ML/Al in regulated context; Case Bittium

Bittium

Antti Siipola 17.9.2021



About Bittium Bittium is a high-tech company specializing in Secure Connectivity, **R&D** Services, Tactical Communications and Medical Technologies.





Biosignals Measuring and Monitoring

Cardiology

Reliable precision and flexibility for cardiac monitoring and analyzing.

Neurology

Cutting edge neuro monitoring with unique ease of use.

Sleep Apnea

Home Sleep Apnea Testing empowered with AI

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Challenges of ML/AI Development addressed in AHMED Project

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- How to combine data visualization and increased AI/ML utilization in products and related SW products into development models and MLOps of Bittium ?
- What kind of MLOps way of working is suitable to Medical Device development and its regulatory environment ?
- How to incorporate new datasets into Products/AI applications while being able to meet the regulatory requirements?
- Design changes, releases and agile iterations, including changes in AI/ML implementation



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AI/ML in Medical: Case Example Atrial Fibrillation

ECG data collected from Faros™ Doctor annotates the data, i.e. marks samples with atrial fibrillation Annotated data is used for training a deep learning model The model is able to classify samples that were not used for training the model

AI/ML in regulated context



AI/ML in Medical: Case Atrial Fibrillation

• Many short annotations



PhysioNet - MIT-BIH, published 1980, https://physionet.org/content/mitdb/1.0.0/

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MLOps – What & Why?

- A practice to manage machine learning algorithm lifecycle management
- A pipeline of version control, build/train, test, deployment and monitoring tools
- Why?
 - Manage high complexity
 - Experiment tracking and reproducibility
 - Automate model development & lifecycle management
 - Help address business domain requirements (traceability...)
 - Harmonize way of working & tooling
 - Avoid expensive redundant systems
 - Cost savings (time, infra, maintenance...)

Machine learning infrastucture



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Summary – Learnings and Identified Opportunities

- "Good data" is required to be able to make good ML/AI models (e.g. various annotations of similar phenomena)
- Regulated development in Medical requires continuous documentation, which is challenging in ML context
- Use of ML/AI to support doctors in their documentary challenges and reduce the barrier to accept ML/AI
- Regulation and interaction with the Notified Body especially in AI/ML context
- Applying high level of automation to regulatory compliance validation

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