acatech POSITION PAPER
Executive Summary and Recommendations

Machine Learning in Medical Technology

Analysis and Recommendations

acatech (Ed.)

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There is consensus among experts, that – as in other areas – machine learning is going to play a very important role in the fields of medicine and medical technology, with the promise of significant benefits for human health. Medical technology companies also stand to gain, since machine learning will allow them to offer better products on the global market, helping them to maintain or even enhance an already strong position. On the other hand, it is also important to recognise the risks associated with the indiscriminate use of machine learning in medical technology. The most frequently asked questions include the following: Does this mean I am going to be treated by computers? Do these systems make errors? Can a doctor intervene at any time? Who makes the final diagnosis and treatment decisions? Are my medical records really protected against unauthorised access?

This acatech POSITION PAPER aims to provide an overview of current and future machine learning applications in the field of medical technology, highlighting a number of key fields of application. It also considers the ethical, legal and regulatory dimensions, asks critical questions about data protection, discusses potential changes in the doctor-patient relationship and makes recommendations concerning the establishment of large medical databases.

The position paper's key recommendations can be summarised as follows:

- Machine learning in the field of medicine will support physicians, but will not replace them. Diagnoses should still be communicated and explained during a personal consultation with a doctor, and human doctors should continue to make the final diagnosis and treatment decisions.

At a glance

Machine learning involves extracting knowledge from large data sets so that it can be processed by algorithms and used to make concrete predictions or inform decision-making processes. Machine learning should aim to complement human thought processes, not mimic them.

Healthcare technology includes both conventional medical products as defined by the EU Medical Device Regulation and consumer products and apps. The healthcare technology sector has particularly high hopes that machine learning can be used to support better and cost-effective disease prevention and healthcare. It is therefore important for Germany to develop first-class expertise in this area.

However, the healthcare technology sector is also highly sensitive from a legal, social and ethical perspective. Thus, machine learning systems must not cause any damage to patients, and the personal relationship between doctor and patient must not be compromised. It is also particularly important to ensure that the appropriate data protection measures are in place.

This POSITION PAPER provides an overview of current and future machine learning applications in the field of medical technology. It categorises the applications of machine learning and assesses them from an ethical, regulatory and legal perspective. It also discusses potential changes in the doctor-patient relationship and asks critical questions about data protection and data security.

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- There may be a handful of exceptions, for instance emergencies, where the situation requires immediate intervention by the machine learning system. It is also possible to conceive of systems that continuously adapt to the patient. Provided that the appropriate safety and security measures are in place, this opens up the prospect of autonomous, continuously learning medical technology systems.
- Wherever possible, machine learning systems used for medical purposes should make explainable why they have reached a particular conclusion and provide confidence limits for its accuracy.
- Research funding for machine learning in the field of medicine is already rated as "good". However, further work is required in areas such as transparency, accuracy, evaluation and clinical applications.
- Personal data protection must be guaranted in accordance with the relevant legislation, in particular the Federal Data Protection Act (BDSG) and the General Data Protection Regulation (GDPR), with special consideration for the possibilities of data protection by design and by default.
- Solutions are required for the creation of large medical databases for research and development purposes. The authors recommend the establishment of a centre for digital medical data.
- More research is needed into how the principles of medical liability and producer liability apply to machine learning systems used for medical purposes. Legal certainty will be indispensable to the introduction of machine learning in the field of medicine.

Methodology

This acatech POSITION PAPER is the product of one year's work by the project group. acatech's "Healthcare Technologies" topic network carried out its work in close coordination with the "Plattform Lernende Systeme", which is also based at acatech. The project group comprised 17 experts from science and industry. A comprehensive review of the literature provided the basis for an expert workshop, the results of which were analysed and discussed by the project group, informing its recommendations. The POSITION PAPER was reviewed by three independent experts and authorised by acatech's Executive Board. The project was funded by the acatech Förderverein.

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