BIOMARKER DISCOVERY AND VALIDATION. SAMPLE MANAGEMENT AND BIOBANKS

STUDY PLAN 2019-2020

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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

S1: Design research studies on new predictive, prognostic, diagnostic or pharmacodynamic biomarkers

S2. Clinical Utility of pharmacogenetic, pharmacodynamics and predictive biomarkers: achieving personalized therapy

S3. Clinical benefit of monitoring prognostic and diagnostic biomarkers.

S4. Legal and ethical principles compliance

S5. Ability to report analytical data resulting from studies with statistical packages

S6. Biobanks as a tool to achieve quality compliance

S7. Learn to manage collection samples for research studies

THEMATIC BLOCKS

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

METHODOLOGY

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

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

b) 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 ≥ 20/50, exam-score ≥20/50, and overall score (attendance + exam) ≥ 50/100. 1 point will be deducted for every 3 wrong answers.

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.