# Clinical Trials Management and Regulatory Compliance 2016–17
## Course Schedule by Date

### Autumn 2016

<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>9/14/16</td>
<td>CLIN 11300</td>
<td>16A1</td>
<td>Statistical Concepts for Clinical Research</td>
<td>Martin King</td>
</tr>
<tr>
<td>10/6/16</td>
<td>CLIN 11100</td>
<td>16A1</td>
<td>Good Clinical Practices</td>
<td>L. Wall</td>
</tr>
<tr>
<td>10/10/16</td>
<td>CLIN 17200</td>
<td>16A7</td>
<td>The Drug Development Process</td>
<td>A. Kucharski, E. Robinson</td>
</tr>
<tr>
<td>11/7/16</td>
<td>CLIN 27100</td>
<td>16A7</td>
<td>Fraud and Misconduct</td>
<td>P. Mason</td>
</tr>
</tbody>
</table>

### Winter 2017

<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>1/9/17</td>
<td>CLIN 17100</td>
<td>17W7</td>
<td>Good Clinical Practices</td>
<td>A. Kucharski</td>
</tr>
<tr>
<td>2/13/17</td>
<td>CLIN 17400</td>
<td>17W1</td>
<td>Fundamentals of Site Management</td>
<td>Eileen Dickman</td>
</tr>
<tr>
<td>3/6/17</td>
<td>CLIN 17300</td>
<td>17W7</td>
<td>Statistical Concepts for Clinical Research</td>
<td>Marty King</td>
</tr>
</tbody>
</table>

### Spring 2017

<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>3/27/17</td>
<td>CLIN 17200</td>
<td>17S7</td>
<td>The Drug Development Process</td>
<td>A. Kucharski</td>
</tr>
<tr>
<td>4/3/17</td>
<td>CLIN 27100</td>
<td>17S7</td>
<td>Fraud and Misconduct</td>
<td>Pamela Mason</td>
</tr>
</tbody>
</table>

For more information visit: [grahamschool.uchicago.edu/clinicaltrials](http://grahamschool.uchicago.edu/clinicaltrials)
Clinical Trials Management & Regulatory Compliance 2016–17
Course Schedule by Date

Summer 2017

<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>5/31/17</td>
<td>CLIN 12100</td>
<td>17S1</td>
<td>Project Management and Leadership</td>
<td>Clarice L. Copeman, Richard Wilson</td>
</tr>
<tr>
<td>7/24/17</td>
<td>CLIN 17100</td>
<td>17U7</td>
<td>Good Clinical Practices</td>
<td>Andrew Kucharski</td>
</tr>
</tbody>
</table>

Course Descriptions by Quarter

**Autumn**

**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 will also be introduced.
Course Code: Clin 11300 | Section 16A1
Wed, Fri, Sat 8:30 am–4:30 pm / Sept 14–16 / Gleacher Center / $1,300

**Good Clinical Practices**
**Lauren Wall**
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: CLIN 11100 | Section 16A1
Thu, Fri, Sat 8:30 am–4:30 pm / Oct 6–8 / 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: CLIN 17200 | Section 16A7
Sat 10:30 am–12 pm / Oct 15, 22, 29, and Nov 5 from 10:30am - 12pm.

**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: CLIN 27100 | Section 15A7
Thu Nov 7–Dec 2 / Online / $1,300/ Synchronous sessions will take place on Nov 10, 17, Dec 1 and 8 from 6–8 pm

For more information visit: grahamschool.uchicago.edu/clinicaltrials
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: CLIN 17100 | 17W7
10:30 am–12 pm / Jan 11–Feb 13 / Online / $1,300
Synchronous Sessions: Jan 21, 28 and Feb. 4, 11 from 10:30am-12pm.

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: CLIN 17400 | Section 17W1
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 will also be introduced.

Course Code: CLIN 17300 | Section 17W7
Wed, Thu, Fri 8:30 am–4:30 pm / Mar 10–12 / Gleacher Center / $1,300

Spring

The Drug Development Process
Andrew Kucharski
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: CLIN 17200 | Section 17S7
10:30 am-12 pm / Mar 27–Apr 29 / Online / $1,300
Synchronous Sessions: April 8, 15, 22, and 29 from 10:30am-12pm.

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: CLIN 27100 | Section 17S7
6–8 pm / Apr 3–May 5 / Online / $1,300
Synchronous Sessions: April 13, 20, 27, and May 4

Project Management and Leadership in the Healthcare Industry
Clarice L. Copeman, Richard Wilson
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: CLIN 12100 | Section 17S1
Wed, Thu, Fri 1:30–3 pm / May 5–Jun 4 / Online / $1,300
Synchronous sessions will take place on Sat May 14, 21, and Jun 4

For more information visit: grahamschool.uchicago.edu/clinicaltrials
Clinical Trials Management & Regulatory Compliance 2016–17
Course Descriptions by Quarter

**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: CLIN 17100 | Section 17U7

10:30am-12 pm / Aug 1-Sep 3 / Online / $1,300

Synchronous Sessions: Aug 5, 12, 19, 26 from 10:30am-12pm

For more information visit: grahamschool.uchicago.edu/clinicaltrials