1. **Title of the module**

LABS516 Data Management and Statistics

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 5

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 Make appropriate use of data management plans and case repot form (CRF) design in clinical trials.

8.2 Understand data listings and their review.

8.3 Understand the key concepts and principles in data transfers and data validation, in association with clinical trials.

8.4 Raise and resolve data queries effectively.

8.5 Demonstrate knowledge and critical understanding of database development and clinical trial specifications.

8.6 Understand data coding.

8.7 Apply appropriate statistics to clinical trial data.

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 Manage their time and use their organisation skills within the context of self-directed learning.

1. **A synopsis of the curriculum**

This module gives an introduction into data management and statistics, with a focus on clinical trials. It will cover database development, clinical trial specifications, and data management plans, to aid case repot form (CRF) design. It will also look at data coding, transfer and validation, including database reconciliation and user acceptance testing, and data listings and their review. It will show how to raise and resolve data queries effectively and how to apply appropriate statistics to clinical trial data.

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

Cleophas, T.J. (2009) Statistics Applied to Clinical Trials. Springer.

Friedman, L.M. (2010) Fundamentals of Clinical Trials. Springer.

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

Coursework assignment (essay; 750 words) and a portfolio

Weighting:

Essay Assignment 50%

Portfolio 50% - composed of 5 individual assignments where topics are applied to the workplace

The pass mark for this module is 40%.

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** |  |  | **x** | **x** | **x** | **x** | **x** |
| **Assessment method** |  |  |  |  |  |  |  |  |  |  |  |  |
| Essay (750 words) | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** | **x** |
| Portfolio | **x** |  | **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**

International vocation is an important part of Applied Bioscience. With regards to the intended learning outcomes, in particular 8.1, 8.3 and 8.5, the target learning outcomes within this module are applicable worldwide as part of the universal principles when managing clinical data. 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. Furthermore, the module covers statistical techniques that are applicable to clinical research, worldwide, and has been developed with global employers to have an international focus.

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**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 |
|  |  |  |  |  |