Effect of Autonomous Assessment Method in Effective Teaching of 'Clinical Trials and Management' Course

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Abstract: Clinical trials and management is a unique course offered to the students of Biotechnology and life science graduates in few engineering institutions. This course recently came into limelight due to its huge value in the pharmaceutical job market in both India and abroad which also made private institutions to offer certification, diploma and special degree courses related to this field. This course needs a practice and activity based teaching-learning approach unlike other courses offered in the programme, due to its novel concepts and as to provide the learners complete knowledge to work in this clinical trial industry. To bring in the practicability approach various special assessment methods are applied which includes case study reports, sample clinical trial document preparation, open book test, seminar and also assessment by industry person. Apart from the unique assessment pattern followed, the activity based teaching-learning process such as mock clinical trials, guest lecture by industry persons, clinical trial documentary sessions, clinical trial scenario discussions, role play activities, etc were also emphasized. From the feedback collected from the 42 Biotechnology undergraduate students who learned the course under this method it was understood that they had a very different learning experience compared to the students who went through the conventional assessment system. As an outcome the impact of this course made many students from this group to get special interest towards this field and made a new trend in the student community, as many went to pursue higher studies and jobs related to this field. The students were able to understand the complete process behind clinical trials in an effective manner than in the conventional method. Thus, based on the learning outcome observed at the end of this course, it was evident that the use of such assessment methods brought in the practicability and effective learning of this course. The faculties and institutions offering similar courses could try such approaches specific for the courses to enhance their teaching- learning process.

Keywords: Assessment, Clinical trials, Activity based learning, Practicability

1. Introduction

The clinical trial is a process in which a new drug candidate or device will be tested on healthy or patient volunteers to check for the safety and efficacy of the product, which is a mandate for marketing it. This process involves a massive investment in both money and time and to do this it involves the participation of enormous professionals managing this process. This makes clinical trials one of the ever blooming industries with huge demand for skilled professionals throughout the world. In recent decades, clinical trials related jobs are emerging in vast amounts in the Indian market and this is due to the large population of India, which helps them in getting both required volunteers and employees with low-cost investment. The pre-requisite for getting a job in this sector needs an undergraduate degree in a life-science stream like biotechnology, microbiology, etc., along with sufficient knowledge about clinical trial processes and regulations (George and Davis-Wiley, 2000). In India, every year a significant number of life science students are graduating out, but most of them are not recruited directly by the companies in this sector. This is because most of the institutions offering the life science based degree programs don't include a course on clinical trials in their curriculum. Thus, many new private institutions offering diploma or certification programs related to clinical trials have emerged (Sprague et al., 2012). Due to this stupendous increase in the limelight for this course, now many colleges and universities have started to include this course in their curriculum for undergraduate or post-graduate students pursuing biotechnology or life science. The problem in implementing this course is that it needs a special method of teaching and assessment to achieve a better learning outcome and to make the participants ready for employment in this field (Tractenberg et al., 2010). In this article, the innovative methodology of teaching and assessment adopted for successful implementation of this course is discussed. The article also discusses the outcomes of this implementation with further suggestions for the teaching community involved with this course.

2. Need for autonomy in teaching and assessment:

The engineering institutions in India usually have a common assessment method for all the engineering programmes with very slight variations. The assessment pattern usually follows 50% weightage for the end semester examination and 50% weightage from the internal assessments. The internal marks usually will be taken from the average of two internal examinations and assignments. Both the internal and external examinations will follow a similar pattern with 20-30% of short answer questions and 70-80% of long answer questions. This kind of pattern may be suitable for a regular course that teaches the basics of the particular programme. But, when it comes to special courses like clinical trials and management, the usual pattern does not succeed in making the participants get ready for the job. This creates a gap in the teaching-

learning process. So, to fill this gap we need to impart special methods based on the course in both teaching and assessment. This is possible only when the academic body of the institution provides autonomy for the faculties handling such courses. The faculty receiving this autonomy should develop a detailed plan and use it appropriately to achieve the outcome it was intended to provide in the teaching-learning process.

3. Course Design and Implementation:

The clinical trials and management course was offered to the final year B.Tech Biotechnology students as an elective course that carries 3 credits. Around 42 students undertook this course and the course consists of 5 modules with 9 hours of teaching for each module leading to a total duration of 45 hours to complete this course. The course had a total of 5 course outcomes with one outcome for each module which is listed in the Table 1.

Table 1. Course Outcomes

Course Outcome No.	Description
CO1	Illustrate the concept of new drug and medical device development process
CO2	Interpret the principles and regulations on good clinical practice and able to outline the roles and responsibilities of different authorities in clinical research
CO3	Summarize the various components of a protocol and to explain various documentation systems in clinical research
CO4	Analyze various levels of clinical trial data management
CO5	Outline on various international clinical trials and its impact on society

A. Autonomy Features:

The autonomy mode of teaching and evaluation had the following features:

i. The internal score carrying the 50% weightage can be modified with special assessment methods than the existing normal pattern.
ii. The questions for the exams can be taken in multiple formats and don't need to be having the usual one where 20% weightage for short answers and 80% weightage for long answers.
iii. The rubrics for the assessments can be framed by the faculties handling the course.
iv. The teaching methodology can have more freedom based on the need of the course and assessment plan devised.

B. Evaluation Plan for Internal Score:

The internal score carries 50% weightage in the final grade of the student. The evaluation method opted to attain the internal score for this course and its individual weightage in the total internal score is shown in Table 2.

Table 2. Evaluation plan

S.No	Clinical Trials and Management Evlauation plan		
	Evaluation pattern	**Weightage (%)**	**Course outcomes (CO) covered**
Internal Assessment			
1	Quiz (Min 25 questions for each CO)	10	1,2 and 3
2	Innovative assignments (one individual assignment for each CO)	10	1,2 and3
3	Case study report	5	4 and 5
4	Seminar	5	4 and 5
5	Open book test	10	4 and 5
6	Evaluation by industry person	10	All
External Assessment			
7	End semester exam	50	All

Quiz:

The quiz assessment pattern was implemented to evaluate the course outcomes CO1, CO 2 and CO 3 which cover the first three modules of the course. The quiz was conducted in two modes, first online and next offline. For each module, two online quizzes were conducted, summing to a total of six online quizzes covering the first three course outcomes. The online quiz was conducted via Google forms along with a timer for 15 mins using timify add-on with each quiz consisting of 10 MCQ questions for 10 marks. The quiz usually had MCQ based questions and was from all three levels like easy, medium and hard. Some of the MCQ questions asked in quiz were provided as sample below:

Q1. Label expansion studies are conducted during the following trial phase

a. Phase I
b. Phase II
c. Phase III
d. Phase IV

Q2. A company recruited a Non-Physician person as a PI for their study but the person is highly knowledgeable related to the study. What should the sponsor do to proceed with the trial?

a. Need to Recruit a New PI
b. Need to Continue the study with PI alone
c. Can recruit a Co-Investigator who is physician to take decisions along with PI

d. Can appoint a study nurse to support PI

Q3. The Exclusion criteria of a study say that "No pregnant Women" should be included. But during the study one of the female volunteers becomes pregnant and what would you do now?

a. Will not report and record it and continue the study
b. She was not pregnant at the time of Screening so will continue her in the study
c. Will terminate the volunteer from the study
d. None of the above

The average of all these six online quizzes was taken into 5% weightage of total 10% weightage allocated for Quiz assessment. The remaining 5% was taken from one final offline quiz consisting of minimum of 25 MCQ questions from all three modules which were conducted for 30 minutes duration.

Innovative assignments:

This evaluation carries 10% weightage, which was taken based on the average of three individual assignments submitted by the participants with one assignment per module thus covering the first three modules. The assignment had a mixed usage of online and offline tools based on the topic assigned to the candidates. Assignments like poster presentation, model preparation, sample document creation, monograph preparation, info-graphic presentation, and chart book preparation, etc were given. The individual topics were given to participants with a deadline for submission of each assignment into the Google classroom LMS platform created specifically for this course. Some of the sample assignments provided for the participants was given below:

1. Create a sample e-CRF document using the online templates.
2. Create sample inclusion/exclusion criteria for a Phase III study of your interested disease target.
3. Develop a model to setup a placebo controlled clinical trial.
4. Develop a monograph on the Phase I clinical trial process.
5. Create a poster analysing the pros and cons of 510K pathway in medical devices trial.

The rubrics for each assignment were prepared along with the topics to set a standard evaluation of all the assignments.

Case study report:

The case study report preparation carried 5% total weightage which covers the CO's 4 and 5. The case study topics were assigned to individual participants. They were asked to submit the case study report online via the Google classroom LMS for evaluation within the given deadline. The report was asked to be prepared using a word document with a minimum of 5 pages. The case study was performed only using real clinical trials conducted or ongoing in India / abroad with details pertaining to clinicaltrials.gov website supported by various online resources. A separate rubric was framed to evaluate the case studies submitted by the participants which is provided below in table 3.

Table 3. Rubrics for evaluation of case study report

Assessment criteria	Excellent	More than Satisfactory	Satisfactory	Below satisfactory	Well below satisfactory
Identification and understanding of the case discuss.	5	4	3	2	1
Analysis and evaluation of the case	5	4	3	2	1
Additional information and research on the case	5	4	3	2	1
Clear and organized presentation of the report	5	4	3	2	1
Effective inference and conclusion	5	4	3	2	1

Seminar:

This had 5% weightage covering the CO's 4 and 5. The students were assigned individual topics based on which they need to prepare a presentation and take a seminar. The minimum duration was 10 minutes and which will be followed by questions from other participants on the topic presented, for which they need to answer. The rubrics were developed consisting of points for presentation, communication, etc which is given in table 4.

Table 4. Rubrics for evaluation of seminar

Assessment criteria	Excellent	More than Satisfactory	Satisfactory	Below satisfactory	Well below satisfactory

Oral presentation is clear and organized	5	4	3	2	1
Sufficient coverage of content on the topic	5	4	3	2	1
Slides present information clearly	5	4	3	2	1
Clear and confident oral communication	5	4	3	2	1
Pace and time management of presentation	5	4	3	2	1

Open – book test:
This assessment pattern covered CO's 4 and 5 with 10% weightage. Many teachers have a thought that open book test will be easier for students, but with a proper formulation of questions it will make students to have a deeper approach during the test (Theophilides and Koutselini, 2000). The open book test was conducted for 90 minutes for a total of 50 marks with questions both in short and long answer formats. Most of the questions were at medium and hard levels with fewer questions at easy level. As the participants can use the study materials to answer the questions the questions were asked mostly in create, evaluate, apply and analyze levels of Bloom's taxonomy. Some of the questions asked in open-book test were given below:

Q1. A trial pharmacist issued 480 pills of study drug to a study volunteer on 9 May 2019 and received 120 pills back on 9 Aug 2019. The dosage prescribed to the volunteer by PI is 2 pills per dose frequencies with 2 dose frequencies a day. Find out the percentage of study drug taken by the volunteer as per the prescribed dosage?

Q2. Samantha has AIDS and wants to take part in the trial that her doctor found for her. Samantha will be meeting with the research team soon. However, Samantha is very worried and confused about some of the terms such as "Randomization, Blinding, Placebo, and Adverse Events" which she googled about clinical trials in net. It will be very important for the research team to interview Samantha and solve her doubts and maintain confidentiality. Now, as a team lead who is going to interview Samantha what all will you say to clear her doubts on the terms she searched in net. Also, what all points will you highlight and explain to her in terms of protecting her confidentiality during the entire course of study so that she gets confident and joins your study.

Q3. A company X is conducting a Clinical trial on a new drug for treatment of Cancer. They are in need to enroll new volunteers for the trial. What are the strategies the company can do to recruit volunteers for the trial.

Evaluation by industry person:
This method of evaluation has a 10% overall weightage which covers all the five CO's and modules. The evaluation involved the participation of an industry person from the clinical trial sector. The industry person was made clear on the syllabus a week before the assessment and the person asked the questions to individual participants via a viva format assessment. The questions were asked randomly from all the modules, but maintaining the diversity of it. This method of evaluation provided the participants a feel of attending an interview process for a job in the clinical trial sector.

End semester examination:
The question pattern was made completely different from the routine pattern, which is 10 two mark questions and 5 sixteen mark questions. This course had more weightage for two mark questions with 20 questions and 6 ten mark questions were asked. Most of the questions were taken from the higher order of the Bloom's taxonomy to evaluate the application, analysis and creative ability of the participant based on their learning.

The implementation of diverse evaluation methods made participants have continuous learning and participation in the course. Most of these assessments were happening in regular intervals, unlike the normal mode in which assessments will happen only after the completion of two modules.

C. Teaching Methodology

When we plan for a unique evaluation pattern our teaching and learning methodology also must change, thus the teaching methods opted for this course was planned based on its evaluation methodology. More practicability approach and activity-based teaching-learning practices were followed, such as:

1) *Infographic Presentations*: To make the participants visualize the clinical trial process in a better way infographic presentation, flashcards, posters and animation videos were utilized.

2) *Gamification*: Online games and simulations related to the clinical trial process were incorporated in classroom teaching. This created an easy understanding of the concept with high involvement of the participants. Apart

from these online games and simulations, few live classroom activities were also employed. The list of online and offline activities incorporated for this course was listed below in table 5.

Table 5. Online and offline activities incorporated

S. No	Mode of activity	Topic covered	Link for activity
1	Online	Drug discovery – Basic concept	https://www.centreofthecell.org/learn-play/games/cure-asifs-cancer/
2	Online	In silico drug development	https://www.centreofthecell.org/learn-play/games/develop-a-drug/
3	Online	Drug development Process Overview	https://www.centreofthecell.org/learn-play/games/how-are-drugs-developed/
4	Offline	Informed consent process	https://www.centreofthecell.org/learn-play/lesson-plans/?tab=5
5	Offline	Blinding process in trials	https://www.centreofthecell.org/learn-play/lesson-plans/?tab=4
6	Offline	Clinical trial phases	https://www.centreofthecell.org/learn-play/lesson-plans/?tab=8
7	Offline	Role of Volunteers in clinical trials	https://www.centreofthecell.org/learn-play/patient-journeys/clinical-research/
8	Online	Design of clinical trial	https://www.nms.ac.uk/explore-our-collections/games/clinical-trial/
9	Online	Role of Principle investigator in clinical trials	http://vct.rice.edu/
10	Offline	Clinical trial terms	https://generationr.org.uk/?game=pictionary-research-activity
11	Offline	Ethics in clinical trials	https://generationr.org.uk/?game=learning-about-research-ethics-in-the-classroom

3) *Role-play activities*: Clinical trial process includes the involvement of different professionals and understanding their roles and responsibilities is one of the objectives of this course. To ensure this, role-play activities and a mock clinical trial skit was conducted.

4) *Guest Lectures and Webinars:* Webinars and guest lectures by industry persons were arranged to have a healthy discussion on the various aspects of clinical trials. This provided them a better understanding of the clinical trial process, as they heard things right away from real professionals working in clinical trials.

4. Students reflection on this course:

A survey on course evaluation methods was collected from all the 42 students. The survey consisted of a total of 5 questions as mentioned below and its corresponding responses are given:

Q1. Which of the following evaluation method was most helpful and effective in understanding the concepts (Check all that apply).
The responses from the participants for this survey question Q1 is depicted as a pie chart as shown in Fig. 1.

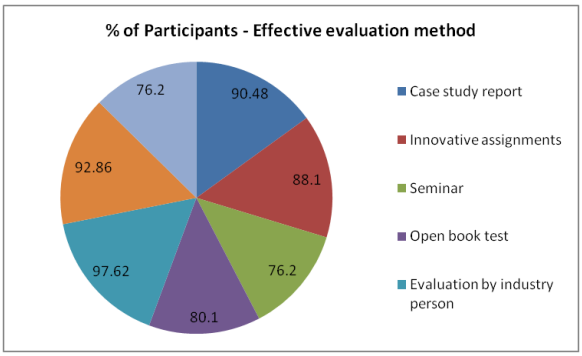

Fig. 1 Response of participants for Survey Question #Q1 on evaluation methods

From Fig 1, it was evident that more than 90 percent of students felt that case study report preparation, evaluation by an industry person, quiz and innovative assignments helped them in understanding the core concepts of clinical trials and management. Also, around 75 percent of participants feel that all the evaluation methods opted was helpful and effective to achieve the learning outcomes of this course.

Q2. The course learning objectives were achieved at the end of this course. The responses from the participants for this survey question number Q2 are depicted in Fig 2.

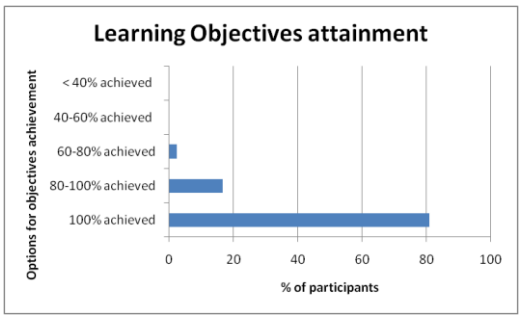

Fig. 2 Response of participants for Survey Question #Q2 on learning objectives

Q3. The combination of regular teaching and special teaching methods like gamification, infographics, role-play activities, guest lectures helped create an interactive atmosphere.

Q4. Gained sufficient knowledge and feel confident to work in the clinical trial industry.

Q5. Recommends this course for others.

The responses from the participants for the survey questions Q3, Q4 and Q5 are depicted in Fig 3.

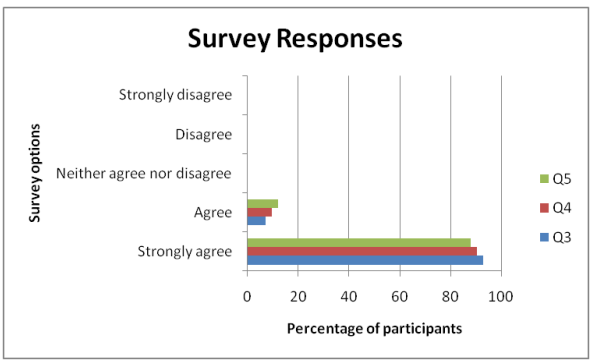

Fig. 3 Response of participants for Survey Question #Q3, #Q4 and #Q5 on teaching methodology, knowledge and recommendation of course respectively

Around 90% of the participants strongly agree on the survey questions Q3, Q4 and Q5 and the other 10% gave agree to the same This indicates that almost everyone undergone this course felt that this unique teaching methodology helped create an interactive atmosphere. They have also gained sufficient knowledge and feel confident to work in the clinical trial industry. Most importantly every participant strongly recommends this course for others.

5. Conclusions

Participants of the course 'clinical trials and management' under this autonomy model had significant achievement in their learning outcomes and experienced effective classroom interactions. Based on the learning outcome observed at the end of this course, it was evident that the use of such assessment methods brought in the practicability and complete knowledge transfer of this course. The faculties and institutions offering similar courses could try such approaches to enhance their teaching-learning process.

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References

1. George, M. A., & Davis-Wiley, P. (2000). Team teaching a graduate course: Case study: A clinical research course. College teaching, 48(2), 75-80.
2. Sprague, S., Pozdniakova, P., Kaempffer, E., Saccone, M., Schemitsch, E. H., & Bhandari, M. (2012). Principles and practice of clinical research course for surgeons: an evaluation of knowledge transfer and perceptions. Canadian Journal of Surgery, 55(1), 46.
3. Tractenberg, R. E., Umans, J. G., & McCarter, R. J. (2010). A mastery rubric: Guiding curriculum design, admissions and development of course objectives. Assessment & Evaluation in Higher Education, 35(1), 15-32.
4. Theophilides, C. & Koutselini, M. (2000). Study behavior in the closed-book and the open-book test: acomparative analysis. Educational Research and Evaluation 6: 379–393