



Federal Institute  
for Drugs  
and Medical Devices



# Big Data, AI and Medical Devices @BfArM

Wolfgang Lauer

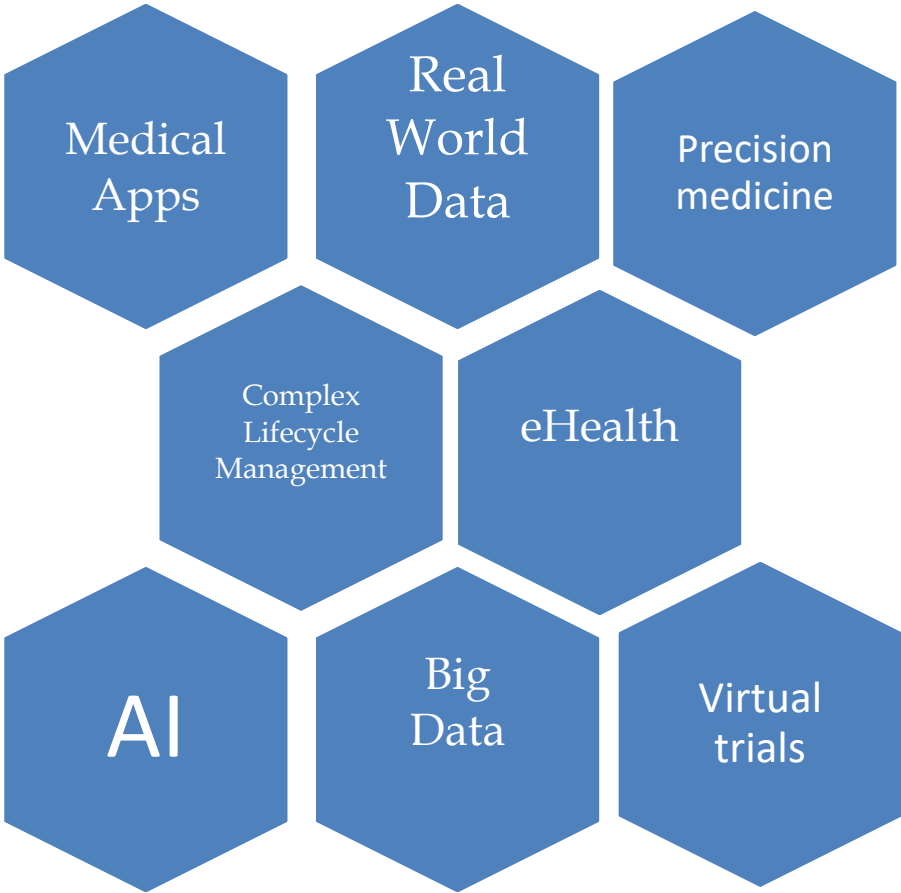
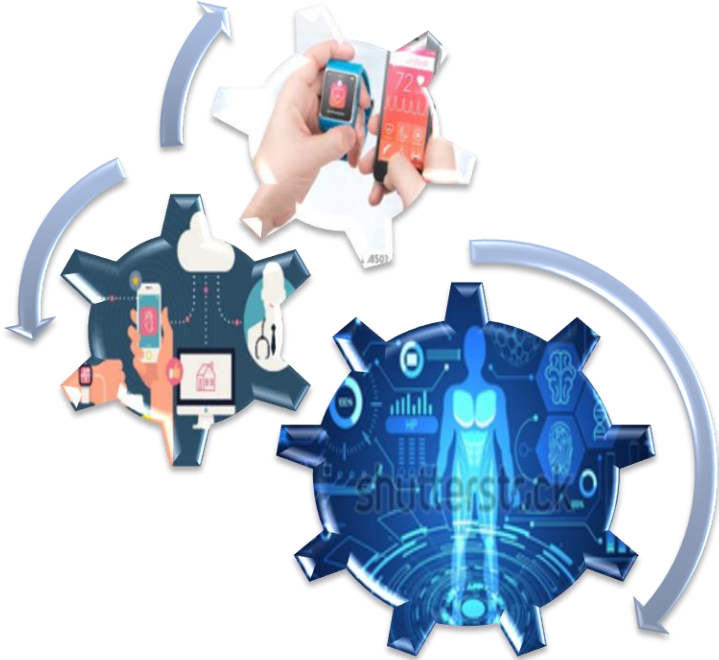
# The German Federal Institute for Drugs and Medical Devices (BfArM)



- 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

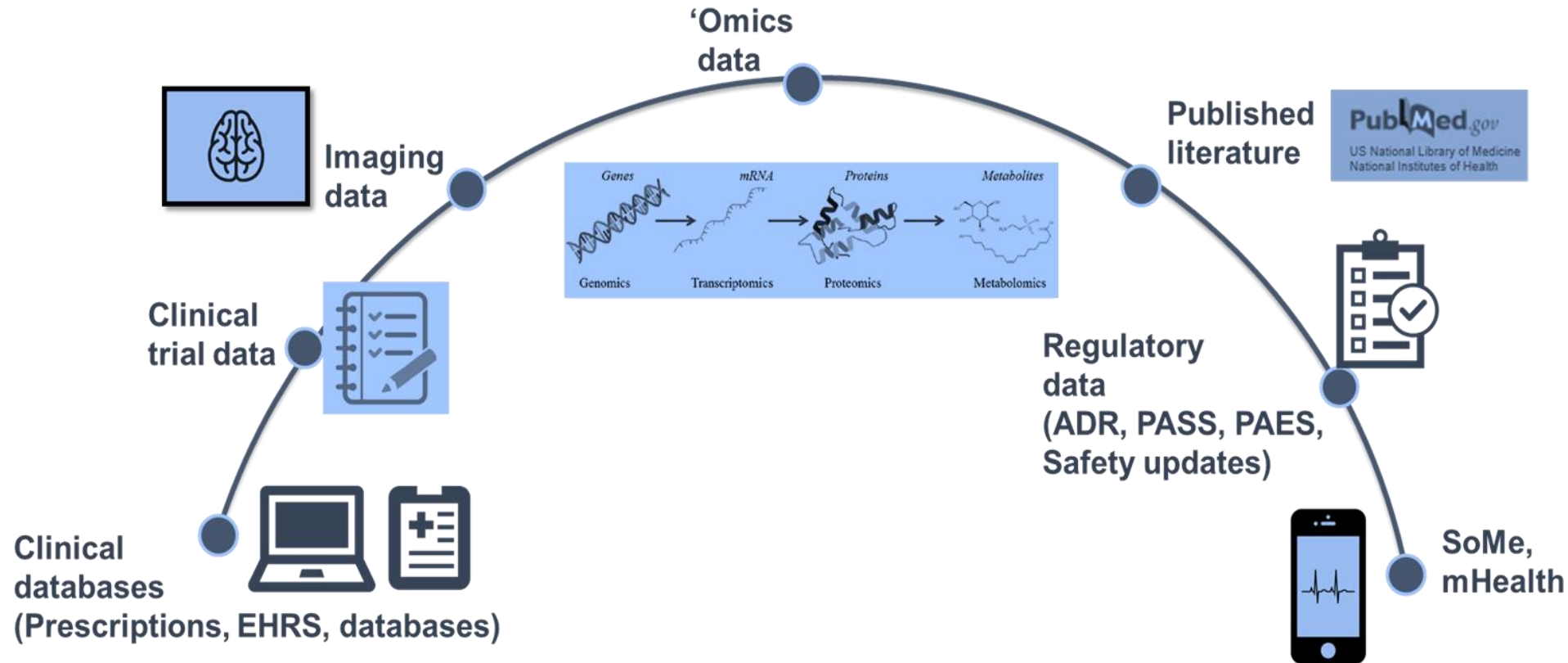


# Rapid changes to the current health care system



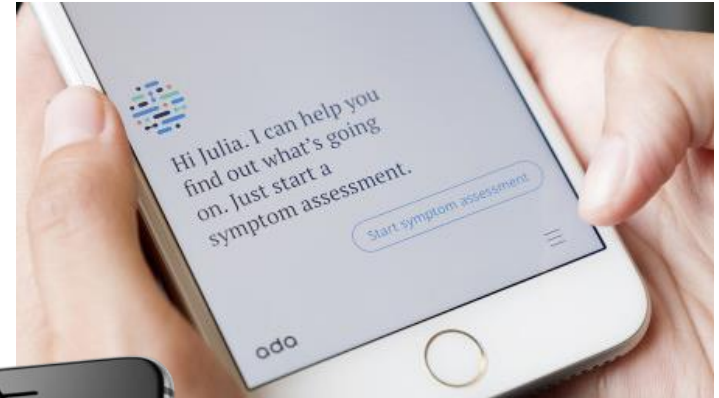
... Challenges and Opportunities for the EU Regulatory Network

# Big Data – Challenges and Chances



# New Devices

# New possibilities regarding information, diagnosis and therapy...



# ...and tomorrow?



Source: Amazon, Paramount Pictures



# 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

### BfArM im Dialog

STARTSEITE → SERVICE → VERANSTALTUNGEN → BfArM IM DIALOG  
→ BfArM IM DIALOG: MEDICAL APPS - CHANCEN, RISIKEN, HERAUSFORDERUNGEN

#### BfArM im Dialog: Medical Apps - Chancen, Risiken, Herausforderungen

Veranstaltung am 8. Juni 2016



Softwareanwendungen für Mobiltelefone und Tablets, sogenannte „Apps“, sind inzwischen alltägliche Begleiter in Beruf und Freizeit. Auch im Gesundheitsbereich ist das Angebot in den letzten Jahren rasant gestiegen. Apps vermessen unsere Fitness, geben Gesundheitstipps, analysieren physiologische Daten und berechnen die Dosierung von Medikamenten.

Das BfArM hatte dieses aktuelle und sehr dynamische Thema bereits im vergangenen Jahr aufgegriffen und in seiner > Dialogveranstaltung insbesondere den Bedarf der Anwender, Fragen der Abgrenzung zwischen Wellness- und Medizinprodukten sowie rechtliche Besonderheiten bei Medical Apps mit vielen Interessierten aus Anwendung, Industrie, Forschung und Politik diskutiert.

Mit dieser Dialogveranstaltung werden wie z.B.

- Wo stehen wir
- Welche Unterstützung
- Welche Rolle
- Wie lassen sich

#### Weitere Informationen

> Programm-Flyer (PDF, 637KB, Datei ist nicht barrierefrei)

#### Vorträge

**Fokus 1: Wo stehen wir?**

- Ergebnisse der Studie „CHARISMHA - Chancen und Risiken von Gesundheits-Apps“ (PDF, 975KB, Datei ist barrierefrei / barrierearm) Dr. Urs-Vito Albrecht, Peter L. Reichertz Institut für Medizinische Informatik an der Technischen Universität Braunschweig und der Medizinischen Hochschule Hannover (PLRI)
- Die BfArM-Orientierungshilfe - Unterstützung für App-Entwickler (PDF, 2MB, Datei ist barrierefrei / barrierearm) Dr. Nicole Rämisch-Günther, Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)

**Fokus 2: Apps in klinischen Studien**

- Das Apple-ResearchKit - eine neue Dimension für klinische Studien? (PDF, 7MB, Datei ist barrierefrei / barrierearm) Dr. Martin Zens, Klinikum Augsburg und Universitätsklinikum Freiburg
- Apps in klinischen Prüfungen bei Arzneimitteln und Medizinprodukten (PDF, 2MB, Datei ist barrierefrei / barrierearm) PD Dr. Thomas Sudhop, Dr. Ulf Schriever, Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)

**Fokus 3: Datenschutz und Datensicherheit**

- Herausforderungen des Datenschutzes bei Medical Apps (PDF, 239KB, Datei ist barrierefrei / barrierearm) Gerald Spyra, Kanzlei Spyra
- Dos und Don'ts bei Datenschutz und Datensicherheit (PDF, 639KB, Datei ist barrierefrei / barrierearm) René Salomon, Bundesamt für Sicherheit in der Informationstechnik (BSI)

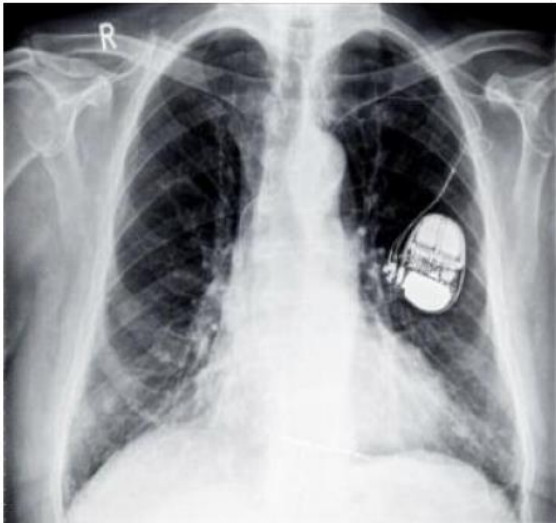


# Cybersecurity of Medical Devices

- 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

# New approaches for risk signal detection

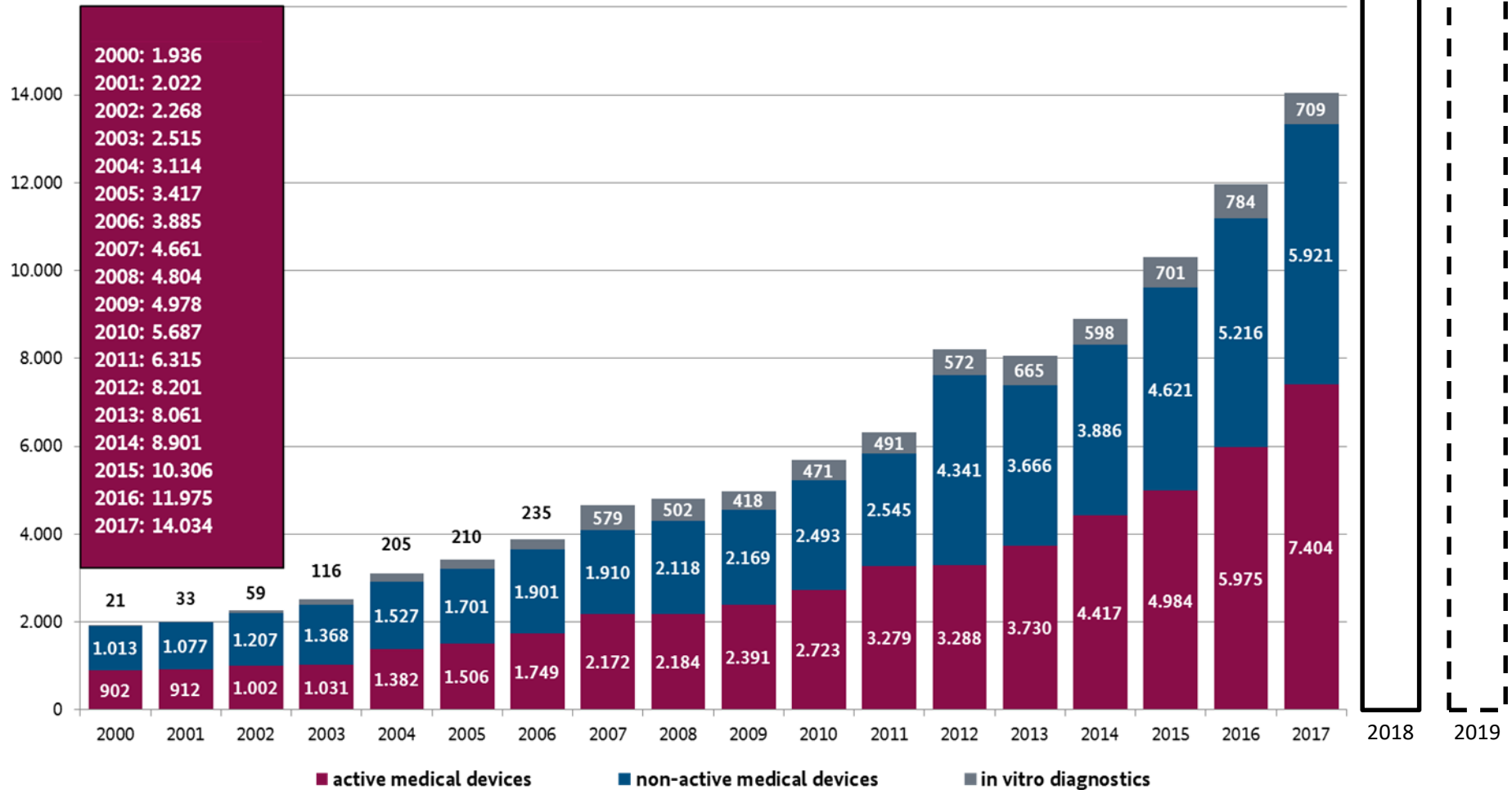
# Medical Devices – challenges



## 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



# 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.

# 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**.



# 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**.

Company:  
**SuperMD**

Type of evaluation:  
**root cause**

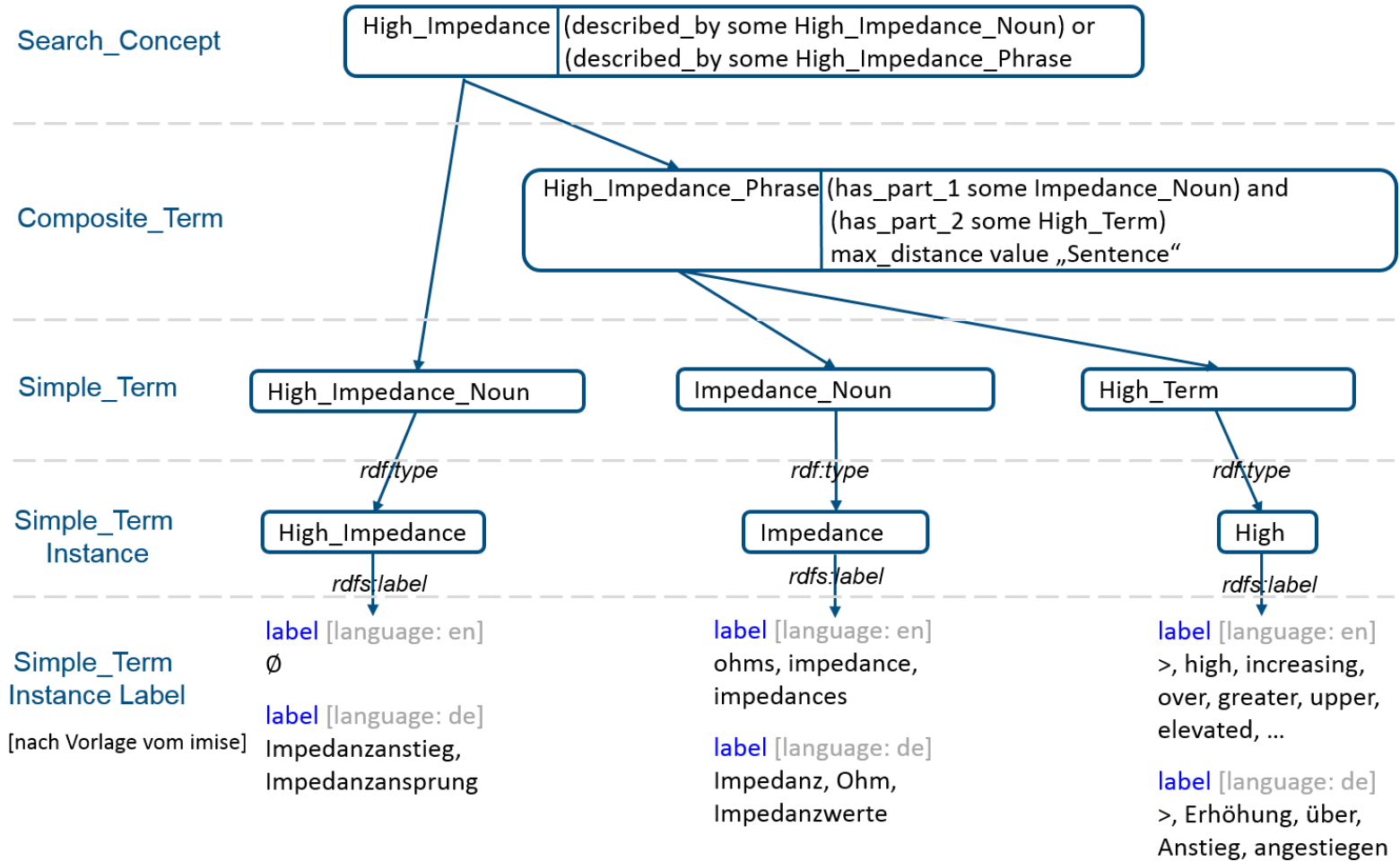
Medical Device Components:  
**bonding wire, coil, soldering pads, loudspeaker, speaker assemblies**

Cause of failure:  
**normal stress**

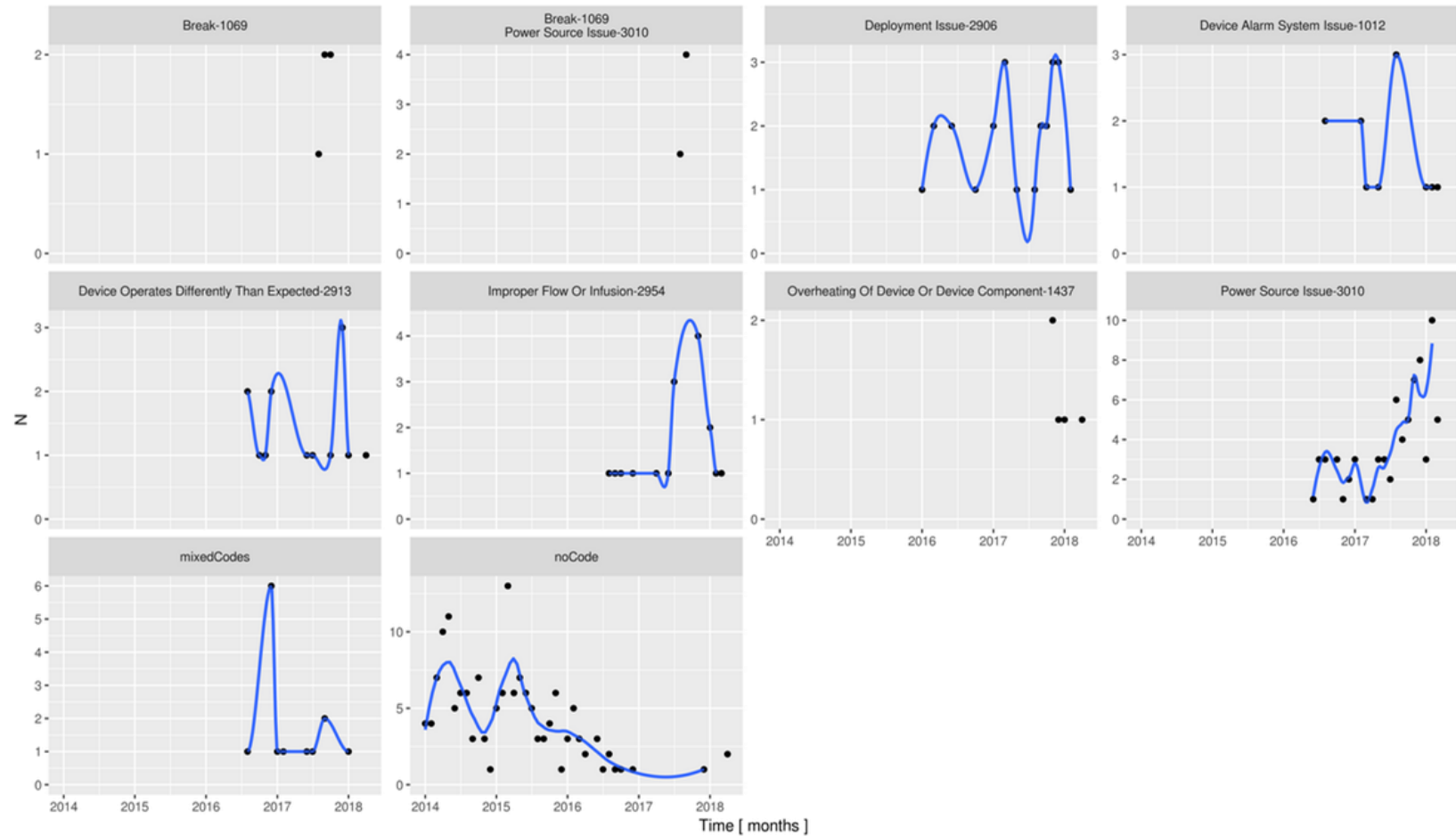
Failure mode:  
**break**

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

# Ontology research: example high impedance



# Coding benefit for identifying trends



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

## 2.5.2 Best Similar

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

high impedance of the pace/sense conductor (>3000 ohms) and oversensing after 45 months of service life. Lead fracture was suspected. No corrective action. Monitoring and trending this type of event.

Information indicated that the lead was replaced after 46 months of service life because of high impedance of the pace/sense conductor (>3000 ohms) and oversensing. Suspected lead fracture was reported. No corrective action. Monitoring and trending this type of event.

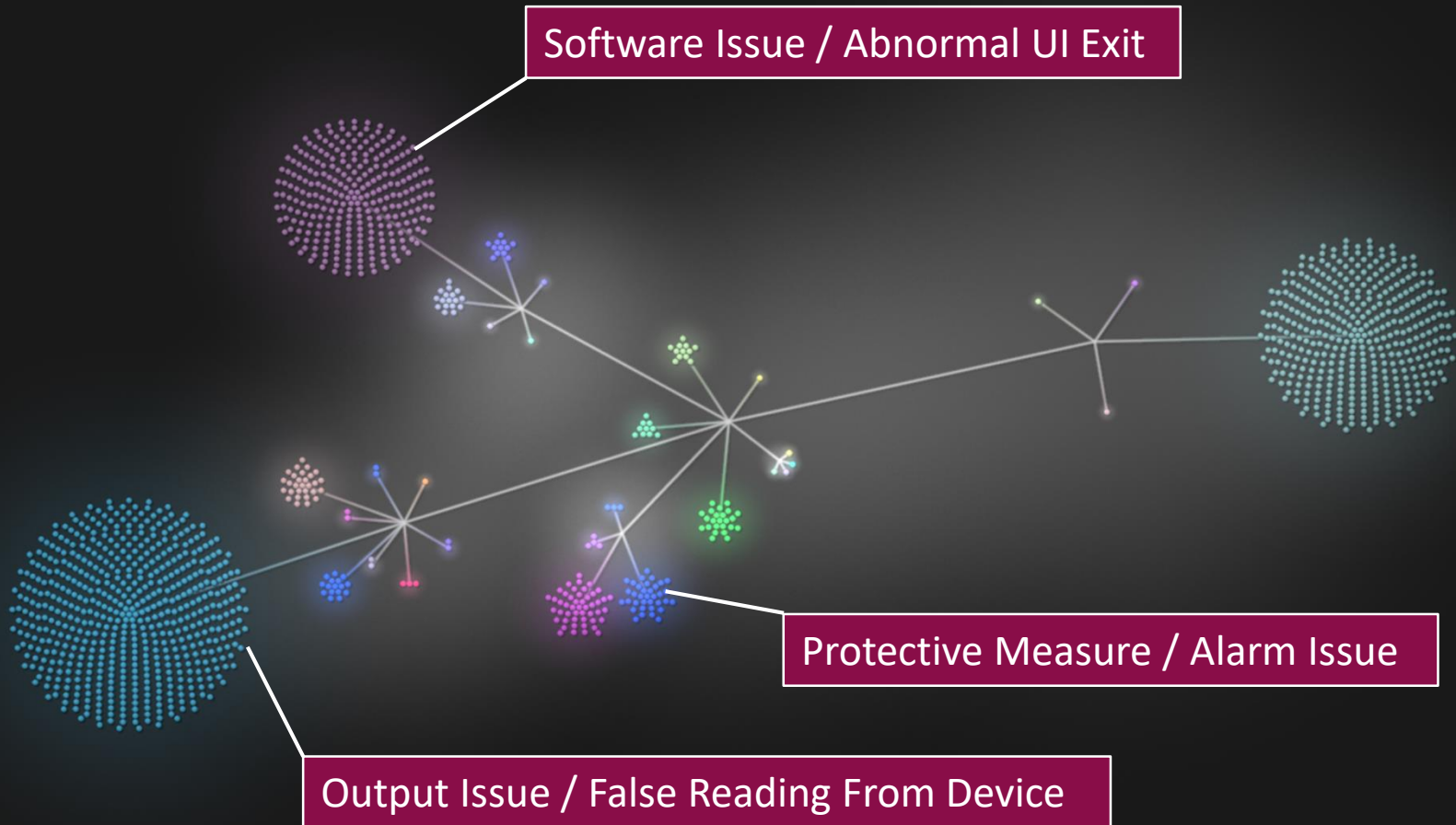
# Our goal: To help our assessors seeing the right details...

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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