



## **SEMMELWEIS EGYETEM**

### **Gyógyszertudományok Doktori Iskola**

# **3/3. Doktori program: Transzlációs és klinikai farmakológia**

## **Komplex vizsga főtárgyak tételsora**



## **Clinical Research, Topics**

1. Introduction to clinical trials
2. Clinical research types
3. Bias in observational studies and randomised controlled trials
4. Reduction of bias and types of randomisation
5. Randomized controlled trials: phases, designs and hypotheses
6. Interventions and outcomes of clinical trials
7. Statistical consideration in clinical trial planning
8. Importance and structure of study protocols
9. Investigator vs pharma company initiated trials
10. Clinical trial regulations, data protection in clinical research
11. Structured data collection
12. Ethical approval, IT development
13. Biobanks, human and financial resources
14. Patient enrolment, quality monitoring
15. Closure of a clinical trial, interim analysis
16. Descriptive statistics
17. Comparative statistics
18. Article structure of randomised controlled trials
19. Authorship policy, publication strategy
20. Networking in science

## **Patient Registry, Topics**

1. Introduction to patient registries
2. The purpose and rationale of a registry
3. The clinical question part 1.
4. The clinical question part 2.
5. Bias in registry analysis
6. Structured data collection
7. Ethical approval, IT development
8. Registry regulations and data protection
9. Biobanks, human and financial resources
10. Patient enrolment
11. Data collection, quality, monitoring
12. Registry maintenance
13. Data retrieval, data cleansing
14. Feasibility, exploratory data analysis
15. Statistical analysis plan
16. Descriptive statistics
17. Comparative statistics
18. Article structure of observational studies
19. Authorship policy, publication strategy
20. Networking in science

## **Systematic reviews and meta-analysis, Topics**

1. Introduction to systematic reviews and meta-analyses
2. Main steps of the workflow
3. Types of systematic reviews
4. Defining the inclusion criteria
5. Protocol registration
6. Systematic search
7. Search and selection
8. Variables in meta-analyses
9. Effect measure
10. Introduction to bias in science
11. Risk of bias in randomized trials
12. Bias due to missing data
13. Summarizing study characteristics and preparing for the synthesis
14. Undertaking meta-analysis
15. Network meta-analysis
16. Synthesizing and presenting findings using other methods
17. Figures in meta-analysis
18. Assessing the level of evidence
19. Reporting guidelines
20. Publication strategy

## **Biostatistics, Topics**

1. Why to learn statistics?
2. Probabilities I-II.
3. Risks, Odds, Ratios
4. Random variables
5. Basic concepts
6. Data types
7. Random variables
8. Estimation
9. Descriptive statistics
10. Estimation
11. Hypothesis testing I-II-III.
12. Tests of means and variances
13. Nonparametric tests
14. Analysis of qualitative (normal, ordinal) data - Relationship between two qualitative
15. Correlation analysis
16. Regression analysis I-II.
17. Survival analysis
18. Diagnostic tests I-II.
19. Statistics used in meta-analysis
20. Statistics used in network meta-analysis



**Tananyag, ajánlott irodalom, kötelező kurzusok:**

A kurzusok angol nyelven történnek, úgynevezett „blended education” keretében, amelyek egyaránt tartalmaznak előzetesen felvett e-tananyagokat, elektronikusan megoldandó feladatokat, és személyes megjelenést megkövetelő szemináriumokat, gyakorlatokat. **A tananyagokhoz kapcsolódó anyagokat, dokumentumot ajánlott irodalmat az internetes felületen keresztül kapják meg a hallgatók.**

1. Systematic review and meta-analysis in science and clinical practice I. (00110-KVA)
2. Systematic review and meta-analysis in science and clinical practice II. (00111-KVA)
3. Patient registries in medical science and clinical practice. (00112-KVA)
4. The role of clinical trials in science and clinical practice (00113-KVA)
5. Biostatistics in translation medicine (00114-KVA) Communication skills in science (00121-KVA)
6. Presentation technique workshop I. (00115-KVA)
7. Presentation technique workshop II. (00116-KVA)
8. Scientific writings in translational medicine (00123-KVA)
9. Additional lectures in the program of translation medicine I. (00107-KVA)
10. Additional lectures in the program of translation medicine II. (00108-KVA)

**A komplex vizsga melléktárgya a témavezetővel egyeztetve szabadon megjelölhető a kutatási téma alapján.**