505-964 Advanced Clinical Trials

Credit Points:	12.500
Level:	Graduate/Postgraduate
Dates & Locations:	2008, This subject commences in the following study period/s: Semester 2, - Taught on campus. Distance
Time Commitment:	Total Time Commitment: 8-12 hours total study time per week
Prerequisites:	505-105 Mathematics Background for Biostatistics 505-106 Epidemiology 505-107 Principles of Statistical Inference 505-939 Design of Experiments & Clinical Trials 505-940 Linear Models 505-975 Probability and Distribution Theory
Corequisites:	None
Recommended Background Knowledge:	None
Non Allowed Subjects:	None
Core Participation Requirements:	For the purposes of considering request for Reasonable Adjustments under the Disability Standards for Education (Cwth 2005), and Student Support and Engagement Policy, academic requirements for this subject are articulated in the Subject Overview, Learning Outcomes, Assessment and Generic Skills sections of this entry. It is University policy to take all reasonable steps to minimise the impact of disability upon academic study, and reasonable adjustments will be made to enhance a student's participation in the University's programs. Students who feel their disability may impact on meeting the requirements of this subject are encouraged to discuss this matter with a Faculty Student Adviser and Student Equity and Disability Support: http://services.unimelb.edu.au/disability
Coordinator:	MEGA Centre
Subject Overview:	Methods in RCTs for determining: stopping rules for interim analysis (O'Brien-Fleming, Peto), spending functions, stochastic curtailment; statistical principles encountered in relation to aspects of regulatory guidelines (ICH, FDA, EMEA), and related to reports prepared for data safety and monitoring committees (DSMC); design and analysis of cross-over trials (period effects, interactions); equivalence and non-inferiority trials; problems of defining and using surrogate endpoints as alternatives to direct clinical outcomes. **Subject Objectives:** This elective subject extends and enhances the concepts developed in Design of Experiments and Clinical Trials (505-939). On completion of this subject, students have the knowledge and skills required at an advanced professional level to design and analyse clinical trials, including cross-over designs and equivalence trials, and to identify and implement statistical methods for trial monitoring and reporting, with appropriate knowledge of regulatory requirements.
Assessment:	Three written assignments to be submitted during semester, two worth 25% each (approx 8 hrs work each) and one worth 10% (approx 6 hrs work). One end of semester at-home examination worth 40% (approx 12 hours)
Prescribed Texts:	Senn S. Cross-over Trials in Clinical Research, 2nd edition 2002, Wiley. (ISBN 0471496537).
Recommended Texts:	Jennison, C. and Turnbull, B.W. Group Sequential Methods with Applications to Clinical Trials 2000, Chapman & Hall. (ISBN 0849303168)
Breadth Options:	This subject is not available as a breadth subject.
Fees Information:	Subject EFTSL, Level, Discipline & Census Date, http://enrolment.unimelb.edu.au/fees

Generic Skills:	Independent problem solving, facility with abstract reasoning, clarity of written expression, sound communication of technical concepts **Level:** 500
Links to further information:	http://www.sph.unimelb.edu.au
Notes:	This subject is not available in the Master of Public Health. **Subject Coordinator:** Assoc Prof Val Gebski, NHMRC Clinical Trials Centre, University of Sydney
Related Course(s):	Master of Biostatistics Postgraduate Certificate in Biostatistics Postgraduate Diploma in Biostatistics