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Key Aspects to Teach Medical Device Software Certification

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Abstract. Certification of Medical Device Software (MDS) according to the EU Medical Device Regulation 2017/745 requires demonstrating safety and effectiveness. Thus, the syllabus of a course on MDS development must provide tools for addressing these issues. To assure safety, risk analysis has to be performed using a four-step procedure. Effectiveness could be demonstrated by literature systematic review combined with meta-analysis, to compare the MDS performances with those of similar tools.

Keywords. Medical device software, MDS certification, meta-analysis, risk assessment, software as medical device

1. Introduction

Most software associated with clinical processes are medical devices. Medical Device software (MDS) development requires several different competencies. EU Medical Device Regulation 2017/745 has increased the requirements to obtain certification. Safety and efficacy are key aspects to be addressed. To assure safety, risk analysis must be performed during the design phase and during all the product life cycle. Effectiveness could be demonstrated by a literature systematic review combined with meta-analysis. The aim of this study is to present the key aspects to be introduced in the syllabus of a course on MDS development for assuring safety and effectiveness.

2. MDS Safety: Risk assessment

Due to its double-sided nature, the safety of a MDS should be evaluated both in terms of cybersecurity (because it is a software) and in terms of hazards for the physical person (because it is a medical device) [1,2]. If for the first there are established guidelines that apply also to other types of software, for the second specific application-driven reasoning must be applied. Operative guidelines are object of the ISO/TR 24971 (2020) guidance, which provides the required basis for the analysis of the problem. The risk assessment and control of a MDS can be effectively divided into four phases.

Phase 1: identification of the possible hazards. The analysis can be grounded on the list of hazards in Appendix D of the UNI EN ISO 14971 (2009) standard but must be

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enriched considering the specific application of the medical software. Phase 2: identification of all possible chains of events (hazard, derived hazardous situation, derived adverse event, derived damage) leading to an actual damage for a physical person. Phase 3: assessment of the risk associated to each of the identified chain of events. The risk assessment can be translated into a quantitative analysis thanks to the tables reported in Annex CCC of the 60601-1-4 standard. At the end of this phase, a decision has to be made regarding the acceptability of the computed risk. Phase 4: application of the measures for risk control and re-assessment of the risk, if the risk was evaluated as not acceptable in Phase 3. Measures for risk control include measures for prevention and protection. A final assessment of the risk must be performed in the end and a final decision about its acceptability must be made.

3. Effectiveness of medical software: Systematic Review and Meta-Analysis

To assess effectiveness of a MDS, it is important to compare its performances with those of similar applications. To this purpose, two methodologies should be introduced in the syllabus: the systematic review of literature and the meta-analysis. For the systematic review, different methods have been proposed. The most used methods are PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) and PICO (Population, Intervention, Comparison and Outcomes).

Once all relevant articles have been retrieved, their results should be aggregated using the meta-analysis. The first step is to extract, from each article, the punctual data about performances, that are measured differently according to the scope of the software. For Computer Aided Detection/Diagnosis (CAD) systems, the performances are measured by comparing the system outcome with a reference standard, in terms of sensitivity, specificity, diagnostic odds ratio, accuracy, and AUC. For Clinical Decision Support Systems (CDSSs) the performances are usually obtained by comparing clinical processes with and without the software usage. In this case different parameters are collected according to the scope of the CDSS (prescription, diagnosis or chronic disease management). The performances reported in the individual studies are then aggregated using meta-analysis.

4. Discussion

The two aspects that are described in detail in the above sections are part of the syllabus as well as methods for requirements elicitation based on process modeling, software description by means of UML, software testing plans construction, and how to conduct clinical trials when needed.

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