Medidata CTMS End User Training
Agenda - Day 1

Session Description: This session provides you with core knowledge on CTMS concepts, users and roles management and other functionality that augments the preparation and setup process. Scenarios of using files that have been organized in the proper import format will be covered. Additionally, standard status rollup and roll-down based on trigger events, predicted recruitment models, and treatment arms functionality will be reviewed.

Approximate Duration: 8 Hrs
Note: All times serve as estimates

Time	Topic
Day 1	
9:00am – 10:00am	Welcome – Getting to Know You
	CTMS Introduction
	● CTMS Knowledge Space
	● Concepts
	● Structure
	● Security
	● Navigation
10:00am - 10:30pm	**Resources Overview**
	● Resource Management
	● Role Management
10:45pm – 11:45pm	**People and Places**
	● Organizations
	● Addresses
	● Contacts
11:45pm – 12:45pm	**Lunch**
12:45pm - 1:45pm	**Study Management**
	● Study Planning
	o Adding a Study
	o Study People such as Members, Contacts, Internal Staff
	● Standard Study Milestones
	● Study Milestones
	● Study Activities

	● Study Level Findings/Actions

1:45pm - 2:15pm	**Country Management**
	● Country Planning
	    o Adding a Country
	    o Country People such as Contacts and Members
	● Standard Country Milestones
	● Country Sites
	● Country Recruitment

2:15pm - 3:15pm	**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

3:30pm - 4:15pm	**Subject Management** ● Subjects ● Subject Standard Status ● Subject Visit Activity Templates ● Subject CRF Tracking ● Subject SAE and Deviation Tracking
4:15pm - 4:45pm	**Standard Status** ● Standard Status Rollup ● Standard Status Roll-down
4:45pm - 5:00pm	**Q&A**

Medidata CTMS End User Training
Agenda - Day 2

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-Rave integration, Telephone Contact Reports, and Document Tracking will be covered.

Approximate Duration: 8 Hrs
Note: All times serve as estimates

Time	Topic
Day 2	
9:00-9:45	**CTMS and Rave Integration**

9:45am – 10:45am	**Site Visits and Monitoring**
	● Study Setup
	    o Visit Report Submission Interval
	    o Confirmation of Internal Staff
	    o Assign Visit Templates:
	    o Assign Visit Report templates (Questionnaires Templates)

11:00am – 12:00pm	**Site Visit Reports Process** ● Site Visit Correspondence ● Authoring the Visit Report o Visit Report Action Items
12:00pm – 1:00pm	Lunch
1:00pm – 2:30pm	**Site Visit Reports Process (Cont'd)** ● Submitting ● Reviewing ● Editing ● Resubmitting ● Approving ● eSignatures
2:45pm – 3:15pm	**Telephone Contact Report** ● Telephone Contact Report o Telephone Contact Report Action Items
3:15pm-4:45pm	**Document Tracking** ● Document Types

	● Tracking Versions
4:45pm-5:00pm	**Q&A**

Medidata CTMS End User Training
Agenda - Day 3

Session Description: This session will provide details on how CTMS payments functionality can be used to setup payees, events and cost triggers. The CTMS payments approval process will be covered.

Approximate Duration: 4 Hrs
Note: All times serve as estimates

Time	Topic
	Day 3

9:00am – 12:30am	**Payments Overview**
	● Add Payee
	● Define Approval Authority
	● Define Billable Event
	● Define Cost Trigger
	● Define Event Costs
	    o Payment Holdbacks
	    o Copy Payments
	● 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

12:30pm-1:00pm	**Q&A**