



FUSE-AI



HISTORY OF FUSE-AI

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FUSE-AI ON THE TOPIC OF „ARTIFICIAL INTELLIGENCE IN MEDICINE“ AT SAFER INTERNET DAY 2018



06.02.2018 FUSE-AI participated in Safer Internet Day 2018 with a contribution on the topic of „Artificial Intelligence in Medicine“.

Applications based on artificial intelligence are becoming more and more important in everyday consumer life. On the occasion of Safer Internet Day 2018, the Federal Ministry of Justice and Consumer Protection (BMJV) and the digital association Bitkom e.V. organised the conference „Artificial Intelligence - Your Friend and Helper?“ The event dealt with opportunities and risks of AI technologies and took place on 6 February 2018 at the capital representative office of Deutsche Telekom.

Gerd Billen, State Secretary in the Federal Ministry of Justice and for Consumer Protection:

„Artificial intelligence (AI) has long been part of the social debate. No contribution, no conference without mentioning its two faces: opportunity and risk. As the Federal Government, we are open to this technology. Instead of putting the brakes on, we want to promote and understand it. It is our task to consider the effects on people from the very first step. Is there a need for digital ethics? Is research made transparent? What about liability issues?“

Achim Berg, Bitkom President:

„Artificial intelligence is the key digital technology par excellence. Germany is one of the strongest locations worldwide in this field and must maintain and expand this good position. The majority of people in Germany are convinced that artificial intelligence is an important factor for the future viability of our country.“

The event also discussed the majority of the population’s openness to the use of artificial intelligence: almost 70 % would rely on artificial intelligence in their decisions.



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FUSE-AI PARTICIPATES IN DEVELOPMENT OF DIN SPEC PAS 13266

Guideline for the development of Deep Learning Image Recognition Systems

„Standards are developed by those who apply them later“. (DIN)

24.06.2019 The aim of a DIN SPEC is to bring standards that develop during a research process to the market. The DIN SPEC is considered a „precursor“ to a DIN standard. **Companies from a specific field have the chance to help develop these standards or guidelines.** The input from different entities creates the opportunity to comprehensively outline a topic and, as a result, enables a high quality of the standard.

To develop the content, at least three companies are brought in to work together on the DIN SPEC. FUSE-AI is developing a new DIN SPEC together with MindPeak and Psiori. This is PAS 13266, a „Guideline for the development of deep learning image recognition systems“. This guideline is intended to create the possibility of being able **to apply and develop image recognition systems from the field of Deep Learning more easily and in a standardised way.**

The kick-off meeting took place on 24 June 2019 in Berlin - with the aim of gathering the most important content for the guideline. In the upcoming work phase, the guide will be developed by FUSE-AI, MindPeak and Psiori. This second phase will take several months due to the amount of work involved. After approval by the consortium, publication of the DIN SPEC PAS is planned for the beginning of 2020.

What is the aim of DIN SPEC PAS 13266?

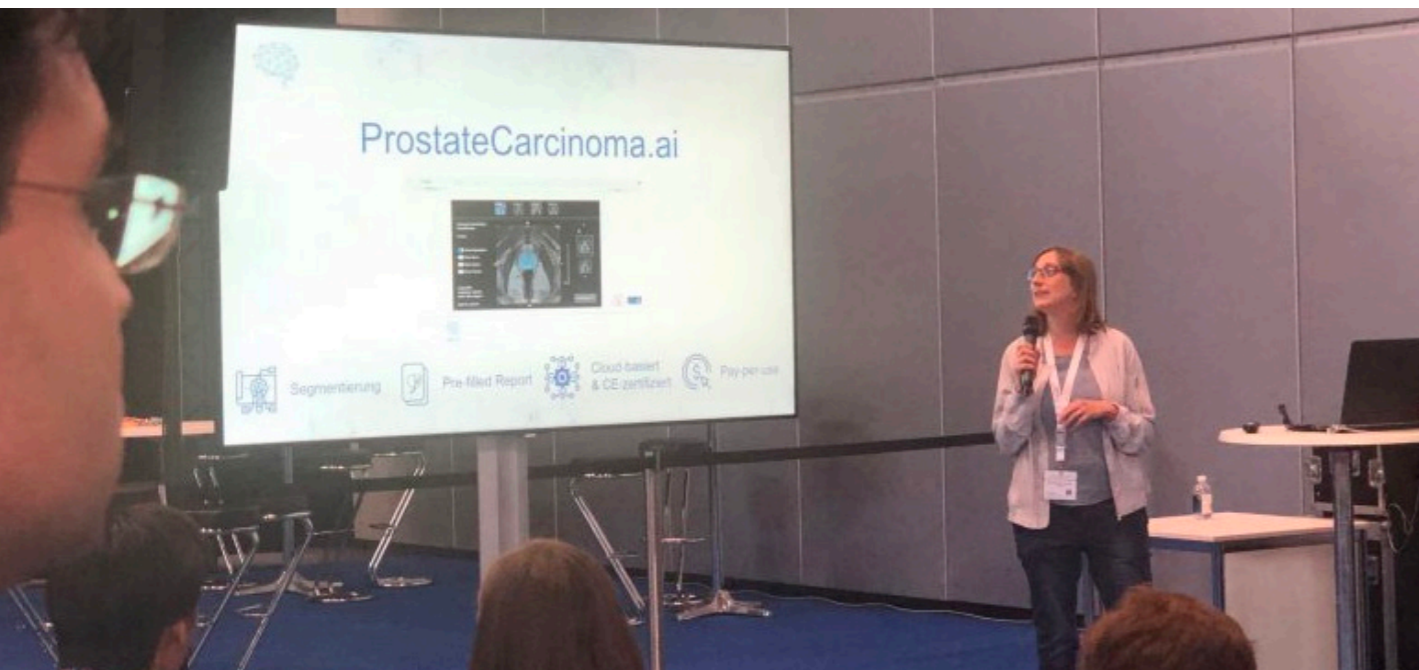
There are a number of sources of error in image recognition that can be compensated for by deep learning systems. The guide is intended to provide assistance with regard to these problems and makes it possible to inform decision-makers about the various possible applications. It not only applies to the decision-makers of the systems mentioned, but is also intended to support the developers of these systems. Furthermore, the guideline provides conclusions about the estimated effort and benefit of a deep learning system. This makes it possible to make more targeted predictions of success.

Consequently, this document is particularly relevant for the implementation of a deep learning system in practice. Last but not least, quality assurance as well as the structuring of data collection and processing are essential components of the guideline.



PROSTATE CARCINOMAS DETECT MORE RELIABLY WITH KI

FUSE-AI and RADPRAX train
new algorithm



03.07.2019 Radiology 4.0 is a reality, as the German Congress of Radiology in Leipzig showed. Everyday life has been digital for a long time and artificial intelligence (AI) processes are increasingly finding their way into German clinics and practices. The reason is simple: **with AI, better diagnoses can be made in less time.**

„Our discussions at the RöKo showed that radiologists are also becoming more willing to provide anonymised data for training algorithms. This is the prerequisite for the development of AI procedures.“ Matthias Steffen, co-founder of FUSE-AI, is pleased.

The first solution of the Hamburg-based start-up is an **assistance system for the diagnosis of prostate cancer** based on a multi-parameter MRI. Its analysis is particularly time-consuming. The number of MRIs has increased by 23 per cent since 2005, but the number of radiologists has only increased by six per cent. In addition, tens of thousands of Germans are incorrectly diagnosed with prostate cancer every year. „These figures make it clear that AI can effectively improve diagnostics here,“ says Steffen.

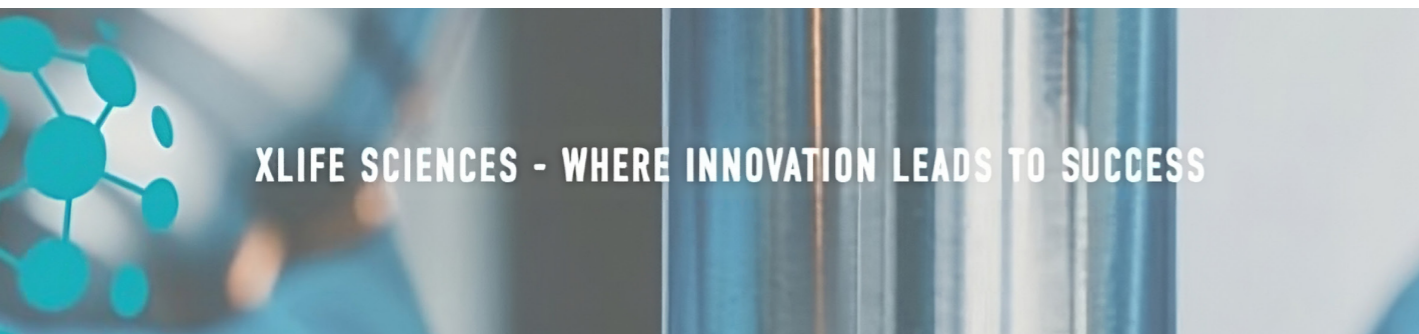
ProstateCarcinoma.ai is a Deep Learning-based solution that marks suspicious areas of the prostate, that are most likely to show malignant tumours and thus improves cancer detection. It involves gradually segmenting the prostate, the individual regions and the lesions in the MRI image and then generating an automated report as a decision support tool.

FUSE-AI is working on the development of the prototype until the end of this year. The finished algorithm will be offered on a pay-per-use or subscription basis and is expected to be available in the first quarter of 2021. **„ProstateCarcinoma.ai will be the first CE-certified, Deep Learning-based software for the detection of prostate cancer on the German market.** A data transfer with DICOM email ensures that the software can be seamlessly integrated into workflows of healthcare institutions,“ explains Dr. Sabrina Reimers-Kipping, Head of Medical Advisory at FUSE-AI.

Currently, FUSE-AI is training the algorithm together with radprax, one of the largest alliances of medical care centres (MVZ) and practices for radiology, nuclear medicine, cardiology and radiotherapy in North Rhine-Westphalia. „Our radiologists perform around 600 to 700 multiparametric prostate MRIs every year,“ says Dr. Heiner Steffens, managing partner of radprax. „With the new solution that is now to be developed, we primarily want to support and relieve our doctors in the reporting of prostate carcinomas. Patients can hope for a more reliable diagnosis in which, on the one hand, less aggressive tumours are overlooked and, on the other hand, unnecessary procedures are avoided.“

SWISS INVESTOR TAKES A STAKE IN FUSE-AI

Xlife Sciences AG invests in
in Hamburg start-up



02.10.2019 Good news at the seed stage - Swiss company Xlife Sciences is investing in AI start-up FUSE-AI. „We are thrilled to have just met with this investor,“ said **Matthias Steffen**, co-founder and CEO of FUSE-AI. „As an experienced early-stage investor in the life sciences sector, Xlife Sciences can offer us not only capital, but above all strategic added value through a corresponding network.“

Oliver R. Baumann, CEO of the Zurich-based company, is also pleased: „We see a large growth market in innovative technologies such as AI. With FUSE-AI, we complement our portfolio of start-ups in an ideal way, because this puts us right at the interface between medicine, pharmaceuticals and artificial intelligence.“

FUSE-AI was exclusively advised by Hamburg Commercial Bank during the capital raising process. „We are convinced that with Xlife Sciences we have found exactly the right partner for FUSE-AI at this stage,“ says Dr. Roland Schulz, Executive Director in the Mergers & Acquisitions division.

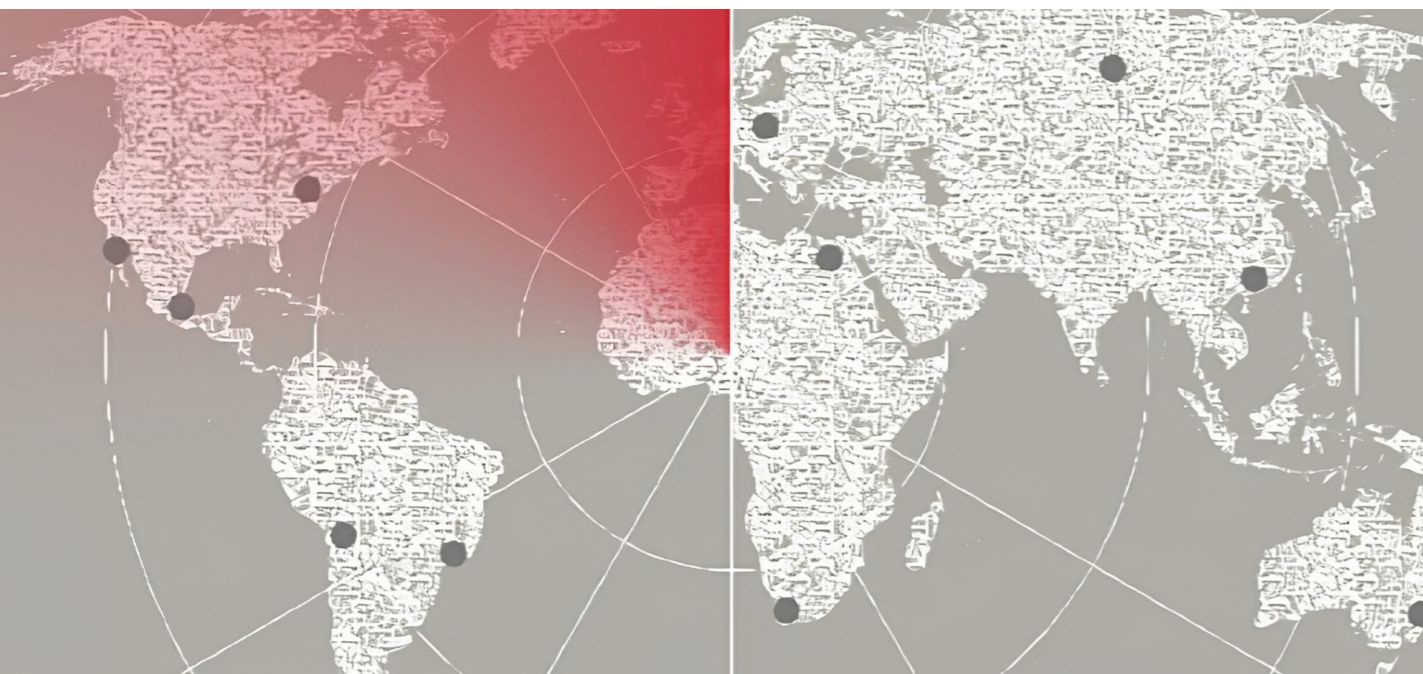
FUSE-AI develops the assistance system ProstateCarcinoma.ai for the diagnosis of prostate cancer on the basis of annotated MRI data sets. The analysis of this MRI is particularly time-consuming for the radiologist. However, while the number of MRIs has increased by 23 per cent since 2005, the number of radiologists has only increased by six per cent. In addition, tens of thousands of Germans are incorrectly diagnosed with prostate cancer on the basis of the image material every year. The use of artificial intelligence can support radiologists in making diagnoses and relieve them of time-consuming tasks.

ProstateCarcinoma.ai is a Deep Learning based solution. It is used to mark the suspicious areas of the prostate that are most likely to show malignant tumours. In the MRI image, the prostate, the individual regions and the lesions are segmented step by step and then an automated report is generated as a decision support. FUSE-AI is working on the development of the prototype until the end of this year. The finished algorithm will be offered on a pay-per-use or subscription basis and is expected to be available in the first half of 2020. „ProstateCarcinoma.ai will be the first CE-certified, Deep Learning-based software for the detection of prostate cancer on the German market. A data transfer with DICOM email ensures that the software can be seamlessly integrated into workflows of healthcare institutions,“ explains Dr. Sabrina Reimers-Kipping, Head of Medical Advisory at FUSE-AI. Currently, FUSE-AI is training the algorithm together with radprax, one of the largest medical care centres (MVZ) for radiology, nuclear medicine, cardiology and radiotherapy in North Rhine-Westphalia.

About FUSE-AI FUSE-AI has two main focuses: Medicine and IT. The guiding principle is to offer physicians a second opinion in diagnosis through the use of artificial intelligence in order to increase the medical quality of medical services. In addition, AI is applicable in numerous other areas. These include drug research, biomarker development, intelligent image recognition, genome analysis and morphometric representation in digital pathology, therapy support systems with healing prognosis, mobile apps for intelligent recording of vital data or the generation of research results from the analysis of annotated data from ethical biobanks. The FUSE-AI team works in an interdisciplinary manner and is staffed with biologists, physicians as well as IT developers and machine learning experts. Together, they design new approaches for optimising processes in the healthcare sector in accordance with German data protection guidelines. For more information, visit www.fuse-ai.de.

About Xlife Life Sciences AG Xlife Sciences AG is a Swiss company focusing on the value development of promising technologies in the life sciences sector. The company bridges the gap between research and development and the healthcare markets and supports researchers and entrepreneurs in positioning, structuring, developing and realising their concepts. Together with industrial partners or university institutions, the company takes projects through the proof of concept phase following an invention disclosure or spin-off. Subsequently, Xlife Sciences AG focuses on the out-licensing or sale of the company, sometimes in combination with a strategic partnership. The company enables its investors a very early and direct entry into the further development of innovative and future-oriented technologies. Further information at www.xlifesciences.ch

FUSE-AI SUCCESSFULLY COMPLETES AN INNOVATION MANAGEMENT ASSESSMENT



12.11.2019 We are proud of these results. The final report by Dr. Margarete Remmert-Riepert from **Tutech Innovation GmbH** shows that FUSE-AI is better positioned than the competition in terms of innovation strategy (defining and setting goals).

Another positive aspect was that suggestions from the idea boards are well documented so that good new ideas - despite a different focus - are not lost.

In this assessment, the founders set a timeframe and recorded in writing that FUSE-AI wants to become a full-range provider of AI solutions in the healthcare sector.

KANTONSSPITAL AARAU AND FUSE-AI AGREE ON COOPERATION



22.11.2019 We made our first contact with the Kantonsspital Aarau at the X-ray Congress 2019 in Leipzig. The congress president, Prof. Michael Forsting from the University Hospital Essen, had put the topic of **artificial intelligence in radiology** on the congress agenda as one of the most important topics of the next few years. Dr. Alexander Cornelius from the radiology department of the Kantonsspital Aarau was interested in getting to know the AI solutions of FUSE-AI at the congress.

The new AI-supported assistance systems are to be understood as support in diagnosis and will not replace radiologists. However, they help to reliably evaluate the ever-increasing number of MRIs. At the same time, this gives hospitals the opportunity to counter the growing shortage of specialists. With the AI-supported assistance systems, fewer radiologists can formulate more reliable findings in less time.

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MATTHIAS STEFFEN FROM FUSE-AI WAS APPOINTED TO THE TRANSFER COUNCIL OF KI SIGS



Photo: KI-SIGS

10.02.2020 **KI SIGS** - Space for Intelligent Health Systems - is a North German centre of excellence for artificial intelligence in medicine funded by the BMWi and led by UniTransfer-Klinik Lübeck. The aim is to develop a platform for intelligent health systems, such as medical systems, learning robotic assistance systems and smart living home assistants.

In the period from April 2020 to March 2023, the project will demonstrate in the model region of northern Germany how medical AI technologies can be better developed and brought into use more quickly. In addition to northern German AI institutes in Hamburg, Bremen and Schleswig-Holstein, medical technology companies and university hospital partners from the region are also involved in setting up the platform.

The Transfer Council advises the steering group of KI-SIGS on practical issues of transfer to the healthcare industry.

PROSTATE CANCER:

AI-based diagnostics in MRI.
FUSE-AI GmbH and
University Hospital Jena are developing
a cost-saving assistance system

29.04.2020 (Hamburg/Jena) According to the Robert Koch Institute, prostate cancer is the most common form of cancer diagnosed in men in Germany, accounting for around 25% of all cases. About 60,000 new cases of this tumour are diagnosed every year. The screening from the age of 45, which is covered by the health insurance funds, currently does not include MRI examinations - although these are gentler for the patient and have a great additional diagnostic benefit. The reason for this is the high technical and time expenditure of the cost-intensive procedure. However, in view of the frequency of the disease and the advantages of MRI imaging for diagnosis, the question arises as to whether and how the necessary capacities for a more extensive use of the procedure in the context of screening examinations can be created and financed.

FUSE-AI GmbH and the University Hospital Jena (UKJ) are therefore now launching a cooperation aimed at developing and validating a deep-learning-based assistance system for the diagnosis of prostate cancer. For this purpose, the partners want to use an MRI protocol that does not require contrast media.

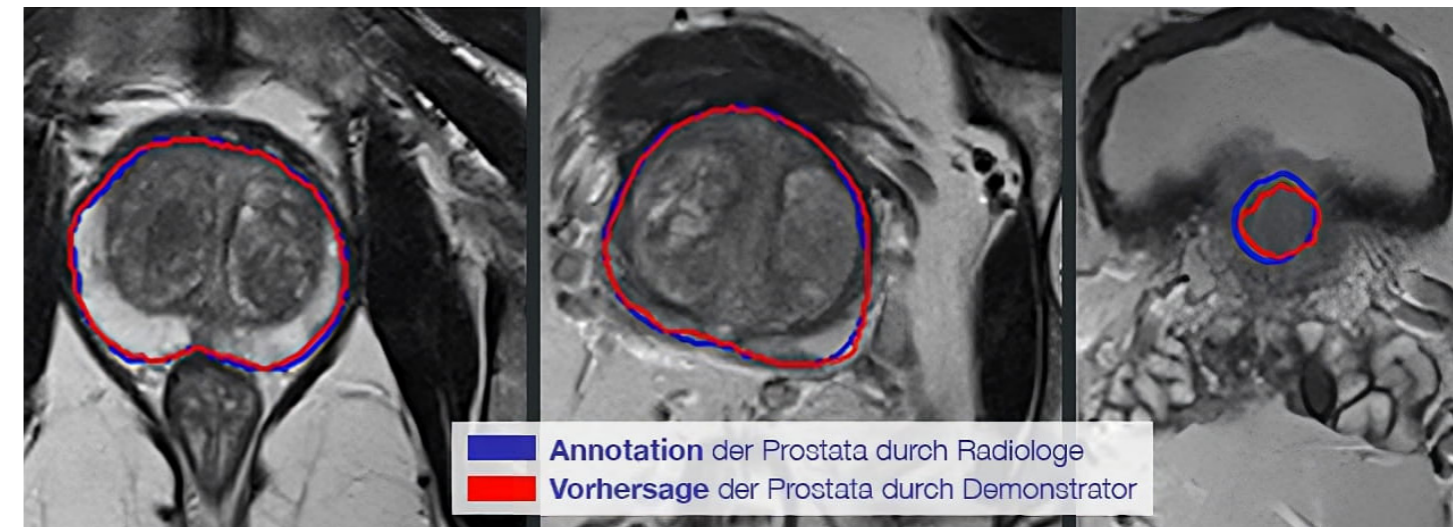
The measurement procedure, which is shortened compared to standard measurements, concentrates on parameters that are necessary for the assessment of the prostate. However, this should not be at the expense of diagnostic accuracy. „As an assistance system, we are developing an AI-based image analysis software that provides the radiologist with relevant information during the diagnostic process,“ says Matthias Steffen, Managing Director of FUSE-AI GmbH in Hamburg.

The advantages of such contrast-free prostate imaging would not only lie in the cost savings for the healthcare system and the time savings for the examining doctor. „For patients, the health risk is reduced if we can do it without contrast media,“ emphasises Prof. Dr. Tobias Franiel, head of oncological and urological imaging at the Institute for Diagnostic and Interventional Radiology at the UKJ and also clinical director of the project. The cooperation is being funded for two years by the Central Innovation Programme for SMEs ZIM of the Federal Ministry for Economic Affairs and Energy.



Photo: Heiko Hellmann/UKJ

MILESTONE REACHED! THE PROSTATECARCINOMA.AI DEMONSTRATOR IS READY



29.05.2020 The FUSE-AI team has continued to work on the development of the ProstateCarcinoma.ai software. **The demonstrator, which has now been completed, proves that the prostate detection and lesion recognition aspects relevant for prostate cancer diagnosis are possible.**

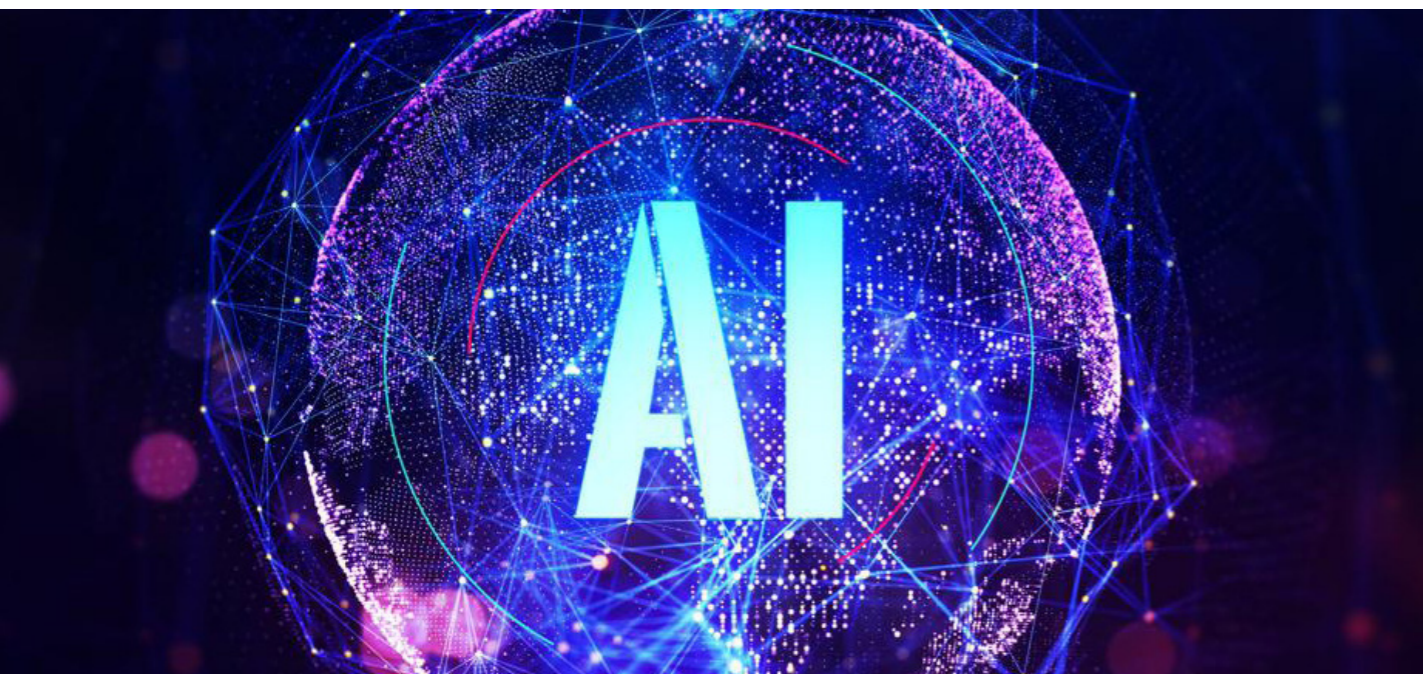
For future users, the product has both **medical and economic advantages**. They are a **prerequisite for future certification and marketing as a medical product**.

For the developed demonstrator, the AI backbone was first finalised. This is an infrastructure for the reproducible and scalable execution of deep learning experiments and the generation of AI modules. Based on a starting set of training data, all central AI modules were created with the help of the AI backbone. We already achieve a very high diagnostic quality for prostate segmentation. This is also a prerequisite for approval as a medical device.

In order to increase the accuracy of lesion detection in the next development phase, we have established **cooperations with various clinics and obtained funding**. This ensures an increase in the amount and quality of training data and opens up the possibility of **clinical validation** of ProstateCarcinoma.ai.

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FUSE-AI WAS AWARDED THE 6TH ANNUAL TECHNOLOGY INNOVATOR AWARD SILVER



23.06.2021 This year, Corporate Vision magazine has presented the Technology Innovator Award for the sixth time in a row. The award is given to companies that, in the opinion of the jury, have shown themselves to be technical pioneers and are able to provide solutions for a variety of challenges. The jury pays particular attention to the innovative strength of companies. Innovation and advances in technology development are crucial, according to the Corporate Vision Magazine jury, to ensure that new products and services can be developed and used to drive the economy and businesses forward.

Numerous sources as a basis for decision-making

Each company applying for the award provides the jury with a wide range of materials. Irrespective of the information submitted, the Corporate Vision Team researches a wide range of publicly available sources in order to create an overall picture of the company's work and activities.

Great success for FUSE-AI

FUSE-AI was officially nominated for the „6th annual Technology Innovator Award“ in March 2021. At the beginning of June, the jury announced that the Life Science Nord member had been awarded silver in the award. For Matthias Steffen, founder of FUSE-AI, the award is a great success for the Hamburg-based start-up. „We are an interdisciplinary team of data analysts, machine learning developers, natural scientists, medical professionals and communication experts. That's what makes our collaboration so successful“, Matthias Steffen is certain.

Specialists for the use of AI

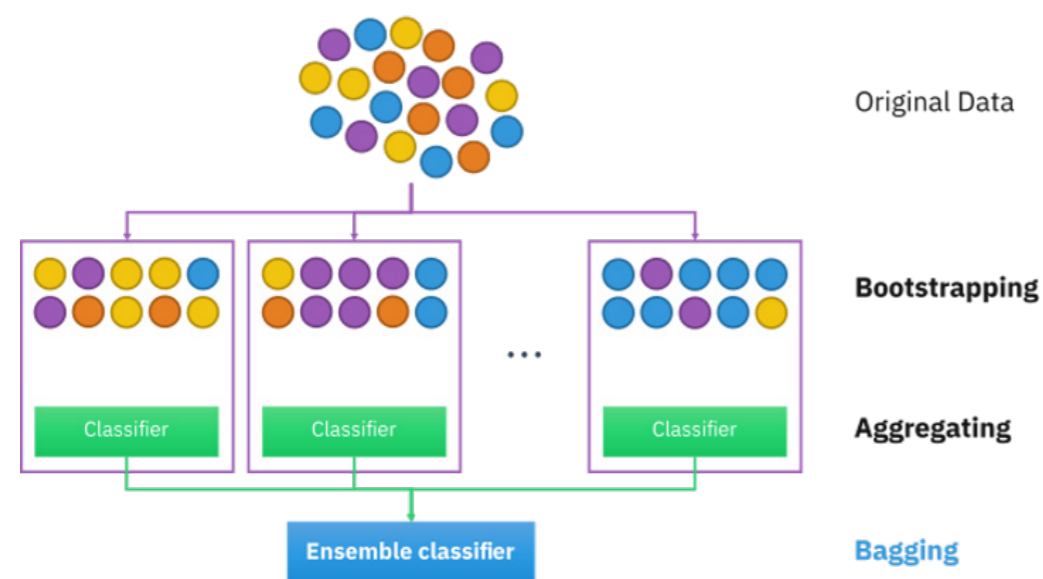
The FUSE-AI team is working with partners to develop intelligent image analysis systems using deep learning, machine learning and other AI-based methods. The software solutions are based on deep neural networks. These consist of many layers of artificial neurons and are trained with a large number of sample images and associated diagnoses. Based on this training, the neural network independently recognises patterns and regularities in the data. These solutions can be used in radiology to establish more efficient processes in the field of imaging procedures for the assessment of existing data. The software thus supports radiologists in the diagnosis of prostate cancer and thus contributes to better patient care. The intelligent software developed by FUSE-AI can be integrated into existing diagnostic software systems via interfaces.

Safety comes first

A widespread network of cooperation partners as well as supporting companies and institutions from all healthcare and life sciences sectors extend FUSE-AI's development competencies and support accelerated implementations. FUSE-AI relies on Deutsche Telekom's cloud, which is certified by the German Federal Office for Information Security (BSI), for the cloud-based applications provided, among others. „We attach great importance to operating in the most technologically secure environment with partners and customers. With our solutions, we show how medical expertise can be networked with IT competence and marketing know-how to analyse and interpret data in a completely new way. And always within the boundaries of Germany's strict data protection laws. Highly innovative AI solutions and - rightly - strict data protection are not contradictory. This has now also been honoured by the Corporate Vision Jury. AI solutions ‚Made in Germany‘ are internationally competitive!“ emphasises Matthias Steffen.

ENSEMBLE-LEARNING:

With multiple AI models we achieve higher sensitivity in the prediction



05.07.2021 „Please go to cabin 2! Take off everything that contains metal and wait until you are called.“ A sentence that is said in this or a similar way hundreds of times a day in radiology. The next time, we may have remembered again that metal and MRI don't match. When we automatically pay attention to it the next time, we feel like a pro - we have learned. The AI models from FUSE-AI, which are trained for the Prostate. carcinoma.ai software, learn in exactly the same way. But much faster, much deeper and in groups.

Our demands on Prostate.carcinoma.ai are high. The software should recognise and measure the prostate, segment it into different zones and mark conspicuous areas that could indicate a lesion. To do this, our neural networks train day and night using Deep Learning methods.

Unlabelled MRI images, annotated MRI images and countless metadata are run through various algorithms, generating models from predictor variables. These models then make a decision that, in the best case, matches the findings from radiology. A large amount of training data, along with a powerful AI model, are the basic prerequisites for a high detection rate and a low false positive rate.

Better results by merging several AI models into one ensemble

At this point, the additional question arises whether the prediction of only one trained model is sufficient for the diagnosis of the MRI images or whether an ensemble (merging of the best models) provides the better result.

For the best possible image analysis, we at FUSE-AI rely on the „expert panel“. For this, we take our models that provide the most accurate results and combine them into ensembles. Translated, this means that for our software, a panel of experts sits at the round table and jointly assesses the MRI image of the prostate and compares it with further metadata.

We already successfully use ensemble learning for segmentation and thus catch weaknesses in individual algorithms. The sensitivity of our ensemble is currently 89.7 % and is thus slightly higher than a single model.

FUSE-AI STARTS WITH THREE SWISS CLINICS A MULTICENTRE STUDY WITH PROSTATE.CARCINOMA.AI



31.08.2021 We are very pleased to have won three Swiss hospitals for a multicentre clinical study. The aim of the study is to prove that our AI-supported software is equivalent or even superior to previous methods in medical image analysis. Together with the three hospitals, we want to show in the study that AI-supported prostate segmentation and lesion detection in multiparametric magnetic resonance imaging (mpMRI) equals or surpasses the previous gold standard. All project partners involved assume that this is the case. In addition, we want to prove that both the efficiency and the safety of the assessment of the MRI examination are increased. Furthermore, we want to prove that the robustness compared to the gold standard can also be increased.

The previous gold standard in MRI reporting

Prostate cancer is the most common cancer and the second leading cause of cancer-related death in men. Standard diagnostics are based on PSA values, digital-rectal examinations and systematic, untargeted biopsies under ultrasound guidance. However, mpMRI for the diagnosis of prostate cancer is becoming increasingly important. For this, radiologists look through the individual MRI images and mark conspicuous areas that are specifically biopsied at a later time. This manual evaluation is the gold standard in MRI reporting. Depending on the complexity, radiologists need between ten and twenty minutes for the assessment.

Efficiency gains through AI

Using AI-based computer vision software such as prostate.carcinoma.ai from FUSE-AI, the process of segmenting the prostate and marking conspicuous areas in the tissue can be automated and thus accelerated. „This would give doctors more of their valuable time for more complex cases or emergencies,“ Dr. Sabrina Reimers Kipping from FUSE-AI is certain. The cooperation partners assume that the AI-based diagnostic process will lead to a significant increase in efficiency compared to the gold standard.

The assumptions of the study

The study pursues three starting points:

- AI-assisted prostate segmentation and lesion detection with prostate.carcinoma.ai is equivalent or superior to the gold standard.
- The time saved by automating lesion detection leads to a significant increase in efficiency.
- AI-based methods increase the reproducibility of the diagnosis in terms of interobserver variability.

The participating clinics

Dr. Felice Burn coordinates the retrospective multicentre study as head of the AI project team at the Kantonsspital Aarau (Switzerland). The pseudonymised prostate MR data of this study come from three radiological institutes in Switzerland that use different equipment manufacturers. This is an important aspect for FUSE-AI, as it allows the software to be additionally trained for possible differences in image generation. The evaluation of all prostate MR data is carried out centrally at the Kantonsspital Aarau by three radiologists without knowledge of the anamnesis data.

Participating clinics:

- Dr. A. Cornelius, Institute for Radiology at the Kantonsspital Aarau (Siemens Healthineers)
- Prof. Dr. Rolf Wyttenbach, Ospedale Regionale di Bellinzona e Valli (Philips Healthcare)
- PD. Dr. Olivio Donati, University Hospital Zurich (GE Healthcare)

PROGRESS IN OUR PRODUCT DEVELOPMENT - PROOF-OF-CONCEPT AND RETROSPECTIVE STUDIES

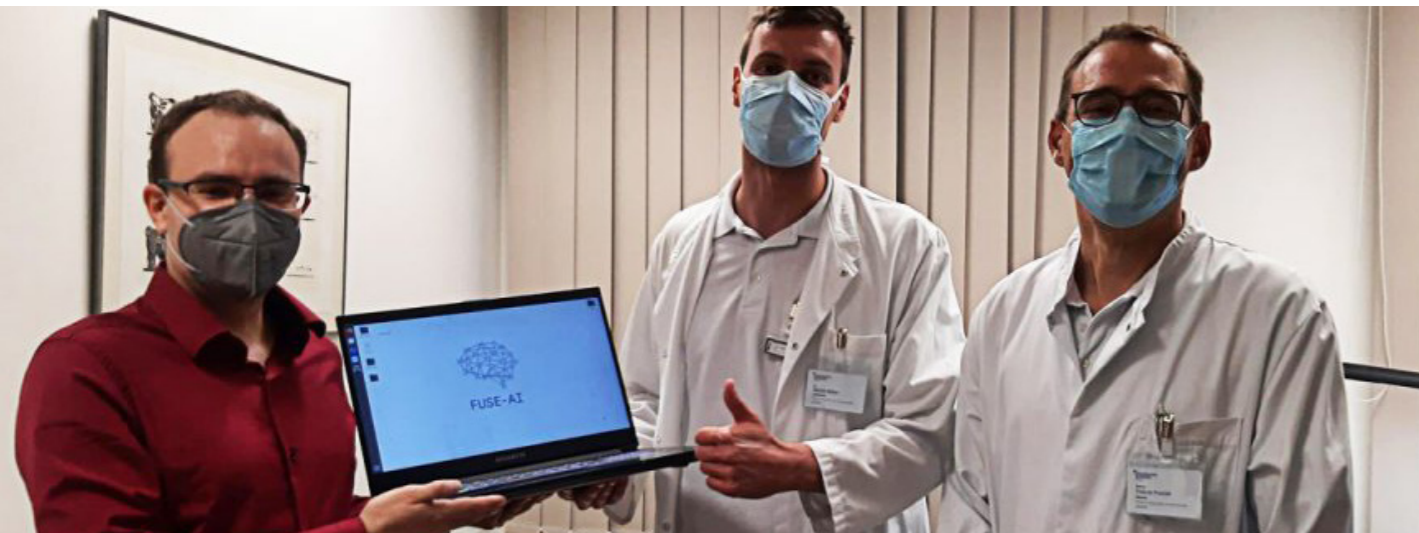


Photo: f.i.t.r Leonard Wägele FUSE-AI, Dr. Daniel Nißler, Prof. Dr. Tobias Franiel, University of Jena

04.10.2021 On the way to a marketable product, we have reached further important milestones: the proof-of-concept and the start of retrospective studies.

For the start of the **retrospective study with Jena University Hospital**, Leonard Wägele handed over a computer with our AI software „ProstateCarcinoma.ai“ to Dr. Daniel Nißler and **Prof. Dr. Tobias Franiel**, Head of Oncological and Uroradiological Imaging at the Institute of Diagnostic and Interventional Radiology at Jena University Hospital, on 13 September 2021. The study will collect initial clinical data on the performance of the AI software. The project with the University of Jena is funded by the Central Innovation Programme for SMEs of the Federal Ministry for Economic Affairs and Energy. In October 2021, **the retrospective multicentre clinical study will also start with three Swiss hospitals**. The aim of the study is to prove that the software equals or surpasses the previous gold standard in diagnosis.

Dr. Felice Burn is coordinating the study as head of the AI project team at the Kantonsspital Aarau. Dr. A. Cornelius from the Institute of Radiology at the Kantonsspital Aarau (Siemens Healthineers), Prof. Dr. Rolf Wytttenbach, Ospedale Regionale di Bellinzona e Valli (Philips Healthcare) and PD. Dr. Olivio Donati, University Hospital Zurich (GE Healthcare).

After completion of the studies, „ProstateCarcinoma.ai“ will be certified as a medical device by Juri Rohde, Head of Regulatory Affairs at FUSE-AI.

Proof-of-concept includes all functionalities of the product

The proof of concept was available in time for the start of the studies. It contains all the central product functions from data import to data pre-processing, the AI modules for image analysis to data post-processing and export. Our machine learning developers trained the individual AI modules with a large data set and optimised the prediction quality.

This is the state of development

Prostate segmentation

„ProstateCarcinoma.ai“ detects the prostate with 91% accuracy and marks it more precisely than an algorithm developed by the German Cancer Research Centre.

Zone detection

The AI module recognises the peripheral and transitional zones of the prostate as reliably as an experienced radiologist.

Lesion detection

Carcinomas are detected by the software as reliably as by radiologists (sensitivity software 0.86, radiologists 0.85).

The result of an additional filter further increases the accuracy of cancer detection (classification as carcinoma with 88% accuracy).

What our product does

Our AI-based software „ProstateCarcinoma.ai“ evaluates MRI images of the prostate almost as reliably as an experienced radiologist. However, the software is faster than the colleague in white.

In practice, this means: The AI software marks the prostate, the prostate zones and suspicious lesions. The evaluation results of the AI software are available to the radiologist in addition to the MRI images when making the diagnosis. In this way, AI provides the physician **with a second opinion already in the process of making the diagnosis**.

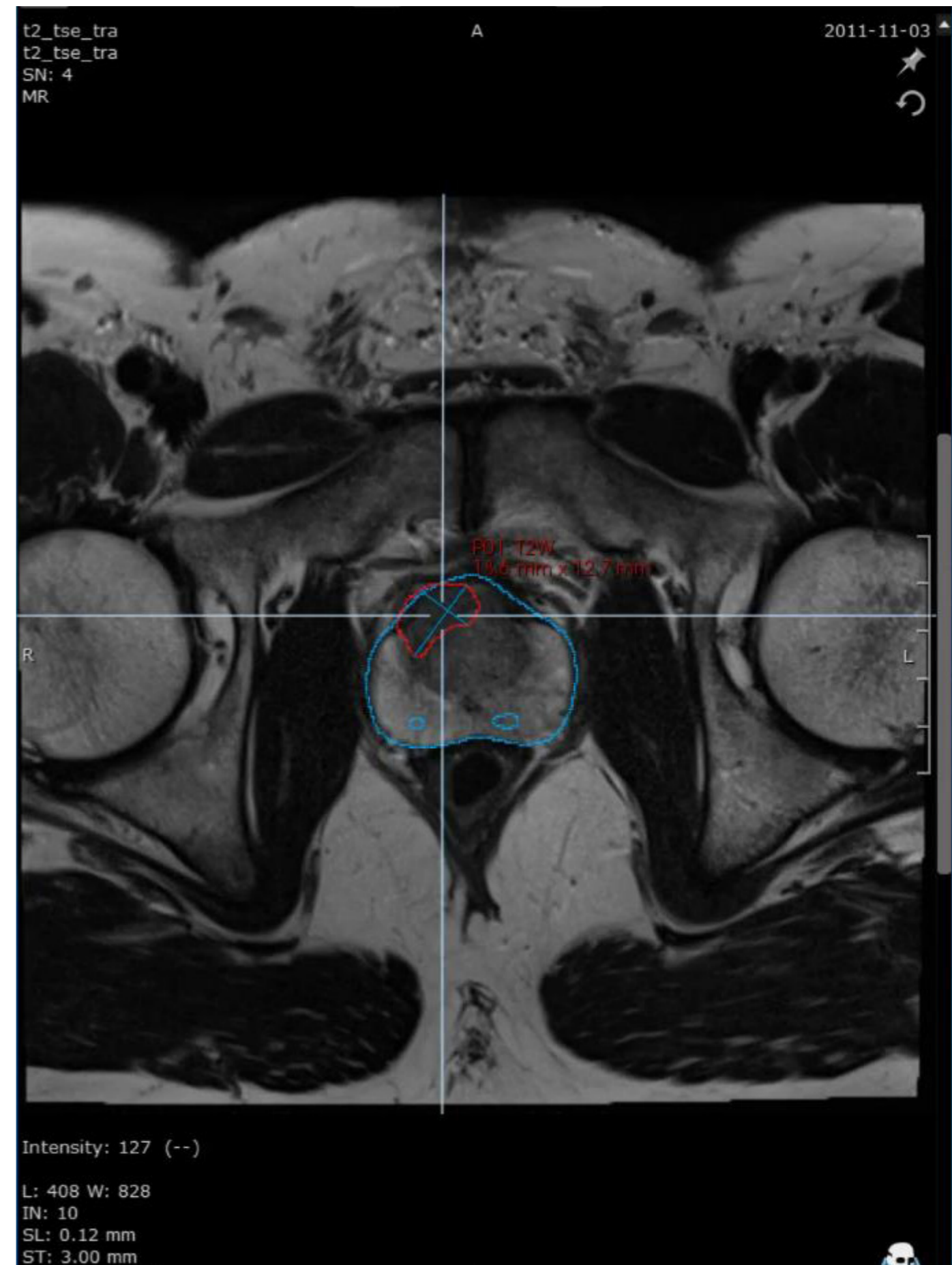
OUR KI SOFTWARE HAD ITS PREMIERE AT THE RSNA IN CHICAGO

06.12.2021 At the largest international radiology congress, the annual meeting of the Radiological Society of North America RSNA in Chicago (USA), radiologists were able to test our AI-based software „prostate.carcinoma.ai“ from 28 November to 2 December 2021. As an integrated AI software solution, it will simplify and accelerate MRI reporting of the prostate from mid-2022. In close cooperation with hospitals in Germany and Switzerland, we have been developing an AI-based radiological diagnostic software „prostate.carcinoma.ai“ since 2019. It will be able to be integrated into all PACS systems so that radiologists can use it in their usual routine for improved MRI analysis of the prostate.

The certification process for the product „prostate.carcinoma.ai“ has already begun. Approval as a medical device according to MDR 2017/745 and by the FDA is expected in mid-2022. Clinical studies with the University Hospital Jena and the Kantonsspital Aarau (Switzerland) are currently reviewing the medical and clinical benefits of the application.



Photo: Dr. Felice Burn



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RADIOLOGIE MAGAZIN REPORTS ABOUT FUSE-AI

OUR PATENT APPLICATION IS FEDERALLY FUNDED



04.04.2022 The current issue of the Radiology Magazine reports under the headline „Future teleradiology“ about an event in which we presented our AI software Prostate.Carcinoma.ai.

In the online event „Structured reporting in radiology - status and future prospects in connection with AI“, Matthias Steffen and Dr Sebastian Schäfer, Head of Research and Development at the PACS software manufacturer mint medical, spoke about our AI solution.

Currently, Prostate.Carcinoma.ai is integrated into mint medical’s diagnostic platform mint Lesion and communicates directly via the DICOM interfaces.

Almost 100 interested parties attended the event in December 2021. Profiled users and manufacturers highlighted their experiences and perspectives on artificial intelligence in radiology.

03.05.2022 The funding programme „WIPANO - Knowledge and Technology Transfer through Patents and Standards“ of the Federal Ministry of Economics and Climate Protection supports us in our patent application. WIPANO particularly supports small and medium-sized enterprises (SMEs) and the economic exploitation of innovative ideas and inventions from public research by helping to efficiently secure intellectual property through patents and utility models. We are pleased about the grants from the ministry and are confident that this will enable us to make even faster progress with patenting.



HEALTH MINISTER LAUTERBACH AT FUSE-AI

03.05.2022 Karl Lauterbach visited the FUSE-AI stand on 26 April 2022 out of over 570 exhibitors at the DMEA. There, he had Dr Sabrina Reimers-Kipping explain our AI-based diagnostic assistance software Prostate.Carcinoma.ai© to him. His very interested questions led us to ask the politicians to recognise the necessity of a separate billing code for computer-assisted diagnoses. This is the only way to ensure the high quality of diagnosis that medical professionals rightly expect. The appeal of FUSE-AI was met with great approval by the assembled visitors, who followed the discussion around our Minister of Health with great interest.



Photo from left to right: Gerrit Schick (Chairman of the bvtg), Martin Ecknig (Managing Director Messe Berlin), Karl Lauterbach, Dr. Sabrina Reimers-Kipping

NEW CONTACTS AND GOOD ACQUAINTANCES AT THE INTELLIGENT HEALTH UK



Photo: Matthias Steffen and Dr. Felice Burn, Head of Artificial Intelligence & Data Science CoE Kantonsspital Aarau, at Intelligent Health in London.

07.06.2022 Matthias Steffen travelled to the German X-ray Congress (RöKo) over Ascension Day to get an up-to-date overview of the market in the presence. He was also looking forward to holding personal discussions, listening to lectures and making new contacts. More than 20 topics of the entire congress deal with artificial intelligence. Dr. Matthias Baumhauer (Managing Director Mint Medical), Steffen Rupp (Sales Director Europe North Mint Medical), Dr. Alexander Cornelius (Institute for Radiology Kantonsspital Aarau, Switzerland) met at the Mint Medical stand. Prostate.Carcinoma.ai®, the AI-based assistance software for prostate diagnostics in MRI developed by FUSE-AI, is being developed through the cooperation with the Kantonsspital Aarau and is integrated into Mint lesionTM for testing purposes.

Both Mint Medical and the Kantonsspital Aarau are already looking forward to being able to use the software, which will be certified and patented as MDR IIa, before the end of the year.

The German X-ray Congress has undergone a comprehensive digital transformation in the last two years. Interested parties can attend the Digital Congress from 27 March to 26 June 2022. The attendance congress took place from 25-27 May 2022 at the RheinMain CongressCenter (RMSS) in Wiesbaden.

DIGITALISATION IN PHARMACIES - FUSE-AI IS A STRATEGIC PARTNER OF GEDISA



07.06.2022 The Gesellschaft für digitale Services der Apotheken mbH (GEDISA for short) was founded in Berlin at the end of 2021 to promote digitalisation in local pharmacies.

We are now supporting GEDISA as a strategic partner in the new field of artificial intelligence. In the „Letter of Intent“ we have just signed, we have agreed on a close and cooperative partnership that covers all issues relating to the analysis of processes through the use of machine learning. Within the framework of the cooperation, concepts and developments are planned for various pharmacy services that will lead to an improvement in the quality of care in the pharmacy sector. Our services include, for example, the development of analysis tools, in particular to identify and eliminate supply bottlenecks in good time.

For this purpose, we make our AI backbone available to GEDISA and thus provide the basis for the AI-supported software solutions to be developed by us. GEDISA is a 100% IT subsidiary of the state pharmacists' associations and societies and is a competent, reliable service provider and service partner for digital progress in the pharmacy sector.

WELL-REHEARSED TEAM MEETS AT THE X-RAY CONGRESS IN WIESBADEN



Photo: f.l.t.r Steffen Rupp (Mint Medical), Dr. Matthias Baumhauer (Mint Medical), Dr. Alexander Cornelius (Kantonsspital Aarau), Matthias Steffen (FUSE-AI)

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PROSTATE.CARCINOMA.AI[©] CERTIFICATION HAS BEEN INITIATED

FDA 510(k)
MDSAP
MDR IIa
ISO 13485



28.07.2022 Despite all oppressive circumstances that are currently making life hard for medical device manufacturers - and which could potentially threaten the existence of some of these companies - we have succeeded: FUSE-AI and their products will be certified by the Notified Body BSI Group!

„We are pleased about our new client FUSE-AI GmbH from Hamburg, Germany. We have been mandated to certify the Quality Management System (QMS) according to ISO 13485 and Medical Device Single Audit Program (MDSAP). The required certification is the basis for CE marking compliance and FDA 510(k) submission to make „Prostate.Carcinoma.ai[©]“ available to the US and European market.“ Frederic Becker, BSI Group.

The MDSAP enables medical device and in vitro diagnostic manufacturers to cover with normative and regulatory requirements of up to five target markets by completing only one audit process. Prostate.Carcinoma.ai[©] will be approved for: Australia, Canada and the United States of America.

An MDSAP audit from BSI can also be combined with ISO 13485 certification. FUSE-AI has been a registered medical device manufacturer with the BfArM (German Federal Institute for Drugs and Medical Devices) since 2021.

The current situation in the regulation of medical devices is very challenging, as there are significantly less Notified Bodies and even less resources than previously available within the EU In-vitro Diagnostic Device Regulation (IVDR) and the EU Medical Device Regulation (MDR) compared to the previous directives. These gaps are confronted with even more products to be certified in a shorter period of time, as well as to more complex audits and examinations.

Associations such as the German Medical Technology Association (BVMed) and the Association of the Diagnostics Industry (VDGH) claimed „immediate interventions to ensure patient care according to MDR & IVDR“ in a common paper already in May 2022. They currently expect negative consequences for the human health care in Germany and Europe.

Also at the ‚Johner Institute Day‘ (we reported in July), the hope for an early relaxation of the situation was very restrained among all guests and a general loss of innovation is feared.

Therefore, we are excited to announce that Prostate.Carcinoma.ai[©] will be soon available in many countries around the world to assist physicians in prostate MRI diagnosis.

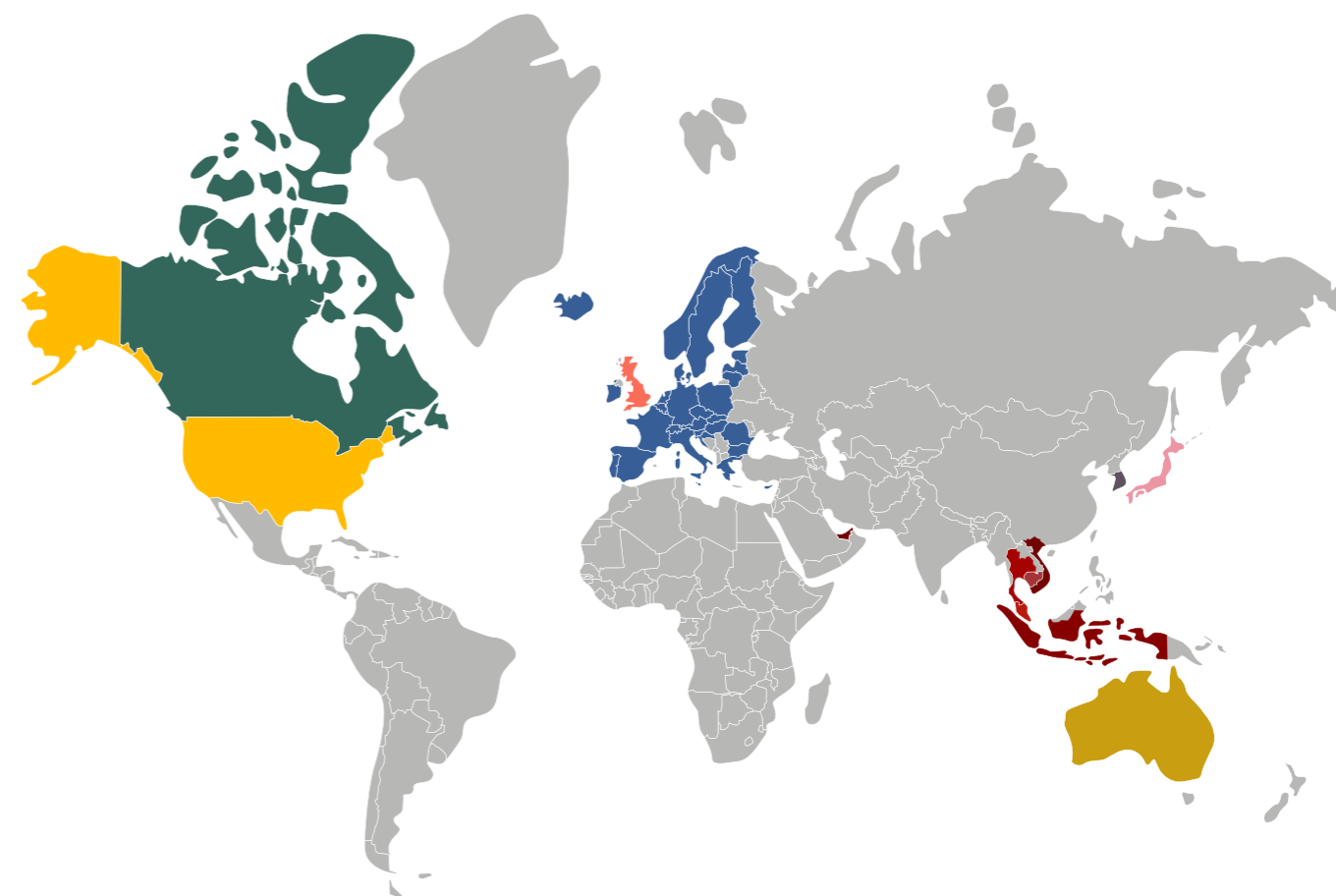
FUSE-AI TAKES OFF

13.09.2022 Global distribution launched at the G20 Digital Innovation Network
The G20 Digital Innovation Network is a high-level forum for sharing knowledge, fostering discussion, and building partnerships between global innovation players. It aims to serve as a bridge for cooperation between different players at the global level. For the last meeting in Bali at the beginning of September, the Federal Ministry of Digital Affairs and Transport (BMDV) nominated five German start-ups, including the Hamburg-based AI experts from FUSE-AI. This gave Dr. Sabrina Reimers-Kipping, Head of Medical and Scientific Affairs, and Juri Rohde, Head of Regulatory & Operations, the opportunity to represent Germany as the only delegates from the health industry.

A solution that inspired

The two brought the AI-based assistance software Prostate.Carcinoma.ai with them to Indonesia. „The software provides reliable and reproducible segmentation of the prostate, prostate zones and suspicious lesions. It determines exact prostate and lesion volumes as well as region-of-interest (ROI) coordinates,“ Dr. Reimers-Kipping explains the software. It can be seamlessly integrated into all image data management and diagnostic systems. The ISO 13458 and MDSAP certified plug-in solution will be routinely available to users from the beginning of 2023. Prostate.Carcinoma.ai also convinced the jury in Indonesia. „They were enthusiastic about the technology, the positioning and the market fit of our AI software,“ says Rohde. FUSE-AI used this praise as the starting signal for international sales in Southeast Asia. „We had the great opportunity to present ourselves to the key innovation players and policy makers of the G20 countries on a global stage and established new interesting contacts with investors and relevant companies. This lays the foundation for a successful market entry,“ Dr. Sabrina Reimers-Kipping is pleased to report.

G20 Digital Innovation Network in Indonesia.



FUSE-AI AT RSNA IN CHICAGO

11.01.2023 The Radiological Society of North America (RSNA) is an annual medical conference held in Chicago. It is one of the largest and most important events of its kind in the world and brings together hundreds of exhibitors and thousands of participants from all over the world.

This year, Matthias Steffen visited the international trade fair and made contacts with PACS manufacturers. The RSNA offers a variety of lectures, workshops and symposia on different topics in radiology and imaging technologies. There is also a large exhibition hall where exhibitors showcase the latest products and services.

One of the highlights of the RSNA is the presentation of new technologies and advances in radiology. This year, for example, new imaging techniques that can be used to better diagnose and treat diseases were presented. There were also presentations on topics such as artificial intelligence and machine learning in medicine as well as new possibilities in telemedicine.

Overall, the RSNA in Chicago was again a great success and showcased important advances in radiology and imaging technologies. It offers professionals from all over the world the opportunity to learn about the latest developments and exchange ideas with colleagues.



RSNA[®]
 Radiological Society
 of North America

「20 23」

WHAT IS IMPORTANT WHEN FILING A PATENT APPLICATION



23.01.2023 We have received the good message from our lawyer: No more obstacles exist to filing our patent application. The following key points must be considered when filing a patent application:

Examination of patentability: before filing a patent application, it is important to make sure that the invention is a patentable invention. This includes ensuring that the invention is new and non-obvious.

Scope of the claims: making the claims as precise as possible is important to ensure that you receive the coverage you request.

Formal Requirements: Some formal requirements exist for patent applications, for example, identifying the inventor and characterizing the invention in a way that is disclosable.

Costs: patent applications may be expensive, and therefore the costs should be considered in advance.

International protection options: An important fact to know is that patents are usually valid for use only inside the territorial jurisdiction of a specified country. When in need of international protection, it is important to learn about the options for international patent applications.

In summary, to apply for a patent for medical software, the criteria are the same as for a patent application for any other technology. These include in particular:

Novelty: The invention must not have been publicly known or sold before the application.

Unforeseeability: The invention must not be obvious to anyone with expertise in the field.

Applicability: The invention must have a technical character and not be based on purely theoretical knowledge or mathematical formulae.

Disclosure: The invention must be disclosed in such a way that it can be understood by someone skilled in the art.

Claim drafting: the claim to the invention must be precisely formulated.

Usability: the invention must be capable of industrial application.

FUSE-AI AT THE EUROPEAN RADIOLOGY CONGRESS ECR IN VIENNA



Photo left to right: Matthias Steffen, Ruben Schulze, Steffen Rupp (Mint Medical Senior Sales Director), Andreas Raguse

16.03.2023 Matthias Steffen, Andreas Raguse and Ruben Schulze have visited the European Congress of Radiology ECR in Vienna from March 2-3, 2023. For us, the ECR is an ideal platform to reach several of our current and potential cooperation partners. We are engaged in concrete discussions with these partners regarding the integration of our AI software into their PACS software. We also discussed new product developments with our strategic partners.



Photo from left to right: Matthias Steffen, Andreas Raguse, Raja Ghanem (Terarecon), Daniele Della Latta (Terarecon), Sinan Batman (CTO Terarecon), Viswaath Ganesan (Terarecon)



Ruben Schulze, Matthias Steffen



Todor Khristoph (Bayer/Calantic), Matthias Steffen

WE HAVE ACHIEVED ISO 13485 CERTIFICATION



We are very proud to have fulfilled ISO 13485 for the quality management system for medical devices! After months of preparation, intensive reviews and revisions of our internal processes, we are now at the finish line. As a manufacturer of medical devices, we thus prove that we develop, implement and maintain a quality management system.

It was a hard piece of work - all the happier we are about this milestone for our company. This is the last decisive step towards marketing our product Prostate.Carcinoma.ai. At the same time, we are making a promise for the future - we will develop and market further AI-based medical products to further improve medical care.

Despite being independent, ISO 13485:2016 and ISO 9001 share similarities. ISO 9001 mandates continuous quality management improvements, while ISO 13485 emphasizes product safety and effectiveness. Its main goal is to ensure compliance through effective processes. ISO 13485 details requirements for areas like medical device design, manufacturing, and marketing. The 2016 version enhances focus on medical IT security and sets data storage precautions. ISO 13485 primarily targets regulated medical devices. It serves to prove compliance with the European Medical Device Regulation (MDR) or In Vitro Diagnostic Device Regulation (IVDR) within the legally regulated area.

MATTHIAS STEFFEN ON DELEGATION TRIP TO THE USA WITH MINISTER PRESIDENT DANIEL GÜNTHER



General Consul Oliver Schramm, Matthias Steffen

One of the focal points of the trip to companies in Boston and San Francisco was artificial intelligence. Around 50 high-ranking representatives from business, politics and science from Schleswig-Holstein visited renowned US companies from the fields of artificial intelligence, energy and health from 4-9 June 2023.

The goal of the trip was to exchange information about current technology trends and to promote the location in the North of Germany. The talks focused on the topics of digitalisation and AI, renewable energies, medical care and smart transport planning.

In Boston, the delegation made contacts at the Johnson & Johnson Innovation Center, Ginkgo Bioworks and MIT-IBM Watson, among others. In San Francisco and Silicon Valley, Google, Microsoft, SAP, CISCO, Eon, Plug and Play and Ruckus Networks were on the agenda.

Matthias Steffen's conclusion was extremely positive: a multitude of new contacts and cooperation opportunities, successful meetings and promising exchanges, as well as a whole bundle of stimulating impressions and innovative ideas.

FUSE AI made valuable contacts with Microsoft, Johnson & Johnson and investors.



Tim, who prepared the trip, Daniel Günther, Michal Preminger, Dirk Schrödter, Minister for Digital Affairs, and two other JNj staff members.

In the middle Mark Filerman, German Accelerator



Vice-President University Lübeck Stefan Fischer and Petra Vorsteher



Ginkgo Bioworks



Group picture at Microsoft

FOR THE SECOND TIME IN A ROW, WE HAVE RECEIVED THE RESEARCH GRANT



Our AI developments are classified as industrial research and development projects and are eligible for tax relief under the German Research and Development Tax Relief Act (FZulG). We have now also received an official seal for this.

„We are again very pleased about the positive decision, because it further underlines our efforts for the complex development of medical AI systems in industrial research.“ (Matthias Steffen, CEO and founder of FUSE-AI).

The new law allows research companies to have their research projects assessed. For this purpose, the Certification Body for Research Grants (BSFZ), as an expert body, examines whether the project meets the legal requirements. If companies receive a positive decision, they can submit a binding application for the allowance to the tax office.

The BSFZ is subject to the supervision of the Federal Ministry of Education and Research (BMBWF) and consists of VDI Technologiezentrum GmbH, AIF Projekt GmbH and the German Aerospace Center (DLR Projektträger) with offices in Bonn, Berlin, Düsseldorf and Dresden.

FUSE-AI OPENS UP SCANDINAVIAN MARKET FOR ITS AI SOFTWARE



The internationalization of FUSE-AI continues to progress. After the United Arab Emirates and the USA, FUSE-AI is now opening up another financially strong market in Scandinavia. The Scandinavian countries are ranked in the top 15 worldwide with the highest level of GDP per capita. (Norway in 2022: USD 105,000 per capita).

Our long-term goal is to sell AI software for diagnostic assistance in 44 countries worldwide. Matthias Steffen presented AI solutions from FUSE-AI at the Oslo conference „Digital Health - The German and Norwegian Market“ on October 17, 2023. The framework was provided by the 5-day delegation trip organized by the German-Norwegian Chamber of Commerce (AHK Norwegen) for German SMEs. The AHK thus opened the way for FUSE-AI to clinics in the Scandinavian region. In addition to the business initiation program, the agenda offered an exchange of knowledge with Norwegian innovation clusters, universities, institutes and companies. Hosts included the Oslo Invention Center of the University Hospital, Radiumhospitalet (Norway's largest oncology clinic) and the incubators Aleap and Health2B. AHK Norway organized the business initiation visit in cooperation with Norway Health Tech, the Norwegian Smart Care Cluster, ZVEI e. V. and Bitkom. The trip was organized on behalf of the Federal Ministry of Economics and Climate Protection (BMWK).

Norway is one of the most digitalized countries worldwide, with a strong focus on life sciences and healthcare. The Scandinavian countries are closely interconnected in this area. Similar to the German healthcare sector, the Norwegian healthcare sector is undergoing profound change: Similar to the German healthcare sector, the Norwegian healthcare sector is undergoing profound change: an ageing society, decreasing population and a shortage of skilled workers are calling for innovative solutions to finance and secure future healthcare provision.

COLLABORATION BETWEEN GERMANY AND CHINA



The German-Chinese Economic Conference 2023 took place from November 6th to 7th and has evolved over the years into one of the most significant conferences on economic exchange between Germany and China.

Matthias Steffen presented FUSE-AI during the 'Flashlights Innovation & Start-Ups' panel. Well-known companies such as Merck, Bosch, Allianz, and Price Waterhouse Coopers took part, as well as representatives from institutions and universities of both countries.



MATTHIAS STEFFEN PITCHED AT MEDICA 2023

FUSE-AI was nominated as one of the 12 finalists for the Startup-Competition, which was pre-selected by Medica from a pool of 260 startups. On November 14, 2023, Matthias Steffen presented Prostate.Carcinoma.ai in light of the global demand for AI-based diagnostic assistance systems and our upcoming market entry.

WHAT METHODS ARE USED TO CODE ROBOTS TODAY?



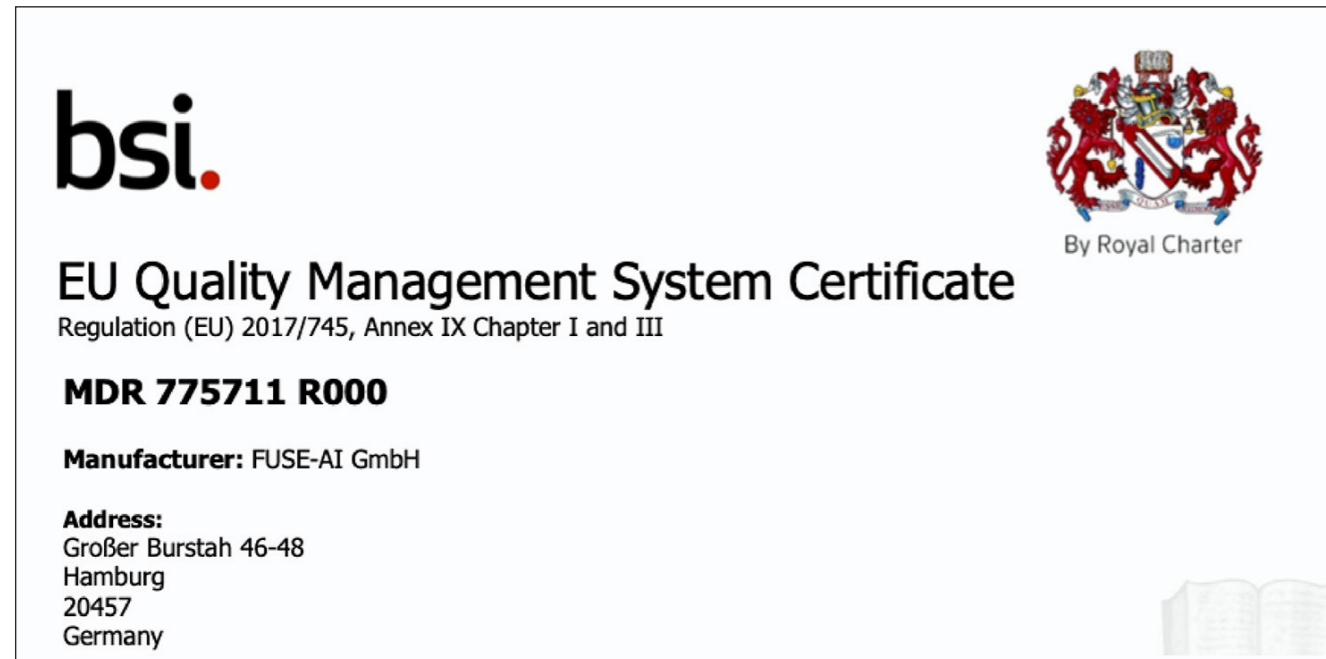
Reinforcement learning (RL) is emerging as a key solution for controlling robots in warehouses. These AI models enable robots to learn autonomously and optimize their operations depending on the results they have achieved, enabling them to respond more efficiently to challenges.

The main difference in reinforcement learning compared to supervised and unsupervised learning is that training data does not need to be provided as an external dataset. These are generated automatically while the robot is being trained. The precondition for this is a simulated environment that is used to train it on safety and time.

In a dynamic environment such as a warehouse, where conditions and requirements may change constantly, this adaptability is essential. Reinforcement learning enables robots to learn from interaction with the environment and thereby continuously optimize performance over time. This contributes to reducing errors as well as increasing efficiency and autonomy.

To sum up, by its ability to self-optimize, adapt to dynamic environments, and handle complex tasks, reinforcement learning represents a cutting-edge solution for controlling robots in warehouses.

PROSTATE.CARCINOMA.AI IS NOW A CERTIFIED MEDICAL DEVICE



On December 15, we were very happy to receive the announcement from our Notified Body that we have fulfilled all the requirements of EU MDR IIa. The whole team is so proud to have achieved this ambitious step!

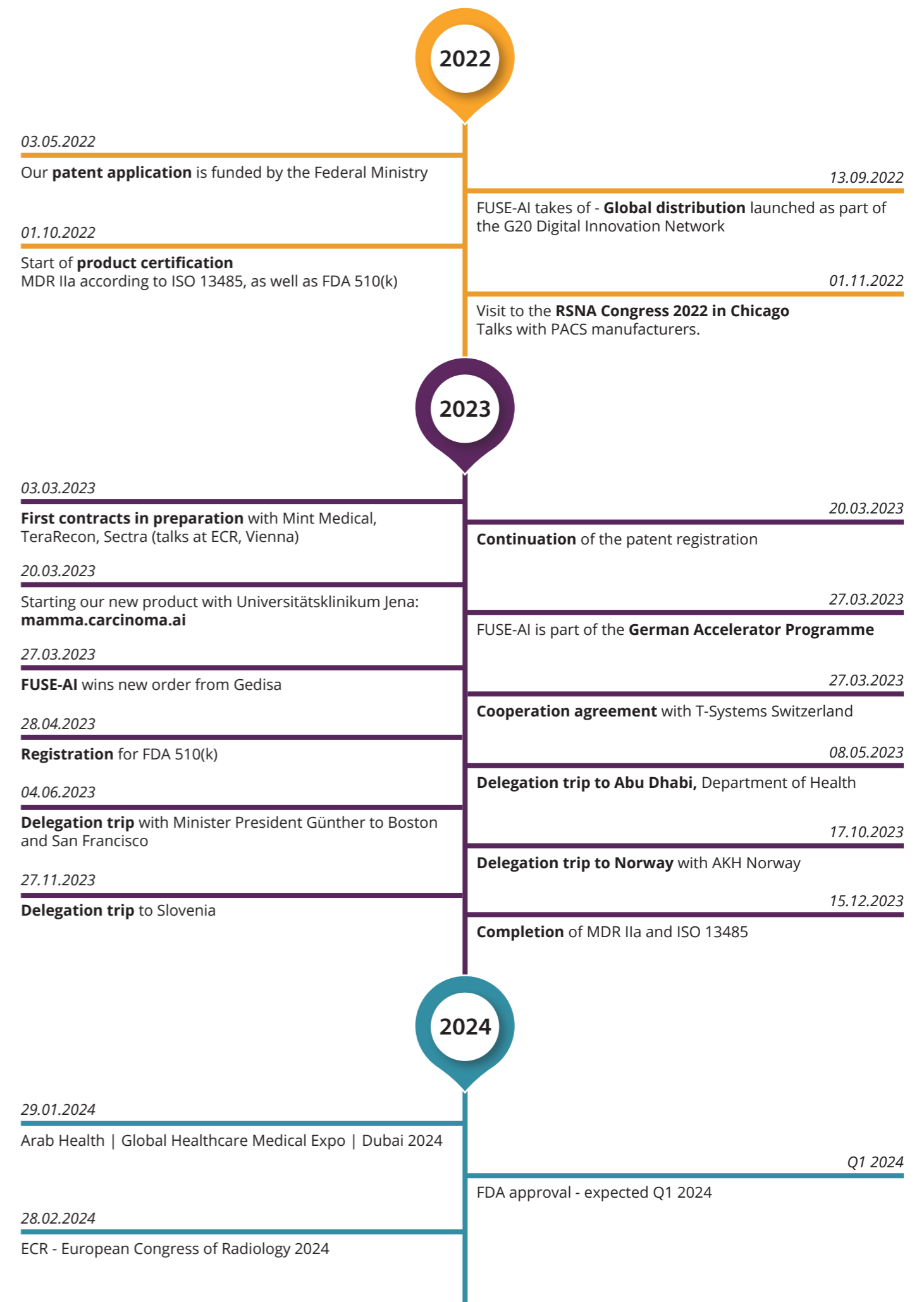
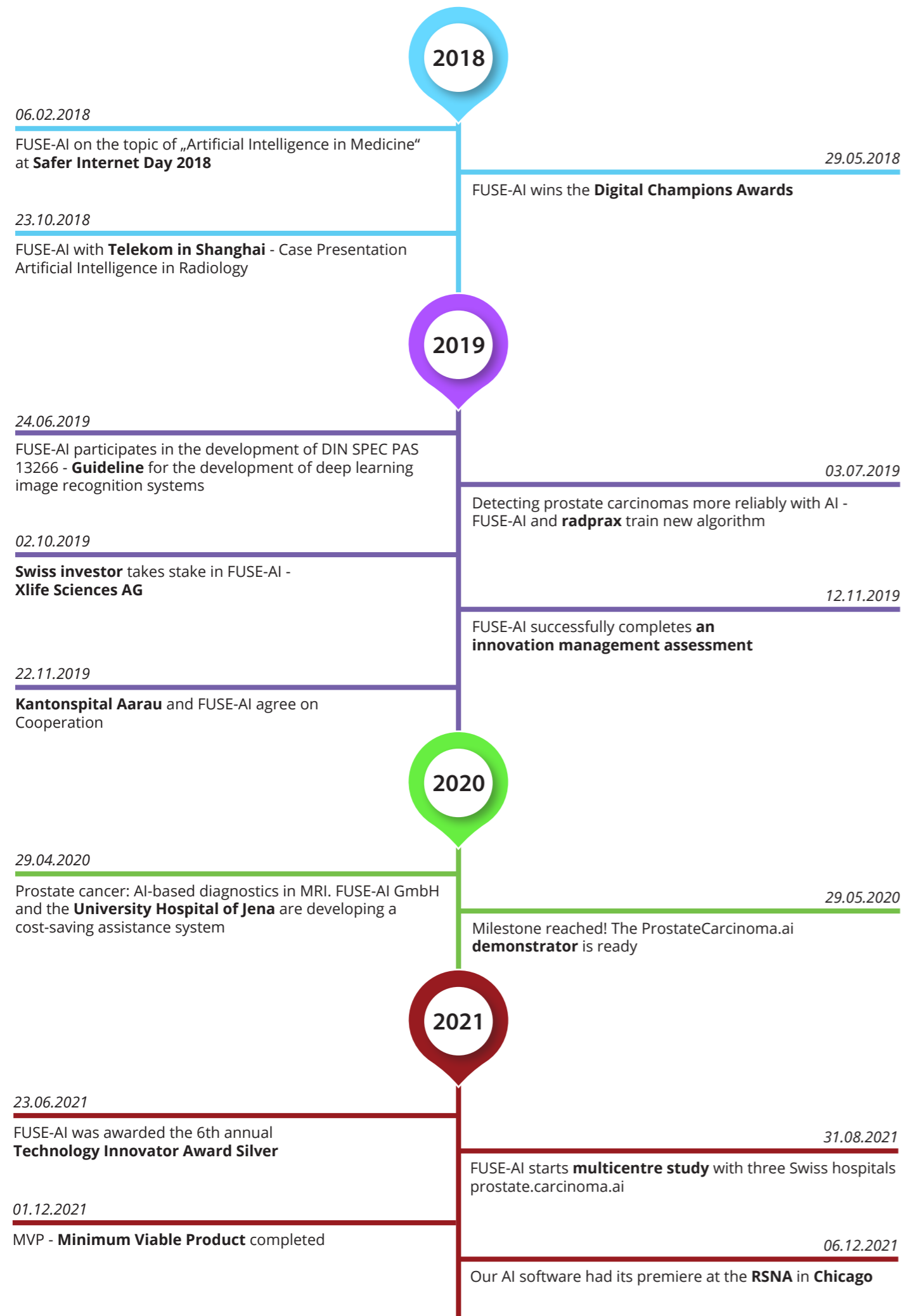
This milestone also points to the next one. We have already defined our global sales strategy and reinforced it with several delegation trips organized by the foreign chambers of commerce.

We also completed our application for FDA approval in the USA and expect to receive a response in the first quarter of 2024. For the upcoming distribution in countries such as Canada and Australia, we will fulfill the requirements of the MDSAP. This entitles us to distribute in 44 countries.

WE HAVE BEEN AWARDED

We are known for our expertise and have been several times awarded





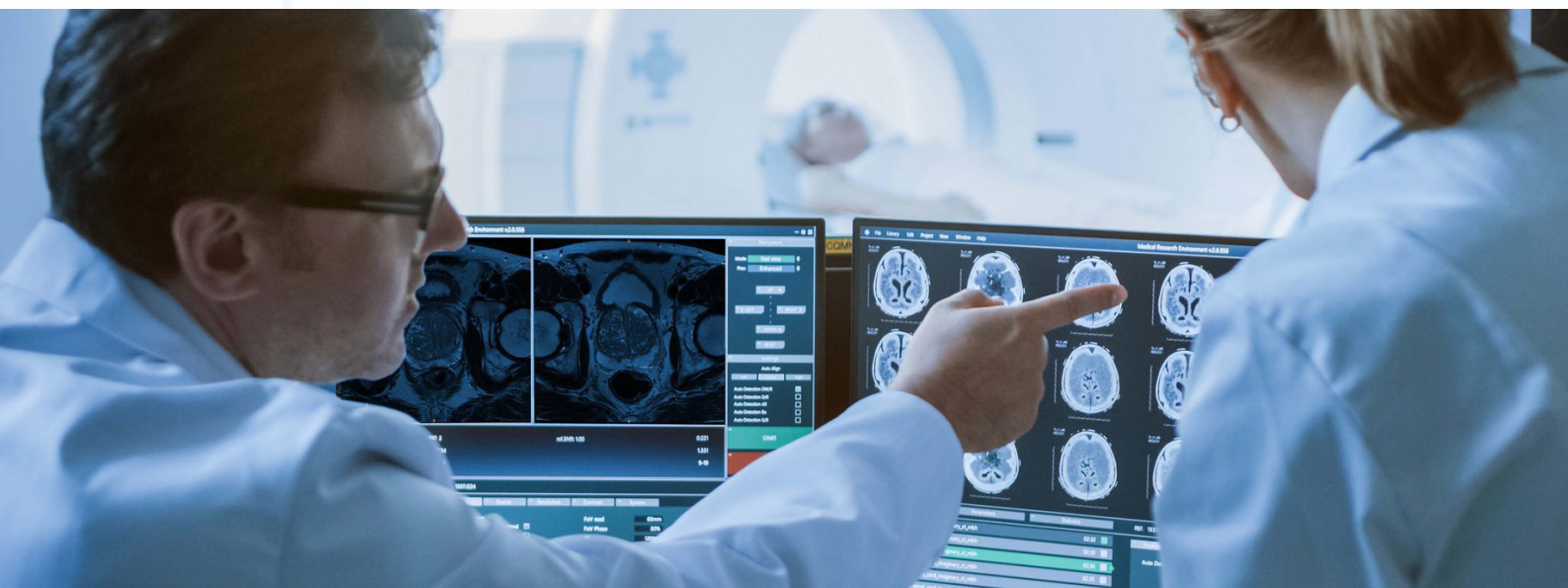


FUSE-AI



We are involved in research projects with university hospitals and institutes, e.g.

- University Hospital Jena
- UKSH University Hospital Schleswig Holstein
- HSU Helmut Schmidt University, Hamburg
- Cantonal Hospital Aarau
- University Hospital Zurich
- Fraunhofer Institute IBMT
- GEOMAR



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