Title of Project

Developing Expertise of CTU Staff through Massive Open Online Resources (MOOCs)

Abstract

Clinical Trials Unit (CTU) staff require training to develop their skills and enable them to develop as specialists in their individual trial discipline. Surveyed CTU staff expressed a desire for broader knowledge about the clinical trial lifecycle and the variety of research related roles. However, lack of staff time and training budget and courses not being available at the most appropriate time for staff, were identified as obstacles to successful training.

This project included the development of three self-sustainable online courses, available at all times, to CTU staff and the wider community, around the globe. The courses are provided on the FutureLearn[1] platform.

The tools developed include a Massive Open Online Course (MOOC) and two additional online courses which sit alongside the MOOC to create an 'ExpertTrack'.[2] This is an in-depth course designed to master new skills in a specialist area.

The MOOC 'An Introduction to Randomised Controlled Trials'[3] focuses on the importance of trials in evidence-based medicine. It describes the lifecycle of a trial and takes learners through the research process from conception of idea through to publication. This course was launched in July 2021 and has enrolled over 2.5K learners with extremely positive feedback.

The two additional courses focus on 'Data Management'[4] and 'An Introduction to Statistics',[5] both identified by CTU staff as important areas for additional training. The development of the content for these courses is almost complete and the creative design technical team are currently in the process of uploading content to the FutureLearn platform. The Data Management course is due to be released by the end of October 2023, and the Introduction to Statistics will be released at the end of November 2023.

All three courses are suitable for individuals working within clinical trials within academia, the NHS or industry, with no previous clinical trial or statistical training. This will include aspiring chief investigators, research nurses, trial co-ordinators, trial managers, data managers, quality assurance team members, trial administrators, and other members of trial teams such as qualitative researchers or health economists.

Introduction

Trials unit staff require training to develop their skills and enable them to develop as specialists in their individual trial discipline. The CTUs also have a responsibility to train the NIHR Clinical Fellows and other clinicians who will be the Chief Investigators of the future.

Prior to the application for funding, a review of training provision for CTU trials staff at Birmingham University was conducted across CTU disciplines. This training-needs analysis included unit wide surveys, focus groups and one-to-one meetings. The obstacles to training

identified included: lack of staff time; lack of a training budget; available material not always being directly relevant to trials or to the development of expertise within a specific trial role; and courses not always being available at the right time.

One of the themes ascertained through the training needs analysis related to a desire for broader knowledge about the trial lifecycle and the variety of research related roles. This type of overview to Clinical Trials was also requested by staff new to the area of trials. An appreciation of the bigger picture better engages individuals and improves productivity and serves to enable maximum efficiency and early productivity. Additional, more focussed areas of required training were identified as data management, an introduction to statistics and trial recruitment.

The funding secured from this bid allowed for the development of a Massive Open Online Course (MOOC) (An Introduction to Randomised Controlled Trials)[3] and three Small Private Online Courses (SPOCs) (Data Management, Introduction to Statistics, Trial Recruitment) to be accessed within the FutureLearn platform[1]. The FutureLearn platform[1] provides easy access to CTU staff and the wider community and access to courses when and where required.

Methods

The two University of Birmingham Clinical Trial Units (BCTU and CRCTU) have an established training collaboration and an aligned strategy which included working together in the delivery of this proposal.

The MOOC, 'An Introduction to Randomised Controlled Trials',[3] was developed first and responds to the identified training need for broader knowledge for CTU staff. The original plan in addition to the completion of the MOOC, was for the development of three smaller private online courses (SPOCs), focussing on data management, statistics and trial recruitment. However, during the project, FutureLearn,[1] re-evaluated its provision to no longer host SPOCs. This resulted in a need for us to re-evaluate this development and to instead develop three online courses, which alongside the MOOC would form part of an 'ExpertTrack'.[2]

Over the course of the development of these materials, there were several issues which led to delay in the delivery of this project. During the COVD-19 pandemic, there was a requirement for the University of Birmingham digital learning team to re-prioritise their workload with the need to move undergraduate and postgraduate teaching online. This unprecedented challenge was further compounded by changes in staff resource within the team and the further impact of this on competing workload. In addition, as the development was underway for the courses on 'Data Management' and 'An Introduction to Statistics', it became evident that the learning hours for participants and the parallel developmental hours for the learning and digital teams for both courses exceeded our original estimate. The learning hours across these two courses were equivalent to the learning hours originally planned across the three smaller courses. The NIHR accepted that within the scope of the grant, the development should be limited to two courses only, in addition to the MOOC.

Whilst these factors have led to significant delay to the delivery of this project, the content for the ExpertTrack is now almost complete and the ExpertTrack will be live by the end of November 2023.

The courses were developed to be self-sustainable, with no activity from course contributors following development of the courses and only occasional updates to content required.

Results and Conclusion

The MOOC[3] was launched in July 2021 and to date 2,590 learners have enrolled. The MOOC has received extremely positive reviews and attained an overall course rating score of 4.7/5. The feedback provided from learners on the MOOC has also been extremely beneficial in informing the development of the two additional ExpertTracks that complete this project.

This course focuses on the importance of trials in evidence-based medicine. It describes the lifecycle of a trial and takes learners through the process from conception of the trial idea through to publication (see Appendix for a list of included topics). The course includes short videos, articles, discussion questions and quizzes to help reinforce knowledge. The duration of the MOOC is 3 weeks, requiring users to complete around 4-5 hours per week of learning. As well as improving knowledge amongst the clinical trial workforce, this course improves engagement with potential investigators and attracts people into the clinical trials workforce. It is also useful for PPI representatives who wish to learn more about the research process.

The Data Management course explores the way we should handle trial data from the design of data collection tools and the collection of trial data, its secure storage and management on computerised systems, through to its archiving at the end of the trial; and the quality processes that are employed to assure the accuracy, reliability and overall credibility of the final data set (see Appendix for a list of included topics).

The Introduction to Statistics course provides participants with an introduction to statistics within clinical trials. It provides an overview of the key statistical concepts and methods used within clinical trials, which are transferable to other types of studies within healthcare research. The focus of the course is on identifying the correct statistical methods to use in different trials and the correct interpretation of analyses. The course does not focus on formulae or conducting analyses oneself, which should always be left to the trial statistician (see Appendix for a list of included topics).

Both the Data Management and Introduction to Statistics courses include the same variety of delivery as the MOOC, but are slightly shorter in length (10-12 hours each).

The MOOC provides free learning and the content is introductory in nature, increasing the appetite for further learning contained within the more specialist online courses that form this ExpertTrack. To sign up for the ExpertTrack and access the other 2 courses, learners are allowed a 7 day free trial after which they pay a monthly subscription of £36 for as long as it takes them to complete the ExpertTrack. The advantages of the MOOC and the accompanying two online courses compared to ‘classroom’ teaching from the user’s

perspective include: the ability to fit learning around work commitments; courses being accessible on PCs, laptops, tablets and mobile phones; access to a wider range of voices in online discussions; and, it avoids the costly outlay often associated with face-to-face courses. From the educator's perspective, whilst the initial development was time-intensive, subsequent runs of the course require little resource. The content of a session is not as limited by time since users can be directed to additional examples and resources online.

The development of these materials has responded directly to the specific areas of need identified through our training analysis and allowed for training resources for a broad audience. The courses are available internationally and are therefore of benefit to the global trials community. A strengthened skill base will have a positive impact on the quality and efficiency of study delivery, reducing research waste and increasing the robustness of NIHR research.

Dissemination

There is open access to the MOOC and it is free to users. It can be accessed through the FutureLearn platform.[3]

This MOOC is advertised in the CTU newsletters and via the University of Birmingham training webpage. It is also accessible through a search of FutureLearn courses.

The accompanying 'Data Management'[4] and 'Introduction to Statistics'[5] online courses that form the ExpertTrack will also be accessed through FutureLearn and will be advertised in similar ways.

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Conflict of interest declaration

There are no conflicts of author's competing interests.

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Appendix – Topics included in each of the three online courses

An Introduction to Randomised Controlled Trials in Healthcare – List of Topics
What are Randomised Controlled Trials?
How do we ensure our results are valid?- Minimising Bias
Different Trial Phases
The Importance of Systematic Reviews
Formulating a Research Question – PICO
The Trial Protocol
Trial Funding
Research Governance
Statistics in Trials
Roles and Responsibilities of the Trial Team
Regulatory and Research Ethics Committee Approval
Trial Registration
Patient and Public Involvement
Essential Documents and the Trial Master File
Risk Assessments and Monitoring Plans
International Trials
Recruitment
Informed Consent
Data Management Process
Safety Reporting
End of Trial Procedures
Statistical Analysis
Reporting and Publication
How Trial Results are Used to Inform Guidelines

Data Management – List of Topics
Data Management Plans
Critical Data Items
Data Validation Plans
CRF Development
Computerised Systems
Clinical Trial Monitoring
Data Entry Quality Checks
The Monitoring Plan
Monitoring Output
Tolerance Limits
The Data Clarification Process
Archiving
Data Cleaning

Introduction to Statistics – List of Topics
The importance of statistics in clinical trials
Measuring & summarising data
Measures of association
Sampling variation & confidence intervals
P values
The basics of statistical tests & regression models
Sample size considerations
Dealing with non-compliance and missing data
Statistical analysis plans and transparent reporting

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