

Fundamentals of Clinical Trials Syllabus
HSPH-HMS 214x
Fall 2013

INTRODUCTION AND COURSE DESCRIPTION

This course is designed for students interested in the scientific, statistical, policy, and ethical aspects of clinical trials research. The course will provide a comprehensive overview of the design and analysis of clinical trials, including first-in-human studies (dose-finding, safety, proof of concept, Phase 1), Phase II, Phase III, and Phase IV studies. It is organized into 12 weeks of material. Each week, you will watch 2 to 3 recorded lectures averaging about 20 minutes in length. Each recorded lecture will be accompanied by assessment questions that test understanding and extend the ideas presented in the video.

RECOMMENDED TEXTBOOKS

The textbooks listed below are not required but are recommended for students who would like to have a single source covering many of the issues discussed during the course. Some chapters in the book by Pocock have been provided as open source material by the publisher and will be posted on the course website.

1. Friedman LM, Furberg CD, and DeMets DL. Fundamentals of Clinical Trials. 4th Edition. 2010 <http://tinyurl.com/n7t6bcx>. Springer.
2. Pocock SJ. Clinical Trials: A Practical Approach. ISBN: 978-0-471-90155-6.
6. John Wiley & Sons. www.wiley.com/buy/9780471901556

Additional readings are also recommended in the feedback text of each assessment question. Many of the referenced readings are readily available online. If they are available, free-of-charge, the URL link is given (the links are also listed on the course page; the tab is titled ‘Open Access Readings’).

HOW TO USE THE COURSE MATERIALS

Watch the videos assigned to each week of the course. Following each lecture is a short assessment; answer the questions to the best of your ability. After answering the questions, make sure to review the feedback text as it gives further information and additional readings. The recommended readings are provided for students interested in learning more about that topic.

CERTIFICATION

Participants who complete 80% of all assessments for the course and contribute to the discussion of at least two of the four cases (see below) will earn a certificate of completion. These certificates will indicate you have successfully completed the

course, but you will not receive a grade. Certificates will be issued by edX under the name of HarvardX. These certificates are issued free of charge.

Students pursuing the certificate of completion are expected to complete the assessments independently.

DISCUSSION BOARDS

The course website provides a separate discussion board for each week. The discussion boards provide an opportunity for you to communicate with the course team and other students. We hope that they contribute to a sense of community and serve as a useful resource for your learning. Here are some guidelines to observe on the forums.

- Search before asking: The forum will be hard to use if there are multiple threads on the same issue and the best discussions happen when several people participate in a single thread. Before asking a question, use the search feature by clicking on the magnifying glass at the top right of the list of postings.
- Be polite: We have learners from all around the world with diverse backgrounds. Something that is easy for you may be challenging for someone else. Let's build an encouraging community.
- Encourage useful posts: This applies to both questions and responses. Click on the green plus button at the top right of the box for either a post or a response. In this way, useful posts can be found more easily.
- Be specific and concise: Try to compose a title that is descriptive and provide as much information as possible without being overly long: In your title, specify the problem or video and, in a few words, what your issue is. In the question text, describe what aspect you do not understand and what you have already tried doing.
- Write clearly: We know that English is a second language for many of you but correct grammar will help others to respond. Avoid ALL CAPS, abbrev of wrds (abbreviating words), and excessive punctuation!!!!

COURSE SCHEDULE				
Week #	Release Date	Videos & Assessments	Case Topic	Other
	10/14/13	<ul style="list-style-type: none"> • Introduction video 	N/A	Complete pre-survey!
1	10/14/13	<ul style="list-style-type: none"> • Why are clinical trials important? • Early clinical trials • What makes clinical research ethical? 	N/A	
2	10/27/13	<ul style="list-style-type: none"> • Clinical trials to improve human health • Designing first in human studies • Ethical issues in early stage research 	N/A	
3	11/3/13	<ul style="list-style-type: none"> • Phase 2 and Phase 3 clinical trials • Choosing the question • The fundamental ethical dilemma 	Ethical Considerations in Phase I studies: Gelsinger Case Ethical Considerations in Phase I studies: TGN1412 Case	Case #1
4	11/10/13	<ul style="list-style-type: none"> • Defining the study population • Defining the treatment groups • Ethical issues in selection of control groups 	N/A	
5	11/17/13	<ul style="list-style-type: none"> • Defining the Outcomes • The Statistical Analysis Plan 	N/A	
6	12/01/13	<ul style="list-style-type: none"> • Sample Size and Power I: Binary Outcomes • Sample Size and Power II: Measured Outcomes • Sample Size and Power III: Time to Event Outcomes 	Vemurafenib in melanoma: Phase 2 trials in action	Case #2
7	12/08/13	<ul style="list-style-type: none"> • Baseline Assessment • Randomization • Data Monitoring 	N/A	
8	12/15/13	<ul style="list-style-type: none"> • Data Analysis: Continuous Variables • Data Analysis: Binary Outcomes • Data Analysis: Time to Event Endpoints 	N/A	
9	01/05/14	<ul style="list-style-type: none"> • Interpretation of Study Findings Part I • Interpretation of Study Findings Part II 	The evidence for race-based therapeutics and the BiDil trials	Case #3
10	01/12/14	<ul style="list-style-type: none"> • Surveillance Part I • Surveillance Part I 	N/A	
11	01/19/14	<ul style="list-style-type: none"> • Non-inferiority Trials Part I • Non-inferiority Trials Part II • Pragmatic Trials 	Post-marketing surveillance and the ongoing Pradaxa controversy	Case #4
Summary	01/19/14		N/A	