ILLINOIS
Bioengineering
GRAINGER COLLEGE OF ENGINEERING

BIOE 489: Regulations, Ethics and Logistics in Biomedical Applications of Machine Learning

Meeting time: 3:30-4:50 MW (80 min)
Location: 106B3 Engineering Hall
Credit hours: 3/4
Semester: Fall
Prerequisites: Enrollment in BICMSc or permission of the instructor.

Instructor Information

Frank Brooks, Ph.D.

Course Description

The application of machine learning (ML) to medical image data is an area of intense, well-funded research. Due to practical logistics, however, the ideas expounded in published research articles do not necessarily translate perfectly into clinical implementation. The purposeful design and assessment of machine learning experiments will be introduced and revisited throughout the course. The financial cost of training, data acquisition and expert labelling will be considered in the context of product delivery. Some relevant university, corporate and governmental regulatory policies will be presented by expert guest lecturers. Specific issues of clinical implementation and adoption of new technology will be covered. The ethics of using images influenced or analyzed by ML in patient care and/or medical research will be explored in depth. Topics include: diagnosis accuracy, mandated system upgrades, informed consent, patient privacy, researcher/vendor liability, and the role and reliability of federal regulations in ethical application of ML to biomedical data. The policies and procedures of NIH study sections and internal review boards will be highlighted and some key issues related to intellectual property will be surveyed.

Textbook and Reading Materials

There are no required textbooks, however, the following references may be interest:

- (optional) *The Alignment Problem* by Brian Christian.
- (optional) *AI and Ethics* a Springer Journal, Electronic ISSN 2730-5961
- (optional) *Possible Minds: Twenty-five Ways of Looking at AI* edited by John Brockman
- (optional) *Deep Learning Illustrated: A Visual, Interactive Guide to Artificial Intelligence* by Jon Krohn

Additional Requirements

A modern computer with access to the University VPN. Those taking the course for graduate credit are required to run rudimentary simulations of random events (e.g., drawing 10 random patients from a sample of 100). These can be done in Python, R, or any modern programming language with which the student is familiar.

Course Objectives

- Effectively identify key philosophical and ethical concerns in deploying biomedical AI
- Effectively identify the root problem a proposed AI is to address
- Know the differences among types of AI and how each type is evaluated
- Be able to read and understand schematic diagrams of various AI architectures
- Be able to design and/or request meaningful evaluations of AI when data and resources come at a premium
- Understand the role of external regulators in biomedical applications of AI
- Be aware of key regulatory, data use, privacy, and intellectual property concerns
- Know that researchers and vendors have an ethical responsibility in the development and deployment of AI
- Appreciate that the AI products vendors sell may not perfectly reflect researchers' intent
- Understand some of the economics of developing and deploying biomedical AI
- Be able to meaningfully communicate with developers, vendors, regulators, and buyers of biomedical AI
- Gain some appreciation of the enormous potential impact of AI on society

Course Policies

- **Lectures**
  - Class meetings will consist primarily of lectures (see schedule and attendance policies, below).
  - The mid-term exam and final exam will take place during normal class hours.
- **Reading**
  - There are numerous articles to read throughout the course. These articles pertain to the lecture topics each week and, ideally, would be be read before attending the lecture.
- **Quizzes**
  - All students are expected to complete 1-2 quizzes per week via Canvas by 6:00 pm on Sunday. Quizzes are over lecture material and assigned reading.
- **Homework**
  - There are *an additional 6 assignments for those taking 489 as a four-credit course*. Each assignment comprises 4-5 multi-part, short-answer questions, which usually are based on additional reading.
- **Exams**
  - Two in-class, pen-and-paper exams will be given. These will comprise several short-answer and short-calculation problems covering key concepts from the course.
- **Attendance & Participation**
  - Students are expected to attend at least 80% of the classroom lectures.
  - Students are expected to meaningfully participate in class.
- **Additional Policies**
  - In general, no make-up exams will be given and quiz/homework deadlines are firm. Special circumstances regarding absence or forbearance will be handled on a case-by-case basis at the discretion the instructor. Please inform the instructor promptly if additional consideration is required.

Grading & Assessment

For those taking 489 as a three-credit-hour course, the overall course grade will comprise: 67% quizzes and 33% exams. For those taking 489 as a four-credit-hour course, the overall course grade will comprise: 33% quizzes, 33% homework, and 33% exams. The course grade is given on absolute scale and will not be curved. Final course grades will be rounded to the nearest whole number. Concerns about individual assignments or grades should be expressed to the instructor promptly.

Grade scale (%):

A+ [97, 100]	**B+** [87, 90)	**C+** [77, 80)	**D+** [67, 70)	**F** [0, 60)
A [93,97)	**B** [83,87)	**C** [73,77)	**D** [63,67)	
A- [90,93)	**B-** [80,83)	**C-** [70,73)	**D-** [60,63)	

Tentative Schedule

(see next page)

Tentative Schedule

Lecture	Fall 2025	Topic	Note
1	August 25	What sort of problems can AI solve and how difficult are they?	
2	August 27	Orders of magnitude: how “big” is AI?	
	September 01	***Labor Day***	No class
3	September 03	How machines can represent data and make decisions	
4	September 08	Taxonomies of machines and tasks; what do “transformers” do?	
5	September 10	Methods of evaluating any observer—human or machine	HW 1 due
6	September 15	What do “risk” and “bias” really mean?	
7	September 17	What is the “standard of care?” Do we need to upgrade our AI?	
8	September 22	Must deployed AI be understandable in order to be trustworthy?	
9*	September 24	What is informed consent and is it even possible an age of AI?	
10	September 29	Legal liability of vendors, hospitals, and physicians.	HW 2 due
11	October 01	The logistics of supporting deployed AI.	
12*	October 06	Integrating AI into clinical workflows.	
13	October 08	L1-12 Review: evaluating an interactive radiology assistant	
	October 13	***Mid-term exam***	HW 3 due
14	October 15	Grant mechanisms: academic, governmental, corporate, and private	
15	October 20	Writing clear proposals for funders and regulators	
16	October 22	Institutional Review Boards, HIPAA compliance, and privacy	
17*	October 27	The role of the Office of Technology Management	
18	October 29	Data lakes: storage, management, and (FAIR) future use of data	HW 4 due
19	November 03	Large-scale learning: federation, standardization, and harmonization.	
20*	November 10	NDAs, ownership, and liability for machine-generated data & results	
21	November 12	Conflicts of interest: should radiologists regulate AI for radiology?	
22*	November 17	The role of the FDA in AI regulation	
23	November 19	Case study: a mock review process (***bring a laptop if you can***)	HW 5 due
	November 22-30	***Fall Break***	No class
24	December 01	The USA and international stances on AI and patient rights	
25	December 03	Case study: potential long-term effects of AI upon society.	
26	December 08	Course review: should the government compel a virtual psychologist to read your social media?	
	December 10	***Final Exam***	HW 6 due

NOTE: *A guest lecturer is planned for weeks indicated with an asterisk **