



UNIVERSITY  
OF LONDON

# Programme Regulations 2022–2023

## Clinical Trials

MSc  
PGDip  
PGCert  
and Individual modules

**Important document – please read**  
This document contains important  
information that governs your  
registration, assessment and  
programme of study





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## **Important information regarding the Programme Regulations**

**Last revised** 16 May 2022

As a student registered with the University of London you are governed by the current General Regulations and Programme Regulations associated with your programme of study.

These Programme Regulations are designed and developed by the London School of Hygiene & Tropical Medicine LSHTM which is responsible for the academic direction of the programme. The regulations take account of any associated arrangements at LSHTM. Programme Regulations, together with the Programme Student Handbook (available to registered students on the [LSHTM VLE](#)), will provide the detailed rules and guidance for your programme of study.

In addition to Programme Regulations you will have to abide by the [General Regulations](#). These regulations apply to all students registered for a programme of study with the University of London and provide the rules governing registration and assessment on all programmes; they also indicate what you may expect on completion of your programme of study and how you may pursue a complaint, should that be necessary. Programme Regulations should be read in conjunction with the General Regulations.

The relevant General Regulations and the Programme Regulations relating to your registration with us are for the current year and not the year in which you initially registered.

On all matters where the regulations are to be interpreted, or are silent, our decision will be final.

Further information about your programme of study is outlined in the Programme Specification which is available on the relevant Courses page of the website. The Programme Specification gives a broad overview of the structure and content of the programme as well as the learning outcomes students will achieve as they progress.

### **Terminology**

The following language is specific to the Clinical Trials programme:

**Modules:** Individual units of the programme are called modules. Each module is a self-contained, formally structured learning experience with a coherent and explicit set of learning outcomes and assessment criteria.

Throughout the Regulations, 'we' 'us' and 'our' mean the University of London; 'you' and 'your' mean the student, or where applicable, all students.

If you have a query about any of the programme information provided, please contact us. You should use the '*ask a question*' button in the [Student Portal](#).

### **Changes to Clinical Trials Regulations 2022-2023**

- Module CTM207 Design & Analysis of Epidemiological Studies has been withdrawn. No new registrations will be permitted for 2022 – 2023.
- Modules CTM102 Basic Statistics for Clinical Trials, CTM202 Trial designs, CTM204 Regulatory affairs, good clinical practice and ethics and CTM208 Further statistical methods in clinical trials will now be assessed by assessed assignment and examination weighted 60:40.
- Modules CTM203 Project management and research co-ordination and CTM209 Cluster randomised trials will now be assessed 100% by one assessed assignment.

- Module EPM101 Fundamentals of Epidemiology will be available as an elective module for those registered on the PGDip/MSc Clinical Trials programmes.

## Alternative Assessments during the Coronavirus (COVID-19) Outbreak

In line with our current General Regulations, the University may offer you alternative assessments where necessary. This includes holding online timed examinations in place of written examinations, which are usually held at examination centres. Please note that this statement replaces any published information relating to assessments or examinations in any of our materials including the website. Previously published materials relating to examinations should therefore be read in conjunction with this statement.

The University of London continues to work towards supporting the academic progression of all its students. The University also continues to be mindful of the health and wellbeing of its students during this pandemic, whilst protecting the academic standards of its awards.

## 1 Structure of the programmes

[Appendix A](#) gives the full module list and structure of the programmes.

### Qualification

#### 1.1

The following named qualifications are awarded under the **Clinical Trials** programme:

- MSc Clinical Trials
- Postgraduate Diploma in Clinical Trials (PGDip)
- Postgraduate Certificate in Clinical Trials (PGCert)

### Qualification structure

#### 1.2

The **MSc Clinical Trials** consists of:

- Four compulsory CTM1 modules
- One compulsory CTM2 module (CTM201)
- Five elective modules selected from a list of options, at least three of which must be CTM2 modules or at least two of which must be CTM2 modules and EPM101 Fundamentals of Epidemiology (which replaces CTM207).
- One compulsory integrating module (CTM210)

#### 1.3

The **PGDip Clinical Trials** consists of:

- Four compulsory CTM1 modules
- Four elective modules selected from a list of options, at least three of which must be CTM2 modules or at least two of which must be CTM2 modules and EPM101 Fundamentals of Epidemiology (which replaces CTM207).

#### 1.4

The **PGCert Clinical Trials** consists of:

- Four compulsory CTM1 modules.

#### 1.5

The Programme Director has the right to consider the suitability of your chosen modules for the MSc or PGDip and, with stated reason, may restrict your chosen options.

#### 1.6

If you have registered for an elective module but have not attempted the assignment or timed examination for that module (or have obtained a fail grade for the module overall at the first attempt), you may apply to change to another elective module but must ensure you still meet the requirements for the qualification. If you fail the module overall at a second attempt, you will not be permitted to change to another option. If you apply to change module(s) and have entered either element of assessment for the elective module concerned, you will not be able to change until after

the results have been published. Up to three elective modules (45 credits) only may be changed in this way. If you change your choice of elective module(s), you will be required to pay the full fee for the newly chosen module.

## **Individual modules**

### **1.7**

You may apply to register for one or more individual modules as a stand-alone module, instead of registering for the MSc, PGDip or PGCert Clinical Trials.

### **1.8**

The following Clinical Trials modules are available on a stand-alone basis:

|        |   |
|--------|---|
| CTM101 | Fundamentals of clinical trials                       |
| CTM102 | Basic statistics for clinical trials                  |
| CTM103 | Clinical trials in practice                           |
| CTM104 | Reporting and reviewing clinical trials               |
| CTM201 | Protocol development                                  |
| CTM202 | Trial designs   |
| CTM203 | Project management and research co-ordination         |
| CTM204 | Regulatory affairs, good clinical practice and ethics |
| CTM205 | Data management                                       |
| CTM206 | Data monitoring and interim analyses                  |
| CTM208 | Further statistical methods in clinical trials        |
| CTM209 | Cluster randomised trials                             |

### **1.9**

Some modules may require you to have prior knowledge or experience in a particular subject area before you study the module. Information on such prerequisites is given in the individual module specifications.

### **1.10**

Successful completion by formal assessment of an individual module may be taken into account for credit towards the MSc, PGDip or PGCert. If you transfer your registration from an individual module to the MSc, PGDip or PGCert, you must meet the rules of progression for that award.

## **Blended learning**

### **1.11**

Blended Learning study enables you to combine distance learning study with a period of full-time study at the LSHTM. If you have registered for the MSc degree or PGDip and have been permitted to proceed to the elective module studies, you may study up to two elective modules (one elective module if registered for the PGDip) at the LSHTM in place of distance learning elective modules. There will be restrictions on the choice of elective modules available for Blended Learning study, the period of time in which the modules must be completed and the number of students who can

register for Blended Learning study each year. Modules studied by Blended Learning are subject to the LSHTM regulations.

Details related to Blended Learning study are set out in the Guidelines for Blended Learning, found on the LSHTM website, under the '[Structure](#)' tab.

## **2 Registration**

### **Effective date of registration**

#### **2.1**

Your effective date of registration will be 1 September (for the MSc, PGDip, PGCert and for individual modules) in the year that you initially registered. (Note: access to the LSHTM Virtual Learning Environment Moodle starts annually on 1 October. If 1 October falls on a weekend the academic year will start on the following Monday: in 2022 the academic year will start on 3 October 2022.)

### **Period of registration**

#### **2.2**

The minimum and maximum periods of registration, from your effective date of registration, are:

|                           | <b>Minimum</b> | <b>Maximum</b> |
|---------------------------|----------------|----------------|
| <b>MSc</b>                | Two years      | Five years     |
| <b>PGDip</b>              | Two years      | Five years     |
| <b>PGCert</b>             | One year       | Five years     |
| <b>Individual modules</b> | One year       | Two years      |

#### **2.3**

If you are registered for individual modules and have been permitted to transfer from an individual module to the PGCert, PGDip or the MSc Clinical Trials, you will be given a new period of registration beginning from the year that you register on the PGCert, PGDip or MSc Clinical Trials. The maximum period of registration will be the same for all students registered for the same programme.

#### **2.4**

If you are registered for the PGCert or PGDip Clinical Trials and progress to the PGDip or MSc Clinical Trials you will not be issued a new period of registration, your registration will continue from the year that you first registered on the PGCert or PGDip Clinical Trials. The maximum period of registration will be the same for all students registered for the same programme.



### 3 Recognition of prior learning and credit transfer

To be read in conjunction with the [General Regulations](#), Section 3 and the [LSHTM Academic Manual](#).

#### Recognition of prior learning and credit transfer

##### 3.1

Where prior learning is recognised, the decision to award credit (known as Recognition of prior learning (RPL)) shall be made by the Programme Director and approved by the Faculty Taught Programme Director.

##### 3.2

Applications for RPL can only be made at the point of entry to the programme and will only apply to specific modules up to a maximum number of credits.

#### Credit transfer

##### 3.3

Only credit transfer for a module previously studied at LSHTM may be considered for the MSc, PGDip or the PGCert. All applications for credit transfer and recognition of prior learning will be considered on a discretionary case-by-case basis.

Further information can be found in the [LSHTM policy document](#).

### 4 Assessment for the programme

In line with our current General Regulations, the University may offer you alternative assessments where necessary. This includes holding online timed examinations in place of written examinations which are usually held at examination centres. Please refer to Programme Specifications for details on equipment that may be required for alternative assessments.

#### Assessment methods

##### 4.1

Each CTM1 module will be assessed by a timed examination, with the exception of CTM102 which will be assessed a timed examination and one assessed assignment weighted at 40:60 and CTM103 which will be assessed 100% by one assessed assignment. Details are given in the [module specifications](#).

##### 4.2

CTM2 modules will be assessed by one or more assignments. Some may also be assessed by a timed examination. Details are given in the [module specifications](#).

##### 4.3

Each EPM, IDM and PHM elective module will be assessed by one or more assignments and/or a timed examination. Details are given in the [module specifications](#).

##### 4.4

CTM210, the integrating module (MSc only), will be assessed by an integrating report.

The types of assessment for each module can be found in the respective [Module Specification](#).

#### 4.5

Assignments, reports and other similar work must be your own work and must be written without the help of other people, except where you are given permission to work in a group and submit a joint piece of work. If you are working in a group you may need to submit a declaration, confirming the nature of your contribution to the submitted work.

### **Date of examinations**

#### 4.6

Timed examinations normally take place in June each year.

See the website for the list of [examination centres](#).

#### 4.7

Assessed assignments and the integrating report (CTM210) must be received by the deadlines given in the requirements for the assignments and the LSHTM Student Handbook, both of which are available to registered students on the LSHTM Virtual Learning Environment. Assessed assignments and the integrating report must be submitted electronically (unless otherwise specified in the assignment guidelines).

#### 4.8

Extensions to assignment deadlines will only be given in extenuating circumstances, and will only be considered if an application to the [LSHTM Extenuating Circumstances](#) Committee is made and has been received **before the deadline**. An assignment received after the deadline, without an agreed extension, will either be downgraded or will not be marked (see section 8b.6.5.10 of the [Academic Manual](#)).

### **Materials and aids allowed in the examination room**

See [General Regulations](#) for Rules for taking examinations

## 5 Number of attempts permitted at an assessment

### 5.1

The maximum number of attempts permitted at any assessed assignment or timed examination is two. If you fail a module at the first attempt, you will be permitted to make a second attempt (resit). Extenuating circumstances may be taken into account which allow for more attempts.

### 5.2

If you fail an elective module which is assessed by two or more elements of assessment (timed examination and/or one or more assignment(s)), you will normally have to resit at least one element of the module assessment, but may have to resit both or all elements, depending on whether the element can be compensated or not (see Chapter 8b of the LSHTM [Academic Manual](#)).

### 5.3

If you fail an elective module which is assessed by two or more elements of assessment (timed examination and/or one or more assessed assignment(s)), having passed one element but not the other, you may only resit the failed element.

### 5.4

If you resit the assessed assignment element of a module assessment, you will be required to submit a fresh assignment in answer to a new question or assignment topic.

## Integrating module

### 5.5

If you fail the integrating module report (CTM210) you must submit a fresh report in answer to a new question or report topic.

### 5.6

For all modules the highest grade awarded will count towards the final award, whether received at the first or subsequent attempt.

More details can be found in the LSHTM [Academic Manual](#) about [extenuating circumstances](#) (Chapter 7) and resits (Chapter 8b), and in the [General Regulations](#).

## 6 Assessment offences and penalties

### 6.1

Penalties may be applied to assessed work that does not comply with the requirements given in programme materials or is not submitted by the stated deadlines. You should check the requirements given for individual assignments and the integrating report (CTM210) in the LSHTM Virtual Learning Environment. Penalties such as grade reductions (including reduction to a fail grade) may apply for work that is late, over-length or for poor academic quality or plagiarism (see sections 7.2 and 8b.6.5 of the [Academic Manual](#)).

## 7 Progression within the programme

See [section 4](#) for method of assessment.

### MSc Clinical Trials

#### 7.1

You may choose to study and be assessed in a maximum of four CTM1 modules. You must successfully complete a minimum of two CTM1 modules to be permitted to progress to elective module studies whilst you complete your remaining CTM1 modules. One of these modules must be CTM101 Fundamentals of Clinical Trials, which you must pass with a Grade Point Average (GPA) of at least 2.0. To be awarded the MSc, you need to have successfully completed all CTM1 modules, six elective modules plus the integrating module (CTM210). (Note that compensation rules may be applied for up to two failed modules, as outlined in section 8b.9.8 of the LSHTM [Academic Manual](#).) These can be completed within two years or up to the five years of registration. Resit attempts may be made in addition to the maximum number of modules stated above.

#### 7.2

Progression to elective module studies before completing the minimum requirement of the CTM1 modules is subject to approval by the Exam Board Chair.

#### 7.3

You are expected to study for the integrating module by submitting the integrating report (CTM210) in the same year that you take your last module assessments or the following year.

### PGDip Clinical Trials

#### 7.4

You may choose to study and be assessed in a maximum of four CTM1 module(s) in any one year. You must successfully complete a minimum of two CTM1 modules to be permitted to progress to elective module studies whilst you complete your remaining CTM1 modules. One of these modules must be CTM101 Fundamentals of Clinical Trials, which you must pass with a Grade Point Average (GPA) of at least 2.0.

#### 7.5

Progression to elective module studies before completing the minimum requirement of the CTM1 modules is subject to approval by the Exam Board Chair.

#### 7.6

If you have been permitted to progress to elective module studies, you may choose to be assessed in the remaining CTM1 modules in the same year as up to four elective modules. Resit attempts may be made in addition to the maximum number of modules stated above.

### PGCert Clinical Trials

#### 7.7

If you are registered for the PGCert you may choose to study and be assessed in a maximum of four CTM1 module(s) in any one year.



## 8 Scheme of award

### 8.1

The Clinical Trials programmes are marked according to the following scale:

| Qualification GPA | Classification       |
|-------------------|----------------------|
| 2.00 - 3.84       | Pass                 |
| 3.70 – 3.84       | Consider merit       |
| 3.85 – 4.29       | Merit                |
| 4.15 - 4.29       | Consider distinction |
| 4.30 - 5.00       | Distinction          |

### 8.2

The Board of Examiners will approve the final qualification classification once the criteria for that qualification have been met. Once you have met the criteria for the qualification on which you were registered, you will not be allowed to resit any failed modules or substitute any failed modules with other modules.

### 8.3

All timed examinations, assessed module assignments and the integrating report (CTM210) (MSc only) will be marked and grades combined according to the LSHTM [Academic Manual](#) (Chapter 8b).

### 8.4

The final outcome of the award of MSc, PGDip or PGCert is decided as set out in the LSHTM [Academic Manual](#) (Chapter 8b).

### 8.5

The final qualification classification will be based on the final qualification GPA, which will be calculated as set out in the LSHTM [Academic Manual](#) (Chapter 8b).

### 8.6

In order to be awarded the MSc, PGDip or PGCert you must satisfy the Examiners in the assessment for all the necessary components of the qualification.

## Exit qualifications

### 8.7

If you registered for the PGDip Clinical Trials or MSc Clinical Trials, an exit qualification (i.e. a related certificate or diploma) may be granted to you if you either do not satisfactorily complete, or withdraw early from, the programme you were registered on, provided that you have fully met the requirements for an exit qualification as detailed in the LSHTM [Academic Manual](#) (Chapter 8b).

The award of the PGCert Clinical Trials or PGDip Clinical Trials will be with effect from the year in which you successfully completed all components for that qualification.

## **Receiving related qualifications**

### **8.8**

If you successfully complete the formal assessment of individual modules, you may apply to receive a related qualification provided that you meet the requirements for that qualification.

Information on assessment criteria and how the grades and credits obtained from individual modules might contribute to a related qualification are given in Chapter 8b of the LSHTM [Academic Manual](#).

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## **9 Transfer of registration**

### **Transfer of registration from the PGCert or PGDip Clinical Trials to the MSc Clinical Trials**

#### **9.1**

If you have passed two CTM1 modules (which must include CTM101 Fundamentals of Clinical Trials with a GPA of at least 2.00), you will be permitted to transfer registration to the MSc degree and advance to elective module studies.

#### **9.2**

If you have been awarded the PGCert or PGDip, you must give up your certificate or diploma to us if you wish to transfer to the MSc degree.

### **Transfer of registration from the PGCert Clinical Trials to the PGDip Clinical Trials**

#### **9.3**

You will be permitted to transfer registration to the PGDip and continue to the elective modules if you have passed two CTM1 modules (which must include CTM101 Fundamentals of Clinical Trials with a GPA of at least 2.00).

#### **9.4**

If you have been awarded the PGCert, you must give up your certificate on transfer to the PGDip as credit from the same modules cannot contribute to two different qualifications.

### **Progression and transfer of registration from an individual module**

#### **9.5**

If you wish to progress from an individual module and register for the PGCert, PGDip or MSc Clinical Trials, you must follow the sequence of modules given within the individual programme structures and module specifications in [Appendix A](#). Advice on the previous knowledge you are expected to have to undertake a particular module is also given within the module specifications.

## Appendix A – Structure of the programmes

### PGCert Clinical Trials

#### Four compulsory core modules (60 credits in total)

|        |  |
|--------|--|
| CTM101 | Fundamentals of clinical trials [15 credits]           |
| CTM102 | Basic statistics for clinical trials [15 credits]      |
| CTM103 | Clinical trials in practice [15 credits] *             |
| CTM104 | Reporting and reviewing clinical trials [15 credits] * |

### PGDip Clinical Trials

#### Four compulsory core modules (60 credits in total)

|        |  |
|--------|--|
| CTM101 | Fundamentals of clinical trials [15 credits]           |
| CTM102 | Basic statistics for clinical trials [15 credits]      |
| CTM103 | Clinical trials in practice [15 credits] *             |
| CTM104 | Reporting and reviewing clinical trials [15 credits] * |

+

#### Four elective modules (60 credits in total) selected from the list of options below.

At least **three** of these must be selected from the CTM2 selection group (or alternatively, EPM101 Fundamentals of Epidemiology may be selected with at least **two** modules selected from the CTM2 selection group). The remaining module can be selected from the EPM3, GHM2, IDM2, IDM3, IDM5 or PHM2 selection groups.

*Credit for one module studied at LSHTM (blended learning study) may be allowed in place of one of the above elective modules, subject to module restrictions.*

### MSc Clinical Trials

#### Four compulsory core modules (60 credits in total)

|        |  |
|--------|--|
| CTM101 | Fundamentals of clinical trials [15 credits]           |
| CTM102 | Basic statistics for clinical trials [15 credits]      |
| CTM103 | Clinical trials in practice [15 credits] *             |
| CTM104 | Reporting and reviewing clinical trials [15 credits] * |

+

#### One compulsory module

|        |                                   |
|--------|-----------------------------------|
| CTM201 | Protocol development [15 credits] |
|--------|-----------------------------------|

+

#### Five elective modules (75 credits in total) selected from the list of options below.

At least **three** of these must be selected from the CTM2 selection group (or alternatively, EPM101 Fundamentals of Epidemiology may be selected with at least **two** modules selected from the CTM2

selection group). The remaining module can be selected from the EPM3, GHM2, IDM2, IDM3, IDM5 or PHM2 selection groups.

**+**

**CTM210 A compulsory integrating module [30 credits]**

*Credit for up to two modules studied at LSHTM (blended learning study) may be allowed in place of up to two of the above elective modules, subject to module restrictions.*

\* You are advised to study CTM101 Fundamentals of clinical trials and CTM102 Basic statistics for clinical trials before studying these modules.

**Elective modules**

MSc and PGDip students must select from the following:

**CTM2**

- CTM201 Protocol development [15 credits]
- CTM202 Trial designs [15 credits]
- CTM203 Project management and research co-ordination [15 credits]
- CTM204 Regulatory affairs, good clinical practice and ethics [15 credits]
- CTM205 Data management [15 credits]
- CTM206 Data monitoring and interim analyses [15 credits]
- CTM208 Further statistical methods in clinical trials [15 credits]
- CTM209 Cluster randomised trials [15 credits]

**EPM1**

- EPM101 Fundamentals of Epidemiology [15 credits]

**EPM3**

- EPM301 Epidemiology of infectious diseases [15 credits]
- EPM302 Modelling and the dynamics of infectious diseases [15 credits]
- EPM304 Advanced statistical methods in epidemiology [15 credits]
- EPM307 Global epidemiology of non-communicable diseases [15 credits]

**GHM2**

- GHM201 Health systems [15 credits]

**IDM2**

- IDM201 Bacterial infections [15 credits]
- IDM202 Nutrition and infection [15 credits]
- IDM203 Parasitology [15 credits]
- IDM204 Viral infections [15 credits]
- IDM205 Healthcare-associated infections [15 credits]
- IDM213 Immunology of infection and vaccines [15 credits]
- IDM215 Water, sanitation and hygiene [15 credits]



**IDM3**

IDM301 Epidemiology and control of infectious diseases [15 credits]

**IDM5**

IDM501 HIV [15 credits]

IDM502 Tuberculosis [15 credits]

IDM503 Malaria [15 credits]

**PHM2**

PHM201 Health decision science [15 credits]

PHM203 Economic analysis for health policy [15 credits]

PHM204 Economic evaluation [15 credits]

PHM205 Environmental epidemiology [15 credits]

PHM206 Environmental health policy [15 credits]

PHM207 Health care evaluation [15 credits]

PHM209 Globalisation and health [15 credits]

PHM210 Managing health services [15 credits]

PHM211 Medical anthropology in public health [15 credits]

PHM212 Organisational management [15 credits]

PHM213 Principles and practice of health promotion [15 credits]

PHM214 Conflict and health [15 credits]

PHM215 History and health [15 credits]

PHM216 Sexual health [15 credits]

PHM218 Applied communicable disease control [15 credits]

**Important Notes:**

- You must check each module specification prior to registration as modules may have specific prerequisites for study. In particular, many of the IDM modules require you to have a prior knowledge of basic biochemistry, cell biology, genetics and immunology in order to be able to work through and benefit fully from the module.
- Some modules have been withdrawn from study and replaced with updated versions. You may not register for or study some current modules if you have already been awarded credits and a grade for an equivalent withdrawn module - see Appendix A1.
- Students must not be registered for, and cannot study both, CTM208 and EPM304.
- Except with the special permission of the Programme Director, a student must study CTM208 *Further Statistical Methods in Clinical Trials* or EPM304 *Advanced Statistical Methods in Epidemiology* before studying CTM209 *Cluster Randomised Trials*.
- Students must not be registered for, and cannot study both EPM101 *Fundamentals of Epidemiology* and CTM207 *Design and Analysis of Epidemiological Studies*.

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- Except with the special permission of the Programme Director, a student must study EPM101 *Fundamentals of Epidemiology* before studying the EPM3 modules.
- Requests from students wishing to register for a module that is not on the lists above will be considered on an individual basis by the Programme Director.
- Some elective modules may not be available every year.

All module specifications can be found on the LSHTM [website](#).

## Appendix A1 – Module restrictions

Some modules have been withdrawn from study and replaced with updated versions. You may not register for or study the following currently available modules if you have already been awarded credits and a grade for the equivalent withdrawn module as follows:

| <b>Module currently available:</b>                      | <b>Previous module withdrawn:</b>                   |
|---|---|
| EPM101 Fundamentals of epidemiology                     | CTM207 Design & Analysis of Epidemiological Studies |
| EPM307 Global epidemiology of non-communicable diseases | EPM303 Epidemiology of non-communicable diseases    |
| IDM215 Water, sanitation and hygiene                    | IDM210 Water and sanitation                         |
| PHM218 Applied communicable disease control             | PHM202 Communicable disease control                 |