During the past decade, advances in life science research, drug discovery, and the development of medical devices have continued at a breathtaking pace. The most notable example is the growth of our understanding of the human genome, human genetic variation, and the role that genes play in our everyday health, response to treatment and susceptibility to disease. These advances -- coupled with faster, better and cheaper information technology -- usher in both opportunity and peril for individuals, companies and societies. Accelerating our progress toward “personalized health care” will require:

- Continued advances in the life sciences
- Improvements in technology to make these advances “work” in human populations
- Thoughtful commercialization to make these advances available to affected human populations on a safe and cost-effective basis
- Knowledge and empowerment to help consumers understand the individualized risks and opportunities that lie in genomic medicine
- Enlightened public and private policies to increase the value-added intersections between the life sciences, technologies, commercialization, and the consumer.

The objective in this interdisciplinary graduate course is to explore the intersections between science, technology, commerce and social policy as they come together to advance (and in some cases retard) progress toward more-personalized health care. The course is a salon-style sampling of the issues facing the core businesses of biology including large and small pharmaceutical companies and biotech, medical device and genetic testing companies. The course is intended for graduate students in medicine, biomedical and health-related science, public health, law, engineering, and business interested in the future of health care. It is designed to provide a framework to enhance the understanding of the complex scientific and socioeconomic trends, opportunities and challenges that are taking place in the rapidly evolving fields of personalized medicine, molecular diagnostics, and targeted therapeutics. Because of the variation in student backgrounds coming into the course, efforts are made at the beginning to establish a shared vocabulary and knowledge base across the disciplines.

A multidisciplinary faculty teaches in the course, supplemented by outside speakers with hands-on experience in their fields. Interdisciplinary student teams are assigned to research a particular company currently operating in the sector and explore it from the perspective of the issues raised in the course. Team reports on these findings will be made at a colloquium at the end of the course attended by faculty and students participating in the section.

Important Notice: The course meets from September 5th to October 15th on Mondays and Wednesdays from 8:20 to 9:50 am in Ross School of Business, Blau building, B3570. There will be four additional required evening sessions: Thursdays 9/6, 9/20, 9/27, and 10/11. The evening sessions will take place from 5:00-7:30pm.

COURSE MATERIALS
All required course reading will be available on the Canvas website. You will receive an email with an invitation to the course site.

CANVAS
Canvas includes announcements, the syllabus, assignments, readings, and the lecture presentations. Optional articles, a bibliography, and additional web resources may also be posted.
TIMES AND LOCATIONS
Regular class sessions are held Monday and Wednesday from 8:20 to 9:50 am in Ross School of Business, Blau building, B3570. Class will start promptly at 8:20 am.

In addition to regular class periods, four evening sessions have been scheduled. These sessions are an integral part of the course; any absence from them must be cleared with the instructor in advance:

- **Evening 1**  
  **September 6, 2017**  
  **5:00-7:30pm**  
  **Location:** Ross School of Business, Blau building, B3570  
  ➢ **Session Title:** The price of new drugs: are they justified and sustainable? Or is Big Pharma gouging the public? The impact of reputation on business.  
  ➢ **Speaker:** John LaMattina

- **Evening 2**  
  **September 20, 2016**  
  **5:00-7:30pm**  
  **Location:** Ross School of Business, Blau building, B3570  
  ➢ **Session Title:** Mid-term discussion / Animal Health  
  ➢ **Speaker:** David Canter/Raja Krishnan

- **Evening 3**  
  **September 27, 2016**  
  **5:00-7:30pm**  
  **Location:** Ross School of Business, Blau building, B3570  
  ➢ **Session Title:** Building a biotech business-the story of two Esperions  
  ➢ **Speaker:** Roger Newton

- **Evening 4**  
  **October 11, 2016**  
  **5:00-7:30pm**  
  **Location:** Ross School of Business, Blau building, B3570  
  ➢ **Group presentations of company case studies**  
  ➢ **External Evaluator:** Diane Bouis and Elke Lipka

* Each group will meet with me for an hour to help in the preparation of the company case presentation

I will hold a few small tutorials to help students who have missed one or two early classes in help them catch up. These tutorials are organized at short notice and as needed.

COMMUNICATION
Below is my contact information. Feel free to communicate with me as needed. E-mail is best for quick exchanges. If you want to talk by telephone, feel free to call. If you want to get together for an in-person discussion, please make an appointment in advance by contacting Ann Savory.

David Canter  
North Campus Research Complex  
2800 Plymouth Road, B18-135  
canterd@umich.edu  
734-764-7814

Course Assistant: Ann Savory  
asavory@umich.edu  
734-615-5242

STUDENTS WITH DISABILITIES
If you think you need an accommodation for a disability, please let me know at your earliest convenience. Some aspects of the course, the assignments, the in-class activities, and the way we teach may be modified to facilitate your participation and progress. As soon as you make me aware of your needs, I can work with the Office of Services for Students with Disabilities to help determine appropriate accommodations**. I will treat information you provide as private and confidential.

RELIGIOUS HOLIDAYS
I know several religious holidays occur during the course period and I respect the needs of those students who observe these holidays. Please talk to me early about missing class.
### Session 1  Wednesday, September 5th

**Topic**  
Introduction to the course; issues affecting the drug industry; Business perspective based on ROI/cost-to-play for development and marketing of drugs (Part 1)

**Leader**  
David Canter

**Reading(s)**  

**Assignment**  
2nd Assignment: Brief analysis of a company. Discussion at September 10th class. Email finished assignment to asavory@umich.edu by 8am, 9/11.

### Session 2  Thursday, September 6th  EVENING SESSION

**Topic**  
The Price of new drugs: are they justified and sustainable? Or is Big Pharma gouging the public?

**Leader**  
John LaMattina, PhD  
Past President of Research and Development, Pfizer, Inc.

**Reading(s)**  
Hwang, Thomas J.; LaMattina, John L. “Measuring the Value of New Medications and Implications for Medicare’s Proposed Part B Drug Payment Model” JAMA Oncology, 2016; 2 (9), 1125-1126.


LaMattina, John L. “There Go Those Drug Companies Inventing Disease Again” Forbes.com, June 20, 2018.


### Session 3  Monday, September 10th

**Topic**  
Business perspective based on ROI/cost-to-play for the discovery/development and marketing of drugs (Part 2)

**Leader**  
David Canter

**Reading(s)**  
n/a

**Assignment Due**  
2nd Assignment Due - Company Analysis  
Email finished assignment to asavory@umich.edu by 8am, 9/11.
<table>
<thead>
<tr>
<th>Session 4</th>
<th>Wednesday, September 12\textsuperscript{th}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topic</td>
<td>Genetics Research and Genomic Medicine – A View From a Physician/Scientist</td>
</tr>
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</table>
| Leader    | David Ginsburg, MD  
Investigator, Howard Hughes Medical Institute  
James V Neel Distinguished University Professor of Internal Medicine, Human Genetics, and Pediatrics |

<table>
<thead>
<tr>
<th>Session 5</th>
<th>Monday, September 17\textsuperscript{th}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topic</td>
<td>Intellectual Property &amp; the Biopharmaceutical Industry, Foundations &amp; Controversies</td>
</tr>
</tbody>
</table>
| Leader    | John Osborn, JD, MIPP  
Senior Advisor, Hogan Lovells; Industry Advisor, Warburg Pincus; Affiliate Professor, Univ of Washington; Contributor, Forbes.com |
Gilead letter  
March-In Rights Under the Bayh-Dole Act, Congressional Research Service (Aug 22, 2016)  
Break the Patent! https://breakthepatent.org |
| Assignment| 3\textsuperscript{rd} Assignment - Personal Genomics. Due 9/24 |

<table>
<thead>
<tr>
<th>Session 6</th>
<th>Wednesday, September 19\textsuperscript{th}</th>
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</thead>
<tbody>
<tr>
<td>Topic</td>
<td>The Cost of Regulation on the Medical Device Industry</td>
</tr>
</tbody>
</table>
| Leader    | Scott Merz, PHD  
Chief Executive Officer and Co-Founder, MC3 Cardiopulmonary |
| Reading(s)| Bomey, Nathan ,"After 'systematic breakdowns' and $35 million FDA fine, Terumo Cardiovascular Systems promises fixes", The Ann Arbor News, Apr 10, 2011  
FDA Impact on U.S. Medical Technology Innovation, A Survey of Over 200 Medical Technology Companies, November 2010  
<p>| Assignment| Group Project Assigned September 19\textsuperscript{th} |</p>
<table>
<thead>
<tr>
<th>Session 7</th>
<th>Thursday, September 20\textsuperscript{th} EVENING SESSION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topic</td>
<td>1) Mid-course discussion</td>
</tr>
<tr>
<td></td>
<td>2) The business approach to research in animal health, medicine, and vaccines</td>
</tr>
<tr>
<td>Leader</td>
<td>David Canter</td>
</tr>
<tr>
<td></td>
<td>Raja Krishnan</td>
</tr>
<tr>
<td></td>
<td>Senior Director, Companion Animals and Equine Biologicals, Global Biologics Research</td>
</tr>
<tr>
<td>Reading(s)</td>
<td>Animal Health R&amp;D A Business Approach to Research presentation pdf and discussion topics pdf.</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Session 8</th>
<th>Monday, September 24\textsuperscript{th}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topic</td>
<td>Building value in an early stage drug discovery and development company</td>
</tr>
<tr>
<td>Leader</td>
<td>Gary Hammer</td>
</tr>
<tr>
<td></td>
<td>Professor of Internal Medicine</td>
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<td></td>
<td>Co-founder, Millendo Therapeutics</td>
</tr>
<tr>
<td></td>
<td>Julia Owens</td>
</tr>
<tr>
<td></td>
<td>Co-founder and CEO, Millendo Therapeutics</td>
</tr>
<tr>
<td>Reading(s)</td>
<td>Orphan drugs attract rich returns for pharmaceuticals. \textit{Financial Times}, Andrew Jack, February 27, 2017.</td>
</tr>
<tr>
<td></td>
<td>OvaScience and Millendo Therapeutics announce Merger to Create Leading Rare Endocrine Disease Company, \textit{Business Wire}, August 9, 2018.</td>
</tr>
</tbody>
</table>

**Assignment Due**

**3rd Assignment Due – Personal Genomics**

Submit by 5 pm, Thursday September 24\textsuperscript{th} email to asavory@umich.edu

<table>
<thead>
<tr>
<th>Session 9</th>
<th>Wednesday, September 26\textsuperscript{th}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topic</td>
<td>Healthcare Venture Capital Investing</td>
</tr>
<tr>
<td>Leader</td>
<td>Paul McCreadie</td>
</tr>
<tr>
<td></td>
<td>Managing Director, Aboretum Ventures</td>
</tr>
<tr>
<td>Reading(s)</td>
<td>Venture Capital Presentation Session #9. pdf</td>
</tr>
</tbody>
</table>
### Session 10  
**Thursday, September 27th  
EVENING SESSION**

<table>
<thead>
<tr>
<th>Topic</th>
<th>Founding and Leading Biotech Businesses in Michigan: The Story of Two Very Different Companies named Esperion Therapeutics</th>
</tr>
</thead>
</table>
| Leader | Roger Newton, PhD  
Founder, Executive Chairman and Chief Scientific Officer, Esperion Therapeutics |
| Reading(s) |  
Esperion Executives Defend Their Drug After Stock Crashes, *Forbes*, May 2, 2018 |

### Session 11  
**Monday, October 1st**

<table>
<thead>
<tr>
<th>Topic</th>
<th>Ethical Issues Now and Later</th>
</tr>
</thead>
</table>
| Leader | Liz Barry  
Special Counsel to the President, University of Michigan |
| Reading(s) |  
Susannah Baruch, J.D., “Pre-implantation genetic diagnosis and parental references: Beyond deadly disease” *8 HOUS. J. HEALTH L. & POL’Y* 245-270 ISSN 1534-7907  
“Parents' Interest in Predictive Genetic Testing for Their Children When a Disease Has No Treatment" *Pediatrics* 2009;124;e432; Beth A. Tarini, Dianne Singer, Sarah J. Clark and Matthew M. Davis 10.1542/peds.2008-2389  
Genetically testing human embryos: what you need to know about the debate. *The Conversation*, Darren Griffen, Alan Thornhill, Cagin Ogur July 16, 2018 |

### Session 12  
**Wednesday, October 3rd**

<table>
<thead>
<tr>
<th>Topic</th>
<th>How Regulatory Agencies shape business decisions in drug development</th>
</tr>
</thead>
</table>
| Leader | Mark Ammann, PharmD  
President, Catalyst Regulatory Services  
Toni Marie Nearing  
Senior Director, Regulatory Strategy, Catalyst Regulatory Services |
| Reading(s) |  
How Orphan Drugs Became a Highly Profitable Industry Government incentives, advances in technology, and an army of patient advocates have spun a successful market—but abuses of the system and exorbitant prices could cause a backlash. Posted on May 1, 2018. By: Diana Kwon  
Taking New Steps to Meet the Challenges of Rare Diseases - FDA Marks the 11th Rare Disease Day. Posted on February 26, 2018 by FDA Voice. By: Scott Gottlieb, MD  
Watch these series of three videos:  
*https://www.youtube.com/watch?v=F1TbvdjmXJ8* – Introduction to Orphan Drugs  
*https://www.youtube.com/watch?v=x1Vn0kqSvfk* – Orphan Drug Costs  
*https://www.youtube.com/watch?v=rZhE2GcFid0* – Gaming the System |
<table>
<thead>
<tr>
<th>Session 13</th>
<th>Monday, October 8th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topic</td>
<td>The commercial potential of personalized medicine</td>
</tr>
</tbody>
</table>
| Leader     | Robert Penny, MD, PhD  
Founder & CEO Paradigm. Past Co-founder & CEO International Genomics Consortium |
| Reading(s) | Precision Medicine: Technology, Regulations and Challenges. March 11, 2016  
The Economist: Health care, All about the base, (June 2016).  

<table>
<thead>
<tr>
<th>Session 14</th>
<th>Wednesday, October 10th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topic</td>
<td>Big Data and Healthcare: How do companies create value in this area?</td>
</tr>
</tbody>
</table>
| Leader     | Alfonso Y. Chang, CFA  
Managing Director  
The AC³ Group |

<table>
<thead>
<tr>
<th>Session 15</th>
<th>Thursday, October 11th EVENING SESSION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructions</td>
<td>Group Project – slide presentations and bibliography are due to Ann Savory by noon. Please email as attachments to <a href="mailto:asavory@umich.edu">asavory@umich.edu</a></td>
</tr>
<tr>
<td>Topic</td>
<td>Group Presentations of Company Case Studies</td>
</tr>
</tbody>
</table>
| External Evaluator | Diane Bouis, PhD, MBA  
Director of Innovation Programs, The Inovo Group  
Elke Lipka, PhD, MBA  
President, TSRL, Inc |
| Final Exam Assigned | Take home – Return by 5:00 pm October 16th email to asavory@umich.edu and canterd@umich.edu |

<table>
<thead>
<tr>
<th>Session 16</th>
<th>Monday, October 15th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topic</td>
<td>New Models and Emerging Trends in Biotech</td>
</tr>
</tbody>
</table>
| Leader     | Craig Parker  
CEO, Surrozen Inc. |
| Reading(s) | Deloitte Centre for Health Solutions, “A new future for R & D (2017)  
Deloitte 2017 Life Sciences Outlook |
**COURSE ASSIGNMENTS AND GRADING**

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Assignment Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>30%</td>
<td>Class preparation including the assigned readings and active class participation. <strong>There will be a sign-in for recording attendance.</strong> Name tags are required to be displayed in class. I ask that laptops, cell phones, pagers, etc. not be used in class.</td>
</tr>
<tr>
<td>30%</td>
<td>Group Project: progress note will be due 9/26 at 11:59 pm. Presentations on <strong>October 11th, 5:00-7:30 pm</strong></td>
</tr>
<tr>
<td>40%</td>
<td>Take-Home Final Exam – <strong>due by 5:00 pm 10/16/18</strong> email to <a href="mailto:asavory@umich.edu">asavory@umich.edu</a> and <a href="mailto:canterd@umich.edu">canterd@umich.edu</a></td>
</tr>
</tbody>
</table>

**Important - Procedures for Accommodating Student Disabilities (e.g. requests for extra time)**

The University of Michigan is committed to providing equal opportunity for participation in all programs, services and activities. Students wishing to receive testing accommodations must register with the UM SSD ([Services for Students with Disabilities](#)) as soon as possible. Students must then submit their Verified Individualized Services and Accommodations (VISA) form via online web form as early as possible, but no later than two weeks prior to the first test or quiz for which accommodations are requested.

Requests must be sent using the [Accommodations Request Form](#) and must include a scanned or photographed copy of the VISA form. This form only needs to be submitted once during your academic career with Ross unless your accommodations expire.

Questions can be directed to the Accommodations Coordinator at RossAccommodationsCoordinator@umich.edu.

In rare cases, the need for an accommodation arises after the two-week deadline has passed (for example, a broken wrist). In these cases, the student should still contact SSD and the Ross Accommodations Coordinator at RossAccommodationsCoordinator@umich.edu, however, due to logistical constraints we cannot guarantee that an accommodation can be made after the two-week deadline has passed.