IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

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PMS for software

apped if you do, apped if you don’t

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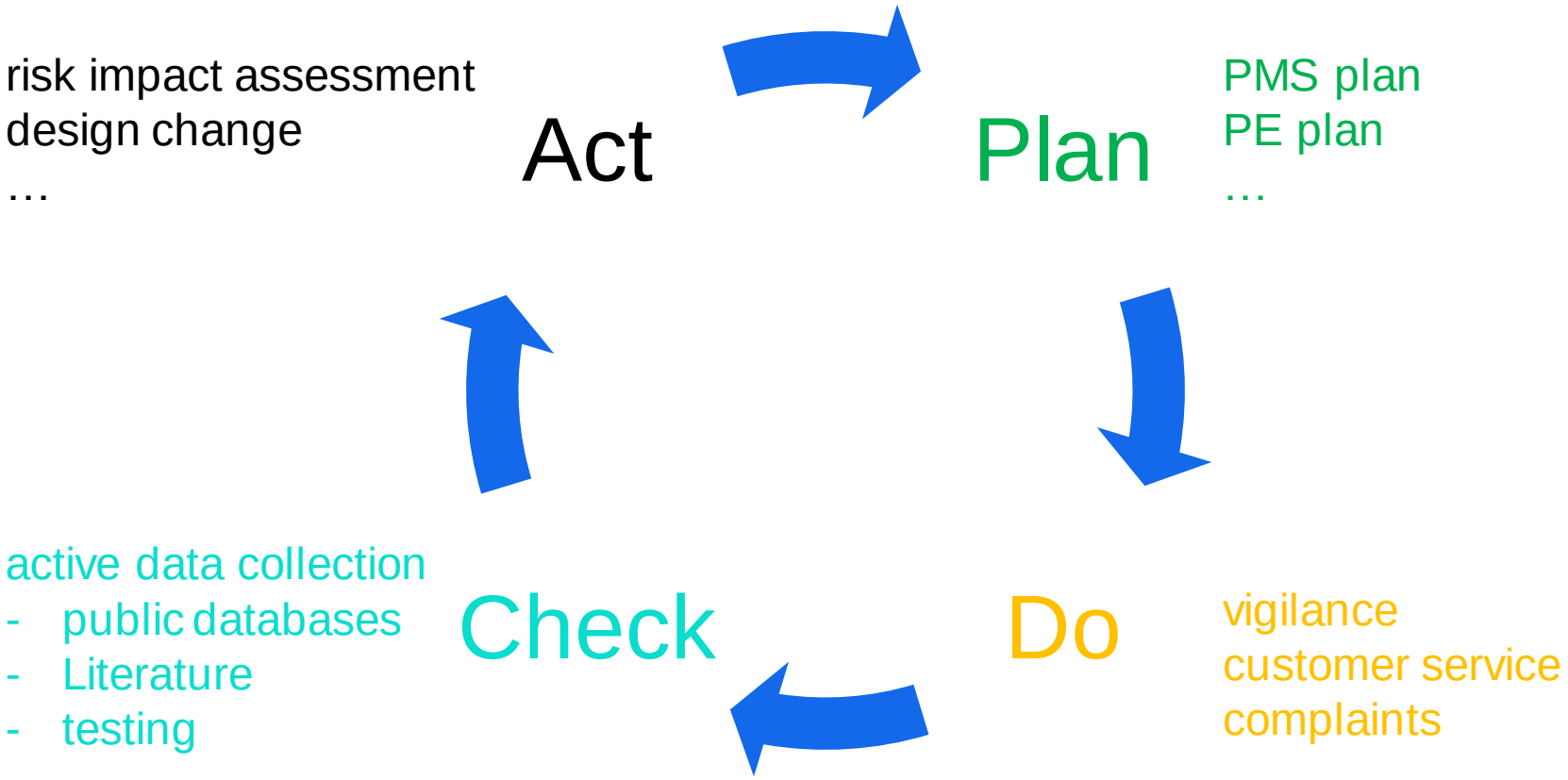
PMS in software life cycle



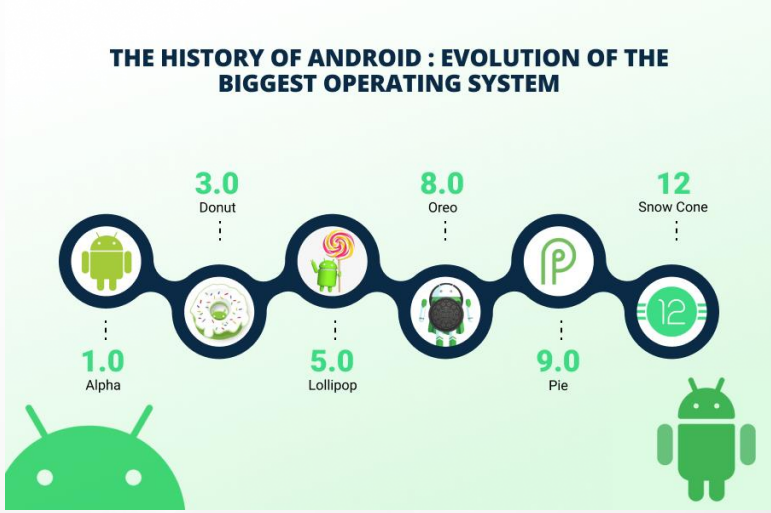
PMS for SaMD

- 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



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MedTech Europe from diagnosis to cure

App PMS impact on manufacturer

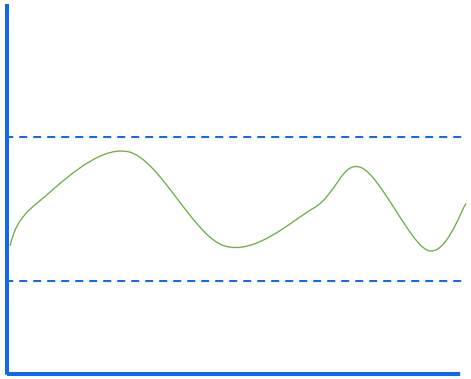
- Faster life cycle
- More OS and device platforms
- More passive input
  - Customer service contacts vs install base
- More sources for active input
  - Social media
  - App store rating
  - OS updates

App PMS impact on manufacturer

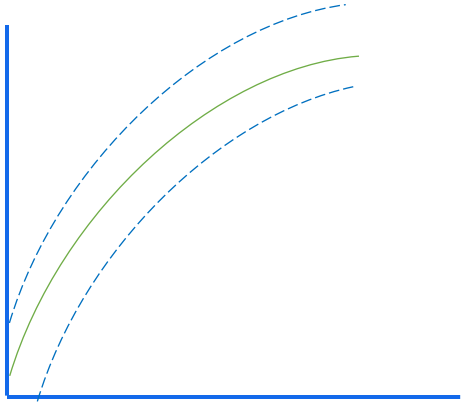
- Increase in vigilance notifications

Relative number

95% confidence interval



Absolute number



Install base

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

THANK YOU

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