

# The Fundamentals of Data Management Workshop

## Durham, NC

### June 20 – June 24, 2011

### PROGRAM AGENDA

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

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

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