Certificate Courses in Biostatistics

Term I : ***September – December 2015***
Term II : ***January – March 2016***
Term III : ***April – June 2016***

Course Code	Module	Unit	Term
BIOS5001	Introduction to Biostatistics	3	I
BIOS5005	Clinical Trials	1.5	I
BIOS5007	Pharmaceutical Statistics Computing in SAS	2	I
BIOS5002	Linear Models	2	II
BIOS5004	ICH – GCP Standard of Clinical Research	1	II
BIOS6005	Pharmaceutical Bioinformatics	1	II
BIOS5003	Categorical and Survival Data Analysis	3	III
BIOS6001	Topics in Linear Models	2	III
BIOS6002	Topics in Multivariate Analysis	1.5	III

Term I : September – December 2015

BIOS5001 Introduction to Biostatistics (3 credits)

Course Coordinator: Prof. Maggie Wang

Course Description

This course introduces basic statistical concepts and methods. The emphasis of the course is on practical applications: choosing the correct method for particular datasets and correct interpretation of the analysis results. Examples from different disciplines of public health including chronic and infectious disease epidemiology, environmental health, and health policy will be used to illustrate the use of biostatistical methods in answering important public health questions.

Learning Outcomes/Objectives

1. Understand the importance of biostatistics in public health and medical research.
2. Develop a conceptual understanding of basic biostatistics,
3. Critically read and understand the statistical methodology and results sections of medical and public health research papers.
4. Be capable of carrying out basic statistical analyses using SPSS statistical software.

Course Schedule

Session	Date	Time	Venue
1	Sep 10, 2015 (Thu)	6:30 – 9:30 pm	School of Public Health Prince of Wales of Hospital **And** CUHK campus, Shatin, N.T., Hong Kong
2	Sep 17, 2015 (Thu)	6:30 – 9:30 pm	
3	Sep 24, 2015 (Thu)	6:30 – 9:30 pm	
4	Oct 8, 2015 (Thu)	6:30 – 9:30 pm	
5	Oct 15, 2015 (Thu)	6:30 – 9:30 pm	
6	Oct 22, 2015 (Thu)	6:30 – 9:30 pm	
7	Oct 29, 2015 (Thu)	6:30 – 9:30 pm	
8	Nov 5, 2015 (Thu)	6:30 – 9:30 pm	
9	Nov 12, 2015 (Thu)	6:30 – 9:30 pm	
10	Nov 19, 2015 (Thu)	6:30 – 9:30 pm	
11	Nov 26, 2015 (Thu)	6:30 – 9:30 pm	
12	Dec 3, 2015 (Thu)	6:30 – 9:30 pm	
13	Dec 10, 2015 (Thu)	6:30 – 9:30 pm	
14	Dec 17, 2015 (Thu)	6:30 – 8:30 pm	

Fee

Application Fee: $100

Course Fee: $12,600

BIOS5005 Clinical Trials **(1.5 credits)**

Course Coordinator: Prof Benny Zee

Course Description

The objective of this course is to provide students with a theoretical and practical knowledge of the issues involved in the design, conduct, analysis and interpretation of randomized clinical trials. We will discuss the basic principle of randomization and its importance, proper randomization and blinding procedures, choice of control arm, the importance of clear definition of endpoints, methods to calculate sample size, other statistical considerations and ethical issues in clinical trials. Attention will be given to the problems of conducting clinical trials in both single center and multi-center, and covers trials initiated by industry as well as trials in academic setting. Students will be trained to develop skills to properly design clinical trial, critically analyze and carry out research and to communicate effectively.

Learning Outcomes/Objectives

1. Understand the advantages and disadvantages of various designs in clinical research.
2. Understand the concepts of randomization in controlled clinical trials.
3. Develop a protocol for a clinical trial to address the research questions.
4. Have a general knowledge of the statistical issues commonly encountered in clinical trials.
5. Be aware of the ethical issues in clinical trials.
6. Have an appreciation of the Good Clinical Practice (GCP) requirements in the operation of clinical trials.
7. Learn some basic elements of data management and quality assurance in multi-center clinical trial set up.

Course Schedule

Session	Date	Time	Venue
1	Oct 19, 2015 (Mon)	6:30 – 9:30 pm	School of Public Health Prince of Wales of Hospital Shatin, N.T., Hong Kong
2	Oct 26, 2015 (Mon)	6:30 – 9:30 pm	
3	Nov 2, 2015 (Mon)	6:30 – 9:30 pm	
4	Nov 9, 2015 (Mon)	6:30 – 9:30 pm	
5	Nov 16, 2015 (Mon)	6:30 – 9:30 pm	
6	Dec 2, 2015 (Wed)	6:30 – 9:30 pm	
7	Dec 16, 2015 (Wed)	7:00 – 8:30 pm	

Fee

Application Fee: $100
Course Fee: $8,400

BIOS5007 Pharmaceutical Statistics Computing in SAS **(2 credits)**

Course Coordinator: Dr. Marc Chong

Course Description

The objective of this course is to familiarize students with the SAS software for pharmaceutical application. The course starts with the introduction of basic SAS skills followed by using SAS to draw tables, figures, and listings (TFL) and to analyze medical data. Practical scenarios will be given to students to understand the needs of SAS in pharmaceutical industry.

Prerequisite (s) or Recommended Background

1. Basic programming knowledge
2. Basic statistical skills (e.g. BIOS5001 Introduction to Biostatistics)

Learning Outcome

1. manipulate data;
2. draw the tables, figures, and listings (TFL);
3. conduct data analysis to solve medical problems by using SAS.

Students will also get familiarize to

1. the role of SAS programming in pharmaceutical industry
2. industry Regulations and Standards to SAS

Course Schedule

Session	Date	Time	Venue
1	Oct 2, 2015 (Fri)	6:30 – 9:30 pm	CUHK campus, Shatin, N.T., Hong Kong
2	Oct 16, 2015 (Fri)	6:30 – 9:30 pm	
3	Oct 23, 2015 (Fri)	6:30 – 9:30 pm	
4	Oct 30, 2015 (Fri)	6:30 – 9:30 pm	
5	Nov 13, 2015 (Fri)	6:30 – 9:30 pm	
6	Nov 27, 2015 (Fri)	6:30 – 9:30 pm	
7	Dec 4, 2015 (Fri)	6:30 – 9:30 pm	
8	Dec 18, 2015 (Fri)	6:30 – 9:30 pm	
9	Jan 8, 2016 (Fri)	6:30 – 8:30 pm	

Fee

Application Fee: $100

Course Fee: $8,400

Term II : January – March 2016

BIOS5002 Linear Models **(2 credits)**

Course Coordinator: Dr. Marc Chong

Course Description

This course will provide a foundation for the practical analysis of data for which the primary outcome is a continuous variable. The course will begin with an introduction to 'real-world' data analysis with a motivating example looking at predictors of infant birthweight in Hong Kong. Methods for multivariate analysis of predictors of continuous outcomes including one-way and two-way ANOVA and multiple linear regression will then be discussed in detail with an emphasis on correct use of these methods in practice.

Learning Outcomes/Objectives

1. Understand and evaluate the use of linear models in the medical literature in an intelligent manner.
2. Develop skills in analyzing epidemiological data with continuous outcomes using linear models and to understand the basic principles that underlie research designs and statistical inference.
3. Perform fundamental statistical procedures for research projects involving continuous outcomes and interpret results.

Course Schedule

Session	Date	Time	Venue
1	Jan 14, 2016 (Thu)	6:30 – 9:30 pm	School of Public Health Prince of Wales of Hospital **And** CUHK campus, Shatin, N.T., Hong Kong
2	Jan 21, 2016 (Thu)	6:30 – 9:30 pm	
3	Jan 28, 2016 (Thu)	6:30 – 9:30 pm	
4	Feb 4, 2016 (Thu)	6:30 – 9:30 pm	
5	Feb 18, 2016 (Thu)	6:30 – 9:30 pm	
6	Feb 25, 2016 (Thu)	6:30 – 9:30 pm	
7	Mar 3, 2016 (Thu)	6:30 – 9:30 pm	
8	Mar 10, 2016 (Thu)	6:30 – 9:30 pm	
9	Mar 17, 2016 (Thu)	6:30 – 8:30 pm	

Fee

Application Fee: $100
Course Fee: $8,400

BIOS5004 ICH – GCP Standard of Clinical Research (1 credit)

Course Coordinator: Prof. Benny Zee

Course Description

The objective of this course is to provide background of regulation of drugs, devices and biological development. We will apply the principles of ICH-Good Clinical Practice in clinical research and discuss the role and responsibilities of key parties described in the document. We will describe the requirements of essential documentation and adverse event reporting. Scenarios will be given to the students to strengthen their understanding of practical application of ICH-GCP to the clinical trial process.

Prerequisite (s) or Recommended Background

1. Familiar with Declaration of Helsinki
2. Clinical Research Personnel

Learning Outcomes/Objectives

1. Understand the background of international standards and technical requirement of ICH-GCP
2. Describe the principles and structures of ICH-GCP
3. Understand the role of responsibilities of key parties of conducting clinical research
4. Demonstrate Informed Consent Process at workplace
5. Apply relevant knowledge for the process of Adverse Event Reporting
6. Familiar with the Essential Documents required by ICH-GCP

Course Schedule

Session	Date	Time	Venue
1	Jan 11, 2016 (Mon)	6:30 – 9:30 pm	School of Public Health Prince of Wales of Hospital Shatin, N.T., Hong Kong
2	Jan 18, 2016 (Mon)	6:30 – 9:30 pm	
3	Jan 25, 2016 (Mon)	6:30 – 9:30 pm	
4	Feb 1, 2016 (Mon)	6:30 – 9:30 pm	
5	Feb 15, 2016 (Mon)	6:30 – 7:30 pm	

Fee

Application Fee: $100

Course Fee: $4,200

BIOS6005 Pharmaceutical Bioinformatics **(1 credit)**

Course Coordinator: Prof. Maggie Wang

Course Description

The course will provide a broad overview and introduction to bioinformatics and its applications in pharmaceutical industry. Topics will cover (1) basic bioinformatics methods: hierarchical clustering, lasso, random forest, LDA, PCA, boosting, bootstrapping, etc. (2) data sequencing and management: microarray data, GWAS data, the raw data treatment and analysis method, batch effect and normalization, parallel programming in R; (3) phylogenic analysis; (4) Chemobioinformatics modeling, 3D structure, chemical - protein relation leading to drug discovery.

Prerequisite

1. BIOS5001 Introduction to Biostatistics

Recommended Background

1. BIOS5002 Linear Models
2. BIOS5003 Categorical and Survival Data Analysis

Learning Outcome

1. Understand the basic bioinformatics methods
2. Know how to use the software of conducting bioinformatics analysis
3. Know when to apply the methods under different scenarios and conduct exploratory research
4. Interpret data analysis output, and use graphical representations

Course Schedule

Session	Date	Time	Venue
1	Jan 29, 2016 (Fri)	6:30 – 9:30 pm	School of Public Health Prince of Wales of Hospital Shatin, N.T., Hong Kong
2	Feb 5, 2016 (Fri)	6:30 – 9:30 pm	
3	Feb 19, 2016 (Fri)	6:30 – 9:30 pm	
4	Feb 26, 2016 (Fri)	6:30 – 9:30 pm	

Fee

Application Fee: $100

Course Fee: $4,200

Term III : April – June 2016

BIOS5003 Categorical and Survival Data Analysis **(3 credits)**

Course Coordinator: Prof Maggie Wang

Course Description

This course will provide a foundation for the practical analyses of categorical and time to event (survival) data. The course will cover the use of logistic regression models for use with binary outcomes and Cox proportional hazards regression models for time to event outcomes. Practical application of these models will be emphasized and model building and the checking of model assumptions will be covered in detail.

Learning Outcomes/Objectives

1. Understand the concepts, assumptions and logic involved in statistical methods commonly used in medical research including categorical data analysis and time-to-event data analysis.
2. Develop appropriate statistical models for the data and correctly interpret the results.

Course Schedule

Session	Date	Time	Venue
1	Mar 24, 2016 (Thu)	6:30 – 9:30 pm	School of Public Health Prince of Wales of Hospital **And** CUHK campus, Shatin, N.T., Hong Kong
2	Mar 31, 2016 (Thu)	6:30 – 9:30 pm	
3	Apr 7, 2016 (Thu)	6:30 – 9:30 pm	
4	Apr 14, 2016 (Thu)	6:30 – 9:30 pm	
5	Apr 21, 2016 (Thu)	6:30 – 9:30 pm	
6	Apr 28, 2016 (Thu)	6:30 – 9:30 pm	
7	May 5, 2016 (Thu)	6:30 – 9:30 pm	
8	May 12, 2016 (Thu)	6:30 – 9:30 pm	
9	May 19, 2016 (Thu)	6:30 – 9:30 pm	
10	May 26, 2016 (Thu)	6:30 – 9:30 pm	
11	Jun 2, 2016 (Thu)	6:30 – 9:30 pm	
12	Jun 16, 2016 (Thu)	6:30 – 9:30 pm	
13	Jun 23, 2016 (Thu)	6:30 – 8:30 pm	

Fee

Application Fee: $100
Course Fee: $12,600

BIOS6001 Topics in Linear Models **(2 credits)**

Course Coordinator: Prof Benny Zee

Course Description

This course will cover advanced statistical modeling techniques for use with complex datasets. Topics will include Poisson and Negative Binomial regression for count outcomes, repeated measures ANOVA, GEE models and multilevel models for longitudinal data and multilevel models for clustered data.

Learning Outcomes/Objectives

Upon completion of this course students will understand the reasons that more complex statistical models need to be used for datasets for which the assumptions of linear or logistic regression are not valid, such as datasets with ordinal or count outcomes, longitudinal or clustered data, and data with non-linear associations between variables. They will understand which models should be used for each of these situations, how to fit and interpret these models, and how to check the assumptions of these models.

Course Schedule

Session	Date	Time	Venue
1	Apr 25, 2016 (Mon)	6:30 – 9:30 pm	School of Public Health Prince of Wales of Hospital Shatin, N.T., Hong Kong
2	May 9, 2016 (Mon)	6:30 – 9:30 pm	
3	May 16, 2016 (Mon)	6:30 – 9:30 pm	
4	May 23, 2016 (Mon)	6:30 – 9:30 pm	
5	May 30, 2016 (Mon)	6:30 – 9:30 pm	
6	Jun 6, 2016 (Mon)	6:30 – 9:30 pm	
7	Jun 13, 2016 (Mon)	6:30 – 9:30 pm	
8	Jun 20, 2016 (Mon)	6:30 – 8:30 pm	

Fee

Application Fee: $100
Course Fee: $8,400

BIOS6002 Topics in Multivariate Analysis **(1.5 credits)**

Course Coordinator: Dr. Lai Xin

Course Description

This course will cover methods importance in the analysis of data collected from questionnaires. Both exploratory and confirmatory factor analysis (under the framework of Structural Equation Models) will be discussed.

Learning Outcomes/Objectives

After taking this course the students will understand the uses of exploratory factor analysis, discriminant analysis and SEM methods including confirmatory factor analysis and path analysis in the exploration and hypothesis testing for data collected from questionnaires.

Course Schedule

Session	Date	Time	Venue
1	Feb 29, 2016 (Mon)	6:30 – 9:30 pm	School of Public Health Prince of Wales of Hospital Shatin, N.T., Hong Kong
2	Mar 7, 2016 (Mon)	6:30 – 9:30 pm	
3	Mar 14, 2016 (Mon)	6:30 – 9:30 pm	
4	Mar 21, 2016 (Mon)	6:30 – 9:30 pm	
5	Apr 11, 2016 (Mon)	6:30 – 9:30 pm	
6	Apr 18, 2016 (Mon)	6:30 – 9:30 pm	

Fee

Application Fee: $100
Course Fee: $6,300