

## End-User Training Courses

Course Title	Objective	Audience	Length (Days)
Oracle Clinical (OC) User	Create and manage study through the clinical trial process. Topics include: Global Library, Study Design, Modeling CRFs, Procedures, Data Entry, Managing Discrepancies, Data Extract, Labs, Batch Data Loading and Mass Changes.	Data managers, programmers	5
TMS User	Code medical and adverse events terms using Who Drug and MedDRA dictionaries	Data managers, dictionary coders	1
RDC User	Enter data, manage discrepancies, verify, approve, and lock data. Create graphic layouts for PDF data entry.	Data managers, project managers, investigating site personnel	2
OC Procedures	Create validation and derivations procedures	Data managers, programmers	1
OC Advanced Procedures	Create complex validation and derivation procedures	Programmers	1
AERS User	Enter, manage and report adverse events	Safety officers, data managers,	3
SQL Plus	Build queries to return data from Oracle tables and views	Data managers, programmers	1
PL/SQL	Learn the basics of the PL/SQL language	Programmers	1
Clintrial User	Create and manage a study through the clinical trial process	Data managers	3

## Technical Training Courses

<b>Course Title</b>	<b>Objective</b>	<b>Audience</b>	<b>Length (Days)</b>
Oracle Clinical Administration	Set-up users, access, configuration and learn the details of the database structure	System administrators	2
TMS Administration	Set-up of TMS dictionaries and configuration of the system	TMS administrators	1
RDC Administration	Set-up RDC users, configuration management, News and Links features	RDC administrators	½ day
AERS Administration	Set-up users, access and configuration of the system	AERS administrators	1
Computer System Validation / 21 CFR Part 11 Workshop	Learn a proven validation methodology. Find out how to best incorporate 21 CFR Part 11 requirements into your validation process.	Validation consultants	1