# Clinical Trials Management and Regulatory Compliance 2015–16

## Course Schedule by Date

### Autumn 2015

<table>
<thead>
<tr>
<th>Start Date</th>
<th>Course Code</th>
<th>Section</th>
<th>Course Title</th>
<th>Instructor</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/23/15</td>
<td>CTGCPR</td>
<td>15A1</td>
<td>Good Clinical Practices</td>
<td>Anne Pohlman</td>
</tr>
<tr>
<td>10/12/15</td>
<td>CTTDDP</td>
<td>15A7</td>
<td>The Drug Development Process</td>
<td>Andrew Kucharski, Elizabeth Robinson</td>
</tr>
<tr>
<td>11/9/15</td>
<td>CTFAMC</td>
<td>15A7</td>
<td>Fraud and Misconduct</td>
<td>Pamela Mason</td>
</tr>
</tbody>
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### Winter 2016

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<tr>
<td>1/11/16</td>
<td>CTGCPR</td>
<td>16W7</td>
<td>Good Clinical Practices</td>
<td>Andrew Kucharski</td>
</tr>
<tr>
<td>2/15/16</td>
<td>CTFOSM</td>
<td>16W7</td>
<td>Fundamentals of Site Management</td>
<td>Eileen Dickman</td>
</tr>
<tr>
<td>3/16/16</td>
<td>CTSCCR</td>
<td>16W1</td>
<td>Statistical Concepts for Clinical Research</td>
<td>Martin King</td>
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### Spring 2016

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<tr>
<td>3/28/16</td>
<td>CTTDDP</td>
<td>16S7</td>
<td>The Drug Development Process</td>
<td>Andrew Kucharski, Elizabeth Robinson</td>
</tr>
<tr>
<td>4/4/16</td>
<td>CTFAMC</td>
<td>16S7</td>
<td>Fraud and Misconduct</td>
<td>Pamela Mason</td>
</tr>
<tr>
<td>5/5/16</td>
<td>CTFOCM</td>
<td>16S7</td>
<td>Fundamentals of Clinical Monitoring</td>
<td>Elizabeth Robinson</td>
</tr>
<tr>
<td>6/1/16</td>
<td>CTPMLH</td>
<td>16S1</td>
<td>Project Management and Leadership in the Healthcare Industry</td>
<td>Clarice L. Copeman, Richard Wilson</td>
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For more information visit: [grahamschool.uchicago.edu/clinicaltrials](grahamschool.uchicago.edu/clinicaltrials)
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Course Schedule by Date

Summer 2016

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<tr>
<td>8/1/16</td>
<td>CTGCPR</td>
<td>16U7</td>
<td>Good Clinical Practices</td>
<td>Andrew Kucharski</td>
</tr>
<tr>
<td>6/15/16</td>
<td>CTINTP</td>
<td>16U1</td>
<td>Observation Study</td>
<td>TBD</td>
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Course Descriptions by Quarter

**Autumn**

**Good Clinical Practices**
Anne Pohlman
This course provides an introduction to good clinical practice (GCP) in clinical research according to FDA regulations and International Conference on Harmonization (ICH) guidelines. Topics include conducting clinical trials in accordance with GCP; regulations established by state, federal, and international regulatory bodies; and the roles and responsibilities of investigators, sponsors, monitors, and auditors.
Course Code: CTGCPR | Section 15A1
Wed, Thu, Fri 8:30 am–4:30 pm / Sep 23–25 / Gleacher Center / $1,300

**The Drug Development Process**
Andrew Kucharski, Elizabeth Robinson
This course provides an overview of the drug development and clinical trials processes. Topics include the discovery of new molecules, how discoveries become drugs or devices, the purpose of clinical and pharmaceutical research and development, the economics of drug development, cost/benefit analyses in clinical development, Phase I–IV clinical trials, and an introduction to the unique issues in each phase.
Course Code: CTTDDP | Section 15A7
10:30 am–12 pm / Oct 12–Nov 7 / Online / $1,300
Synchronous sessions will take place on Sat Oct 17, 24, 31, and Nov 7

**Fraud and Misconduct**
Pamela Mason
This course will provide an overview of clinical research-related fraud and scientific misconduct. Students are introduced to topics which include the identification of suspected fraud and misconduct, significant cases that shaped the definition of clinical research-related fraud, recent regulatory changes, and the clinical research professional’s role in the identification and reporting of suspected fraud and misconduct. Students will gain an understanding of the various acts that define fraud and misconduct and the impact that they have on the clinical research process. At the conclusion of the course, students will present a recent fraud and/or misconduct case study to the class.
Course Code: CTFAMC | Section 15A7
Nov 9–Dec 4 / Online / $1,300
Synchronous sessions will take place on:
Tue, Thu 6–8 pm / Nov 12, 24 Dec 3
Sat 10–12 pm / Nov 21

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Clinical Trials Management & Regulatory Compliance 2015–16
Course Descriptions by Quarter

**Winter**

**Good Clinical Practices**
Andrew Kucharski

This course provides an introduction to good clinical practice (GCP) in clinical research according to FDA regulations and International Conference on Harmonization (ICH) guidelines. Topics include conducting clinical trials in accordance with GCP; regulations established by state, federal, and international regulatory bodies; and the roles and responsibilities of investigators, sponsors, monitors, and auditors.

Course Code: CTGCPR | Section 16W7
10:30 am–12 pm / Jan 11–Feb 13 / Online / $1,300
Synchronous sessions will take place on Jan 23, 30, Feb 6, and 13

**Fundamentals of Site Management**
Eileen Dickman

This course covers the process of coordinating and managing a clinical study from the perspective of the study site. Students will learn the essentials of coordinating and managing the day-to-day operations of a clinical research study, from planning site logistics and constructing timelines for the study initiation visit to closing out a study. The course will focus on the operational, interpersonal, and data-management aspects of the process.

Course Code: CTFOSM | Section 16W7
10 am–12 pm / Feb 15–Mar 12 / Online / $1,300
Synchronous sessions will take place on Feb 27, Mar 5, and 12

**Statistical Concepts for Clinical Research**
Martin King

This course introduces basic statistical concepts, such as hypothesis testing, the meaning of P value, and power determination. Other concepts covered that have particular relevance to clinical research design and monitoring are the importance of randomization and randomization procedures, stratification, crossover designs, nonrandomized concurrent control studies, and the use of historical controls which will also be introduced.

Course Code: CTSCCR | Section 16W1
Wed, Thu, Fri 8:30 am–4:30 pm / Mar 10–12 / Gleacher Center / $1,300

**Spring**

**The Drug Development Process**
Andrew Kucharski, Elizabeth Robinson

This course provides an overview of the pharmaceutical industry, drug development and clinical trials processes. Topics include the economics of drug development, R&D productivity, human subject protections, inspections and audits, safety reporting and clinical trials.

Course Code: CTTDDP | Section 16S7
10:30 am-12 pm / Mar 28–Apr 30 / Online / $1,300
Synchronous sessions will take place on Sat Apr 9, 16, 23 and 30

**Fraud and Misconduct**
Pamela Mason

This course will provide an overview of clinical research-related fraud and scientific misconduct. Students are introduced to topics which include the identification of suspected fraud and misconduct, significant cases that shaped the definition of clinical research-related fraud, recent regulatory changes, and the clinical research professional’s role in the identification and reporting of suspected fraud and misconduct. Students will gain an understanding of the various acts that define fraud and misconduct and the impact that they have on the clinical research process. At the conclusion of the course, students will present a recent fraud and/or misconduct case study to the class.

Course Code: CTFAMC | Section 16S7
6-8 pm / Apr 4–May 5 / Online / $1,300
Synchronous sessions will take place on Apr 14, 21, 28, and May 5

**Fundamentals of Clinical Monitoring**
Elizabeth Robinson

This course introduces students to the processes and procedures of monitoring a clinical trial from the perspective of the sponsor or contract research organization from the site-initiation visit to the closing out of a clinical study.

Course Code: CTFOCM | Section 16S7
1:30-3 pm / May 5–Jun 4 / Online / $1,300
Synchronous sessions will take place on Sat May 14, 21, and Jun 4

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**Project Management and Leadership in the Healthcare Industry**

Clarice L. Copeman, Richard Wilson

This course focuses on advanced strategic, operational, and project management topics in clinical research with an emphasis on increasing efficiency and quality at all levels of the process. Topics include allocating staff and resources effectively; assessing financial and regulatory implications from a business perspective; developing, negotiating, and managing comprehensive clinical trials budgets; managing timelines; and leading and motivating effective teams.

Course Code: CTPMLH | Section 16S1
**Wed, Thu, Fri 8:30 am–4:30 pm / Jun 1–3 / Gleacher Center / $1,300**

**Summer**

**Good Clinical Practices**

Andrew Kucharski

This course provides an introduction to good clinical practice (GCP) in clinical research according to FDA regulations and International Conference on Harmonization (ICH) guidelines. Topics include conducting clinical trials in accordance with GCP; regulations established by state, federal, and international regulatory bodies; and the roles and responsibilities of investigators, sponsors, monitors, and auditors.

Course Code: CTGCPR | Section 16U7
**10:30 am-12 pm / Aug 1–Sep 3 / Online / $1,300**
Synchronous sessions will take place on Aug 13, 20, 27 and Sep 3

**Observation Study**

TBD

Please contact Lisa Malvin at lmalvin@uchicago.edu prior to registering for this course.

*Prerequisites: Good Clinical Practices, Fundamentals of Site Management, and Fundamentals of Clinical Monitoring*

Course Code: CTINTP | Section 16U1
**Jun 15–Sep 15 / Hyde Park / $600**

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