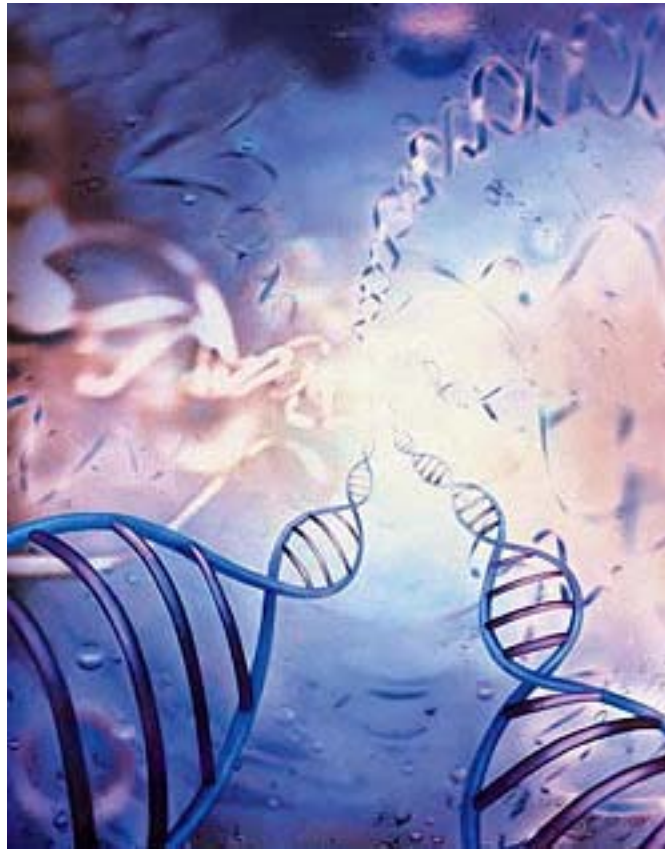


Medical Biotechnology and Drug Development

Fall 2009



Instructor: Regitze Illum

DIS DANISH INSTITUTE
FOR STUDY ABROAD

Medical Biotechnology and Drug Development

Course Description

Core course for semester students in the Biotechnology & Biomedicine program. This course will examine biomedicine, drug discovery and development, and biotechnological tools; exploration of the opportunities and challenges biotechnology has for medicine: personalized medicine, biomaterials, stem cells, tissue engineering, etc.; and the Danish pharmaceutical and biotech research community.

Course Objectives

Upon completion of this course, students will be able to:

1. Give a basic explanation of biomedical drug discovery and development
2. Review characteristics and principles of biotechnological tools, methods, and different biomedical research
3. research biotechnological information and present it in a clear and critical way
4. Participate actively in discussions of biotechnology and biomedicines in class and with biomedical professionals

Course Schedule

Meeting time: Monday and Thursday, 8:30-9:50.

Location: TBA.

Introduction to Course

The emphasis of the course will be on biomedicine, drug discovery & development, showcased through a focus on the Danish pharmaceutical and biotech research community.

The general principles of drug discovery & development will be covered, including registration, safety, toxicology, and clinical trials. The course will explore the opportunities and challenges biotechnology has for medicine; among them the different new types of biotechnological drugs, gene therapy, personalized medicine, delivery problems, stem cells, and genetically engineered animals.

The course will incorporate a great deal of group work; presenting case stories of local biomedical companies, and working on Wikipedia edits/entries based on these, presented in a group report. Group work helps prepare students for the way work is organized in professional life and can improve the quality of the work produced, by adding the different strengths of the students.

The focus in working with the biomedical company case stories and with Wikipedia will be on researching information, being able to critically review of sources of information, recognizing and communicating the central, interesting, and relevant points in the specific biotechnological products of the chosen biomedical companies.

The project will conclude with using Wikipedia as a conduit for the work of the students. This fulfils two major purposes:

- 1) The project will have a purpose beyond the course, providing interesting and relevant information to the world at large. In this way the course will not just finish with a report, only seen by the students and the teacher,
- 2) The students will gain a behind-the-scene look at Wikipedia, which will help them gauge its usability, trustworthiness, strengths, and weaknesses.

Instructor



Regitze Illum

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Education: BSc (Pharmacy), Danish University of Pharmaceutical Sciences 1998. MSc (Human Biology), University of Copenhagen 2001. Diploma in adult training and education 2007.

Employment: Research assistant, Bispebjerg Hospital (2001), IAESTE Trainee at Praecis Pharmaceuticals, Waltham, Massachusetts (2001), Research assistant, Danish University of Pharmaceutical Sciences (2002), PhD student at Drug Research Academy, Danish University of Pharmaceutical Sciences (2002-2005). Lecturer at The Nursing College Roskilde, University College Zealand (2007-2009), External lecturer at DIS (2007-2009), Assistant Program Director, Science and Health, DIS (2009-present).

Prerequisites

One year of biology and one year of chemistry at the university level.

Elements

Lectures, case stories, group presentations of case stories, field studies visiting biotech companies, solution sessions (alone/in groups), and “Communication through Wikipedia” group project.

Evaluation

“Communication through Wikipedia” (group project)	15%
Case story presentations (group project)	15%
Tests (2 at 15%)	30%
Final	20%
Participation	10%
Study tour assignment	10 %

Participation covers the following areas:

1. Attendance
2. Level of preparation and ability to answer questions asked in class
3. Involvement in class and group discussions
4. Level of individual research and contribution to discussions

Tests and Final

There will be two tests throughout the semester, one after the introductory lectures on drug discovery and development, and one after the lectures on the different types of biomedical medicines/therapies.

These tests will consist of a mix of short answer questions, long answer questions, and multiple choice questions. Tests in the class will generally last approximately 30 minutes. The final for this course will be cumulative and will be written in the same manner as the tests, but will be based on all the material covered in class. The final will be two hours in duration.

Wikipedia Group Project

The Wikipedia Group Project will deal with the technologies and/or biomedicines of some of the biotech companies that have been presented in the case story presentations. The students are encouraged to visit their chosen company, if possible, during the course of the semester.

The group will search for information concerning the company's product(s) or product pipeline, and focus on what is especially interesting about this product, what its technological edge is. This will require thorough research and critical thinking. The case story presentations will help the students prepare for this.

The information chosen will either be written up as a Wikipedia entry or be used to edit an existing entry on a company, technology, disease, or therapy, in accordance with the Wikipedia guidelines concerning notability, references etc. A report containing the proposed entry or edit, a description of the group's information seeking, and their discussions and considerations concerning the edit/entry will be handed in to the professor who will correct and grade it, following which the group will upload the edit/entry on Wikipedia.

At the final lecture, each group will present their Wikipedia edit/entry and their considerations to the class.

Practical Information

Biotechnology & Biomedicine faculty and staff have put many hours into selecting and organizing the readings and company cases for this course. Please make sure to read all the material assigned and to thoroughly investigate the websites of the companies listed in the syllabus; the reading material and the websites have been carefully chosen and are pertinent to your success in Medical Biotechnology and Drug Development. You have an obligation to your fellow classmates and yourself to come prepared to class.

If you have questions or need clarification about a reading or lecture material do not hesitate to speak up. This is very important. The professor for this course have no office hours, as such, but please feel free to email them or Pamela Wilson at pw@dis.dk to set up an appointment or simply ask a question.

The program director for this course is Anette Birck.

DIS Forum

The DIS Forum was developed as a web-based communication group to further the connection within the DIS organization. The system links student, faculty and staff, here and in the North American Office.

Just by coming to DIS you are automatically enrolled in several DIS Forum groups. You are part of the general DIS student group and, more specifically, groups that are dedicated to your program. In addition, you are enrolled in groups for your individual classes. While the Forum is run and monitored by the DIS staff, you are welcome to make your own group and invite members to join. For example, students in the past have created student travel groups and organized trips through the Forum. The DIS staff will post helpful and useful information about activities, directions and maps to Copenhagen landmarks, information about DIS sponsored (and non-DIS sponsored, but fun) events around town. You are also more than welcome to share pictures, start online discussions, chat with other students, ask questions to interns and staff and create polls. This is a useful part of the DIS curriculum and should be used to its full capacity (remember that the Forum is a DIS-run tool, so keep in mind that anything posted can be seen by any administrator).

On a more school-based level, the Forum pages contain information about your course calendar, make-up classes, downloadable lectures by professors and notifications of all changes and cancellations to schedules. There are also copies of the syllabi and other administrative papers pertaining to your classes posted in easy- to-spot locations. So anything lost should be able to be found.

To log on to the DIS Forum website for the first time, go to <http://disforum.dk>. Please refer to the “Welcome to DIS Forum” email you received before your arrival in Copenhagen. Otherwise, enter the email address that you provided to DIS, as this is now your username. Click “forgot password” and the password will be sent to your email account. Use the password to log on and then you can change your password under “my info.” If you are having problems please contact forumhelp@dis.dk.

Field Studies

Wednesday, date and time to be announced, Lundbeck

Ottoliavej 9

DK-2500 Copenhagen Valby

Lundbeck is an international pharmaceutical company conducting research into, developing, manufacturing, marketing, selling and distributing pharmaceuticals for the treatment of neurological disorders, including depression, schizophrenia, Alzheimer’s disease, Parkinson’s disease and insomnia.

Wednesday, date and time to be announced, TopoTarget

Fruebjergvej 3

2100 København Ø

TopoTarget is a dynamic international biotech company dedicated to finding “Answers for cancer”. It was founded by clinicians with a thorough knowledge of the molecular mechanisms of cancer. They have launched their first product Savene® (Totect® in the US) and have several products in their pipeline.

Study Tours

Short study tour dates: September 10-12. Visit to Odense and Århus in Western Denmark.

Long study tour dates: October 4-10. Visit to Edinburgh.

Objectives:

- To obtain insights into biotechnology-based methods for diagnosis and treatment of disease through academic visits
- To develop an understanding of the dynamics of drug discovery and development through observation of biomedicine and biotech research facilities
- To learn how biotech research and biotech business work together in Western Denmark as well as Edinburgh
- To understand technology transfer from university to business

Study tour assignment:

Before your short study tour, you will form groups of 2-3 people. Within these groups, you will come up with a question/research hypothesis to research during your study tours. After the study tour, you will, in the group, write a short paper (4-5 pages) in which you reflect upon the academic visits on both the short and long study tours. More information will be provided before the short study tour.

Required readings

Textbook:

Edited by Daan J. A. Crommeling and Robert D. Sinclair: *Pharmaceutical Biotechnology – An Introduction for Pharmacists and Pharmaceutical Scientists*. Third Edition, 2007, Taylor and Francis. (PB)

Reading compendium:

Most assigned readings that are not in the textbook are in the reading compendium. This will be given to you when you arrive and is for you to keep. Some assigned readings are posted on forum.

Content of the reading compendium:

H. P. Rang: “Drug discovery and development – technology in transition”, Churchill Livingstone/Elsevier, 2006, Chapter 3: “Therapeutic modalities”, p. 33-40.

H. P. Rang: “Drug discovery and development – technology in transition”, Churchill Livingstone/Elsevier, 2006, Chapter 15: “Drug development: introduction”, p. 221-225.

Gary Walsh: “Pharmaceutical Biotechnology – Concepts and Applications”, John Wiley and Sons Ltd., 2007, Chapter 4: “The drug development process”, p. 80-89.

H. P. Rang: “Drug discovery and development – technology in transition”, Churchill Livingstone/Elsevier, 2006, Chapter 6: “Choosing the target”, p. 63-74.

O. Kayser & R.H. Müller: “Pharmaceutical Biotechnology”, Wiley-VCH, 2004, Chapter 9 by R. Lipp og E. Punger: “Formulation of Biotech products”, p. 173-185.

O. Kayser & R.H. Müller: “Pharmaceutical Biotechnology”, Wiley-VCH, 2004, Chapter 10 by D. B. Resnik: “Patents and in the Pharmaceutical Biotechnology Industry: Legal and Ethical Issues”, p. 187-200.

D. W. Mount: “Bioinformatics, Sequence and Genome Analysis”, Cold Spring Harbor Laboratory Press, 2004, 2nd ed., Chapter 1: Historical Introduction and Overview”, p. 5-24.

C. G. Smith and J. T. O’Donnel: “The Process of New Drug Discovery and Development”, Informa Healthcare, 2nd Edition, Chapter 4: The Impact of Combinatorial Chemistry on Drug Discovery, p. 62-76.

H. Ulrich, A. H B. Martins, J. B. Pesquero, 2004: “RNA and DNA aptamers in cytomics analysis”, Cytometry Part A, Volume 59A, Issue 2, pages: 220-231.

R. J. Y. Ho & M. Gibaldi: “Biotechnology and Biopharmaceuticals – Transforming Proteins and Genes into Drugs”, John Wiley and Sons, 2003: Chapter 8: “Hormones”, p. 209-214.

T. Eschenhagen & W. H. Zimmerman, 2005: ”Engineering Myocardial tissue”. Circulation research, Vol. 97, p. 1220-1231.

J. M. Ossewaarde, 1995: “New methods in diagnostic and epidemiological research of *Chlamydia trachomatis* infections: the tide is turning molecular”, Journal of the European Academy of Dermatology and Venereology, Vol 5, p. 111-123.

R. S. Larson (edited by): “Bioinformatics and Drug Discovery”, Humana Press, 2006, Chapter 2 by S. A. Ness: “Basic Microarray analysis”, p. 13-33.

R. J. Y. Ho & M. Gibaldi: “Biotechnology and Biopharmaceuticals – Transforming Proteins and Genes into Drugs”, John Wiley and Sons, 2003: Chapter 14: “Individualization of drug regimens: integration of Pharmacokinetic and Pharmacogenetic Principles in Drug Therapy”, p. 381-399.

Karl Illmensee, 2002: “Biotechnology in reproductive medicine”, Differentiation, V. 69, I. 4- 5, p. 167-173.

S. P. Wainwright, C. Williams, M. Michael, B. Farsides, A. Cribb, 2006: “Ethical boundarywork in the embryonic stem cell laboratory”, Sociology of Health & Illness, Volume 28, Issue 6, Date: September 2006, p: 732-748.

M. P. Faggioni, 2008: “Anthropological and ethical reflections on the production and use of embryonic stem cells”, Cell Proliferation, Vol. 41, Suppl. 1, p. 71-77.

A. Kuliev, S. Rechitsky, I. Tur-Kaspa and Y. Verlinsky, 2005: “Preimplantation genetics – Improving Access to Stem Cell Therapy”, Annals of the New York Academy of Sciences, Vol. 1054, p. 223-227.

Required Readings (files or links on forum)

How Your Immune System Works. Print from website, How stuff works:

<http://health.howstuffworks.com/immune-system.htm/printable>

Drug Volunteer's Living Hell: <http://news.bbc.co.uk/2/hi/health/4813478.stm>

Horror Clinical Trial in Test Tube Recreation: <http://www.newscientist.com/article/dn10747-horror-clinical-trial-in-test-tube-recreation-.html>

Team Creates Rat Heart Using Cells of Baby Rats:

http://www.nytimes.com/2008/01/14/health/14heart.html?_r=4&oref=slogin&pagewanted=print&oref=slogin&oref=slogin

Useful Links and Online Biotech Dictionaries

Medicon Valley Alliance

www.mva.org

Biotech Research and Innovation Centre, Copenhagen

<http://www.bric.dk>

Nature Biotechnology

<http://www.nature.com/nbt/index.html>

Biotech Industry Organisation

<http://www.bio.org/>

European Union BioTech - information on BioTech in EU

<http://www.euractiv.com/en/biotech>

Glossary of Biotechnology Terms

<http://biotechterms.org/>

Technology Review – Biotech section

<http://www.technologyreview.com/Biotech/>

The Weblog Biotech

<http://www.biotech-weblog.com/>

Medicon Valley Patent Guide

[http://www.mva.org/media\(1947,1033\)/Medicon_Valley_Patent_Guide.pdf](http://www.mva.org/media(1947,1033)/Medicon_Valley_Patent_Guide.pdf)

	DATE	LECTURE	TEXT
1.	Thursday, Aug. 27	<p>Course introduction The structure and didactics of the course</p> <p>What is biotech?</p> <ul style="list-style-type: none"> - History of biotech - Where do you meet biotech? - Why should you learn about biotech in Denmark? <p>General introduction to the immune system</p>	<ul style="list-style-type: none"> - How your immune system works. (LINK) - Reading compendium (RC): Chapter 3: “Therapeutic modalities”, p. 33-40.
2.	Monday, Aug. 31	<p>Drug discovery and development Registration of a drug - overview of the different phases:</p> <ul style="list-style-type: none"> - Drug discovery - Pre-clinical - Clinical trials - Small molecule pharmacy contrasted with biotech <p>Groups must be formed</p>	<ul style="list-style-type: none"> - (RC): Chapter 15: “Drug development: introduction”, p. 221-225. - (RC): Chapter 4: “The drug development process”, p. 80-89.
3.	Thursday, Sep. 03	<p>Drug discovery and development Drug discovery:</p> <ul style="list-style-type: none"> - Target identification - Disease models - Molecule libraries - Screening - Small molecule pharmacy contrasted with biotech <p>Elect Class Representatives</p>	<ul style="list-style-type: none"> - PB: Chapter 7: “Genomics, Other “Omics” Technologies, Personalized..”, p. 165-168. - (RC): Chapter 6: “Choosing the target”, p. 63-74.
4.	Monday, Sep. 07	<p>Drug discovery and development Pharmaceutical problems:</p> <ul style="list-style-type: none"> - Formulation - Delivery - Storage - Small molecule pharmacy contrasted with biotech 	<ul style="list-style-type: none"> - (RC): Chapter 9 by R. Lipp og E. Punger: “Formulation of Biotech products”, p. 173-185.
		Short Study Tour in Western Denmark (Sep. 10-12)	
5.	Monday, Sep. 14	<p>Drug discovery and development Focus on disadvantages and advantages:</p> <ul style="list-style-type: none"> - Clinical trials - Safety – from animal to man - Example: TeGenero - Patent law 	<ul style="list-style-type: none"> - PB: Chapter 6: “Immunogenicity of Therapeutic Proteins”, p. 126-132 - “Drug volunteers’ ‘living hell’” – link on DISforum. - “Horror clinical trial in test tube recreation” – link on DISforum. - (RC): Chapter 10 by D. B. Resnik: “Patents and in the Pharmaceutical Biotechnology Industry: Legal and Ethical Issues”, p. 187-200.

6.	Thursday, Sep. 17	<p>Test: Drug discovery and development</p> <p>Biotechnological tools Target identification:</p> <ul style="list-style-type: none"> - Genomics - Proteomics - Bioinformatics - Knockout mice and gene inserts 	<ul style="list-style-type: none"> - PB: Chapter 7: “Genomics, Other “Omics” Technologies, Personalized..”, p. 133-140 +153-155.
7.	Monday, Sep. 21	<p>Biotechnological tools Libraries of compounds</p> <ul style="list-style-type: none"> - Combinatorial approaches - Looking in living organisms 	<ul style="list-style-type: none"> - (RC): Chapter 4: “The Impact of Combinatorial Chemistry on Drug Discovery”, p. 62-76. - (RC): Ulrich et al., 2004, Cytometry Part A, Volume 59A, Issue 2, pages: 220-231.
8.	Thursday, Sep. 24	<p>Biotechnological tools Production and fermentation:</p> <ul style="list-style-type: none"> - Bioreactors - Bacteria and eukaryotic organisms <p><i>Case story presentation: Percell</i></p>	<ul style="list-style-type: none"> - PB: Chapter 3: Production and downstream processing of Biotech Compounds, p. 49-65.
9.	Monday, Sep. 28	<p>Biomedicines Gene therapy</p> <ul style="list-style-type: none"> - Vectors, viral and non-viral - SiRNA 	<ul style="list-style-type: none"> - PB: Chapter 8: “Gene therapy”, p. 175-183+193-204. - and Chapter 9: “Oligo-nucleotides”, p. 211-222.
10.	Thursday, Oct. 1	<p>Biomedicines Peptides</p> <ul style="list-style-type: none"> - Properties - Peptidomimetics 	<ul style="list-style-type: none"> - PB: Chapter 5: “Pharmacokinetics and Pharmacodynamics of Peptide and Protein Drugs”, p. 95-108. - and Chapter 7: “Genomics, Other “Omics” Technologies, Personalized..”, p. 156-162.
		<p>Long study tour to Edinburgh (Oct. 4- April 10)</p>	
11.	Monday, Oct. 12	<p>Biomedicines Vaccines Antibodies</p>	<ul style="list-style-type: none"> - PB: Chapter 21: “Vaccines”, p. 405-425. - PB: Chapter 15: “Monoclonal antibodies: From structure to therapeutic Application”, 309-329.
12.	Thursday, Oct. 12	<p>Biomedicines Antibodies, continued</p> <p><i>Case story presentation: DAKO</i></p> <p>Diagnostics, Principles and uses</p> <ul style="list-style-type: none"> - Tests using monoclonal antibodies - Tests using DNA/RNA (PCR) 	<ul style="list-style-type: none"> - (RC): Ossewaarde: “New methods in diagnostic and epidemiological research of Chlamydia trachomatis infections: the tide is turning molecular”, p. 111-123.
13.	Monday, Oct. 19	<p>Guest lecturer: Astrid Iillum (MA in Philosophy and Communication) & Bodil</p> <p>Wikipedia</p> <ul style="list-style-type: none"> - What is Wikipedia - Guidelines for posting and editing - Trustworthiness - Advantages/disadvantages - How to! 	<ul style="list-style-type: none"> - Guidelines at wikipedia.org

		<ul style="list-style-type: none"> - The Wikipedia Group Project begins - Expectations and requirements 	
14.	Thursday, Oct. 22	Biomedicines Recombinant coagulation factors <ul style="list-style-type: none"> - Recombinant thrombolytic agents - Hematopoietic growth factors Example: NovoSeven	<ul style="list-style-type: none"> - PB: Chapter 10: “Hematopoietic Growth Factors”, p. 225-239. Chapter 14: “Recombinant Coagulation Factors and Thrombolytic Agents”, p. 293-305.
15.	Monday, Oct. 26	Biomedicines Hormones: Insulin <i>Case story presentation: Novo Nordisk and Eli Lilly</i>	<ul style="list-style-type: none"> - (RC): Chapter 8: “Hormones”, p. 209-214. - PB: Chapter 12: “Insulin”, p. 265-278. Chapter 13: “Growth hormone”, p. 281-289. and Chapter 20: “Follicle-stimulating hormone”, p. 399-403.
	Wednesday TBA	Field Study: Lundbeck	
16.	Thursday, Oct. 29	Test: Biomedicines Genetically engineered animals: <ul style="list-style-type: none"> - Chimeras - Xenotransplants - Drug producing animals (pharming) Tissue engineering and stem cells: <ul style="list-style-type: none"> - Externally grown organs - Stem cells 	<ul style="list-style-type: none"> - PB: Chapter 7: “Genomics, Other “Omics” Technologies, Personalized..”, p. 148-153. - PB: Chapter 7: “Genomics, Other “Omics” Technologies, Personalized..”, p. 162-165. - (RC): Eschenhagen et al.: “Engineering Myocardial tissue”, p. 1220-1231. - “Team Creates Rat Heart Using Cells of Baby Rats” – link on DISforum.
17.	Monday, Nov. 16	Guest lecturer: Hans Martin Dufva , professor at MIC at the Technical University of Denmark Diagnostics Scaling up: <ul style="list-style-type: none"> - Microchips – lab on a chip - Microarrays Wikipedia report needs to be handed in	<ul style="list-style-type: none"> - (RC): Chapter 2 by S. A. Ness: “Basic Microarray analysis”, p. 13-33. -
	Wednesday, TBA	Field Study: TopoTarget	
18.	Thursday, Nov. 19	Pharmacogenomics Personalized medicine (theranostics): <ul style="list-style-type: none"> - Which drug for which person - High/low metabolizer Genetic diagnosis: <ul style="list-style-type: none"> - Cancer type - Risk of disease - Example: Medical Prognosis Wikipedia report returned to	<ul style="list-style-type: none"> - PB: Chapter 7: “Genomics, Other “Omics” Technologies, Personalized..”, p. 140-146. - (RC): Chapter 14: “Individualization of drug regimens: integration of ..”, p. 381-391+395-399. - (RC): Chapter 14: “Individualization of drug regimens: integration of ..”, p. 391-399. - (RC): Illmensee: “Biotechnology in reproductive medicine”, p. 167-173.

DIS Fall 2009 Medical Biotechnology and Drug Development

		students	
19.	Monday, Nov. 23	Ethics: - Stem cells - Chimera Genetic testing	- (RC): Wainwright: "Ethical boundarywork in the embryonic stem cell laboratory", p. 732-748. - (RC): Faggioni: "Anthropological and ethical reflections on the production and use of embryonic stem cells", p. 71-77. - (RC): Kuliev et al.: "Preimplantation genetics – Improving Access to Stem Cell Therapy", p. 223-227.
		Fall break (Nov. 26-29)	
20.	Monday, Nov. 30	No class	-
21.	Thursday, Dec. 3	No class	-
22.	Monday, Dec. 7	Presentation of Wikipedia project - Each group presents their edit/entry and considerations - Common discussion - Wrap up	-
23.	Thursday, Dec. 10	No class	
	Dec. 14-18	DIS Final exams	