1. Course objectives

- Fundamentals in Drug Development

2. Course format

- Lectures
- Seminars
- Practical sessions
- Lab sessions

3. Course Dates and Topics

<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
<th>Presenter</th>
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4. Course Description

The ‘Fundamentals in Drug Development’ course will cover the main aspects of the drug development and drug discovery processes and will expose students to the essential activities in the pharmaceutical development.

Lectures will be given by guest-lecturers from Teva and the BLAVATNIK CENTER for Drug Discovery, Tel Aviv University.

5. Course Requirements

- A minimum of 75% attendance is required.
- There will be a comprehensive final exam at the end of the course.
- Students will be evaluated based on their performance in the final exam, presentations, homework, and participation in class discussions.

Drug Development course @ TAU, Oct 2018
<table>
<thead>
<tr>
<th>#</th>
<th>Date</th>
<th>Topic</th>
<th>Presenter/Institution</th>
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<tbody>
<tr>
<td>#1</td>
<td>15.10.18</td>
<td>Overview to pre clinical development</td>
<td>Dr. Aric Orbach</td>
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<tr>
<td>#2</td>
<td>22.10.18</td>
<td>Early stage drug discovery and HTS</td>
<td>Dr. Eddy Pichinuk, Dr. Avi Raveh, BLAVATNIC CENTER for Drug Discovery</td>
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<tr>
<td>#3</td>
<td>29.10.18</td>
<td>Computational tools for early stage drug discovery: CADD and Medchem</td>
<td>Dr. Tali Engel, Dr. Elvira Haimov, BLAVATNIC CENTER for Drug Discovery</td>
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<tr>
<td>#4</td>
<td>5.11.18</td>
<td>Introduction to intellectual property</td>
<td>Osnat Bell</td>
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<td>#5</td>
<td>12.11.18</td>
<td>Clinical pharmacology</td>
<td>Dr. Ofer Spiegelstein</td>
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<td>#6</td>
<td>19.11.18</td>
<td>Drug manufacturing to support a clinical study (CMC)</td>
<td>Dr. Tal Hasson</td>
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<td>#7</td>
<td>26.11.18</td>
<td>Personalized and predictive medicine</td>
<td>Dr. Merav Bassan</td>
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<td>#8</td>
<td>3.12.18</td>
<td>Case Studies</td>
<td>Dr. Leah Klapper, BLAVATNIC CENTER for Drug Discovery</td>
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<tr>
<td>#9</td>
<td>10.12.18</td>
<td>Personalized medicine for rare diseases; case studies</td>
<td>Prof. Miguel Weil, BLAVATNIC CENTER for Drug Discovery</td>
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<tr>
<td>#10</td>
<td>17.12.18</td>
<td>Planning of a clinical trial</td>
<td>Dr. Eran Harary</td>
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<td>#11</td>
<td>24.12.18</td>
<td>Analytics and big data in drug development</td>
<td>Dr. Lena Granovsky</td>
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<td>#12</td>
<td>31.12.18</td>
<td>Legal aspects of the clinical study + Regulatory affairs</td>
<td>Efrat Shalom Berenson, LLM, Levana Volovsky, MSc</td>
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<tr>
<td>#13</td>
<td>7.1.19</td>
<td>Tour in the Teva Factory</td>
<td>Dr. Tal Yoetz</td>
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6. תומך קריאה (רשוי)

- [http://www.fda.gov/ForPatients/Approvals/Drugs/default.htm](http://www.fda.gov/ForPatients/Approvals/Drugs/default.htm)
- [http://www.fdareview.org/index.shtml](http://www.fdareview.org/index.shtml)
Pharmacovigilance from A to Z, Barton L. Cobert, MD; Pierre Biron, MD.


MHRA – Good Pharmacovigilance Practice Guide

FDA – Guide to FDA Drug Safety Regulation, FDAnews.

Operational activities of the Clinical Trials/Data Management and Clinical Programming


Medical Monitoring during clinical study

FDA Guidance for Industry - Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring, August 2013

FDA Guidance for Industry - Establishment and Operation of Clinical Trial Data Monitoring Committees, March 2006

Regulatory Affairs

Communication from the Commission 2010/C 82/01 — Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1), March 2010

United States Code Title 21, Part 312, Investigational New Drug Application, April 2012

FDA Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants, May 2009

European Commission: Notice to Applicants Vol. 2A: Procedures for marketing authorisation, June 2013


The CDER Handbook, produced by the Department of Health and Human Services, Food and Drug Administration, March 1998
Introduction to nonclinical safety testing

- Beishon M., Approval rating: how do the EMA and FDA compare?, 12 I CancerWorld I January-February 2014
- Navigating the Regulatory Landscape for Healthcare Product Development: Key principles and best practices, MaRS Discovery District, October 2012
- ICH M3(R2) guideline. 11 June 2009.