# Drug Development Boot Camp

**DATE/TIME:** Every Monday from Jan 29 – March 26, 2018, 4:00pm – 6:00 PM (Tuesday Session on Feb. 20 and March 20)

**LOCATION:** 622 W 168th St., PH building, 10th floor, room 405 A/B

(Location Tues Feb.20 and Tues Mar. 20- 701 W 168th st, corner of 168th and Ft.Washington Ave, room LL1-103)

**COURSE OUTLINE:** The TRx Boot Camp is an 8- session course designed to give academic investigators an overview of early development aspects of therapeutic design and commercialization. The lecture series will provide an overview of the drug development process with a special focus on resources available.

Upon completion of the boot camp, attendees will be able to position their therapeutic discoveries for future commercial value.

Boot camp attendance is mandatory for investigator teams that have submitted pre-proposals and are interested in submitting a full proposal for the TRx Resource Pilot Award but open to all Columbia faculty, staff, and students.

**COURSE SCHEDULE:**

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<tr>
<th>Session</th>
<th>Topic</th>
<th>Presenter</th>
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<tr>
<td><strong>Session I</strong>&lt;br&gt;January 29</td>
<td>“Kick Off Session &amp; Drug Development”&lt;br&gt;Team Introductions</td>
<td>Bruce Conway, PhD&lt;br&gt;Program Director, Robertson Therapeutic Fund at Rockefeller University</td>
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<td><strong>Session II</strong>&lt;br&gt;February 5</td>
<td>Team Introductions “Who is my Target Customer”&lt;br&gt;Unmet clinical need, competitive landscape and stakeholder discovery</td>
<td>Harvey Homan, PhD, MBA&lt;br&gt;HDH Associates International Jumpstart NJ Angel Network</td>
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<td><strong>Session III</strong>&lt;br&gt;February 12</td>
<td>“What Does My Target Product Look Like”&lt;br&gt;Target Product Profile development</td>
<td>Randall Kaye, MD&lt;br&gt;Global Head of Medical Affairs, SSI Strategy</td>
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<td><strong>Session IV</strong>&lt;br&gt;February 20 (TUESDAY)&lt;br&gt;Joint with BiomedX Room: Hammer Health Sciences Building, LL1-103</td>
<td>“How do I Protect My Innovation”&lt;br&gt;Patenting and licensing discussion with Columbia’s licensing office</td>
<td>Jeffrey Sears, PhD, JD&lt;br&gt;Office of General Counsel&lt;br&gt;Ron Katz, PhD, MBA&lt;br&gt;Columbia Technology Ventures</td>
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| Session V | February 26 | “What are the right Pre-Clinical Studies and What Resources are available at Columbia?” A review of IND enabling studies and Columbia’s core facilitates | Stephanie Oestreich  
EVP, Head BRIDGEs  
Partnerships NA- Evotec  
Brian Walsh  
Serge Cremers, PhD, PharmD  
Columbia University |
|-----------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| Session VI | March 5 | “How do I Approach the FDA” IND and Clinical trial design, led by Columbia’s Clinical Trials Office | Helen Kim, PharmD  
Executive Director, Columbia Clinical Trials Office  
Jane Cho, MS, MPH  
Manager of Regulatory Science, Columbia Clinical Trials Office |
| Session VII | March 12 | “How do I Fund My Studies” A Panel discussion with industry and NIH representatives, led by SPA. | Nader Halim, PhD  
Senior Director, Pfizer CTI  
Alexis Desrichard, PhD  
BMS, II-ON  
Moderator: Rudi Odeh-Ramadan, PharmD  
Vice President for Research Administration, Columbia Sponsored Projects Administration |
| Session VIII | March 20 (TUESDAY)  
Joint with BiomedX  
Room: Hammer Health Sciences Building, LL1-103 | “How to Pitch my Innovation” Pitch crafting techniques | Joint with BiomedX |
| Session IX | March 26 | “Closing Session” | |

Additional Resources: [Dropbox Link](#)

**CONFIDENTIALITY:** We ask all participants to read and adhere to the following Confidentiality Statement:

“As a participant in this course, I understand that my fellow participants may wish to pursue patent protection for their course projects and that confidentiality is often essential for doing so. In order to promote a free exchange of information among participants, I shall treat all communications on course projects that I receive from participants during the time period of the course as confidential. I shall not disclose these communications to any third party, except for that which is already known or rightfully obtained by me prior to its disclosure to me by the participants or other advisors.”