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Medical Software in Transition 2020-2022: MDR, AI & CI/CD

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Medical device software development 2020

- *Development governed by MDD*
  - *Normative requirements for active medical devices*
  - *Normative requirements for active in vitro* diagnostic medical devices
- Intelligence included in medical systems by design
  - *Requirements define how the system operates*
  - *Everything predefined*
- *Iterative development of features, waterfall development of products*
  - *Hardening sprint at the end*

Transition to MDR

- *New requirements*
  - *MDD around 60 pages, MDR around 120 pages*
    - *No existing interpretation*
  - *Numerous updates to QMS documentation*
- AHMED lessons to survive
  - *Trust your interpretation*
  - *Do not over-analyze*
  - *Gap analysis is a solid basis to successfully implement MDR requirements*

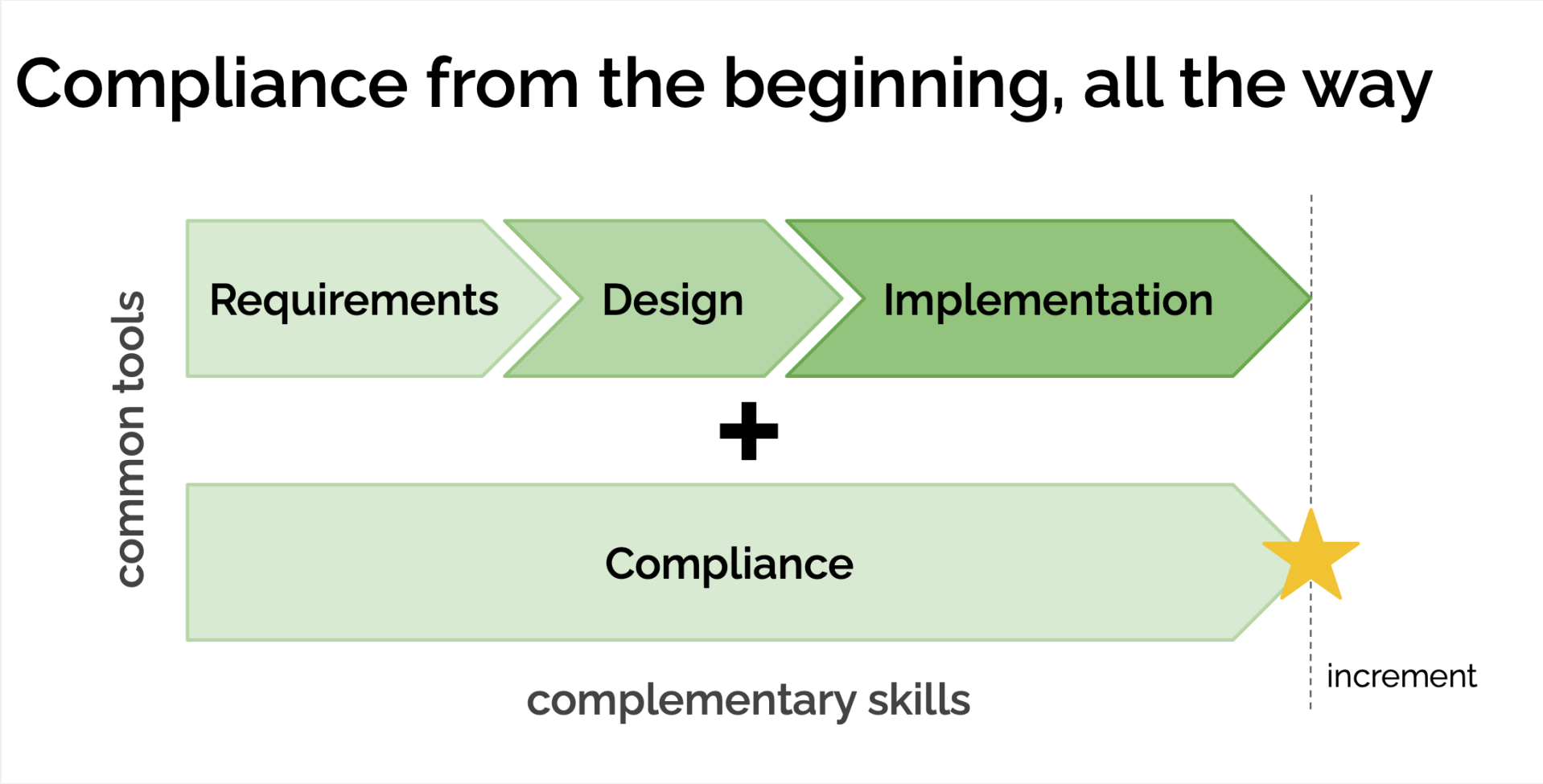
Transition towards AI

- *Connected, digital world means that there are tons of data concerning just about everything*
- *For precision of analysis and prediction, data is the king*
  - *Legalities, personal confidentiality, private data assets, technical issues, organizational boundaries, …*
  - *Rules and regulations vary between countries*
- AHMED lessons to survive
  - *Data & training separated from software & operations*
  - *Implement AI in locked state in products*
  - *Everything must still be deterministic*

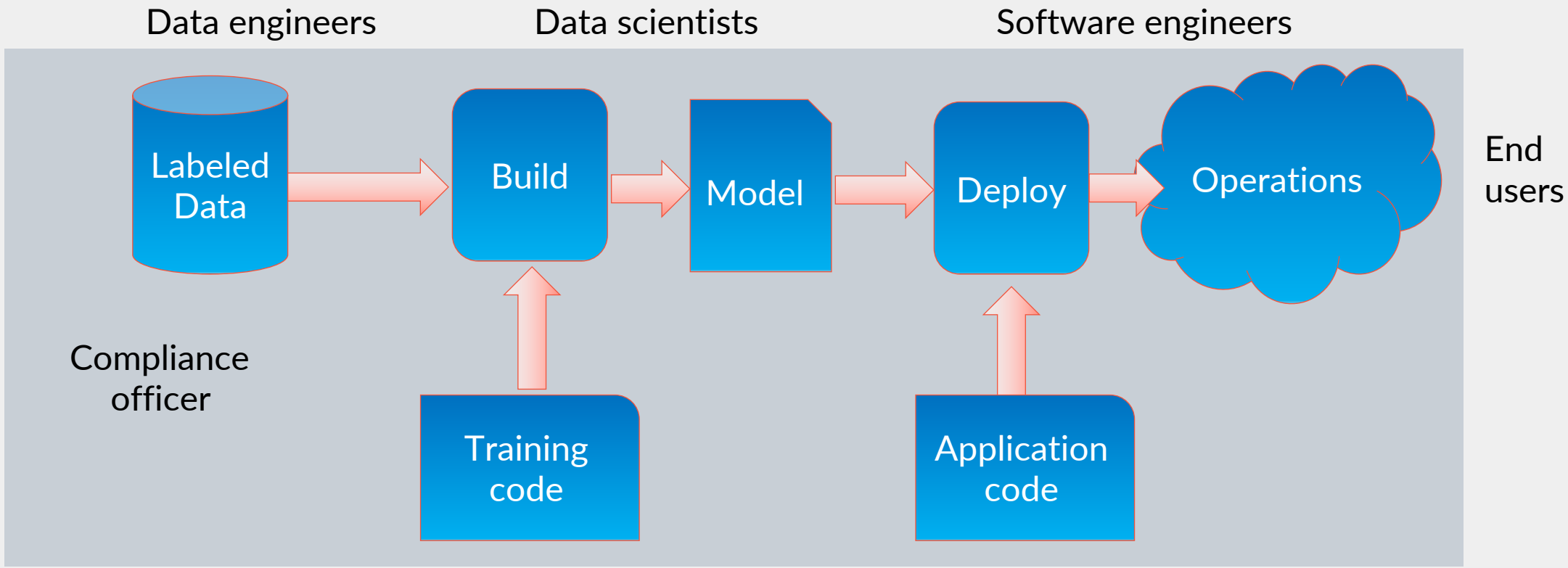
Transition towards CI/CD

- *Development style everywhere moving to continuous development*
  - *Developers that wish to work with waterfallish ways not easy to find*
  - *Practice has shown that also bugs will be revealed earlier with CI/CD*
- AHMED lessons to survive
  - *Continuous compliance tooling (CompliancePal.eu)*
    - *Bring compliance officer to the same team*
    - *Document everything in the same way as code changes*
  - *Integrate ML/AI in the process*
    - *CD4ML, MLOPS*
    - *Model cards as the means of documentation*

Continuous Compliance



MLOPS in regulated context



Conclusions

- *AHMED research hit numerous dimensions of software development in transition*
  - *MDD -> MDR*
  - *Classical software -> AI/ML*
  - *Waterfall -> CI/CD, MLOPS*
- Concrete evidence as results
  - *MDR-compatible QMS*
    - *https://www.bittium.com/about-bittium/management-systems/quality-management-system*
  - *AI/ML in medical products: Oravizio*
    - *https://oraviz.io/*
  - *Continuous compliance tooling: Compliancepal*
    - *https://www.compliancepal.eu/*

Questions?

- Happy to answer also later:

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