HDAT9000 Clinical AI Final assignment Brief.

Executive Summary

In the form of a graphical summary, this represents a summary of your report.

- Briefly state basic relevant information about your AI technology, including name, type, manufacturer (when applicable).
- Briefly state its intended use, including target patient population, user and use environment.
- Briefly summarise evidence (or lack of evidence) of algorithm performance, expected clinical utility, human factors analysis, and impact on processes of care or patient outcomes.
- State if there are any pre-marketing approvals (when applicable).

PART 1: TECHNOLOGY DESCRIPTION AND USE

Intended use

Describe the intended use of your AI technology, the target patient population, the intended user and use environment, and other indications of use (including operational context, human-technology interaction, and limitations of use).
Include relevant background context (such as the motivation behind the technology or other relevant information). Include pre-market approvals (when applicable).

AI technology description

Describe your AI technology including what it does, its various components, the core algorithm, inputs (data acquisition) and outputs (results), the user interface, connections or integration with other software or devices (when applicable), manufacturer etc.

Competing/comparable technologies

List competing technologies or variations of this technology (if none, then state there are none).

PART 2: TECHNOLOGY ASSESSMENT

Algorithm performance

Provide information on the performance of the algorithm of your chosen AI technology. Include the target outcome of the algorithm and relevant measures of discrimination, calibration, coverage, or other measures of performance that are relevant to your algorithm.
Include your sources of information (e.g. a research publication, company website, FDA approval document), as well as the characteristics of the study (e.g. retrospective/prospective, sample size). When applicable, provide information on how the algorithm performs compared to competing algorithms and/or humans.

Expected clinical utility

Provide information on the expected clinical utility of your chosen AI technology, including the sources of your information. If no information on expected clinical utility is available, state so in your report. Then, assuming reasonable values for cost, benefit, and the true and false positive rates of usual care, use these values and the values from the section above to estimate the expected clinical utility of your tool.

Human factors analysis

Provide findings from human factors validation testing. Include occurrences of use errors, close calls and use problems, and feedback from interviews with test participants (as applicable). Include your sources of information (e.g. a research publication, company website, FDA approval document), as well as the characteristics of the studies: test type, environment and conditions, number of participants, training provided, critical tasks and use scenarios included in the testing.

If no information on human factors analysis is available, state so in your report, and, instead, produce a short analysis of hazards and risks associated with the use of your AI technology. Select the critical tasks, and include potential use errors, and their corresponding severity, suggesting risk management strategies to eliminate or reduce risk if required.

Clinical impact

Provide findings from randomised control trials or other experimental or quasi-experimental studies of the impact of your chosen technology on patient outcomes and/or processes of care. Include the primary and secondary outcomes of the studies and their corresponding treatment effects. Include your sources of information (e.g. a research publication, company website, FDA approval document), as well as the characteristics of the study: study design, inclusion/exclusion criteria, sample size and action/treatment protocol).

If no information on clinical impact is available, state so in your report, and, instead, describe a study you would design to test your tool. Include information on study design, inclusion/exclusion criteria, sample size, action/treatment protocol, primary and secondary outcomes, and chosen measures of treatment effect.