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Health

Oracle Health Summary of Artificial Intelligence and Machine Learning Development Practices

Introduction

At Oracle Health, we believe artificial intelligence (AI) and machine learning (ML) technology offer unmatched potential for transforming health IT and the healthcare industry in positive ways. Ensuring that such technology is developed, implemented, and maintained in a thoughtful and responsible way is essential to achieving AI's potential benefits in healthcare. To support this critical principle, Oracle Health has established an internal assessment and review process for all AI and ML technology incorporated into its healthcare products, applications, and services.

Oracle Health's AI and ML review process is designed to review healthcare-related AI and ML technology in alignment with relevant regulatory requirements, including the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology's (ASTP/ONC) intervention risk management (IRM) requirements for predictive decision support interventions (DSI), along with industry best practices for AI and ML development. By adhering to these rigorous standards and development principles, we are committed to maintaining safety and efficacy in our AI and ML technology.

The following is a summary of Oracle Health's robust process designed to review whether AI and ML technology deployed in or through our healthcare products, applications, and services are fair, appropriate, valid, effective, and safe (FAVES).[1] These objectives are accomplished by establishing requirements and standards that must be met prior to general availability (GA).

AI/ML technology assessment and review foundations

The assessment and review process for AI and ML in healthcare is a science-based review for AI and ML technology across Oracle Health products, applications, and services. The requirements of the process are designed to identify risks and mitigations, review against desired performance standards, and align with applicable regulatory requirements.

The process utilizes impartial expert health and data science reviewers to assess AI and ML technology based on the extensive standardized documentation submitted by the technology's developers. It involves an assessment of AI and ML technology that is organized around three core areas: risk analysis, risk mitigation, and governance.

Risk analysis

The process is centered on identifying and assessing risks related to the AI and ML technology developed with quality and trustworthiness up front and establishing ongoing monitoring of the AI and ML. This assessment is performed in conjunction with standard hazard analysis assessments that are a part of Oracle Health's software development lifecycle (SDLC) where risks are classified and prioritized.

To facilitate these assessments, the following are completed by the technology's developers to analyze potential for risk with AI and ML technology:

- **Scope documentation**
- **Privacy and security plan assessment**

[1] https://www.healthit.gov/sites/default/files/page/2024-01/DSI_HTI1%20Final%20Rule%20Presentation_508.pdf#page=7

- **Design plan**
- **Data assessment**
- **Model evaluation**
- **Operations plan**
- **Health Model Card** defining detailed reference information about AI and ML technology made accessible to EHR system end users to provide maximum transparency for the AI and ML they interact with.

Additionally, the review process includes consideration for whether AI and ML technology includes a "human in-the-loop" as deemed appropriate or necessary on a case-by-case basis.

Collectively, these standardized assessments review risks related to the following categories: validity, reliability, robustness, fairness, intelligibility, safety, privacy, and security.

Risk mitigation

Focused on the user and patient, mitigating potential risks related to the development and use of AI and ML in healthcare is a key area of emphasis in Oracle Health's AI and ML healthcare assessment and review process. The process is designed to identify and mitigate risks on a case-by-case basis. This is accomplished by bringing together those directly involved in the AI and ML technology's development with independent experts who carry out the review. Each review follows a consistent format and process while considering the unique characteristics of each AI and ML feature.

Furthermore, the development teams are required to define an operations plan to facilitate tracking and monitoring of identified risk areas with a defined plan and schedule. This plan includes the following focal points:

- **Scaling to new customers**
- **Internal operations reviews**
- **Maintaining the service**
- **Monitoring data inputs**
- **Monitoring model performance**
- **Bias, fairness, and toxicity considerations**

Governance

Governance of Oracle Health's process for assessment of AI and ML technology in healthcare is organized under a collection of specific practices.

First and foremost, the process is adopted as part of Oracle Health's SDLC applicable to Oracle Health products, applications, and services. Accordingly, the review is conducted on any customer-facing AI and ML technology as a pre-requisite for releasing software to the market.

Second, Oracle Health has defined standards and processes related to the acquisition, management, and use of data for AI and ML, while also applying appropriate privacy and security controls.

Finally, Oracle Health's Quality Management System (QMS) imposes measures that evaluate whether risk analysis and risk mitigation practices are being carried out as specified in the process on an ongoing basis.

