Course Specifications
Valid as from the academic year 2017-2018

Course

Course size (nominal values; actual values may depend on programme)

<table>
<thead>
<tr>
<th>Credits</th>
<th>Study time</th>
<th>Contact hrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0</td>
<td>75 h</td>
<td>24.0 h</td>
</tr>
</tbody>
</table>

Course offerings and teaching methods in academic year 2018-2019

A (year) Dutch guided self-study lecture self-reliant study activities

3.75 h 10.0 h 10.0 h

Lecturers in academic year 2018-2019

De Bacquer, Dirk GE12 lecturer-in-charge
Rottey, Sylvie GE09 co-lecturer

Offered in the following programmes in 2018-2019

<table>
<thead>
<tr>
<th>Crdts</th>
<th>Offering</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>A</td>
</tr>
</tbody>
</table>

Master of Medicine in Specialist Medicine (main subject Adult Psychiatry)
Master of Medicine in Specialist Medicine (main subject Adult Psychiatry)
Master of Medicine in Specialist Medicine (main subject Anaesthesia and Resuscitation)
Master of Medicine in Specialist Medicine (main subject Anaesthesia and Resuscitation)
Master of Medicine in Specialist Medicine (main subject Cardiology)
Master of Medicine in Specialist Medicine (main subject Cardiology)
Master of Medicine in Specialist Medicine (main subject Child and Adolescent Psychiatry)
Master of Medicine in Specialist Medicine (main subject Child and Adolescent Psychiatry)
Master of Medicine in Specialist Medicine (main subject Dermatology and Venerology)
Master of Medicine in Specialist Medicine (main subject Dermatology and Venerology)
Master of Medicine in Specialist Medicine (main subject Emergency Medicine)
Master of Medicine in Specialist Medicine (main subject Emergency Medicine)
Master of Medicine in Specialist Medicine (main subject Forensic Medicine)
Master of Medicine in Specialist Medicine (main subject Forensic Medicine)
Master of Medicine in Specialist Medicine (main subject Gastro-Enterology)
Master of Medicine in Specialist Medicine (main subject Gastro-Enterology)
Master of Medicine in Specialist Medicine (main subject Geriatrics)
Master of Medicine in Specialist Medicine (main subject Geriatrics)
Master of Medicine in Specialist Medicine (main subject Gynaecology-Obstetrics)
Master of Medicine in Specialist Medicine (main subject Gynaecology-Obstetrics)
Master of Medicine in Specialist Medicine (main subject Internal Medicine)
Master of Medicine in Specialist Medicine (main subject Internal Medicine)
Master of Medicine in Specialist Medicine (main subject Laboratory Medicine)
Master of Medicine in Specialist Medicine (main subject Laboratory Medicine)

(Approved)
Master of Medicine in Specialist Medicine (main subject Laboratory Medicine) 3 A
Master of Medicine in Specialist Medicine (main subject Medical Oncology) 3 A
Master of Medicine in Specialist Medicine (main subject Medical Oncology) 3 A
Master of Medicine in Specialist Medicine (main subject Neurology) 3 A
Master of Medicine in Specialist Medicine (main subject Neurology) 3 A
Master of Medicine in Specialist Medicine (main subject Neurosurgery) 3 A
Master of Medicine in Specialist Medicine (main subject Neurosurgery) 3 A
Master of Medicine in Specialist Medicine (main subject Nuclear Medicine) 3 A
Master of Medicine in Specialist Medicine (main subject Nuclear Medicine) 3 A
Master of Medicine in Specialist Medicine (main subject Ophthalmology) 3 A
Master of Medicine in Specialist Medicine (main subject Ophthalmology) 3 A
Master of Medicine in Specialist Medicine (main subject Orthopaedic Surgery) 3 A
Master of Medicine in Specialist Medicine (main subject Orthopaedic Surgery) 3 A
Master of Medicine in Specialist Medicine (main subject Otorhinolaryngology, Head and Neck Surgery) 3 A
Master of Medicine in Specialist Medicine (main subject Otorhinolaryngology, Head and Neck Surgery) 3 A
Master of Medicine in Specialist Medicine (main subject Paediatrics) 3 A
Master of Medicine in Specialist Medicine (main subject Paediatrics) 3 A
Master of Medicine in Specialist Medicine (main subject Pathological Anatomy) 3 A
Master of Medicine in Specialist Medicine (main subject Pathological Anatomy) 3 A
Master of Medicine in Specialist Medicine (main subject Physical Medicine and Rehabilitation) 3 A
Master of Medicine in Specialist Medicine (main subject Physical Medicine and Rehabilitation) 3 A
Master of Medicine in Specialist Medicine (main subject Plastic, Reconstructive and Aesthetic Surgery) 3 A
Master of Medicine in Specialist Medicine (main subject Plastic, Reconstructive and Aesthetic Surgery) 3 A
Master of Medicine in Specialist Medicine (main subject Radiation Oncology) 3 A
Master of Medicine in Specialist Medicine (main subject Radiation Oncology) 3 A
Master of Medicine in Specialist Medicine (main subject Radiology) 3 A
Master of Medicine in Specialist Medicine (main subject Radiology) 3 A
Master of Medicine in Specialist Medicine (main subject Respiratory Medicine) 3 A
Master of Medicine in Specialist Medicine (main subject Respiratory Medicine) 3 A
Master of Medicine in Specialist Medicine (main subject Rheumatology) 3 A
Master of Medicine in Specialist Medicine (main subject Rheumatology) 3 A
Master of Medicine in Specialist Medicine (main subject Stomatology and Oral and Maxillo-Facial Surgery) 3 A
Master of Medicine in Specialist Medicine (main subject Stomatology and Oral and Maxillo-Facial Surgery) 3 A
Master of Medicine in Specialist Medicine (main subject Surgery) 3 A
Master of Medicine in Specialist Medicine (main subject Surgery) 3 A
Master of Medicine in Specialist Medicine (main subject Urology) 3 A
Master of Medicine in Specialist Medicine (main subject Urology) 3 A

(Approved)
Teaching languages
Dutch

Keywords
Clinical trials, drug development, evaluation of therapeutic interventions, multiple regression techniques

Position of the course
The course aims at enhancing knowledge regarding the design and conduct of clinical trials and other therapeutic interventions and the correct and critical appraisal of their results.

Contents
Partim “GCP and Belgian law”:
• Aspects of clinical trial design and conduct in practice
• Belgian law: investigation on the human being
• European directives and European registration (Eudract-CT number)
• Ethics committee and FAGG
• Rights and duties of the investigator and the sponsor
• Essential documents in clinical trials
• Role of Bimetra Clinics
• Good Clinical Practice Guidelines
• Registration of clinical trials (ClinicalTrials.gov)
Partim “Biostatistics”:
• Simple and multiple regression techniques (linear/logistic model)
• Survival analysis (Kaplan-Meier estimation, Cox proportional hazards model)

Initial competences
The course builds on certain learning outcomes of the study programme leading to the academic degree "Master of Medicine (in Medicine)" (or "Physician" or "Doctor of Medicine, Surgery and Obstetrics").

Final competences
1 Acquiring in-depth knowledge of the Belgian legislation concerning the conduct of clinical studies and being able to apply this knowledge.
2 Acquiring knowledge about the support of Bimetra for clinical studies conducted at Ghent University and Ghent University Hospital.
3 Understanding principles underlying multiple regression methods.
4 Understanding basic concepts of survival analysis.

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, self-reliant study activities

Learning materials and price
Copy of slides, textbook, scientific papers

References

Course content-related study coaching
Individual consultation (after appointment)

Evaluation methods
end-of-term evaluation

Examination methods in case of periodic evaluation during the first examination period
Written examination

Examination methods in case of periodic evaluation during the second examination period

(Approved) 3
Written examination

Examination methods in case of permanent evaluation

Portfolio

Possibilities of retake in case of permanent evaluation

examination during the second examination period is not possible

Extra information on the examination methods

The periodic evaluation includes: written examination with questions on biostatistics and GCP and Belgian law. If the student does not participate in the examination on biostatistics and/or GCP and Belgian law, he/she cannot be evaluated for this course.

Calculation of the examination mark

For the calculation of the final examination mark following formula is used: “1/3 of points for test on GCP and Belgian law (maximum 20 points) + 2/3 of points for examination on biostatistics (maximum 20 points)”. Subsequently, a “pass” / “fail” result is given.

For the presence during the lesson on GCP and Belgian law no mark is given, but the student cannot pass this course without participation in this mandatory lesson.