OXFORD BROOKES UNIVERSITY

PLANNING AND MANAGING CLINICAL TRIALS

Distance learning

Department of Clinical Health Care

This **distance learning** course offers you the opportunity to develop your knowledge and skills in planning and managing clinical drug trials.

ARE YOU...

- **a Researcher leading and/or managing clinical trials?**
- **a Research Nurse or Study Site Co-ordinator involved in clinical trials?**
- **a Clinical Researcher within the BioPharma industry?**
- **a Research & Development Manager responsible for overseeing clinical trials?**
- **involved in clinical trials in some other way or would like to be?**

KEY DETAILS

Module P46650 ■ M Level 20 CATS points (equivalent to 10 ECTS credits)
This course requires 200 hours of student effort and runs twice a year:

Semester 1 start date

24th September 2013 - 21st December 2013

Semester 2 start date

27th January 2014 - 16th May 2014

DESCRIPTION OF THE MODULE'S ELEMENTS:

Brookes Virtual

Brookes Virtual Learning Environment will be used to support your studies. You will be given secure access, via the internet, to a secure site. This portal provides access to the module's electronic resources, learning tools and discussion boards.

Course materials/module workbook

After you enrol, you will receive a copy of the module workbook. This contains detailed information about each of the module units. The workbook is also available through Brookes Virtual and includes direct links to a wide range of internet-based resources.

Online learning activities

Brookes Virtual facilitates the online learning activities; both individually and in assigned groups. These activities can be completed at any time and serve to reinforce learning and to provide opportunities for sharing ideas and experiences with the other course participants.

Module assessment

The assessment comprises of one short structured essay and an online examination. Detailed guidance and tutor support to assist you with this are provided.

DESCRIPTION OF MODULE

This course comprises a single M level module, designed for those who work in clinical trials or who wish to become involved in such work. It provides training in line with the relevant European Directives, International Conference for Harmonisation Good Clinical Practice Guideline, the applicable UK regulations and the NHS Research Governance Framework.

It offers an opportunity for you to gain an understanding of the principles of planning and managing clinical trials on patients and healthy volunteers. You will be able to explore and apply relevant knowledge and skills to your own working environment. The module uses a blended learning approach, which includes a detailed workbook supplemented by internet-based learning materials.

Discussion boards

Secure Discussion Boards are used to support some of the learning activities. In addition, they also provide regular access to the teaching staff as well as the other module participants.

Tutor support

Each module unit has a Supervising Tutor who will feedback on the learning activities and answer questions via the Discussion Boards. You will be allocated an academic advisor who can be contacted by email for other issues.

Library access

You will be enrolled as an associate student of the university. This allows you to access library resources online. You will be given an Athens account to access the electronic journals which Brookes subscribes to.

Other resources

You will also be sent the module handbook. This provides information about all aspects of the module's organisation, the teaching team, Brookes Virtual, learning outcomes, assessments and marking criteria. It also includes information about support and university procedures and rules.

UNIT DESCRIPTION

1. **General introduction and literature skills**
General information; Brookes Virtual Learning Environment (contents, quizzes, electronic activities, assessments and discussion boards); tutor support, assessment criteria; literature searching and critical appraisal skills; databases.

2. **Introduction to clinical trials and good clinical practice**
Definition of a clinical trial; phases of clinical development; evolution of Good Clinical Practice, Declaration of Helsinki, International Committee for Harmonisation Good Clinical Practice Guideline.

3. **European and UK law and research governance**
European Directives; UK Medicines for Human Use Regulations; Research Governance; clinical trial design.

4. **Project and risk management and clinical trial supplies**
Principles of project mangement, project lifecycle; risk management; clinical trial supplies.

5. **Responsibilities and quality assurance**
Sponsor responsibilities; investigator responsibilities; quality assurance; monitoring; quality management systems; standard operating procedures; training; audit.

6. **Regulatory applications and research ethics**
Pre-trial applications and registrations; clinical trial authorisation; Research Ethics Committee application; purpose of ethical review; ethical principles; risk assessment; ethical approaches; ethical issues in clinical trials.

7. **Informed consent and data protection**
Informed consent; informed consent process; vulnerable groups: patient information sheet/informed consent form; data protection; Caldicott.

8. **Investigator's Brochure, protocol and data management**
Investigator's Brochure, design of protocols, data management.

9. **Pharmacovigilance and trial master file**
Pharmacovigilance; EudraVigilance; safety reporting requirements; trial master file.

10. **Trial closure, reports, publications and inspections**
Trial closure; clinical study report; publications; CONSORT; archiving; fraud and non-compliance; inspections.

ENTRY REQUIREMENTS

Enquiries about the module content should be directed to the Programme Administrator.

Applicants need to meet the module's minimum criteria in order to demonstrate that they will be able to study at an appropriate level. Applicants offered a place on the module must have reliable access to the Internet and email.

Note: Applicants whose home language is not English must demonstrate that their level of English is appropriate for study at postgraduate level with fluent writing skills.

The English language requirements are: IELTS level 6.5 or above, TOEFL 600/250 or above, or equivalent. For further details contact the Programme Administrator, preferably by email.

COST

The cost of the module is £1,300 for UK/EU students. (£1,350 for international students).

HOW DO I APPLY?

For an application pack please email the Programme Administrator or you can download a copy from our website (details below).
You will be required to submit a signed application form and a funding statement.

The closing date for applications is:
23rd August 2013 for September 2013, and
20th December 2013 for January 2014.

CONTACT DETAILS

Programme Administrator
Department of Clinical Health Care
Faculty of Health and Life Sciences
Oxford Brookes University
Jack Straw's Lane
Marston
Oxford
OX3 0FL

Email: **clinicaltrials@brookes.ac.uk**
Telephone: **+44 (0)1865 488111**
Website: **www.chc.brookes.ac.uk**

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