Lernende Systeme

GERMANY'S PLATFORM FOR ARTIFICIAL INTELLIGENCE

Business models for AI in healthcare

White Paper

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Executive Summary

Whether in nursing, rehabilitation or outpatient medical care, artificial intelligence (AI) promises enormous potential to improve healthcare. New types of innovation processes and innovative business models are needed to enable patients to benefit from this potential. This involves overcoming technical, ethical, regulatory and economic challenges. Economically viable business models help to bring AI-based innovations to the breadth of the healthcare system and to accelerate the digitization necessary for this.

Experts from the working group Health Care, Medical Technology, Care and from the working group Business Model Innovations of Plattform Lernende Systeme provide an overview of how AI-based business models can be successfully implemented in the healthcare sector in Germany. The focus will be on opportunities, challenges, and the regulatory framework in Germany.

AI as an opportunity for healthcare companies

When analyzing the opportunities of AI applications for healthcare companies, it is important to keep in mind that the medical technology industry in Germany is strongly characterized by small and medium-sized enterprises. However, especially for many small and medium-sized enterprises (SMEs) and startups, the financing and approval of AI medical devices in healthcare poses major challenges. Specific challenges include the lack of suitable training data, data security issues, lack of AI expertise, lack of confidence in AI

technologies, or the unclear prospect of reimbursement. Pre-financing through the hope of increasing market share also appears risky in some cases. This is especially true for comparatively small companies, as the AI economy is a platform economy dominated by large hyperscalers. For the long-term success of AI-based business models, the prospect of new technology reimbursement as well as specialized funding programs would be helpful.

Nevertheless, AI-based business models offer great potential in both the primary and secondary healthcare markets. The secondary healthcare market is becoming increasingly relevant, which has great potential with meaningful, high-quality AI applications in terms of monetization as well as for personal health and health maintenance. Promising applications for new AI business models for healthcare companies in the secondary healthcare market include personal AI-based health applications such as the evaluation of wearables as well as applications in the field of care and rehabilitation. For healthcare companies, AI applications also offer the opportunity to expand their business models by optimizing existing and developing novel offerings with AI.

AI healthcare applications are based on technologically (complex) AI models and often apply training procedures using numerous clinical data. This costly process must be refinanced via revenue models. The following two revenue models are particularly worthy of mention:

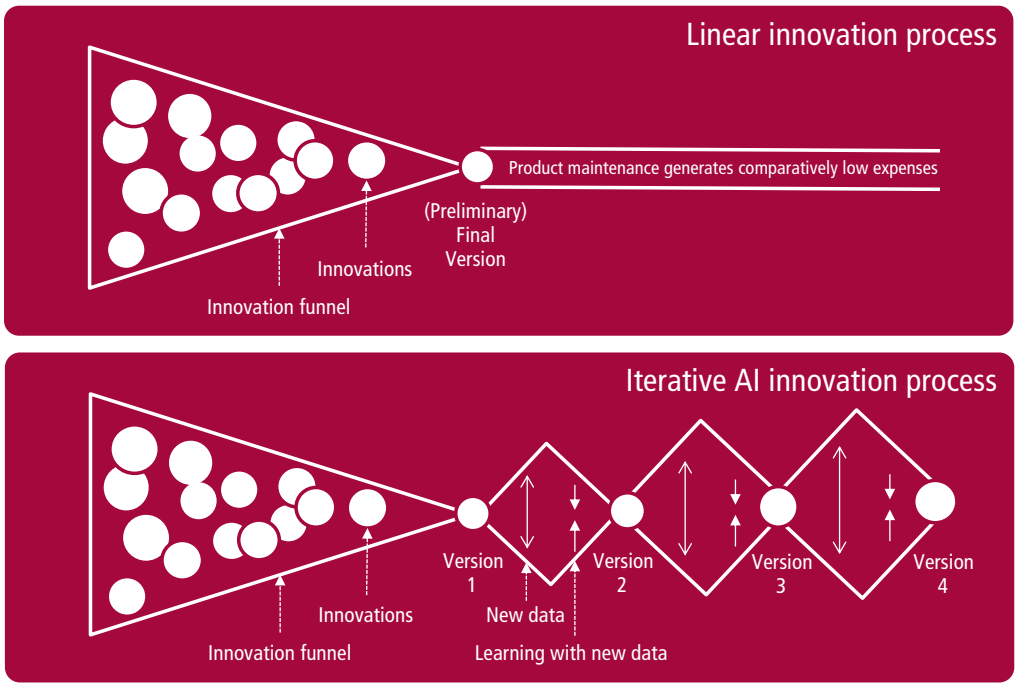
- **Same revenue model for AI-based improvement of an existing offering:** There are applications that can improve, facilitate, and automate an existing offering with AI. AI enhances work and process steps but does not fundamentally change them. Typically, companies use such enhancements to differentiate their products. However, the existing business model – such as the sale of a capital good with maintenance and services – remains unchanged.

- **Opportunity of new revenue models for novel AI offerings:** The situation is different, for example, in the case of decision support systems (e.g., in the pre-classification of radiological image data): Here, the use of AI enables a novel service. To monetize this, different business models can be examined – away from the licensing business with one-off payments to the „software-as-a-service" business, rental model, or usage-dependent payments. At first glance, this benefits the providers of such solutions, because they can forecast revenue much more precisely based on their user numbers over a longer period of time. Users also benefit from such service offerings through reduced costs for the maintenance and configuration of the software, for example through the automatic provision and updating of the service via the internet or cloud applications. In addition, the expenses for the services, which replace high one-off financing, are spread over the entire term. Very often, the business models are also supplemented by continuous product maintenance and included services such as protection against cyber-attacks and data loss. In this way, customers can also insist on continuous high quality since they are paying continuously.

AI-specific innovation problems: The causality dilemma

One AI-specific innovation problem is the so-called causality dilemma: The quality of the result depends strongly on the quality and the number of data sets, so that the benefit can often only be proven in the long term. Since the proof of benefit is costly, many companies cannot afford the considerable validation effort. To provide an economic incentive, temporary cost coverage should be discussed until the benefit has been proven. Based on the experience of innovation funding for medical technology and pharmaceuticals, the new German regulation on low-risk *Digital Health Applications* (Digitale Gesundheitsanwendungen, DiGA) can serve as a temporary reimbursement option as a model to bridge the time from potential recognition to reliable proof of benefit.

Linear innovation process and iterative AI innovation process



Field of action: Reimbursement and funding

Based on the evaluation of the pathways to reimbursement by the health insurance, it should be discussed whether the existing conditions are already sufficiently tailored to AI-based innovations. Short innovation cycles, the large heterogeneity of applications, and the potential changeability of functionality are just some of the features. It is also unclear whether the existing evaluation processes sufficiently consider the potential of AI. Based on the problem of the causality dilemma, it is apparent that the quality of the technology may increase with more data and training, and thus at the beginning of development the actual benefits may not yet be sufficiently demonstrable. Digital health applications (DiGA) already address this issue for low-risk applications with a trial period of one year when the potential

benefit is recognized, this could also be extended for high-risk class digital medical devices. The secondary healthcare market also offers a lot of potential. Nevertheless, AI-based examination and treatment methods for which the benefit, medical necessity and economic viability have been proven should be integrated into the primary healthcare market. Only in this way all citizens can benefit from holistic, personalized, patient-centered healthcare. This close link between the primary and secondary healthcare markets requires, among other things, a high level of quality assurance in the secondary healthcare market as well.

Field of action: Data

The availability of data, especially training and validation data for AI, is one of the key prerequisites for successful AI business models in healthcare. Much progress has been made in this field of action in recent years, among other things, treatment data are being made usable for research with the help of coordinated patient consents, and possibilities for intersectoral data exchange are being tested. Within the framework of GAIA-X, a European federated data infrastructure is being created in which health data can be evaluated securely and for distributed AI applications across countries in the future. These secure and interoperable possibilities for data storage and data use not only create advantages for individual treatment and patient sovereignty. They also enable new applications at the population level, for example in epidemiological questions.

Field of action: Startup funding and secondary healthcare market

Despite some successful examples of German AI health startups, it is apparent that the funding sums generated in Germany are rather low in international comparison. In this context, among other things, the high investment sums and long waiting times present themselves as challenges for SMEs and startups: In the case of digital business models, a lot of money often must be invested in order to build up and establish platforms. This can be particularly difficult for startups or SMEs. Therefore, from a European and German perspective, ways should be found to bring AI into the mainstream and make it financeable. The main issue here is to create regulatory framework conditions that make it easier to participate in AI health startups with venture capital/corporate venture capital. It would be important, for example, to make it easier for large institutional investors to invest in startups.

Field of action: Innovation and value creation networks

As in other application fields of digital transformation, the aspect of networking is also of central importance for the healthcare sector. A major added value of digitization in the healthcare sector could be the large number of data points from different sources (multiple devices, different employees, different processes in a value chain), which can be related to each other and thus become the base for a higher level of knowledge. In addition, health status data of a person (holistically or partially) are particularly relevant in the healthcare sector. They can form the base for a digital health twin of a person, which, enriched with information on nutrition, activities, stress, etc., can also enable a simulation of the future state.

Field of action: Certification and liability

When AI is certified as a medical device or diagnostic procedure, it is currently done as standalone software or primarily as part of an overall product. For a medical device to be introduced to the EU market, it must be regulated uniformly throughout the EU, which requires a conformity assessment procedure to prove defined safety, quality, and performance requirements. Depending on the risk class, the respective conformity procedure and the involvement of a notified body differ to independently test and certify the medical device.

The European Commission's White Paper on AI points out the danger of unclear regulations on risks, which can lead to legal uncertainty for companies and ultimately reduce their competitiveness. Similarly, users, doctors and patients should not bear the entire risk. For a trained AI system that does not continue to learn during use, there is no significant difference in liability from medical devices.

Liability issues could arise in the more distant future with AI systems that continue to learn. This raises the question of whether the liability system needs to be adapted, at least for AI technologies of high-risk classes. Liability for AI systems in healthcare should therefore clearly consider the special characteristics of AI systems, such as errors in the algorithms, or that AI systems can learn based on trial and error or mistakes.

Field of action: Digital ethics and patient perspective

For these AI technologies to establish themselves on the market, acceptance by patients and users is necessary. Important foundations for creating the trust that is essential for the acceptance of AI in healthcare are the establishment of digital ethical principles and their consideration in the development and application of new digital healthcare solutions, as well as the consideration of the patient perspective along the entire digital value chain. This applies to applications that directly affect patients or are used by them. Trust must be promoted and maintained by all players in the healthcare sector, including private-sector market participants. Only in this way there can be long-term acceptance (and success) of these innovations. Trust arises when the technically feasible is measured against legal and ethical standards. This can be achieved through standards, guidelines or "seals of approval", but above all through proven, transparent action. Players in the healthcare sector should proactively and openly commit to taking these principles into account to promote acceptance of and trust in AI-based innovations. To maintain this trust, AI-based business models must always and first be evaluated against the background of the medical benefit as well as against general ethical and social criteria.

Imprint
Editor: Lernende Systeme – Germany's Platform for Artificial Intelligence | Managing Office | c/o acatech | Karolinenplatz 4 | D-80333 München | kontakt@plattform-lernende-systeme.de | www.plattform-lernende-systeme.de | Follow us on Twitter: @LernendeSysteme | Status: April 2022 | Photo credit: Framestock/Adobe Stock/Title.

This executive summary is based on the white paper *KI-Geschäftsmodelle für die Gesundheit: Innovation stärken, Finanzierung gestalten*, Munich, 2022. The authors are members of the working group Business Model Innovations and of the working group Health Care, Medical Technology, Care of Plattform Lernende Systeme.
https://doi.org/10.48669/pls_2022-3

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