REG 6180 Introduction to Vaccine Development

Spring 2023

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

Location: Virtual Class via Zoom

# Instructor Information

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| **Course Director** |  |  |
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| **Jeff Barrett, PhD, FCP**Senior Vice-PresidentCritical Path Institute**1371eagles@gmail.com** |  |  |
| Course Coordinator |  |  |
| **Nik Kroushl****Instructional Designer, ITMAT Education****Perelman School of Medicine, University of Pennsylvania** **nkroushl@upenn.edu** |  |  |

# General Course Information

## 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 the [Critical Path Institute](https://www.c-path.org), a non-profit organization funded primarily through grants from the US Food & Drug Administration. In his current 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

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| **Category**  | **Percentage**  |
| Attendance & Participation  | 10% |
| Assignments (Blogs, Presentations) | 70% |
| Final Project | 20% |

## Course Policies:

### Academic Integrity:

As a student at The University of Pennsylvania, you are required to uphold the [Code of Academic Integrity](https://provost.upenn.edu/policies/pennbook/2013/02/13/code-of-academic-integrity). Specifically, this means that materials that you submit either online or in person should be independent works created by you that uphold all tenets of academic integrity (i.e., do not cheat, fabricate, or plagiarize, amongst others). We encourage you to reach out to the course director or coordinator if you are not clear on what potential violations are.

### Attendance & Participation

Students are expected to attend *and participate* in all classes. If for any reason a student will not be in class, they should contact the course coordinator prior to class to alert them of the absence and make arrangements to make up course content. Two excused absences are allowed during the course which will not affect the attendance grade.

### Canvas:

All course materials (ppts, announcements, lecture recordings) and assignments will be posted on Canvas (canvas.upenn.edu). We recommend that you choose the “Notify me right away” option for your most frequently checked email address in the “Announcements” area of the “[Notification Preferences](https://canvas.upenn.edu/profile/communication)” page.

### Course Evaluations:

Course evaluations are completed via BLUE at the end of the semester. These are a required part of course participation. Students can access evaluation forms with their PennKey and password and will also receive emails when forms are available.

### Student Disabilities 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 me and the course coordinator as soon as possible in order to discuss your accommodations and your needs. If you have not yet contacted SDS, and would like to request accommodations or have questions, you can make an appointment by calling SDS at 215-573-9235 or accessing the [**MyWeingartenCenter**](https://urldefense.com/v3/__https%3A/upenn.us10.list-manage.com/track/click?u=6c89def14a1d88f5cb78518e7&id=22bdd97ae3&e=66d3273cbf__;!!IBzWLUs!TPk0vqHbPJWCqAbCO7VesoIOuzTIRx0XQlopbkilPnv5gR0wbSaeTXYnBN_6NAjVSIuRAaKPwFQXf2DnJwtfp5gVDFMNo7LhEQ2R$) portal. The office is located in the Weingarten Learning Resources Center at Hamilton Village, 220 S 40th St Suite 260. All services are confidential.

# Course Schedule

## Introduction & Overview

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| **Week** | **Date** | **Time Frame** | **Topic** | **Facilitator** |
| 1 | Wed. 1/18 | 45 min | Class Introductions | Barrett |
| 45 min | Personal Introductions  | *Class*  |
| 30 min  | **Introduction to Vaccine Development - a Case for Vaccines (Lecture 1)** | Barrett |
| 15 min  | Break  |  |
| 45 min  | **History of Global Health Initiatives and Vaccine Development - A Place for Vaccines (Lecture 2)** | Barrett |
| 2 | Wed. 1/25 | 30 min | **History of Vaccine Development****(Lecture 3)** | 30-minute Q&A regarding Dr. Plotkin’s recorded lecture (Review full lecture before class) |
| 30 min  | Project 1 Assignment: Review Plotkin’s lecture in the context of vaccine development; what does the current and next generation of vaccine leaders and developers look like relative to Dr. Plotkin?  | Barrett/*Class discussion* |
| 45 min  | **Who develops vaccines in the modern era? (Lecture 4)** | Barrett |
| 3 | Wed. 2/1 | 1.5 h | **Developed vs Developing world: vaccine delivery (Lecture 5)** | *Class* |
| 45 min | Project 1: Class Presentation & Discussion | *Class* |
| 45 min | **The Global Burden of Disease (Lecture 6)** | Barrett |

## Phases of Vaccine Development

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| **Week** | **Date** | **Time Frame** | **Topic** | **Lecturer** |
| 4 | Wed. 2/8 | 45 min | **Phases of Vaccine Development: Vaccine vs Drug paradigms (Lecture 7)** | Barrett |
| 1.5 h | ~~Class discussion – Guidance on Vaccine Development~~ | *~~Victoria Javes (former student of the class) shares details of her Capstone project with the class and experiences so far interviewing vaccine developers and regulators~~* |
| 5 | Wed. 2/15 | 1.5 h | **Discovery / Preclinical Stage (Lecture 8)** | Barrett |
| 15 min | Break  |  |
| 1.25 h  | **Phase 1 (Lecture 9)** | Barrett |
| 6 | Wed. 2/22 | 1.5 h | **Phase 2 (Lecture 10)** | Barrett  |
| 15 min | Break  |  |
| 1.25 h | Project 2: (in-class) Designing Phase 2 trial – planning efficiency with predictive modeling | Class Project |
| 7 | Wed. 3/1 | 1.5 h | **Phase 3 (Lecture 11)** | Barrett |
| 15 min | Break  |  |
| 1.25 h | **Approval, Post-approval, and Policies (Lecture 12)** | Barrett |
| 8 | Wed 3/8 | N.A. | ***No Class –Spring Break***  |  |

## Topics in Vaccine Development

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| **Week** | **Date** | **Time Frame** | **Topic** | **Lecturer** |
| 9 | Wed. 3/15 | 1.25 h | **Correlates of Protection (Lecture 12)** | Barrett  |
| 15 min | Break  |  |
| 1.25 h | **Linking Prevention of Infection to Prevention of Disease (Lecture 13)** | Barrett  |
| 15 min | Project 3: Blog Assignment: Pandemic readiness | *Barrett / Class*  |
| 10 | Wed. 3/22 | 1.5 h (Synchronous) | Class discussion – Guidance on Vaccine Development | *Victoria Javes (former student of the class) shares details of her Capstone project with the class and experiences so far interviewing vaccine developers and regulators* |
| 45 min (Asynchronous) | **Vaccine development and new technologies for expression of vaccine antigens (Lecture 14 - asynchronous)** | Barrett – **Asynchronous**  |
| 45 min (Asynchronous) | **Vaccine Manufacturing (Lecture 15 - asynchronous)** | Barrett – **Asynchronous**  |
| 11 | Wed. 3/29 | 1.5 h | **Key issues in vaccination schedules and policy (Lecture 16)** | Barrett  |
| 15 min | Break |  |
| 30 min  | Review of Course Project: Shark Tank Project: proposals to accelerate vaccine development (group projects) | *Class* |
| 12 | Wed. 4/5 | 1 h | **Regulatory Milestones and a successful submission (Lecture 17)** | Barrett |
| 15 min | Break  |  |
| 1 h | **The cost of vaccines around the world (Lecture 18)** | Barrett |
| 1 h | **Optimizing Immunization Schedules (Lecture 22)** | Professor Benedetto PiccoliDepartment of Mathematical Sciences and Center for Computational and Integrative Biology, Rutgers University |
| 13 | Wed. 4/12 | 1.5 h | **Pharmacoepidemiology and the Global Burden of Disease (Lecture 19)** | Barrett  |
| 15 min | Break |  |
| 30 min | **DNA-encoded vaccines for viral pre-cancers and cancer** | Jeffrey Skolnik, MD - live 30-minute Q&A with Dr. Skolnik on the next year of drug development after mRNA vaccines. (Review full lecture before class) |
| 14 | Wed. 4/19 | 4-5 pm | **Vaccine Development for LMICs****(Lecture 20)** | Alexander Schmidt, MD- guest lecture  |
|  | 5-5:45 pm | **Country level adoption and Policy recommendations (Lecture 21)** | Barrett |
| 15 | Wed. 4/26 |  | Catch up & office hours/ Q&A re: Shark Tank |  |
| 16 | Wed. 5/3 |  | Project 5 Presentations – Shark Tank |  |

## Course Project: “Shark Tank” Business Plan

Students will write a business plan as their final project. Detailed guidance and sample documents will be shared later in the semester. The plan will be 2-4 pages in length and will include:

* Executive summary. An introductory overview of your business.
* Company description. A more in-depth and detailed description of your business and why it exists.
* Market analysis. Research-based information about the industry and your target market.
* Products and services. What you plan to offer in exchange for money.
* Regulatory strategy and plan. The details of your regulatory strategy and plan should it require review and approval by various regulatory authorities.
* Marketing plan. The promotional strategy to introduce your business to the world and drive sales.
* Logistics and operations plan. Everything that happens in the background to make your business function properly.
* Financial plan. A breakdown of your numbers to show what you need to get started as well as to prove viability of profitability.

## Assignment Overview

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| **Project** | **Date Assigned** | **Date Due** |
| Project 1: Confidence in Vaccine Development (Presentation) | 1/25/23 | 1/31/23 |
| Project 2: Designing a Phase 2 Trial (In-class completion) | 2/22/23 | 2/22/23 |
| Project 3: Pandemic Readiness Blog | 3/15/23 | 3/21/23 (initial blog); 3/29/23 (peer responses) |
| ~~Project 4: Vaccine Litigation Blog~~ | ~~4/5/23~~ | ~~4/11/23~~ |
| Course Project: Shark Tank Plan (Presentation + Plan) | 3/22/23 | 5/3/23 |