Federal Institute
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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:

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

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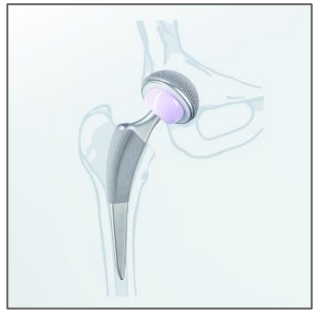
The changing World of Medical Devices…



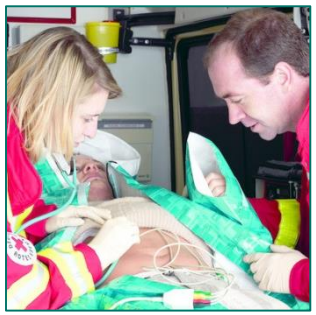


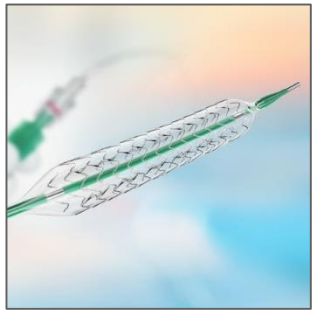


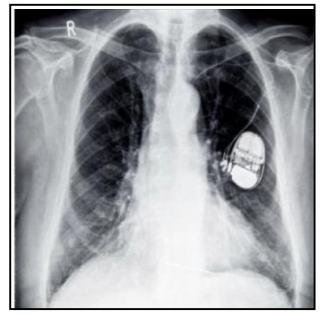










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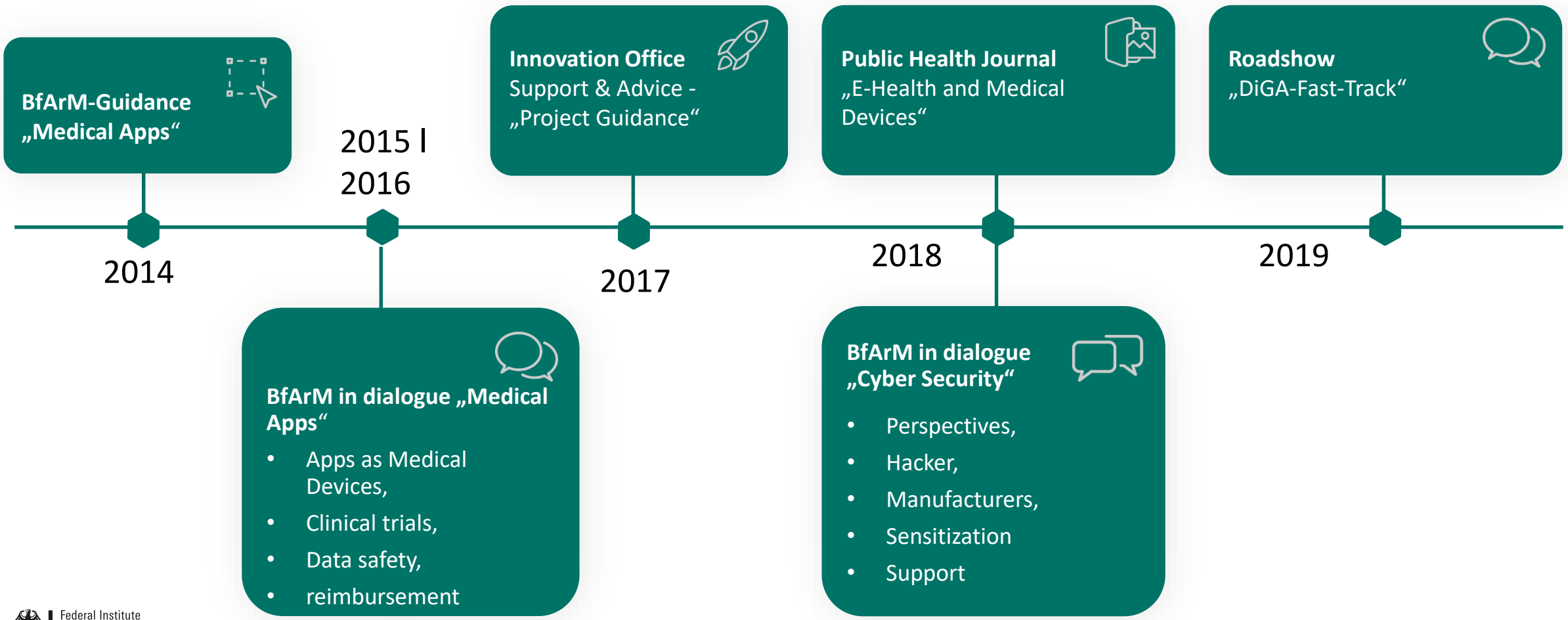
…and tomorrow?

Source: Amazon, Paramount Pictures

...and tomorrow?

Source: Amazon, Paramount Pictures

Digital Medical Devices - Initiatives of BfArM



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„AI“ – reliability?

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

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

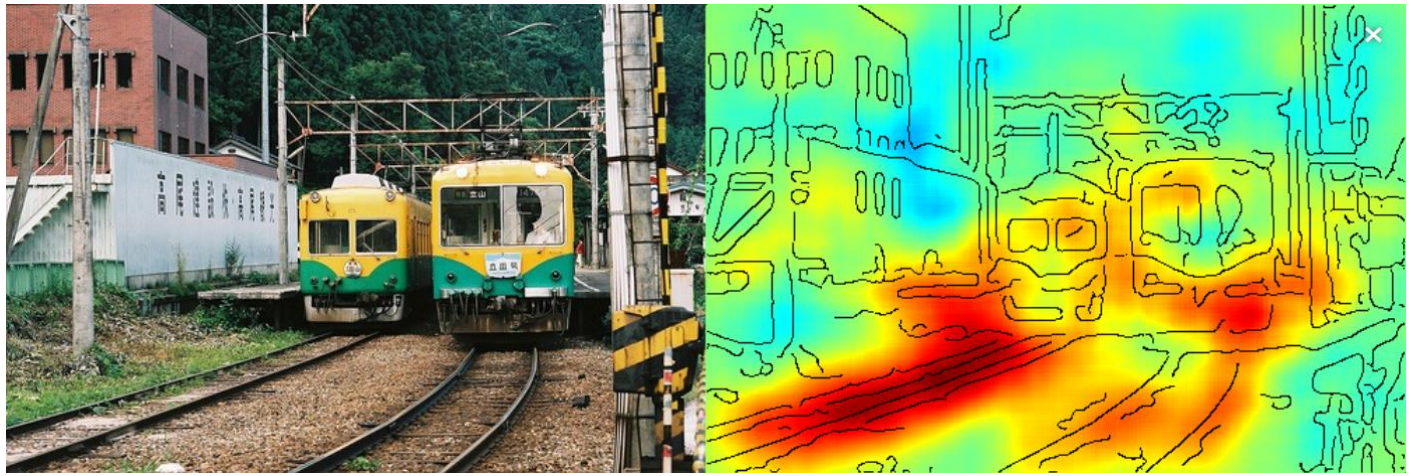
„AI“ – reliability?

Unmasking Clever Hans predictors and assessing what machines really learn

Sebastian Lapuschkin, Stephan Wäldchen, Alexander Binder, Grégoire Montavon, Wojciech Samek & Klaus-Robert Müller

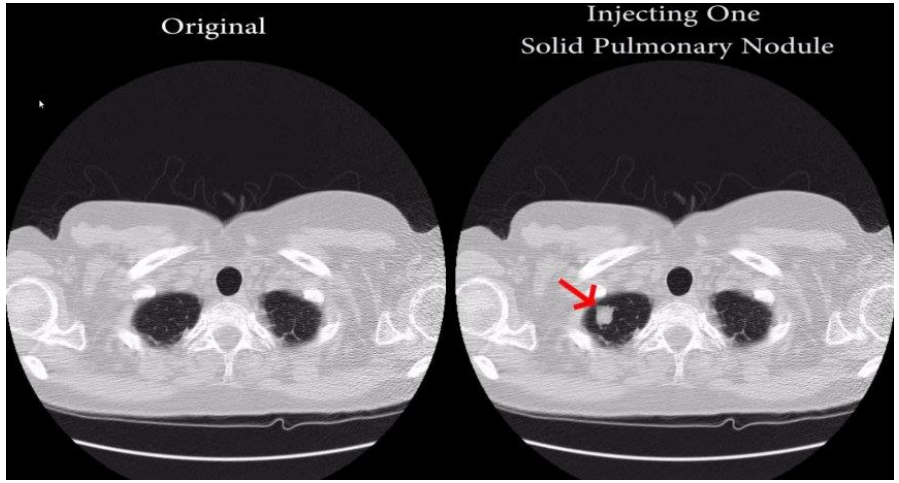
Nature Communications **10**, Article number: 1096 (2019) | Download Citation

“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.”



„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.



https://youtu.be/_mkRAArj-x0

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 at least one of these positive healthcare effects:

Medical Benefits

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

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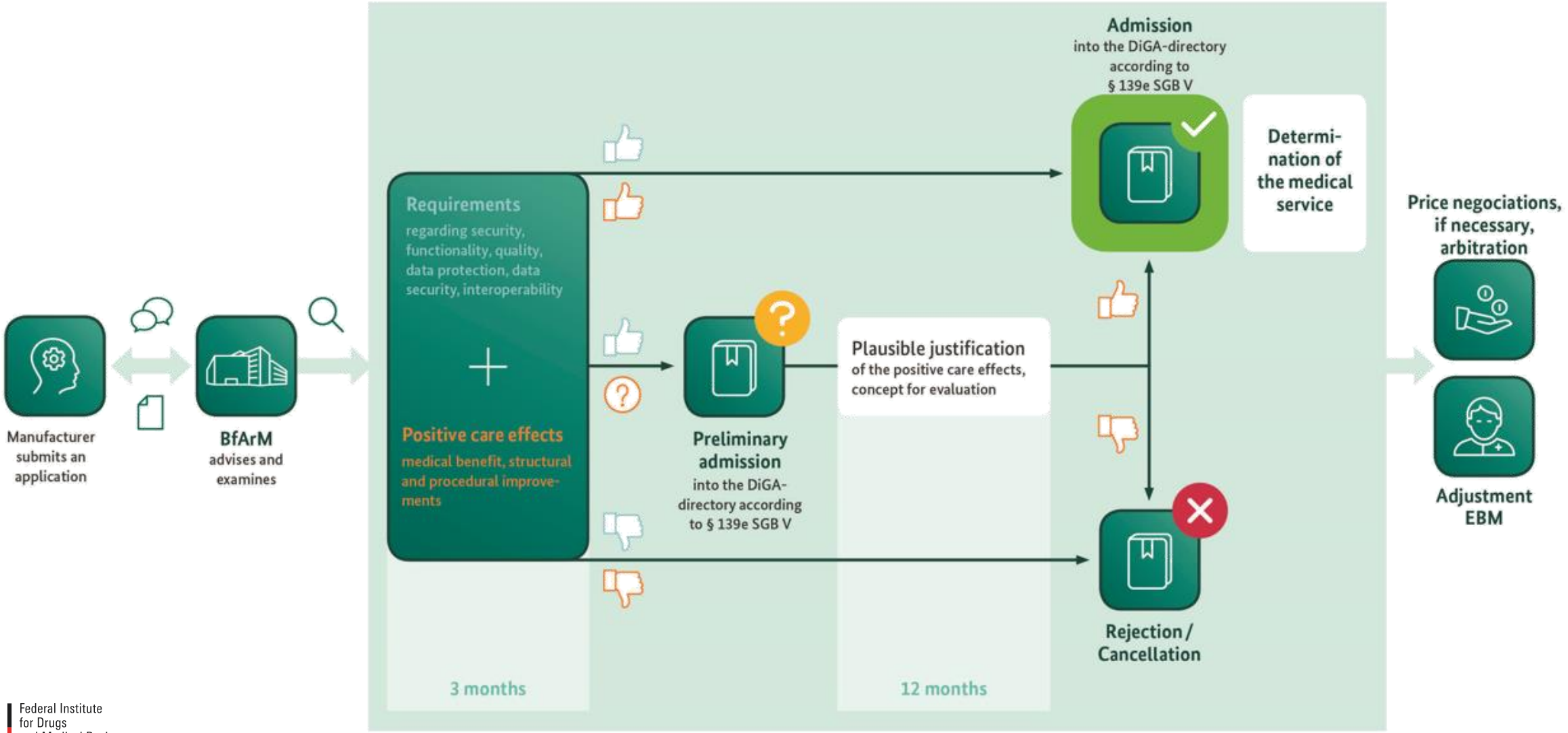
The DiGA Fast-Track Procedure



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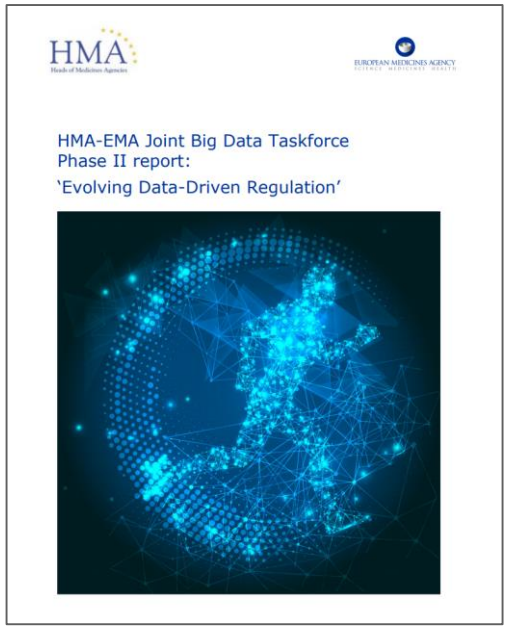
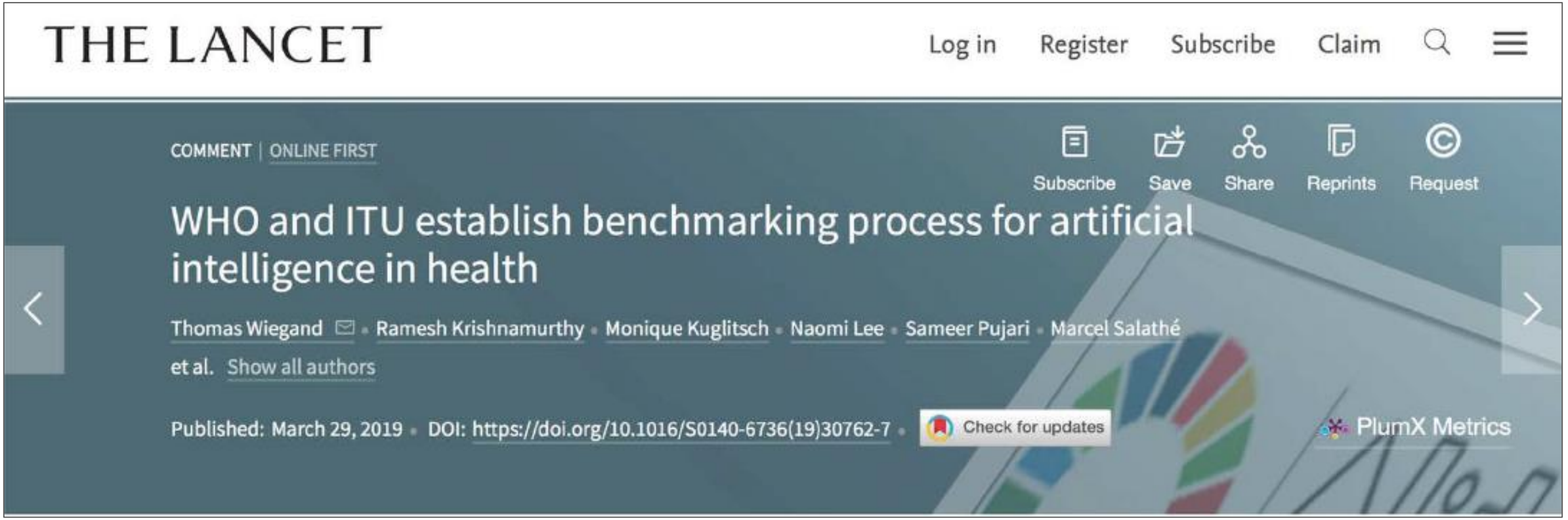
AI – better in a network

- DARWIN EU
- Data quality & representativeness
- Data discoverability
- EU Network skills
- EU Network processes
- Network capability to analyse
- Delivery of expert advice
- Governance framework
- International initiatives
- EU stakeholder implementation forum
- Veterinary recommendations

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



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



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ITU World Health Organization

AI for Health
An ITU Focus Group
In collaboration with WHO

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

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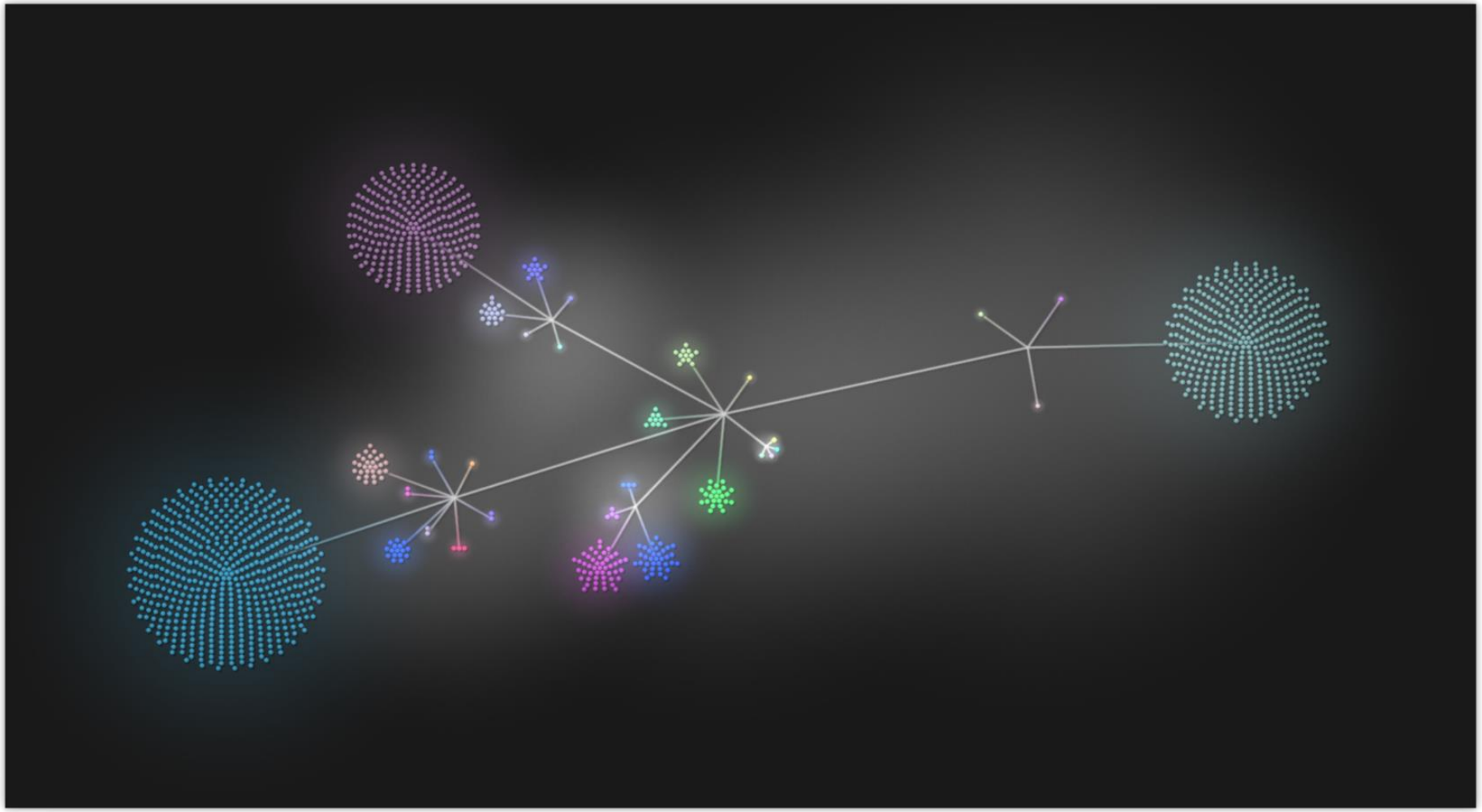
AI – helping BfArM to keep the focus on the big picture…



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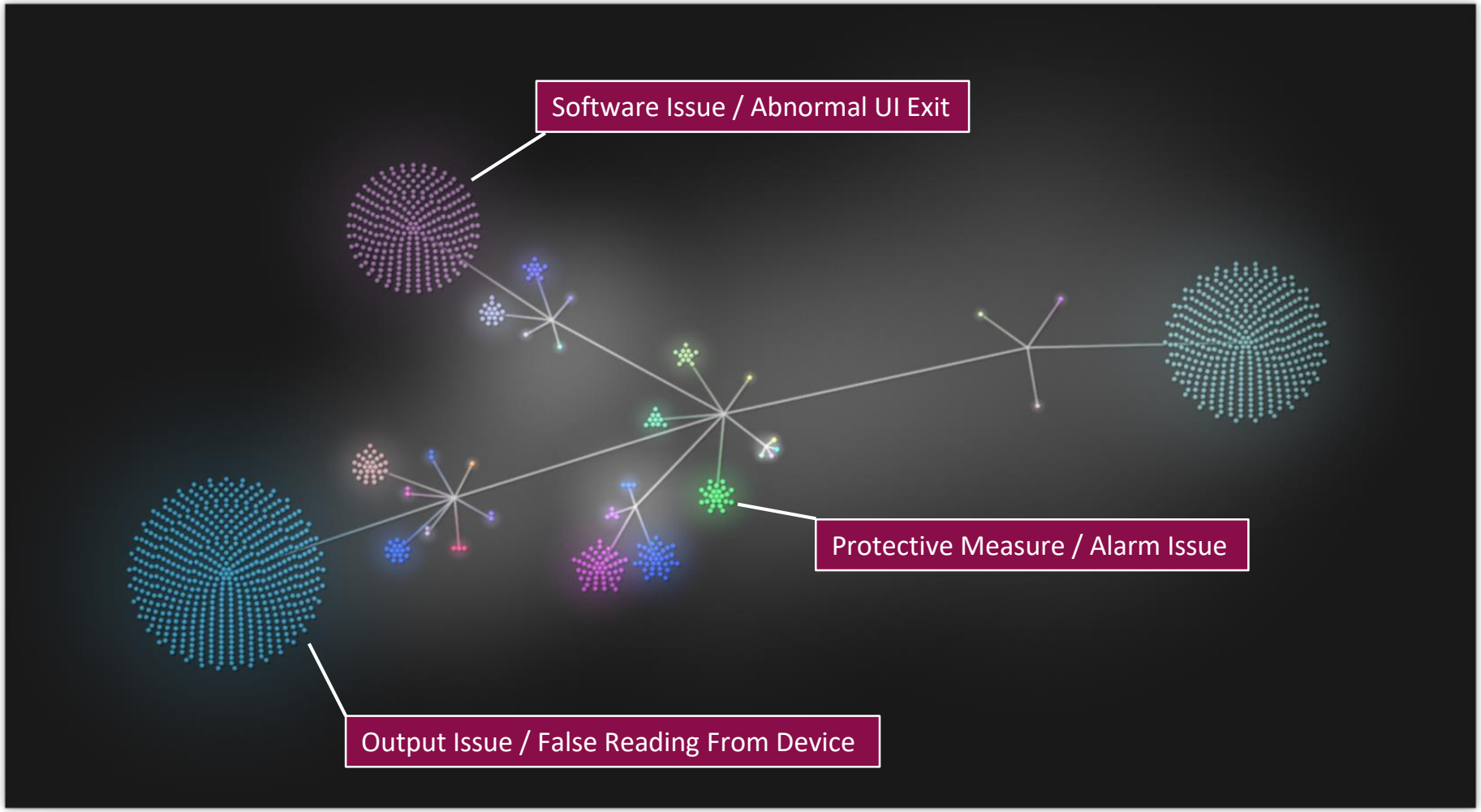
AI – helping BfArM to keep the focus on the big picture…



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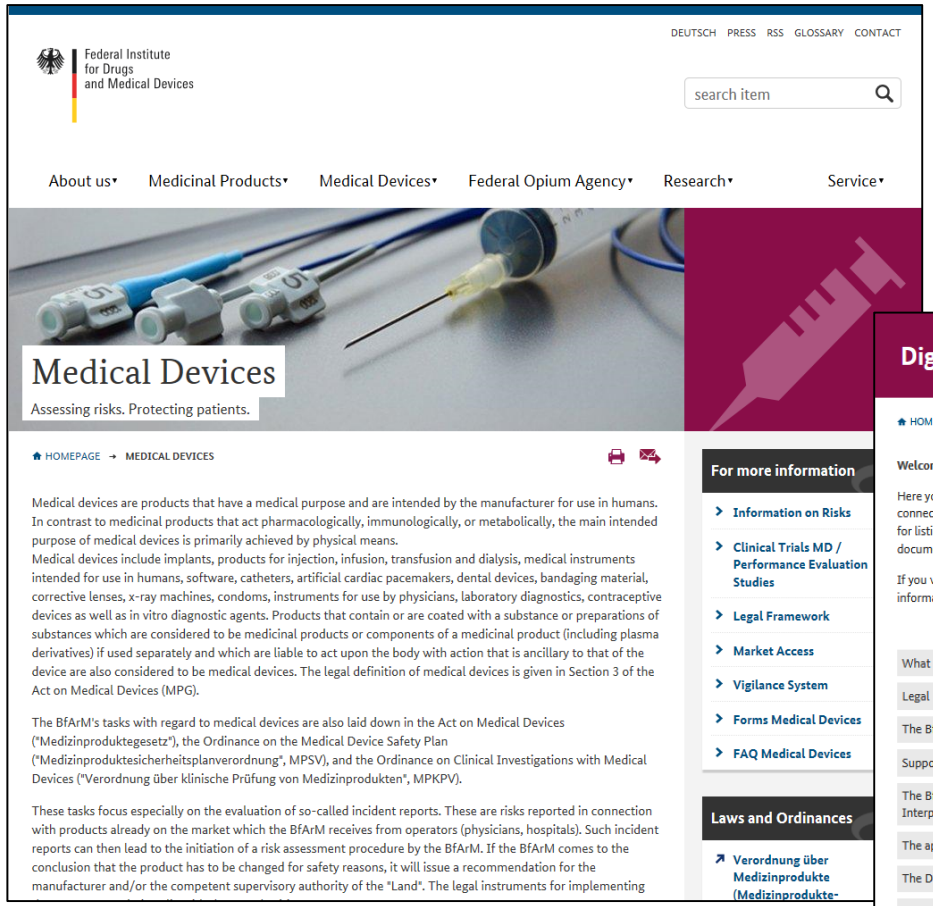
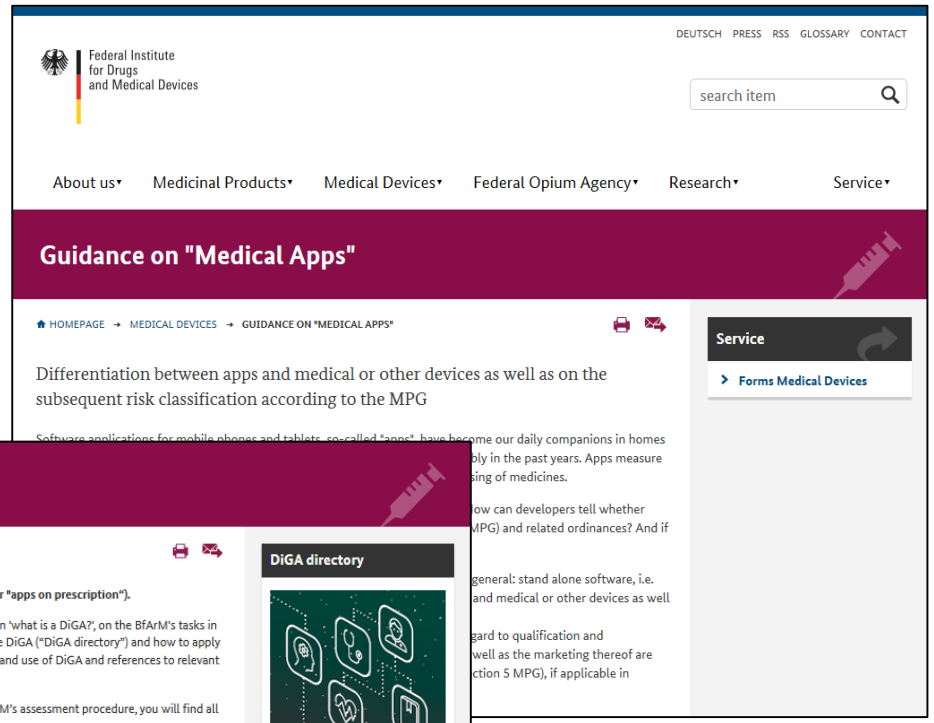
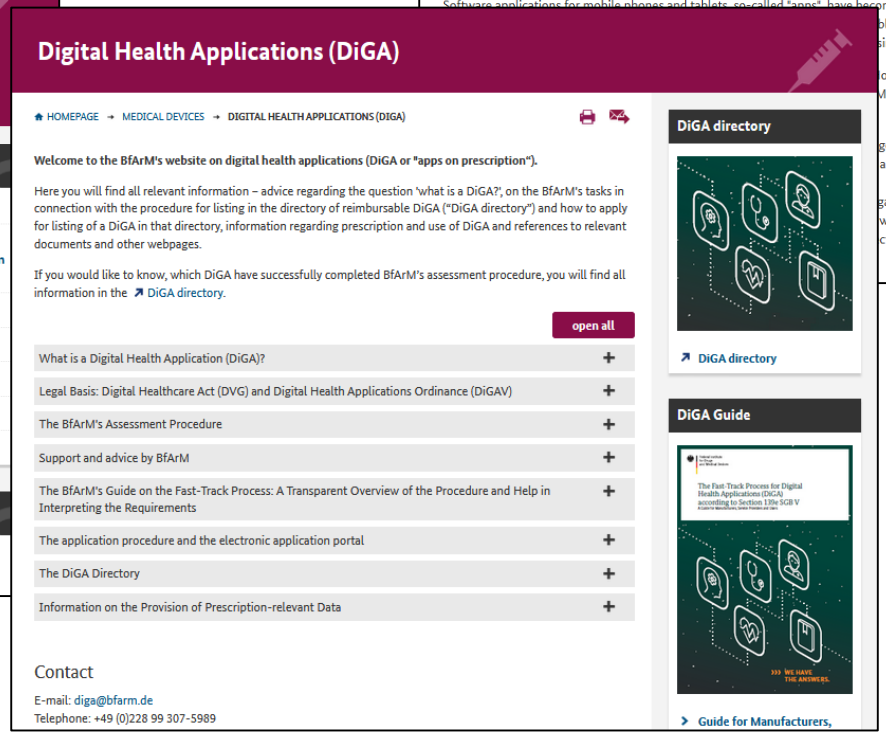
Find out more at www.bfarm.de







Thank you very much for your attention!

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