



# Clinical Trial Manager (CTM) TRAINING COURSE

## COURSE DETAILS & CURRICULUM

**Are you looking for a way to better support your existing Clinical Trial Managers (CTM)?**

Are you looking to promote candidates to CTM from the Clinical Research Associate, Clinical Trial Assistant or other role? Do you want to set them up for success and longevity?

*We have your solution!*



At ClinEssentials, we are resolute in our mission to revolutionize quality and efficiency for the benefit of clinical trials and research teams. ClinEssentials offers an All Access + LIVE Clinical Trial Manager training course for those that have at least 1 - 2 years of prior clinical trial experience.

**Our CTM training goes far beyond what is typically offered to CTMs during the on-boarding process and more in-depth guidance than company Standard Operating Procedures.**

*Let's face it, CTMs have varying degrees of experience and in order to set them up for success so they can jump right in and start managing their trials, they need training (or a refresher) on how-to perform their responsibilities.*

**The ClinEssentials CTM Training teaches key strategies with professional guidance and proven methods.**

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*The material covered in this course is relevant, industry standard, and empowers students with exactly what is needed to become a successful CTM.*

— Jeslyn A., Clinical Research Associate & CTM Course Student

**View the expansive topics we'll discuss throughout the course!**





*This is the new way to have courses; much more valuable than a university. There's no place else to learn it. And Tiffany is one of the only people who could have taught it!*



**DAN SFERA** The Clinical Trials Guru



## COURSE OVERVIEW

**MODULE 1: COURSE OVERVIEW** Welcome! The CTM Training Course will take you step by step from Study Initiation to Study Conduct to Study Close-Out. We will kick off the course with introductions and introductory information! This is our opportunity to learn about the other participants (for the All Access + LIVE course only) and become familiar with CTM Training and how the course will work.

**MODULE 2: STUDY INITIATION** Our learning begins with a detailed discussion of the Clinical Trial Manager role, including its importance on each study and characteristics of successful CTMs. We then dive into Study Initiation, which can be one of the most challenging phases for CTMs due to numerous activities and responsibilities that occur simultaneously. From Project Kick-Off and Site Feasibility to Project Plans and Investigator Meetings, we will cover it all - *and then some!*

**MODULE 3: STUDY CONDUCT** Study Conduct, also called Study Maintenance, is when Clinical Trial Managers are responsible for achieving key study milestones. During this phase, CTMs are actively involved with study metrics, recruitment, and retention. We begin with Site Initiation Visits and end with Last Patient Last Visit - and you will learn about everything in between!

**MODULE 4: STUDY CLOSE-OUT** Study Close-Out is the final phase of the Clinical Trial Life Cycle and the Clinical Trial Manager ensures all study activities are completed prior to Database Lock so the study remains on track for the Clinical Study Report (CSR) and final eTMF closure. You may realize this is more complicated than it sounds - and you are right! However, you will be ready to tackle Close-Out after this training!

**MODULE 5: GENERAL CONSIDERATIONS AS A CTM** A Clinical Trial Manager is a management-level position, which comes with a unique set of responsibilities that are important to a CTM's success in the role and to the overall success of the clinical trial. The course continues with best practices for working with teams, communication techniques, problem solving, and yes... a discussion about how to achieve that precious work/life balance!

**MODULE 6: CAREER RECOMMENDATIONS AS A CTM** The CTM Training Course wraps up with a focus on your future! We'll discuss reviewing job descriptions, resume and interview tips, as well as how to become a CTM contractor. We will even share our secret on how you can get \$5K more in salary!

**BONUS CONTENT MODULE: UNBLINDED CLINICAL TRIAL MANAGER** This is bonus information that you may not realize you need, but will be thankful to know! Does your study have an unblinded component? If so, you must have an Unblinded Clinical Trial Manager (uCTM). This module outlines the uCTM role which is different from the Clinical Trial Manager role discussed in the course.

**BONUS CONTENT: SUPPLEMENTAL LIBRARY** This bonus library contains additional in-depth videos on various CTM topics.





## COURSE AGENDA

### MODULE 1: COURSE OVERVIEW

Welcome  
Course Roadmap and Outline  
Suggested Self-Paced Learning Schedule  
CTM Training Course Exclusive Support Group  
Office Hours  
Supplemental Training Library  
CTM Training Workbook  
Where Can I Find Course Contents?  
Sponsor CTM or CRO CTM  
Meet Your Instructor

### MODULE 2: STUDY INITIATION

#### PART 1

Clinical Research Overview  
The Clinical Trial Manager Role  
Characteristics of Successful CTMs  
Who Does the CTM Routinely Interact With?  
Am I a CTM or Study Manager?  
Career Paths to CTM  
Study Initiation: 8 Sub-Categories  
Request for Proposal (RFP)  
Bid Defense  
Study Award  
Statement of Work (Scope of Work)  
Project Resourcing

#### PART 2

Project Kick-Off  
Core Document Finalization and Processes  
Site Feasibility  
Vendor Selection/Set-Up

Project Plans  
Site Materials  
Investigator Meeting Planning  
Other Considerations

### MODULE 3: STUDY CONDUCT

Site Initiation Visit  
Key Milestones  
First Site Initiated  
Site Greenlight to Screen  
First Patient First Visit  
First Patient Enrolled  
Study Metrics  
Subject Recruitment  
Subject Retention  
Subject Recruitment and Retention Plan  
Ongoing CTM Responsibilities - Recurring Actions  
Less Frequent Activities  
Activities Dependent on Statement of Work or Protocol  
Last Patient Last Visit

### MODULE 4: STUDY CLOSE-OUT

Preparing for Database Lock  
Close-Out Visits  
Final Payment Reconciliation  
Central IRB Closure  
Team Meetings  
Project Resourcing  
Clinical Study Report  
Final eTMF Closure  
Lessons Learned

### MODULE 5: GENERAL CONSIDERATIONS AS A CTM

Working with Teams  
Communication  
Problem Solving  
Study Phase Nuances  
Study Transitions  
Ongoing CTM Tasks  
Working with Technology

### MODULE 6: CAREER RECOMMENDATIONS AS A CTM

Job Descriptions  
Resume/Curriculum Vitae  
Interviews  
Salary Negotiations  
Contract CTM  
Mighty Networks Membership  
Other ClinEssentials Services  
Course Completion

### BONUS CONTENT: UNBLINDED CLINICAL TRIAL MANAGER

What is an Unblinded Clinical Trial Manager?  
Core Responsibilities of an uCTM  
Allocated Time uCTMs and uCRAs Spend on a Study  
Tips for Maintaining the Blind on Unblinded Studies

### BONUS CONTENT: SUPPLEMENTAL LIBRARY

Additional in-depth videos on various CTM topics



## PRACTICAL APPLICATION & CONTINUED SUPPORT

Participants also have the opportunity to practically apply what they learn through problem-solving real-life CTM scenarios in instructor-led LIVE sessions. Course activities walk participants through the actual planning of an Investigators Meeting as well as teaching CTM responsibilities during a bid defense and many other real-life situations.

Each participant will not only receive a Course Workbook which contains these practical applications and activities but they also get a FREE membership to our exclusive CTM Course group hosted on Mighty Networks.





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*The CTM role is so important and there is so much to know, so when you take advantage of opportunities to learn and equip yourself with knowledge and strategies, you are paving your path to success.*

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**TIFFANY ASHTON** MAS, CCRA, ClinEssentials Expert CTM Course Instructor



## ALL ACCESS + LIVE CTM TRAINING COURSE PARTICIPANTS ALSO RECEIVE:

- ✓ Ongoing access to the instructor for up to 1-year to ask additional questions or receive additional support.
- ✓ Lifetime access to course content including the supplemental library with additional in-depth videos to refer to and utilize throughout their career.
- ✓ Certificate of Completion after completing the CTM Training Course and passing the Final Exam.
- ✓ Continuing Education units through ACRP and SOCRA



## INVEST IN THEIR SUCCESS (AND YOURS!)

High turnover rates in Clinical Research often lead to increased budgets, delayed timelines, and frustrated, exhausted employees. These issues caused by turnover challenges are the reason for many failed studies. However, employees who are equipped with the knowledge and resources they need to be successful in their job are more likely to remain in their roles.

Organizations that invest in Clinical Trial Managers benefit from decreased turnover, top-performing industry professionals, and more effective studies that conclude on time and within budget.

**Invest in your employees (and your company's future) with the ClinEssentials CTM Training!**

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*As a rookie CTM, it was extremely beneficial to receive oversight of a CTM's role and responsibilities during all phases of a study. We learned many practical pro tips that I wouldn't have known about without the CTM Training Course. The course helped to set me up with knowledge and good organizational habits from the start. Having had the opportunity to ask case-specific questions during the live training and Q&A sessions elevated my confidence in conducting my day-to-day tasks!! Thank you for a wonderful course!*

— Wilna B., (new) Clinical Trial Manager & CTM Course Student

**ARE YOU READY**  
to sponsor an employee  
for the CTM Training?

**\$4,997 PER STUDENT** PAYMENT PLANS & FINANCING AVAILABLE!

REGISTER YOUR EMPLOYEE FOR THE NEXT SESSION

Have multiple employees you'd like to enroll? Contact us for group training rates!  
[ctmcourse@clinessentials.com](mailto:ctmcourse@clinessentials.com)