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| **DOCUMENT** | | | | |
| **Source:** | | Editor | | |
| **Title:** | | DEL04: AI software life cycle specification | | |
| **Purpose:** | | Discussion | | |
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| **Abstract:** | This document contains the proposed initial structure for the FG-AI4H Deliverable 3, “AI Software Life Cycle Specification”. |

# Introduction

TBA

# Objective of the deliverable

This first deliverable includes the following tasks:

1. Identification of all standards and best practices that are relevant for the AI for health software life cycle. Similar to other software life cycle processes, the AI software life cycle process needs to be specified.
2. Summary and critical review of the identified documents including a discussion of their limits/gaps and need for action.
3. Identification of life cycle steps that are specific/characteristic for AI for health software, such as training and test procedures based on data that potentially need to be annotated.
4. Specification of the AI for health software life cycle and definition of best practices for the different life cycle steps in one document (under consideration of a, b, and c).Overview and examples of best practices

# Background (“why do we care?”)

* Need for disciplined lifecycle process
* What additional lifecycle considerations are needed for AI?

# Resource Landscape

Provides an inventory of existing resources with a brief description of their scope, including

* IEC 62304:2006, Medical device software: software life cycle processes. [[link](http://webstore.iec.ch/preview/info_iec62304%7Bed1.0%7Den_d.pdf)]
* IEC 82304-1:2016, Health software – Part 1: General requirements for product safety. [[link](https://www.iso.org/standard/59543.html)]
* DIN SPEC 92001-1, *Artificial Intelligence – Life Cycle Processes and Quality Requirements – Part 1: Quality Meta Model*. [[link](https://www.beuth.de/en/technical-rule/din-spec-92001-1/303650673)]
* DIN SPEC 92001-2, *Life Cycle Processes and Quality Requirements – Part 1: Technical and organizational requirements*. [[link](https://www.din.de/en/about-standards/din-spec-en/projects/wdc-proj:din21:298702628?sourceLanguage&destinationLanguage)]
* IMDRF (2018), *Good Regulatory Review Practices Group. Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*. [[link](http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf)]

Provide a summary comparison (perhaps a table or a diagram) between the lifecycle stages in the scope of each document.

# Discussion of residual gaps for AI

# Proposed solution

TBD

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