

The Fundamentals of Data Management Workshop

Durham, NC

June 20 – June 24, 2011

PROGRAM AGENDA

	Start Time	Session - Presenter	Tab
Monday	8:30AM	Coffee and Tea in the Rotunda	
June 20	9:00AM	Introduction/ Logistics (Patrick Murphy/Laura Phillips)	
	9:30AM	Quick Introduction to Open Clinica (Lalitha Venkatasubramanian)	1
	10:00 AM	How Good Clinical Practices and Other Regulatory Guidance Applies to DM (Patrick Murphy)	2
	10:30 AM	Break	
	11:00 AM	Recent FDA Guidance (Patrick Murphy)	3
	11:30 AM	Data Management Plans (Patrick Murphy)	4
	12:00 PM	Lunch - Vista Restaurant	
	1:00 PM	Data Management Plans (continued)	
	1:30 PM	Breakout Session: Create Flowchart Of Data, Forms, and Lab Samples	5
	2:00 PM	Group presentations of breakout session materials	
	2:30 PM	Break	
	3:00 PM	Standard Operating Procedures (SOPs), Work Instructions, and Workflow Forms (Patrick Murphy)	6
	3:30 PM	Breakout Session: Annotate Flowchart With SOPs, Work Instructions, Data Tracking Forms	7
	4:00 PM	Group presentations of breakout session materials	
	4:30 PM	Announcements	
Tuesday			
	8:30 AM	Coffee and Tea in the Rotunda	
June 21	9:00 AM	How To Create Effective Case Report Forms (Erik Jolles)	8
	9:45 AM	Breakout Session: Draft Case Report Form Based on Examples Provided	9
	10:30 AM	Break	
	11:00 AM	Group presentations of breakout session materials	
	11:45 AM	Questions and Answers	
	12:00 PM	Lunch - Vista Restaurant	
	1:00 PM	Demonstration: Create data entry screen in OpenClinica (Erik Jolles)	
	1:45 PM	Data Cleaning and Validation (Lalitha Venkatasubramanian)	10
	2:30 PM	Break	
	3:00 PM	Demonstration: Create data cleaning programs in OpenClinica (Erik Jolles)	
	3:30 PM	Electronic Case Report Form design (Erik Jolles)	11
	4:00 PM	The Elements of a Robust Data Management Software System (Patrick Murphy)	12
	5:00 PM	Questions and Answers	

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	Start Time	Session - Presenter	Tab
Wednesday	8:30 AM	Coffee and Tea in the Rotunda	
June 22	9:00 AM	Data Entry System Design (Justin Dash)	13
	10:00 AM	Validating and Documenting Data Management Systems (Patrick Murphy)	14
	10:30 AM	Break	
	11:00 AM	CRF Processing, Data Entry, and Filing (Erik Jolles)	15
	12:00 PM	Free Afternoon	
Thursday	8:30 AM	Coffee and Tea in the Rotunda	
June 23	9:00 AM	Generating, Tracking, Reviewing, and Resolving Data Discrepancy Reports (Veronica Evans-Johnson)	16
	9:45 AM	Data Querying Design (Justin Dash)	17
	10:30 AM	Break	
	11:00 AM	Group Discussion about Data Querying	
	11:30 AM	Breakout session: Plan for Data Querying	18
	12:00 PM	Lunch - Vista Restaurant	
	1:00 PM	Group Presentations of Breakout Session Materials	
	1:30 PM	Creation and QA of Data Sets (Lalitha Venkatasubramanian)	19
	2:00 PM	Lab Samples and Tracking (Patrick Murphy)	20
	2:30 PM	Break	
	3:00 PM	Group discussion about Lab Samples and Tracking	
	4:00 PM	Data Management in Multicenter Studies (Patrick Murphy)	21
	4:30 PM	Breakout session: Planning for Multicenter Studies	
	5:00 PM	Group discussion about Multicenter Studies	
	5:30 PM	Questions and Answers	

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Friday	8:30 AM	Coffee and Tea in the Rotunda	
June 24	9:00 AM	Database Lock (Lalitha Venkatasubramanian)	22
	9:30 AM	Archiving Paper and Electronic Data (Patrick Murphy)	23
	10:00 AM	Short Topics (Patrick Murphy) <ul style="list-style-type: none"> • Top priorities for implementing DM systems • CRF and source document table • Data upload/download tracking sheet • Data management resources • Software specification document 	24
	10:30 AM	Break	
	11:00 AM	Data Structures – Long and Skinny vs. Short and Wide (Patrick Murphy)	25
	12:00 PM	Lunch - Vista Restaurant	
	1:00 PM	Review of Appendices	
	1:30 PM	Questions and Answers	
	2:00 PM	Evaluations	
	2:15 PM	Certificates	
	2:30 PM	Adjourn	