SOP AI development (ML-SOP-01)

# 1. Meta Information

## 1.1 Purpose

This standard operating procedure and the standard operating procedures referenced herein pursue the following objectives:

* Accelerate product development, including the development of AI (especially the machine learning model), by avoiding unnecessary iterations
* Develop models that are performant and as secure as possible, serve the intended purpose of the device, and correspond to the state of the art
* Ensure a uniform understanding and level of knowledge within the company

This standard operating procedure also aims to provide an overview of all software and AI development activities. To this end, it also establishes ...

## 1.2 Scope

This standard operating procedure applies to developing all AI models that become part of medical devices or IVD, which serve as high-risk AI systems within the definition of the AI Act.

That means that AI developments for non-critical devices are exempt, as are AI developments for internal tools.

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## 1.3 Addressees

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## 1.4 Distribution List

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## 1.5 Process Owner

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## 1.6 Training

The process owner is responsible for training on this standard operating procedure.

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## 1.7 Key Performance Indicators

|  |  |  |
| --- | --- | --- |
| KPI | Explanation | Target Value |
| Percentage of model requirements that are fully completed and released | In this way, we want to ensure that the model's requirements are derived from the intended purpose and the product requirements, not from the training data. | 100% |
| Number of labeling quality reviews | … | … |
| … |  |  |

# 2 General

## 2.1 Procedure Overview

The “AI development” procedure consists of several steps, which are shown in the following figure.

<Illustration – Workflow Diagram>

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## 2.2 Roles

The following roles with the following expertise are to be involved in AI development.

|  |  |
| --- | --- |
| Role | Expertise |
| Data Scientist | State-of-the-art methods, procedures, and tools for machine learning (including validation/testing of models and documentation of the procedure) |
| Software Architect |  |

The tasks/activities of these roles are defined in the respective standard operating procedures.

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# 3. Details

## 3.1 Phase/Activity: Derive requirements for model

### Input

* Intended purpose/use
* Product requirements
* Software architecture including planned interfaces to the model
* Template “Model Requirements” (ML-TPL-04)

### Activities

The **Product Manager** and the **Software Architect** fill out the template “Model Requirements.” In doing so, they ensure that the model requirements are suitable for fulfilling both the product requirements and the intended purpose.

During this activity, the software architecture may need to be adjusted.

If necessary, those responsible seek support from Clinical Affairs.

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### Output

* …

## 3.2 Phase/Activity: Release requirements to model

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# Annex

## Applicable Documents

|  |  |
| --- | --- |
| Document ID | Description / Name |
| ML-SOP-02 | SOP “Collection and Reprocessing of Training Data” |
| … |  |
| ML-TPL-04 | Template "Model Requirements" |
| … |  |

## Version History

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Effective Date | Author | Change Description |
| 0.1 | … | … | First Version |
| … |  |  |  |