CTMS End User
Training Agenda[1]

Day 1

Session Description: This session provides you with core knowledge on CTMS concepts, users and roles management and other Super User functionality that augments the preparation and setup process. Scenarios of using files that have been organized in the proper import format will be reviewed.

Approximate Duration: 4 Hrs

Time	Topic
8:00am – 9:30am	**Welcome** • Getting to Know You **CTMS Introduction** • CTMS Knowledge Space • Concepts • Structure • Security • Navigation
9:30am – 9:45am	**Break**
9:45am – 10:30pm	**Resources Overview** • Resource Management • Role Management
10:30pm – 12:00pm	**People and Places** • Organizations • Addresses • Contacts – no vendors

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[1] Note: All times serve as estimates

Day 2

Session Description: This session will take you through the process of creating and managing study, country, sites, and subjects efficiently in CTMS.

Approximate Duration: 4 Hrs

Time	Topic
8:00am – 9:30am	**Study Management** • Study Planning • Adding a Study • Study People such as Members, Contacts, • Internal Staff • Standard Study Milestones • Study Milestones • Study Activities • Study Level Findings/Actions
9:30am – 9:45am	**Break**

9:45am – 10:30am	**Country Management**
	• Country Planning
	    o Adding a Country
	    o Country People such as Contacts and Members
	• Standard Country Milestones
	• Country Sites
	• Country Recruitment

10:30am - 12:00pm	**Site Management**
	• Site Planning
	    o Adding a Site
	    o Site Addresses
	    o Site Contacts
	    o Site Members
	    o Site IRB/IEC
	• Standard Site Milestones
	• Standard Site Activities
	• Site Level Findings/Actions

Day 3

Session Description: This session will focus on the process of site visits and monitoring. It will provide details on how to add and manage site visits reports, and learn the stages of visit reports review and approval process. Additionally, CTMS and Rave integration will be reviewed.

Approximate Duration: 4 Hrs

Time	Topic
8:00am – 9:30am	**Subject Management** • Subjects • Subject Standard Status • Subject Visit Activity Templates • Subject CRF Tracking • Subject SAE and Deviation Tracking
9:30am – 9:45am	**Break**
9:45am - 10:15am	**Standard Status** • Standard Status Rollup • Standard Status Roll--down

10:15am –12:00pm	**Site Visits and Monitoring**
	
	• Preparation for Site Visit
	    o Enabling/Disabling Visit Report Authoring
	    o Visit Report Submission Interval
	    o Confirmation of Internal Staff
	• Adding Site Activities
	    o Setup Templates:
	        ▪ SQV
	        ▪ SIV
	        ▪ IMV
	        ▪ COV
	• Questionnaires Templates

Day 4

Session Description: This session will continue to focus on the process of site visits and monitoring. It will provide details on how to add and manage site visits reports, and learn the stages of visit reports review and approval process. Additionally, CTMS and Rave integration will be reviewed.

Approximate Duration: 4 Hrs

Time	Topic
8:00am – 8:45am	**CTMS and Rave Integration[2]**
8:45am – 9:15am	**Site Visit Reports Process** • Correspondence Letter • Overview of the visit report
9:15am – 9:30am	**Break**
9:30am - 11:00am	**Site Visit Reports Process (Cont'd)** • Authoring • Reviewing • Editing • Approving • Submission • eSignatures
11:00am – 11:30am	**Site Level Finding & TCR Action Items** • Site Level Findings/Actions • Telephone Contact Report
11:30am – 12:00pm	**Document Tracking** • Document Types • Tracking Versions

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[2] Note: Set up demo only

Day 5

Session Description: This session will be used for a course review

Approximate Duration: 4 Hrs

Time	Topic

8:00am – 9:30am	**Payments Overview**
	
	• Add Payee
	• Define Approval Authority
	• Define Billable Event
	• Define Cost Trigger
	• Define Event Costs
	    o Payment Holdbacks
	    o Copy Payments

9:30am – 9:45am	**Break**

9:45am - 11:15pm	**Payments Continued**
	
	• Link Payee to Event Amount
	• Cost Generation
	• Cost Approval
	• Payment Approval
	    o All Rejections
	• Processing Payments
	• Review Payments
	• Additional Payments Types
	    o Ad Hoc
	    o Advance Payments
	    o CRF Based Payments

11:15am – 12:00pm	**CTMS Review** • Q&A • Evaluations