



## University of London External Programme

### Postgraduate Diploma Clinical Trials Programme Specification 2007-08

General Information	
Programme title	Clinical Trials
Final award	Postgraduate Diploma
FHEQ level of final award	Masters 'M' Level
Associated Programmes (including short courses)	MSc degree Some individual core and advanced modules may be taken as short courses.
FHEQ level of associated award(s)	Masters 'M' Level
Awarding body	University of London
Lead College	London School of Hygiene and Tropical Medicine
Programme Director	Professor Diana Elbourne and Kendall Searle
Mode of study	Distance learning
Programme accredited by	None
Programme started	2006
Study year start date	September
Relevant QAA subject benchmarks	Not applicable
Registration period (minimum/maximum)	Minimum period is one academic year Maximum period is five academic years
Average time to graduation	Expected to be 1-3 years
Teaching Institution attendance required?	No

Admissions Details	
Intake (quota)	Joint with MSc Clinical Trials, limited to 100 in the second year
Admission requirements – general entrance requirements, programme specific entrance requirements	An applicant must have: <i>Either</i> (a) A first degree from a university or other institution acceptable to the University of London, in a subject appropriate to the course or in another discipline which has, in the opinion of the University, included suitable preliminary training <i>or</i> (b) Previous education and experience without a first degree, which satisfies the University that the applicant has obtained a level of academic proficiency equivalent to a first degree.

	<p>For all applicants an advanced level of ability to work in English is required. Applicants may be required to pass or to have passed within the last five years, at the appropriate level, an English proficiency test acceptable to the University e.g.</p> <p style="padding-left: 40px;">A TOEFL score of 600 (or 250 in the computerised test) and a and a minimum of 5 in the TWE</p> <p>or</p> <p style="padding-left: 40px;">a British Council (IELTS) overall score of 7 or over with a minimum of 7 in the written sub-test.</p> <p>Students should refer to the MSc and Postgraduate Diploma in Clinical Trials Programme Regulations that are reviewed annually for current admission requirements.</p>
Possible exemptions	None
<p>Credit and transfer/progression arrangements</p> <p>Credits are given to students who have University of London qualifications; students can be credited with the same or equivalent subject previously passed and the mark they achieved will carry.</p>	<p>Successful completion by formal assessment of a short course may be taken into account for credit towards the MSc degree or Postgraduate Diploma. Students progressing from a DL short course will be required to satisfy the rules of progression for the MSc degree and/or Postgraduate Diploma. Students should refer to the Clinical Trials DL Short Course Regulations.</p> <p>Applications for credit from students and graduates of the University of London will be considered for exceptional cases only on a discretionary basis.</p>

<b>Programme Outcomes</b>	
Distinctive features of the Programme	The course aims to provide students with a theoretical and practical understanding of the issues involved in the design, conduct, analysis and interpretation of randomized controlled trials of health interventions. It will be suitable for students working in high, middle and low income countries. Students will be trained to develop skills to scrutinize information, to critically analyse and carry out research, and to communicate effectively.
Possible routes to further study	In order to transfer their registration to the MSc degree from the Postgraduate Diploma, students must normally pass at the required level in each of the four Postgraduate Diploma modules and receive a recommendation from the Examiners that they may proceed to the advanced modules of the MSc. At the discretion of the Examiners, students who have been examined in and have passed three modules only, may be permitted to transfer their registration to the MSc and proceed to the advanced modules.
Possible graduate employment routes	This course will be relevant both for those wishing to gain an overall understanding of clinical trials before moving into the field, and for those who have general or specialist experience in this area and aim to broaden their role in the design, management, analysis and reporting of clinical trials.

<b>Programme content and structure</b>	
Learning aims, objectives and	The course aims to provide students with a theoretical and practical understanding of the issues involved in the design, conduct, analysis

intended outcomes	and interpretation of randomised controlled trials of health interventions. It will be suitable for students working in high, middle and low income countries. The core study modules are common to the Diploma and MSc courses. MSc students may choose from a number of advanced modules which will allow them to expand and deepen their conceptual and practical skills. The main disciplinary perspectives will come from clinical trials, statistics and epidemiology, but others will contribute in both the core and optional modules. Students will be trained to develop skills to scrutinize information, to critically analyse and carry out research and to communicate effectively.								
Learning and Teaching methods, including support, guidance, materials provided and study requirements	<ul style="list-style-type: none"> <li>• The course is predominantly internet-based.</li> <li>• The online learning environment includes ‘try it yourself’ questions with hints and feedback; animations, interactive diagrams and table; and vibrant graphics.</li> <li>• Students also have access to a student-to student internet-based discussion forum and registered students are encouraged to communicate with each other to provide mutual support.</li> <li>• There are tutor-marked assignments to help students review their progress and receive tutorial feedback.</li> <li>• A registered student may also receive: Programme Regulations, Student handbook, some textbooks, readers (containing copies of recent articles etc.), and CD roms</li> </ul>								
Programme structure	<p>The Postgraduate diploma consists of the following:</p> <ul style="list-style-type: none"> <li>• <b>four</b> compulsory core modules.</li> </ul> <p>In any one year, students registered for the Postgraduate Diploma may choose to study and be examined in a maximum of <b>four</b> core modules.</p> <p>For additional information students should refer to the MSc and Postgraduate Diploma in Clinical Trials Programme Regulations which are reviewed annually.</p>								
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Programme Regulations	For additional information students should refer to the MSc and Postgraduate Diploma in Clinical Trials which are reviewed annually. <a href="http://www.londonexternal.ac.uk/current_students/general_resources/regulations/index.shtml">http://www.londonexternal.ac.uk/current_students/general_resources/regulations/index.shtml</a>								
Assessment methods, including proportion of different methods used	Each compulsory <b>core</b> module will be assessed by one two-hour unseen written paper, with the exception of <b>CT104 Reporting and reviewing clinical trials</b> which will be assessed by one two-hour unseen written paper and written assignment(s), and will be weighted on the scale <b>50:50</b> .								
Marking scheme and classification criteria	<p>The Postgraduate Diploma will be awarded with a grading of Distinction, Pass, Fail. The award is normally given on the basis of achieving grades within the appropriate range in each module. Examiners have complete discretion to take into account the student's overall performance.</p> <table> <thead> <tr> <th><b>Grade</b></th> <th><b>Class Equivalent</b></th> </tr> </thead> <tbody> <tr> <td>A</td> <td>Distinction</td> </tr> <tr> <td>B+,B,C</td> <td>Pass</td> </tr> <tr> <td>D,E</td> <td>Fail</td> </tr> </tbody> </table>	<b>Grade</b>	<b>Class Equivalent</b>	A	Distinction	B+,B,C	Pass	D,E	Fail
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	For additional information students should refer to the MSc and Postgraduate Diploma in Clinical Trials Programme Regulations which are reviewed annually.
Estimated study hours overall	In order to complete the programme in the minimum period (i.e. one year for the Postgraduate Diploma) a student should be prepared to study between 15 and 25 hours per week during the annual study calendar of 36 weeks.
Intellectual development (rationale of progression through course)	The core modules deal with the main disciplinary perspectives: fundamentals of clinical trials, basic statistics, clinical trials in practice and reporting and reviewing clinical trials.

<b>Quality Assurance</b>	
Particular indicators of quality	<p><i>Assessment procedures</i> External examiners, together with the Board of Examiners approve examination papers and assignments together with the marking schemes.</p> <p>All assessed course work and examinations are blind double marked.</p> <p>External examiners review samples of students' written assignments and examination scripts, and grades awarded.</p> <p><i>Quality of tutoring</i> A system of ongoing review of written tutor feedback is in place</p> <p><i>Quality of course material</i> All study modules are reviewed by an external assessor, followed by periodic internal review.</p> <p>Annual update of course material as appropriate to take into account tutor and student comments throughout the year.</p> <p><i>Systematic reporting and review</i> A Course Committee meet three times a year to review all current course issues.</p> <p><i>Student feedback</i> Students are invited to complete an evaluation form for each study module completed.</p> <p>An on-line discussion conference is available for students to comment on the programme.</p> <p>All student feedback is summarised, with action plans produced to deal with issues raised at the end of each academic year. These are approved by the Course Committee and followed through.</p>
Methods for assuring, evaluating and improving quality and standards of this programme	<p>The University of London statute 66 (2), states that: 'Candidates granted degrees and other awards shall have attained the same academic standard irrespective of mode or place of study or examination.' Degrees and Diplomas awarded to External students are, therefore, examined to the same standard as those granted to Internal students of the University.</p> <p>In support of this statute, the External Programme and individual Lead</p>

	<p>Colleges share responsibility for ensuring the quality of External provision. The Quality Assurance Framework for the External Programme defines this shared responsibility and covers areas including:</p> <p><i>The bidding process</i> External programmes must undergo validation &amp; approval under Lead College mechanisms and with reference to national QAA benchmark statements.</p> <p><i>Student and programme management</i> This includes the admission, registration and progression of students, establishment of assessment procedures and appointment of boards of examiners.</p> <p><i>System wide matters</i> Academic policy and development is the responsibility of the External System Lead Colleges Committee, the membership of which is made up of representatives of all the Lead Colleges at Vice-Principal level. The qualifications framework for External programmes outlines the different levels of undergraduate and postgraduate study and the awards which may be made to External students.</p> <p><i>Systematic reporting and the review process</i> External Examiners make annual reports on assessment procedures and standards set and achieved. Annual Programme Reports provide annual summaries of programme information. These reports are considered and acted on as part of an annual review process.</p>
Programme validation/approval	This course was approved by the School's Education Committee and subsequently by the Senate.
Appointment of external examiners	External Examiners for External Programmes are nominated and appointed by the Lead College or Consortium, using approval processes which are parallel with those used for the appointment of External Examiners to Boards of Examiners assessing College-based students.
Student feedback mechanisms	External Programme wide student feedback mechanisms are currently under development therefore no standard data is available yet.