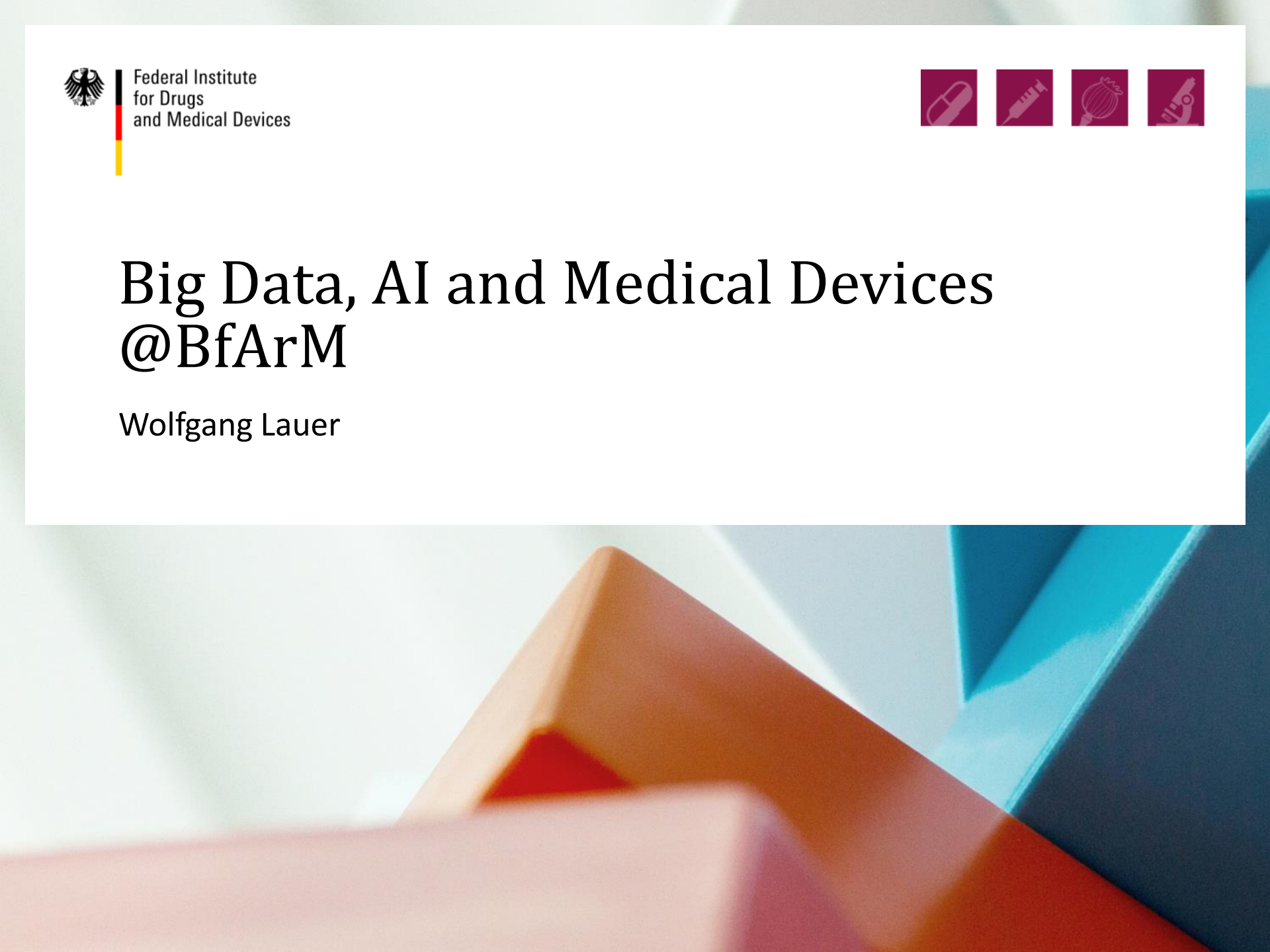
Federal Institute
for Drugs
and Medical Devices

Big Data, AI and Medical Devices @BfArM

Wolfgang Lauer



The German Federal Institute for Drugs and Medical Devices (BfArM)

- Independent federal higher authority within the portfolio of the German Federal Ministry of Health (BMG)
- About 1.100 employees in 10 divisions, located in Bonn
- Tasks
  - Licensing of and improving the safety of medicinal products
  - Detecting and assessing risks of medical devices
  - Monitoring the legal traffic in narcotic drugs and precursors
  - Research with regard to regulatory tasks
- Member of German, European and International networks for research, standardisation and regulatory coordination

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 February 2019
EMA/105321/2019

HMA-EMA Joint Big Data Taskforce

Summary report

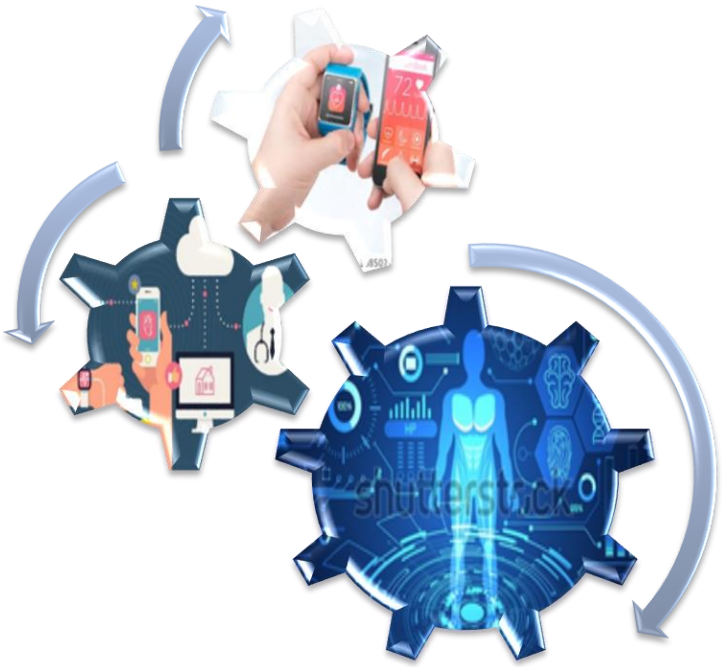
See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is an agency of the European Union

https://www.ema.europa.eu/en/about-us/how-we-work/big-data

Rapid changes to the current health care system



Medical Apps

Real World Data

Precision medicine

Complex Lifecycle Management

eHealth

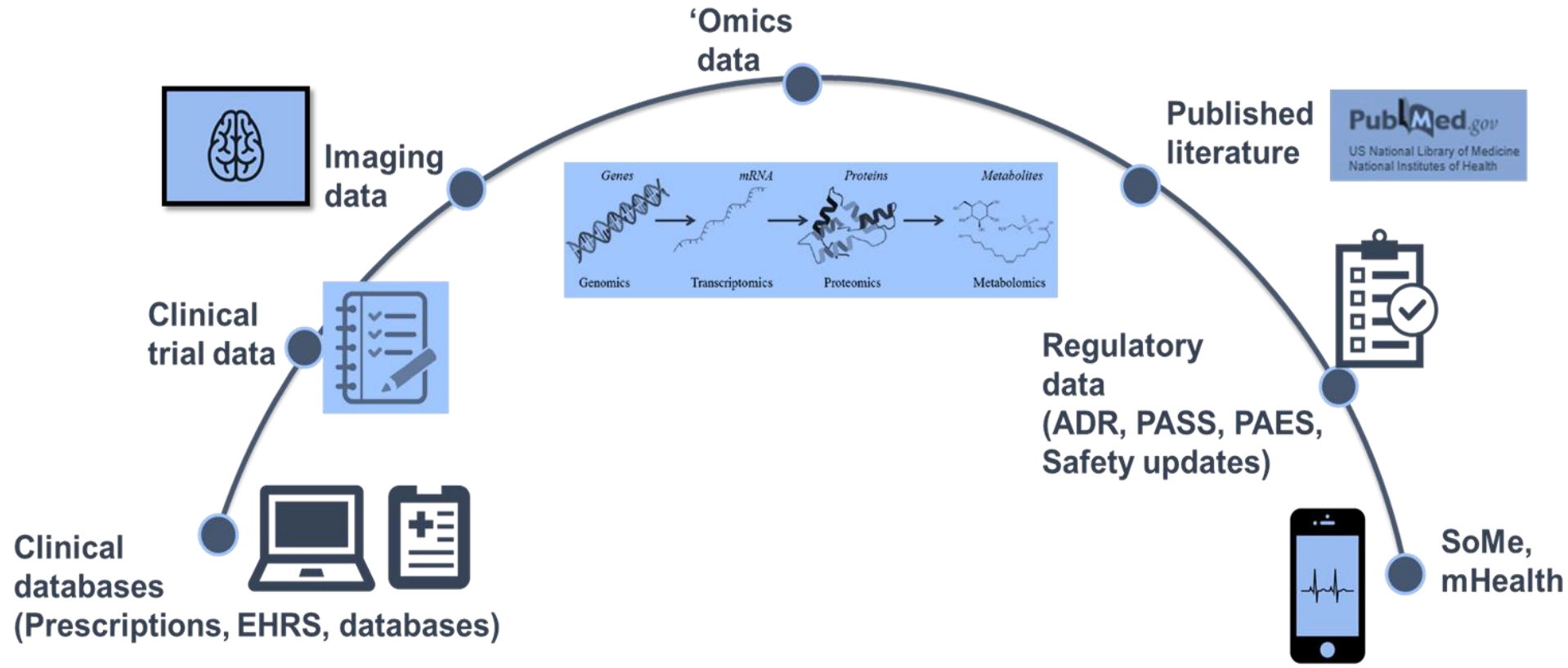
AI

Big Data

Virtual trials

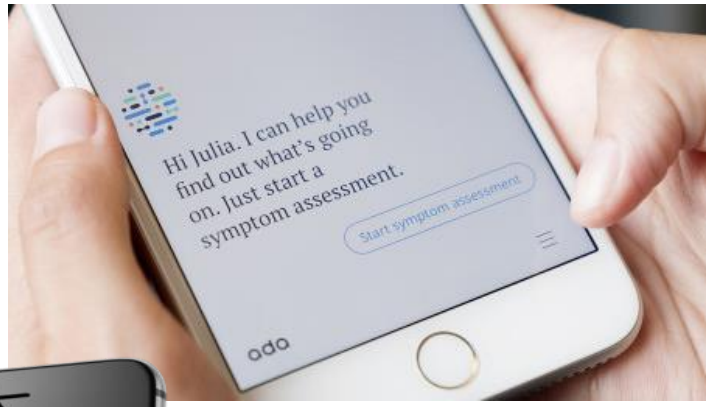
… Challenges and Opportunities for the EU Regulatory Network

Big Data –
Challenges and Chances



New Devices

New possibilities regarding information, diagnosis and therapy…



Source: Apple, CardioSecur, Ada Health

…and tomorrow?

Source: Amazon, Paramount Pictures

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Regulatory Questions

When are apps regulated as medical devices?

Which consequences does it have?

Who is responsible for risk management?

How can AI-based devices be regulated and assessed?

How to ensure cyber security and data protection?

Are developers, hospitals and users aware of these aspects?

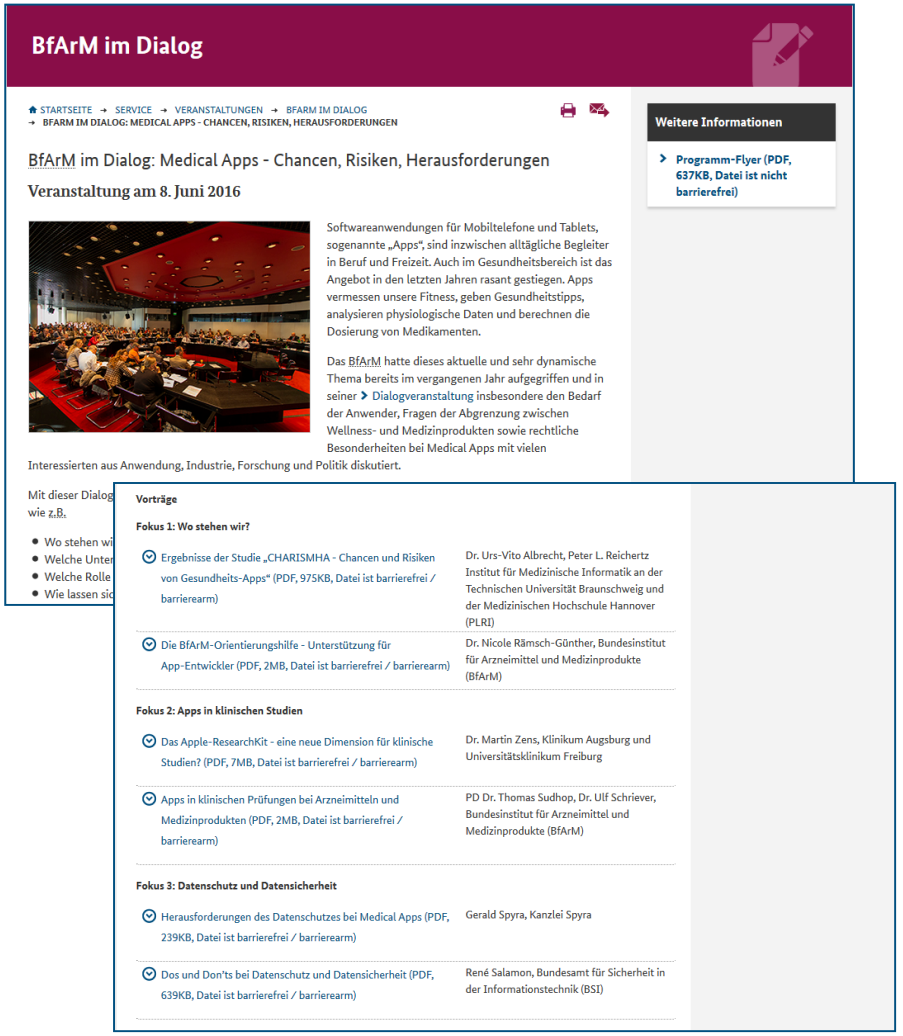
„BfArM in Dialogue - Medical Apps“

Medical Apps 2015

- What happens in clinical reality?
- What is the regulatory framework?
- What are the patient’s needs?
- Which support do authorities and notified bodies provide?
- What are we going to see 2025?

Update 2016

- BfArM Web-Guidance for Medical Apps
- Apps in clinical trials
- Data safety and security
- Start-up experiences with regulation
- From idea to reimbursement – needs, wishes and possibilities



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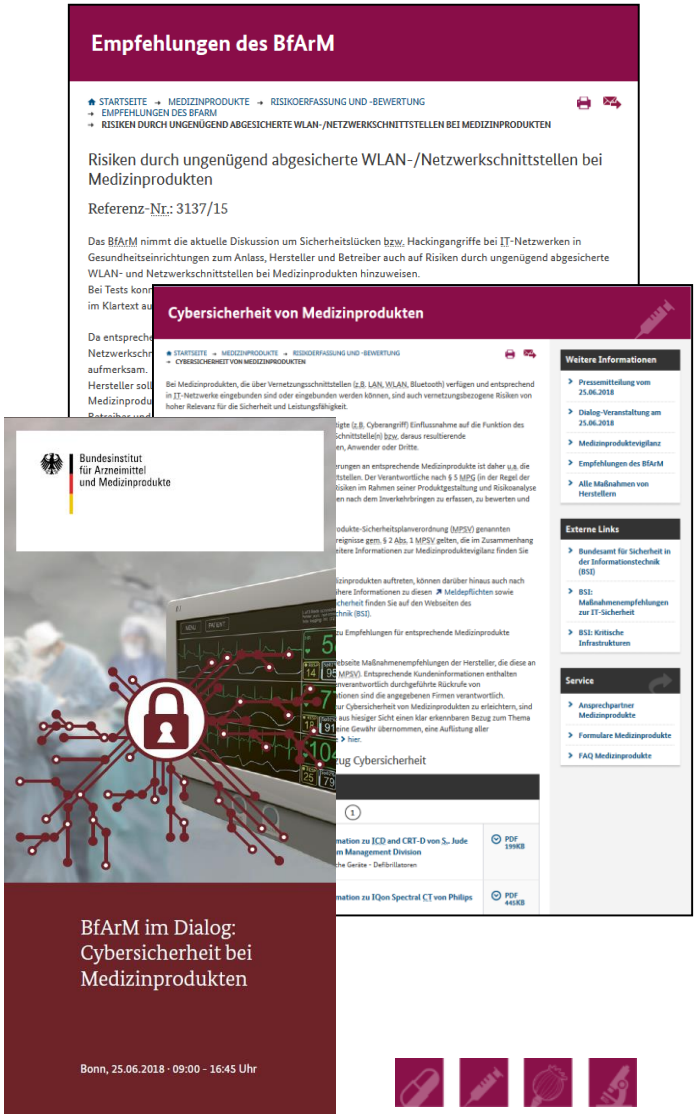
Cybersecurity of Medical Devices

- Already in 2015 recommendations for manufacturers and hospitals regarding non-secure WiFi/Network interfaces
- Since 2018 joint initiative together with BSI (German Federal Office for Information Security): intense information exchange, joint risk assessment, joint recommendations)
- New BfArM website especially on cybersecurity
- „BfArM in Dialogue“ on 25.06.2018
  - Views of Hacker, Manufacturers, Operators
  - Sensitisation for the topic
  - Information on BfArM-support



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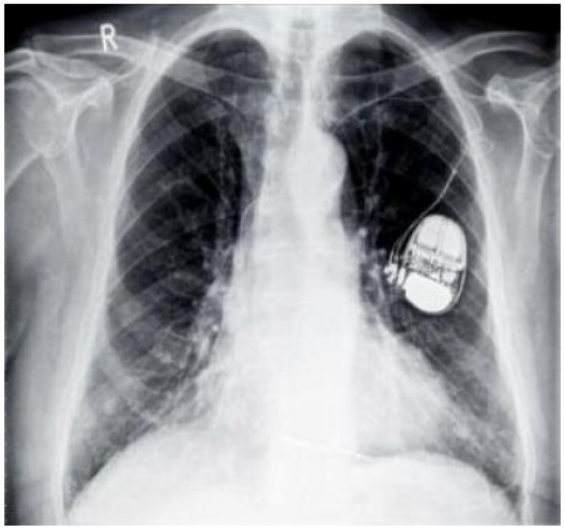
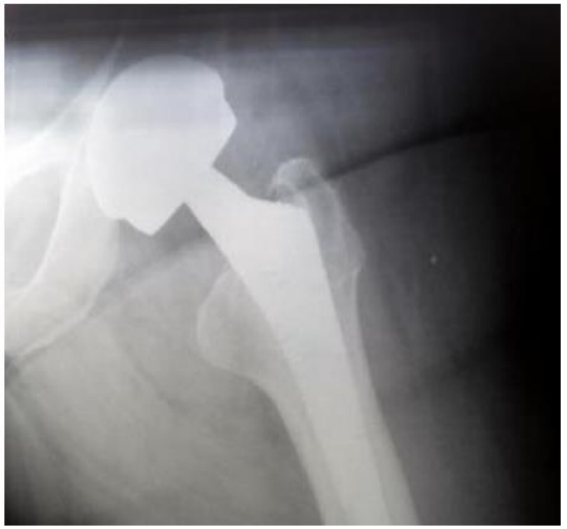
New approaches for risk signal detection

Medical Devices – challenges

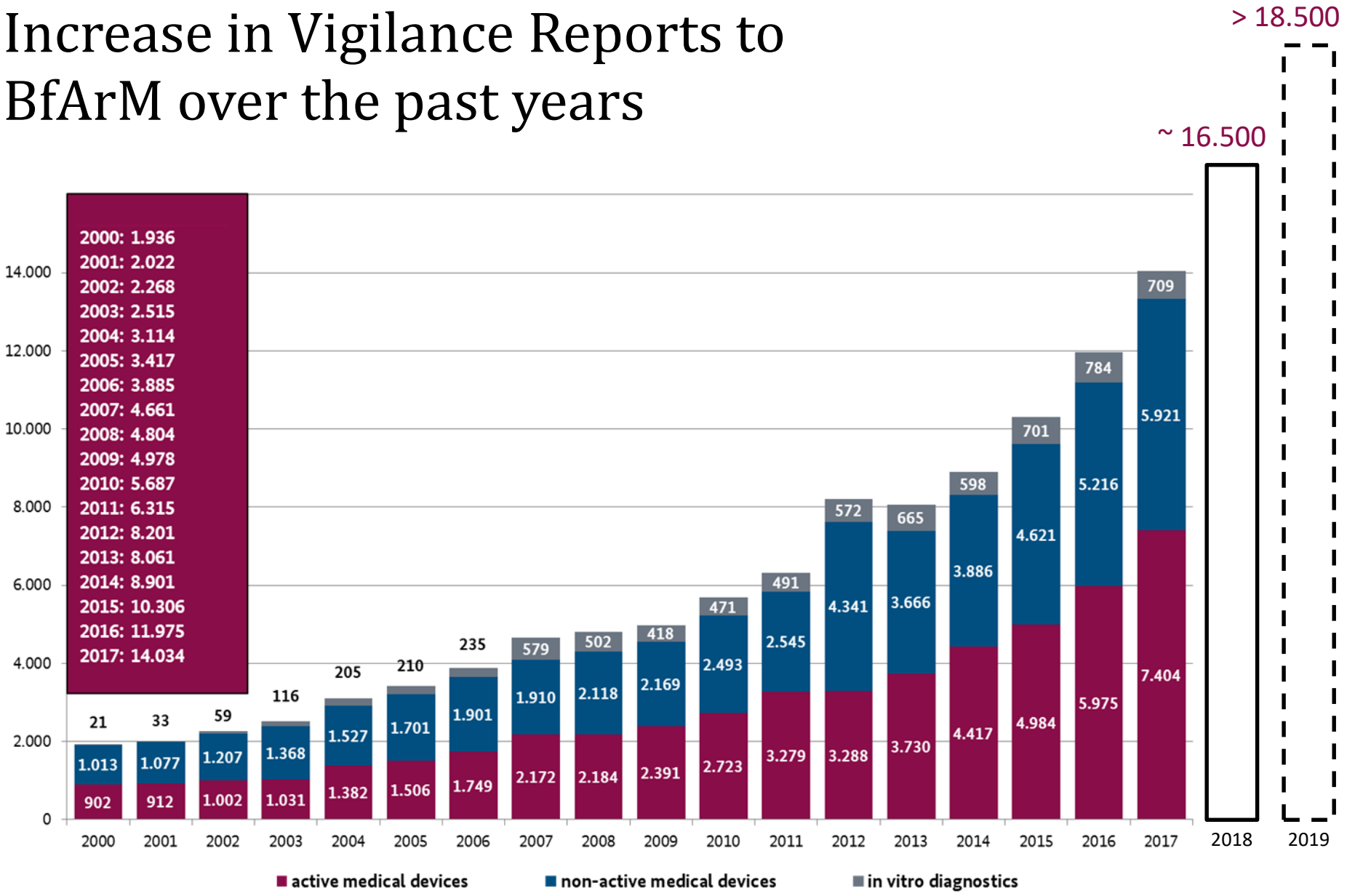


Early and reliable risk detection and scientific assessment

- Increasing product complexity (material, design, digitisation, AI)
- Increasing amount of information (reports, literature, media, …)
- Increasing time pressure

Increase in Vigilance Reports to BfArM over the past years



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Entity indexing / text mining in vigilance reports

The root cause of these failures has been identified to be that the bonding wire from the coil to the soldering pads within the loudspeaker does not withstand normal stress and can break during prolonged usage. SuperMD Ltd will be sending each affected customer an Field Safety Notice. The Urgent Medical Device Correction notification will inform the customer about the future replacement of their speaker assemblies.

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Company:
SuperMD

Type of evaluation:
root cause

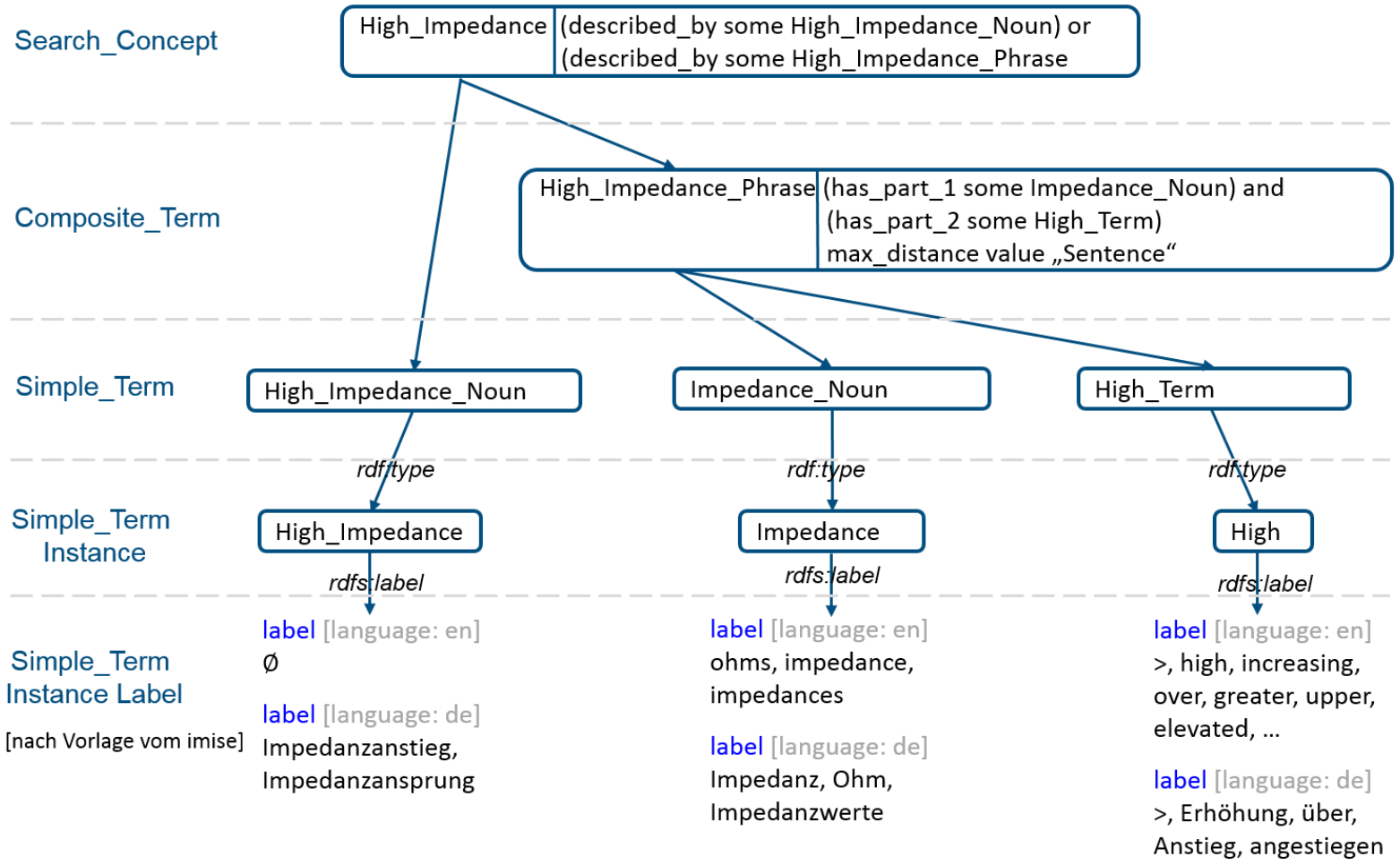
Medical Device Components:
bonding wire, coil, soldering pads, loudspeaker, speaker assemblies

Cause of failure:
normal stress

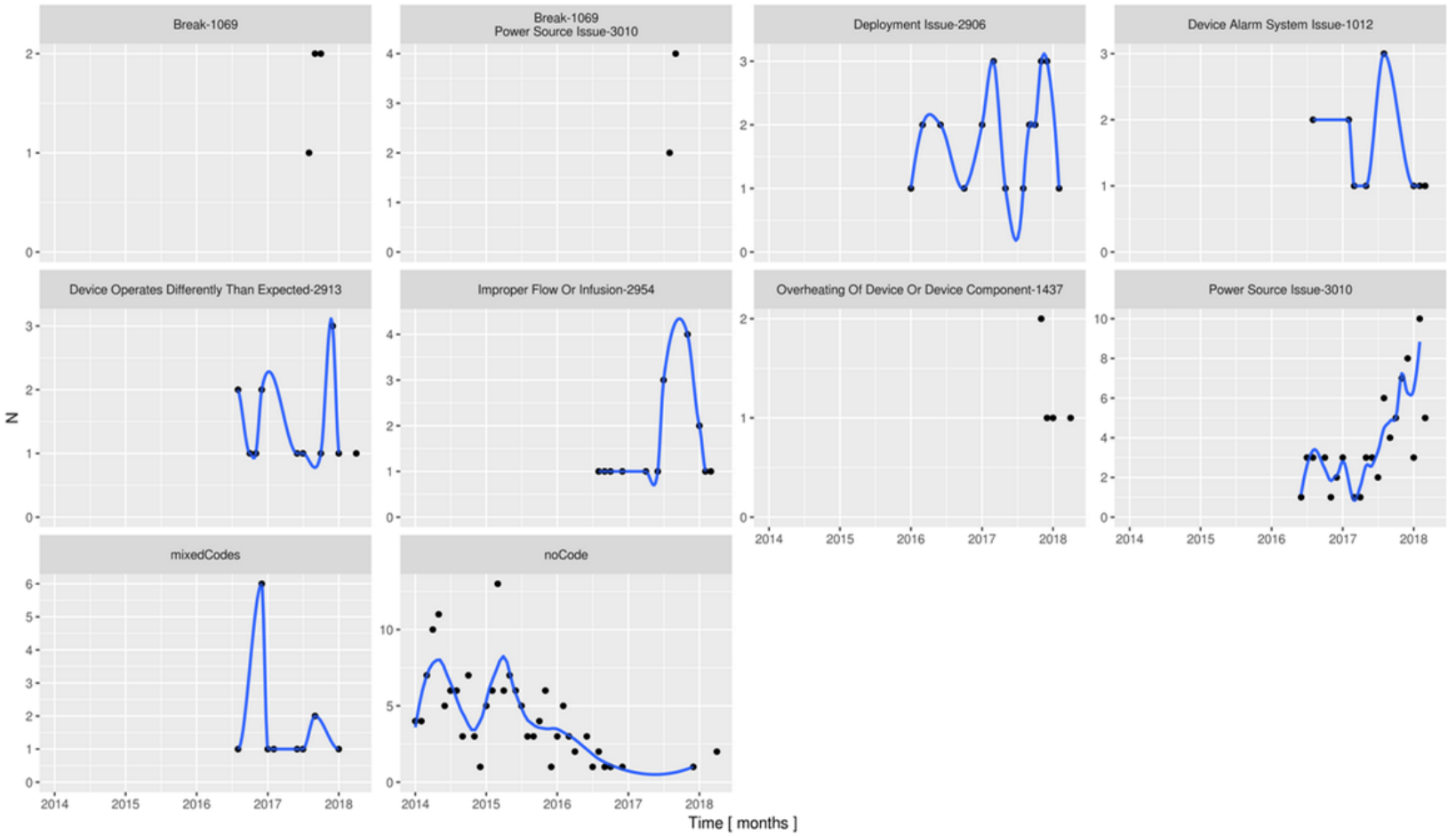
Failure mode:
break

Counter action:
Field Safety Notice, Urgent Medical Device Correction notification, replacement

Ontology research: example high impedance



Coding benefit for identifying trends



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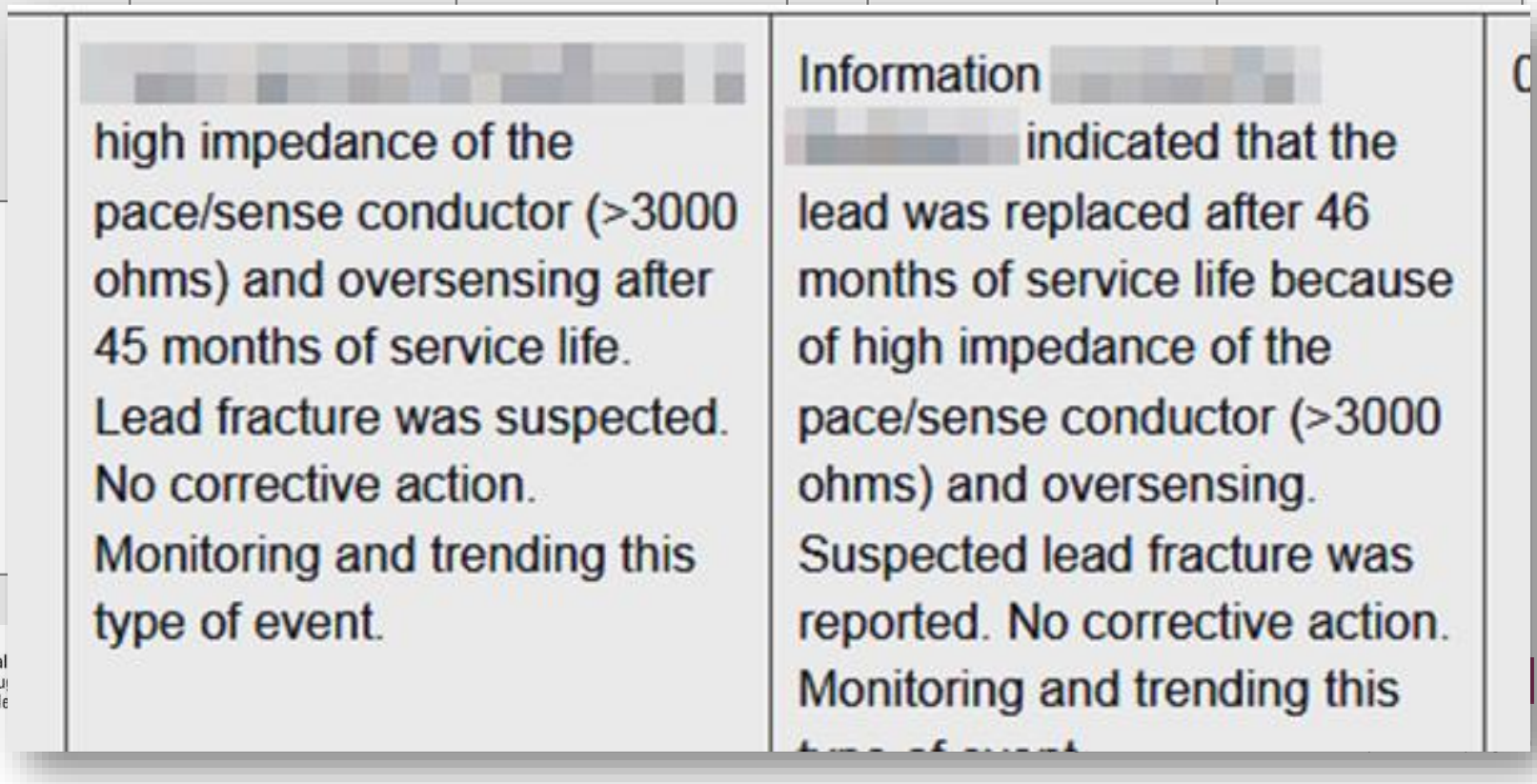
Current research: Proprose free-text classification by using textmining and similarity scores

2.5.2 Best Similars

New incident to be classified	Already classified Incidents	Dissimilarity score	FDA classification	Reference number of the incident already classified
high impedance of the pace/sense conductor (>3000 ohms) and oversensing after 45 months of service life.	Information indicated that the lead was replaced after 46 months of service life because of high impedance of the	0.093	c("High Impedance", "Oversensing")	0298



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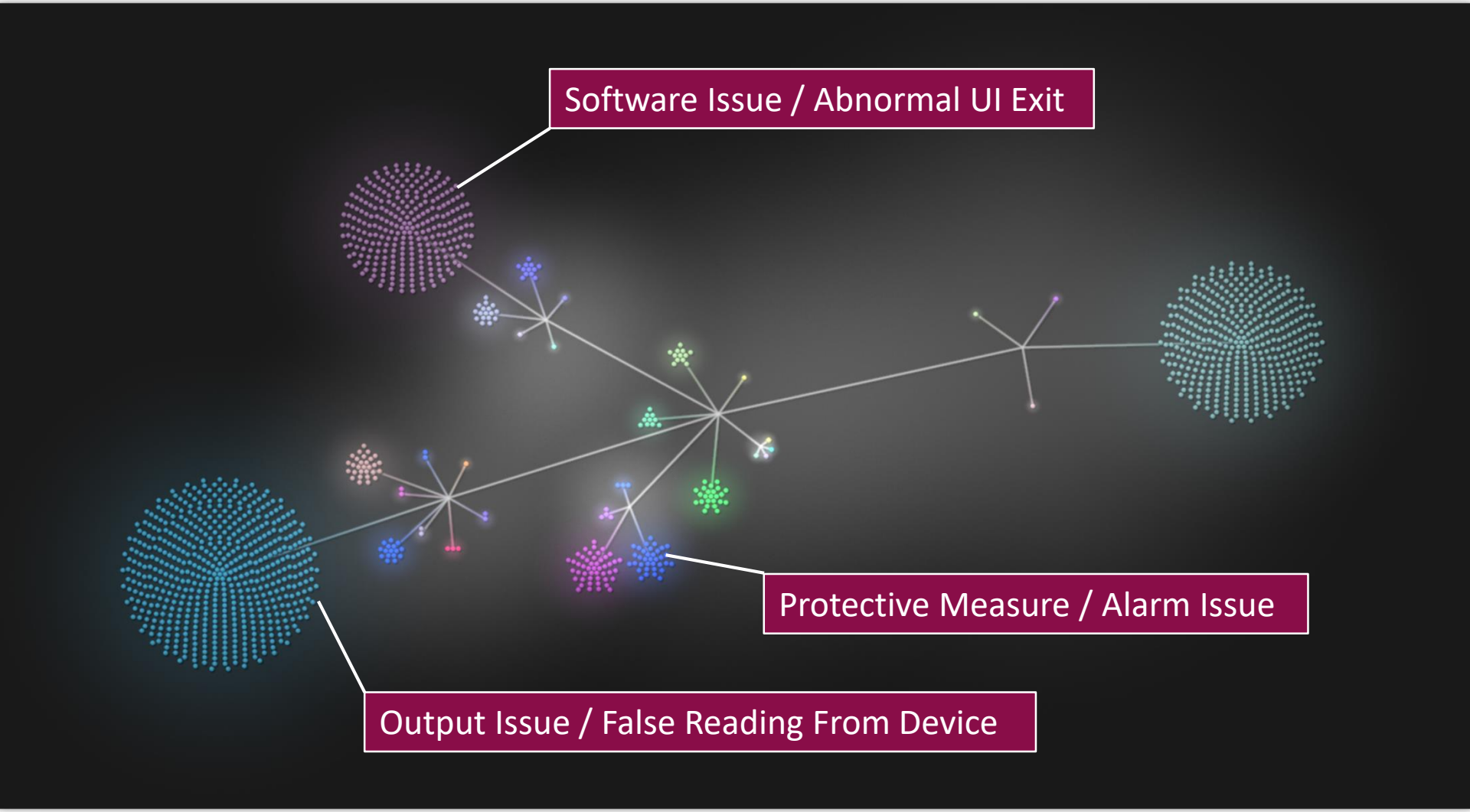
Our goal: To help our assessors seeing the right details…

Software Issue / Abnormal UI Exit

Protective Measure / Alarm Issue

Output Issue / False Reading From Device

…within the big picture. For patient safety.



Thank you very much for your attention!

Contact

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