



**IMDRF**  
International Medical Device  
Regulators Forum

**EU2023**  
EUROPEAN UNION  
*Chair*



European  
Commission

European  
Union

# PMS for software

apped if you do, apped if you don't

**Kees Maquelin, GMTA/ MedTech Europe**

**March 27, 2023**



# PMS in software life cycle

risk impact assessment  
design change  
...

Act



Plan

PMS plan  
PE plan  
...



Do

vigilance  
customer service  
complaints  
...



Check

active data collection  
- public databases  
- Literature  
- testing  
...



# PMS for SaMD

- Software as a Medical Device (**SaMD**) = Medical Device Software (**MDSW**) = Medical Device (**MD**) /In-vitro Diagnostic medical device (**IVD**)
  - Active and passive PMS data collection
- Horizontal legislation: AI act, GDPR, Cyber resilience act, Data governance act, EHDS

# SaMD specifics

	SaMD general	App specific
Revision turn around time	fast	very fast
Operating systems	several	very many
Range of devices	many	enormous
Typical user	HCP	lay-person
Number of users	many	enormous



## THE HISTORY OF ANDROID : EVOLUTION OF THE BIGGEST OPERATING SYSTEM



# App PMS impact on manufacturer

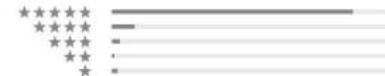
- Faster life cycle
- More OS and device platforms
- More passive input
  - Customer service contacts vs install base
- More sources for active input
  - Social media
  - App store rating
  - OS updates



## Ratings & Reviews

[See All](#)

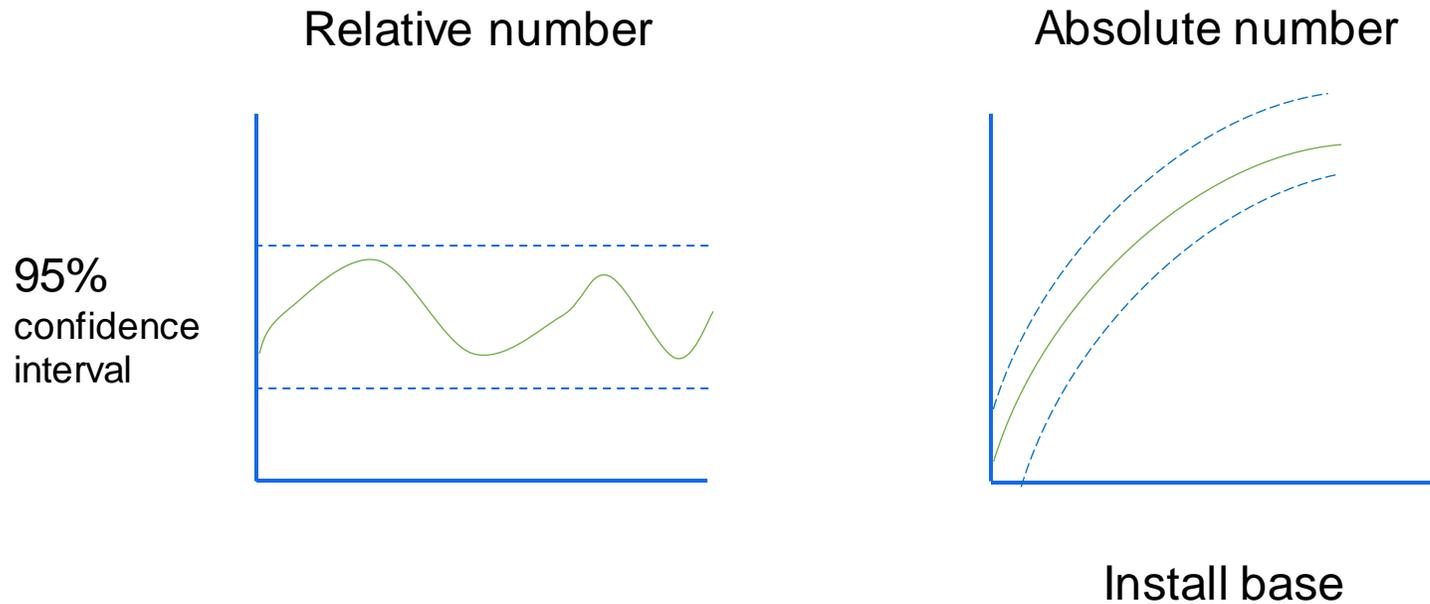
**4.7**  
out of 5



4,922,118 Ratings

# App PMS impact on manufacturer

- Increase in vigilance notifications



# App PMS impact on competent authorities

- Increase in vigilance notifications
- Resource considerations
- Understanding of app eco-system

# Topics to consider for PMS strategy

- Decentralization of care (apps) will increase significantly
- Guidance on SaMD/app PMS signal processing
- Harmonized approach in vigilance assessments by competent authorities
- Standardization



**IMDRF**  
International Medical Device  
Regulators Forum

**EU2023**  
EUROPEAN UNION  
*Chair*

# THANK YOU

**Kees Maquelin**

**GMTA, MedTech Europe**

**[kees.maquelin@abbott.com](mailto:kees.maquelin@abbott.com)**

## Disclaimer

This document was produced by the International Medical Device Regulators Forum. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the International Medical Device Regulators Forum.

Copyright 2021 by the International Medical Device Regulators Forum.

