AHMED Project

Final Seminar

MDR approved analysis service, aspects of operations & business

Case Bittium – Tuulia Nissinen & Antti Siipola

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Bittium

Bittium

Biosignals Measuring and Monitoring

QUALITY MANAGEMENT SYSTEM
EU-CERTIFICATE
Regulation (EU) 2017/745

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Cardiology

Reliable precision and flexibility for cardiac monitoring and analyzing.

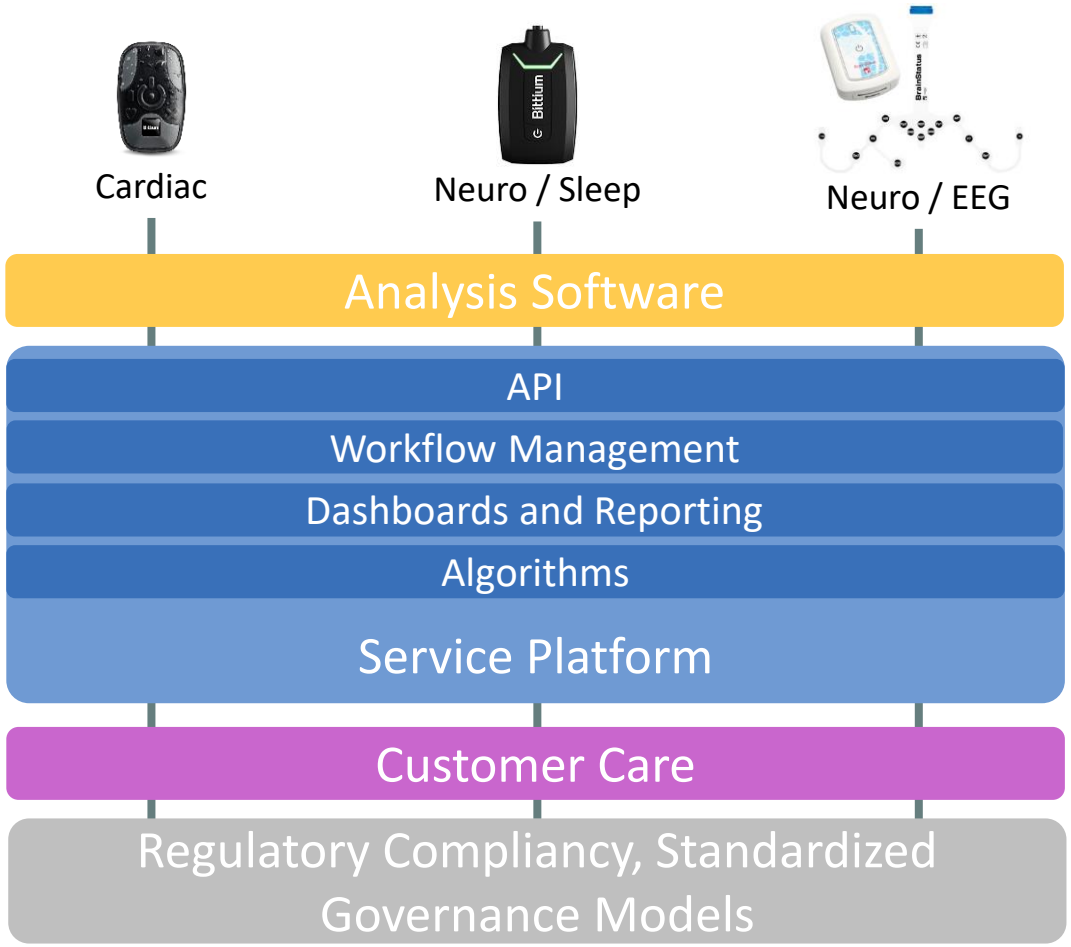
Neurology - EEG

Cutting edge neuro monitoring with unique ease of use.

Neurology - Sleep

Home Sleep Apnea Testing empowered with AI

End to End Diagnostics – Bittium Perspective



Challenges for E2E Remote Diagnostics in Medical Domain

Regulation driven
AI / ML driven continuous analysis
Device-Edge-Cloud utilization
Scalability
E2E Security

Key accelerating factor is ML/AI with intensive SW methods development

Enabler for recurring revenue and scalable business model!

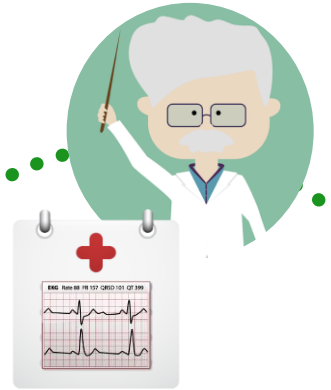
Holter+ Measurement Customer Journey

Doctor will prescribe 14-days heart long-term registration.

Patient wears measurement device 14-days and marks if he/she feels any symptoms in heart.

Mobile application is used to synchronize measurement data and marked symptoms to the service platform.

Recordings are saved to the Service Platform.



Experienced doctor analyses daily measurements using the analysis software.

Attending doctor gets analysis results and ends measurement period when reason for heart problems have been found.

Challenges of ML / AI Development addressed in AHMED Project

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

1. SW development plan must address these. Having MLOps is beneficial.
2. Consider MLOps maturity model. Basically, what you can document and replicate.
3. Investing in verification and validation suite – ensure the models are improving compared to status quo
4. With the above – MLOps and validation methods – implementing design controls for ML is possible.

Key Learnings of MDR process

- Lead time from application to certification exactly 1 year
- Subsequent similar product certification with couple of months lead time
  - Analysis SW under more scrutiny (now on 5th month since submission).
- New requirements (MDD 60 pages versus MDR 228 pages) where there are no existing interpretation. Trust your interpretation and the verdict comes from the audits. Do not over analyze.
  - Gap-analysis is basis for successful implementation of MDR requirements
- Many updates to QMS documentation as overall (proactive and reactive)

Experiences of ML/AI in regulated context – Journey 2021-2022

- Feedback / questions from NB on use of ML mostly on understanding the design:
  - Is on-line learning used or not,
  - Transparency on what datasets have been used, how performance has been evaluated?
    Proof of equivalence and applicability of the material is important.
- Closing thoughts:
  - A lot of data is needed, as one needs good validation dataset and data for training the model (do not mix the two),
  - While ML/AI is cool, what matters in the end is if the product fulfills the intended use and can be proven to be effective.

Contact us.

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