

Introduction to Medical Software and Medical AI Certificate Program

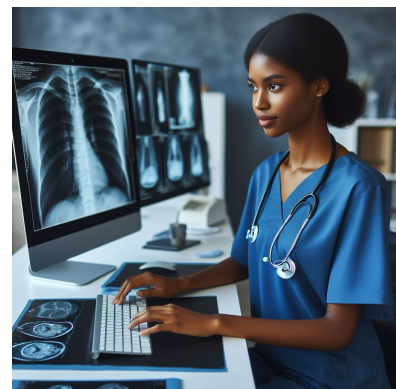
Motivation for the Program

There is an exploding interest in the use of AI for medical application and more generally in healthcare. However, there are (at least) two common misconceptions that we need to address. The first is that AI is simply magic and that its use will end all the issues we face. The second is that all we really need is a better set of algorithms. The pictures shown on this page hopefully help frame the current reality. (Both are AI-generated using Microsoft Copilot.) The first shows a car with its hood open and the engine visible. This can be



thought of a good illustration of the role of AI tools in modern medical software. The AI is a component of the car, perhaps an important component such as the engine. However, our users drive a car not an engine, and as such, and ultimately the solution to the needs of our user is going to be a complete software tool as opposed to just a better neural network. This is the motivation behind structuring this program as a combined medical software/medical AI course. We need to understand about AI (engine), and how to design and optimize it for the task at hand. But we must remember that ultimately our users use systems, which consist of multiple components, and, importantly, that the FDA and other regulatory agencies, review systems not algorithms. Furthermore, issues such as bias, security, usability, are often better addressed as the system (car) level and not necessarily at the AI (engine) level.

The second picture is that of a radiologist looking at a workstation showing a chest x-ray. The question here is what is the system? Is the system the software (plus the computer), or does the system also include the radiologist? From the perspective of the patient whose chest x-ray is being viewed, the system in fact includes the radiologist, as the diagnosis will be the output of the combined effort of the human plus whatever “AI” is running inside our software. Hence our task does not end with the design of our tool, but we must consider how this integrates with the human component of medicine. As in the previous example, issues with our software (e.g., safety risk) may also be better addressed at the overall system (human + software) level as opposed to the software or the AI level.



Program Overview

The certificate program consists of four modules. In the first we present an introduction to medical software. This includes the regulatory aspects, foundational management tools such as quality systems and risk management, and a description of the actual lifecycle process of designing, implementing, and testing the tools. At this stage, we focus on traditional software without any AI components.

The second module presents a rapid overview of artificial intelligence or machine learning (in our use the two terms are basically synonymous) and relate this to classical probability theory which lies at the heart of these algorithms. We discuss both classical machine learning methods, neural networks, and present an introduction to the reason for all the current excitement in the field, “generative AI” techniques.

The third module of the program aims to integrate the first two and to think about how AI changes the software process, both from a regulatory and an engineering aspect. In addition, the use of substantial amounts of data to create the algorithms means that we need to think both about data organization and data privacy. Finally, the excitement around AI means that we also have new legislation/regulations that, while non-medical in origin (e.g. the EU AI Act), affect the creation of medical software tools.

The concluding fourth module focusses on applications. First, we discuss imaging, which represents close to 75% of all FDA-cleared AI tools on the market. Next, we discuss the issues involved in the creation of modern clinical decision support tools. In Week 15, we will present vignettes ranging from the use of AI to improve healthcare delivery, to multimodal AI, to emerging applications such as pharmaco-genomics. The program concludes with an overview lecture on the state of the use of AI in medical devices, which summarizes the content of the course.

Program Structure

The program is structured in a 4 week on/1 week off format. Each week, the students will be given 60-75 minutes of video material to review and then be asked to complete a short 12-15 question multiple choice quiz. We will then discuss the material in weekly live zoom sessions scheduled appropriately (i.e., there will be more than one session) to allow students from multiple timezones to participate. (In 2024, we had two sessions, one at 12 pm EST, and one at 8 pm EST.) Students will be to select whichever session was most convenient on any given week. The course director, the instructors for the week, and guest experts from industry will join the zoom sessions to answer questions and to offer additional thoughts.

Weekly Schedule:

- Videos released on Wednesdays. (e.g., 1/15/2025)
- Quizzes due on Mondays. (e.g., 1/20/2025)
- Zoom review sessions on Tuesdays. (e.g., 1/21/2025)

Dates (each module runs for four weeks from a Wednesday to a Tuesday)

Module 1: 1/15/2025 – 2/21/2025

Module 2: 1/19/2025 – 3/18/2025

Module 3: 3/26/2025 – 4/22/2025

Module 4: 4/30/2025 – 5/27/2025

The videos are supplemented by set of guest expert interviews which are offered as supplementary material, and which are freely available on YouTube — see [this link for a complete list](#).

Admissions

Admissions will open on Oct 15, 2024, and close on January 5, 2025. We will be performing rolling admissions, i.e. applications received by Nov 5th will be reviewed the week of Nov 11th and applications received by Dec 5th will be reviewed on Dec 9th. There will be limited financial aid available (primarily for learners from outside developed countries.) There is a tuition discount for Yale affiliates, please contact us directly.

Module 1: Introduction to Medical Software

Learning Objectives

- Acquire a core understanding of the basics of medical software regulatory process.
- Understand quality management systems, risk management and software lifecycle processes.
- Understand the unique aspects of software engineering for medical software.

Week 1: Introduction and Regulatory Issues

Segments

1. Systems and Models (Cartoons)
2. A Guided Tour of Medical Software
3. FDA & Regulatory History
4. Regulatory Fundamentals
5. The Regulatory Process

Week 2: Quality Management Systems and Risk Management.

Segments

1. History of Quality Systems
2. The IMDRF QMS Guidance

3. The IMDRF QMS Guidance II
4. Introduction to Risk Management
5. The Risk Management Process
6. The Risk Management Process II

Week 3: Medical Software Engineering I

Segments

1. Lifecycles and the IEC 62304 Standard
2. Agile Processes and AAMI TIR 45:2023
3. A Guided Tour of the Life Cycle Process
4. Identifying User Needs
5. Identifying User Needs II
6. The System Requirements Specification (SRS)

Week 4: Medical Software Engineering II

Segments

1. A Template for the System Requirements Specification
2. The Software Design Document
3. A Template for the Software Design Document
4. Introduction to Software Testing
5. Medical Software Testing
6. Usability Engineering and the IEC 62366 Standard
7. Usability Engineering II: Evaluation Strategies

Module 2: Introduction to Medical AI and ML

Learning Objectives

- Understand what AI/ML are and their role in the development of medical software.
- Understand what deep learning is and why it is the most promising ML technique.
- Understand the role and potential of generative AI in medical applications.

Week 5: Introduction to Machine Learning

Segments

1. AI: History and Relation to Other Fields
2. Introduction to Probability Theory
3. Estimating Probability Density Functions
4. Individual vs. Group Prediction
5. Introduction to Signal Detection
6. Machine Learning Without Tears

Week 6: Classical Machine Learning Techniques

Segments

1. Concepts for Classical Machine Learning

2. Regression
3. Classification
4. Clustering
5. Evaluating Predictive Models

Week 7: Neural Networks and Deep Learning

Segments

1. Neural Networks are Universal Function Approximators
2. Anatomy of a Neural Network
3. How to Train a Neural Network: Backpropagation
4. Practical Considerations in Neural Network Training
5. Motivation for Advanced Neural Network Architectures
6. Recurrent Neural Networks (RNN)
7. Convolutional Neural Networks (CNN)
8. Other Topics in RNNs and CNNs

Week 8: Generative AI

Segments

1. Introduction to Generative AI
2. Large Language Modules
3. Applications of Generative AI in Healthcare
4. Understanding the Role and Potential of Generative AI in Medical Applications
5. Proof of Concept Clinical Application of Generative AI

Module 3: Medical Software with AI

Learning Objectives

- Understand how the use of AI/ML techniques is changing how medical software works.
- Learn about the emerging regulatory structure for AI/ML-enabled medical software.
- Learn about critical social aspects and horizontal "AI" regulations.

Week 9: Regulatory Landscape for AI/ML Enabled Medical Devices

Segments

1. Survey of AI-Enabled Medical Software
2. The FDA Good Machine Learning Guidance
3. Pre-determined Change Control Plans
4. The Singapore Guidance and AI/ML
5. Risk Management and AAMI TIR 34971

Week 10: Software Engineering and AI/ML

Segments

1. Dual Life Cycle Processes for AI/ML Enabled Medical Software
2. Specifications and Data Science Code
3. Data as a Core Software Component
4. Validation Challenges for AI/ML
5. GPUs, Clouds, and Other Details

Week 11: Data Management and Privacy

Segments

1. Introduction to Relational Databases
2. Introduction to the Structured Query Language
3. Introduction to Ontologies
4. Real-World Data and Data-Driven Health IT Applications
5. Navigating Health Privacy Regulations
6. Protecting Privacy

Week 12: Cybersecurity, Broader Issues and Horizontal Regulations

Segments

1. Introduction to Cybersecurity
2. Cybersecurity Guidance Documents
3. Explanations for Machine Learning Systems
4. Non-Medical AI Regulations
5. ChatGPT as a Medical Device?
6. Optimists and Pessimists: The Current AI Debate

Module 4: Current and Emerging Medical Applications

Learning Objectives

1. Understand the use of AI/ML enabled software applications in Radiology/Medical Imaging.
2. Understand what clinical decision support systems are and how they are used.
3. Learn about emerging applications such as multimodal AI, auditing, and genomic analysis.

Week 13: AI/ML Software in Radiology and Medical Imaging

Segments

1. A Survey of Medical Imaging
2. Medical Images and PACS/DICOM
3. Interpretability and Medical Image Analysis
4. A Demo of PACS and EHR
5. Radiology Workflow and AI

6. Example Medical AI Imaging Applications
7. Imaging Guided Therapy

Week 14: Clinical Decision Support Systems

Segments

1. Overview of the Development of CDS Systems
2. CDS Systems and Medical Devices: Similarities and Differences
3. Integration of Artificial Intelligence in CDS Development
4. AI-CDS Applications

Week 15: Emerging Applications of AI-Enabled Medical Software.

Segments

1. The Patient Digital Experience Reimagined
2. The Future of Patient-Generated Health Data
3. Electronic Health Record Audit Logs: A Lens into the Process of Healthcare
4. Privacy-Enhancing Technologies
5. Blockchain: Introduction and Healthcare Applications
6. Multimodal Medical AI
7. An Introduction to Pharmacogenomics

Week 16: Course Summary: AI & Medical devices:

Five simple questions

Segments

1. What is going on?
2. How did we get here?
3. What are we talking about?
4. What can go wrong?
5. What is different now? What is the same?

Sample course videos can be found on our YouTube Channel [at this link](#).