

Federal Institute for Drugs and Medical Devices

# AI in Medical Devices and Digital Healthcare Applications – the BfArM perspective

Joint HMA/EMA Workshop on Artificial Intelligence in Medicines Regulation - 19-20 April 2021

Dr. Wolfgang Lauer



#### Central tasks of the BfArM:

- $\rightarrow$  To license and to improve the safety of drugs
- $\rightarrow$  To register and to evaluate the risks of medical devices
- $\rightarrow$  To monitor the traffic with narcotics and precursors
- $\rightarrow$  To establish classifications, terminologies, standards and data based information systems for health care





# The changing World of Medical Devices...



### ...and tomorrow?



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Source: Amazon, Paramount Pictures

### ...and tomorrow?



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Source: Amazon, Paramount Pictures

# Digital Medical Devices - Initiatives of BfArM



# "AI" – reliability?

With regard to the F1 measure, ped which combines accuracy and inte hit rate of data, the AI system, ruying at 0.885, was better than the ruying two groups with younger physicians, **but worse than the other three. The most experienced group of physicians r** 

### medicine

Letter | Published: 11 February 2019

Evaluation and accurate diagnoses of pediatric diseases using artificial intelligence

Huiying Liang, Brian Y. Tsui, [...] Huimin Xia 🟁

Nature Medicine 25, 433–438 (2019) | Download Citation 🛓

The most experienced group of physicians reached 0.923.

• • •

However, the algorithms used are not traceable **and it cannot be explained how a decision is reached.** 

https://www.heise.de/newsticker/meldung/Kuenstliche-Intelligenz-fuer-Diagnosen-in-der-Kindermedizin-

4304048.html



# "AI" – reliability?

Unmasking Clever Hans predictors and assessing what machines really learn

Sebastian Lapuschkin, Stephan Wäldchen, Alexander Binder, Grégoire Montavon, Wojciech Samek <sup>™</sup> & Klaus-Robert Müller <sup>™</sup>

Nature Communications 10, Article number: 1096 (2019) | Download Citation 🚽

"At the same time it is important to comprehend the decision-making process itself. In other words, transparency of the what and why in a decision of a nonlinear machine becomes very effective for the essential task of judging whether the learned strategy is valid and generalizable or whether the model has based its decision on a spurious correlation in the training data."





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# "AI" – reliability?

- Researchers at Ben Gurion University (Israel) have shown how malware can be used to manipulate the basics of cancer diagnosis.
- In a simulated cyber attack on a hospital, the researchers showed how an attacker could use special malware to modify the image files in question.
- Their technology would make it possible both to simulate cancer and to remove existing cancer cells from the images.
- The researchers describe the system with which the files are transferred from the computer tomographs to the radiologists' computers as the central weak point.



© Ben Gurion University https://youtu.be/\_mkRAArj-x0

Federal Institute for Drugs and Medical Devices https://www.spiegel.de/netzwelt/web/cyberattacke-im-krankenhaus-wie-forscher-eine-krebsdiagnose-manipulieren-a-1261330.html

# "AI" – Regulatory challenges

"The traditional paradigm of medical device regulation was not designed for adaptive AI/ML technologies, which have the potential to adapt and optimize device performance in real-time to continuously improve healthcare for patients." (FDA)

- Output changes not only depending on input parameters but also on training data, current state of adaptation...
- What/How to regulate?
- How to test and ensure safety and performance?
- Risk Management?
- Responsibility? Manufacturer vs. Training?





# What is a "DiGA"? And how are they assessed?



### What is a "DiGA"?



### **Definition of Digital Health Applications (DiGA)**

- Medical device of risk class I or IIa
- Supports the recognition, monitoring, treatment or alleviation of diseases, injuries or disablilties
- Main function based on digital technologies
- Used only by the patient or by the patient and the healthcare provider together

#### **Requirements for being listed in the DiGA Directory:**

- Safety and performance (CE-marking according to MDD/MDR)
- Data protection, information security and futher quality requirements
- Positive healthcare effects



# Positive healthcare effects of DiGA

DiGA listed in the directory must have proven <u>at least one</u> of these positive healthcare effects:



perceptible effects for a patient specifically regarding:

- improvement of the state of health
- shortening of the duration of the disease
- extension of survival
- improvement in the health-related quality of life.

# Patient-relevant improvement of structure and processes in healthcare (pSVV).

supporting the health behaviour of patients or integrating the processes between patients and healthcare providers. Might be one of the following:

- 1. coordination of treatment procedures,
- 2. alignment of treatment with guidelines and recognized standards,
- 3. adherence,
- 4. facilitating access to care,
- 5. patient safety,
- 6. health literacy,
- 7. patient autonomy,
- 8. coping with illness-related difficulties in everday life, or
- 9. reduction of the therapy-related efforts and strains for patients and their relatives



## The DiGA Fast-Track Procedure





# AI – better in a network

Federal Institute for Drugs and Medical Devices



BfArM is an active member of the HMA-EMA Big Data Taskforce



# ITU/WHO Focus Group AI for Health https://itu.int/go/fgai4h



# ITU/WHO Focus Group AI for Health https://itu.int/go/fgai4h

- Artificial Intelligence for Health (A4IH) offers substantial improvements for public and clinical health, e.g. early detection, diagnosis and risk identification, treatment decision support, self-management, improved coutcomes, ...
- For world-wide adoption, need evaluation standards on effective AI for Health
- Focus Group AI for Health (FG-AI4H) created July 2018; open platform (Chair: Thomas Wiegand, TU Berlin/Fraunhofer HHI)
- FG-AI4H goals: standardized framework for benchmarking and evaluation of AI solutions



# AI – helping BfArM to keep the focus on the big picture...





# AI – helping BfArM to keep the focus on the big picture...





# Find out more at www.bfarm.de

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			and Medical Devices			search item Q
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About us• Medicinal Products• Medical Devices• Federal Opium Agency• Res	earch• Service•	★ H Dif sult	HOMEPAGE → MEDICAL DEVICES → GU fferentiation between appe bsequent risk classification	JIDANCE ON "MEDICAL APPS" s and medical or other devic a according to the MPG	ees as well as on the	Service Forms Medical Devices
Medical Devices Assessing risks. Protecting patients.		Digital Health Applications (DiGA)	Busice analisations for mobile oboose	DiGA directory	come our daily companions in homes bly in the past years. Apps measure ing of medicines. Iow can developers tell whether MPG) and related ordinances? And if	
★ HOMEPAGE → MEDICAL DEVICES Wedical devices are products that have a medical purpose and are intended by the manufacturer for use in humans. In contrast to medicinal products that act pharmacologically, immunologically, or metabolically, the main intended purpose of medical devices is primarily achieved by physical means. Medical devices include implants, products for injection, infusion, transfusion and dialysis, medical instruments intended for use in humans, software, catheters, artificial cardiac pacemakers, dental devices, bandaging material, corrective lenses, x-ray machines, condoms, instruments for use by physician, laboratory diagnostics, contraceptive devices as well as in vitro diagnostic agents. Products that contain or are coated with a substance or preparations of substances which are considered to be medicinal products or components of a medicinal product (including plasma derivatives) if used separately and which are liable to act upon the body with action that is ancillary to that of the device are also considered to be medical devices. The legal definition of medical devices is given in Section 3 of the Act on Medical Devices (MPG).	For more information     We       > Information on Risks     Corr       > Clinical Trials MD / Performance Evaluation Studies     If y info       > Legal Framework     If y	Welcome to the BfArM's website on digital health applications (DiGA or "apps on prescription").       Here you will find all relevant information – advice regarding the question 'what is a DiGA?' on the BfArM's tasks in connection with the procedure for listing in the directory of reimbursable DiGA ("DiGA and references to relevant documents and other webpages.       If you would like to know, which DiGA have successfully completed BfArM's assessment procedure, you will find all information in the "> DiGA directory.       If you would like to know, which DiGA have successfully completed BfArM's assessment procedure, you will find all       If you would like to know, which DiGA have successfully completed BfArM's assessment procedure, you will find all       If you would like to know, which DiGA have successfully completed BfArM's assessment procedure, you will find all       If you would like to know, which DiGA have successfully completed BfArM's assessment procedure, you will find all       If you would like to know, which DiGA have successfully completed BfArM's assessment procedure, you will find all       If you would like to know, which DiGA have successfully completed BfArM's assessment procedure, you will find all       If you would like to know, which DiGA have successfully completed BfArM's assessment procedure, you will find all       If you would like to know, which DiGA have successfully completed BfArM's assessment procedure, you will find all       If you would like to know, which DiGA have successfully completed BfArM's assessment procedure, you will find all       If you would like to know, which DiGA have successfully completed BfArM's assessment procedure, you will find all       If you would ble have successfully completed BfArM's assessment procedure, you will find all       If you would ble have successfully completed BfArM's assessmen			general: stand alone software, i.e. and medical or other devices as well gard to qualification and well as the marketing thereof are ction S MPG), if applicable in	
	Market Access     W     Vigilance System     Le	/hat is a Digital Health Application (DiGA)? egal Basis: Digital Healthcare Act (DVG) and Digital Health Applications Ordinanc	+ e (DiGAV) +	DiGA directory		
The BfArM's tasks with regard to medical devices are also laid down in the Act on Medical Devices ("Medizinproduktegesetz"), the Ordinance on the Medical Device Safety Plan ("Medizinproduktesicherheitsplanverordnung", MPSV), and the Ordinance on Clinical Investigations with Medical Devices ("Verordnung über klinische Prüfung von Medizinprodukten", MPKPV).	Forms Medical Devices     FAQ Medical Devices     Su	he BfArM's Assessment Procedure upport and advice by BfArM he BfArM's Guide on the Fast-Track Process: A Transparent Overview of the Proce	+ + edure and Help in +	DIGA Guide		
These tasks focus especially on the evaluation of so-called incident reports. These are risks reported in connection with products already on the market which the BFArM receives from operators (physicians, hospitals). Such incident reports can then lead to the initiation of a risk assessment procedure by the BFArM. If the BFArM comes to the conclusion that the product has to be changed for safety reasons, it will issue a recommendation for the manufacturer and/or the competent supervisory authority of the "Land". The legal instruments for implementing	Laws and Ordinances In Verordnung über Medizinprodukte Th (Medizinprodukte-	terpreting the Requirements he application procedure and the electronic application portal he DiGA Directory	+ +			
Federal Institute for Drugs and Medical Devices	In CC E-n Tel	nformation on the Provision of Prescription-relevant Data ONTACT mail: diga@bfarm.de lephone: +49 (0)228 99 307-5989	+	<ul> <li>A bit were set of the set of th</li></ul>		

Federal Institute for Drugs DEUTSCH PRESS RSS GLOSSARY CONTACT

# Thank you very much for your attention!

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