German Implant Register will initially go into operation to register breast implants.

Medium-term

- Establish a national access point for healthcare data as a touch point for stakeholders from research and the public health service to link health and care data from multiple sources (ePA, routine data, study-related data, etc.).
- By the end of 2026, no less than 300 research projects will be conducted or initiated using data from the Health Data Lab (FDZ).
- Gradual development towards achieving the realm of the ideal in real-time availability of health and care data. Work towards ensuring that selected routine data from SHI healthcare provision is transferred to the ePA and to the Health Data Lab in a structured format and on a monthly basis at minimum. Service providers will be required to meet appropriate deadlines.
- Drive harmonisation and standardisation of IT infrastructures and an across-the-board increase of the

digital maturity level of healthcare and long-term care institutions – especially among healthcare providers not previously in the focus of digitalisation activities (such as physiotherapy/rehab).
- Create rules and regulations for secure use of health and care data in AI testing and training. The EU legal framework as well as prevailing national, EU and international initiatives will be taken into account.
- In a first phase, certain data from all Länder-specific cancer registers nationwide will be compiled by the German Centre for Cancer Registry Data (ZfKD) at the Robert Koch Institute. In a second phase, all cancer register data should be compiled as needed, linked with other data via a common platform and made accessible. Transparency regarding data storage sites will be ensured and duplicate structures dismantled.
- Following successful evaluation of the model project on genome sequencing according to Article 64e SGB V, its integration into standard healthcare provision will be enabled and an assessment made regarding its expansion to other indications and datasets for personalised medicine. This also ensures connectivity with other national and EU data infrastructures.
- Operation of the German Implant Register (IRD) will be expanded to cover endoprostheses and aortic valves.

Long-term

- Technical and organisational infrastructures will be expanded to ensure that access to health and care data is available for healthcare provision and research across EU borders.
- With the model project on genome sequencing according to Article 64e SGB V, a sustainable structure for personalised medicine is created – among other things for use by various omics datasets in healthcare provision and research.
- Operation of the German Implant Register (IRD) will be expanded to cover implant types.

93% (N=450)

of participants in the online survey see **data models and interoperability** as the second most important field of action in the Digitalisation Strategy.

86 percent of respondents in the online survey believe that **faster and more secure exchange of patient data** will improve the quality of healthcare, nursing and long-term care, and make it more benefit focused. (N=441)

Learning from other countries
Access to relevant, centrally stored healthcare data for all citizens and healthcare providers improves the quality of healthcare provided and helps secure better results. Finland began storing the medical data of all its citizens on a central portal (Kanta) about 20 years ago. Using a password, insurance holders can log on to the secure portal at any time from wherever they may be. Via the portal, they can view authorisations and results, order prescriptions and upload personal data, such as from fitness or activity trackers. With patients' approval, healthcare providers can quickly and easily view the relevant healthcare data with a minimum of effort involved. This enables better and more targeted medical care. The Finnish healthcare system requires that healthcare providers use the database. Secondary use of data is regulated by an opt-out process: Patients can object to their data being used for research purposes at any time. The data made available is used for various kinds of studies, such studies to improve the treatment of cancer and diabetes.

AI assists in language assessment for early diagnosis of neurodegenerative diseases.
AI can process a large amount of speech data quickly and efficiently. Melodic aspects of speech are taken into account. Changes can be used as a kind of digital biomarker, which the AI programme, uses to detect disease-related changes in speech. AI can detect abnormalities at a very early stage and at a level which without technical equipment, would be undetectable to the human ear.[1]

1 AI speech assessment can simplify diagnosis of neurodegenerative diseases – DER PRIVATARZT DIGITAL (der-privatarzt.de)

2.3 Benefit-oriented **technologies** and **applications**

I. INTRODUCTION AND OBJECTIVES

The number of digital applications in use continues to grow, including in health and care. To accelerate their integration into everyday healthcare provision, the following objectives apply:

1. The electronic patient record (ePA) will evolve into a platform on which structured data can be stored and used to provide value added services (such as checks for medication interactions).
2. The telematics infrastructure (TI) and its applications will be continuously developed and enhanced as the underlying infrastructure for digitally assisted provision and communication processes in health and care. Via the TI, digital applications are interconnected in such a way that data can be exchanged in a structured, secure, timely approach across disciplines, facilities and sectors.
3. Digital innovations which are proven to be benefit-inducing and efficiency-enhancing are identified. The necessary conditions are created to ensure that those applications are integrated in a timely manner into health and care.
4. Acceptance of digital applications among users is fostered by providing transparency and by facilitating their early inclusion and participation.

Use of innovative technologies is always in line with the goals and objectives set out in the Digitalisation Strategy, thereby helping to ensure longer, healthier lives, making healthcare people-centric and stabilising funding for health and care.

II. STRATEGIC GUIDELINES

To achieve these objectives, the measures taken in the coming years will comply with the guidelines set out below:

- The electronic patient record (ePA) will be evolve and become an integrated, individual digital healthcare platform for insurance holders and, in combination with other applications, become the standard in healthcare provision:
  - By 2025 80 percent of statutory insurance holders will have an ePA. An associated opt-out provision will be introduced.
  - The ePA will be further developed and enhanced to serve as the foundation for data-based value added applications. People in Germany should be supported in all matters concerning their personal health. Access to the ePA occurs via a digital identity and via mobile devices, both for insurance holders and service providers.

- The data stored on the individual digital healthcare platform is accessible for specific software programmes. For example, interactions, abnormal laboratory results, reminders for follow-on prescriptions and other health-related notifications can be automatically displayed. Healthcare providers should also be able to obtain evaluation reports (for example to detect changes in a patient's health status since they were last seen). Secure and practicable encryption processes must therefore be used.

- The TI and its applications facilitate connectivity of and between all stakeholders in health and care.
  - Through mandatory connection of all service providers with the TI and broad-based, regular use of its applications and services, the TI ensures the creation of a secure digital healthcare ecosystem.
  - As part of the digital transformation, the specifications are provided and the requirements for the interoperability, user-friendliness and cost-effectiveness of applications are set out. Application development takes place on a competitive basis.
  - The TI approach will be further developed as part of an ongoing process and in line with technical and legal developments and trends. The existing hardware-based connectivity (via TI client hardware) will be updated in line with the times. Applications surrounding the TI and its use should be particularly user-oriented. These will be carefully selected, developed and subject to ongoing evaluation, using a participative approach from the outset. Using a model for technology evaluation from the user perspective, the potential of digital healthcare technologies can be estimated in early development phases.
  - All stakeholders in the TI environment must meet binding interoperability and IT security requirements.
  - Digital applications, such as digital healthcare and long-term care apps (DiGAs/DiPAs), telemedicine/telecare solutions, digital aids and digital measures to improve the home environment will be better connected in the interests of providing interoperable, digitally assisted healthcare and long-term care.

III. MEASURES

Short-term

- A Digital Health Agency will be established as the authoritative body for digital applications in the German health and care system, especially with regard to the telematics infrastructure. When identifying and formulating the requirements for appropriate applications, users are to be involved at an early stage.
- Lifting of the restriction on telemedicine to 30 percent of consultations and the establishment of performant structures and services enable the potential of telemedicine to develop and unfold.
- Digital healthcare and long-term care apps (DiGAs and DiPAs) will be developed as integral components of digitally assisted healthcare processes. In the future, DiGAs and DiPAs can not only export data to the ePA (opt-out), but can also read data from the ePA where it is necessary and useful for DiGA/DiPA personalisation.
- The DiGA approach will be extended to beneficial digital medical devices in risk class IIb.

- In the future, DiGAs will be able to include detailed telemedicine treatment plans with doctors' involvement.
- Use of secure, cloud-based systems in outpatient and inpatient healthcare and long-term care facilities as well as for TI applications will be simplified – among other things, by adapting the regulatory framework.
- In mid-2023, the technical conditions for nationwide use of the e-prescription will be created and preparations will be made for an accelerated, mandatory rollout in 2024.
- The existing funding programme for digital and technical procurements in care facilities to relieve the burden on nursing staff will be expanded to include additional items in accordance with Article 8 (8) SGB XI.
- The Innovation Fund will be continued, further developed and enhanced. This will pave the way for innovative forms of healthcare to be tested over time and transferred to everyday healthcare routine.

Medium-term

- All healthcare providers are required to connect to the TI, and the capabilities for automated ePA filling will be continually expanded (in the short-term, via the electronic patient summary – ePKA).
- By 2027, at least 80 percent of laboratory results will be stored in the ePA and can be forwarded to the Health Data Lab (FDZ).
- The ePA will be further developed to enable algorithm/AI-based healthcare interventions and public health measures in real time.
- Procedure for low-threshold access to digital applications: After receiving detailed information on the potential risks, users can select the data security/data protection level for authentication in digital apps. IT security in healthcare and long-term care apps should thus be simplified for first-time users. Awareness to this issue must also be promoted.
- Develop simple, transparent opt-out solutions regarding use of the ePA and a transparent and simplified ePA authorisation management system that takes the insurance holder's perspective.
- Digitally assisted care documentation is to be used across the board in day-to-day care and, in particular, contribute to a noticeable reduction in the workload of healthcare professionals and to their efficient use.

Long-term

- The ePA will perspectively be developed to become a cross-Social Code portal, services (such as from health and long-term care insurance, and from statutory pension and accident insurance) will be integrated, and a joint database is to be created.

83% (N=395)

of respondents in the online survey say **digital innovations** are very or quite important.

Uniformly regulated standards and development processes are cited as the most **important measure for intensified use of technologies.** (N=410)

4. Digitally Literate, Sovereign Citizens

85%

(N=449)

of respondents in the online survey see **“digital literacy and patient sovereignty”** as important or very important.

The objectives, guidelines and measures outlined above are designed to help strengthen patient sovereignty by enabling informed, self-determined actions and decisions.

By means of the technologies and applications described, all insurance holders and their family members will be given the tools they need to codetermine and plot their course in digitally assisted healthcare and long-term care. They will receive relevant information, and be able to assess, understand and communicate it to healthcare providers. Insurance holders can actively exercise their right to portability and interoperability of data that involves them and their health – with help from others where needed. This improves access to appropriate and necessary healthcare services. In the redesign of processes as described, it must be taken into account that certain groups (such as people with relatively poor digital affinity or digital health literacy) require tailored services.

It is important that patients and people in need of long-term care can properly understand and classify health and care data. Information must thus be prioritised and provided in easy-to-understand form. And where needed, opportunities for personal consultation and discussion must be provided.

Representatives from healthcare and social welfare professions should also be supported in their decision-making and actions – both in interdisciplinary constellations such as councils and in additional use of healthcare data in the ePA. They should also be given the tools they need to be able to help other stakeholders in using digital applications, thereby serving as facilitators.

Discussion in the specialist forum on “Digital Literacy and Patient Sovereignty”

The gesund.bund.de portal could be further developed and transformed into a health and care platform with intuitively prepared and validated specialist information on illnesses and diseases, treatments and (digital) support programmes for insurance holders, their family members and healthcare providers. In the longer term, it could assume the function of a trustworthy pilot to help users navigate their way around the healthcare system. Interfaces with existing platforms and portals containing support and healthcare services are to be taken into account.

4. Regulatory Framework

78% (N=446)

of respondents in the online survey believe that the field of action **"regulatory framework"** is very or quite important in the digital transformation of health and care.

50% (N=446)

For more than 50 percent of respondents in the online survey, clarifying **responsibilities concerning specifications and standards** is especially important in achieving targeted digitalisation of health and care.

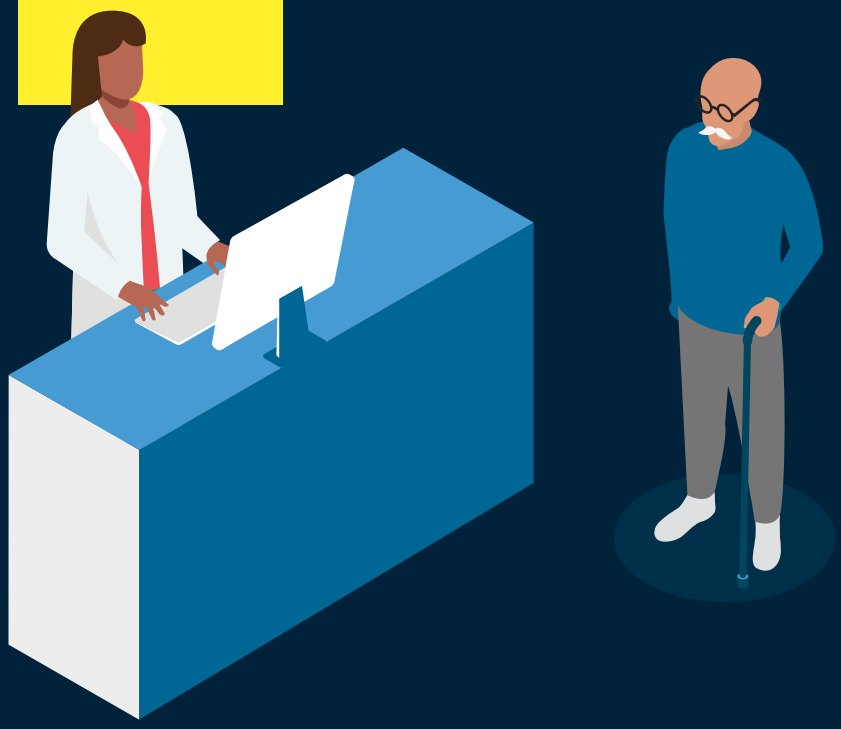
I. INTRODUCTION AND OBJECTIVES

Use of digital applications in health and care changes provision models and processes, and can require alignment of the prevailing regulatory framework. The regulatory framework should be designed in such a way that the objectives defined in the fields of action can be achieved.

II. STRATEGIC GUIDELINES

To achieve the objectives described, action and measures will comply with the guidelines set out below:

- The regulatory framework is to be implemented with clear provisions and rules, including standards, to enable flexible response to digital developments and trends and to ensure a sufficient degree of freedom in developing people-centric solutions in fair market competition (striking a balance between competition and regulation).
- By means of a User Experience Design Lab (UX = User Experience), the Digital Health Agency ensures that the user perspective is taken into account when designing TI applications. In addition, in specifications for TI applications, the user experience will become an integral component of confirmation and approval procedures for manufacturers.
- Uniform conditions will be created in which health and care data can be used more quickly and more easily for healthcare and healthcare research, both for the benefit of patients and for the common good, while complying with data protection and data security regulations.
- In the development and operation of digital applications and infrastructures, funding aspects will be taken into account. The emergence and maintenance of innovation potential in Germany and Europe is supported and promoted.
- At the same time, cost aspects and patient safety are kept in mind and a balance is sought between quality, cost-effectiveness and sustainability in the introduction of digital applications and as well as in the replacement of analogue solutions.
- Drive and actively shape EU-wide harmonisation of legal and technical provisions in relation to digitalisation of the health and care system (e.g. the EHDS, eIDAS/ Digital Identity).
- Promote and support competent development and expansion of harmonised digital infrastructures in the various areas of healthcare.
- Monitor the impact of legal and regulatory measures on the user-friendliness of digital applications and reduce bureaucratic obastcales.



5. Governance, Stakeholders, Responsibilities and Roles

As part of the digital transformation, existing responsibilities and roles in health and care will need to change. Some will be expanded or become more focused, while others will disappear and new ones will emerge.

For example, patients and those in need of long-term care can collect vital data themselves, regardless of time and place, and specialised telemedicine providers can make diagnoses and issue electronic prescriptions. Such developments have an impact on how the stakeholders involved see their purpose and roles. In some cases, this may result in the need to evolve existing professional profiles and develop new ones – a process that must include dialogue with the stakeholders involved.

Digitalisation is also giving rise to new models of stakeholder collaboration, such as via platforms and portals, in ecosystems and collaborative approaches. These developments will be closely monitored, and those that prove useful, such as the creation of ecosystems, will be encouraged and enabled.

In monitoring and managing both implementation and continuous development and enhancement of the Digitalisation Strategy, transparent processes must be defined which include clear responsibilities and roles.

The role of the Federal Ministry of Health is to assume responsibility for the Strategy's further development, to measure and evaluate progress, and derive concrete measures from the results. The areas of responsibility for the definition, integration and ensuring broad use of uniform technical and semantic standards will be described in such a way as to enable the emergence and use of digitally assisted healthcare solutions in the form of a cohesive, networked healthcare landscape.

The autonomy of the planned Digital Health Agency will be strengthened by means of a completely new governance approach.

The Agency is responsible for designing technical aspects in the establishment of end-to-end processes. It creates transparent, efficient, clear processes – such as for use in drawing up specifications. The Agency is also responsible for establishing strict approval procedures in relation to TI applications and will have a mandate to define comprehensive, binding interoperability requirements, and centrally certify their implementation. The Digital Health Agency will also have operational responsibility in the context of the Digitalisation Strategy's continuous development and enhancement.

The design of specific applications around the TI is carried out in compliance with prevailing competitive market standards and requirements, usually between providers in the private sector. End users will be continuously and systematically involved in the evaluation and adaptation of the respective applications as well as in implementation projects.

Actual implementation of measures contained in a dedicated implementation plan which is to be developed as needed will be conducted wherever possible by individual system stakeholders or in collaboration with several stakeholders involved in or affected by the respective topic and where the goal of overarching interoperability does not prevent it.

5. The Transformation Approach

89% (N=450)

For 89 percent of respondents in the online survey, the topic of **"satisfaction and acceptance"** was seen as important.

The digital transformation of health and care is both a top priority and urgently needed. This makes its structured, phased, but ambitious implementation and further development essential.

The objectives set out in the earlier sections will thus be transferred to an implementation plan, which will be regularly evaluated and adapted as needed. In the Strategy's execution, state institutions, healthcare providers, health and long-term insurance funds as well as other cost carriers and private companies will assume their respective responsibilities and roles in a targeted, solution-oriented approach.

Digitalisation of the health and care system system also gives rise to ethical issues, not least those around dignity, autonomy and self-determination of insurance holders. This calls for social discourse on the question of how health and care data and digital innovations should be used in a legally sound, ethically justified way for the common good. Focusing on human welfare as the ultimate benchmark, the various issues involved must be in constant balance.

The ethical debate must not focus solely on possible risks. Rather, it must be conducted as an open-ended deliberation that also includes in the questions of which digitalisation measures might be ethically necessary because their omission could endanger people's health and lives in the short or longer term. The Digitalisation Strategy is therefore intended as a basis for this debate.

In order to prepare for important decisions, make responsibilities and roles transparent, and ensure acceptance for the transformation, patients, people in need of long-term care, family members, service providers, the science community, the industrial healthcare economy, health and long-term insurance funds and other cost carriers must work constructively together – for example in evaluating, further developing and finalising measures, and in developing viable funding models for necessary initial investment and to cover operational costs. To facilitate collaboration, an ongoing format with working groups will be initiated. To implement the Strategy, the working groups will identify potential for improvement in associated processes and technical conditions, and develop fitting solutions and approaches.

In the participative process used in the Strategy's development, the importance of satisfaction and acceptance among all stakeholders and not least among end users has emerged as a key success factor in achieving the digital transformation. Satisfaction and acceptance can only be promoted if measurable improvements in line with Strategy goals and objectives are achieved and added value can be experienced in a timely manner –through target group-specific communication and interaction in the field as well as broad-based integration into everyday practice. All implementation phases must therefore be accompanied by a corresponding communications plan. Above all, this should explain the advantages of digitalisation and the opportunities for self-determined use.

Organisations such as health and long-term care insurance funds and other cost carriers, healthcare providers and patient interest groups, people in need of long-term care and self-help groups assume an informational and navigational function for their members. Participatory approaches such as living labs, model regions and pilot projects can provide end users with low-threshold access to applications so they can test and try them out. This is where planning security for stakeholders is essential. Binding deadlines are therefore to be set for trials of new technologies, applications and processes via field tests, with realistic implementation phases.

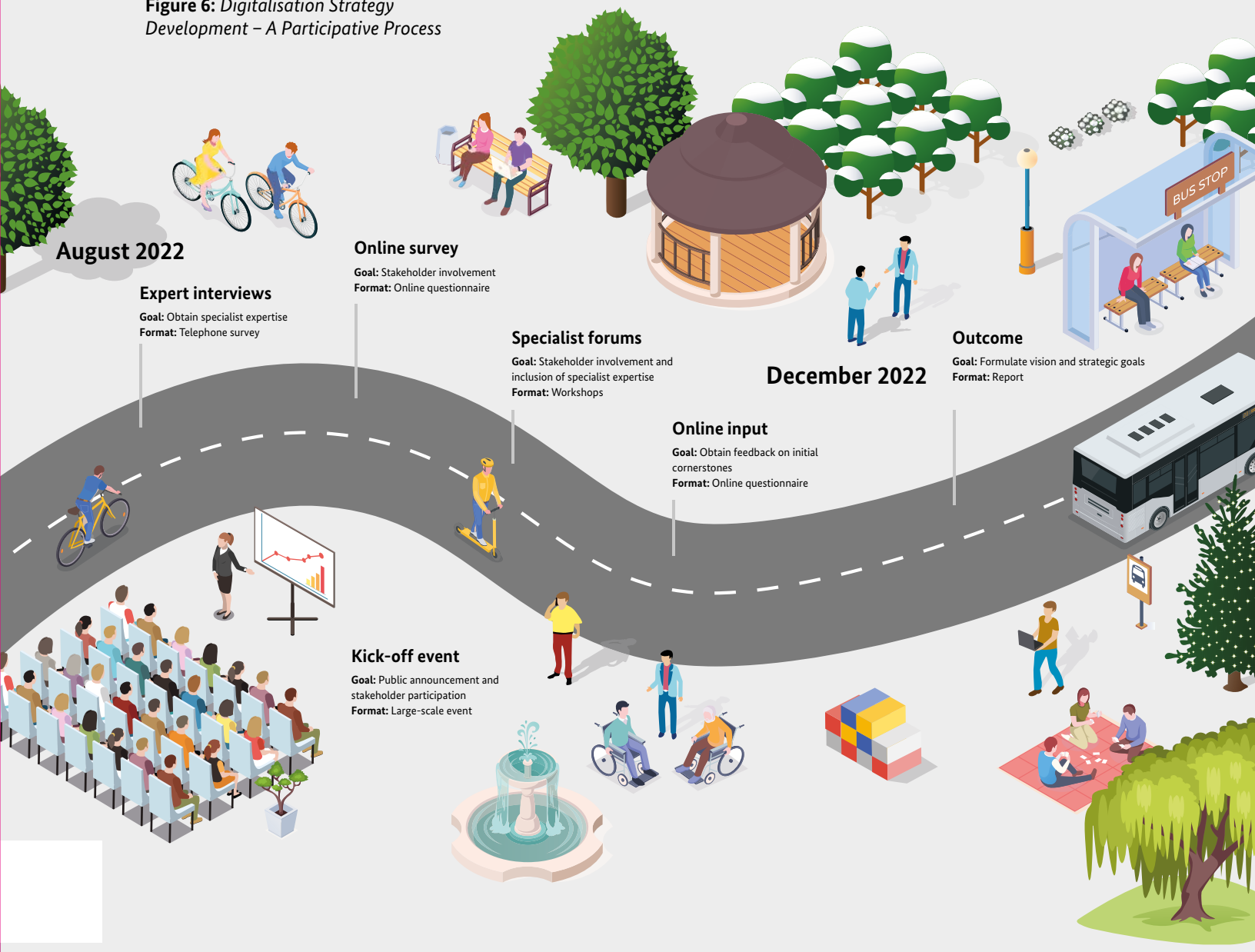
The Digitalisation Strategy initially defines short-term, medium-term and long-term measures to be implemented in the fields of action of processes, data use, technologies and applications. The basis for implementation is formed by the associated implementation plans. Each field of action

is assigned a timeline, aim, responsibilities and roles. The successes achieved in the course of implementation will be evaluated as part of an ongoing process using suitable instruments, such as measuring the degree of digital maturity, and – where appropriate – backed up by KPIs. Based on regular reports from the working groups as well as national and international policy, technology and social developments, the Strategy will be reviewed at two-year intervals and, if needed, further developed and enhanced in a participative process.

Learning from other countries
Canada's Drug and Health Technology Agency (CADTH), a non-profit organisation, procvides objective data Canadian decision-makers in the healthcare system. In doing so, it considers the view of citizens in a variety of ways and involves them in healthcare decision-making. For example, civil society is represented in bodies such as administrative councils, committees, and annual consultative meetings, and is involved in dialogue with the industry. CADTH also involves civil society in the evaluation of publicly funded healthcare technologies to ensure both the relevance and the quality of the technologies in question.

Discussion in the specialist forum "Satisfaction and Acceptance among Insurance Holders"
Support for family carers will be enabled by an optimal mix of digital and analogue programmes. Courses on caregiving skills, but also on improving personal well-being, including relaxation techniques, are offered via an online platform. Appropriate DiGAs and DiPAs are made available through the platform. In addition, information on personal services and support groups is provided.

Figure 6: *Digitalisation Strategy Development – A Participative Process*



DIGITALISATION STRATEGY DEVELOPMENT – A PARTICIPATIVE PROCESS

The Digitalisation Strategy for Health and Care was developed with the broad involvement of relevant stakeholders from health and care, notably patients, representatives of people in need of long-term care, family members, the science community, the industrial healthcare economy, the public health service, health and long-term care insurance funds and other cost carriers, and healthcare providers. The public announcement for this participative process was made in September 2022 with a kick-off event in Berlin, which was attended by Federal Minister of Health Karl Lauterbach. In parallel, intensive background talks were held with experts from healthcare and from the worlds of healthcare policy, science and research, industry, and patient representation. Stakeholders from the health and care system also had the opportunity to input their views and expertise in a publicly accessible online survey. The outcomes from the kick-off event, expert interviews and online survey were further explored in eight topic-related specialist forums attended by insurance holders and topic-related experts from healthcare practice. After consolidating the results, a second online stakeholder input process was conducted in which participants from the various participative formats were again able to provide feedback.

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LIST OF ABBREVIATIONS

AI	Artificial Intelligence
BMG	Federal Ministry of Health
DiGA	Digital Healthcare Application
DiPA	Digital long-term care application
DMP	Disease Management Programme
EHDS	European Health Data Space
eIDAS	Regulation on Electronic Identification and Trust Services
eMP	Electronic Medication Plan
ePA	Electronic Patient Record
FAIR	Findable, Accessible, Interoperable and Reusable
FDZ	Health Data Lab (FDZ Health)
IT	Information Technology
MIO	Medical Information Object
PHS	Public Health Service
SGB	German Social Code
TI	Telematics Infrastructure
UX	User Experience

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