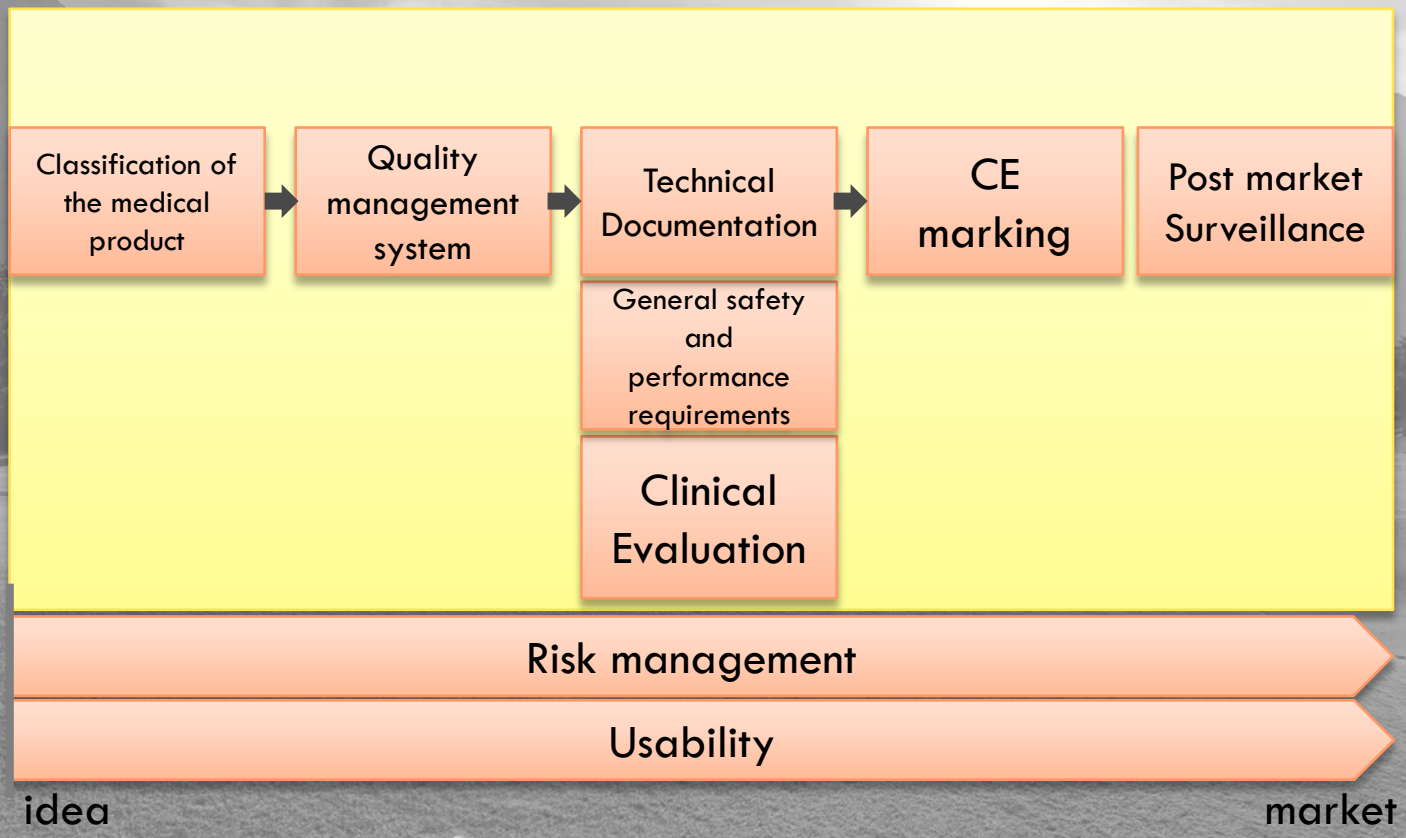
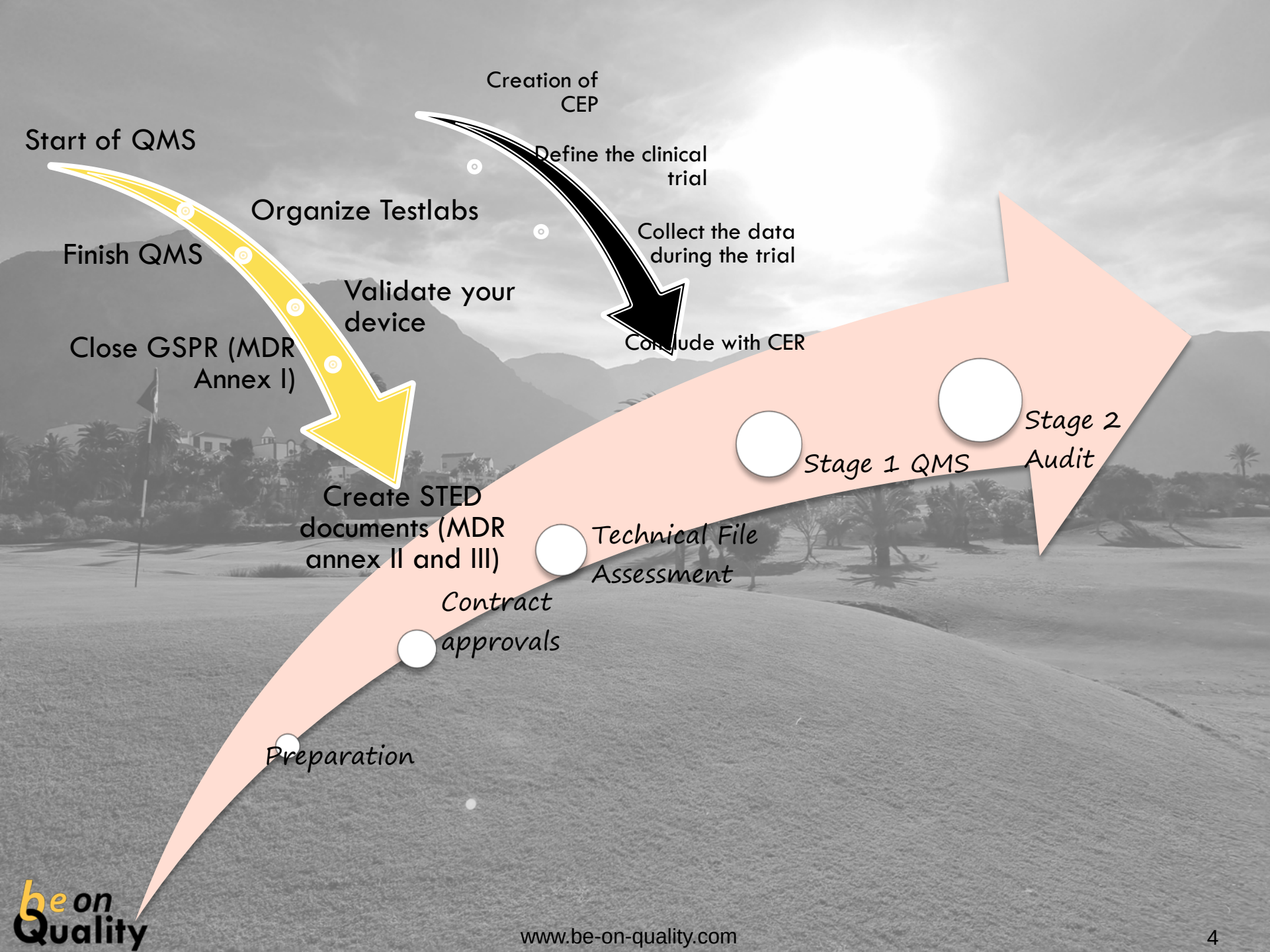
Regulatorik und Zulassung von KI-Produkten

EU REGULATIONS:

The goal is to ensure a simple and easy to understand regulatory environment for medical devices, which ensures the efficient functioning of the internal market.

Konformitätsbewertung




Creation of CEP
Start of QMS
Define the clinical trial
Organize Testlabs
Collect the data during the trial
Finish QMS
Validate your device
Close GSPR (MDR Annex I)
Conclude with CER
Stage 2 Audit
Stage 1 QMS
Create STED documents (MDR annex II and III)
Technical File Assessment
Contract approvals
Preparation

CLAIMS

WHAT the device does

- *Prevention*
- *Diagnosis/Prognosis (Support)*
- *Management/Monitoring*
- *Treatment/Alleviation*

INTENDED USE

HOW to use the device

INTENDED PATIENT POPULATION

The DEMOGRAPHICS of the patient

INDICATIONS FOR USE

The CLINICAL PICTURE of the patient

Contraindications

INTENDED USER

WHO should use the device

PRINCIPLES OF OPERATION

HOW the device achieves its Intended Purpose

FLOWCHARTS

MACHINE LEARNING

LOCKED-IN ML ALGORITHM

SELF-ADJUSTING ALGORITHM

DEEP LEARNING

FLOWCHARTS

RULES OF THE AI MEDICAL CLUB

RULE 1: A Software is a Software

RULE 2: A Software is a Software

RULE 3: A Software is a Software

RULE 4: DO NOT EXPECT REGULATORS TO BE DIFFERENT ON YOU!

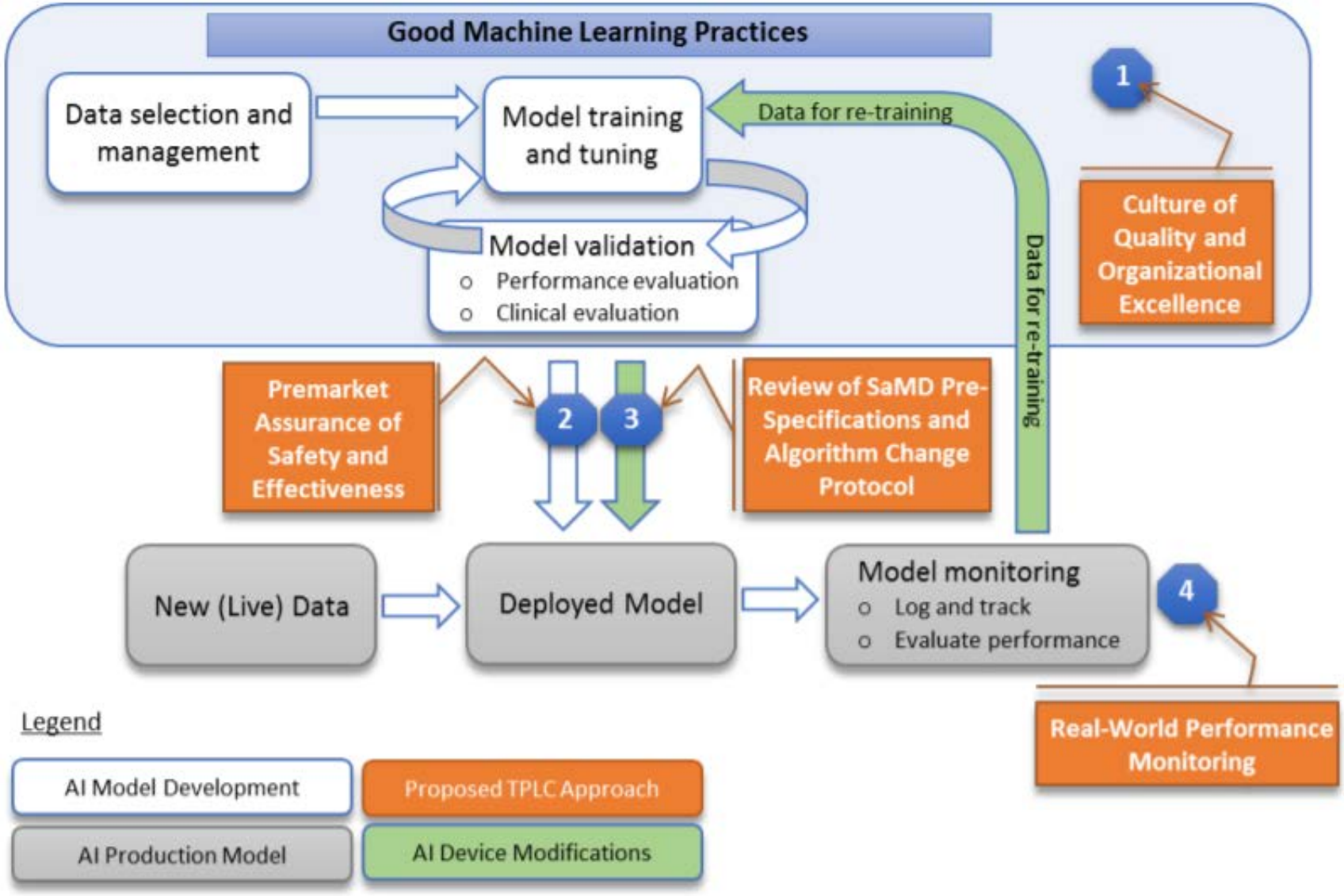
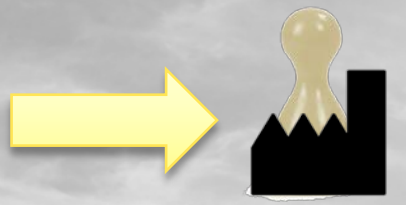


Figure 2: Overlay of FDA's TPLC approach on AI/ML workflow

WORKING WITH TRAINING DATA

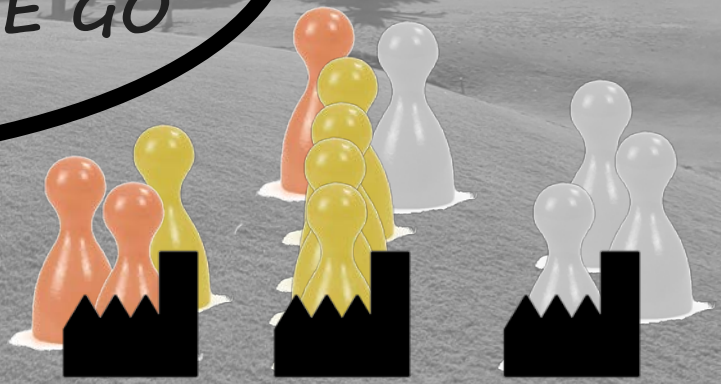


EXISTING TRAINING DATA/MODEL

ADAPTION ON THE GO

CONFIGURATIONS

OF AN APPROVED DEVICE



OUTGOING SIGNIFICANCE

Finally

Clear performance sheet and ACP needed

Control the outcome at any time with routine validation

Do not lose track on the documentation

Validation of DATA TO MODEL and MODEL TO DEVICE

AI is OK - even for certification

The process of certification it like AI – infinite and continous

WEAK component coupling e.g. Tensorflow

Deployment based on ACP


be compliant
be on Quality
be on Quality
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