

## Course analysis (course evaluation)

<b>Course code</b> 4FF011	<b>Course title</b> GCP and Clinical Pharmaceutical Trials	<b>Credits</b> 3.5
<b>Semester</b> HT25	<b>Period</b> 250918-251003	
<b>Course coordinator</b> Duarte Ferreira		<b>Examiner</b> Gunnar Schulte
<b>Teacher in charge of component</b>		<b>Other participating teachers</b> Anders Hellgren, Mikael Åström
<b>Number of registered students during the three week check</b> 26	<b>Number approved on the last course date</b> 26	<b>Response frequency course valuation survey</b> 76,92%
<b>Other methods for student influence</b> (in addition to concluding course valuation) Email contact with the course coordinator; in class Q&A; feedback during presentation session.		
<b>Feedback reporting of the course valuation results to the students</b> Shared with Education Committee and Programme Coordinating Committee		

### Note that...

The analysis should (together with a summarising quantitative summary of the students' course valuation) be communicated to the education committee at the department responsible for the course and for programme courses also the programme coordinating committee.

The analysis was communicated to the education committee on the following date: 2025-12-10

### 1. Description of any conducted changes since the previous course occasion based on the views of former students

Compared with HT24, we clarified the learning outcomes and the assessment criteria, presenting these explicitly at the start of the course as well as available on Canvas. We streamlined lectures and teaching material to screen for Swedish phrasing and ensuring consistent use of ICH GCP and Declaration of Helsinki terminology across all materials. Also, the exam was proof read by different teachers to avoid Swedish terms and promote fairness. We kept the five minute presentation format with mandatory peer questions, as this continued to promote engagement and fairness across groups.

### 2. Brief summary of the students' valuations of the course

Students' overall impressions of the course were very positive. They described the learning environment as welcoming and respectful, and they consistently found the coordination and lecturing approachable and engaging. In quantitative terms, inclusion and respect received the

highest ratings (mean about 5.8/6), and students felt that the course activities were well aligned with the intended learning outcomes and grounded in current research (both around 5.6/6). Overall course quality was also rated highly (about 5.4/6), and students reported a strong sense of responsibility for their own learning (about 5.6/6). Organisation was appreciated (about 5.4/6), although several students noted that the immediate sequence of the written exam followed by presentations made the end of the course feel compressed. At the same time, students asked for more opportunities to practise and apply concepts in interactive formats. While the presentation assignment was considered useful and motivating, some learners felt that parts of the online component were too passive and requested additional workshops or case-based activities. A recurring theme in comments concerned assessment calibration: a number of respondents perceived that the practice questions were easier than the written exam and asked for clearer guidance on the expected level of specificity (conceptual understanding versus precise ICH GCP/Declaration of Helsinki references). Several students also expressed interest in a little more support with statistics, and a clearer, more explicit connection between sustainable development and contemporary GCP practices (e.g., remote monitoring, e consent, data stewardship).

### **3. The course coordinator's reflections on the implementation and results of the course**

***Strengths of the course:*** The course continues to be characterised by strong engagement and a positive learning climate. Students describe the environment as inclusive and respectful, and they perceive the lecturing and coordination as approachable and knowledgeable. The combination of a written exam and a concise group presentation seems to triangulate knowledge, reasoning, and application effectively; the time limit and peer question requirement sustain attention and accountability. The preparatory structure (online self study and complemented by a practice exam seminar) supports foundational learning before on campus consolidation with live lectures, exam and oral presentations.

***Weaknesses of the course:*** Several respondents wished for more hands on activities during taught sessions, such as applied statistics or additional case based work. A recurring theme concerned assessment calibration: some felt that mock questions were easier than the actual exam and requested sharper guidance on the expected specificity (conceptual mastery versus precise citation of ICH GCP/DoH clauses). The sequence of exam followed by presentations made the end of the course feel intense for a subset of students. In addition, there were requests for a little more statistics support and a more explicit connection between sustainable development and contemporary GCP practice, including remote monitoring, e consent, and data protection.

### **4. Other views**

**5. Course coordinator's conclusions and any suggestions for changes**

For HT26 we will retain the overall structure, but we will deepen applied learning and sharpen assessment transparency. A new short workshop will be introduced about protocol synopsis in which small groups design a Phase II synopsis and receive rapid feedback. To align preparation with what is examined, we will expand the practice question bank with difficulty mirroring the real exam and with full rationales.

Where feasible in the timetable, we will separate the written exam and the group presentations by at least twenty four hours. To address statistics needs, we will provide an asynchronous "Stats Booster Pack" containing worked examples, a concise formula sheet, and ten practice MCQs, followed by a brief live Q&A. Finally, we will integrate a short sustainability micro lecture explicitly linking risk based monitoring, decentralised elements such as e-consent and tele visits, and data protection to current GCP revisions.

**Appendices:**