GÖTEBORG UNIVERSITY **COURSE PLAN MSA620**
Faculty of Sciences
Mathematical Sciences

MSA620, DESIGN AND ANALYSIS OF CLINICAL TRIALS, 7.5 credit points

Level: advanced

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1. Authorisation.
The course plan has been authorised by the vice-dean of the Department of Mathematical Sciences on November 09, 2006, to be valid from the same date.

Educational field: Mathematical Sciences

2. Educational context.
The course is part of the Master Program in Mathematical Sciences. It is also open for students outside the program who meet the course prerequisites.

3. Prerequisites.
Calculus-based probability and mathematical statistics will be used throughout. Many area of statistical inference can be useful in the context of clinical trials (categorical methods, linear models, mixed models, survival analysis etc). Because of that, the more knowledge the student have the better he or she will be able to assimilate the content of this course. Minimum requirement is MSG500 Statistical linear models.

4. Learning outcomes
The student shall be familiar with common study designs in clinical trials and explain their rational.
The student shall know what statistical analysis that are appropriate for the different designs covered in the course and be able to perform them using software packages.

5. Course description.
The clinical trial protocol, sources of bias in clinical trials, blinding, randomization, sample size calculation; design and analysis of phase I, phase II, phase III and hybrid trials; interim analysis, non-inferiority studies; stochastic curtailment, Bayes designs, and administrative issues in study design.

6. Literature.
Design and Analysis of Clinical Trials: Concepts and Methodologies (Wiley Series

in Probability and Statistics) (Hardcover) by Shein-Chung Chow, Jen-Pei Liu plus some handouts.

7. Assessment.
Home assignments and written final examination

8. Grades.
The grade levels are Fail (U), Pass (G), and High Pass (VG). A wish for an ECTS grade should be reported to the examiner at the beginning of the course.

9. Course evaluation.

In the middle of the course the teacher arranges an oral feedback discussion with the students. At the end of the course the students are asked to answer an internet based questionnaire. The results of the questionnaire will be processed by the lecturer together with student representatives.

10. Additional information.