MACHINE LEARNING FOR HEALTH

Regulation and the Life Cycle: From Bench to Product

SaMD, transparency, MLOps, and surveillance for sustainable clinical AI

TECHNICAL HANDOUT · SESSION 15

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Academic teaching material based exclusively on the PDFs available in the project

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Introduction

When software performs a medical purpose, safety and effectiveness must be supported throughout its life cycle. For learned models, this obligation includes data, versions, validation, deployment, monitoring, and changes. [1]

This session organizes risk, evidence, transparency, and operations and incorporates official sources on Brazilian Resolution RDC 657/2022 and TRIPOD+AI reporting [5] [6] [7].

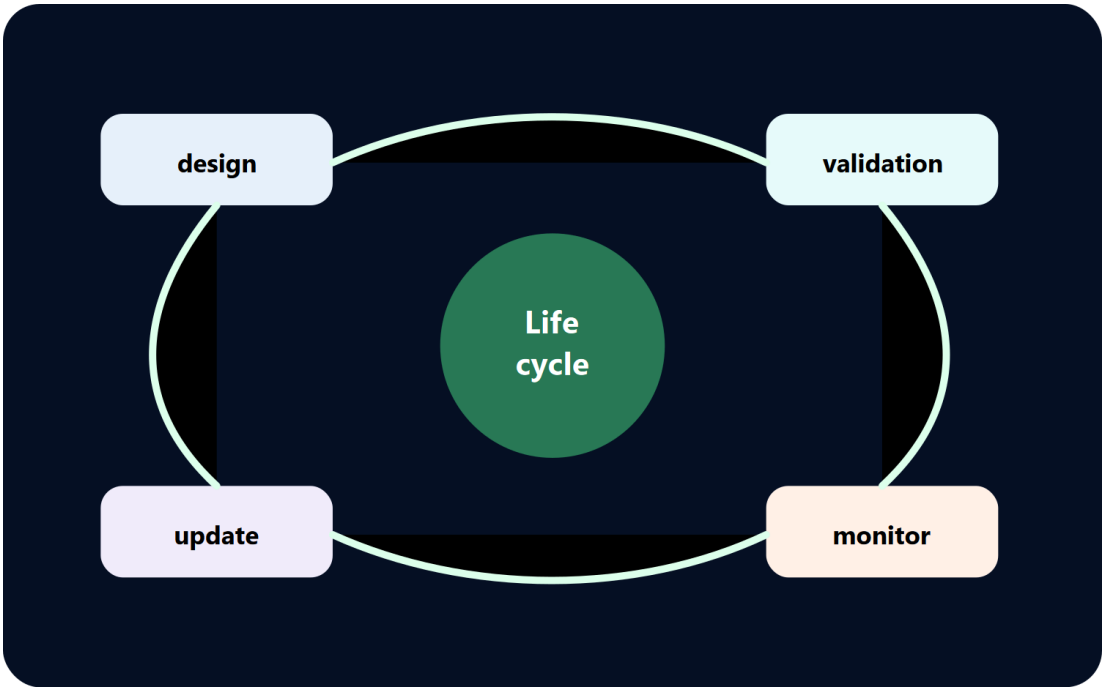

Figure 1 — Regulated life cycle of an AI solution. Source: original illustration based on [1]–[4].

1. Software as a medical device and risk

SaMD is software intended for one or more medical purposes without being part of a physical device. The degree of oversight depends on the intended use, the severity of the condition, and whether the user can independently verify the output [1].

A system that offers a simple, verifiable recommendation differs from one that recognizes instability from continuous signals and guides urgent action. The intended-use description delimits the population, user, environment, input, output, and consequence [1].

2. RDC 657/2022 in the Brazilian context

RDC 657/2022 governs the authorization of software as a medical device in Brazil. Classification begins with the medical purpose; the regulation also identifies situations outside its scope, such as exclusively administrative and financial software, and requires authorization to follow the general provisions applicable to medical devices [5].

For SaMD, documentation must support safety and performance. The official text includes requirements for labeling and instructions for use, product and version identification, interoperability, and cybersecurity; for higher-risk classes, the technical report also covers architecture, platform, compatibility, cybersecurity controls, verification, and validation [5].

Anvisa's questions-and-answers document is explanatory and nonbinding. It states that analytical or clinical validation must be included in the dossier or technical report for any SaMD and, for AI used for a medical purpose, requests the technical rationale, size and justification of the datasets, training history, and a description of the source and data used for learning, verification, and validation [6].

3. Evidence and transparency

Analytical validation asks whether the system computes or measures correctly; clinical validation asks whether the output is related to the intended state or outcome; impact evaluation asks whether use improves processes or outcomes without disproportionate harm. These levels should be aligned with risk [2].

Transparent reporting should record selection, preprocessing, label definition, partitioning, metrics, uncertainty, and limitations. This documentation makes it possible to assess applicability and reproduce decisions [2] [7].

TRIPOD+AI covers studies that develop or evaluate prediction models using regression or machine learning. Its 27 items span the title, abstract, introduction, methods, open science, patient and public involvement, results, and discussion. The guideline directs reporting; it does not prescribe a method and is not a tool for assessing quality or risk of bias [7].

4. Operations and monitoring

ML operations connect versioning of data, code, and models to testing, deployment, and observability. In health care, they must also incorporate approval, traceability, access, and the clinical response to failures [3].

Changes in demographics, incidence, institutions, guidelines, and practices can reduce discrimination or calibration. Monitoring should be mandatory and compare performance with reference values, examine subgroups, and establish thresholds for investigation, recalibration, re-estimation, or suspension [4].

5. Controlled change and postmarket surveillance

Updating a model changes the product that was evaluated. Changes require a defined scope, tests, acceptance criteria, records, and rollback procedures. Post-deployment surveillance connects incidents and performance trends to maintenance decisions [2].

SOURCE LIMITATION
CONSORT-AI, SPIRIT-AI, and DECIDE-AI are contextualized in the course material but were not included as complete PDFs in this revision.

Session summary

Software as a medical device and risk: samd is software intended for one or more medical purposes without being part of a physical device.
RDC 657/2022 in the Brazilian context: rdc 657/2022 governs the authorization of software as a medical device in brazil.
Evidence and transparency: analytical validation asks whether the system computes or measures correctly; clinical validation asks whether the output is related to the intended state or outcome; impact evaluation asks whether use improves processes or outcomes without disproportionate harm.
Operations and monitoring: ml operations connect versioning of data, code, and models to testing, deployment, and observability.
Controlled change and postmarket surveillance: updating a model changes the product that was evaluated.

References

[1] Visweswaran, S.; King, A. J.; Cooper, G. F. Integration of AI for Clinical Decision Support. In: Intelligent Systems in Medicine and Health. Springer, 2022. External link

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