**Assignment specifications**

On this course you are expected to complete 4 assignments.

|  |  |
| --- | --- |
| Site: | [University of Edinburgh Moodle](https://www.moodle.is.ed.ac.uk) |
| Course: | Introduction to Clinical Trials [2013-2014] [SEM 1] |
| Book: | Assignment specifications |
| Printed by: | Christina Mainka |
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**Table of contents**

* [1 Introduction](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch100)
* [2 Assignment weighting](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch102)
* [3 Online participation](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch103)
	+ [3.1 Participation requirements](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch108)
	+ [3.2 Grading criteria general](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch109)
	+ [3.3 Grading criteria: Part I](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch111)
	+ [3.4 Grading criteria: Part II](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch141)
	+ [3.5 General format](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch313)
	+ [3.6 Submission date and procedures](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch110)
	+ [3.7 A week on the discussion boards](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch112)
	+ [3.8 Time management tips](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch113)
* [4 Individual project I](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch104)
	+ [4.1 Learning outcomes](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch156)
	+ [4.2 General format](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch146)
	+ [4.3 Grading criteria](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch148)
	+ [4.4 Indicative readings](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch144)
	+ [4.5 IP I Exemplar](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch317)
	+ [4.6 Submission date & procedures](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch147)
* [5 Individual project II](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch105)
	+ [5.1 Learning outcomes](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch293)
	+ [5.2 General format](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch294)
	+ [5.3 Grading criteria](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch295)
	+ [5.4 Indicative readings & resources](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch296)
	+ [5.5 Submission date & procedures](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch297)
* [6 Group project](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch106)
	+ [6.1 Learning outcomes](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch159)
	+ [6.2 General format](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch160)
	+ [6.3 The learning contract](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch302)
	+ [6.4 Indicative resources](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch162)
	+ [6.5 Your Turn: CTIMP or not?](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch301)
	+ [6.6 Grading criteria](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch161)
* [7 Case study details](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch152)
* [8 Group work guidelines & support](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch122)
	+ [8.1 Submission date & procedures](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch163)
	+ [8.2 Timeline](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch121)
* [9 Help with writing & referencing](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch119)
* [10 Marking scale](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch153)
* [11 Overview](https://www.moodle.is.ed.ac.uk/mod/book/tool/print/index.php?id=8794#ch107)

**1 Introduction**

**Learning, teaching & assessment**

The MSc in Clinical Trials has been designed to offer opportunities for personalised and applied learning wherever possible.  You will engage with key issues and concepts in clinical trials illustrated by case study examples and explore these further within your own professional context.  From the outset you will engage with the subject matter and one another through a series of individual and collaborative tasks that feed into the assessed work described in more detail in the following sections.

[Please note that grading criteria details for the Individual projects I & II and the Group project will be released at a later time in the term]

**2 Assignment weighting**

As you will know from the Course guide you must complete four (4) assignment for assessment which contribute to your final grade as follows:

|  |  |  |
| --- | --- | --- |
| **Assignment** | **weighting** | **word count**  |
| Online participation + reflection | 20% | 1000-1200 |
| Group project + reflection | 25%+10% | 1500+500 |
| Individual  project I | 15% | 800 |
| Individual  project II | 30% | 1200 |
| **TOTAL** | 100% | 5000-5200 |

Details of each can be found in the sections that follow here.

**3 Online participation**

**Overview**

The asynchronous (time-delayed) discussion board serves a key purpose: to provide a collaborative online communication space within Moodle in which you reflect, share and debate issues and topics with one another prompted by a series of Thought questions per Unit of study.

Participating with your peers on the asynchronous discussion board is a core course activity. In order to be successful on this course it is imperative that you are an active member of the discussion boards. A course tutor will be online to moderate, but it is you, course participants, who will drive the conversation forward.

Each Unit Thought discussion will be preceded by a lesson and recommended readings list.  The discussion board will open with the Thought questions for deeper and collaborative exploration and will normally remain open for participation for 2-3 weeks.

**Learning outcomes**

2. Engage and contribute to current and emerging debate around clinical tril transparency, registration and disclosure

4. Critically discuss the challenges of clinical trials delivery including study design, trial set-up, recruitment, follow up and data collection.

**3.1 Participation requirements**

By enrolling on the MSc in Clinical Trials programme you have made a commitment to participate regularly in the asynchronous Thought discussions from weeks 3-10.

There will be **4 Unit Thought discussions** each open for contributions for 2 or 3 weeks. Thereafter the discussions become ‘read only’.

These are held in the table below:

|  |  |  |
| --- | --- | --- |
| **Unit** | **Date** | **Week** |
| **Unit 1** Introduction to clinical trials  | Sept 30th  – Oct 13th |  3 - 4 |
| **Unit 2** Types of clinical trials  | Oct 7th – Nov 3rd |  4 – 6 incl. break |
| **Unit 3** Statistics and clinical trials design | Nov 4th – 24th |  7 – 9 |
| **Unit 4** Professional conduct of clinical trials | Nov 18th – Dec 8th |  9 – 11 |
| **[Unit 5 No new materials** | Dec 2nd – Dec 15th | 11 - 12] |

Of the four Thought discussions you are expected to contribute to at least two (2), but you are encouraged to join as many as possible as the information discussed in each will extend beyond the Unit lessons in Moodle and inform the assessed Individual and Group projects.

It is expected that you join the Unit discussions regularly. Plan on being online at least 4-5 times during each discussion period. You should try to participate as though you are having an ongoing conversation. There is no "wrong" participation as long as yours is topic-related and polite. However, "I agree," is not conducive to a thought provoking class discussion.

You are expected to adhere to the general rules of online etiquette (netiquette) which can be reviewed under Course guide in week 1. Online discussion induction activities have been created in the Technology toolkit folder.

**3.2 Grading criteria general**

Online discussion participation makes up 20% of your final grade.

Discussion participation reflects the quality of your online engagement within the Thought discussions according to the discussion participation criteria in the next section. The format of your engagement should not simply involve directly answering the question, but rather responding to your peers’ ideas and thoughts relating to the question as well as linking to your individual professional experience and subject expertise.

Discussion participation overall is worth 100 marks:

* 50 marks for the quality of your (self-assessed + tutor assessed) online participation +
* 50 marks for your (tutor-marked) reflections on the online participation assignment in general.

The final grade is therefore comprised of your self-assessed (25%) online participation and the tutor's assessment of your online participation (25%) plus the tutor’s assessment of your reflections (50%). For example, if you awarded yourself 36/50 marks for your online participation but the tutors felt this was closer to 30/50 pts and you have been awarded 40/50 pts for your reflections the calculation would be: (36 + 30) pts/2 + (40 pts) = 33 + 40 = 73 pts/100 = 73%

**3.3 Grading criteria: Part I**

Your online participation assessment consists of two parts:

**Part I. Participation self-assessment**

You will  put forward to your PebblePad portfolio the 4 - 6 posts (this is flexible in order to allow for variation in posting word count up to 1200 W) from at least 2 Unit Thought discussions which you will demonstrate on a feedback sheet  together best fulfil the marking criteria (10 marks each):

Clinical trials come alive in dialogue and you are evaluated for your Thought discussion participation as follows:

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Description** | **Max marks** |
| Timeliness  | A post on Sunday night before the close of a discussion is too late for anyone to have a chance to respond to you. You are online early in the week in order to give your peers a chance to engage with you and your views. | 10 |
| Engagement   | You are an attentive participant in the discourse going on around you in the Thought discussion. Your posts draw from thoughts posted and ideas discussed by others in a constructive way (ie, not simply confirming a similarity or difference in views, but elaborating and explaining similarities or differences.) | 10 |
| Relevance   | Your posts relate directly to the general themes of theThought discussion as prompted by  the questions and/orsubsequent discussion. | 10 |
| Critical Thinking | Postings demonstrate evidence of critical analysis and exploration of concepts and ideas beyond the lessons and resources of the course, but still relevant to the general themes of the Thought Questions, or other themes that have emerged in the discussion.  | 10 |
| Evidence base | Postings are supported by evidence from your ownexperience, current literature, an earlier Unit discussion, etc. Where relevant third party material is referenced. | 10 |

Remember, a repetition of what another course participant has written is not worth full credit on top of standing in the way of learning anything at all!

You will assess the quality of your contributions overall. Not every post is expected to fulfill each criteria, but rather the sum of 4-6 posts (1000-1200 W) in at least 2 out of the 4 main Thought discussions are relevant.

**3.4 Grading criteria: Part II**

Part II. Reflection in a maximum of 500 W on the online discussion assignments in general covering the following areas (50 marks):

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Description** | **Marks** |
| Short opening reflection   | How did you initially feel and generally experience participating in the discussions | 10 |
| Reflections on participation in the Thought discussions | This should explore the questions and issues you engaged with, main ideas from the medical literature including regulatory bodies and research guidelines agreed or disagreed with, specific views from your peers that helped shape your understanding and views about knowledge relating to the themes of the chosen Units. | 30 |
| Short concluding reflection | This is a summary of what you have gained from participating in the dicussions, including areas for further learning and any implications for your own clinical practice. | 10 |

**3.5 General format**

Your Online participation submission should include a title page containing:

* The words ‘Online participation submission for ITCT course’
* Your UUN number
* The words ‘ University of Edinburgh 2013/14 Semester 1’

In terms of written content you are guided by the assignment specification Sections 3.3 Grading criteria Part I and 3.4 Grading criteria Part II.

**Self-assessment written format**

Your self-assessment piece should be included in the first assignment section marked "Part I: Self-assessment".

For ease of reading and marking please sse the structure below for organising your chosen posts which best fulfil the marking criteria as then assessed by yourself in the last column (a self-assessment table template will become available here shortly).

One post may satisfy more than one marking criteria, but in total the sum of the posts should be close to 1200 (unique) W or 4 - 6 different posts. Be as specific as possible in your justification-do not write "I have fulfilled the marking criteria a, b, & c." We want to know the reasons why you believe you have earned the marks:

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Your supporting post(s)  (total word count around 1200 W) copy-pasted into this column** | **Points out of 10 you have awarded yourself & justification (75-100 W/criteria))** |
| Timeliness  | Unit 1 (Wed. Oct....) "Supporting post 1 timeliness......' | X/10 pts: "I feel I have attained X/10 pts for timeliness overall as I usually posted over a week before the Unit discussion closed. This was the case for Unit 1 (see supporting posts), for example. The Unit 1 post I selected was responded to by.....which prompted a new debate about.....for the rest of the week.......Had I posted later this may not have been possible...." |
| Engagement  | Unit 2 (Wed Oct....) "Supporting post 1 engagement.....'Unit 3 (Sat. Nov...): "Supporting post 2 timeliness.......'  | X/10: "I have awarded myself X/10 pts for engagement as I have met most of the criteria for engagement demonstrated by the posts selected. In Unit 2 I responded a number of times to my peer by commenting.......and in Unit 3 I directed a number of questions to the tutors about..." |
| Relevance  | Unit 4 (Wed. Oct....) "Supporting post 1 relevance......' | X/10: "I feel  I have attained X/10 pts for relevance against the criteria set out in the marking scheme. The selected post demonstrates this well as the question asked......was met by my thoughts around......" |
| Critical Thinking | Unit 3 (Wed. Oct....) "Supporting post 1 critical thinking......'Unit 4 (Mon. Nov....) "Supporting post 2 critical thinking......' | X/10: "I have given myself  X/10 pts for critical thinking for the posts selected. In the Unit 3 post I challenged the notion that....and in Unit 4......." |
| Evidence base | Unit 2 (Wed. Oct....) "Supporting post 1 evidence-base......' | X/10: "I feel  I have attained X/10 pts for evidence base as I usually included the reference from which the information shared evident in the Unit 2 post (previously highlighted above for relevance) where....." |

**Reflective element**

Your reflective piece should be included in a second section clearly marked "Part II: Reflections".

For the reflective piece you are otherwise free to choose any format you like guided by the questions put forward in Section 3.4: Grading criteria II.

Your reflections are limited to 500 words in length (font size 11 or 12, typed, single spacing fine).

The online participation assignment (self-assessment + reflections)  should be submitted as one document to the appropriate submission box in Turnitin (NOT PebblePed+ as originally instructed).

**3.6 Submission date and procedures**

After completing the online participation assignment (self-assessment + reflections) as instructed above, both parts should be submitted as one document to the appropriate submission box in Turnitin (NOT PebblePed+ as originally instructed) **no later than midnight (GMT) Sun. Dec 1st, 2013.**

**3.7 A week on the discussion boards**

**Overview**

Our week will always be a very busy one and there are a number of different discussion boards to be aware of. Only the Unit Thought discussions are assessed.

**1. Permanent discussion boards**

****

Three discussion boards will remain available to you throughout the term. These are:

* NEWSNEWSNEWS: Check this discussion board regularly as it will contain important changes and updates to the course materials, schedule or technology tools.

--> Information posted by course teaching and IT team only

* Introductions & more: This is a discussion area for getting to know one another in weeks 1-2. Thereafter feel free to use this space for informal conversation. It will remain open from week 1 to week 12.

-->Encouraged online participation

-->Non-tutor moderated (but we will say hello!)

* (Not just for) Problems Forum: Here is the space we ask you to use FIRST for questions about the nature of the assignments or any other module or programme related problems you are experiencing. You are encouraged to help each other out!

We kindly request that you do not email questions that are academic in nature to the course leader or tutors. More likely than not, other course participants are experiencing similar problems and will benefit from your inquiry posted to this forum. This discussion board will remain open from week 1 (for Induction activity problems) to the end of the term.

-->No online participation requirement.

-->Tutor supported (response time Mon-Fri: 24 h/Sat-Sun & Holidays: 48 hrs)

**2. Themed non-assessed discussion boards**

* **Foundation module (week 1-2)**

Library skills & Basic medical statistics: These discussion boards are directly related to the induction tasks assigned during the Foundation module only and offer opportunities for practicing the use of the Moodle discussion tool

--> Encouraged online participation

--> Tutor supported

**3. Themed & assessed Unit Thought discussion boards (weeks 3-12)**

****

* **Unit 1-4 Thought discussions:** New discussions will be made available to you in week 2 (from 08 Oct), 3 (from 15 Oct) , 11 (from 10 Dec) and 12 (from 17/12) beginning on a Monday. The discussions will usually remain open for responses for 3 weeks and will be ‘read only’ thereafter.

--> Compulsory online participation

-->Tutor moderated

**4. Group project discussion boards (weeks 5 - 11)**

In addition there will be private group discussion areas for the group project.

* **Group work discussion boards:** Beginning in week 5 (Oct 21st ) you will have been assigned to your groups for your group project and each group will have a dedicated group project discussion board. Each group will be made up of approximately 4-5 people. You have five weeks to complete a joint project, the nature of which is described in the group project assignment specification, with further guidance to be provided in week 5.

In week 11 a back-up copy of the completed group project (authored in the group WIKI) should be published to the group project discussion board

-->Compulsory online participation

-->Non-tutor moderated (but checked for non-participation)

**3.8 Time management tips**

Communicating online will be new for many of you and it can become time consuming to keep track of potentially branched discussion threads. The following tips will help you become a more effective online communicator in order to make the best use of your time online.

1. Do not underestimate the time it could take to stay abreast of new postings-set aside time regularly for online discussion activities and stick to it! Consider activating the email alert to new postings.
2. Always add a meaningful subject to the subject line of your reply post in order to make it easier for others to spot a relevant post
3. Limit yourself to < **250-300 words per post** which gives everyone a fair chance at expressing their thoughts
4. Do not post messages in attachments-it takes more time to post and more time for others to read.
5. Draft longer posts offline first in order to avoid accidental loss of work online

**4 Individual project I**

**Overview**

For your Individual project I you will assess the methodological quality of two published clinical trials as follows:

You will choose two (2) clinical trials reports in which a novel antithrombotic agent (eg, rivaroxaban/dabigaltran) was tested for efficacy and safety in the prevention and/or treatment of venous thromboembolic events and appraise their methodology sections, respectively. Based on your appraisals you will rate the quality of both and select the one you would refer to for your own clinical practice.

**Details**

Your Individual project I will account for 15% of your final mark for the course.

The word limit is 800 words.

This assignment is designed for you to draw from the lessons in the Library skills & Medical statistics tutorials as well as the Unit 1 lesson and activities. It will prepare you for the Individual project II and the Group project.

**4.1 Learning outcomes**

1. Critically assess the factors that contribute to suitable trial design for a research question including selection of appropriate endpoints, choice of sample size, data analysis, presentation of results and implementation in routine clinical practice.

2. Contribute to the design, authoring and evaluation of clinical trials protocol

**4.2 General format**

Your Individual project I submission should include a title page containing:

* The words ‘Individual project I submission for ITCT course’
* Your UUN number
* The words ‘ University of Edinburgh 2013/14 Semester 1’

In terms of written content you are guided by the five (5) questions introduced by Trisha Greenhalgh in Ch. 4 Assessing methodological quality in her book "How to read a paper" which is available as a University e-resource at <http://lib.myilibrary.com.ezproxy.is.ed.ac.uk/Open.aspx?id=268650>.

The questions to guide your review are:

1. Was the study original
2. Whom is the study about?
3. Was the design of the study sensible?
4. Was systematic bias avoided or minimised?
5. Was it large enough and continued for long enough to make the results credible?

Your critical review should be ca. 800 words in length (typed, single spacing fine) plus the bibliography (citations in Vancouver or Harvard style).

**4.3 Grading criteria**

Your work will be assessed to give you a final mark out of 50 against the following criteria:

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Description** | **Marks** |
| Introduction | The introduction sets the scene for the revew to follow. Each trial is introduced briefly, while including enough detail to put the reviews into a meaningful context. | 5 |
| Review I | Review identifies the key methodological factors  and is organised logically. Terminology is used correctly | 15 |
| Review II | Review identifies the key methodological factors  and is organised logically. Terminology is used correctly | 15 |
| Discussion & selection | The robustness of methodology sections in Paper I & Paper II are compared and contrasted based on their respective reviews against the criteria set out in 'General format' section | 15 |
| Total |  | **50** |

**4.4 Indicative readings**

Before beginning this assignment:

* Please review your notes taken during the Foundation module’s lesson II (Library skills) for searching and selecting the appropriate clinical research papers.
* Consult Foundation module lesson III (Basic medical statistics) for relevant statistical parameters
* Read  Trisha Greenhalgh’s Chapter 4 (which describes the questions 1-5 that guide your review) in the University of Edinburgh ebook ‘How to read a paper‘ introduced in Foundation module II (week 2).

[Available at <http://lib.myilibrary.com.ezproxy.is.ed.ac.uk/Open.aspx?id=268650> ]

* Please bear in mind that the focus of this appraisal is on the research methodology. Feel free to consult the CONSORT checklist (available at <http://www.consort-statement.org/consort-statement/overview0/#checklist> ), but focus more on selecting one of the two papers to inform clinical practice rather than assessing the entire paper for its reporting quality.
* The two papers you choose for the appraisal is up to you, but you are welcome to draw from the following trial reports, for example (if only to familiarise yourself with the research area):
	+ The EINSTEIN Investigators. Oral rivaroxaban for symptomatic venous thromboembolism. N Engl J Med. 2010;363(26):2499-2510.
	+ Eriksson BI, Borris LC, Friedman RJ, et al; for the RECORD1 Study Group. Rivaroxaban versus enoxaparin for thromboprophylaxis after hip arthroplasty. N Engl J Med. 2008;358(26):2765-2775.

**4.5 IP I Exemplar**

**The report**

 The purpose of this report is to critically assess two separate papers in which the safety and efficacy of Rivaroxaban is studied, in order to draw conclusion as to which trial is more appropriate for clinical implementation. The first analysis will be of the RECORD 1 Study (1), in which the conclusion was that Rivaroxaban was superior to Enoxaparin for DVT thromboprophylaxis post op. However, an author pointed out that the incidence of post-op infection was not analysed (2). This leads to the second analysis of a more recent study comparing Rivaroxaban and Tinzaparin (3), and the rates of return to theatre due to infection, which had a less favourable result for Rivaroxaban.

The RECORD study was initialized to analyse the efficacy and safety of Rivaroxaban vs Enoxaparin for thromboprophylaxis post hip or knee arthroplasty. The study was a randomized, double-blinded multinational trial that was longer and had a larger trial size than previous studies (4).  More data greatly contributes to the power of a study.  To avoid selection bias, subjects were randomized by appropriate methods such as permuted blocking by central phone system and computer generated lists. Subjects were selected from twenty-seven countries worldwide, taking into factor different ethnic groups and lifestyles in each area, accompanied by Cochrane-Mantel-Haenzel tests.  Charts displayed the reasons subjects would be ineligible. Exclusion bias was largely avoided by analysing subjects with a modified intention to treat protocol, thus mimicking results that would be similar to everyday practice.

The treatment offered (Rivaroxaban for one group, Enoxaparin for the other) was double-blinded, eliminating performance and selection bias offering to achieve comparable groups as randomly as possible. Outcomes were measured by statistical analysis.  The study set a null hypothesis of inferiority of Rivaroxaban, and a secondary hypothesis to prove superiority.  A power calculation was done in order to show how many subjects were needed in order to show non-inferiority to a power of 95% with a low one-sided error percentage.  The researchers also adjusted for a lack of subjects with valid venogram analysis by increasing the target sample size in order to maintain that power. One could concur from the thorough data analysis, clear elimination of bias, and by following the CONSORT flow diagram (5) there is clear transparency of the trial data, the collection and reporting.

Secondly the Return to Theatre following Total Hip and Knee Replacement Before and After Rivaroxaban study (3) was to evaluate Rivaroxaban vs Tinzaparin and their incidences of post op. infection.  The end result showed that there was a statistically significant increase in infection in the subjects who had received Rivaroxaban. The study is a retrospective, non-randomized cohort trial, which is most open to bias.  As the “controlling” is done in the analytic stage, it is much more difficult to have groups that are equal in age, gender and others.  The statistic tests of probability and confidence levels will be misleading, if not analysed correctly.  Since it was done retrospectively, there could be no fixed criteria in patient selection. The subjects effectively became “cases”, which could cause bias.

The study displayed the CONSORT diagram with their study design, however as this is a non-randomized trial, the Trend Checklist (6) might have been a better reference. The sample size was relatively small compared to the RECORD 1 study. The treatment given and respective durations were decided by the time the hospital changed protocols to reflect the NICE clinical guidelines, (7) so the duration of study for both groups were unequal.  The null hypothesis was ruled out by the data testing, however sample sizes between the two groups were different, as well as incidences between THR and TKR in each group and study duration were not similar, making the study weaker. Statistical analysis was done on an intention to treat basis, with Chi-squared analysis to account for the missing data, however no power calculations were done due to sample size. Using theatre logs may not be the most free from bias as human error can occur while recording. There were also multiple surgeons during the study duration, with no mention of individual infection rates that could possibly influence data analysis.  The combination of all these factors greatly reduce the chances of the data collected being as credible as an RCT would demonstrate.

In conclusion, due to the fact that the Jensen et all cohort study was non-randomized, short in duration, smaller sample size, and the data would easily be affected by bias, it would be premature to fully change clinical practice based on the findings alone.  As the authors suggested, this study highlights the need to further investigate Rivaroxaban with a larger RCT.  As the RECORD study is much larger, follows an appropriate design and clearly outlines the matter in which subjects were randomised, the data is more likely to closely reflect real life than the retrospective trial. As much as a contrasting study can potentially weigh on clinical practice, a poorly designed trial can influence decisions for the wrong reasons.  By thoroughly investigating all factors that contribute to a suitable trial design, it is easier to digest a study and relate it to your own clinical practice in the most relevant manner.

**Bibliography**

1)Eriksson BI, Borris LC, Friedman RJ, et al; RECORD1 Study Group. Rivaroxaban versus Enoxaparin for thromboprophylaxis after hip arthroplasty. *New England Journal of Medicine* 2008 Jun 26;358(26):2765-75

2)Lotke PA. Rivaroxaban for thromboprophylaxis. *New England Journal of Medicine* 2008;359:2174

3)Jensen CD, Steval A, Partington PF, et al. Return to theatre following total hip and knee replacement, before and after the introduction of Rivaroxaban: a retrospective cohort study. *The Bone and Joint Journal* 2011 Jan;93(1):91-5.

4)Eriksson BI, Borris LC, Dahl OE, et al. Dose-escalation study of Rivaroxaban (BAY 59-7939) -- an oral, direct Factor Xa inhibitor -- for the prevention of venous thromboembolism in patients undergoing total hip replacement. *Thrombosis Research Journal* 2007;120:685-693

5) Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials.  *Annals of Internal Medicine Journal* Epub 24 March 2010;152

6) Des Jarlais DC, Lyles C, Crepaz N, and the TREND Group. Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *American Journal of Public Health*. 2004;94:361-366.

7 )No authors cited**.** Venous thromboembolism: reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in inpatients undergoing surgery. *NICE clinical guideline* 46, 2007. http://www.nice.org.uk

**The feedback**

Introduction (max 5 pts): 5

Excellent introduction, showing understanding of clinical question addressed by the two selected RCTs with justification of the selection of clinical trial reports selected. Well-written, with good referencing style.

Review I (max 15 pts): 13

Good attention to detail  regarding the randomisation stategies. Some trials go further in transparency by describing computer protocols/algorithms also.Very good discussion of influences on bias; factors synthesised well and sensible conclusion drawn for overall bias estimate.

Review II (max 15 pts): 13

Well-acknowledged limitations of study design for second paper discussed, all very clearly explained and relevant. It is interesting to note that the findings of the retrospective Jensen study have not yet been replicated, and are in contrast with analyses of pooled data from several large RCTs (see JBJS Br 2012; 94-B: 573-2578).

Discussion (max 15 pts): 13

Well-explained final discussion of each paper and overall conclusion.

TOTAL (max 50 pts): 44

**4.6 Submission date & procedures**

Your Individual project I is due by **midnight (GMT) Sunday, October 13th 2013** to the Turnitin dropbox as announced in week 4.

**Note**: Remember to KEEP A COPY of your work at all times.

**5 Individual project II**

**Overview**

For your Individual project II carefully consider the following scenario:

An academic group have found that levels of the cytokine IL-25 are raised in patients with osteoporosis. They go on to perform a preclinical study and found that a small molecule inhibitor of IL-25 termed GE-456 was not only effective at preventing bone loss in a mouse model of osteoporosis but actually increased bone density by about 4% (equivalent to about 0.4 standard deviations of the mean BMD) in the mice compared with vehicle. Further investigations revealed that GE-456 stimulated bone formation. Based on this, the academics have partnered with a pharma company who are interested in commercialising GE-456 as a new way of treating osteoporosis.

You have been hired as project manager to progress the development of GE-456 in the treatment of osteoporosis in humans

**Your task**

As project manager you are tasked with authoring a report in which you describe the series of clinical trials that would need to be performed in order to assess the safety and efficacy of GE-456 in man, with a view to gaining marketing authorisation. Please discuss the design type that would need to be employed at each stage to achieve this aim.

For each of the trial designs you select, please include the following:

* Justification of why you have chosen that design
* What the aim of the individual trial at each stage of the process would be
* What the sample size and duration of the study would be
* At which stage placebo or active comparators would be used
* What factors would be taken into account in choosing the dose at each stage
* Which endpoints would be studied at each stage.

In formulating your report, please bear in mind that several effective treatments for osteoporosis are already available.

**Details**

Your individual project II will account for 30% of your final grade for the course.

This assignment is an opportunity for you to demonstrate a firm and practical knowledge of the trial design types introduced and scrutinised in Unit 2 further informed by the basic statistical understanding and skills developed in the Foundation module and Unit 3.

The word limit for this assignment is 1200 words.

**5.1 Learning outcomes**

The learning outcomes for the Individual project II are:

1. Critically assess the factors that contribute to suitable trial design for a research question including selection of appropriate endpoints, choice of sample size, data analysis, presentation of results and implementation in routine clinical practice.

6. Critically appraise the methods by which procedural and epidemiological data underpin the development of clinical trials

7. Identify and apply the principles of Good Clinical Practice (GCP) ensuring safety of participants and integrity of data in relation to clinical trials.

**5.2 General format**

Your Individual project II submission should include a title page containing:

* The words ‘Individual project II submission for ITCT course’
* Your UUN number
* The words ‘ University of Edinburgh 2013/14 Semester 1’

In terms of written content you are guided by the case study scenario set out in the Overview and your role within it as project manager in the development of the drug described to gain marketing authorisation.

Your critical review should be 1200 words in length (font size 11 or 12, typed, single spacing fine) plus the bibliography (citations in Vancouver or Harvard style).

**5.3 Grading criteria**

Your Individual project II will be assessed to give you a final mark out of 100 against the following criteria:

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Description** | **Marks** |
| Introduction | The introduction sets the scene for the report and offers enough clinical background information to put the prospective drug development and its rationale into a meaningful context. | 20 |
| Structure & content | The report is structured logically and has engaged with the relevant questions (6) put forth in the task description as well as any further important aspects for each chosen developmental stage. The report is written clearly and terminology is used correctly. | 30 |
| Discussion & analysis | Medical literature is consulted and informs the report throughout.  Each design decision is underpinned by evidence from credible, reliable sources that can extend beyond the course readings. Limiting factors are considered and where relevant alternatives scrutinised. | 30 |
| Conclusion & bibliography | The recommended drug development pathway is summarised convincingly including estimated timescales and projected collaborations. In-text citations and bibliography comply with Vancouver or Harvard referencing style. | 20 |
| Total |  | **100** |

**5.4 Indicative readings & resources**

While working on this assignment:

* Review your notes taken during the Foundation module’s lesson II (Library skills) for researching relevant clinical literature
* Remind yourself of Foundation module lesson III (Basic medical statistics) for relevant statistical parameters
* Consult the feedback to Individual project I
* Review your notes particularly carefully to the readings, lessons and activities in Unit II and keep relevant statistical procedures introduced in Unit III in mind
* Consult the CONSORT checklist (available at <http://www.consort-statement.org/consort-statement/overview0/#checklist> ) as a reminder of the standard expected for a robust trial and the transparency of its report

**5.5 Submission date & procedures**

Your Individual project II is due by **midnight (GMT) Sunday, December 15th 2013** to the Turnitin IP II dropbox as announced in week 10.

**[Note**: Remember to KEEP A COPY of your work at all times.]

**6 Group project**

**Overview**

Working in groups of 5-6+ your main task for this assignment is twofold.

First you will author a clinical trial phase III study design based on the open phase II trial MARS-3 introduced to you by Prof. D. Newby from University of Edinburgh in Unit 2. The second element of the group project is a reflective piece that each course participant will complete  individually on their group work experience.

The main piece of work to be submitted will be a study design protocol that should be jointly authored and presented by your group using a wiki in Moodle. To help facilitate effective group working, each group will be required to submit a Learning contract first that covers agreed roles, responsibilities, and other important issues.

To help support you in undertaking  this assignment, each group will be supported by a designated group tutor.

The Group project counts 35% toward your final grade in total of which the group report constitutes 25% and the reflective element 10%.

**Details**

The **collaborative group report** should be no longer than 1500 words excluding references.  The report may include screenshots, links to relevant clinical trial documents, links to electronic journal papers or other online reference material that you cite, and any other figures, data, pictures or information that you think is relevant.

The **reflective piece** should be no longer than 500 words.

Note: There will also be a **learning contract** (non-assessed) to complete in which member roles and tasks are listed and agreed by the group which the group tutor must sign off before group activities commence.

[**Note**: The Group project resource base including indicative readings, grading criteria, wiki instructions, Adobe Connect host access details, group working spaces, and learning contract template will be made available in week 6]

**6.1 Learning outcomes**

1.Critically assess the factors that contribute to suitable trial design for a research question including selection of appropriate endpoints, choice of sample size, data analysis, presentation of results and implementation in routine clinical practice.

2.Contribute to the design, authoring and evaluation of a clinical trials protocol

3. Critically discuss the challenges of clinical trial delivery including study design, trial set up, recruitment, follow up and data collection

4. Apply the principles of data analysis, dissemination of results and implementation of key findings

**6.2 General format**

The group project you submit has two elements: a collaborative clinical trial design report comprised of 2 parts (please see case study assignment for details) and a reflective element (see reflective assignment for details).

**Clinical trial design report**

Use a basic written report format that includes:

* Titled sections with numbers (1.0, 1.1, 2.0 etc)
* A contents list at the start of the report (as you are producing a wiki, you should ensure the report is easy to navigate, e.g. section titles in your contents list could be hyperlinked to the correct sections-two sections have been created for you in your wiki to help get you started).

Your report should also include a title page or header section that provides:

* An appropriate title for the report (it should be descriptive enough to reflect the content)
* The words ‘Group X project submission for the ITCT module’
* Alphabetical listing of group members
* The words ‘Edinburgh University Semester 1 13/14

In terms of your co-authored content, your group report should include the following information in addition to anything else that you think is relevant:

* Introduction to the report including brief systematic review
* Response to Part I
* Response to Part II and all its sections (description and rationale of chosen study design, eligibility criteria etc)
* Discussion (potential limitations, barriers, regulatory/ethics issues etc)
* Summary
* Reference list (which should be formatted in Vancouver or Harvard style)

Although the above will help give you some idea of what the general sections in your report might contain, and their order, you should structure and the body of the report (intro, discussion, summary etc) as you see fit. The group report should not be longer than 1500 W.

**Reflective element**

Your reflective piece  should include a title page containing:

* The words ‘Group project reflections for ITCT course’
* Your UUN number
* The words ‘ University of Edinburgh 2013/14 Semester 1’

For the reflective piece you are otherwise free to choose any format you like guided by the following questions:

* What were your responsibilities in the team (provide at least one concrete example of your engagement with the team process)?
* What were the benefits and drawbacks of working on this assignment as a team (include evidence)?
* Was working in a team an important part of your learning overall? Why or why not?

It should be submitted separately to the appropriate submission box in Turnitin and not to the group wiki (please note that PebblePad+ will **not** be used as originally planned). The reflective piece should not be longer than 500 W.

**Learning contract**

The learning contract template has been attached to each group discussion board for downloading and completion. It is split into the following sections:

* Names of group members + group tutor
* Group chairperson
* Agreed roles and responsibilities
* Key dates
* Group communication
* Other considerations
* Date of learning contract completion

Each group member must acknowledge the information agreed in the learning contract in a final written statement.

**6.3 The learning contract**

The learning contract must be completed and signed off by the group tutor before group work can commence. The learning contract template is made available to the respective group discussion boards as an attachment in the 'Welcome to the group project' post.

**6.4 Indicative resources**

In the early stages of the group project you are advised to review the following readings and resources in order to consolidate knowledge and understanding around planning for and designing a successful clinical trial. Primarily, however, you will be drawing from the course lessons and activities up to Unit 3 throughout the assignment.

**Readings**

Chapter 10: A concise guide to clinical trials by A. Hackshaw

Available at <http://lib.myilibrary.com.ezproxy.is.ed.ac.uk/Open.aspx?id=213959>

Part I & Part II: Evidence-based practice workbook bridging the gap between health care research and practice (2007) by Paul Glasziou

Available online at <http://ezproxy.is.ed.ac.uk/login?url=http://lib.myilibrary.com?id=268497>

**Web resources**

MHRA CTIMP guidance

<http://www.mhra.gov.uk/home/groups/l-unit1/documents/websiteresources/con009394.pdf>

In addition there is a Your turn activity below in which each group member can check their knowledge of CTIMP.

**6.5 Your Turn: CTIMP or not?**

**Clinical Trials of Investigational Medicinal Products**

[**Note:** This is an independent activity aimed at those members in the group who are not familiar with CTIMPS. This is not to be submitted as part of the group project]

Clinical trials in the UK are regulated by The Medicines for Human Use (Clinical Trials) Regulations 2004 which implement the [Directive 2001/20/EC of the European Commission ('The Clinical Trials Directive')](http://ec.europa.eu/enterprise/newsroom/cf/itemdetail.cfm?item_type=252&lang=en&item_id=3303).

In the UK, **C**linical **T**rials of **I**nvestigational **M**edicinal **P**roducts (CTIMP) requires authorisation by the MHRA (as well as a favourable opinion by an ethics committee and other R&D approvals).

The authorisation is granted in the form of a clinical trial authorisation (CTA). In view of this it is important to know whether a clinical trial is a CTIMP or not.

In this activity you will first remind yourself what constitutes a CTIMP  by reviewing the MHRA CTIMP guide listed in the Indicative resources section, and then consider the following 3 problems.

**Problem 1**

An investigator asks you for advice about whether he should apply for a CTA for a randomised clinical trial in which he wants to determine if blood transfusion is of clinical benefit at shortening hospital stay in patients admitted to the intensive care unit with a haemoglobin of 100 or less.

How would you respond and why?

**Problem 2**

An investigator asks you for advice about whether he should apply for a CTA for a proposed randomised clinical trial in which he wants to compare the effects of infliximab (an anti-TNF drug) with adalimumab (another anti-TNF drug) on disease flares in patients with Crohn’s disease. The investigator explains that because both drugs are liccensed for the treatment of crohn’s he does not think a CTA would be necessary but he wants to check to make sure.

How would you respond and why?

**Problem 3**

An investigator is planning to carry out a retrospective analysis of the effects of antihypertensive treatments in patients who have been seen over the past 5 years in clinic. The investigators aim is to compare levels of blood pressure in the different treatment groups and to compare the frequency of adverse effects. He is wondering if this would be considered a clinical trial and would require consent from his patients and also whether a CTA would be required.

 How would you respond and why?

Do you know your CTIMP?

**6.6 Grading criteria**

Your work for the entire group project, including the reflective element, will be assessed to give you a final mark out of 100.

Your group’s case study report will account for up to 70 of the marks you receive, with the remaining 30 accounted for by the individual self-reflective piece.

**Group report marking scheme**

**Word limit 1500 W.** **Please indicate the word count at the end of your report.**

Your tutor will assess your group report out of 70 marks against the following criteria:

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Description** | **Max marks** |
| Presentation | Specified report format and referencing style adhered to, including references to sources drawn upon in body of report and reference list at the end to the expected MSc CT standard; medical terminology used correctly and overall script is structured well in wiki and written clearly | 5 |
| Collaboration | Learning contract submitted in a timely manner; discussion board and/or Adobe Connect communication and wiki developments evident over lifetime of project; planning, designing, authoring, monitoring activities shared fairly and transparently to group members and tutor; problems addressed and resolved promptly and cooperatively. | 5 |
| Introduction  | Intro to Parts I & II sets the scene succinctly and puts the subject matter of the research (ie the clinical trial) into a meaningful context (brief medical/chemical background) | 5 |
| Part I | Question answered accurately including evidence-based  discussion of result presented and any links to relevant,underpinning course material. | 10 |
| Part II | Items 1-9 each addressed fully/the clinical science presented is correct;  responses are valid and explanations brought forth are supported by evidence (background course materials and external literature); any assumptions made are noted and limitations/risks of method/criteria/intervention chosen are identified; details of calculations included;  descriptions in sufficient detail to enable replication | 40 |
| Summary | Succinct summary of the key elements reported in the main body indicating the most important features of the follow-up study. | 5 |
| Sub-Total |  | 70 |

**Reflective piece marking scheme**

**Word limit: 500 W Please indicate the word count at the end of your reflection.**

Your tutor will assess your reflective piece out of 30 marks against the following criteria:

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Description** | **Max marks** |
| Presentation | As described in the General format section | 5 |
| Q1 | Description of your agreed responsibilities in the team and at least one concrete example illustrating how you have fulfilled your role as a member of the group.  | 5 |
| Q2 | Personal reflection on at least one benefit and one drawback of working on this assignment as a team, including specific examples (from the discussion board, wiki, group proceedings, your own time management, etc) to support your arguments. | 10 |
| Q3 | Description of the role that working in a team on a project played in your learning overall on the course. Provide examples from your personal experience to underpin your views. | 10 |
| Sub-Total |  | 30 |

**7 Case study details**

This collaborative assignment has two parts. Please complete both of them.

**Part I. Genuine background**

Review Professor David Newby’s video clip and all associated resources in [Unit 2](https://www.moodle.is.ed.ac.uk/mod/book/view.php?id=7934) in which he describes the MARS-3 trial.

In the clip Prof. Newby described this as a phase II trial and also mentioned that it was a CTIMP. He also mentioned that if MARS-3 was successful, he was planning to go on to perform a phase III trial as a follow-up.  You will recall from Professor Newby’s recording that the aim of MARS-3 is to investigate how well MRI performed with a new contrast agent to predict the occurrence of ruptured aortic aneurysms, or the need for surgical repair of an expanding aneurysm.

**Your task as a group**

Please explain why MARS-3 is considered to be a CTIMP (there is a course glossary entry!) and discuss why MARS-3 differs from the usual type of phase II CTIMP that we have considered in this course. There is a Your Turn activity in an earlier section to remind you what a CTIMP is. Complete this activity first (each member on their own) in case you are not sure.

**Part 2. An imagined scenario**

Let’s suppose that MARS-3 enrols to target and succeeds in recruiting 350 patients with aortic aneurysms who are asymptomatic and are followed up for two years.

At the end of the study, it turned out that 126 patients (36% of original group) needed surgery because of an expanding aortic aneurysm.

In 95% of these patients the surgery was successful but 5% died because of complications. Another 14 patients (4% of original group) died of a ruptured aneurysm before surgery could be performed.  Analysis of the imaging data showed that the imaging procedure was abnormal in 75% of the patients who developed needed surgery or those who died. The proportion of patients picked up by imaging was similar in those who died and those who needed surgery.

The company that makes the imaging agent is delighted that the technique can identify 75% of people with aneurysms and is successful in gaining marketing authorisation for the use of this agent in detecting people at risk of developing ruptured aortic aneurysms.

Professor Newby has hired you to design a follow-up study based on the results reported in MARS-3 to further investigate the clinical value of this imaging procedure.

**Your task as a group**

1. Formulate your question and describe the type of study design you would employ to investigate this question including the rationale
2. Provide details of the selection of centres for the study
3. List and justify your enrolment criteria
4. Describe the study groups
5. Include details of the interventions (if any)
6. Report the power calculations and sample size
7. Report the duration of follow-up
8. Identify the primary and secondary endpoints.
9. Please indicate whether this study would also be considered a CTIMP.
10. Anything else?

**8 Group work guidelines & support**

This project will require all members to work with one another to form an effective and productive online team. Working in groups can be challenging-especially online-but it can also be very rewarding and a richer learning experience than working individually.

To help ensure that your collaborations on the group project are as constructive as possible, please review the following guidance.

**General guidelines**

* Once the groups have been allocated contact your fellow group members via your group’s private discussion area immediately – don’t wait to be contacted.
* If someone hasn’t suggested this already, try and find a time you can all be online together at the earliest opportunity (for example, perhaps via your Adobe Connect  virtual meeting room).
* Select a group chairperson to co-ordinate deadlines and assign tasks, and who can liaise with your group tutor to seek support and advice on group working issues and who can take responsibility for submitting the learning contract and confirming completion of the final group report.
* The bulk of communication proceedings should occur within your group’s discussion board where details of work allocated and decisions made can easily be viewed by all members, including the group tutor.
* Agree individual responsibilities, tasks and initial deadlines early on, mindful of what the assignment specification indicates each element requires. Work should be distributed evenly in overall effort (which doe not have to be spread evenly over time).
* Be polite and respectful towards each other (which you already are). Make use of each other’s expertise and skills, and don’t disregard an idea without due consideration. Proof read each other’s work, and never re-write another’s work without permission or having agreed editorial control.
* The group project runs over 35 days. A good team will be able to accomodate time zone differences and absences announced in advance-be open and honest about your availability.

**Group working & communication spaces**

In addition to a WIKI, each group will be provided with a private discussion board, and each will be allocated to an Adobe Connect virtual meeting room including a host login.

**Group tutorial support**

Each group is supported by a subject expert group tutor who will be available to join the group discussion board or an Adobe Connect meeting upon request.

**8.1 Submission date & procedures**

Your deadline for the collaborative case study design report and individual reflective piece is:

**Midnight (GMT) Sunday, Dec 8th, 2013**

Your individual reflective piece should be submitted online to the designated area in Turnitin in Moodle.  Your study design report will be created in your group wiki.

A copy of your design reports produced in a Word or HTML file should also be submitted via the appropriate group discussion area as an attachment.

**8.2 Timeline**

**Timeline for completion**

The following timeline summarises the key dates for this assignment, and suggests dates by which certain tasks should be completed or in hand:

**Monday October 21st (week 5)**

Tutors will confirm group membership

**Monday October 28th (week 6)**

Tutors will release the Group study area to each group-check the group discussion board for an update.

During this week, your main tasks should be to assign group roles and responsibilities, timetable work, undertake an initial exploration of the resources and readings, and familiarise yourself with the group tools. Group chairperson to submit completed Learning Contract to group tutor in the group discussion board by Sunday.

**Monday November 4th (week7)**

Group chairperson to submit completed Learning Contract to group tutor in the group discussion board *at the latest* early this week, along with a short update of initial progress in the first week of the group assignment.

**Monday November 11th (week 8)**

Undertake case study research including exploring the wider medical literature.  By the end of this week you should be well into the process of exchanging and discussing ideas.

**Monday November 18th  (week 9)**

As week 8

**Monday November 25th (week 10)**

During the 2 weeks beginning Monday November 25th  at the latest you should undertake and complete the authoring and formatting of your group report.

**Sunday December 8th (week 11)**

Deadline for submission of group reports to group wiki and reflective element to ~~PebblePad+ (currently under review)~~ to the designated Turnitin dropbox.

**9 Help with writing & referencing**

There is writing help available online for non-native English speakers which might also prove useful for those course participants who have not had recent opportunity to write an academic  paper.

Please have a look at the resources held at: <http://www.ed.ac.uk/schools-departments/institute-academic-development/postgraduate/taught/learning-resources/english>

There is a writing tutorial available at the 'Prepare for success' website at: <http://www.prepareforsuccess.org.uk/study_pathways.php> (select ‘academic writing’).

The University has recently subscribed to [Cite them Right](http://www.citethemrightonline.com/) which describes the referencing styles, Vancouver and Harvard, in much detail including many relevant examples.

**10 Marking scale**

**For each of the course assignments please be aware that the mark awarded is provisional. Be sure you understand the following:**

“Please note that the marks awarded for assessed assignments in Introduction to Clinical Trials are provisional, and are provided to give you an indication of your progress ahead of the course concluding.

At the end of the course, the quality of all your coursework will be assessed to provide a final grade on the scale provided below:”

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Max points** |  |  |  |  |  |  |  |  |  |  |  |
| **100 pts** | **0-9 pts** | **10-19 pts** | **20-29pts** | **30-39 pts** | **40-49 pts** | **50-59 pts** | **60-69 pts** | **70-79 pts** | **80-89 pts** | **90-100 pts** |  |
| **50 pt**s | **0-4.5 pts** | **5-9.5 pts** | **10-14.5 pts** | **15-19.5 pts** | **20-25 pts** | **25-29.5 pts** | **30-34.5 pts** | **35-39.5 pts** | **40-44 pts** | **45-50 pts** |  |
| **Letter grade** | **H** | **G** | **F** | **E** | **D** | **C** | **B** | **A3** | **A2** | **A1** |  |
| **Commentary** | (Bad fail) | (Bad fail) | (Clear fail) | (Fail) | (Satisfactory) | (Good) | (Very good) | (Excellent) | (Excellent) | (Outstanding) |  |

Thank you

**11 Overview**

**I.           Overview of the assessed course assignments**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Due date | Assignment | Topic | Submission in Moodle | Learning outcomes | Weighting |
| Sunday ~~Oct 13~~~~th~~ extended to Oct 16th | Individual project I | Published clinical trial report appraisal(800 W) | Turnitin dropbox | 1 & 3 | 15% |
| Sunday Nov 3rd    | Group learning contracts | Group member roles & tasks are assigned and agreed including milestones | Group wiki | NA | Must be submitted before case study resource base is released |
| Sunday Dec 1st  | Choice of 4 - 6 best discussion posts  from at least 2 Thought discussions | The final mark is a weighted average of self-assessment & tutor mark (1200 W) | PebblePad+ | 2 & 4 | 20% |
| SundayDec 8th  | Group project report & reflective element about group work experience | Phase III trial design (informed by a current open  Phase II trial)(1500 + 500 W) | Group wiki | 1, 3, 4 & 5 | 25% + 10% |
| Sunday  Dec 15th  | Individual project II | Clinical trial design for study of  new drug treatment (1200 W) | Turnitin dropbox | 1, 6 & 7 | 30% |