

Course Title: Personalized Medicine and Research Methodology for Doctoral Students

Course Level: PhD / Doctoral Program

Contact Hours: 30 lectures + 10 workshops (approx. 40 hours total)

Course Description

This course introduces doctoral students, primarily medical doctors and biomedical researchers, to the foundations of personalized medicine and advanced research methodology. Students will gain an in-depth understanding of -omics technologies, integration of clinical and molecular data, and modern approaches to study design in personalized medicine. A strong emphasis is also placed on academic writing, preparing scientific manuscripts, systematic reviews, and effective dissemination of results.

Course Objectives

By the end of the course, participants will be able to:

1. Explain the fundamental principles of personalized medicine and its applications across clinical disciplines.
2. Critically evaluate technologies such as genomics, transcriptomics, proteomics, metabolomics, and their integration in research.
3. Design clinical and translational studies using advanced models (basket, umbrella, adaptive, N-of-1).
4. Apply concepts from population genetics and causal inference to biomedical research.
5. Recognize and assess biomarker discovery and validation pathways.
6. Prepare high-quality manuscripts, conference abstracts, systematic reviews, and publication strategies.

Prerequisites

- Basic knowledge of clinical medicine and biomedical sciences.

Teaching Methods

- **Lectures:** thematic blocks on personalized medicine and methodology.
- **Workshops:** interactive sessions on writing and analysis.
- **Case discussions:** critical review of selected papers.

Block I – Fundamentals of Personalized Medicine

1. Introduction to Personalized Medicine (3h)

- Definitions and paradigms: from “one-size-fits-all” to targeted therapies.
- Clinical examples: oncology (HER2, EGFR), cardiology (pharmacogenomics), psychiatry (CYP2D6).

Outcome: Ability to distinguish between the classical and personalized approaches.

2. Clinical Genomics and Pharmacogenomics (2h)

- NGS, WES, WGS, targeted panels.
- Interpretation of genetic variants (ACMG).
- Applications in pharmacogenomics (CPIC guidelines).

Outcome: Understanding core genomic methods and their applications.

3. Transcriptomics, Epigenomics, Proteomics, and Metabolomics (2h)

- RNA-seq, single-cell technologies, ATAC-seq.
- Proteomics (MS, DIA) and metabolomics (NMR, LC-MS).
- Integration of large-scale data.

Outcome: Critical evaluation of technologies for research purposes.

4. Integration of Clinical and Biological Data (2h)

- Patient registries, EHR, OMOP, FHIR standards.
- Predictive models combining molecular and clinical data.

Outcome: Knowledge of preparing clinical and molecular datasets for joint analysis.

Block II – Research Methodology

5. Designing Studies in Personalized Medicine (2h)

- Basket, umbrella, and N-of-1 trial designs.
- Adaptive trial methodologies.

Outcome: Ability to design studies for personalized hypotheses.

6. Population Genetics and Causal Inference (2h)

- Mendelian randomization.
- Polygenic risk scores (PRS).
- DAGs and basics of causal inference.

Outcome: Understanding when correlation may or may not imply causation.

Block III – Practical Applications

9. Biomarkers – from Discovery to Validation (2h)

- Stages: discovery, analytical validation, clinical validation.
- Criteria for clinical utility of biomarkers.

Outcome: Knowledge of biomarker development in translational research.

10. Assessment of Clinical and Scientific Value (1h)

- How to evaluate the clinical significance of results.

Outcome: Ability to interpret findings in terms of value for patients and science.

11. Translational Models in Personalized Medicine (2h)

- Examples of successful translational pathways.
- Barriers: heterogeneity of patients, lack of replication.

Outcome: Understanding the steps from discovery to practice.

Block IV – Writing Workshops

12. Writing Scientific Articles (Part I) (3h)

- IMRAD structure.
- Formulating hypotheses and research objectives.

Exercise: drafting a title and abstract.

13. Writing Scientific Articles (Part II) (3h)

- Creating tables and figures.
- Drafting the discussion and conclusions.

Exercise: analysis of a sample article.

14. Systematic Reviews and Meta-Analyses (2h)

- Narrative vs. systematic reviews.
- Tools: PRISMA, PROSPERO.

Exercise: preparing a literature search scheme.

15. Publication Strategies and Presentation of Results (2h)

- Choosing journals, bibliometric indicators.
- Responding to reviewers, open access, preprints.

Exercise: drafting a reviewer response letter.

Learning Outcomes

Upon successful completion, participants will be able to:

1. Understand the principles of -omics technologies and their clinical applications.
2. Design research projects that incorporate elements of personalized medicine.
3. Critically appraise scientific publications in the field.
4. Prepare manuscripts, abstracts, and systematic reviews suitable for publication.
5. Develop a coherent doctoral research plan within the framework of personalized medicine.