Course number PED 5400-090

Introduction to Clinical Pharmacology

Fall Semester 2018

Department: Pediatrics, Division of Clinical Pharmacology

Prerequisites: None

Credit Hours: 2

Academic term offered: Fall semester

Course Primary Instructor:

Elena Y Enioutina, MD, PhD,
Research Assistant Professor,
Division of Clinical Pharmacology, Pediatrics,
School of Medicine, University of Utah

Office Hours: By appointment. Please email or call to set up an appointment.

- Office consultations at Williams Building, Research Park, 495 Chipeta Way, 1S100, Salt Lake City, Utah 84108
- via Zoom
- Phone: 801-587-1916 (office)
- Email: elena.enioutina@hsc.utah.edu

Course lectures have been prepared by the faculty members and postdoctoral fellows of the Division of Clinical Pharmacology:

- Jonathan E. Constance, PhD, Research Assistant Professor,
- Kathleen (Kate) M. Job, PhD, Visiting Instructor
- Joseph E. Rower, PhD, Research Assistant Professor
- Venkata (Kash) K. Yellepeddi, PhD, Research Assistant Professor
- Eman Biltaji, PhD, MSc, BPharm, Postdoctoral Fellow
- Silvia M. Illamola, PharmD, PhD, Postdoctoral Fellow
- Shaun S. Kumar PhD, BMedSc, Postdoctoral Fellow
- Jahid Rahshid, BPharm, MS, PhD, Postdoctoral Fellow

Course Description: The “Introduction to Clinical Pharmacology” online course is a series of prerecorded lectures covering the fundamentals of clinical pharmacology as a translational discipline focused on rational drug development and utilization in therapeutics. This course includes lectures on pharmacokinetics, methods of drug and drug metabolites analysis, pharmacogenomics, assessment of drug efficacy and adverse reactions, and clinical pharmacology of special populations such as pregnant and nursing women, neonates, children, elderly and
patients with impaired liver and kidney functions. The course consists of recorded lecture, topic for discussions and assignments.

**Learning objectives:**

At the end of the course, the student will be able to:

1. Identify the fundamental principles of pharmacokinetics in humans.
2. Appreciate the role of molecular genetics and genomic principles in pharmacotherapeutics.
3. Assess the drug effectiveness, drug-drug interactions and adverse drug reactions.
4. Understand the fundamentals of drug and drug metabolite analysis
5. Identify the ways of optimizing the use of the existing medicine
6. Assess the approaches to the new drug development

**Teaching methods:** This course is delivered asynchronously online. Content is organized into modules and is delivered and assimilated through recorded presentations, peer discussions and assignments. Since the course is asynchronous in format, participants do not meet together at scheduled times, and rely on their own initiative and autonomy to meet timelines and due dates for assignments. Consequently, the course teaching philosophy is based on self-directed learning for highly motivated students.

**Course topical outline:**

1. Introduction to clinical pharmacology
2. Clinical Pharmacokinetics
   - Drug absorption and bioavailability
   - Compartmental analysis of drug distribution
   - Preclinical prediction of human Pharmacokinetics
   - Drug metabolism and transport
3. Methods of drug and drug metabolites analysis
4. Pharmacodynamics
   - Assessment of drug effects
   - Pharmacogenomics
   - Drug-drug interactions
   - Adverse drug reactions
5. Clinical pharmacology of special populations
   - pediatric population and neonates
   - pregnant women
   - patients with impaired liver function
   - patients with impaired kidney function
   - elderly patients
6. Design of Clinical Development Programs
Recommended Text / Reading List:

The major content of the course will be presented in lectures and/or will be available at the course Canvas website.

We recommend “Principles of Clinical Pharmacology” 3rd Edition by Arthur Atkinson, Jr., Darrell Abernethy, Charles Daniels, Robert Dedrick and Sanford Markey

Available at: http://web.b.ebscohost.com.ezproxy.lib.utah.edu/ehost/ebookviewer/ebook/bmXtYmtfXzQ3NzU xM19fQU41?sid=fe12006d-39f6-4744-a274- 48827ea5b669@sessionmgr101&vid=0&format=EB&lpid=lp_1&rid=0

The textbook should serve as a source for clarification and elaboration of materials presented by the instructors and as a source for additional information on specific drugs not covered in the course.

Assessment and Grading Criteria:

Assessment: Learning will be evaluated according to the quality and depth of students in question responses and group discussions and assignment presentation. The course is organized into modules, and each lecture within the module is associated with a question and discussion assignment. Though discussions are a group activity, each student will receive an individual discussion grade.

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<thead>
<tr>
<th>Activity &amp; Grade Contribution</th>
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<tbody>
<tr>
<td>Course Activity</td>
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<tr>
<td>“Who I Am and why I decided to take this course” 2 slide presentation</td>
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<tr>
<td>“What is clinical pharmacology” 1 page essay</td>
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<tr>
<td>Introduction to clinical pharmacology, response to questions</td>
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<tr>
<td>Introduction to clinical pharmacology, question discussion with peers</td>
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<tr>
<td>Pharmacokinetics module (7 lectures), response to questions</td>
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<tr>
<td>Pharmacokinetics module (7 lectures), question discussion with peers</td>
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<tr>
<td>Methods of drug and drug metabolites analysis, response to questions</td>
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<tr>
<td>Methods of drug and drug metabolites analysis, question discussion with peers</td>
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<tr>
<td>Pharmacodynamics module (5 lectures), response to questions</td>
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<td>Pharmacodynamics module (5 lectures), question discussion with peers</td>
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<td>Special population module (5 lectures), response to questions</td>
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<td>Special population module (5 lectures), question discussion with peers</td>
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<td>Design of Clinical Development Programs, response to questions</td>
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<tr>
<td>Design of Clinical Development Programs, question discussion with peers</td>
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<tr>
<td>“How do I see future of clinical pharmacology”, 1 page essay</td>
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<td><strong>Total Points Possible</strong></td>
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Final grades will be awarded in accordance with the following guidelines, which are outlined in the University of Utah Student Handbook.
Final Grading Scale:

95-100% of available points = A
90-94% of available points = A-
87-89% of available points = B+
84-86% of available points = B
80-83% of available points = B-
77-79% of available points = C+
74-76% of available points = C
70-73% of available points = C-

There are 450 points available in the course, so the minimum number of points a student needs to earn the B- grade required of all graduate nursing students in 360 points, or 80%.

How are discussion groups formed?

Depending on the class size, groups will be formed 4 students per group. You will be randomly assigned to a group before the course begins.

What goes into a question or discussion assignment?

You will watch prerecorded lectures read, viewing resources posted by the instructor on the course Canvas site; if necessary, you will search for external references, then you post answers to questions, followed by talking over answers with each other. The instructor role in the group is to correct misperceptions, challenge assumptions, and promote intellectual rigor.

How will discussions be graded?

Responses and Discussions are graded on this scale: Outstanding (10 points), Proficient (7 points), Basic (5 points), and Below Expectations (2 points). Requirements for each of these levels are described in detail in the grading rubric.

When is my work due and what about late work? Due dates that can be found on the Weekly Schedule in the Syllabus portion of Canvas.

Online environment: Students and instructors will work together and follow University policies and procedures to create an environment conducive to teaching and learning in this course. As with all courses at the University, the online environment is considered to be equivalent to in-person (land) classrooms and offices. E-mail, discussions, and other online communications in the course are part of the classroom and as such, are University property and subject to GRAMA regulations and the Student Code. Privacy regarding these communications within the academic community must not be assumed, while professionalism regarding these communications is required. Students are responsible for maintaining in working condition the hardware and software that they need to access the course and its materials.
**Contacting Dr. Enioutina:** E-mail is best. You can call my office phone number and leave message. Message will appear in my outlook. I will respond to e-mails and phone calls in ~2-3 business days.

**Plagiarism:** Plagiarized material submitted for assignments may result in failure in the course and potential dismissal from the University of Utah. Read the University of Utah Code of Student Rights and Responsibilities outlining policies regarding plagiarism.

**Accommodations for Disabled Students:**

“The University of Utah seeks to provide equal access to its programs, services and activities for people with disabilities. If you require such accommodations in the class, reasonable prior notice needs to be given to the Center for Disability Services, 162 Olpin Union Building, 581-5020 (V/TDD). CDS will work with you and the instructor to make arrangements for necessary and appropriate accommodations. All written information in this course can be made available in alternative format with prior notification to the Center for Disability Services”.

**Center for Student Wellness Statement:**

“Are you concerned about stress, sleep difficulties, anxiety, depression, cultural differences, relationship difficulties, balancing work and school, or finances? Would you like to perform better in class, help a friend in distress, or learn more about physical activity or nutrition? Contact the Center for Student Wellness at: wellness@sa.utah.edu; or www.wellness.utah.edu; or 801-581-7776.”

**Student Responsibilities:**

Students are expected to follow the Code of Student Rights and Responsibilities (“Student Code”) as delineated in the University of Utah Policies and Procedures Manual.

**Faculty Responsibilities:**

These guidelines are delineated in the University of Utah Policies and Procedures Manual. 

- convene class unless a valid reason and notice are given
- perform and return evaluations in a timely manner
- inform students at the beginning of class about: general content, course activities, methods of evaluation, grade scale, schedule of lectures, assignments, laboratory, examinations, etc.
- Ensure an environment conducive to learning
- Enforce the student code

在这个大纲中，教员可以随时根据合理的通知向学生进行调整。教员也可以根据教学需求调整课程安排。如果您有任何关于大纲的问题或疑虑，请联系教员以获取澄清。“