# UNIVERSITA' DEGLI STUDI DI MILANO
# PROGRAMME DESCRIPTION - ACADEMIC YEAR 2025/26
# IN
# SAFETY ASSESSMENT OF XENOBIOTICS AND BIOTECHNOLOGICAL PRODUCTS (Classe LM-9)
# For students enrolled from 2015/16 until 2024/25 academic year

## *HEADING*

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|---|---|
| **Degree classification - Denomination and code:** | LM-9 |
| **Degree title:** | Dottore Magistrale |
| **Length of course:** | 2 years |
| **Credits required for admission:** | 180 |
| **Total number of credits required to complete programme:** | 120 |
| **Course years currently available:** | 2nd |
| **Access procedures:** | open, subject to entry requirements |
| **Course code:** | E52 |

## *PERSONS/ROLES*

**Head of Study Programme**

Prof. Emanuela Corsini - Tel. +39 02503 18241 Email: emanuela.corsini@unimi.it

**Tutors - Faculty**

Academic guidance tutors

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Master's degree admission tutors

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Erasmus and international mobility tutors

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Prof. Stefania Maria Ceruti – Via Balzaretti, 9 Milano Tel. +39 02 5031 8261 Email: stefania.ceruti@unimi.it

Internship tutors

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**Degree Course website**

https://safetyassessment.cdl.unimi.it

**Contact**

Email: saxbi@unimi.it

**Enrolment and Admission**

https://www.unimi.it/en/study/enrolment

**Student Desks**

Via Celoria 18, Milano Tel. 02 5032 5032 https://www.unimi.it/en/node/360 https://www.unimi.it/en/node/359

**Student Office of the Department of Pharmacological and Biomolecular Sciences Dr.ssa Sara Cosentino**

Via Balzaretti, 9 Milano Tel. 02 5031 8231 Email: didattica.disfeb@unimi.it

**Suggestions to improve**

Email: didattica.disfeb@unimi.it

## *CHARACTERISTICS OF DEGREE PROGRAMME*

**General and specific learning objectives**

The aim of the Master Course is to present provision of training program in risk assessment based on common European and international criteria, easily adoptable by institutions across Europe and focusing on Risk Assessment methodology and procedure. The project focuses on understanding the profile and training requirements of risk assessors in order to design a degree covering a range of disciplines in risk assessment and providing a model to establish a recognition of risk assessors. To this end, the Master degree in "Safety Assessment of Xenobiotics and Biotechnological Products" (SAXBi) has been certified (the first one in Europe), according to the Standard UNI EN 16736 and to the AICQ SICEV Regulation RG 06-1, that well define the formation for risk assessors.

The Master level "Safety assessment of xenobiotics and biotechnological products (SAXBi)" is equivalent to the second-level higher education award that refers to the second cycle in the Qualifications Framework of the European Higher Education Area (EHEA), designed by the Bologna Accords (1999) which refers to level 7 of the European Union's European Qualifications Framework. The degree requires 120 European Credit Transfer System (ECTS), and the expected learning outcomes will meet those specific to the second Dublin descriptor.

**Expected learning outcomes**

The Master Course provides specific knowledge in the analysis and assessment of risk, taking into account the international regulations. In addition, the ambition of the course is to provide the students with a multidisciplinary background sufficient to initiate research on the novel methodologies to be applied in the field of risk assessment. It is believed that the professional profiles formed will find employment in the European and international Institutions and Agencies dealing with the protection of health of consumer and the environment, as well as in companies operating in the chemical, agrochemical, pharmaceutical and food field.

As mentioned in the program of activity of ECHA "In the evaluation of dossiers ECHA produces scientific judgments. These judgments must be based on scientific principles accurate and require well-trained and competent experts. A number of scientific disciplines, such as toxicology, chemistry, epidemiology, occupational hygiene, environmental fate and effects on the environment, exposure assessment and characterization and risk management, must come to comprehensive evaluation results from the scientific point of view."

The Master provides the methodological background, knowledge and skills necessary to apply current methodologies and generate novel protocols, to acquire competence in problem-solving, to assess risks arising from production and use of chemicals and biotechnological products, with particular attention to the implementation of European Regulations through the integrated development of different areas including legislation, chemistry, toxicology and pharmacology, biotechnology and risk analysis. The graduates will have specific expertise in the areas of:

- community law, national and international legislation on chemicals, risk and safety;
- toxic and eco-toxic properties of chemicals and biotechnological products;
- methods and procedures for the characterization of chemical substances and biotechnological products;
- computational techniques for the estimation of the chemical and toxicological properties of substances;
- procedures for registration of chemicals under various European regulations;
- evaluation of risks inherent to the production and use of chemicals and biotechnological products;
- evaluation of new materials such as those produced by nanotechnologies and new processes;
- strategies of synthesis and production of alternatives to the toxic and/or eco-friendly;
- basis on risk perception and risk communication.

**Professional profile and employment opportunities**

The professional profiles generated will be employed by:

- public administration for the control, implementation and management of human health and environmental protection;
- industry Associations (Food, Cosmetics, Pharma, Chemicals);
- pharma Companies in the sector of drug development;
- biotech Companies;
- contract Research Organization for the drug toxicity testing;
- food and Chemical Companies in Quality Control divisions;
- bioremediation Companies;
- innovative energy plants;
- public and Private Companies for the implementation and application of appropriate RA procedures;
- private sectors as consultants for RA of chemicals, food contaminants, water and air pollutants;
- public and Private Research Institutions;
- universities and secondary schools;
- researcher at public and private research institutions;
- researcher in industry (research and development sector);
- risk assessor in public and private organizations;
- quality certifier.

**Pre-requisites for admission**

Admission Requirements

To be admitted to a 2nd course/level degree course, a 1st level degree or a suitable equivalent foreign qualification is required (see also the "Admission criteria" section).

Access to the Master in "Safety Assessment of Xenobiotics and Biotechnological Products" (SAXBi) is open to:
- graduates with Italian degree (ex. DM 270/04 or equivalent ex. DM 509/99) in the areas L2 or L29;
- graduates from areas other than the above listed, provided they have earned the following credits:
- at least 9 credits (ECTS) in disciplines of CHIM/01, CHIM/03 or CHIM/06 (analytical chemistry; general and inorganic chemistry; organic chemistry);
- at least 5 credits in disciplines BIO/09 (physiology);
- at least 12 credits in disciplines BIO/10, BIO/11 or BIO/13 (biochemistry; molecular biology; applied biology);
- at least 6 credits in disciplines BIO/14 (pharmacology/toxicology);
Students with foreign qualification recognised as equivalent may access to the Master in SAXBi if they can demonstrate background knowledge and skills in biology, chemistry, biochemistry, pharmacology, toxicology and physiology, equivalent to those listed above. A committee of teachers appointed by the Board of Faculty will check the presence of these requirements.

Knowledge Assessment
Students meeting the above minimum requirements are invited to an interview for admission (in English) with the Commission for Admittance to the Master, composed by teaching members appointed by the Teaching Board. The interview, done remotely via electronic devices if necessary, is aimed at verifying the above mentioned skills and the knowledge of the English Language equivalent to B2 level.

Students who have not yet graduated but who expect to graduate by October 2024 can also apply for admission to the Master in SAXBi.

Interviews of applicants will be held according to a calendar proposed individually to each applicant.
The committee evaluates the candidate on a 100-point scale:
-up to 25/100 will be given for the graduation mark
-up to 25/100 for the curriculum (free courses, others...)
-up to 50/100 for the interview
The minimum requirement for admission is 60/100.

**Programme structure**

The 2nd cycle course, also known as a Laurea Magistrale (qualification Dottore Magistrale), provides the student with advanced education and training for professions in specific fields that require a high level of qualification. The course lasts two years, and each year is subdivided into two semesters. To obtain the qualification (2nd level degree) it is necessary to accumulate 120 credits. Each credit corresponds to a standard student workload of 25 hours, including:
- 8 hours of lectures followed by 17 hours of individual study;
- 16 hours of practical labs followed by 9 hours of individual study;
- 25 hours of training activities related to the thesis;
- 25 hours of individual study.
The SAXBi Master Degree integrates chemical, biological and toxicological disciplines with a particular focus on the regulatory field.
The Department of Pharmacological and Biomolecular Sciences at the Università degli Studi di Milano is the reference point and the main Institution responsible for the SAXBi Master Degree.

ATTENDANCE
Recommended to the course, see section "Compulsory attendance" for the labs.

STUDY PLAN DEFINITION AND SUBMISSION FOR APPROVAL
The student must provide an individual study plan indicating the elective course units for a total of 8 credits. These will be chosen freely among all courses provided by the University of Milan if they are consistent with the educational project, after consulting the Study Programme committee. As alternative, the student can also choose the Laboratory of Risk assessment (8 CFU). This laboratory aims to deepen the theoretical and practical aspects of the research topic of the thesis and it will be agreed with the thesis tutor.
Other training activities (3 ECTS)
In order to facilitate the completion of cultural and professional training of students, activities of orientation to the career are also planned, including meetings and seminars of experts in various fields inherent to the degree.
The credits obtained in these activities ("Other training activities" in the study plan) must be cumulated to reach 3 ECTS= (including at least 24 hours of lectures). Students are expected to provide certificates of the activities attended and to deliver short presentations of the attended activities during specific days planned during the academic year.
Additional Language Skills: Italian (foreign students)
Among the electives, those who do not hold an Italian high school diploma or degree can obtain 3 credits in Additional language skills: Italian by demonstrating A2 level in Italian per the Common European Framework of Reference for Languages (CEFR). This level can be assessed in one of the following ways:

- by submitting a certificate of A2 or higher level issued no more than three years prior to the date of submission. You

will find the list of language certificates recognized by the University at: https://www.unimi.it/en/node/349/ ). The language certificate must be uploaded through the dedicated Platform (http://studente.unimi.it/uploadCertificazioniLingue).

- by an entry-level test administrated by SLAM that can be taken only once and is compulsory for all students who do not have a valid language certificate. Those who fail to reach A2 level will have to attend one or more than one 60-hour Italian course(s) geared to their level. Those who do not take the entry-level test or fail to pass the end-of-course test after six attempts will have to obtain language certification privately in order to earn the 3 credits of Additional language skills: Italian. As an alternative, they can modify their course programme by choosing a different elective.

The study plan must be submitted online in the 1st year, within the deadline set by the Direzione Segreteria Studenti. For information on dates and procedures for submitting the official study plan, please visit the relevant section of the UNIMI website available at https://www.unimi.it/en/study/bachelor-and-master-study/following-your-programme-study/plan-study. After the approval of the study plan, the student can independently take further exams in addition to his/her educational path.
In addition, activities included in the University project for the development of soft skills can be chosen: https://www.unimi.it/en/study/bachelor-and-master-study/following-your-programme-study/soft-skills. These educational activities have a compulsory attendance, a limited number of places is available and they can be included in the study plan, under the “Elective activities”, only if they have been subscribed to by the Course of Study. For more details, please refer to the following webpage: https://safetyassessment.cdl.unimi.it/en/courses/soft-skills

TESTING AND ASSESSMENT PROCEDURES
Course exams must be passed, with grades calculated on a 30-point scale, to obtain course credits, with 18/30 being the minimum pass grade. The assessment will consist of an oral or written exam. For courses structured into modules, a head lecturer will be identified as the coordinator, and evaluation procedures for course outcomes and the registration of examination grades will be agreed by all associated teaching members.
The schedule of the examination sessions for the assessment of the learning outcomes is available through the on line service available at https://www.unimi.it/en/node/134/
Exam registration is compulsory and must be carried out through the on line service available at
https://www.unimi.it/en/node/130/

TEACHING CALENDAR AND LECTURE TIMETABLE
- 1st Semester: September 29th, 2025 - January 23rd, 2026
- 2nd Semester: March 2nd, 2026 - June 19th, 2026
Exams are taking place mainly during February and July-September sessions, and in other dates to be agreed with students, possibly not in conjunction with lessons. The lecture timetable is available at https://www.unimi.it/en/node/128/
Download “Lezioniunimi”, LaStatale app for Android, iOS and Windows phone.

**Conscientious objection policy**
The teaching activities do not include laboratories involving the use of animals. In case students during their internship period for thesis will attend a laboratory activity involving the use of animals, the Teaching Board of SAXBi acknowledges the uncontested right of conscientious objection according to the Italian law n. 413, October 12 1993, "Norme sull’obiezione di coscienza alla sperimentazione animale".

**Campus**
Città Studi teaching facilities
Lectures are held in the classrooms indicated in the timetable of the courses of Università degli Studi di Milano.
All the classrooms are accessible to students with disabilities.

**Laboratories**
Città Studi teaching facilities
Laboratory activities are held in the labs of the Faculty of Pharmacy, according to the timetable of the courses of Università degli Studi di Milano.

**Libraries**
At the Biomedical Library of Città Studi, Valvassori Peroni Street, n. 21 (Milan), texts, scientific journals and collections are available.
More info: http://www.sba.unimi.it/Biblioteche/bcittastudi/11688.html

**Tutoring**
Tutors are available to help the students
i) to learn the material in individual courses;
ii) understanding how to use the syllabus, by means of meetings with the students, regularly throughout the semesters.

Students can contact the tutors, whose names are listed in the first page of the programme official description.

**Compulsory attendance**

Mandatory to the labs, recommended to the courses.

Students who are working
If the student is enrolled in working activities in laboratories in which techniques that are subject of the teaching laboratories are used, he/she is entitled of a partial/total exemption from laboratory attendance.
To take advantage of such concession, the student has to present to the Secretariat of the Teaching Committee copy of the job contract and timetable at the beginning of each academic year.
Alternatively, the students who are working are entitled to enrol as part-time students (see below).

Part-time students
In agreement with the University of Milan rules, students who cannot attend classes with academic continuity and take exams within the regular duration of the course, can be granted the possibility to follow a specific path based on the particular situation and can be enrolled as part-time students.
For further information, please visit the website https://www.unimi.it/en/node/113/

**Internship criteria**

The final exam requires a previous internship (thesis) during the degree course, in academic, private or governmental institutions with expertise in health risk assessment, to acquire the expected 29 ECTS.
In order to request the internship (thesis) at least 28 ECTS shall be acquired, with the request to be made not before the second semester of the 1st academic year.
In order to start the internship (thesis) at least 51 ECTS shall be acquired.
The final exam consists of: written text, oral presentation and defence of a risk assessment exercise conducted on a case-study, agreed by the tutor and the candidate. The objective of the examination is to assess the students' broader and deeper knowledge and skills to independently apply the knowledge presented in the taught courses and be able to perform a full risk assessment integrating the different elements of the risk-assessment-process.
In addition to the expected 29 ECTS, the Laboratory of Risk Assessment (8 ECTS) offers the possibility to the students to add their free credits to the scheduled credits for the preparation of their thesis, with the evaluation of the student's performance based on the experimental thesis period.
Otherwise, students can acquire 8 ECTS with free credits, choosing courses among those offered by the University of Milan, relevant to SAXBi programmes.
Internships and traineeships carried out in external organizations and companies are managed through agreements signed with COSP and require the student to activate a procedure through a dedicated platform. More information is available on the website https://www.unimi.it/it/node/483/

**Degree programme final exam**

The final exam requires a previous internship (thesis) during the degree course, in academic, private or governmental institutions with expertise in health risk assessment, to acquire the expected 29 ECTS. In order to start the internship (thesis) at least 51 ECTS shall be acquired.
The student can choose to convert the optional course in thesis, then period of the thesis will be prolonged of 8 ECTS (Laboratory of Risk assessment).
The final exam consists of: written text, oral presentation and defence of a risk assessment exercise conducted on a case-study, agreed by the tutor and the candidate.
The objective of the examination is to assess the students' broader and deeper knowledge and skills to independently apply the knowledge presented in the taught courses and be able to perform a full risk assessment integrating the different elements of the risk-assessment-process.
To be admitted to the final examination, students must have achieved all the credits required by all the topic listed in the second cycle program, except those reserved to the final examination.

## *EXPERIENCE OF STUDY ABROAD AS PART OF THE DEGREE PROGRAM*

The University of Milan supports international mobility by providing its students with the opportunity to spend study and internship periods abroad. It is a unique chance to enrich your educational path in a new exciting environment.
The agreements entered into by the University with over 300 universities from the 27 EU member countries under the European Erasmus+ programme allow regularly enrolled students to carry out part of their studies at one of the partner universities or to undertake internships at companies, training and research centres and other organizations.
Similar international mobility opportunities are provided outside Europe, through agreements with a number of prestigious institutions.

**Study and internships abroad**

Thanks to mobility Erasmus programs and other Mobility opportunities, the Master Course in SAXBi offers its students the opportunity to spend periods of training abroad. The Programs also offer the opportunity to play an internship abroad at companies, universities or other organizations. Universities and Institutions partners involved in these programs offer the possibility to engage in a wide range of areas. In the mobility period, the student can:
- carry out the thesis.
Each student is followed by a tutor identified within the Course. The url https://www.unimi.it/en/node/12879/ lists all the information related to the fields of study and training opportunities offered by the host locations. Procedure for the

recognition of study periods abroad: each student must propose a Learning Agreement regarding training activities that lead to the recognition of a number of credits adequate to the period spent abroad.
The period of study abroad will be recognized as valid after obtaining at least 70% of the credits specified in the learning agreement, while the activity of the thesis or internship will be valid only after acquisition of all credits. For students who have accomplished satisfactorily the training program, there are appropriate incentives, proposed by the teacher in charge, will be paid by the Faculty in the diploma achievement session. It provides additional points to the degree mark varying from a minimum of 1 to a maximum of 3 points depending on the duration of the study period, the amount of credits attained, and the overall results obtained by the student.

**How to participate in Erasmus mobility programs**

The students of the University of Milan can participate in mobility programmes, through a public selection procedure.
Ad hoc commissions will evaluate:
Academic career
the candidate's proposed study programme abroad
his/her foreign language proficiency
the reasons behind his/her application

Call for applications and informative meetings
The public selection for Erasmus+ mobility for study generally begins around February each year with the publication of a call for applications specifying destinations and requirements. Regarding the Erasmus+ Mobility for Traineeship, the University of Milan usually publishes two calls a year enabling students to choose a destination defined by an inter-institutional agreement or to find a traineeship position on their own.
The University organizes informative meetings to illustrate mobility opportunities and rules for participation.

Erasmus+ scholarship
The European Union grants the winners of the Erasmus+ programme selection a scholarship to contribute to their mobility costs, which may be supplemented by the University funding for disadvantaged students.

Language courses
Students who pass the selections for mobility programmes can benefit from intensive foreign language courses offered each year by the University Language Centre (SLAM).
https://www.unimi.it/en/node/8/
Learn more at https://www.unimi.it/en/node/274/

For assistance, please contact:
International Mobility Office
Via Santa Sofia 9 (second floor)
Tel. 02 503 13501-12589-13495-13502
Contacts: InformaStudenti; mobility.out@unimi.it
Student Desk booking through InformaStudenti

## *ADMISSION CRITERIA: 1ST YEAR OPEN, SUBJECT TO ENTRY REQUIREMENTS*

**Application and enrolment information and procedures**

All students must submit the online admission application for the admission by the following deadlines:
Italian students and students with foreign qualification from EU Countries: from January 22 to August 25, 2024.
Undergraduates who intend to graduate by October 31st, 2024 may also apply.
Students with foreign qualification from extra-EU Countries must complete the admission application online from January 22nd to April 30, 2024 in order to facilitate the necessary procedure for issuing visas by the competent Authorities.
Non-European candidates residing abroad applying for a visa are required to submit an application for pre-enrolment through Universitaly within July 31st, 2024.
See for all details the section above "Pre-requisites for admission".
For more information: https://www.unimi.it/en/study/bachelor-and-master-study/degree-programme-enrolment

If coming from another university or other degree program, admission to second year of the course will be evaluated by competent organs of the course.

**N° of places reserved to non-EU students resident abroad**

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### *1st COURSE YEAR (Cancelled since academic year2025/26)Core/compulsory courses/activities*

| Scheduling | Learning activity | Module/teaching unit | Ects | Sector | Teaching method |
|---|---|---|---|---|---|
| | Development Biology and Differentiation | | 6 | BIO/13 | 40 hours Lectures, 16 hours Laboratory individual activity |

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|---|---|---|---|---|---|
| | Functional, Metabolic and Epigenetic Biochemistry | | 6 | BIO/10 | 48 hours Lectures |
| | Methods of analysis of chemicals in water, air, biological fluids, tissues, food (Total number of ects:6) | Methods of analysis of chemicals | 3 | CHIM/01 | 24 hours Lectures |
| | | Physical-chemical characterization, identity | 3 | CHIM/06 | 24 hours Lectures |
| | Organ Physiopathology and Histopathology (Total number of ects:10) | Organ Physiology and Pathology | 7 | (4) MED/04, (3) BIO/09 | 48 hours Lectures, 16 hours Tutorials |
| | | Lab of Comparative Histopathology | 3 | VET/03 | 16 hours Lectures, 16 hours Laboratory individual activity |
| | Bioremediation (Total number of ects:7) | Environmental Microbiology and Biotechnological Remediation | 3 | BIO/19 | 8 hours Lectures, 32 hours Laboratory individual activity |
| | | Laboratory of Cell Biology | 4 | BIO/13 | 16 hours Lectures, 32 hours Laboratory individual activity |
| | Biotechnology and Pharmacotoxicology (Total number of ects:10) | Biotechnology and Pharmacology | 5 | BIO/14 | 40 hours Lectures |
| | | Genotoxicology, Cancerogenicity, Immunotoxicology, Reproductive and Developmental Toxicity | 5 | BIO/14 | 32 hours Lectures, 16 hours Tutorials |
| | Regulatory Aspects in toxicology (Total number of ects:6) | Regulatory Aspects of Medicaments, Medical Devices and Health products | 3 | CHIM/09 | 24 hours Lectures |
| | | Legislation in European Union | 3 | IUS/14 | 24 hours Lectures |
| | | Total number of compulsory credits/ects | 51 | | |

## *2nd COURSE YEAR Core/compulsory courses/activities*

| Scheduling | Learning activity | Module/teaching unit | Ects | Sector | Teaching method |
|---|---|---|---|---|---|
| *year* | Quantitative Chemical Structure and activity relationship (Total number of ects:10) | In Silico Methods in Toxicology | 5 | CHIM/08 | 40 hours Lectures |
| | | Structural Bioinformatics | 5 | BIO/10 | 32 hours Lectures, 16 hours Laboratory individual activity |
| *1 semester* | Databases and Exposure scenarios (Total number of ects:6) | Informatics and Database | 3 | INF/01 | 24 hours Lectures |
| | | Statistics applied to Epidemiology | 3 | SECS-S/01 | 24 hours Lectures |
| *1 semester* | System Toxicity and Risk Assessment | | 7 | BIO/14 | 48 hours Lectures, 16 hours Tutorials |
| *2 semester* | Pharmacogenetics and Epigenetics in Toxicology | | 6 | BIO/14 | 48 hours Lectures |
| | | Total number of compulsory credits/ects | 29 | | |

## *Elective courses*

**STUDENTS HAVE TO CHOOSE OPTIONAL COURSE FOR 8 CREDITS.**
**These will be chosen freely among all courses provided by the University of Milan if they are consistent with the educational project, after consulting the Study Programme committee. As alternative, the student can also choose the Laboratory of Risk assessment 8 CFU. This laboratory aims to deepen the theoretical and practical aspects of the research topic of the thesis and it will be agreed with the thesis tutor.**
**In addition, activities included in the University project for the development of soft skills can be chosen.**
**https://www.unimi.it/en/study/bachelor-and-master-study/following-your-programme-study/soft-skills**

| | | | | | |
|---|---|---|---|---|---|
| | Laboratory of Risk assessment | | 8 | ND | Individual study and activity |

**TO OBTAIN THE DEGREE, STUDENTS HAVE TO ACQUIRE AN ADDITIONAL 3 CREDITS (OTHER ACTIVITIES).**
**More information in the "Study plan definition and submission for approval" above.**

| | | | | | |
|---|---|---|---|---|---|
| | Additional Language Skills: Italian (3 ECTS) | | 3 | ND | Valutazione della lingua |
| | Other training activities<br>*(i.e. meetings and seminars of experts in various fields inherent to the degree)* | | 3 | NA | Individual study |

## *End of course requirements*

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|---|---|---|---|---|---|
| | Thesis | | 29 | NA | Individual study |
| | | Total number of compulsory credits/ects | 29 | | |