Whether in prevention, early diagnosis or selecting the ideal treatment, Artificial Intelligence (AI) and Machine Learning (ML) could soon be playing a big part in ensuring that people receive better and more personalised medical care. There is a whole variety of ways that self-learning systems could be put to use in the medical practices and hospitals of the future. For instance, doctors could use AI systems across the board to help them evaluate imaging procedures, thereby obtaining more accurate diagnoses. By using networked data, self-learning systems could derive proposals for suitable preventive approaches or treatments, thus helping medics and patients make important decisions.

Collaboration between humans and machines also has a great deal of potential in the care sector. For example, AI-supported voice recognition systems could help care workers with routine tasks such as completing documentation, thus freeing them up to spend more time with people in their care. Assistance robots and AI-based technologies such as exoskeletons, meanwhile, could in future make it possible for people to live independently well into their old age.

It is not just the sick who can benefit from medical AI applications, as smartphone apps and wearables can enable people to record and evaluate their own health data, whether they are ill or not. This gives people the opportunity to make their day-to-day life more healthy or identify symptoms of illness early on. AI offers huge potential, particularly when it comes to the prevention and early detection of illnesses. The focus is shifting from cure to prevention.

The aim of AI applications across all healthcare sectors is to unburden medical and care staff and give them the best possible support. All the technological achievements are centred firmly on the benefits for patients and people in need of care.
EXECUTIVE SUMMARY

To ensure self-learning systems in the healthcare system are reliable, safe and will work entirely in the interest of people – and to harness their full economic potential at the same time – certain prerequisites and parameters need to be put in place. Representatives from science, business, hospitals, social businesses, and patient representative organisations have come together in the working group Health Care, Medical Technology, Care of Plattform Lernende Systeme to discuss the opportunities and challenges of self-learning systems in health care. Their work is funded for a further three years. As an initial interim outcome, the working group is formulating recommendations for action within the following fields:

Health data

- Make the personal health data of insured persons, healthcare providers and cost carriers in standard care continuously usable for machine learning.
- Share data from all healthcare sectors.
- Make existing stores of data visible, open them up, assess their usability and network them. Examples include publicly recorded data from the cancer and heart valve register, study results, hygiene data, etc.
- Establish a representative, structured and controlled health database that could be organised in a Centre for Digital Health Data or Digital Health Institute, as is the case in neighbouring European countries.
- Give German and European research institutions and companies equality of access to anonymised health data to ensure individual companies cannot establish monopolies.
- Store and train health data in localised architectures as far as possible, so as to improve security and data protection and thus guarantee the protection requirements of healthy and sick people alike.
- Develop options for a legal and technical framework for the voluntary and secure donation of data (including the data custodian model).
- Make compliance with the requirements of the General Data Protection Regulation (GDPR) – which is strict by international standards – an advantage in global competition.

Build up expertise in medical training and in care provision

- Integrate AI into the training of medical and care personnel, such as expanding study courses and training programmes on digital health.
- Reinforce further training in AI and statistical processes for medical and healthcare purposes so that personnel understand the individual applications and can put them to optimum use.
- Train medics, nurses and care staff for their new roles regarding patients, e.g. communicating AI-supported diagnoses and treatment recommendations.
- Create information and training offerings for patients.

Bring innovations to patients

- Pave the way for AI innovations in the healthcare system with outstanding research and drive forward lighthouse projects and pioneering use cases. Utilise structural and project funding instruments that extend beyond purely basic research to roll out AI projects in medical practice.
Specify a clear process for clinical studies to assess AI-based medical products. Legislators, notified bodies and the industry are to work together to develop processes for clinical studies that reliably review the security and benefits of AI applications.

Design a process for approving AI-based medical technology that takes account of the specific challenges affecting a dynamic technology that changes as it learns. (For accessing the European market producers of medical devices must undergo a so-called conformity assessment procedure. For the purposes of readability, we refer to this process as approval.)

Finance health care in an innovation-friendly way so that AI innovations can be assessed and, if appropriate, adopted into standard care as quickly as possible based on clear criteria.

Investment in AI and digitalisation must not mean funding cuts in other important areas of the healthcare system.

Design a clear legal liability framework that gives medical and care personnel legal certainty.

**Ethical issues**

- Guarantee the data sovereignty of all parties. Defined rules for anonymisation, pseudonymisation, the right not to know and an opt-out option all play a key role.
- Carefully weigh up medical benefits against the protection of personal rights when establishing the legal framework.
- Put in place the prerequisites to ensure the decisions made by AI-based systems and the background assumptions can be traced by all users.
- Reflect on and discuss the consequences of AI for society’s understanding of health, illness and the concept of humanity.
- Conduct a clear, honest and evidence-based discussion of the opportunities and risks associated with AI in the healthcare system that gives all stakeholders the scope to contribute their ideas, interests and concerns.
- Work in ethics committees at institutional and national levels to develop standards for AI-based human-machine interactions in the healthcare system.