Course Specifications
Valid as from the academic year 2017-2018

Clinical Study Design and Biostatistics (E003280)

Course size

<table>
<thead>
<tr>
<th>Credits</th>
<th>Study time</th>
<th>Contact hrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0</td>
<td>90 h</td>
<td>25.0 h</td>
</tr>
</tbody>
</table>

Course offerings and teaching methods in academic year 2017-2018

A (semester 1)
- seminar: practical PC room classes 7.5 h
- lecture: plenary exercises 2.5 h
- lecture 15.0 h

B (semester 1)
- seminar: practical PC room classes 7.5 h
- lecture: plenary exercises 2.5 h
- guided self-study 15.0 h

Lecturers in academic year 2017-2018

Vanderstraeten, Barbara GE17 lecturer-in-charge
De Wagter, Carlos GE17 co-lecturer

Offered in the following programmes in 2017-2018

<table>
<thead>
<tr>
<th>Offered</th>
<th>B (nominal values; actual values may depend on programme)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bridging Programme Master of Science in Biomedical Engineering</td>
<td>3 A</td>
</tr>
<tr>
<td>Bridging Programme Master of Science in Biomedical Engineering</td>
<td>3 B</td>
</tr>
<tr>
<td>Master of Science in Biomedical Engineering</td>
<td>3 A</td>
</tr>
<tr>
<td>International Master of Science in Biomedical Engineering</td>
<td>3 A</td>
</tr>
<tr>
<td>Master of Science in Biomedical Engineering</td>
<td>3 B</td>
</tr>
</tbody>
</table>

Teaching languages
Dutch, English

Keywords
Probability, inference, inductive statistics, parametric and non-parametric tests, survival analysis, design and statistical analysis of clinical trials, Excel

Position of the course
Thoroughly understanding statistical methods commonly used in medicine and biomedical research. Applying statistical functions in Excel. Understanding the considerations in clinical study design for medical devices.

Contents
- Assessing probability in an experimental construct, collection, interpretation and presentation of data, intrinsic uncertainty, measuring errors
- Bayesian statistics and its application to screening
- Inductive statistics, null and alternative hypothesis, the sample, central limit theorem, randomization, testing of hypotheses, reliability, level of significance, power, effect size, p-value, paired and unpaired tests, non-parametric statistics, choosing between parametric and non-parametric tests
- Analysis of variance (ANOVA), two-way ANOVA, interaction
- Data relationships, association and correlation, linear regression analysis
- Design and critical analysis of a clinical trial, safety and efficacy, prospective nature, randomization and stratification, blinding, phases 0-V, sample size, superiority and non-inferiority, health-care decision making, evidence based medicine
- Considerations in clinical study design for medical devices: business goals and strategy, targeted market, learning curve, human factors, investigational use, improved design versions

(Approved)
• Survival analysis, censored survival data, Kaplan-Meier method, comparing survival curves, log-rank test, potential problems and traps with survival studies
• Statistical pitfalls in biomedical research, selection bias, publication bias, positive sampling, regression to the mean, interpreting non-significant p-values

Initial competences
Mathematics, basics of probability and descriptive statistics (bachelor level).

Final competences
1. Critically approaching commonly used statistical methods in medicine and biomedical research
2. Acknowledging the importance of clinical trials for health-care decision making and reimbursement of new medical technologies
3. Understanding the specific considerations in clinical study design for medical devices
4. Applying statistical functions in Excel

Conditions for credit contract
Access to this course unit via a credit contract is determined after successful competences assessment

Conditions for exam contract
This course unit cannot be taken via an exam contract

Teaching methods
Guided self-study, lecture, lecture: plenary exercises, seminar: practical PC room classes

Learning materials and price
Extensive syllabus available from Minerva website.

References

Course content-related study coaching

Evaluation methods
end-of-term evaluation and continuous assessment

Examination methods in case of periodic evaluation during the first examination period
Open book examination, oral examination

Examination methods in case of periodic evaluation during the second examination period
Open book examination, oral examination

Examination methods in case of permanent evaluation
Report

Possibilities of retake in case of permanent evaluation
examination during the second examination period is possible

Extra information on the examination methods
• During examination period: oral open book exam, written preparation
• During semester: 1 practical exercise on PC.

Calculation of the examination mark
• During examination period = 80%
• Throughout semester = 20%

(Approved)