

Medidata CSA End User Training ILT Course Outline

Course Description: Medidata Centralized Statistical Analytics (CSA) integrates and analyzes data across multiple domains, generating patient-centric reports to allow for quick and easy clinical trial review. The reports are available via a study portal, which leverages trial data to create and display a customized study dashboard, site dashboards, listing tables and interactive visualizations like adverse events and concomitant medications, along with visit dates and time on study drug. The portal also uses our patent-pending statistical algorithms to mine the database and automatically identify data discrepancies, anomalies, outliers, potential misconduct and procedural issues—enabling sponsors to work more effectively and attain faster, safer clinical trial data reviews.

This 2 Day, face to face, practice based, Instructor Led Training Course provides the learner with an in-depth look at the statistical methodology underlying CSA, detailed navigational walkthroughs of the various components of CSA (including role based navigation), and real world examples of how to properly utilize CSA to improve the quality and oversight of your clinical trials.

Approximate Duration: 2 Days

Module	Topic
Welcome (15 min)	Objectives and Introductions
What is CSA? (3 hours)	Industry Reality How CSA Works CSA Machine Learning CSA Nomenclature Critical Thinking Risk Assessment and Key Risk Indicators
CSA Navigation (4.75 hours)	Logging into CSA Detailed Navigation and Practice of Available Views <ul style="list-style-type: none"> • Summary • Dashboard • Sites Dashboard • Patient Profiles
DAY 2	
CSA Navigation (continued) (3 hours)	<ul style="list-style-type: none"> • Trends • Variables • Graphs

	<ul style="list-style-type: none"> • Timelines • Listings
Practical Exercises (1 hour)	<p>Practical Exercise #1</p> <p>Practical Exercise #2</p> <p>Practical Exercise #3</p>
OneView (30 min)	Navigating the Oneview Table
OneView Practical Exercises (1 hour)	<p>Oneview Practical Exercise #1</p> <p>OneView Practical Exercise #2</p>
CSA Analysis Workflow (30 min)	<p>Prepare</p> <p>Study Overview</p> <p>KRI Review</p> <p>OneView Table Review</p> <p>Variable Review</p> <p>Graph Review</p> <p>Finalize</p>
CSA Role Based Navigation (1 hour)	<p>Data Management/Analytics</p> <p>Centralized Monitoring</p> <p>Field Monitoring</p> <p>Medical Review</p>
Practical Exercises (1 hour)	Practical Exercise #1
Final Exercise (1 hour)	Final Exercise
Wrap Up	Wrap up and Final Questions