MASTER OF SCIENCE IN PHARMACOMETRICS

UC LOUVAIN & KU LEUVEN

INITIAL ACCREDITATION • REPORT

FRAMEWORK FOR THE EUROPEAN APPROACH FOR QUALITY ASSURANCE OF JOINT PROGRAMMES

10 October 2024

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1 Executive summary

The self-assessment report, along with the detailed programme materials reviewed before the site visit and discussions with dedicated stakeholders, has given the panel a thorough understanding of the programme. The panel, which evaluated the programme according to the standards set by the European Approach for Quality Assurance of Joint Programmes, concluded that the advanced Master of Science in Pharmacometrics meets all required standards.

There is clear evidence that both partners have actively participated in developing the programme and are deeply committed to its successful implementation. The Cooperation Agreement addresses all crucial elements necessary for establishing, governing, and executing the Master of Science in Pharmacometrics programme as a joint effort between the two universities.

The panel appreciates the set-up of the Steering Committee, including student members, to ensure and safeguard the quality of the programme. The panel trusts they will further develop the programme and closely monitor the quality of the programme. In order to establish structural input from external stakeholders in this process, the panel advises to establish an advisory board that includes a complete range of external stakeholders including representatives from the pharmaceutical industry, contract research organizations, academia, university hospitals and the regulatory authorities. Their insights could greatly benefit both the Steering Committee and the further development of the programme overall.

The Domain Specific Learning Outcomes (DSLO) coincide with the Programme Specific Learning Outcomes (PSLO). Even though the panel understands why the programme has made this decision as a new and unique programme in Belgium, the panel believes the programme, (prospective) students and the professional field will benefit from more specific learning outcomes focussing on the unique selling point of this programme and therefore advises the programme to develop these. The panel recommends the programme to do this in one or two years, after they have experienced where the programme naturally evolved to. This will enable the programme to show via their PSLOs what specific choices they made in the further development of the programme.

The panel found the structure of the programme to be very well-designed. The panel appreciates the integrated group work, incorporated in the curriculum. Also, the set-up of the master's thesis, which is integrated in the entire curriculum, is a strong feature. The panel recommends the programme to communicate clearly to students about this set-up to ensure clarity and support for students. The assessment methods are comprehensive and diverse, with a strong emphasis on feedback, which is greatly appreciated.

The panel considers the content of the curriculum to be complete and inspiring. The panel values the clear vision regarding software-agnostic learning paired with hands-on experience with selected modelling software within the curriculum. The vision that students should be able to transport their knowledge and skills from one software tool to another, is greatly endorsed.

The faculty is highly qualified and motivated, contributing significantly to the programme's success. Some of the staff have an extensive track-record in the field and are widely

recognized for their expertise. The panel agrees with the programme in installing a dedicated point of contact for students and supports the aim to attract a wide range of guest lecturers. The panel also appreciates the collaboration between the staff from both partner universities in developing the programme and their active involvement in delivering various teaching units. The panel is reassured that the programme will monitor and uphold the staff workload.

Students seem to be confident in and enthusiastic about the programme. They trust the workload and set-up, finding it feasible and manageable. The panel however advises, in line with the programme's intentions, to closely monitor the workload for the students, as the programme is expected to be heavy.

Regarding the admissions procedures, the panel found that these were all adequate. The panel suggests the programme to consider offering the preparatory programme in different formats, such as summer schools, to enhance accessibility.

The panel concludes that there are well established systems in place for supporting students. Both institutions work together in such a way that students will experience the support provided as coming from one team. The programme will be structured to ensure students have full days of classes at both campuses, minimizing commuting challenges.
Students will need their own laptop but will be provided with access for the required software and programs. Challenges regarding data protection and licensed software have been sufficiently thought through by the programme. Solutions to this include the use of simulated and/or synthetic data, the attention for data protection in the curriculum, the support for students with installing software, facilitating students with laptops to borrow and the availability of computer rooms.

Regarding the Quality Assurance (QA) system, the panel praises the merging of the best practices from both institutions, creating a robust framework for continuous improvement. According to the panel, this evidently demonstrates the added value of working together in a joint degree. The panel is very pleased with the extra effort the programme will put into conducting surveys, student hearings and other evaluations in the first year(s) of the programme being implemented.

Regardless of these recommendations, the panel confirms it is very positive and enthusiastic about the quality and expected added value of the advanced Master of Science in Pharmacometrics.

The Hague, 10 October 2024

On behalf of the expert panel convened to assess the Master of Science in Pharmacometrics,

Panel chair
Prof. dr. Yvette Michotte

Secretary
Drs. Lisette Sandifort-Meijer

2 Assessment – Standards for Quality Assurance of Joint Programmes

2.1 Eligibility

The panel assesses the Eligibiliy standard as compliant.

2.1.1 Status

The institutions that offer a joint programme should be recognised as higher education institutions by the relevant authorities of their countries. Their respective national legal frameworks should enable them to participate in the joint programme and, if applicable, to award a joint degree. The institutions awarding the degree(s) should ensure that the degree(s) belong to the higher education degree systems of the countries in which they are based.

KU Leuven and UCLouvain are both officially registered institutions for higher education in Belgium. The status of KU Leuven as university and degree-awarding body is recognised and protected by Flemish law. On the basis of Article II.172 of the Flemish Code of Higher Education, KU Leuven is allowed to organize their degree programmes as joint programmes with other universities in or outside the Flemish Community. Joint degrees or double degrees can be awarded at the end of these joint programmes. UCLouvain fulfills teaching duties, assigned by a decree of the French Community on 7 November 2013 concerning the regime of university studies and academic grades (Moniteur Belge: 18 December 2013), as well as research duties and other services to society.

The institutions decided to join forces to collaboratively develop the "Master of Pharmacometrics" programme. Although related expertise can be found at the different Belgian universities and abroad, no master in Pharmacometrics exists in Belgium. However, expertise in this field seems highly needed in pharmaceutical industry, hospitals and drug evaluation agencies in Belgium, offering important job opportunities.

The programme therefore seeks to attract candidates from diverse academic backgrounds (such as pharmaceutical sciences, biomedical sciences, medicine, and statistics) and provide them with the opportunity to specialize in the rapidly expanding field of pharmacometrics. Graduates will be prepared to pursue careers in the pharmaceutical industry, hospitals, the public sector, or scientific research. Both institutions have made significant investments in building robust research in pharmacometrics, including mentoring PhD students. They aim to leverage this expertise to support candidates who wish to specialize in this area, working alongside industry, hospital, and public sector experts. By offering a joint programme, the teams from both universities intend to complement and enhance each other’s strengths, ensuring a high-level training.

Successful completion of the Master of Science in Pharmacometrics leads to the award of the joint degree “Master of Science in Pharmacometrics” offered by KU Leuven and UCLouvain. As stated in the Cooperation Agreement, the Coordinating Party (UCLouvain) is responsible for setting up the joint degree diploma to be awarded. The joint degree, including the names, logos and seals of both universities, shall be signed by the rectors of both Universities, and shall be issued by the UCLouvain (article 9 Cooperation Agreement).

The panel is impressed by the great commitment and enthusiasm of the management of both institutions.

2.1.2 Joint design & delivery

The joint programme should be offered jointly, involving all cooperating institutions in the design and delivery of the programme.

As stated in the self-assessment report, the programme was collaboratively developed by representatives from KU Leuven and UCLouvain. They held both online and on-site meetings with professors, assistants, and educational staff from both universities to (further) develop the curriculum and discuss key components for each course. ECTS-files were created by joint teams from both institutions and reviewed by a core group of professors, with support from an educational staff member from KU Leuven.

The two universities will jointly offer this educational programme, with all programme-specific courses taught by a team of lecturers from both universities. Classes will be held at both KU Leuven and UCLouvain, with the goal of scheduling two days of classes at each university each week to ensure convenience for students and staff.

Some elective courses will be drawn from other faculties, allowing students to join peers from different programmes. These electives will be taught separately at each university, but students can choose from the options available. Each student must complete at least one elective course worth 3 ECTS. Both institutions have carefully discussed these electives to ensure they contribute effectively to the desired learning outcomes.

The panel reviewed the commitment of the partner institutions to jointly establish and deliver the programme. After assessing the self-assessment report, additional documentation, and discussions, the panel confirms its full agreement that the programme is the outcome of extensive preparation and collaboration between both universities.

2.1.3 Cooperation Agreement

The terms and conditions of the joint programme should be laid down in a cooperation agreement. The agreement should in particular cover the following issues:

- *Denomination of the degree(s) awarded in the programme;*
- *Coordination and responsibilities of the partners involved regarding management and financial organisation (including funding, sharing of costs and income etc.);*
- *Admission and selection procedures for students;*
- *Mobility of students and teachers;*
- *Examination regulations, student assessment methods, recognition of credits and degree awarding procedures in the consortium.*

The panel has studied the Consortium Agreement that describes the principles of the Master of Science in Pharmacometrics in all its detail. The agreement lays down the governance structure, financial arrangements and all necessary procedures determining the cooperation between both partners for the delivery of this joint master programme. The panel praises in particular the well-thought-out financial arrangements that are clearly set up in the advantage of the students.

The Cooperation Agreement states that the programme shall be directed by a Steering Committee, which will be composed as follows:

- two academic representatives from each of the participating universities, one of whom is the person in charge of the related programmes at their respective university (Programme Directors).
- one administrative staff member dedicated to the programme from each of the universities.
- one teaching assistant involved in the programme from each of the universities.
- two students in the programme for all matters related to the content and quality assurance of the programme.

The Steering Committee plays a key role in ensuring the quality of the programme and the importance of their role is underlined by the panel. However, the panel feels that the Steering Committee needs a systematic external input as well. The panel therefore recommends the programme to install an Advisory Board, composed of a wide range of stakeholders (including industry, academia, hospital and regulatory agencies) to feed the Steering Committee with external input to continuously ensure a state of the art programme development. An external Advisory Board can provide the Steering Committee with valuable input regarding the learning outcomes and the programme.

Regardless of the suggestion made above, the panel confirms that the Cooperation Agreement covers all essential aspects to set-up, govern and implement the programme. The panel concludes that the evidence demonstrates that the programme is fully compliant with the different criteria in the Eligibility standard.

2.2 Learning Outcomes

The panel assesses the Learning Outcomes standard as compliant.

2.2.1 Level

The intended learning outcomes should align with the corresponding level in the Framework for Qualifications in the European Higher Education Area (FQ-EHEA), as well as the applicable national qualifications framework(s).

The nine learning outcomes (annex 2) of the Master of Science in Pharmacometrics are aligned with the core qualifications of master graduates as defined in the European Qualifications Framework (EQF), level 7.

The self-evaluation report demonstrates in Table 1 that the Master of Science in Pharmacometrics programme has sufficiently aligned the learning outcomes with the level descriptors in the Flemish and French-speaking Community Qualification Frameworks. The learning outcomes are structured according to the 5 elements on which the Dublin descriptors were built: knowledge and understanding, applying knowledge and understanding, making judgements, communication skills and learning skills.

The panel has seen sufficient evidence that the learning outcomes are defined at the right level.

2.2.2 Disciplinary field

The intended learning outcomes should comprise knowledge, skills, and competencies in the respective disciplinary field(s).

The panel found a concise but sufficient illustration in the self-assessment report of how the institutions decided on the content of the learning outcomes. The self-assessment report states that students will acquire knowledge on the following topics:

- The pre-clinical and clinical development plan (phases 1 to 4), decision criteria, and assessment by the regulatory agencies.
- Basics in pharmacometrics and notions of compartmental mathematics OR basics in pharmacology and drug development.
- Data handling skills in pharmacometrics.
- Compartmental analyses, PK and PK-PD modelling.
- Pharmacometrics simulation and clinical trial design.

As the master is new in Belgium, domain-specific learning outcomes (DSLO/ in Flanders DLRs = domeinspecifieke leerresultaten) had to be formulated by Flemish law. This was done by experts from the programme. They were reviewed by external experts at the level of the Flemish Higher Education Council (VLUHR) and validated by NVAO. The programme-specific learning outcomes (PSLO) coincide with the DSLOs.

During the preparation of the site-visit and the site-visit itself the panel spent a lot of time on understanding the intented learning outcomes in relation to the programme, the profile of the programme and the choices the programme made. Since the programme chose to use the DSLOs as PSLOs, this inevitably lead to broad intented learning outcomes for the programme. The panel finds this a logical choice, considering the DSLOs where developed by staff of this programme, but by using the DSLOs as the intented learning outcomes, the PSLOs do not reflect any specific choices made by the programme. For example a profile choice or an accent choice.

In learning outcome 5 this is the most visible. In this learning outcome all stakeholders of the professional field are mentioned as equally important stakeholders. Even though the interests of all stakeholders of the professional field are represented in the programme, the panel feels that the programme emphasizes a little on two of those stakeholders. The panel underlines the fact that making this kind of a choice in the programme is perfectly fine to do, but states that the programme could provide more insight into those choices by developing OLRs. Dialogues on this learning outcome were very insightful for both the panel and the programme. Ideas were shared on whether to adjust the programme to meet the domain specific learning outcomes that seem to address the interest of all stakeholders of the professional field equally or formulate more specific programme specific learning outcomes if the programme truly intends to emphasize on two of those stakeholders.

After many constructive discussions on this topic, the panel concluded that the intented learning outcomes are broad but complete and comprise of the relevant knowledge, skills and competencies in the field of pharmacometrics. The panel furthermore concludes that in order to have a full alignment between the PSLO's and the programme, either the PSLO's should be formulated more specific or the programme should be adjusted in order for students and the professional field to have more fine grained expectations of what students will have achieved when completing the programme.

Both options mentioned above are adequate for the panel. However, the panel does have a preference for the programme to develop more specific PSLO's anyway (regardless of any changes in the programme). The panel thinks the programme, (prospective) students and the

professional field will benefit from more specific PSLO's. The panel recommends the programme to do this in one or two years, after they have experienced where the programme naturally evolved to once fully established. This will enable the programme to show via their PSLO's what specific choices they made in the further development of the programme.

2.2.3 Achievement

The programme should be able to demonstrate that the intended learning outcomes are achieved.

A curriculum mapping, table 3 in de self-assessment report, shows how the learning outcomes are achieved. The evaluations (i.e. exams, master's thesis, etc.) will guarantee that the learning outcomes are effectively realized. The programme provides details on the evaluations Section 5.2 of the self-assessment report.

The choice to use the DSLOs as PSLOs resulted in some questions for the panel. This discussion was elaborated on under 2.2.2 disciplinary field. The results of this discussion and the recommendation of the panel do not stand in the way of concluding that the programme is sufficiently able to demonstrate that the intented learning outcomes are achieved.

2.2.4 Regulated Professions

If relevant for the specific joint programme, the minimum agreed training conditions specified in the European Union Directive 2005/36/EC, or relevant common trainings frameworks established under the Directive, should be taken into account.

Not applicable

2.3 Study Programme

The panel assesses the Study Programme standard as compliant.

2.3.1 Curriculum

The structure and content of the curriculum should be fit to enable the students to achieve the intended learning outcomes.

The self-assessment report and the other documents provided to the panel give an extensive overview of the curriculum, its structure and its content.

The master's programme is structured around 4 blocks that follow the logical workflow of constructing a pharmacometric model (the programme illustrates this in figures 2 and 3 of the self-assessment report). The first three blocks will conclude with an integrative group project. In the fourth block the master's thesis is conducted. The programme explains that groups will be diverse, consisting of students with complementary backgrounds to ensure cross-disciplinary learning. Each block is worth 15 ECTS. The majority of courses (total of 57 ECTS) are compulsory, 3 ECTS are offered as elective courses. The elective courses are borrowed from other programmes or students can also choose a university-wide course.

Regular courses are typically taught by mixed teams of lecturers from both universities, who collaboratively develop the syllabus, teach, and evaluate the courses. For the master's thesis, students can choose a topic from various options presented by pharmaceutical companies, consulting firms, hospitals, regulatory agencies, or academic research groups. Each student

will be mentored by a promotor (an expert with a PhD) from either KU Leuven or UCLouvain, who will be supported by a daily supervisor.

The programme provided the panel with thorough and detailed information about all teaching units (TU's) of the programme. The panel thinks the programme is very well structured. The panel qualifies the programme as ambitious. In discussions during the site visit the programme agreed with this. The programme acknowledges that the motivation and autonomy of students is really important for successful completion of the advanced master programme. The programme incorporates a mixture of forms of learning to help students process the content and stay on track. The programme furthermore offers two different courses for students with different academic backgrounds (TU2) to help students get on the same level in either statistics or pharmacokinetics and pharmacodynamics. Students who want or need to follow both can do so. The professional field representatives expressed that they are very pleased to see that graduates from this programme will 1) have hands-on experience, incl. data-set construction and 2) are expected to scope a research question within the spectrum of pharmacometrics techniques and methods available. These two aspects are seen as important skills for future pharmacometricians.

The panel had some interesting discussions with the teaching staff regarding the content of the programme. They discussed the presence of some important topics in the curriculum, such as PBPK and Population PK, whilst at the same time, pointing out that other topics are underrepresented: QSP, the position of modelling in the regulatory assessment of medicines, and machine learning. The programme convincingly showed the panel how they incorporated these topics in the curriculum and explained their thought-process on the design (e.g. integration of knowledge, incorporating an elective course, the attention given to literature reviews) and further expansion of the programme to cover some of these underrepresented topics.

As discussed earlier in this report, the panel had interesting conversations with the management and teaching staff regarding the level of attention in the programme for the different professional careers available to future pharmacometricians. The programme gave insight in their plans to incorporate attention to specific stakeholder (such as regulatory agencies) in for example an elective course. The panel concluded in the end that in order to have a full alignment between the PSLO's and the programme, either the PSLO's should be a little more specific or the programme should be adjusted a little. In both cases the panel advises the programme to do this in close collaboration with the stakeholders (an Advisory Board).

Regarding the master's thesis, the panel had some questions and concerns going into the site visit. The panel was under the impression that students had to deliver an entire master's thesis in the last seven weeks of the programme and felt this was not a sufficiently long period of time to deliver something of quality. During the site visit the panel learned that the set-up of the master's thesis is different: students choose their topic in the beginning of the programme (week 4) and work on their thesis throughout the entire year (workload for this is accounted for in the programme). This allows the students to put into practice what they have learned during the classes. The last nine week are fully dedicated to the master's thesis. The panel was reassured by this set- up and feels it is adequately designed. They are positive about the idea to integrate the master's thesis in the entire programme. The panel advises

the programme to be more clear in the communication to students on this specific set- up of the master's thesis.

The panel concludes that the structure of the programme is well-thought-out and well organized. The panel praises how the programme reflects the joint efforts in designing (and executing) this programme.

2.3.2 Credits

The European Credit Transfer System (ECTS) should be applied properly and the distribution of credits should be clear.

Both universities adhere to the European Credit Transfer System (ECTS). The curriculum spans two semesters and 60 ECTS. The programme consists of 57 ECTS of mandatory courses (including the master's thesis) and 3 ECTS of electives. The mandatory courses include 31 ECTS of regular classes, 11 ECTS of integrative work, and 15 ECTS for the Master's thesis.

2.3.3 Workload

A joint bachelor programme will typically amount to a total student workload of 180-240 ECTS-credits; a joint master programme will typically amount to 90-120 ECTS-credits and should not be less than 60 ECTS-credits at second cycle level (credit ranges according to the FQ-EHEA); for joint doctorates there is no credit range specified. The workload and the average time to complete the programme should be monitored.

The joint Master of Pharmacometrics consists of 60 ECTS credits. At KU Leuven each ECTS credit represents an average of 25 to 30 hours of total learning activities, resulting in a total workload of 1500 to 1800 hours. At UCLouvain, each credit corresponds to 30 hours of learning activities. In both cases, this includes not only classroom instruction and exercises but also all student-related activities for each course, such as practical work, personal exercises, assignments, projects, studying, research, exams, and any professional immersion. Thus, the two approaches from KU Leuven and UCLouvain are quite consistent.

After reviewing the self-assessment report and accessory documentation, the panel decided to discuss the workload of the students with the programme representatives. The panel felt the workload could possibly be high for students. Therefore, the panel was curious on how the institutions (management, students and teaching staff) reflect on the workload for the programme, what systems the institutions have in place for students who fall behind and how the workload will be monitored in the coming years.

The panel understood from the dialogue with the students that they are not worried about the workload. They feel the programme is well structured and that the workload meets their expectations. During the discussions with the teaching staff and management the panel learnt that the programme is considered "full but balanced" and that even though it asks a lot of students, the staff strongly believes it is feasible. This believe is based on their careful consideration of the number of ECs when designing the courses. The programme ensures a fast notice of students who might fall behind, because of the many formative feedback moments incorporated in the programme.

The panel learnt via the self-assessment report and the discussions at the site visit, that the effective workload of the programme for the students is monitored via the joint Steering

Committee (in which students are represented). Possible problems (e.g. organizational difficulties, possible overloads, etc.) can immediately be signalled and possible solutions at the programme level be proposed and implemented. The Steering Committee also monitors the percentage of students who finish the programme in the expected year.

Furthermore, the panel learnt that online student evaluations will be conducted. In this system the students are asked to complete a questionnaire on each of the courses in a programme at least once every six years and this questionnaire includes questions on the workload. Leading up to the site visit, the panel had concerns regarding the (high) workload for students and the monitoring thereof. After constructive discussions during the site visit, the panel is convinced that the programme will carefully measure and monitor the workload for students, specifically during the first year(s) of the programme. The panel underlined the importance of monitoring the workload of students and was pleased to learn that the programme will take this seriously.

2.4 Admission and Recognition

The panel assesses the Admission and Recognition standard as compliant.

2.4.1 Admission

The admission requirements and selection procedures should be appropriate in light of the programme's level and discipline.

Only students holding a master's degree will be admitted to this advanced master. Depending on the diploma the admission is either direct or subject to evaluation by the admissions committee. Directly admissible are students with a (Belgian or European) master's degree in Pharmacy, Biomedical Sciences. Medicine or Veterinary Medicine. Subject to the evaluation of the admissions committee are students with a master's degree in Pharmacy, Biomedical Sciences, Medicine or Veterinary Medicine obtained at a non-European institution and students with a master's degree (bio-)Engineering, Biology, Chemistry, Statistics, Epidemiology, Mathematics, Physics or any other related discipline. Candidates must submit an explanatory dossier to UCLouvain, which should include a comprehensive academic curriculum (previous degrees, transcript, ranking, etc.) along with a motivation letter. If needed, the admissions committee may ask to discuss candidates' motivations further. A preparatory programme for up to 60 ECTS might be imposed.

After studying the self-assessment report the panel had some questions regarding the preparatory programmes for students who are not directly admissible. The panel wondered who would be offering these programmes and how students can follow these programmes. The panel understood that these programmes are not to be developed, but will consist of existing courses offered by both institutions. For the panel that raised a serious concern, since a lot of those courses are not taught in English. The programme explained that students are also able to follow preparatory courses at other universities. Staff from the master programme will decide on what is needed as preparation for the master programme. This will ensure a wide range of possibilities for students who want to enter the advanced master programme.

Furthermore, the panel learnt during the site-visit that students who need up to 15 EC extra courses can follow these preparatory courses whilst already in the master programme. The

panel has some concerns about this set- up, since the master programme already comes with a heavy workload.

The panel found all admission modalities clearly described and finds the policy on preparatory programmes adequate. The panel does however advise the programme to carefully consider the set-up of these preparatory programmes. The panel feels it would benefit the student to consider offering summer schools for example, instead of offering extra courses during the programme itself. Furthermore, the panel advises to monitor the workload for students who are obliged to follow extra courses during the programme.

2.4.2 Recognition

Recognition of qualifications and of periods of studies (including recognition of prior learning) should be applied in line with the Lisbon Recognition Convention and subsidiary documents.

The panel has no doubts on the procedures in place to grant recognition of prior learning and/or qualifications. The panel concludes, based on the information provided in the self-assessment report, that the recognition of qualifications and periods of studies will be applied according to the Lisbon Recognition Convention.

Students can apply for an exemption for a course given previous studies and/or work experience. For applicants from outside Belgium, the programme realizes that comparability of the diploma is not always easily established. The panel concludes that for these applicants the programme has a sufficient procedure in place to value the admissibility.

2.5 Learning, Teaching and Assessment

The panel assesses the Learning, Teaching and Assessment standard as compliant.

2.5.1 Learning and teaching

The programme should be designed to correspond with the intended learning outcomes, and the learning and teaching approaches applied should be adequate to achieve those. The diversity of students and their needs should be respected and attended to, especially in view of potential different cultural backgrounds of the students.

The panel has studied the programme outlines for the Master of Science in Pharmacometrics in detail and finds that the programme uses a variety of teaching methods aiming at reaching the learning outcomes in an efficient way. The various teaching methods employed are lectures, practical work, teamwork projects, reporting tasks, presentations, demonstrations, and seminars. The curriculum is structured into three course blocks, each including integrative work, and one block dedicated to the master's thesis. The panel finds that the integrative work in each block is a strong feature, fostering collaboration and applied learning. Students are encouraged to apply their knowledge and skills in professional-like scenarios and the panel strongly agrees with this didactical view. A detailed overview of the teaching methods for specific courses is provided by the programme in annex 4 of the self-assessment report and the details appear adequate in relation to the objectives set.

The panel had interesting discussions with the teaching staff and management with regard to the possibility for students to choose their own modelling software. At first, the panel had some concerns on how this would be supported and guided by the teaching staff. The panel

learnt that the teaching staff is not only able to do so, but does this from a very strong vision on learning to use modelling software. The programme aims to provide students with freedom to choose and to not only expose them to one tool. The programme finds it extremely important that students will be able to bridge between different software tools, stating “a tool is just a tool, they should be able to transport their knowledge and skills from one tool to another”. The panel finds this a very strong, albeit ambitious, vision for this programme.

The panel discussed the possibility of offering the programme blended with the teaching staff. The panel finds it positive that the programme intends to record all the lessons to facilitate online course participation in the future.

The didactical team selects the most suitable teaching methods to effectively achieve the learning outcomes. The Steering Committee reviews all teaching proposals to ensure alignment with these outcomes.

With regard to the master’s thesis, topics for the master’s thesis will be presented at the start of the year. Topics will be provided by university research units, pharmaceutical industry, hospitals or regulatory agencies. The panel learnt that students choose their topic from a list of proposals. The dialogue of the panel with management and teaching staff was instructive to understand how the master’s thesis is set up (see also 3 – Study Programme).

2.5.2 Assessment of students

The examination regulations and the assessment of the achieved learning outcomes should correspond with the intended learning outcomes. They should be applied consistently among partner institutions.

The evaluation process for the Master of Science in Pharmacometrics is integrated into the broader evaluation policies of KU Leuven and UCLouvain. At KU Leuven, the Louvain Learning Lab supports the development of assessments that align with learning outcomes, offering both technical and pedagogical guidance for various assessment methods, including traditional exams and innovative tools like portfolios and peer reviews. A range of evaluation formats will be used to assess knowledge, communication, and research skills, ensuring a fair experience for all students. The panel finds the assessment of students to be complete and underlines the importance of transparency as stated by the programme.

The Steering Committee oversees the evaluation methods to ensure they are appropriate and varied. Clear criteria for pass/fail boundaries, transparency, and feedback opportunities are prioritized at the individual course level. The exam format and criteria are communicated to students via the ECTS file and Moodle at the start of the semester.

Feedback is emphasized to help students improve throughout the semester, particularly regarding integrative work and the master’s thesis. The panel finds the emphasis on formative feedback a strong feature of the programme. The evaluation methods for the programme are outlined in a table, showcasing various formats for different courses, from written and oral exams to presentations and practical assessments.

For the master's thesis, students select topics early in the academic year and are guided by a supervisor and a daily assistant. The final score is based on evaluations of the thesis,

presentation, and overall process, assessed by a jury that includes the supervisor and an external expert. Each component is graded on a scale of 3 to 10, and discrepancies in scores are discussed by the jury. The thesis evaluation focuses on aspects such as the introduction, hypothesis, methodology, results, discussion, conclusion, layout, and writing skills. For presentations, students are assessed on communication skills, question responses, and their professional attitude. The combined scores from these evaluations determine the final grade for the thesis. The panel finds the thesis assessment to be adequately designed.

2.6 Student Support

The panel assesses the Student Support standard as compliant.

The student support services should contribute to the achievement of the intended learning outcomes. They should take into account specific challenges of mobile students.

The panel has learnt that UCLouvain, as the coordinating university for the Master of Science in Pharmacometrics, will provide daily student support services. To address the diverse needs of students, a video summarizing available information will be shared at the start of the academic year, alongside an introductory session for new students. This session will help students connect with one another and learn about the programme 's structure, key contacts, and available facilities. New students will also receive a brief tour of the campuses.

While UCLouvain will lead student support, KU Leuven will also offer assistance at the Gasthuisberg campus. KU Leuven provides relevant information and access to the Student Health Center for well-being and health-related issues. A student counselor will be available at UCLouvain, and lecturers will be easily approachable (due to the limited number of students). International students can receive help with administrative issues from the International Offices of either university. The panel is positive about all the support students are able to receive at both campuses. The dialogue with the supporting staff has shown the panel that the programme will be supported by professionals from both institutions who are clearly used to working together.

The programme will be structured to ensure students have full days of classes at both campuses 2 days at KU Leuven and 2 days at UCLouvain, minimizing commuting challenges. Various transportation options are available for convenient travel between KU Leuven and UCLouvain. The panel has some questions regarding international mobility and after discussing the topic learnt that students who would like to gain some international experience can do so in the last nine weeks of the programme, for example via the Erasmus+ programme.

The panel concludes that there are well established systems in place for supporting students. Both institutions work together in such a way that students will experience the support provided as coming from one team.

2.7 Resources

The panel assesses the Resources standard as compliant.

2.7.1 Staff

The staff should be sufficient and adequate (qualifications, professional and international experience) to implement the study programme.

The range of staff specializations is wide enough to address all the programme's learning outcomes. The teaching staff comprises highly knowledgeable academics who are experts in their respective fields, which greatly enhances the Master of Science in Pharmacometrics programme. Staff members have been selected based on their expertise and qualifications as to research and teaching. The CV's of 6 academic staff members from UCLouvain and of 5 academic staff members of KU Leuven are provided. The teaching staff is involved in academic research, publishes in international journals, participates in international conferences, and has membership in international research networks, editorial boards and/or programme committees of international conferences. During the site visit, the panel learnt that the programme intends to attract a wide range of guest lecturers.

The self-assessment report stated that exercises and practical sessions and daily guidance of master's theses will be provided by teaching assistants, mostly PhD students involved in the research units of the staff members. This raised some concerns with the panel, mainly because of the workload for PhD students. During the site visit, the panel therefore discussed the composition of the teaching staff, the ratio between professors and teaching assistants (mostly PhD students) and their workload. The panel learnt that PhD students get a limited amount of teaching hours (120 hours per year) and that the institutions monitor and uphold this well. Furthermore, the panel learnt that a post-doc at UCLouvain (0,5 FTE for the academic year 2024-2025) will support the mounting of the master and will help developing the educational material, and that UCLouvain will attract a teaching assistant dedicated to the programme who will be appointed for six years and who will be the main point of contact for students.

The programme explained in the self-assessment report that UCLouvain as coordinating institution, will ensure the administrative support of the programme, such as enrolling students in courses, scheduling teaching activities and exams, supporting evaluation activities, facilitating quality assessment procedures, helping to promote the programme, and providing information for the students. Similar services will be organized at KU Leuven for the courses depending on this institution. The discussions with the management and supporting staff convinced the panel that the professionals involved in this programme are very capable of supporting the programme.

The panel agrees that staff involved in the programme are highly qualified, with experience in both academia and industry. Some of the staff have an extensive track record in the field and are widely recognized for their expertise. The panel also appreciates the collaboration between the staff from both partner universities in developing the programme and their active involvement in delivering various teaching units. The panel is reassured that the programme will monitor and uphold the staff workload.

2.7.2 Facilities

The facilities provided should be sufficient and adequate in view of the intended learning outcomes.

As to infrastructure, the programme has access to the lecture rooms, auditoria at the campuses of KU Leuven and the campuses of UCLouvain, which guarantees that all activities can be scheduled. The programme will be designed and organised so that students will have

classes 2 days at KU Leuven and 2 days at UCLouvain. In this way students don't need to change campus the same day. The panel appreciates this set up.

The e-learning platform that will be used is Moodle. This is the e-learning platform of UCLouvain. Moodle supports a very wide range of e-learning to enhance the education experience for both students and faculty. Moodle also can be used by the KU Leuven teachers. The panel agrees with the programme on the importance of using one e-learning platform for all students and staff involved in order to strengthen the jointness of the programme.

Students will have access to the digital and physical libraries of both institutes. Through the library services, the students will be able to access all electronic databases of both institutes, not only on site but remote as well.

The programme explained in the self-assessment report that students will need their own laptop but will be provided with access for the required software and programs. This raised some concerns with the panel regarding data protection and licensed software. After discussing these issues with management, students, teaching staff and supporting staff, the panel concludes that the programme has sufficiently thought these issues through. This includes the use of simulated and/or synthetic data, the attention for data protection in the curriculum, the support for students with installing software, facilitating students with laptops to borrow and the availability of computer rooms.

2.8 Transparency and Documentation

The panel assesses the Transparency and Documentation standard as compliant.

Relevant information about the programme like admission requirements and procedures, course catalogue, examination and assessment procedures etc. should be well documented and published by taking into account specific needs of mobile students.

As the coordinating university for this program, UCLouvain will offer general information on its website, covering topics such as registration, study paths, exams, diplomas and certificates, as well as the educational vision and policies at UCLouvain.

The Consortium agreement includes relevant and detailed information on the diverse aspects of the collaboration of the partner universities for the organisation of the programme. Detailed program-specific information will be available in the online programme description within the programme catalog. This description will not only outline the standard study path and curriculum but also provide contact information for the programme and Study Advice Services. Other relevant documents, such as the exam regulation, complete essential information for students.

UCLouvain utilizes mailing lists and Teams, in addition to Moodle, to facilitate communication between students and teaching or administrative staff. Students also have access to My UCLouvain, a virtual portal where they can view their Individual Study Programme (ISP), class schedules, and Individual Examination Schedules (IES). This portal includes the student's academic progress file (SVD).

While UCLouvain is the coordinating institution, KU Leuven will also feature information about the Master in Pharmacometrics on its website. The Faculty of Pharmaceutical Sciences will create a dedicated webpage in both English and Dutch, providing all necessary information and links. Registration will be redirected to the UCLouvain website. The panel discussed the two websites with the supporting staff, addressing concerns about the potential for inconsistent information between them. The supporting staff explained that the UCLouvain website will be the main source of information and the KU Leuven website will mainly function as a portal to the UCLouvain website. All information will be provided in English. The panel concludes that both institutions have sufficient experience in ensuring that the information provided will be consistent.

2.9 Quality Assurance

The panel assesses the Quality Assurance standard as compliant.

The cooperating institutions should apply joint internal quality assurance processes in accordance with part one of the ESG.

The self-assessment report explains that UCLouvain's quality assurance method will be applied to the Master of Science in Pharmacometrics. Every six years, UCLouvain must report on its teaching quality system to the Agence pour l'Évaluation de la Qualité de l'Enseignement Supérieur (AEQES), which evaluates higher education programmes in the Wallonia-Brussels Federation. UCLouvain's quality assurance is structured at multiple levels: faculty, programme, and course levels.

The Cooperation Agreement explains the three levels of quality assurance as follows. At the faculty level, each faculty conducts a self-evaluation of its programmes every six years using the EFaQ methodology, aligned with European Standards and Guidelines (ESG). At the programme level, each programme undergoes a student evaluation survey every six years, with committees of faculty and student representatives meeting each semester to monitor the programme. Programme managers receive training and support to enhance collective accountability for quality. At the course level, standardized student evaluations occur at least every six years. Members of teaching staff are encouraged to improve their teaching through training and support, and their teaching efforts are considered in career promotions alongside research contributions.

The Cooperation Agreement furthermore states that the Steering Committee will be responsible for quality assurance with respect to the programme. The Steering Committee oversees and coordinates the self-evaluation process for external evaluations and manages the evaluations at both programme and course levels.

The panel asked for more information than initially provided on the quality assurance to get a better understanding of the systems in place. Specifically with regard to the initial phase of the programme. The panel wondered if there would be any additional quality assurance instruments used to monitor the quality of the programme in the first years of executing the programme. The panel received an additional quality assurance policy document. Furthermore the panel discussed the quality assurance policy with both management, students, teaching staff and supporting staff during the site visit.

The panel learnt that even though the quality assurance policy of UCLouvain is the leading policy, the programme added some important parts of the quality assurance policy of KU Leuven. This specifically counts for the evaluation policy and instruments regarding evaluations in the first year(s). The panel is very pleased to have heard that the programme will put extra effort into conducting surveys, student hearings and other evaluations in the first year(s) of the programme being implemented.

The panel is convinced that the programme combined the strong parts of the individual quality assurance policies of both institutions to develop a quality assurance policy that will benefit the programme the most. According to the panel, this evidently demonstrates the added value of working together in a joint degree.

3 Final judgement

The panel is positive about the advanced Master of Science in Pharmacometrics that is proposed as a joint, English taught programme by the two partner universities. There is no doubt that the programme satisfies all standards of the framework for the European Approach for Quality Assurance of Joint Programmes.

The panel is very enthusiastic about the programme and the engaging conversations they had with all stakeholders during the site visit. The panel gained a clearer understanding of its purpose, particularly how the joint efforts of the two institutions create a truly collaborative environment for this joint advanced master's degree. The panel concluded that the programme contains a lot of strong aspects.

To start, the structure of the programme is very well-designed. The panel appreciates the integrated group work, incorporated in the curriculum. Also the set-up of the master's thesis, which is integrated in the entire curriculum, is a strong feature. The assessment methods are comprehensive and diverse, with a strong emphasis on feedback, which is greatly appreciated. The student panel was confident in and enthusiastic about the programme. They trust the workload and set-up, finding it feasible and manageable.

The panel finds the content of the curriculum to be adequate and inspiring. They specifically value the clear vision regarding software-agnostic learning coupled with hands-on practice with selected tools/ software within the curriculum. The vision that students should be able to transport their knowledge and skills from one tool to another, is greatly appreciated. The panel is confident that the programme aligns with the right vision for future developments.

Additionally, the faculty is highly qualified and motivated, contributing significantly to the programme's success. Some of the staff have an extensive track record in the field and are widely recognized for their expertise. The panel agrees with the programme in installing a dedicated point of contact for students and supports the aim to attract a wide range of guest lecturers. The panel also appreciates the collaboration between the staff from both partner universities in developing the programme and their active involvement in delivering various teaching units. The panel is reassured that the programme will monitor and uphold the staff workload.

Regarding the Quality Assurance (QA) system, the panel praises the merging of the best practices from both institutions, creating a robust framework for continuous improvement. According to the panel, this evidently demonstrates the added value of working together in a joint degree. The panel is very pleased with the extra effort the programme will put into conducting surveys, student hearings and other evaluations in the first year(s) of the programme being implemented.

The panel has nevertheless formulated a number of recommendations that could help the institutions to fine-tune their programme.

In order to establish structural input from external stakeholders, the panel advises to establish an advisory board that includes a complete range of external stakeholders, including the pharmaceutical industry, contract research organisations, academia, university hospitals

and regulatory agencies. Their insights could greatly benefit both the Steering Committee and the programme overall.

Furthermore, the panel thinks the programme and (prospective) students will benefit from more specific PSLO's and therefore advises the programme to develop these. The panel recommends the programme to do this in one or two years, after they have experienced where the programme naturally evolved to. This will enable the programme to show via their PSLO's what specific choices they made in the further development of the programme.

The panel also recommends, in line with the programme's intentions, to closely monitor the workload for the students, as the programme is expected to be heavy.

The panel also suggests the programme to consider offering the preparatory programme in different formats, such as summer schools, to enhance accessibility.

The last recommendation of the panel focusses on the communication regarding the master's thesis set up. The panel advises the programme to improve the communication regarding the master's thesis process to ensure clarity and support for students.

Regardless of these recommendations, the panel confirms it is very positive and enthusiastic about the quality and expected added value of the advanced Master of Science in Pharmacometrics.

4 Assessment procedure

The assessment was carried out in line with the 'Framework for the European Approach for Quality Assurance of Joint Programmes – November 2020'.

The panel prepared itself for the assessment on the basis of the Self-Assessment Report and annexes submitted by the institutions when applying for initial accreditation. Prior to the preparatory meeting of the panel, each panel member formulated initial impressions and questions to be discussed. During the preparatory online meeting on Wednesday 25 September 2024, the panel discussed all information received with the application and also prepared the dialogue with the programme. Impressions and questions were collected and merged into a document before the dialogue with the institutions.

The dialogue took place on 1 and 2 October 2024. The dialogue took place on the Gasthuisberg campus of KU Leuven. The dialogue included discussions with representatives of both cooperating institutions.

During the dialogue the panel investigated the context of the joint programme and the institutions and collected all required information to make a judgement on the quality of the joint programme.

During a closed meeting of the panel on 2 October 2024 the panel discussed all information obtained and translated it into a judgement per standard and for the programme as a whole. The panel took this conclusion in full independence.

All information obtained led to a draft assessment report that has been sent to all panel members. The feedback from the panel members has been processed. The assessment report adopted by the chairperson was submitted to NVAO on 10 October 2024.

5 Overview of the assessments

The panel presents their assessments per standard, as outlined in chapter 2.

Standard	Assessment
1 Eligibility	Compliant
2 Learning Outcomes	Compliant
3 Study Programme	Compliant
4 Admission & Recognition	Compliant
5 Learning, Teaching & Assessment	Compliant
6 Student Support	Compliant
7 Resources	Compliant
8 Transparency & Documentation	Compliant
9 Quality Assurance	Compliant
Programme as a whole	**Positive**

Annex 1: General information on the programmes

Institutions	• UCLouvain • KU Leuven
Addresses, institutions websites	Place de l'Universite 1, 1348 Louvain-la-Neuve https://uclouvain.be/en/index.html Oude Markt 13, 3000 Leuven https://www.kuleuven.be/english
Degree, qualification of the degree, specification of the degree	Master of Science in Pharmacometrics (Advanced master)
(Additional) title	N.A.
(Parts of) field of study(s)	Pharmaceutical Sciences ISCED: 0916 Pharmacy
Specialisations	N.A.
Programme routes	N.A.
Locations where the programme is offered	UCLouvain Campus Brussels Woluwe, Avenue Emmanuel Mounier 50, 1200 Woluwe-Saint-Lambert KU Leuven Campus Gasthuisberg, Herestraat 49, 3000 Leuven
Teaching language	English
Study load (in credits)	60 EC

Annex 2: Programme-specific Learning Outcomes

The Master in Pharmacometrics:

1. has in-depth knowledge and understanding of the concepts of pharmacokinetics and pharmacodynamics, and the interrelationships with human biology, disease mechanisms and pharmacology.
2. has knowledge and understanding of the statistics and mathematics underlying the pharmacometric modelling of complex data to answer pharmacological questions.
3. has knowledge and understanding of the methods and software tools used in the field of pharmacometrics.
4. applies statistical/mathematical language, pharmacometric tools and methods to specific problems.
5. translates results of pharmacometrics modelling and simulations correctly into actionable insights, recommendations and decisions that can be used in drug discovery, development, regulatory and clinical care.
6. is able to independently scope a pharmacological project, (re-)formulate the critical pharmacometric questions, define the workflow and perform the project on the basis of the knowledge and skills acquired.
7. communicates audience-tailored, orally and in writing, in an appropriate and effective manner to diverse stakeholders.
8. participates constructively in an international team and in interdisciplinary activities in the different phases of drug development on the basis of acquired expertise, including in decision making.
9. demonstrates the scientific curiosity and competences to independently continue to study developments in the field of pharmacometrics.

Annex 3: Composition of the panel

The composition of the panel that assessed the quality of the Master of Science in Pharmacometrics of UCLouvain and KU Leuven was as follows:

Prof. dr. Yvette Michotte (*chair*), emeritus professor in Pharmaceutical Sciences, former vice rector educational policy Vrije Universiteit Brussel, Belgium;

Prof. dr. Jean-Baptiste Woillard (*panel member*), Professeur/Praticien Hospitalier Pharmacologie, CHU de Limoges, France;

Prof. dr. Pieter Colin (*panel member*), Associate professor and senior pharmacometrician University Medical Centre Groningen, seconded to Scientific Advice Office European Medicines Agency, The Netherlands;

Léa Le Bars (*student*), MSc. in Biology – major systems biology, Swiss student union (VSS-UNES-USU) - Responsable QA & accreditation, Switzerland.

The panel was assisted by:

- **Dagmar Provijn**, policy advisor Flanders NVAO, process coordinator;
- **Lisette Sandifort-Meijer, MSc,** secretary.

All panel members and the process coordinator/secretary have signed NVAO's code of deontology.

Annex 4: Schedule of the site visit

The site visit by the panel to the programme was conducted on 1 and 2 October 2024 as part of the external assessment procedure regarding the Master of Science of Pharmacometrics of UCLouvain and KU Leuven. The schedule was as follows:

1 October 2024 and 2 October 2024

Time	Meeting
Tuesday 1 October 2024	
13.00 – 14.00	Session 1: programme management (+ faculty management)
14.30 – 15.30	Session 2: students
16.00 – 17.00	Session 3: (alumni and) professional field
17.30 – 18.30	Session 4: teaching staff
Wednesday 2 October 2024	
09.00 – 10.00	Session 5: supporting staff
10.30 – 11.00	Session 6: programme management
14.30 – 15.00	Closing dialogue between panel and programme representatives

Annex 5: Documents reviewed

During the site visit the programme management presented the following documents:

Information file

- Self-Assessment Report

Mandatory annexes to the information file

- Cooperation agreement, including annexes
- Course syllabi of all partners
- Academic staff CVs (all partners)
- Overview of the teaching methods used in the different courses
- Assessment scale for the master's thesis evaluation

Documents made available during or leading up to the dialogue

- Modules Advanced Clinical Drug Development with a Focus on Pharmacometrics – KU Leuven
- Conference posters – KU Leuven Pharmacometrics
- Conference posters – UCLouvain
- Doctoral theses – KU Leuven Pharmacometrics
- Doctoral theses – UCLouvain
- MSc Pharmacy advanced PK elective course – UCLouvain
- Master theses – KU Leuven Pharmacometrics
- Master thesis Modeling – UCLouvain
- Pharmaceutical Medicine – MIDD – KU Leuven
- Publications – UCLouvain Pharmacometrics
- Publications (selected) – KU Leuven Pharmacometrics
- Quality Assurance System UCLouvain
- TU1 Drug Life Cycle – KU Leuven
- TU2a Concepts of Multilevel, Longitudinal and Mixed Models – KU Leuven

Annex 6: List of abbreviations

AEQES	Agence pour l'Évaluation de la Qualité de l'Enseignement Supérieur
DSLO	Domain-specific learning outcomes (domeinspecifieke leerresultaten)
ECTS	European Credit according to the European Credit Transfer and Accumulation System
ESG	European Standards and Guidelines
IW	Integrative Work
KU Leuven	University of Leuven / Katholieke Universiteit Leuven
NVAO	Accreditation Organisation of the Netherlands and Flanders (Nederlands-Vlaamse Accreditatieorganisatie)
PSLO	Programme-specific learning outcomes (Opleidingsspecifieke leerresultaten)
TU	Teaching Unit
UCLouvain	Université catholique de Louvain

The panel report has been ordered by NVAO for the initial accreditation of the Master of Science in Pharmacometrics of UCLouvain and KU Leuven according to the Framework for the European Approach for Quality Assurance of Joint programmes.

Colofon

Master of Science in Pharmacometrics
UCLouvain and KU Leuven (VL131215-24)
Initial accreditation • Panel report
10 October 2024
Composition: NVAO • Vlaanderen

Nederlands-Vlaamse Accreditatieorganisatie
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