1. **Title of the module**

LABS416: Regulation of Clinical Research

1. **School or partner institution which will be responsible for management of the module**

Centre for Higher and Degree Apprenticeships

1. **The level of the module (Level 4, Level 5, Level 6 or Level 7)**

Level 4

1. **The number of credits and the ECTS value which the module represents**

15 credits (7.5 ECTs)

1. **Which term(s) the module is to be taught in (or other teaching pattern)**

Flexible delivery model

Autumn and/or Spring and/or Summer

1. **Prerequisite and co-requisite modules**

N/A

1. **The programmes of study to which the module contributes**

BSc (Hons) in Applied Bioscience

FdSc in Applied Bioscience

1. **The intended subject specific learning outcomes.  
   On successfully completing the module students will be able to:**

8.1 Understand who the regulatory authorities are for clinical research and be able to compare and contrast these within the EU and US.

8.2 Understand the basics of clinical research regulation outside the International Council for Harmonisation (ICH) area.

8.3 Demonstrate knowledge of the underlying concepts and principles associated with how regulatory authorities regulate and protect patients, including marketing authorisations, clinical trial applications, regulatory inspections, legal powers and other services that they provide.

8.4 Understand the general roles, responsibilities, constitution, and function of ethics committees that are associated with clinical research.

8.5 Demonstrate knowledge of the different types of ethics committees and their role in the protection of vulnerable subjects.

8.6 Understand the submission process.

8.7 Understand the ongoing role of the ethics committee throughout clinical trials.

1. **The intended generic learning outcomes.  
   On successfully completing the module students will be able to:**

9.1 Develop and demonstrate an ability to work and communicate effectively with others.

9.2 Analyse, evaluate and correctly interpret data.

9.3 Present and communicate data effectively.

9.4 Obtain and use information from a variety of sources as part of self-directed learning.

9.5 Demonstrate time-management and organisational skills within the context of self-directed learning.

1. **A synopsis of the curriculum**

The module provides an introduction into the regulation of clinical research. It looks at the regulatory authorities, including who they are, with examples from different countries, and compares those within the EU and the US. It also looks at regulation outside of the ICH area and how the regulatory authorities regulate and protect patients, by describing marketing authorisations, clinical trial applications, regulatory inspections, legal powers and other services that they provide. Furthermore, it looks at the ethics committees associated with clinical research, including their general roles and responsibilities, constitution and function, types of ethics committees, their role in the protection of vulnerable adults (children and incapacitated adults), submissions to ethics committees, and their ongoing role throughout the trial.

1. **Reading list (Indicative list, current at time of publication. Reading lists will be published annually)**

Smyth, R. L. (2011) Regulation and Governance of Clinical Research in the UK; New report aims to remove unnecessary burdens and bureaucracy. British Medical Journal

Pavlou, A., and Saurat, E. (2015) Clinical Trials Regulation: A Further Step towards Increased Medical Innovation in the EU. European Journal of Risk Regulation.

1. **Learning and teaching methods**

Blended distance learning:

Contact Hours: 100 hours

Private Study Time: 50 hours

Total Learning Time: 150 hours

1. **Assessment methods**
   1. Main assessment methods

Two coursework assignments (Essays; 500 words each)

Weighting:

Essay assignment 1 50%

Essay assignment 2 50%

The pass mark for this module is 40%. Both assessments need to be passed to cover all learning outcomes.

13.2 Reassessment methods

Like for like

1. ***Map of module learning outcomes (sections 8 & 9) to learning and teaching methods (section12) and methods of assessment (section 13)***

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Module learning outcome** | 8.1 | 8.2 | 8.3 | 8.4 | 8.5 | 8.6 | 8.7 | 9.1 | 9.2 | 9.3 | 9.4 | 9.5 |
| **Learning/ teaching method** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Private Study** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** |
| Teaching | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** |  |
| Work based experience |  |  |  |  |  |  |  | **x** | **x** | **x** | **x** | **x** |
| **Assessment method** |  |  |  |  |  |  |  |  |  |  |  |  |
| Essay 1 (500 words) | **x** | **x** | **x** |  |  |  |  | **x** | **x** | **x** | **x** | **x** |
| Essay 2 (500 words) |  |  |  | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** |

1. **Inclusive module design**

The School/Collaborative Partner recognises and has embedded the expectations of current equality legislation, by ensuring that the module is as accessible as possible by design. Additional alternative arrangements for students with Inclusive Learning Plans (ILPs)/declared disabilities will be made on an individual basis, in consultation with the relevant policies and support services.

The inclusive practices in the guidance (see Annex B Appendix A) have been considered in order to support all students in the following areas:

a) Accessible resources and curriculum

b) Learning, teaching and assessment methods

1. **Campus(es) or centre(s) where module will be delivered**

Blended distance learning – delivered from Medway or Canterbury campus

1. **Internationalisation**

Regulation of clinical research is explored from international perspectives. With regards to the intended learning outcomes, in particular 8.1, the target learning outcomes within this module are applicable worldwide as part of regulation of clinical research. With regard to subject content, the material within the syllabus is applied to a wide range of international contexts, where it draws on and compares current standards and regulations across Europe and the US. Current regulations of clinical trials have international implications for institutions and organisations initiating, managing or/and financing clinical trials. Furthermore, this module has been developed with global employers to have an international focus.

**FACULTIES SUPPORT OFFICE USE ONLY**

**Revision record – all revisions must be recorded in the grid and full details of the change retained in the appropriate committee records.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date approved | Major/minor revision | Start date of delivery of revised version | Section revised | Impacts PLOs (Q6&7 cover sheet) |
| 05/10/20 | Minor | Sep 20 | 13 | No |
|  |  |  |  |  |