The Life of a Clinical Data Point: How Thinking of Data's Role across the Entire Clinical Lifecycle Improves Data Quality and Streamlines Operations

Much is made in today's clinical development culture of the importance of clean data. But far too often the focus on clean data brings attention only to the last steps in the clinical process, when sponsors and partners frantically work to prepare data for submission to regulatory authorities. Rather, clinical sponsors need to understand the complete lifecycle of clinical data in order to identify areas to improve data quality from start to finish. Just as the quality of a human life is defined not merely by any one point in time, so too is the quality of a clinical data point impacted by multiple steps and processes. From study design through to data extraction, sponsors can identify multiple locations for improved data capture and management and better operations downstream as a result.

This Medidata presentation will explore the life of a single clinical data point and the best practices in technology and process management for ensuring the high quality of data throughout. It will help you understand in detail the trial processes crucial to data quality:

- The point at which its purpose in life is defined in the protocol, leveraging emerging industry standards and the mapping of procedures to objectives and endpoints;
- How the data point's purpose is further refined in the randomization plan, where clinical scientists and biostatisticians ensure that the right data point is collected at the right time from the right patient;
- The birth of the actual data point at the initial investigator visit, where it continues to leverage industry standards and seamless integration across the data value chain;
- The impact of centralized monitoring and targeted source data verification to ensure the data point is accurately handled through its maturation; and
- The importance of industry standard support through to its graduation into extraction in support of report preparation and regulatory submission.

This presentation will also specifically examine the discrepancy between data specified in the protocol vs the Statistical analysis plan at the end of the study, showing similar discrepancies in the data collection, monitoring and cleaning requirements vs statistical requirements.

Presenter: Richard Young,

Director, Regional Sales, EMEA, Medidata Solutions

Richard brings 15 years of operational and business development experience within pharma, CRO and technology to his position as regional sales director. Richard is responsible for cultivating relationships with sponsor companies to support business development activities at Medidata Solutions. His

responsibilities include coordination and management of all the contract negotiations and approvals, bid-defense meetings, planning successful strategy for each project and responding to all Management of Request for Information and Request for Proposal requests received.

Prior to Medidata, Richard was the director of business development for Cmed Group, Ltd, where he gained extensive experience in developing and establishing solid relationships with both sponsors and partners, as well as executing operations for the delivery of contracted services. His extensive background in data management assisted in the development, management and support of resource tracking tools that allowed management to monitor performance on trials and allow trials to be appropriately resourced. In the data manager roles that Richard has previously held, he handled client relations, performed trial data management assessments and developed processes to enable data management operations to work effectively with third party vendors. Richard has spent time working in Europe and the United States for both sponsor and vendor organizations, and has focused on adaptive trial designs, oncology, CDISC standardization and strategic technology reviews.

Richard is a frequent presenter at key industry events and is a member of the Association of Data Management, Society of Clinical Data Management, DIA, ICR and eClinical Forum. He graduated with honors from Coventry University in England with a B.S. in Biochemical Sciences.