REG 6180 Introduction to Vaccine Development

Spring 2025

Time: Wednesday, 4:00-7:00PM

Location: Virtual Class via Zoom

Instructor Information

Course Director

Jeff Barrett, PhD, FCP

Chief Science Officer

Aridhia Bioinformatics

General Course Information

Learning Objectives

1. Recall the history of vaccine discovery and development
2. Describe the 4 phases of vaccine development
3. Discuss the global history and impact of vaccines and the interests of major global stakeholders
4. Differentiate the vaccine development process from drug development processes
5. Describe the regulatory basis by which vaccines are evaluated, approved, and distributed
6. Generate and refine novel ideas for innovating vaccine development processes

Description

Vaccine development is the process by which new vaccines are discovered, studied in laboratory and preclinical models and investigated clinically in patients to determine if they are safe and efficacious. Assuming the vaccine under investigation passes systematically defined milestones, submission of all documentation to regulatory authorities (e.g., US FDA and equivalent global regulatory authorities) can ensue and, pending a favorable review, market access can be granted. The process is highly regulated and there is significant cost involved for pharmaceutical sponsors to research and develop vaccines with the entire process averaging around 12 years once a product is discovered.

This introductory course lays the foundation for conducting vaccine research in many ways. It begins with a brief review of the history of vaccine discovery and development and explains the phases of vaccine development in detail. Global Health history and impact of vaccines is described as well as the various stakeholders (e.g., WHO and World Bank) involved which distinguish vaccine from drug development. The decision-making process, vaccine development milestones and compound progression metrics are defined and explained with examples. At the conclusion of this course, students should have a working knowledge of the vaccine development process, understand the regulatory basis by which new vaccines are evaluated, ultimately approved, and distributed around the world.

This course is directed and taught primarily by Dr. Jeff Barrett of the Perelman School of Medicine who has over 30 years' experience in pharmaceutical and vaccine research and development experience, 17 years of which were spent in the pharmaceutical industry from 1990 to 2003 and 2013 to 2017. Most recently, Dr. Barrett has been recently employed at Aridhia Bioinformatics as their Chief Science Officer. Previously, he was Senior Vice President at the Critical Path Institute, a non-profit organization funded primarily through grants from the US Food & Drug Administration. In this role, Dr. Barrett leads the development of a data and analytics platform across all rare diseases to accelerate therapy development. RDCA-DAP aiming to aggregate existing data from multiple sources into a single integrated database and develop an analytic platform to help users use and interpret that data. Working in collaboration with colleagues at the National Organization for Rare Disorders and FDA to help understand how rare diseases progress and how to measure such progression and therefore to accelerate new treatments and cures. Before C-Path, Dr. Barrett worked at the Bill & Melinda Gates Medical Research Institute, a wholly owned subsidiary of the Gates Foundation which focuses on the development of products to fight malaria, tuberculosis, diarrheal diseases and improve outcomes in maternal and newborn health — major causes of mortality, poverty, and inequality in Low- and Middle-Income Countries (LMIC). Vaccines are one of the more attractive modalities in the mission of the Gates MRI and Dr. Barrett's team has been involved in the research and development of both malaria and tuberculosis vaccines. Dr. Barrett's sessions are filled with anecdotes from his time in the industry, academia and the non-profit sector and he shares numerous examples from personal experience as well as many which represent milestones in the industry. Guest facilitators will provide topical variety throughout the course.

Evaluation Methods:

Students will be graded based on class attendance, participation, group assignments and a short final project.

Grading Scale

Category	Percentage
Attendance	10%
Assignments (Blogs, Presentations) (5 total)	70%
Final Project	20%

Program and Course Policies:

Online Community Standards and Program Expectations

All students taking ITMAT Education online and hybrid courses must ensure that their learning environment for synchronous course meetings is appropriate and free from distractions to themselves, other students, and instructors. Specifically, participate in the session in a physical space and surrounding environment that allows you to devote your full attention to the course meeting. Remain stationary in that location for the duration of class. You are expected to log on using a computer, with working microphone and video capabilities. During class, your video must be operational and be on at all times, with your background blurred and your microphone muted to minimize unexpected distractions to you and your fellow students. Please be appropriately attired (casual wear is fine). If you identify issues that compromise your ability to meet these expectations, contact the course director to seek ways to resolve the situation in a timely manner.

Two general rules of thumb are (i) if you wouldn't expect your instructor to facilitate a class under any condition or set of conditions, it is equally unacceptable for a student to attend class under those same conditions; (ii) if you would not do something in an in-person classroom environment, it should not be done in a synchronous online class. Some examples of unacceptable conduct during synchronous sessions include attending class while driving; attending class while walking; attending class while also working; attending class while being physically located in a busy environment or an environment likely to be disrupted by other people or significant background noise; attending class using your cell phone.

ITMAT Ed is committed to creating a supportive, respectful, and productive learning environment for all students. Students will remain professional and respectful of their peers, course instructors, and guest lecturers. We expect students to approach debates and disagreements in a thoughtful and respectful manner.

Attendance

If you will be absent from a synchronous class, contact the director prior to your absence, at least 48 hours in advance. Students should not make absence a habit: More than 2 absences may result in negative impacts to your participation or final grade. Students who have a recurring conflict with the class time/day (4 p.m. Eastern time on Wednesdays) should not enroll in the class.

 If you have other concerns regarding attendance requirements, contact the Course Director as soon as possible.

Students will be on time, keep their video feed on, and remain present engaged in class for the duration of the class. If you will be late to class or need to leave early, please email the course coordinator and instructor prior to class. Any student more than 15 minutes late or who does not keep video on will be considered absent from class. Additionally, any student who leaves early may be marked absent.

Students who are absent from any class are at a minimum always responsible for reviewing and other materials covered during a class. This may include recording, slides, assigned readings.

Participation and Active Participation

Participation in class is crucial to students' success. Students will attend and actively engage with the content and participate in discussion all courses.

Examples of active participation in a synchronous session include:

- asking or answering questions during class
- collaborating with other students during group work
- sharing relevant expertise with other students and the instructor
- incorporating knowledge or information from out-of-class readings and videos to enrich the conversation

Examples of active asynchronous participation include:

- asking or answering questions after class via Canvas or email
- interacting with other students outside of synchronous class

Student Disability Services

The University of Pennsylvania provides reasonable accommodations to students with disabilities who have self-identified and been approved by the office of Student Disabilities Services (SDS). Please make an appointment to meet with your instructor and the course coordinator as soon as possible to discuss your accommodations and your needs. To request accommodations or ask questions, you can make an appointment by calling SDS at 215-573-9235 or accessing the MyWeingartenCenter portal. The office is in the Weingarten Learning Resources Center at Hamilton Village, 220 S 40th St Suite 260. All services are confidential.

Learn more about the types of services and accommodations offered by Weingarten.

Grading, Late Work, Extension, and Resubmission

Grading

The grading system is as follows: A, excellent; B, good; C, fair; D, poor; and F, failure.

LETTER GRADE	PERCENT SCORE
A	93-100
A-	90-92
B+	87-89
B	83-86
B-	80-82
C+	77-79

C	73-76
C-	70-72
D+	67-69
D	63-66
D-	60-62
F	0-59

At the graduate level for students enrolled in ITMAT Ed programs, **the minimum standard for satisfactory work in each course is a B-.**

Extensions & Late Work
Please contact the coordinator & director at least 48 hours prior to a due date to request an extension on an assignment and share a rationale. The course director reserves the right to grant or deny extensions, or to take off points (or refuse to accept) late assignments.

Course Evaluations

Course evaluations are an opportunity to share feedback on the strengths of the course, and opportunities for improvement. We welcome constructive feedback in the BLUE system. Completing evaluations is a required part of course participation. An email from the BLUE system is sent to students with a link and directions on how to complete the course evaluation(s).

Course Management: Canvas

All course materials and assignments will be managed on Canvas. Log in with PennKey and password. Additional information on configuring and using Canvas will be provided in the Canvas site.

Student Conduct

ITMAT Ed students must comply with the University's Code of Student Conduct and other University policies that appear in The PennBook: Resources, Policies and Procedures Handbook. An important principal of code of conduct is to behave in the virtual space in the same way you would during an in-person class and/or a work meeting. **If you wouldn't do it in a work meeting or in-person class, don't do it in the virtual space.**

Academic Integrity
The fundamental value of our academic community is intellectual honesty; accordingly, our academic community relies upon the integrity of every member. Students are responsible not only for adhering to the highest standards of truth and honesty but also for upholding the principles and spirit of the Academic Code. Violations of the Code include but are not limited to plagiarism, cheating, and fabrication, among others. Please review the Code of Academic Integrity in the PennBook.

Alleged violations of the Code of Academic Integrity are reviewed by the Program Director and as necessary referred to the Penn Center for Community Standards and Accountability. If a student is unsure whether their action(s) constitute a violation of the Code of Academic Integrity, it is that student's responsibility to consult with the instructor to clarify any ambiguities.

Use of Generative AI

It is plagiarism to submit work produced by a generative artificial intelligence (AI) service as your own without citing the source. Any use of generative AI services must be in alignment with course requirements and restrictions. Course Directors have full discretion to allow or deny use of ChatGPT or similar AI tools in their courses.

In the past, students have used generative AI in this class (Intro to Vaccine Development) to generate ideas and protocols for critique and additional analysis. For the purposes of REG 6180, students may use generative AI (such as ChatGPT) for assignments, if they:

- Distinguish what is their own writing vs. what was written by AI
- Critique AI-generated content as necessary
- Take responsibility for the validity of AI-generated content
- Do NOT use AI for the final project (TPP/Portfolio)

Recognize that any use of AI is likely to provide you only with a starting point, as this class emphasizes critical thinking and problem-solving in specific arenas.

Religious and Cultural Holidays

Religious and cultural holidays are listed on the University of Pennsylvania's Chaplain website. If a student observes any of the listed holidays and they conflict with a class date, please contact program staff with class date with which the holiday coincides.

If an assignment is due during a holiday, program staff and faculty will work with the student to determine an alternative due date.

Course Schedule

Introduction & Overview

Wk	Wed. @ 4 p.m.	Time (mins)	Topic	Lecturer	Project	Date Assigned	Due Date
1	Wed. 1/15	45	Class Introductions	Barrett			
		45	Personal Introductions	*Class*			
		30	**Introduction to Vaccine Development - a Case for Vaccines (Lecture 1)**	Barrett			

Wk	Wed.	Time	Topic	Lecturer	Project	Date Assigned	Due Date
		15	Break				
		45	**History of Global Health Initiatives and Vaccine Development - A Place for Vaccines (Lecture 2)**	Barrett			
2	Wed. 1/22	30 min	**History of Vaccine Development (Lecture 3)**	Dr. Stanley Plotkin – asynchronous lecture + 30-minute Q&A			
		30 min	Project 1 Assignment: Historical emphasis on pandemics and infectious diseases – missed opportunities for vaccine development?	Barrett/ *Class discussion*	**Project 1 Assigned:** Bias in vaccine development (Presentation)	*1/22/25*	*Materials due Tues. In Canvas 1/28/25*
		45 min	**Who develops vaccines in the modern era? (Lecture 4)**	Barrett			
3	Wed. 1/29	1.5 h	**Developed vs Developing world: vaccine delivery (Lecture 5)**	Barrett			
		1.5 h	Project 1: Class Presentation & Discussion	*Class*	**Project 1 Due:** Bias in Vaccine Development (Presentation)	*1/22/25*	*Materials due Tues. In Canvas 1/28/25*

Phases of Vaccine Development

Wk	Wed. @ 4 p.m.	Time (mins)	Topic	Lecturer	Project	Date Assigned	Due Date
4	Wed. 2/5	45 min	**The Global Burden of Disease (Lecture 6)**	Barrett			
		15 min	Break				
		45 min	**Phases of Vaccine Development: Vaccine vs Drug paradigms (Lecture 7)**	Barrett			
		1.5 h	Class discussion – Guidance on Vaccine Development	Dr. Peter Weina			
5		1.5 h	**Discovery / Preclinical Stage (Lecture 8)**	Barrett			

Wk	Wed.	Time	Topic	Lecturer	Project	Date Assigned	Due Date
	Wed. 2/12	15 min	Break				
		1.25 h	**Phase 1 (Lecture 9)**	Barrett			
6	Wed. 2/19	1.5 h	**Phase 2 (Lecture 10)**	Barrett			
		15 min	Break				
		1.25 h	**Phase 3 (Lecture 11)**	Barrett		*Assigned 2/19/25*	*Present on 2/26/25*
7	Wed. 2/26	1.5 h	Project 2: (in-class) Designing Phase 2 trial – gaining efficiency with novel designs / approaches	Class Project	**Project 2 (in-class project discussions)**		
		15 min	Break				
		1.25 h	**Approval, Post-approval, and Policies (Lecture 12)**	Barrett			

Topics in Vaccine Development

Wk	Wed. @ 4 p.m.	Time (mins)	Topic	Lecturer	Project	Date Assigned	Due Date
8	Wed. 3/5	1.25 h	**Correlates of Protection (Lecture 13)**	Barrett Jeff Sachs, PhD (Merck)			
		15 min	Break				
		1.25 h	**Linking Prevention of Infection to Prevention of Disease (Lecture 14)**	Barrett			
		15 min	Project 3: Blog Assignment: Where is regulatory guidance for vaccine development still lacking?	*Barrett / Class*	**Project 3 Assigned:** Regulatory guidance (Blog)	*3/05/25*	*3/19/25*

9	Wed. 3/12	N.A.	*No Class -Spring Break*				
10	Wed. 3/19	1.25 h	**Vaccine development and new technologies for expression of vaccine antigens (Lecture 15 - asynchronous)**	Barrett	**Project 3 Due:** Regulatory guidance (Blog)	*3/05/25*	*3/19/25*
		15 min	Break				
		30 min	Review of Course Project: Correlates of Protection (COP) plan proposal for new vaccine	*Class*	**Course Project Assigned (Final Presentation)**	*3/19/25*	*4/30/25*
		1.25 h	**Vaccine Manufacturing (Lecture 16 - asynchronous)**	Barrett			
11	Wed. 3/26	30 min	**Supply Chain Considerations for vaccine development, manufacturing and distribution – Q&A based on asychronous material**	Donna Humski			
		1 hr	Jeff Sachs, PhD (Merck)	Sachs			
		1 hr	**Regulatory Milestones and a successful submission (Lecture 17)**	Barrett			
12	Wed. 4/2	30 min	**DNA-encoded vaccines for viral pre-cancers and cancer** Video lecture + live 30-minute Q&A with Dr. Skolnik on the next year of drug development after mRNA vaccines.	Jeffrey Skolnik, MD			
		15 min	Break				
		1 h	**The cost of vaccines around the world (Lecture 18)**	Barrett			
		15 min	Project 4 Blog Assignment: Supply chain considerations for future pandemics – what can we do better?	*Barrett / Class*	**Project 4 Assigned:** Supply Chain Considerations Blog	*4/2/25*	*4/7/25*
13	Wed. 4/9	1.5 h	**Pharmacoepidemiology and the Global Burden of Disease (Lecture 19)**	Barrett			
		15 min	Break				
		1.5 h	Review of Project 4 assignment; class discussion	*Class*	**Project 4 Due:** Supply Chain Considerations Blog	*4/2/25*	*4/9/25*

14	Wed. 4/16	4-5 pm	**Vaccine Development for LMICs (Lecture 20)**	Barrett			
		15 min	Break				
		30 min	Project 5 Blog Assignment: Vaccine litigation Questions & discussion of Course Project	*Barrett / Class*	**Project 5 Assigned:** Vaccine Litigation Blog	*4/16/25*	*4/21/25*
15	Wed. 4/23	4-4:45 pm	**Country level adoption and Policy recommendations (Lecture 21)**	Barrett			
		4:45-5:45 pm	**Optimizing Immunization Schedules (Lecture 22)**	Professor Benedetto Piccoli Rutgers University			
		15min	**Break**				
		6-6:30	**Legal Concerns Q&A with Litigator &** Review of Project 5 assignment	Judge Tom Gowen to field questions based on student's blog assignment	**Project 5 Due:** Vaccine Litigation Blog	*4/16/25*	*4/21/25*
16	Wed. 4/30		Project Presentations – COP Plan and Strategy presentations		**Final Presentations**	*3/19/25*	*4/30/25*

Course Project: Correlates of Protection Plan and Strategy

- More details to come.