CLINICAL TRIALS, CERTIFICATE

Certificate Program in Clinical Trials

NOTE: This certificate program may be completed entirely online!

OVERVIEW

TheClinical Trials#Certificate Program focuses primarily on the design, conduct, and analysis of randomized clinical trials for the evaluation of licensed and non-licensed medical products and other health interventions, the regulatory framework for the evaluation of data from clinical trials, and ethical principles for the conduct of clinical trials.

Clinical trials are a key study design for the evaluation of health interventions. The design, conduct, analysis, and interpretation of clinical trials require the integration of knowledge and skills from the fields of epidemiology, biostatistics, regulatory science, medicine, and ethics. The certificate program requires mastering relevant materials from each of these disciplines through the successful completion of coursework and development of a protocol and informed consent document for a randomized clinical trial.

EDUCATIONAL OBJECTIVES

After completing the certificate, students will be able to:

1. Summarize the history of clinical trials and describe the role they play in the evaluation of health interventions.
2. Explain the key differences, advantages, and disadvantages of experimental versus observational study designs.
3. Develop a protocol, consent statement, monitoring plan, and data collection plan for a clinical trial.
4. Review and critique manuscripts presenting the results of clinical trials using CONSORT guidelines.
5. Explain the key ethical principles regarding the design, conduct, and analysis of clinical trials.

SPONSORING DEPARTMENT

Epidemiology (https://publichealth.jhu.edu/departments/epidemiology/)

ADMISSIONS

Contact information and complete admissions information are available on the certificate program page (https://publichealth.jhu.edu/academics/clinical-trials-certificate-program/) on the Bloomberg School of Public Health website.

REQUIREMENTS FOR SUCCESSFUL COMPLETION

The certificate program requires at least 18 credit units that consist of core courses in clinical trials, epidemiology, biostatistics, and research ethics, as well as elective courses focusing on specific issues in the design, conduct, and analysis of clinical trials.#The required courses in clinical trials include introductory courses in epidemiology, clinical trials design and interpretation, and clinical trials methodology.#Students are also required to take at least two additional courses relating to clinical trials, one course in research#ethics, and one course in biostatistics.

Each student will be required to develop a protocol and plan for obtaining consent, e.g., a prototype consent statement, for a randomized clinical trial. The protocol will be 8 to 12 pages long and accompanied by consent statement(s) or other materials appropriate for obtaining consent for a proposed clinical trial. Most students should be able to complete these requirements as a part of one or more class project(s), e.g., 340.861 or 340.655.#Alternatively, the student may sign up for 1 to 2 credits of independent study for this project with a faculty member in the Department of Epidemiology, Clinical Trials and Evidence Synthesis Track. The credits for an independent study to work on the protocol and consent statement(s) can be counted towards the 18 credits required for the certificate program.

Students are strongly encouraged to participate in the seminars, research-in-progress meetings, journal club, and other activities sponsored by the Clinical Trials and Evidence Synthesis Track and the Center for Clinical Trials and Evidence Synthesis.

All required and elective courses must be taken for a letter grade; a minimum grade of C is required in all certificate coursework and students must maintain a 2.75 or better overall GPA for all#certificate coursework. Please note that all students must complete at least two elective courses. Courses completed as required clinical trials coursework will not also count as electives for the certificate program. The certificate program length is flexible; it varies from student to student; however, the program must be completed within three#years.

The student should review thesection of the website that addresses#completionbefore completing the certificate program requirements.#The student's transcript will not indicate that the certificate was earned until the Notification of Completion has been submitted, verified by the certificate program, and processed by the Registrar.

COURSE OF STUDY

Students should check the Bloomberg School course directory (https://publichealth.jhu.edu/courses/) to confirm when the courses are offered. Students should also check for prerequisites and whether instructor consent is required.

Code	Title	Credits
PH.550.860	Academic & Research Ethics at BSPH (All students are required to complete this noncredit online course in their first term of study)	
Required Clinical Trials Coursework: Students must complete the following 3 required courses: (340.601 or 340.721 or 340.751 or 340.761), 340.645, and 340.694. Students must also complete 340.861 (Sequence A below) OR 340.633 and 340.648 (Sequence B below).		
Students must complete one of the following 3 courses:		
PH.340.601	Principles of Epidemiology (typically offered onsite in the Summer Institute)	5
PH.340.721	Epidemiologic Inference in Public Health I (typically offered onsite in 1st term, and online in 1st, 3rd, and Summer terms and Summer Institute)	5
PH.340.751	Epidemiologic Methods 1 (typically offered onsite in 1st term)	5

PH.340.761	Epidemiologic Methods for EPI Doctoral Students I (on-site, first term (restricted to Epi - PhD students only))	5
Students must complete the following 2 courses		
PH.340.645	Introduction to Clinical Trials (typically offered online in 2nd term)	3
PH.340.694	Power and Sample Size for the Design of Epidemiological Studies I (typically offered online in 3rd term and during the Summer and Winter Institutes)	1
Students must complete all courses in either Sequence A or Sequence B		
Sequence A		
PH.340.861	Clinical Trials: Procedures, Design, and Interpretation of Results (typically offered online in 3rd term)	3
Sequence B		
PH.340.633	Data Management in Clinical Trials (typically offered onsite in 3rd term)	3
PH.340.655	Advanced Methods in Clinical Trials	3
Students must complete one of the following Biostatistics courses		
PH.140.611	Statistical Reasoning in Public Health I (typically offered online in 1st term and onsite during the Summer Institute)	3
PH.140.621	Statistical Methods in Public Health I (typically offered onsite in 1st term)	4
PH.140.651	Methods in Biostatistics I (typically offered onsite in 1st term)	4
Students must complete one of the following Ethics courses		
PH.306.665	Research Ethics and integrity (typically offered onsite in 3rd term)	3
PH.390.673	Emerging Ethical and Regulatory Issues in Clinical Research (typically offered onsite in 1st term and online in 2nd term)	3
PH.550.600	Living Science Ethics - Responsible Conduct of Research (typically offered onsite in 1st and 4th term)	1
PH.700.621	Ethics in Clinical Practice: Fundamentals, Problems and Approaches (typically offered online in 2nd term)	3
Students must complete at least two of the following elective courses		
PH.140.633	Biostatistics in Medical Product Regulation (typically offered online in 1st term)	2
PH.140.642	Design of Clinical Experiments (typically offered onsite in 3rd term)	3
PH.223.662	Vaccine Development and Application (typically offered onsite in 2nd term)	4
PH.223.664	Design and Conduct of Community Trials (typically offered onsite in 3rd term)	4
PH.223.690	The Design and Analysis of Cluster Randomized Trials (typically offered onsite in 4th term)	2
PH.223.705	Good Clinical Practice: A Vaccine Trials Perspective (typically offered online in 4th term)	4
PH.340.606	Methods for Conducting Systematic Reviews and Meta-Analyses (typically offered onsite in 3rd term)	4
PH.340.619	Topics in Pharmacoepidemiology (typically offered online during the Summer Institute)	2
PH.340.633	Data Management in Clinical Trials	3
PH.340.660	Practical Skills in Conducting Research in Clinical Epidemiology and Investigation (typically offered onsite in 1st term)	3
PH.340.671	Topics in Management of Clinical Trials (typically offered online during the Summer Institute)	2
PH.340.676	Bayesian Adaptive Trials (typically offered onsite during the Summer Institute)	2
PH.340.682	Pharmacoepidemiology Methods (typically offered online in 2nd term)	3
PH.340.684	Pharmacoepidemiology: Drug Utilization (typically offered onsite in 3rd term)	3
PH.340.686	Introduction to Systematic Reviews and Meta-Analysis (typically offered onsite during the Summer Institute)	2
PH.340.840	Special Studies and Research Epidemiology (Note: Students interested in pursuing this option should contact a faculty member before registering; course is typically offered onsite in 1st, 2nd, 3rd and 4th terms)	1 - 22
PH.340.861	Clinical Trials: Procedures, Design, and Interpretation of Results	3
PH.390.631	Drug Development and Real-World Evidence (RWE) (typically offered onsite in 1st term)	2
PH.390.750	Introduction to Clinical Research (typically offered onsite in Summer term)	2
One of the following courses, but not both, may be counted towards the certificate program as an elective course.		
AS.410.649	Introduction to Regulatory Affairs - Medical Products	4
AS.410.676	Food And Drug Law	4