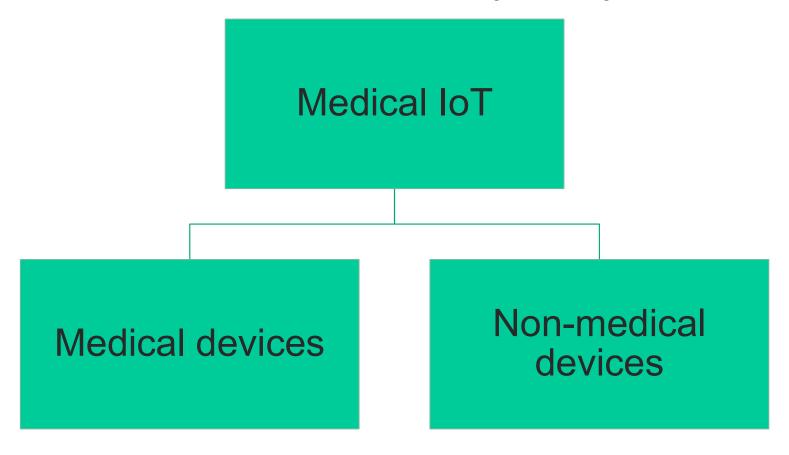
## Warsaw University of Technology

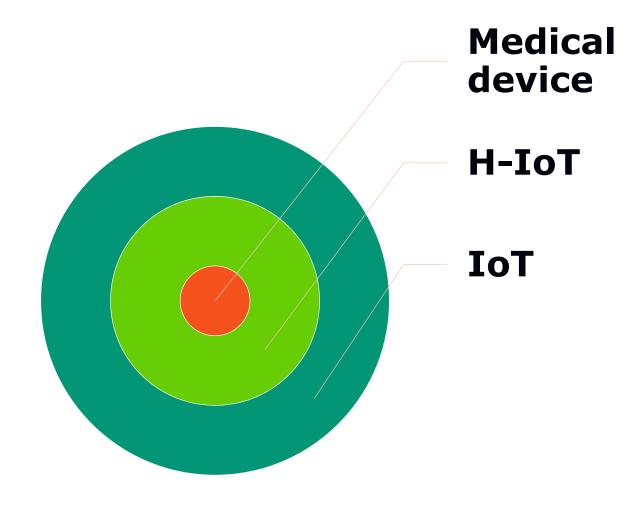
# **Cybersecurity Requirements in Post Market Surveillance of Medical IoT**

Jarosław Greser, PhD

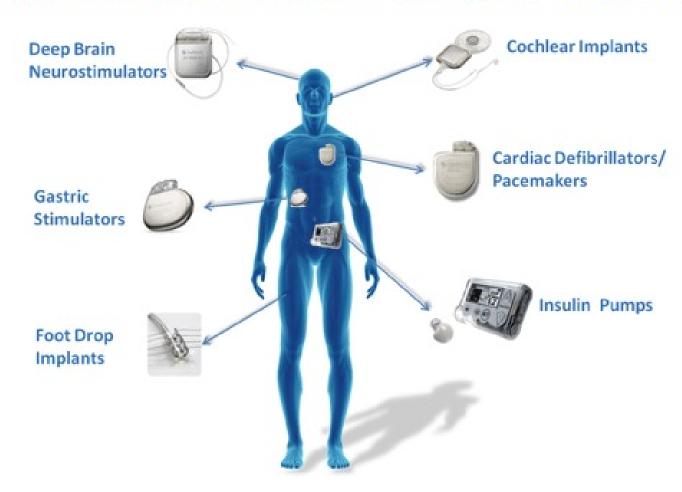
#### **Medical IoT definition (M-IoT)**



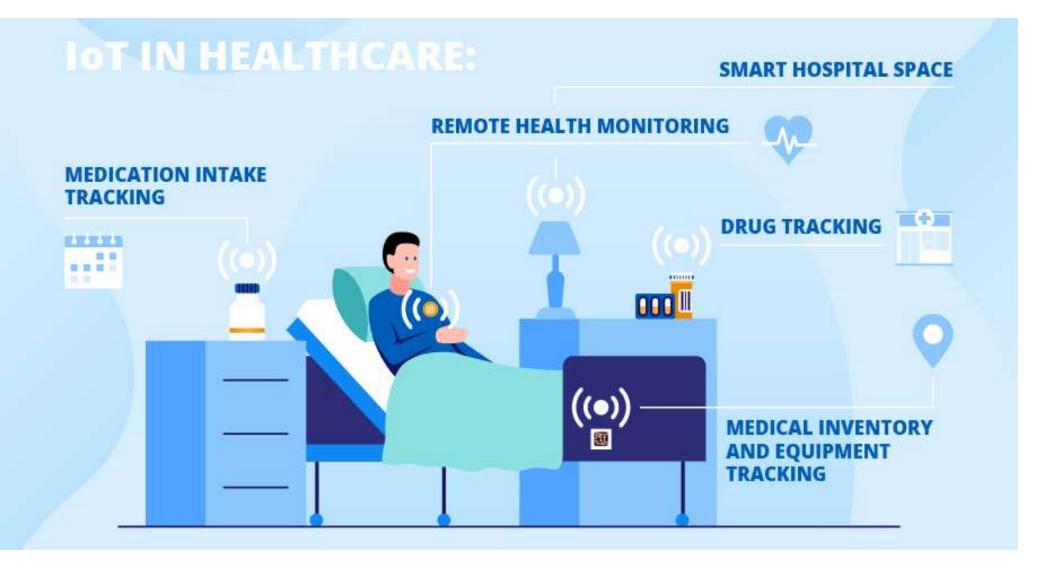
#### **Medical IoT definition (M-IoT)**



#### WIRELESS IMPLANTABLE MEDICAL DEVICES



https://www.researchgate.net/publication/326568227/figure/fig2/AS:652452772724738@1532568271763/Example-IoT-medical-devices-on-a-patients-body.png



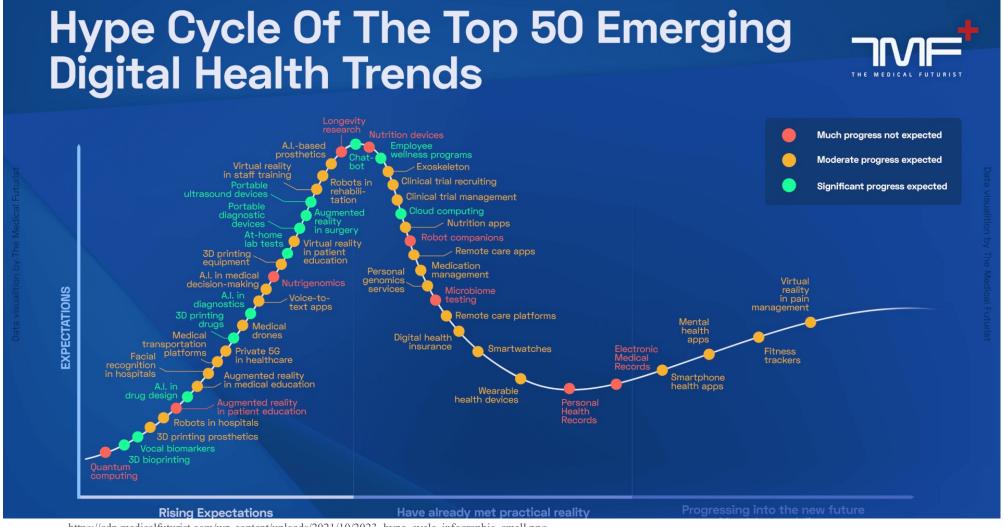
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https://zaufanatrzeciastrona.pl/post/hakowanie-warunkiem-przezycia-o-lamaniu-zabezpieczen-ktore-ratuje-pacjentow/

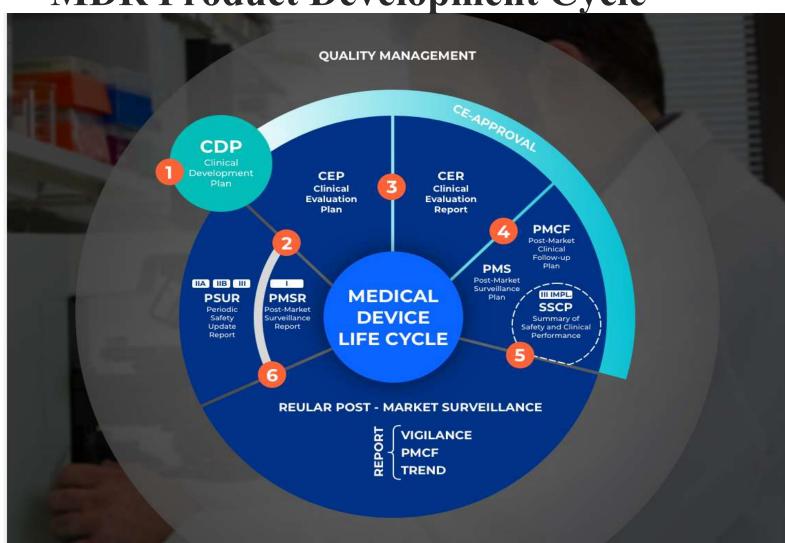
#### **Future of M-IoT**



#### Typical cybersecurity issues of IoT

- 1. Design and prototyping methods
- 2. Technical requirements
- 3. Orphant devices

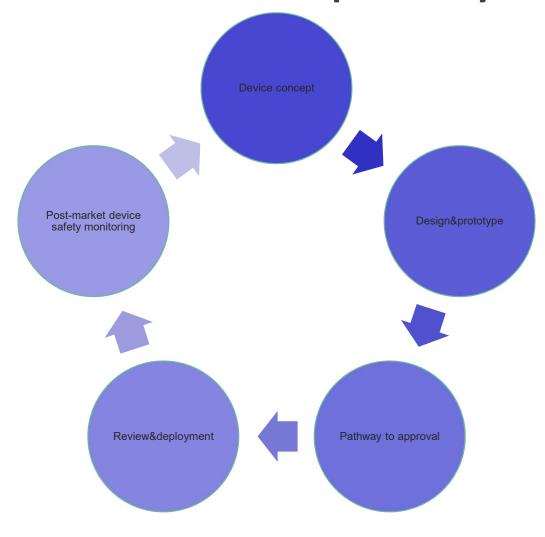
**MDR Product Development Cycle** 

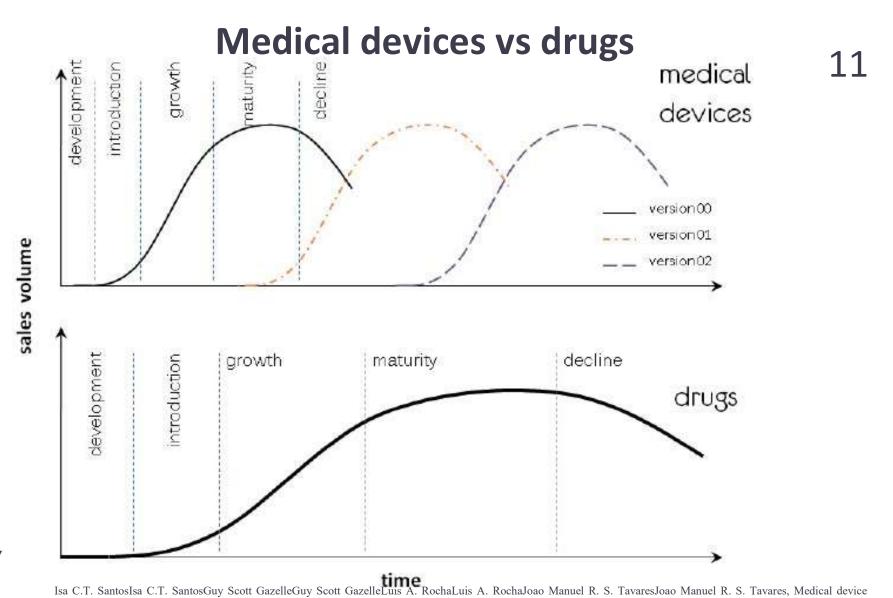


https://vilmate.com/blog/mdr-compliance/

#### 10

#### **FDA Product Development Cycle**





Isa C.T. SantosIsa C.T. SantosGuy Scott GazelleGuy Scott GazelleGuy A. RochaLuis A. RochaJoao Manuel R. S. TavaresJoao Manuel R. S. Tavares, Medical device specificities: opportunities for a dedicated product development methodology, Expert Review of Medical Devices 9(3):299-311, DOI: 10.1586/erd.12.3

#### Types of surveillance activities in MDR

**Manufacturers** 

1.Post-marketSurveillance2.Vigilance

Competent authorities of a Member State

1.Market
Surveillance

#### Types of surveillance activities in MDR

### Post-market Surveillance

- 1.post-market surveillance plan2.periodic safety update report3.analysis reporting of serious incidents
- 4.safety corrective actions

#### Vigilance

- 1. trend reporting
- 2. analysis of vigilance

#### Cybersecurity of medical devices in MDR

- 1. Lack of direct cybersecurity regulations
- 2. Any medical device placed on the market must meet the general safety and performance requirements set out in Annex I which applies to it, taking into account its intended purpose
- 3. The **IT security** is addressed explicitly in Annex I, Articles 17.2, 17.4, 18.8 and inexplicitly in section 1 of Medical Devices Regulations Annex I

#### Cybersecurity of medical devices in MDR

- 1. Guidance on Cybersecurity for Medical Devices (December 2019)
- 2. Issued by Medical Device Coordination Group under art. 105(c)

Representative sources of data to build appropriate capture system. MDRs Non conformance Audits

Recalls Complaints OOS

Service Data

Literature Media

PM Clinicals

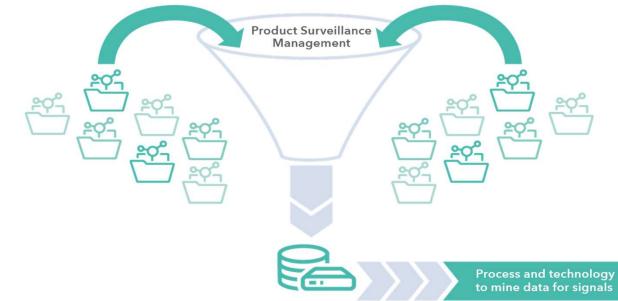
RWE

Custon Surve

**PROACTIVE** 

Required set of processes to handle events in a timely and efficient manner. This will include prioritization and handling algorithms.

Master Data Set that is available for reporting and signal detection. Need to bring the current post-market safety data from across Company into a centralized system



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https://www.iqvia.com/blogs/2018/09/planning-for-the-medical-device-market

#### Cybersecurity of medical devices in other legal acts

- 1. GDPR, in particular Articles 5(1)(f) and 32
- 2. Cybersecurity Act the European Cybersecurity Certification Framework
- **3. Al Act** article 15 According to recital 30, this Regulation will only apply where the Al system is a safety component of the product and undergoes the conformity assessment procedure with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation.

#### **Cybersecurity of non-medical devices**

- 1. Commission Delegated Regulation 2022/30
- 2. Proposal for Cyber Resilience Act
- 3. Sectoral regulations
- 4. Consumer regulations

Thank you for your attention!