

# PHARMACOEPIDEMOLOGY AND DRUG SAFETY, CERTIFICATE

## Pharmacoepidemiology and Drug Safety Certificate OVERVIEW

The Certificate Program in Pharmacoepidemiology and Drug Safety is designed for master's and doctoral degree students enrolled at Johns Hopkins Bloomberg School of Public Health and in other Johns Hopkins University divisions, including the Schools of Medicine and Nursing and the Krieger School of Arts and Sciences. It is also available to early and mid-career public health professionals who wish to expand their knowledge of pharmacoepidemiology and drug safety to inform their work in academic, regulatory, or industry settings. The Certificate is a key offering (<https://publichealth.jhu.edu/center-for-drug-safety-and-effectiveness/training/>) of the Center for Drug Safety and Effectiveness (<https://publichealth.jhu.edu/center-for-drug-safety-and-effectiveness/>). Students are encouraged to participate in the activities of the Center. (<https://publichealth.jhu.edu/center-for-drug-safety-and-effectiveness/get-involved/student-opportunities/>)

## EDUCATIONAL OBJECTIVES

This certificate program will provide learners with core knowledge of pharmacoepidemiology and drug safety, as well as insights from these fields that can inform the work of policymakers, patients, clinicians, and payers seeking to improve the quality and safety of medication use. Upon completion of the core courses required for the Pharmacoepidemiology certificate program, participants will have the ability to:

1. Identify the processes of drug development;
2. Explain key requirements in biomedical product regulation and their rationale;
3. Participate in the design of studies, both observational and experimental, to assess the effectiveness and safety of drugs;
4. Employ techniques to study the patterns and determinants of drug utilization;
5. Apply methods appropriate to the surveillance for adverse drug events.

## SPONSORING DEPARTMENT

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

## ADMISSIONS

Contact information and complete certificate program admissions information is available on the certificate program page (<https://publichealth.jhu.edu/academics/pharmacoepidemiology-and-drug-safety-certificate-program/>) on the Bloomberg School of Public Health website.

## REQUIREMENTS FOR SUCCESSFUL COMPLETION

The certificate requires a minimum of 20 term credits. 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.

The certificate program length is flexible; it varies from student to student, however, the certificate must be completed within three years.

The student should review the section of the website that addresses completion (<https://publichealth.jhu.edu/academics/certificate-programs/requirements-for-successful-completion-of-a-certificate-program/>) before completing 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 BSPH course directory (<https://publichealth.jhu.edu/courses/>) to confirm when courses are offered, and students should also check for pre-requisites and whether instructor consent is required.

Code	Title	Credits
PH.550.860	Academic & Research Ethics at BSPH (All students are required to complete this online noncredit course in their first term of study)	

**Required Courses: Students must take one of the following Epidemiology Series\*** \* Non-degree students may waive the Epidemiology series by providing a transcript from another institution demonstrating successful completion of at least one graduate level course in epidemiology and one in biostatistics. These students must still complete a minimum of 20 term credits of required, core, and elective certificate program coursework. \* Bloomberg Degree Students who earn at least a B in one introductory epidemiology (340.601, 340.721 or 340.751, 340.761) and one biostatistics course (140.611, 140.621, 140.651, or 140.751) may use these courses to fulfill the Epidemiology series requirement

*In Series A, students may choose between either 340.601 or 340.721, and they must also complete 340.722*

PH.340.601	Principles of Epidemiology (typically offered onsite in Summer and Summer Institute)	5
PH.340.721	Epidemiologic Inference in Public Health I (typically offered online in 1st, 3rd, Summer and Summer Institute terms)	5
PH.340.722	Epidemiologic Inference in Public Health II (typically offered onsite in 2nd term, and online in terms 2 and 4)	4

*In Series B, students must complete both 340.751 and 340.752*

PH.340.751	Epidemiologic Methods 1 (typically offered onsite in 1st term)	5
PH.340.752	Epidemiologic Methods 2 (typically offered onsite in 2nd term)	5

**Required Courses: Students must also complete the following course:**

PH.340.645	Introduction to Clinical Trials (typically offered online in 2nd term)	3
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**Core Courses: Students must take at least 2 of the following 3 courses:**

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.390.631	Drug Development and Real-World Evidence (RWE) (typically offered onsite in 1st term)	2

*Elective Courses: Students complete the 20 credit requirement by selecting among the following:*

PH.140.633	Biostatistics in Medical Product Regulation (typically offered onsite in 1st term)	2
PH.140.664	Causal Inference in Medicine and Public Health I (typically offered onsite in 3rd term and online in 4th term)	4
PH.140.665	Causal Inference in Medicine and Public Health II (typically offered onsite in 4th term)	3
PH.221.610	Pharmaceutical Systems: Advancing Access to Medicines in the Field (typically offered onsite in 3rd term)	3
PH.308.630	U.S. Pharmaceutical Policy (typically offered onsite in 4th term)	3
PH.317.600	Introduction to the Risk Sciences and Public Policy (typically offered onsite in 1st term and online in 3rd term)	4
PH.317.610	Risk Policy, Management and Communication (typically offered onsite in 2nd term and online in 4th term)	3
PH.340.617	Pharmacoepidemiology (NB: This course is only appropriate for the certificate program if 340.682 was not taken. Course is typically offered onsite in Summer Institute.)	2
PH.340.722	Epidemiologic Inference in Public Health II (typically offered onsite in 2nd term, and online in terms 2 and 4)	4
PH.340.776	Study Design and Analysis for Causal Inference With Time-Varying Exposures (typically offered onsite in 4th term)	3
AS.410.651	Clinical Development of Drugs and Biologics	4