OFFICIAL MASTER IN TRANSLATIONAL MEDICINE
FACULTY OF MEDICINE (CAMPUS CLÍNIC)
UNIVERSITY OF BARCELONA

- STUDENT’S GUIDE -

MASTER IN TRANSLATIONAL MEDICINE
EDITION 2019-2020
THE COORDINATOR

Josep M. Llovet is Professor of Research-ICREA, Liver Unit, IDIBAPS-Hospital Clinic of Barcelona (Spain). Director of the Master in Translational Medicine at the Faculty of Medicine University of Barcelona); Director of the Liver Cancer Program, and Full Professor of Medicine at the Mount Sinai School of Medicine in New York. He has been President of the International Liver Cancer Association (ILCA) and Chairman of the European Clinical Practice Guidelines on the Management of Liver Cancer (EASL-EORTC). He has published more than 285 articles in peer-reviewed journals, 54 book chapters, and has been awarded the AACR–Landon International Award and the International Hans Popper Prize, among others. Josep M. Llovet has devoted his academic career to the study of the molecular pathogenesis and treatment of liver cancer, and has received competitive funding from the European Commission and the US National Institute of Health.

WELCOME FROM THE COORDINATOR

The Official Master in Translational Medicine-MSc from the University of Barcelona will offer you the opportunity to gain an excellent training both in academia and research. It will provide you comprehensive and updated knowledge of the basics, clinical and epidemiological entities associated with major human pathogenesis, examined from a cross-sectional view. Moreover, it will give you access to knowledge and skills necessary to develop translational research projects in the field of biomedicine.

Prof Josep M Llovet
Master Coordinator
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GENERAL INFORMATION

The Master in Translational Medicine is an Official Master from the University of Barcelona that allows posterior enrolment to PhD degree. It is a 60 credits Master in which we offer 4 compulsory subjects, 7 optional subjects (the student has to choose 4) and 500 hours (minimum) of research training for the Master Thesis. The Master is taught in English and can be completed in 1 or 2 years.

Virtual Campus
Students have a virtual environment with access to a range of specialized resources (updated programs for each subject, lecturer’s PowerPoint presentations, videos, articles, etc.) and activities to ensure proper preparation for face-to-face sessions in the classroom. This online tool gives access to academic, administrative and information resources.

You can access the “Virtual Campus” through the following link: https://campusvirtual2.ub.edu/my

Each student has its own ID, which is provided by the Secretariat of the University of Barcelona upon registration.

Calendar
Lectures are scheduled from Monday to Thursday from 16h to 20h, from September 30, 2019 to June 18, 2020, most lessons will be taught at Classroom 14 (5th Floor) of the Faculty of Medicine. Please note some lessons/exams might be scheduled differently.

Evaluation
Compulsory and Optional subjects will be evaluated considering attendance (which will account for 50% of the final score) and the students’ performance in a exam/project (which will account for the remaining 50%). Specifically, attendance will be evaluated as: 95%-100% → 50 points / 80% - 95% → 40 points / 30-80% → 20 points / <30% → Subject Failure. The exam will consist on a written test, oral presentation or written report. The maximum score will be 50 points, and the minimum mark requested to pass the subject will be 20 points.

To pass the subject, students will have to fulfill three requisites: Attendance-score ≥ 20/50, exam-score ≥20/50, and overall score (attendance + exam) ≥ 50/100.

The final score of the Master thesis will be calculated from the written report mark (40%), the oral defense mark (40%) and the practicum assessment (20%). Following UB regulations, students need to pass all master subjects in order to be able to defend their master thesis.

Re-evaluation
In case of failing the ordinary evaluation, students might have the chance to pass the subject by doing a report, exam or presentation (please check this point on each subject’s study plan). The maximum score on the re-evaluation is 50/100.
PRE-ADMISION REQUIREMENTS

Students seeking for admission to the Master program should possess any of the following qualifications: Medicine, Biomedical Sciences, Biomedical Engineering, Biology, Biochemistry, Biotechnology, Pharmacy, Genetics and other health-related disciplines.

Students who meet the entry criteria will be assessed according to the evaluation of the following items:

- Curriculum Vitae
- Motivation Letter, explaining the student’s interest on the Master
- Proven High level of English (level B2 CEFR, First Certificate or equivalent)

International students must validate their previous studies to access the Spanish Education System. More information is available on the master’s website.

MASTER COMMITTEE

• Master Coordinator
• Subjects Coordinators
• Students representatives
• Representatives of the Faculty of Medicine – University of Barcelona staff.

USEFUL LINKS

1.- Campus useful information: [http://www.ub.edu/monub](http://www.ub.edu/monub)
2.- Virtual Campus access: [https://campusvirtual2.ub.edu](https://campusvirtual2.ub.edu)
6.- Financial Information: [http://www.ub.edu/acad/matricula/preus.html#master](http://www.ub.edu/acad/matricula/preus.html#master)
12.-UB sport services: [http://www.ub.edu/esports](http://www.ub.edu/esports)
### Master Coordinators

<table>
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<tr>
<th>Subject</th>
<th>Coordinator(s)</th>
<th>Contact(s)</th>
</tr>
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<tbody>
<tr>
<td><strong>Compulsory</strong></td>
<td></td>
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</tr>
<tr>
<td>1. Molecular Biology in Human Diseases</td>
<td>Dr Morales</td>
<td><a href="mailto:morales@clinic.cat">morales@clinic.cat</a></td>
</tr>
<tr>
<td><em>Processos Biológics Claus en les Malalties Humanes</em></td>
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<tr>
<td>2. Animal Modeling in Translational Research</td>
<td>Dr Clària</td>
<td><a href="mailto:jclaria@clinic.cat">jclaria@clinic.cat</a></td>
</tr>
<tr>
<td><em>Experimentació Animal en Recerca Translacional</em></td>
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<tr>
<td>3. Translational Medicine</td>
<td>Dr Llovet Dr Pinyol</td>
<td><a href="mailto:jmllovet@clinic.cat">jmllovet@clinic.cat</a> <a href="mailto:rpinyol@clinic.cat">rpinyol@clinic.cat</a></td>
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<tr>
<td><em>Estudi de les Òmiques en Recerca Translacional</em></td>
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<tr>
<td>4. Biomarker Discovery and Validation</td>
<td>Dr Brunet Dr Bosch</td>
<td><a href="mailto:mbrunet@clinic.cat">mbrunet@clinic.cat</a>安娜 <a href="mailto:bosch@efclif.com">bosch@efclif.com</a></td>
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<tr>
<td><em>Sample Management and Biobanks</em></td>
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<tr>
<td>5. MASTER THESIS - Treball Final de Màster</td>
<td>Dr Llovet</td>
<td><a href="mailto:jmllovet@clinic.cat">jmllovet@clinic.cat</a></td>
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<tr>
<td><em>Bases de la Recerca Translacional i Biobancs</em></td>
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<td><strong>Optional</strong></td>
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<tr>
<td>5. Bioinformatics in translational Research</td>
<td>Dr Tamborero Dr Bigas-López</td>
<td><a href="mailto:david.tamborero@irbbarcelona.org">david.tamborero@irbbarcelona.org</a></td>
</tr>
<tr>
<td><em>Bioinformática en Recerca Translacional</em></td>
<td></td>
<td><a href="mailto:nuria.lopez@irbbarcelona.org">nuria.lopez@irbbarcelona.org</a></td>
</tr>
<tr>
<td>6. Imaging in Translational Research</td>
<td>Dr Planas Dr Soria</td>
<td><a href="mailto:anna.m.planas@gmail.com">anna.m.planas@gmail.com</a> <a href="mailto:guadalupe.soria@idibaps.org">guadalupe.soria@idibaps.org</a></td>
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<tr>
<td>7. Stem Cell Research</td>
<td>Dr Gomis</td>
<td><a href="mailto:roger.gomis@irbbarcelona.org">roger.gomis@irbbarcelona.org</a></td>
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<td>8. Translational Research in Public Health</td>
<td>Dr Dominguez</td>
<td><a href="mailto:angela.dominguez@ub.edu">angela.dominguez@ub.edu</a></td>
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<tr>
<td>9. Clinical Trials Design and Evaluation of Molecular Therapies</td>
<td>Dr Torres Dr Llovet</td>
<td><a href="mailto:ferran.torres@idibaps.org">ferran.torres@idibaps.org</a> <a href="mailto:jmllovet@clinic.cat">jmllovet@clinic.cat</a></td>
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<tr>
<td><em>Principis sobre el Disseny d’Assaigs Clinics i Descobriment de Noves Molècules.</em></td>
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<tr>
<td>10. Principles of Clinical Medicine</td>
<td>Dr Llovet Dr Lens</td>
<td><a href="mailto:jmllovet@clinic.cat">jmllovet@clinic.cat</a> <a href="mailto:slens@clinic.cat">slens@clinic.cat</a></td>
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<tr>
<td>11. Responsible Research, Innovation and Entrepreneurship</td>
<td>Dr Martínez Dr Bigorra</td>
<td><a href="mailto:pmsamper@uoc.edu">pmsamper@uoc.edu</a> <a href="mailto:bigorra@clinic.cat">bigorra@clinic.cat</a></td>
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# CALENDAR 2019-2020

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<td>CLINICAL TRAUM EXAM (Home/Exams)</td>
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<td>HOLIDAY</td>
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**Notes:**
- “OPT” denotes optional courses.
- “HOLIDAY” indicates a holiday or break in the academic schedule.
- “Day 1” refers to the first day of an examination or event.
- “Day 2” and subsequent days refer to continuation or second day of the examination or event.

**Additional Information:**
- The calendar includes a variety of courses and exams, with specific dates for each activity.
- The schedule is designed to accommodate both theoretical and practical components of the program.
- There are holidays interspersed throughout the year, providing time for rest and recuperation.
- The program is structured to ensure a well-rounded educational experience, including opportunities for hands-on learning and research.

**Contact Information:**
- For further information or inquiries, please contact the Program Director or the Academic Coordinator.

**Acknowledgments:**
- The faculty and staff at Universitat de Barcelona are dedicated to providing a high-quality educational experience for all students.
- The program is supported by a range of resources and facilities to support student success.

**Disclaimer:**
- The content of the calendar is subject to change based on academic and programmatic considerations.
- The program reserves the right to make adjustments to the schedule as necessary.
DEADLINES

✓ Pre-registration process:  
  May 2019 to August 2019

✓ Registration process:  
  From 2nd September 2019

✓ Course start:  
  The introductory class will be on September 30th at 15h at classroom 14th (5th floor) at the Faculty of Medicine followed by Module lessons.

✓ Deadline for acceptance to a research group:  
  November 29th 2019

✓ Master Thesis short evaluation: (5 minutes oral presentation)  
  December 17th to 19th 2019

  Structure:  
  1. Introduction (main ideas listed)  
  2. Working Hypotheses and Objectives  
  3. Material and Methods (draft)  
  4. Results (draft)

✓ Deadline to send your Master Thesis written report presentation:  
  June 5, 2019

✓ Master Thesis oral presentation: (10 minutes oral presentation + 5 minutes questions & answers)  
  From June 15 to June 18, 2019
CONTACT DETAILS

MASTER'S SECRETARIAT

CONTACTS:  ARIADNA FARRÉ (afarrec@clinic.cat)
            SARA BAYARRI (bayarrri@clinic.cat)
ADDRESS:    3rd Floor CEK Building, Rosselló, 153
PHONE:      +34 93-3129499
OPENING HOURS: From 9am to 7pm (Monday to Friday)

www.ub.edu/medicina/masters/traslacional

FACULTY OF MEDICINE SECRETARIAT

ADDRESS:    CASANOVA, 143 - BARCELONA
PHONE:      +34 93-4035250 / 51/52
EMAIL:      secretariamedicina@ub.edu
OPENING HOURS: From 9.30 to 13.30 (Monday to Friday)
            From 16 to 18 (Monday to Thursday)
WEBSITE:    http://www.ub.edu/medicina
STUDY PLANS & PROGRAMS

COMPULSORY SUBJECTS (24 ECTS) ........................................................................................................... 24 ECTS

1. Molecular Biology in Human Diseases
2. Animal Modeling in Translational Research
3. Translational Medicine
4. Biomarker Discovery and Validation. Sample Management and Biobanks

OPTIONAL SUBJECTS (3 ECTS EACH; 4 SUBJECTS x 3ECTS=12 ECTS) .......... 12 ECTS

5. Bioinformatics in Translational Research
6. Imaging in Translational Research
7. Stem Cell Research
8. Translational Research in Public Health
9. Clinical Trials Design and Evaluation of Molecular Therapies
10. Principles of Clinical Medicine
11. Responsible Research, Innovation and Entrepreneurship

THESIS MASTER (24 ECTS) .......................................................................................................................... 24 ECTS

TOTAL NUMBER OF CREDITS ...................................................................................................................... 60 ECTS
MOLECULAR BIOLOGY IN HUMAN DISEASES
STUDY PLAN 2019-2020

Coordinated by:
Dr Manuel Morales Biochemistry and Molecular Genetics Department, Hospital Clinic, IDIBAPS

GENERAL INFORMATION

Subject Name Molecular Biology in Human Diseases
Code 566658
Type Compulsory
Teaching First semester
Coordinator Dr. Manuel Morales
Contact details morales@clinic.cat
ECTS credits 6

OBJECTIVES

The overall objective of the subject is to provide an interdisciplinary, profound and updated background on the fundamental mechanisms involved in the reparation and maintenance of tissue formation. In that way, four key biological processes are addressed whose interrelationship determine the presence of diseased or normofunctional tissue: 1) inflammation 2) angiogenesis 3) tissue remodeling and 4) cancer.

Specifically, the dual objective pursued on this subject is:

• To provide students a broad, interdisciplinary, functional, pathogenic and methodological knowledge about the commonly used concepts in biomedical research, inflammation, angiogenesis, tissue remodeling and theoretical cancer.

• To provide students with a holistic view of all the above mentioned processes, addressing their interrelations in different physiological and pathophysiological contexts.

COMPETENCES TO BE GAINED DURING THE STUDY

General
G1: Understand the fundamental basic, clinical and therapeutic principles of pathologies with abnormalities in the mechanisms of inflammation, angiogenesis, tissue remodeling and cancer.
G2: Understand, interpret and discuss with clinicians pathogenic aspects.
G3: Meet the analytical procedures used in the translational study of these biological processes.
G4: Become familiar with advances in biomedical and interdisciplinary research.
Specific
S1: Be able to design experimental protocols in vitro and in vivo to study processes related to translational medicine.
S2: Know how to properly formulate hypotheses and research objectives.
S3: Be able to design research projects potentially applicable.
S4: Be able to integrate the acquired knowledge on basic research and clinical research.
S4: Be able to identify public health problems and communicate them to the project rating agencies.

Transverse
T1: Reflection, synthesis and release of trials.
T2: Ability to disseminate the acquired knowledge.
T3: Be able to interact with professionals from different medical specialties resolutely.
T4: Use of English as a global language in science.

THEMATIC BLOCKS
1. Introduction and holistic view of biological mechanisms
2. Inflammation
3. Angiogenesis
4. Tissue remodeling
5. Cancer
6. Photonics
7. Research project proposal

METHODOLOGY
Total training hours: 6 credits ECTS x 25h/credit = 150h
a) Face-to-face training (48h):
   - Lectures
   - Research projects presentation
   - Seminars
b) Home training (102h):
   - Individual work

The home training time is intended to write projects and doubt resolution.

EVALUATION
To pass the module, students must obtain a minimum of 50 points. The score will be established as follows:

• Attendance 50% of the score
• Research project 50% of the score
To pass the subject, students will have to fulfill three requisites: Attendance-score $\geq 20/50$, project-score $\geq 20/50$, and overall score (attendance + project) $\geq 50/100$.

Reevaluation: In case of failing the ordinary evaluation, students will have to critically appraise 2 scientific articles and present the analysis in form of an oral presentation. The re-evaluation final score will never get over 50 points. English will be preferred in the presentation, but Catalan or Spanish will be also accepted.

REFERENCES

4. [www.nature.com/nature/insights/6835.html](http://www.nature.com/nature/insights/6835.html)
5. [www.nature.com/nature/supplements/insights/inflammation/](http://www.nature.com/nature/supplements/insights/inflammation/)
6. [www.nature.com/nature/supplements/insights/angiogenesis/](http://www.nature.com/nature/supplements/insights/angiogenesis/)
ANIMAL MODELING IN TRANSLATIONAL RESEARCH

STUDY PLAN 2019-2020

Coordinated by:
Dr Joan Clària  Senior Consultant at the Department of Biochemistry and Molecular Genetics, Biomedical Diagnostic Center, Hospital Clinic, – Tenure-track Professor, Department of Biomedical Sciences, Faculty of Medicine, University of Barcelona

GENERAL INFORMATION

Subject Name  Animal Modeling in Translational Research
Code  566657
Type  Compulsory
Teaching  First semester
Coordinator  Dr. Joan Clària
Contact Details  jclaria@clinic.cat
ECTS credits  6

OBJECTIVES

Upon completion of this subject students will be able to:

1. Identify the most appropriate experimental model to investigate mechanisms of a specific disease.
2. Identify the most appropriate methodology of laboratory employed in animal research studies.
3. Describe the strengths and weaknesses of a particular model of experimental disease.
4. Define the value and limitations of in vivo, ex vivo, in situ and in vitro experiments.
5. Understand the technicalities of the cellular and molecular biology methods most frequently used in experimental research.
6. Translate the results obtained in basic research to the diagnosis, prevention and therapy of particular diseases.
7. Understand offspring basic techniques used in genetic engineering of animal laboratories.
8. Understand fundamental aspects of the generation and husbandry of knockouts and transgenic models.
9. Appreciate the main advantages and disadvantages of the most common experimental models of prevalent diseases.
10. Know the basic technical aspects of proper handling in animal laboratories.
11. Understand the ethical and legal provisions of the experimental research.
12. Design organ functioning studies (kidney, heart, lung, etc.) and vascular and hemodynamics function.
13. Correctly design pathophysiological studies ex vivo and in situ.
14. Learn the basic principles of cell culture and manipulation.
15. Design studies in isolated cells, in vitro cell lines and primary cells.
16. Interpret pre-clinical studies and their use in the pharmaceutical industry.
17. Get acquainted with non-mammalian model systems.
COMPETENCES TO BE GAINED DURING THE STUDY

General
G1: Knowledge of the main tools for translational research
G2: Knowledge of the scientific biochemical, molecular and genetic basis used in translational research

Specific
S1: Acquire the necessary skills to properly interpret the results obtained with experimental models
S2: Develop the required skills to design a translational study in experimental models of a particular disease
S3: Complement the knowledge and skills acquired in the course of ‘Animal Experimentation at the Laboratory’

THEMATIC BLOCKS

1. Introduction and basic principles of experimental models
2. Ethical and legal dispositions in experimental research
3. Genetically modified animals: transgenic and knockouts
4. Mice colony management: breeding, assisted reproduction techniques and cryopreservation
5. Research studies in large animals
6. Models for “non-mammalian” (zebra fish) model systems
7. Experimental models for respiratory diseases
8. Experimental models for neuroscience
9. Experimental models for gastrointestinal diseases
10. Experimental models for liver disease
11. Experimental models for transplantation
12. Experimental models for cancer
13. Methods and Models for endothelial biology
14. Methods and Models in microbiology
15. Methods and models in immunology
16. Mathematical models
17. Chromatographic methods for biomarker identification
18. Design of pre-clinical studies in biomedical research
19. Screening methods in the pharmaceutical industry
20. Translating experimental studies into the industry

METHODOLOGY

Total training hours: 6 credits ECTS x 25h/credit = 150h

a) Face-to-face training (48h):
   - Lectures
   - Journal clubs
   - Seminars/Group discussion
   - Experimental project presentation
   - Seminars
b) Home training (102h):
- Individual and group work
- Preparation of journal clubs
- Preparation of experimental project presentations

**EVALUATION**

To pass the subject, students must obtain a minimum of 50 points. The score will be established as follows:

- **Attendance**: 50% of the overall grade
- **Exam**: 40% of the overall grade. The exam is on site and consists of 25 questions with multiple choices (5, only 1 is correct; each mistake subtracts 0.2 points).
- **Experimental project oral presentation**: 10% of the overall grade.

To pass the subject, students will have to fulfill three requisites: Attendance-score ≥ 20/50, exam/project oral presentation-score ≥20/50, and overall score (attendance + exam/project oral presentation) ≥ 50/100.

**Reevaluation**: In case of failing the ordinary evaluation, students will have to send the coordinator a written report dissecting two different experimental models appearing in a single scientific article. The re-evaluation final score will never get over 50 points.

**REFERENCES**

**Bibliography:**
- González de Buitrago. Técnicas y métodos de laboratorio clínico. Elsevier España, 2004
- González Hernández, A. Principios de bioquímica clínica y patología molecular, Elsevier España, 2007

**Webography:**
- [www.jax.org/](http://www.jax.org/)
- [www.informatics.jax.org/](http://www.informatics.jax.org/)
- [genetics.hms.harvard.edu/](http://genetics.hms.harvard.edu/)
- [www.complexttrait.org/](http://www.complexttrait.org/)
TRANSLATIONAL MEDICINE
STUDY PLAN 2019-2020

Coordinated by:
Dr Josep M Llovet ICREA Professor, IDIBAPS, University of Barcelona. Director of the Liver Cancer Program, MSSM (New York). Professor of Medicine, Department of Medicine, Faculty of Medicine, University of Barcelona
Dr Roser Pinyol, Liver Cancer Translational Research Laboratory, IDIBAPS - Hospital Clínic. Associated Professor, Department of Medicine, Universitat de Barcelona.

GENERAL INFORMATION

<table>
<thead>
<tr>
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<tr>
<td>Code</td>
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<td>Teaching</td>
<td>First semester</td>
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<tr>
<td>Coordinator</td>
<td>Prof. Josep M Llovet, Dr Roser Pinyol</td>
</tr>
<tr>
<td>Contact Details</td>
<td><a href="mailto:jmllovet@clinic.cat">jmllovet@clinic.cat</a>, <a href="mailto:rpinyol@clinic.cat">rpinyol@clinic.cat</a></td>
</tr>
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</tbody>
</table>

OBJECTIVES

The purpose of this subject is to provide students with scientific, conceptual, methodological and practical knowledge about translational medicine. Specifically, the genomics and epigenomic bases will be assessed, as well as their applications in translational research. These concepts will be integrated with the study of the signaling pathways involved in various diseases and their functional role.

The overall objective is to provide a scientific basis for the design and implementation of translational research, and the knowledge related to relevant methods, techniques and applications in biomedicine.

COMPETENCES TO BE GAINED DURING THE STUDY

Generic
G1: Capacity for learning and responsibility (capacity for analysis and synthesis, to adopt global perspectives and to apply the knowledge acquired/capacity to take decisions and adapt to new situations).
G2: Learning skills that are necessary to undertake further research studies with a high degree of autonomy.
Specific
S1: Understand the basic, clinical and therapeutic principles of different pathologies
S2: Learn the procedures and methodologies used in translational studies
S3: Become familiar with the development of biomedical research and learn the basic tools for translational research
S4: Ability to explain the basic molecular principles underlying pathologies, ability to understand the role of genes in human cancer and the basic concepts of oncodrivers and targeted therapies.

THEMATICAL BLOCKS

1. Basic Principles
- Introduction
- Role of epigenetics in human diseases
- Personalized medicine in oncology
- Molecular pathology in oncology
- Principles of genetic engineering
- Immunology and cancer
- Principles of experimental Design
- Bioinformatics and Managing of Big Data

2. High throughput technologies
- Gene expression
- SNP array, CNVs and GWAS
- Exome sequencing
- Methylome analysis
- Single Cell Genomics
- Proteomics

3. Signaling pathways
- Signaling pathways.
- Resistance to molecular therapies
- TGF-beta signaling in liver cancer

4. Genomics in cancer
- Molecular classification of hepatocellular carcinoma
- Targets for therapies in pancreatic cancer
- miRNA in human diseases and digestive cancer
- Angiogenesis: Drugs & mechanisms of resistance
- Colorectal cancer: genetics and genomics
- Molecular classification of breast cancer
- Molecular therapies and immunotherapy in melanoma
- Immunotherapies in cancer
- Role of adult stem cells in cancer

5. Genomics in other diseases
- Next generation sequencing in hematological diseases
- Pluripotent cells in translational medicine: recent advances and open problems
- Chronic Hepatitis C: from genotyping to therapies
- Liver portal hypertension and fibrosis
- Inflammatory disease / Crohn's disease
- Inflammatory bowel disease (IBD)
- Translational medicine in Alzheimer disease
- Translational medicine in Parkinson disease
- Translational research in psychiatric disorders
- Genomics in Multiple Sclerosis
- Genomics in autoimmune encephalitis.
- Genomics in autoimmune diseases
- Endocrinology
- Translational medicine in renal diseases
- Fetal and perinatal translational medicine
- Translational research in cardiovascular diseases
- System biology in lung diseases

6. Trial design and Biomarkers
- Innovation in translational medicine
- Translational medicine: implications in trial design
- Statistical principles for clinical trials
- Trial design and innovation.
- From Bench to Spin off
**METHODOLOGY**

Total training hours: 8 credits ECTS x 25h/credit = 200h

a) Face-to-face training (72h): Lectures and Seminars
b) Home training (128h): Individual and group work

**EVALUATION**

Evaluation criteria: 50% of the final score will depend on the attendance and active participation in class. The remaining 50% will be obtained through a written exam. The written exam will be based on a multiple option test.

To pass the subject, students will have to fulfill three requisites: Attendance-score ≥ 20/50, exam-score ≥20/50, and overall score (attendance + exam) ≥ 50/100.

Reevaluation: In case of failing the ordinary evaluation (overall-score ≤ 50/100), students that have a minimum of 1/3 of the exam questions correct will have the chance to be re-evaluated. For that, they will need to present a critical appraise of 3 scientific articles in front of an evaluation committee. The re-evaluation final score will never get over 50 points.

**REFERENCES**

**Books**

- Translational Medicine: The Future of Therapy?
  - Autors: James Mittra and Christopher-Paul Milne
  - Data: Apr 17, 2013
- Genomic and Personalized Medicine, Second Edition: V1-2
  - Autors: Geoffrey S. Ginsburg and Huntington F Willard PhD
  - Data: Nov 29, 2012
- Translational Medicine and Drug Discovery
  - Autors: Bruce H. Littman MD and Rajesh Krishna PhD FCP
  - Data: Oct 15, 2014

**Articles**

BIOMARKER DISCOVERY AND VALIDATION
SAMPLE MANAGEMENT AND BIOBANKS
STUDY PLAN 2019-2020

Coordinated by:
Dr Mercè Brunet  Head of Pharmacology and Toxicology, Biomedical Diagnostic Center, Hospital Clínic, IDIBAPS. CIBERehd. Adjunct medical lecturer, Dept Salut Pública, Faculty of Medicine, University of Barcelona.
Dr Anna Bosch, PhD. Managing Director, EF Clif. Associated Professor, Department of Medicine, University of Barcelona

GENERAL INFORMATION

Subject Name  Biomarker discovery and validation. Sample management and biobanks.
Code  573670
Type  Compulsory
Teaching  Second semester
Coordinator  Dr. Mercè Brunet and Dr. Anna Bosch
Contact Details  mbrunet@clinic.cat / anna.bosch@efclif.com
ECTS credits  4

OBJECTIVES

The overall objective of the module is to achieve the necessary concepts for the design of translational studies on Biomarker discovery and validation, sample management and biobanks:

- The process of biomarkers discovery, validation and regulatory approval.
- Clinical and Therapeutic Utility of Biomarkers.
- Design of research studies based on new therapeutic targets and biomarkers validation
- Quality and safety in the laboratory
- Biological samples management and processing
- The role of Biobanks in translational research

COMPETENCES TO BE GAINED DURING THE STUDY

General
G1. Design of translational studies on Biomarkers
G2. Acquire the ability to design a translational study: population selection, biomarker panel selection, samples selection, platform or other methodologies selection, different phases of validation, clinical qualification and regulatory approval.

G3. Be able to organize a sample collection for future biomarker studies

**Specific**
- Design research studies on new predictive, prognostic, diagnostic or pharmacodynamic biomarkers
- Clinical Utility of pharmacogenetic, pharmacodynamics and predictive biomarkers: achieving personalized therapy
- Clinical benefit of monitoring prognostic and diagnostic biomarkers.
- Legal and ethical principles compliance
- Ability to report analytical data resulting from studies with statistical packages
- Biobanks as a tool to achieve quality compliance
- Learn to manage collection samples for research studies

### THEMATIC BLOCKS

- Biomarker discovery and validation. Predictive and prognostic pharmacodynamic, pharmacogenetic and Genetic biomarkers in transplantation.
- Prognostic and predictive biomarkers of cardiovascular risk and treatment response.
- Translational study design on Biomarkers of immune-mediated inflammatory diseases, cancer diseases, HIV vaccines
- Legal and ethical principles. Quality and safety in the laboratory
- Sample management and biobanks
- Results analysis and interpretation

### METHODOLOGY

Total training hours: 4 credits ECTS x 25h/credit = 100h

**Face-to-face training (48h):**
- Lectures and practical cases
- Exam

**Home training (52h):**
- Individual and group work

### EVALUATION

To pass the subject, students must obtain a minimum of 50 points. The score will be established as follows:
- **Attendance:** 50% of the overall score
- **Exam:** 50% of the overall score
To pass the subject, students will have to fulfill three requisites: Attendance-score \( \geq \frac{20}{50} \), exam-score \( \geq \frac{20}{50} \), and overall score (attendance + exam) \( \geq \frac{50}{100} \). 1 point will be deducted for every 3 wrong answers on the exam.

Reevaluation: In case of failing the ordinary evaluation, students will have to critically appraise 2 scientific articles and send the analysis by email to the coordinators. The re-evaluation final score will never get over 50 points.

REFERENCES

References will be provided at the beginning of the course by each of the lecturers.
BIOINFORMATICS AND HIGH-THROUGHPUT DATA ANALYSIS

STUDY PLAN 2019-2020

Coordinated by:
Dr David Tamborero, Scientist, Karolinska Institutet, Sweden
Dr Núria López-Bigas, IRB group Leader, ICREA Research Professor, UPF Assistant Professor, ERC Consolidator Grant

GENERAL INFORMATION

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<tr>
<td>Coordinator</td>
<td>Prof. Nuria Lopez-Bigas, Dr David Tamborero</td>
</tr>
<tr>
<td>Contact Details</td>
<td><a href="mailto:nuria.lopez@irbbarcelona.org">nuria.lopez@irbbarcelona.org</a></td>
</tr>
<tr>
<td></td>
<td><a href="mailto:david.tamborero@scilifelab.se">david.tamborero@scilifelab.se</a></td>
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<tr>
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OBJECTIVES

Current technologies enable the examination of biological systems in unprecedented detail. While the use of these technologies has become widely available in clinical and research settings, the interpretation of these data remains an important bottleneck with a diversity of technological and scientific challenges. This module is aimed to review the main computational methods and available resources to analyze high-throughput data generated in biological experiments. We will alternate theoretical concepts with practical exercises in which we will use bioinformatics tools to address specific questions related with the biology of human diseases.

COMPETENCES TO BE GAINED DURING THE STUDY

Specific
S1: Understand the principles behind high throughput data and the knowledge that can be extracted
S2: Learn how to use available computational resources and methods to analyze these data
S3: Develop skills to address specific questions about human diseases by using the above
S4: Basic knowledge of biology and Genetics.

THEMATIC BLOCKS

Subject Name: Bioinformatics and high-throughput data analysis
Code: 566660
Type: Optional
Teaching: Second semester
Coordinator: Prof. Nuria Lopez-Bigas, Dr David Tamborero
Contact Details: nuria.lopez@irbbarcelona.org, david.tamborero@scilifelab.se
Credits: 3
1. Introduction
2. Databases and genome browsers
3. High throughput data overview
4. Variant data analyses
5. Expression data analyses
6. Cancer genomics and therapeutic strategies
7. Computer assisted drug design
8. Network analyses
9. Integrative work

**METHODOLOGY**

Total training hours: 3 credits ECTS x 25h/credit = 75h

a) Face-to-face training (32h):
   - Lectures
   - Hands-on
   - Integrative work

b) Home training (43h):
   - Individual and group work

**EVALUATION**

To pass the subject, students must obtain a minimum of 50 points. The score will be established as follows:

- **Attendance**: 50% of the overall score
- **Teamwork Presentation**: 50% of the overall score

To pass the subject, students will have to fulfill three requisites: Attendance-score ≥ 20/50, presentation-score ≥20/50, and overall score (attendance + presentation) ≥ 50/100.

**Reevaluation**: In case of failing the ordinary evaluation, students will have to critically appraise 2 scientific articles and send the analysis by email to the coordinators. The re-evaluation final score will never get over 50 points.

**REFERENCES**

References will be provided during the course.
IMAGING IN TRANSLATIONAL RESEARCH

STUDY PLAN 2019-2020

Coordinated by:
Dr Anna Planas  IIBB-CSIC-IDIBAPS Researcher at the team Brain ischemia: Clinical and experimental studies
Dr Guadalupe Soria  Coordinator of the Experimental 7T MRI Unit, IDIBAPS

GENERAL INFORMATION

<table>
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<td>Dr. Anna Planas / Dr Guadalupe Soria</td>
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<tr>
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</table>

OBJECTIVES

The purpose of this subject is to provide students scientific, conceptual, methodological and practical knowledge on biomedical imaging. Students must acquire basic knowledge of a wide range of different imaging modalities applicable in humans and experimental animals. They will be guided by expert teachers through different technologies in order to acquire basic knowledge about imaging techniques and modalities and image analysis. The overall objective of this subject spans from imaging techniques including biological samples for use in microscopy (optical, fluorescence, confocal, and electron microscopy) and flow cytometry, to imaging in vivo including different types of MRI, nuclear medicine techniques (PET and SPECT), optical imaging, fluorescence, chemiluminescence and laser. These techniques will show students the different available tools for biological imaging, from structural to molecular imaging.

COMPETENCES TO BE GAINED DURING THE STUDY

General
G1: Understand, interpret and discuss issues with clinicians
G2: Become familiar with bioimaging research progress and learn the tools necessary to access the continuous training
G3: Read, understand and discuss scientific texts
G4: Use of spoken and written English

Specific
S1: Understand the major diagnostic and therapeutic imaging techniques
S2: Know the latest imaging technology techniques and applications for clinical and basic research as well as their advantages and limitations
S3: Distinguish, use, and analyze various microscopy and biomedical imaging techniques
S4: Gain knowledge on processing, quantification and optimization of various types of biomedical images
S5: Visit experimental units, confocal microscopy, electron microscopy, MRI, and practical demonstration.

THEMATIC BLOCKS

1. Introduction to Imaging Techniques and Analyses
2. Microscopy
   2.1. Confocal microscopy
   2.2. Microscopic analysis of living cells
   2.3. Electron microscopy
   2.4. Intravital microscopy
   2.5. Microscopy image processing, optimization, and quantification
3. Optical imaging in living animals and humans: laser technology
4. Bioluminescence in experimental research
5. Flow Cytometry: technical description and applications
6. Autoradiography
7. Positron Emission Tomography (PET) and Single Photon Emission Computed Tomography (SPECT)
8. Magnetic Resonance Imaging (MRI)
9. PET and MRI image analyses

METHODODOLOGY

Total training hours: 3 credits ECTS x 25h/credit = 75h

a) Face-to-face training (32h): - Lectures
   - Seminars

b) Home training (43h): - Individual and group work

EVALUATION

To pass the subject, students must obtain a minimum of 50 points. The score will be established as follows:

- **Attendance**: 50% of the overall score
- **Research Project**: 50% of the overall score

To pass the subject, students will have to fulfill three requisites: Attendance-score ≥ 20/50, research project-score ≥20/50, and overall score (attendance + research project) ≥ 50/100.

**Reevaluation**: In case of failing the ordinary evaluation, students will have to send a written report to the coordinator. The re-evaluation the final score will never get over 50 points.
REFERENCES

Books
- Gonzalez, Woods, Digital image processing. Addison-Wesley

Publications
- James ML, Gambhir SS. A molecular imaging primer: modalities, imaging agents, and applications. Physiol Rev. 2012

Links
- http://wwwbdbiosciences.com/
- http://www.leica-microsystems.com/
- http://health.siemens.com/
- http://www.microscopyu.com/articles/fluorescence
- http://www.med.harvard.edu/aanlib/home.html
- http://www.cis.rit.edu/htbooks/mri/
- http://www.humanconnectomeproject.org

Software
- Image Processing and Analysis in Java (http://imagej.nih.gov/ij/)
- FMRIB Software Library v5.0 (http://fsl.fmrib.ox.ac.uk/fsl/fslwiki/)
- Statistical Parametric Mapping (http://www.fil.ion.ucl.ac.uk/spm/)
- AFNI (http://afni.nimh.nih.gov/afni)
- The Brain Imaging Software Toolboxhttp://www.bic.mni.mcgill.ca/software/
- Talairach software (http://www.talairach.org/)
STEM CELL RESEARCH
STUDY PLAN 2019-2020

Coordinated by:
Dr Roger Gomis, ICREA Professor and Researcher at the IRB Barcelona

GENERAL INFORMATION

Subject Name: Regenerative medicine and stem cells
Code: 566661
Type: Optional
Teaching: Second semester
Coordinator: Dr. Roger Gomis
Contact Details: roger.gomis@irbbarcelona.org
ECTS credits: 3

OBJECTIVES

The overall objective of this module is to offer next generation scientists a meticulous training in regenerative medicine and stem cell so they can contribute to the stem cells biology knowledge with its clinical and therapeutic applications.

PRE-SKILLS AND REQUIREMENTS

General
The program proposes basic training in cancer biology and its development. The offered methodology intends to provide the necessary knowledge to create study and apply stem cells and its surroundings to experimental treatments in human beings.

Specific
Stem cell biology and methods used for identification. Types of stem cells: adult; hemopoietic: mesenchymal somatic and iPS. Regeneration and homeostasis: cellular therapies expectations. Development of advanced therapies, from the hypothesis to the patient.

THEMATIC BLOCKS

1. Introduction
2. Stem cell Biology
3. Methods for stem cells identification
4. Generating iPS cells
5. Adult stem cell
6. Progenitors and endothelial cells: angiogenesis
7. Production techniques: apheresis
8. Production factory in cell therapy

Official Master in Translational Medicine Secretariat
Rosselló 153, 08036 Barcelona
+34 933129499 traslacional@ub.edu
9. Regulation of the procurement, processing and administration of advanced therapies
10. Stem cell, cancer and development
11. Senescence, aging and reprograming
12. Intestinal epithelium and Colorectal Cancer Stem Cells
13. Regeneration of hematopoiesis by progenitors transplantation
14. Platelet lysate as a source of cell growth factors
15. Lung Regeneration: pneumocytes transplant
16. Therapeutic vaccines generation: dendritic cell and infectious diseases
17. Mesenchymal cell: regeneration, immunosuppression and tumors
18. Gene Therapy
19. Chimeric antigen receptors generation
20. Future applications in cell therapy

**METHODOLOGY**

Total training hours: 3 credits ECTS x 25h/credit = 75h

a) Face-to-face training (32h)
   - Lectures
   - Computer sessions
   - Seminars
   - Laboratory Practices (subject to individual’s availability)
   - Presentation of research projects (subject to individual’s availability)

b) Home training (43h)
   - Individual and group work

**EVALUATION**

To pass the module, students must obtain a minimum of 50 points. The score will be established as follows:

- **Attendance**: 50% of the score
- **Oral presentations**: 50% of the score (*based on continuous evaluation during Journal Clubs*)

To pass the subject, students will have to fulfill three requisites: Attendance-score $\geq 20/50$, Oral presentations-score $\geq 20/50$, and overall score (attendance + Oral presentations) $\geq 50/100$.

Reevaluation: In case of failing the ordinary evaluation students will have to contact the subject’s coordinator. The re-evaluation final score will never get over 50 points.

**REFERENCES**

References will be recommended by each of the lecturers.
TRANSLATIONAL RESEARCH IN PUBLIC HEALTH

STUDY PLAN 2019-2020

Coordinated by:
Prof. Ángela Domínguez Medicine Department, Faculty of Medicine and Health Sciences, University of Barcelona. Epidemiology and Public Health CIBER, Instituto de Salud Carlos III

GENERAL INFORMATION

Subject Name  Translational Research in Public Health
Code  566665
Type  Optional
Teaching  Second semester
Coordinator  Dr. Ángela Domínguez
Contact Details  angela.dominguez@ub.edu
ECTS credits  3

OBJECTIVES

At the end of this Module, students must be able to:

- Explain the terms cluster, outbreak and epidemic
- Interpret and describe the value of an epidemic curve
- Discuss some of the biases that might affect case-control studies
- Discuss some of the biases that might affect cohort studies
- Calculate the proportion of attributable risk in the exposed
- Calculate the proportion of attributable risk in the population
- Discuss what does the proportion of attributable risk in the exposed and the proportion of attributable risk in the population imply for the practice of public health
- Discuss the criteria for causation in an observational study
- Describe the applications and limitations of matching in case-control studies
- Describe the method to analyze matched case-control data
- Calculate the odds ratio for triplets and quadruplets in a matched case-control study
- Calculate the predictive value of the two sequence tests in a screening program
- Discuss the criteria considered in evaluating a screening program in public health practice
- Define public health surveillance and to identify the key features of a surveillance system
- Develop a case definition for an outbreak investigation
- Explain how hypotheses can be generated and tested in an outbreak investigation
- Discuss the advantages and disadvantages of using a sensitive and/or specific case definition in an epidemic investigation
- List the factors that can account for a change in the reported incidence of a disease
- Discuss the effect of a different case definition on the sensitivity of a surveillance system
- Calculate the vaccine effectiveness and discuss its interpretation
COMPETENCES GAINED DURING THE STUDY

Generals
G1: Be able to design, plan and properly interpret experimental protocols in the field of Translational Medicine
G2: Be able to dynamically integrate modern knowledge and techniques developed within the field of Translational Medicine
G3: Be able to interact with professionals from other medical specialties in a creative and decisive way
G4: Have a clear appreciation of disciplinary actions and communications necessary to establish the link between basic science and clinical medical research

Specifics
S1: To be capable of teaching and divulging knowledge in the social environment for expert and non-expert people
S2: To be capable of integrating knowledge and ways to do in front complex situations and to formulate a judgment with a limited information, but in a reflexive way, taking into account the social and ethical repercussions of them
S3: To be capable of knowing the bioethical and legal principles of research and professional activities in the field of translational research
S4: To be capable of using adequate technologies for the design, analysis and interpretation of epidemiological data
S5: To be capable of identifying problems of public health, to design epidemiological studies and to interpret the results

Pre-requisites
All oral sessions, presentation of lectures and practical sessions will be offered in English, thus students should have a good comprehension and oral English level.

THEMATIC BLOCKS

1. Introduction to Global Public Health
2. Bioethics
3. Fundamentals of outbreak investigations. Case study: Oswego
5. Sensitivity of a surveillance system. Case study: Paralytic illness in Ababo
8. Unmatched and matched case-control studies. Case study: Toxic shock syndrome
9. Screening programs in public health practice. Case study: Screening for antibody to the human immunodeficiency virus

METHODOLOGY

Total training hours: 3 credits ECTS x 25h/credit = 75h
Classroom activities will consist in sessions which firstly show the conceptual aspects needed for the different types of epidemiological studies and secondly, problem solving using different case studies.
In this way, the students will acquire knowledge and skills to apply translational research to public health and the basics of epidemiology by means of the analysis of real situations. **Face-to-face training** (32 hours) will consist in Lectures and Case studies. **Home training**: Students should prepare the Case studies before each session, study the concepts explained in the classroom, read the recommended reading material and prepare the oral presentation to complete 75 hours corresponding to the 3 ECTS credits of the subject.

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**EVALUATION**

To pass the subject, students must obtain a minimum of 50 points. The score will be established as follows:

- **Attendance 50% of the score**
- **Oral presentation 50% of the score**

To pass the subject, students will have to fulfill three requisites: Attendance-score ≥ 20/50, oral presentation score ≥20/50, and overall score (attendance + oral presentation) ≥ 50/100.

**Oral presentation**: Students will have to present in class an observational study dealing with the association between risk factors or preventive measures (primary prevention or secondary prevention) and a specific communicable or non-communicable disease. Students should select an article from the options listed in the Virtual Campus task consultation.

The oral presentation must include an introduction to the topic, as well as the research question, objectives, methodology (describing the design of the study and the variables included and the ethical aspects), results, a discussion (including limitations and possible biases of the study) and conclusions. Students should also make recommendations in relation to the author’s conclusions. A pdf file containing the PowerPoint slideshow supporting the oral presentation must be submitted to the lecturer after the presentation. Slideshows will be posted on the Virtual Campus.

**Re-evaluation**: After the final grades have been posted, a multiple-choice examination is set for students who have not met the assessment criteria. There is only one correct answer out of four options per question. Incorrect answers incur a penalty of 25% of the mark given for each correct answer. The re-evaluation final score will never get over 50 points.

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**REFERENCES**


• Miettinen OS (2012). Up from clinical epidemiology & EBM. Heidelberg: Springer.


CLINICAL TRIALS DESIGN AND EVALUATION OF MOLECULAR THERAPIES
STUDY PLAN 2019-2020

Coordinated by:
Dr Josep M Llovet, ICREA Professor, IDIBAPS, University of Barcelona. Director of the Liver Cancer Program, Icahn School of Medicine at Mount Sinai (NY, USA). Professor of Medicine, Department of Medicine, Faculty of Medicine, University of Barcelona.
Dr Ferran Torres, Scientific director of the Medical Statistics core facility at IDIBAPS – Hospital Clinic Barcelona.

GENERAL INFORMATION

Subject Name
Clinical Trials Design and Evaluation of Molecular Therapies
Code
572714
Type
Optional
Teaching
Second semester
Coordinator
Dr Josep M Llovet, Dr Ferran Torres
Contact Details
jmllovet@clinic.cat, ferran.torres@idibaps.org
ECTS credits
3

OBJECTIVES

The purpose of this module is to gain knowledge on the drug development process, and be able to understand the basics of clinical trial design within a product development program.
At the end of this subject, students must be able:

- To list the phases of product development of new chemical entities and understand their objectives.
- To interpret and the type of evidence coming from each phase of product development.
- To understand basic concepts of pharmacokinetics relevant for drug development.
- To discuss the key features of clinical trial design.
- To discuss basic aspects of statistical considerations in clinical trials, including apriorism, protection against errors and multiplicity issues.
- To interpret results for comparison of proportions, means and survival analyses.
- To understand the concepts of superiority, equivalence and non-inferiority.
- To explain the terms exploratory, confirmatory, biomarker and validation.
- To explain the main steps to reach a marketing application approval in Europe.
- To know the different interactions with regulatory agencies during a product development process, and their objectives.
- To have notions on post-marketing surveillance and the adaptive licensing initiatives.

COMPETENCES TO BE GAINED DURING THE STUDY

Official Master in Translational Medicine Secretariat
Rosselló 153, 08036 Barcelona
+34 933129499 traslacional@ub.edu
General
G1: Be able to design, plan and properly interpret clinical protocols in the field of Translational Medicine
G2: Be able to dynamically integrate modern knowledge & techniques developed within the field of Translational Medicine
G3: Be able to interact with professionals from other medical specialties in a creative and decisive way
G4: Have a clear appreciation of disciplinary actions and communications necessary to establish the link between basic science and clinical medical research

Specific
S1: To be capable of teaching and divulging knowledge in the social environment for expert and non-expert people
S2: To be capable of integrating knowledge and ways to do in front complex situations and to formulate a judgment with a limited information, but in a reflexive way, taking into account the social and ethical repercussions of them
S3: To be capable of knowing the bioethical and legal principles of research and professional activities in the field of translational research
S4: To be capable of using adequate technologies for the design, analysis and interpretation of epidemiological data
S5: To be capable of identifying problems of public health, to design epidemiological studies and to interpret the results

Pre-requirements
All oral sessions, presentation of lectures and practical sessions will be offered in English, thus students should have a good comprehension and oral English level.

THEMATIC BLOCKS

A) Design of Clinical trials

A.1 Basic applied statistics. Type of Studies. Observational studies and Randomised Clinical Trials (RCT)

- Statistical inference: p-values and confidence intervals. Sample Size determinants.
- Study types. Observational vs Experimental designs. Non-Randomised studies.

A.2 Statistical issues in the Analysis and interpretation of RCT

- Analysis and interpretation of RCT. Handling of Multiplicity. Subgroups.
- Surrogate end-points and biomarkers. Predictive and prognostic factors.
- Interim analyses and stopping rules.
- Non-Inferiority Designs. Selection of the non-inferiority margin. Impact of different end-points types.
- Assessment of events: count, recurrence and censoring. Survival Analysis.

A.3 Practical planification of RCT. Sample size. Alternative designs. Estimands

- Planification of a clinical trial. Regulatory and scientific sources.
- Sample Size predetermination for continuous, binary, count and survival end-points in superiority and non-inferiority
trials.
- Basic designs: Factorial, crossover, multi-Arm trials.
- Alternatives to traditional for trial optimisation: adaptive, Bayesian, repeated measurements, withdrawal, enrichment, simultaneous multiple end-points. Umbrella and basket trials.
- Handling of missing data. Impact on estimands.

- Meta-analysis of observational and experimental studies
- Reporting of clinical trials
- Data Collection, data quality, data management and Database

B. Clinical trials – from Phase I to III

B.1 Overview of trial design. Phase I trials
- Overview of trial design, levels of evidence, end-points and magnitude of benefit
- Regular vs accelerated approval
- Phase I –
- Phase I- Examples

B.2 Phase II trials
- Phase II and randomized Phase II –
- Phase II- Examples

B.3 Phase III trials
- Phase III –
- Phase III- Examples

C. Drug development, regulatory issues and safety

C.1 Product development plan. Drug Discovery. Non-Clinical development
- Product development plans and target product profile.
- Drug discovery process, from bench to bed.
- Non-Clinical development and early safety tests.

C.2 Good Clinical Practice. Marketing Authorization Procedures
- Fundamentals of clinical research. International Council for Harmonization, Good Clinical Practice: What do I need to know as a clinical investigator?
- Regular process for Marketing Authorization Procedure. EMA, other drug agencies.

C.3 Real-world data. Safety
- Effectivity assessment and real-world data
- Safety data reporting in clinical trials. Concepts of Adverse Event, Adverse Drug Reaction, SAEs and related safety topics
METHODOLOGY

Total training hours: 3 credits ECTS x 25h/credit = 75h

Face-to-face training (48h) will include lectures and case studies.
Home training (27h): In order to complete 3 ECTS credits of the subject, students will have to prepare and present one case study based on the concepts explained in face-to-face training.

Classroom activities will consist in sessions which firstly show the conceptual aspects and secondly, problem solving using different case studies. In this way, the students will acquire knowledge and skills to apply translational research by means of the analysis of real situations.

EVALUATION

To pass the subject, students must obtain a minimum of 50/100 points. The score will be established as follows:

- **Attendance: 50% of the score**
- **Oral Presentation or examination: 50% of the score** (This will be described in detail during the 1st day of class)

To pass the subject, students will have to fulfill three requisites: Attendance-score $\geq 20/50$, oral presentation/report-score $\geq 20/50$, and overall score (attendance + exam) $\geq 50/100$.

Reevaluation: In case of failing the ordinary evaluation, students will perform an oral exam. The re-evaluation final score will never get over 50 points.

REFERENCES

Clinical Trials

- DeMets DL, Furberg CD, Friedman LM. Data Monitoring in Clinical Trials - A Case Studies Approach. Springer, 2006,
Biomarkers

- Simon R. Genomic Clinical Trials and Predictive Medicine. Cambridge University Press, National Institutes of Health 2013, New York, USA
- Catenacci DV. Next-generation clinical trials: Novel strategies to address the challenge of tumor molecular heterogeneity. Mol Oncol. 2015 May;9(5):967-96.
- Simon R. Biomarker based clinical trial design. Chin Clin Oncol 2014;3(3):39

International Conference of Harmonization (ICH)

- Other ICH guidances can be found at: www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html
- EMA Guidelines
- Useful links
- Simon Two-Stage Design:
  - http://cancer.unc.edu/biostatistics/program/ivanova/SimonsTwoStageDesign.aspx
- Sample Size:
  - POWER de Un. IOWA: http://homepage.stat.uiowa.edu/~rlenth/Power/
  - Power and sample size de Vanderbilt University, by Dupont WD, Plummer: http://biostat.mc.vanderbilt.edu/twiki/bin/view/Main/PowerSampleSize
PRINCIPLES OF CLINICAL MEDICINE

STUDY PLAN 2019-2020

Coordinated by:
Prof Josep M Llovet  ICREA Professor, IDIBAPS, University of Barcelona. Director of the Liver Cancer Program, MSSM (New York). Professor of Medicine, Department of Medicine, Faculty of Medicine, University of Barcelona and Dr Sabela Lens Hepatologist at Hospital Clínic of Barcelona, CIBERehd, IDIBAPS, University of Barcelona.

GENERAL INFORMATION

Subject Name: Principles of Clinical Medicine
Code: 573671
Type: Optional Subject
Teaching: Second Semester
Coordinator: Prof Josep M Llovet and Dr Sabela Lens
Contact Details: jmllovet@clinic.cat and slens@clinic.cat
ECTS credits: 3 credits

OBJECTIVES

The purpose of this subject is to provide students with scientific and practical knowledge about the principles of clinical medicine. Specifically, the bases of the homeostatic mechanisms of the human body will be assessed, as well as their imbalance during illness. These concepts will be integrated with the study of the anatomical and physiopathological mechanisms involved in various organ-specific diseases for the design and implementation of translational research. The overall objective is to provide the knowledge and a scientific basis in the setting of clinical medicine in order to explore areas of interest in clinical research.

COMPETENCES TO BE GAINED DURING THE STUDY

Generic:
G1. Learn the principles of general internal medicine balanced with a comprehensive exposure to the medical subspecialties.
G2. Adopt the learning skills that are necessary to undertake further translational research studies.

Specific:
S1. To understand and to recognize the normal structure-function of the human body, at molecular, cellular, tissue, organ and system levels.
S2. Gain an adequate knowledge of the sciences on which medicine is founded, as well as a good understanding of the analysis of the biological functions.
S3. Receive a balanced exposure of the physiopathological mechanisms involved in organ-specific diseases.

**THEMATIC BLOCKS**

1. Basic Principles
   - Human Anatomy
   - General Pathology
   - Molecular Pathology
2. Principles of Internal Medicine and Radiology
   - Principles of Internal Medicine
   - Radiology
3. Cardiovascular and Lung diseases
   - Cardiology
   - Lung Diseases
4. Digestive and Metabolic Diseases
   - Hepatology
   - Gastroenterology
   - Endocrinology
5. Oncology and Hematopoietic diseases
   - Hematology
   - Medical Oncology
   - Radiotherapy
6. Principles of Surgery
   - General Surgery
   - Abdominal Surgery
7. Renal, dermatological and rheumatological diseases
   - Nephrology
   - Dermatology
   - Rheumatology
8. Public Health and Infectious Diseases
   - Infectious Diseases
   - Prevention and Public Health
9. Nervous System Diseases
   - Neurology
   - Neurosurgery
   - Psychiatry
   - Psychology
10. Obstetrics, Gynecology and Pediatrics
    - Obstetrics and Gynecology
    - Pediatric diseases
    - Neonatology

**METHODOLOGY**

Total training hours: 3 credits ECTS x 25h/credit = 75h

a) Face-to-face training (30h): Lectures and Seminars
b) Home training (45h): Individual and group work

**EVALUATION**

Evaluation criteria: 50% of the final score will depend on the attendance and active participation in class. The remaining 50% will be obtained through a written exam. The written exam will be based on a multiple option test. To pass the subject, students will have to fulfill three requisites: Attendance-score ≥ 20/50, exam-score ≥ 20/50, and overall score (attendance + exam) ≥ 50/100.

Reevaluation: In case of failing the ordinary evaluation, students will have to critically appraise 3 scientific articles and present the analysis in form of oral presentation in front of an evaluation committee. In the re-evaluation the final score will never get over 50 points. English should be the language for the oral presentation.
REFERENCES

Books:
Farreras/Rozman. Internal Medicine.
Authors: P. Farreras Valenti, C. Rozman
Editorial: Elsevier, May 2016

Harrison Principles of Internal Medicine.
Authors: Kasper, Fauci, Hauser, Longo, Jameson, Loscalzo

Guyton and Hall. Textbook of Medical Physiology.
Authors: John E.Hall
http://jpkc.hactcm.edu.cn/2012yxslx/file/Textbook%20of%20Medical%20Physiology.pdf

Articles:


RESPONSIBLE RESEARCH, INNOVATION AND ENTREPRENEURSHIP

STUDY PLAN 2019-2020

Coordinated by:
Dr Joan Bigorra  Director of Innovation at the Hospital Clínic Barcelona, IDIBAPS
Dr Pastora Martínez  Vice-rector of Globalization and Cooperation, (UOC) Universitat Oberta de Catalunya

GENERAL INFORMATION

Subject Name  Responsible Research, Innovation and Entrepreneurship
Code  572713
Type  Optional
Teaching  Second semester
Coordinator  Dr. Joan Bigorra and Dr. Pastora Martínez
Contact details  bigorra@clinic.cat  /  pmsamper@uoc.edu
ECTS credits  3

OBJECTIVES

Part 1: Responsible Research and Innovation
This subject has two differentiated blocks and the main objectives are:
A) Scientific communication for a scientific audience
   • Improve the student’s capacity to communicate and disseminate the results obtained from their research in different formats (oral presentations, posters, scientific papers, CV)
   • To contextualize such communications within the different stages of research
B) Responsible Research and Innovation (RRI) or Scientific communication for a general public
   • Report the key issues from the Responsible Research and Innovation (RRI) actions promoted by the European Commission within the action research program Horizon 2020
   • Skills to delve deeper in systems and mechanisms

Part 2: Entrepreneurship
The overall objective of the subject is to provide students the basic set of knowledge, know-how and skills to understand the basic policies and procedures to capture value from basic and translational research in Biomedicine and Biotechnology.
COMPETENCES TO BE GAINED DURING THE STUDY

**General**
G1: Broader view of biomedicine and biotechnology
G2: Communication, initiative and personal development

**Specific**
S1: Negotiation skills
S2: Basic bio-business trends
S3: Learn in a scientific and social context how the research careers develop (Horizon2020 framework)
S4: Learn how to disseminate research results (audiovisual tools, social networking, scientific databases)
S5: Learn the key aspects in what is called public engagement (education, ethics, dissemination, open science...)

THEMATIC BLOCKS

**Part 1: Scientific Communication (Dr Martinez)**

1. Introduction
2. Block A: Scientific communication for a scientific audience
   - Speaking in public: tips for impact presentations
   - How to write a scientific paper
   - How to make a scientific poster
   - Introduction to leadership
   - Career development in a scientific environment
   - How a teacher (or a funding agency) will evaluate your résumé
3. Block B: Scientific communication to the general public (public engagement)
   - The need for a renewed relationship between science and society: towards responsible research and innovation
   - Science dissemination 2.0
   - Ethics, research and public engagement: analysis of case studies
   - Two other ways of cooperation in science: the open access initiative and the citizen science movement

**Part 2: Entrepreneurship (Dr Bigorra)**

1. Introduction: how does the sector looks like?
2. Public-Private partnerships
3. Patents in Biomedicine and related areas
4. Biopharma: key strategic challenges and future perspectives
5. The Organization of Transfer policies in a University Hospital
6. Creation and development of start-up companies
METHODOLOGY

Total training hours: 3 credits ECTS x 25h/credit = 75h

a) Face-to-face training (40h):
- Lectures
- Seminars
- Research projects presentation

b) Home training (35h):
- Individual and group work

EVALUATION

To pass the subject, students must obtain a minimum of 50 points. The score will be established as follows:

- **Attendance**: 50% of the overall score
- **Oral Presentation** (related to Part 1): 25% of the overall score
- **Test exam** (related to Part 2): 25% of the overall score

To pass the subject, students will have to fulfill three requisites: Attendance-score ≥ 20/50, exam+oral presentation-score ≥ 20/50, and overall score (attendance + exam and oral presentation) ≥ 50/100.

Reevaluation: In case of failing the ordinary evaluation, students will have to send a written report to the coordinators. The re-evaluation final score will never get over 50 points.

REFERENCES

**Part 1: Scientific Communication**

**Biomedical Articles**


Raymon H. Mulford Library / Medical College of Ohio. Instructions to Authors in the Health Sciences. http://www.mco.edu/lib/instr/libinsta.html. Instrucciones para los autores de más de 3.500 revistas biomédicas, con conexión con la fuente primaria. Incluye otros documentos de interés, como la Declaración CONSORT (normas de preparación de manuscritos para ensayos clínicos controlados) y la última edición de las normas de Vancouver.

http://www.bmj.com. Ir a “advise to contributors”. Normas de publicación, guías para evaluación de los artículos, editoriales sobre temas de publicación médica de interés.

http://www.thelancet.com. Ir a “info for authors” (writing for the Lancet). Reflexiones sobre qué quiere y qué espera de los autores la Revista, cuáles son sus secciones, los intereses de sus lectores, etc. El contenido, variando de disciplina, puede ser aplicable a muchas otras revistas.


Peer Reviews


Posters

- Campbell RS. How to present, summarize, and defend your poster at the meeting. Resp Care 2004; 49:1217-21.

Biomedical science databases

- Web of knowledge
- Scopus
- Pubmed

Part 2: Entrepreneurship

- www.biocat.cat
- Nature Biotechnology Journal
MASTER THESIS
STUDY PLAN 2019-2020

Coordinated by:
Dr Josep M Llovet ICREA Professor, IDIBAPS, University of Barcelona. - Director of the Liver Cancer Program, Icahn School of Medicine at Mount Sinai (NY, USA) – Professor of Medicine, Department of Medicine, Faculty of Medicine, University of Barcelona.

GENERAL INFORMATION

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<td>Teaching</td>
<td>Second semester</td>
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<td>Coordinator</td>
<td>Prof. Josep M Llovet</td>
</tr>
<tr>
<td>Contact details</td>
<td><a href="mailto:jmllovet@clinic.cat">jmllovet@clinic.cat</a></td>
</tr>
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<td>ECTS credits</td>
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OBJECTIVES

To obtain the Master Degree the Master Thesis is compulsory (RD 1393/2007). It consists of a research project, with 24 ECTS credits, resulting from the student individual work during his/her practical training in a research laboratory.

EVALUATION

There will be a mid-term evaluation in December where students will have to briefly present in form of oral presentation their master thesis. Each student will have 5 minutes to introduce the topic, the working hypothesis and objectives of the research work, materials and methods that he/she is planning to use and a brief description of the expected results.

The final evaluation of the Master Thesis will take place in May/June. The final score of the Master Thesis will reflect the quality of the master thesis written report, oral defense and practicum assessment. Language: The written report should be submitted in English and the public defense may be done in Catalan, Spanish or English.

Deadlines: The written report has to be submitted by June 5th, with the tutor’s approval. The public defense will take place in front of a panel of experts. The oral presentation date will be announced by the Master Secretariat.
The Master Coordination Committee will nominate the Master Evaluation Panels (constituted by professors or researchers) which will evaluate the written report as well as the oral presentation. Evaluation panels may request clarifications from the student or his/her tutor regarding the work submitted before, during and after the oral presentation.

**Written Report:** Students will have to submit a digital version of their master thesis to the master secretariat in .pdf format. The evaluation panel will take into account the quality of the written report, and whether a) the objectives are well defined, described and achieved, b) the results are clearly presented and c) the discussion includes a correct and consistent interpretation of the result. The correct citation of reference articles will also be evaluated. The written report will count 40% of the final Master Thesis score.

**Oral presentation:** Students will have defended their work in front of the Evaluation Panel. They might help themselves by using a Power Point presentation (or similar tool). Students will have **10 minutes** to present their work, and **5 minutes** for discussion with the members of the evaluation panel. Defending the master thesis in English will be a plus in the evaluation. The oral presentation will count 40% of the final Master Thesis score.

**Practicum assessment:** Students will undertake their practicum in a laboratory. This training, which should consist of at least 500h, will be evaluated by the tutor and will count 20% of the final Master Thesis score.

The **written report** should have the following sections:

1. **Title page** (1 page): This page should contain the research title, student's full name, affiliation (Department, Institution or Research Centre where the project is done) and the tutor’s name.
2. **Abstract** (1/2 page)
3. **Introduction** (2 pages): Outlines the background of the topic and sets the research context.
4. **Working Hypotheses and Objectives** (1 page): This section should be concise.
5. **Material and Methods** (2 pages): This section should be detailed and complete. It is recommended to specify the type of study, sample size, experimental designs, patterns "in vivo" or "in vitro" (if applicable), data collection and statistical processing of the results. If appropriate, they should explain the ethical aspects of the study in this section.
6. **Results** (5 to 10 pages): In this section results will be described. Tables and figures and its corresponding descriptions have to be included if considered necessary.
7. **Discussion** (2 pages): In this section, findings should be discussed and the results should be framed in relation to the known literature in the field.
8. **Conclusions** (1 page): Conclusions of the research study have to be listed in this section.
9. **References** (2 pages): References have to be listed in this section. They have to be updated and focused on the data related to the presented project. It is recommended to avoid long collections or literature not mentioned in the project. The citation rules should follow the Vancouver style (Index Medicus).

If you have been involved in a research article, this can be integrated in the “results” section.
Formatting guidelines for written project:
Font: Arial or Calibri / 12pt
Language: English
Spacing: 1 or 1,5
PDF to be sent to translational@ub.edu by 5th June 2020

Formatting guidelines for oral presentation:
Supported with a Power Point or similar
Language: English preferred, but Catalan or Spanish will be accepted
Duration: 10 minutes (presentation) + 5 minutes (questions)
Presentations: 15th-18th June 2020

Scores will be: from 5 to 6.9, “aprovat”; from 7 to 8.9, ”notable” and from 9 to 10, “excel·lent”. To be able to obtain an excellent with distinction, students should have a score above 9.5 and other merits that the evaluation panel and Master Coordination Committee will consider. If students do not obtain a score over 5, they have to register for the subject again. These students may choose whether they want to improve the same project they had presented or rather start a new one. If a student has published an original paper in an indexed journal as first or second author, this work will be considered equivalent to the written report associated to the Master Thesis. However, they will need to present a 1-page-document describing their contribution to the submitted paper. Articles in press will also be accepted.

Since the Master Thesis is individual, each piece of research work presented may only be submitted by a single student. A student who submits a thesis that was not written by himself/herself or who presents as his/her own any research findings (ideas, words, work) of a third party, is guilty of plagiarism. Any text, passage, excerpt, etc. from a source other than one’s own must be duly and fully identified and acknowledged. Plagiarism will be penalized as stated in the Faculty’s Study Regulations.

Following UB regulation, students need to pass all master subjects in order to be able to defend their master thesis.

Following UB regulation, students cannot conduct their practical stage abroad.
LIST OF MASTER THESIS PRESENTED IN 2018-2019

1. Morphological identification of Chronic Lymphocytic Leukaemia cells using imatge analysis
2. Functional validation of MCM8 variants for germline predisposition to early-onset in mismatch repair-deficient colorectal cancer
3. Enhancing the efficacy of CAR-T cells against solid tumors with genome editing approaches
4. Antitumoral activity of IRAK1/4 and bet bromodomain inhibition in ABC-DLBCL with MYD88 mutation
5. An Exploratory Analysis of contacting 2 as a new Creutzfeldt-Jakob disease Biomarker
6. Transgene optimization of armed oncolytic adenovirus with the Purine nucleoside 2’-deoxyribosyltransferase (PDT) prodrug-activating enzyme. A novel strategy to potentiate virotherapy against pancreatic tumors
7. Pathogenic mechanisms underpinning the detrimental impact of obesity on chronic liver disease
8. Surface modification of nanocapsules towards application in targeted pancreatic cancer treatment
9. Analysis of Regulatory T-Cell Frequency and Phenotype in Chronic Hepatitis C patients Undergoing Interferon-Free Therapies
10. Generation of patient-derived tumor spheroids (PDTS): a new tool for immunotherapy testing in NHL
11. Regulation of YAP-1 by Mtor: Paper in the differentiation and neoplastic transformation of mammary cells
12. PMEPA1 as a biomarker of the oncogenic status of the TGF-β pathway in hepatocellular carcinoma
13. β-Catenin interaction with TCF1 and LEF1 in T-Cell Acute Lymphoblastic Leukaemia
14. Synthesis and biological multitarget profiling of huprine-catechol hybrids against Alzheimer’s disease
15. Revealing higher susceptibility to cardiovascular diseases in adult rats with intrauterine growth restriction
16. The use of chimeric citrullinated / homocitrullinated and proteins for diagnosis of undifferentiated arthritis
17. Analysis of small non-coding RNAs in colorectal cancer
18. 3d imaging of MBNL1 and toxic RNA foci colocalization and subsequent effects on alternative splicing in DM1 myoblasts
19. Application of epigenetic biomarkers to study a large set of chronic lymphocytic leukemia patients
20. Assessment of the immunomodulatory role of cabozantinib and its effects in combination with anti-PD-1 treatment in a murine model of hepatocellular carcinoma
21. Hypertrophic Cardiomyopathy in vitro Biomimetic Model using Human Induced Pluripotent Stem Cells
22. Human monocyte-derived microglia-like cells: culture characterization and role of C/EBP transcription factors in neuroinflammatory response
23. Functional validation of genetic variants to achieve the diagnosis of patients with mitochondrial disorders
24. Characterization of the adipose tissue-liver axis in NAFLD
25. Effect of new immunomodulatory compounds, used in HCT, on the endothelium. Role in the development of the engraftment syndrome
26. Myocardial remodeling triggered by high endurance exercise. A comparison between sex and heart cavity
27. Role of the TNFR2 gene in stressed respiratory epithelial cells. Relevance in cystic fibrosis pathology
28. Virological characterization of HBV/HDV-related hepatocellular carcinoma in Mongolia
29. Identification of somatic variants in at-risk healthy mucosa from patients with colorectal neoplasia
30. Selective NUDIX5 inhibition as a novel target against cancer stem cells
31. Role of Wisp1 in Pancreatic β-cell proliferation
32. Effects of blocking GM-CSF receptor α with mavrilimumab on macrophage activation in an *in vitro* co-culture model in Giant Cell Arteritis

33. Study of a novel hypoxia system to evaluate endothelial dysfunctionality in CTEPH

34. Lipid Metabolism and Epithelial Differentiation in Kidney Fibrosis

35. The potential effect of Cerium Oxide Nanoparticles in an experimental model on NAFLD

36. Role of cholesterol and StARD1 in cholestatic liver disease

37. Evaluation of neuroprotective therapies in a neurosphere model of IUGR

38. Metabolomic profile of patients with active Cushing syndrome

39. Functional characterization in atypical early infantile epileptic encephalopathy-9

**Examples of Practical Stage Locations**

The Master includes 24 credits for the Master Thesis which should be conducted in a Laboratory, the student’s practicum will last minimum 500 hours. Below is the list of all the Laboratories assigned to the students which presented the Master Thesis in the past:

- Institut d’Investigacions Biomèdiques August Pi i Sunyer, IDIBAPS
- Hospital Universitari de Bellvitge, Bellvitge Biomedical Research Institute, IDIBELL,
- Hospital Clínic
- Universitat de Barcelona, Facultat de Medicina i Ciències de la Salut
- Institut d’Investigacions Biomèdiques de Barcelona, IIBB
- Hospital Duran i Teynals
- Consejo Superior de Investigaciones Científicas, CSIC
- Banc de Sang i Teixits, BST
- Hospital Sant Joan de Déu
- Fundació Sant Joan de Déu
- Vall d’Hebrón Institut de Recerca, VHIR
- Vall d’Hebrón Hospital
- Instituto de Química Avanzada de Cataluña, IQAC
- Institut de Bioenginyeria de Catalunya, IBEC
- Banc de Sang i Teixits, BST
- Institut de Ciències Fotòniques, ICFO
- Centre Nacional d’Anàlisi Genòmica, CNAG
- Institute for Research in Biomedicine, IRB
- FIRHU Vall d’Hebrón
- Institut Català d’Oncologia, ICO
- Parc Taulí Sabadell
- Institut Germans Trias i Pujol, IGTP
- Industry: Grífols
Please find the list of practical stage offers following the link below:

http://www.ub.edu/mastertranslationalmedicine/

Deadline for acceptance to a research group: **29th November 2019**

**MASTER WEBSITES**

[www.ub.edu/mastertranslationalmedicine](http://www.ub.edu/mastertranslationalmedicine)
VIRTUAL CAMPUS – FACULTY OF MEDICINE, UB

RESUM DE CURSOS

Module 1 - Dr Morales - Research in Inflammation, Angiogenesis, Tissue Remodeling and Cancer

Module 2 - Dr Joan Claria - Experimental models, animal handling and genetic engineering

Module 3 - Dr Llovet - Genomics, Proteomics and Metabolomics in Translational Research

Module 4 - Dr Bosch & Dr Brunet - Biomarker discovery and validation. Sample management and Biobanks

Module 5 - Dr Lopez-Bigas / Dr Tamborero - Bioinformatics and Data analysis for High-Throughput Data

Module 6 - Dr Anna Planas - Advanced Techniques of Image Analysis

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