Metrics Champion Consortium Industry Practices Insight Report

Clinical Trial Site Data Entry Study

An examination of how organizations measure site data entry cycle times, performance expectations compared to actual results and site management strategies.

2016 Site Data Entry Practices Survey

Executive Report

MCC
Metrics Champion Consortium

Executive Summary

With the adoption of the ICH E6 (R2) Addendum and the increasing focus on risk management in clinical trials, the timely data entry by sites following subject visits is becoming more important. Delayed data entry can lead to increased risk both to subjects and the trial. The Metrics Champion Consortium (MCC) conducted an online survey to elicit industry's perspective on the critical process of data entry by investigative sites after a subject visit.

To accomplish this goal, the survey gathered detailed data about the following data entry topics:

- Importance of Rapid Data Entry
- Data Entry Cycle Time Calculation
- Data Entry Cycle Time Expectations
- Data Entry Cycle Time Experience
- Reasons for Data Entry Delays
- Data Entry Cycle Time Management Strategies
- Utilization of eSource Systems
- Relationship Between Data Entry Cycle Times and Data Quality
- Relationship Between Data Entry Cycle Times and Overall Site Performance
- Relationship Between Data Entry Cycle Times and LPLV to DBL Cycle Times

The survey contained 28 questions and represents the experiences of 35 respondents at large and small organizations from across the industry. Results should be taken as indicative if not necessarily fully representative of practices across the industry. The rich data gathered in the survey are presented in 20 tables, charts and graphs.

There is no agreement across industry on how to define the data entry "complete".

Survey results reveal that organizations most often define data entry "complete" cycle in one of two ways [Figure 1]:

- Data entry is "complete" when a ***single data point*** for the visit has been entered into EDC (43%)
- Data entry is "complete" when ***all data*** for a complete visit have been entered into EDC (31%)

Surprisingly ***only 17% defined data entry "complete" when all critical data*** has been entered into the EDC. This definition appears to match most closely with the aim of assessing risk (safety and data quality) in a trial. Indeed, the focus on critical data is explicitly stated in the ICH E6 (R2) Addendum. Of the three EDC vendors that participated in the survey, two defined data entry "complete" when the first data point is entered and one defined it being to all critical data are entered. Some of the free field comments provided by respondents point to frustrations with measuring this cycle time metric – "This metric is one of the most complicated to calculate," "This is a very difficult metric to measure in a

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meaningful way but is very important." Several respondents mentioned that different EDC systems define the cycle time in different ways.

Currently, the MCC metric defines data entry complete when all data from a subject visit are entered. This metric is currently under review and is expected to move to the end point being when all critical data has been entered. This revised definition will bring challenges in implementation in the near term. However, EDC systems will eventually be updated to accommodate the need to track critical data as outlined in ICH E6 (R2).

Data entry cycle time is calculated from the actual date of the subject's visit to the date that _____has/have been entered in the EDC.

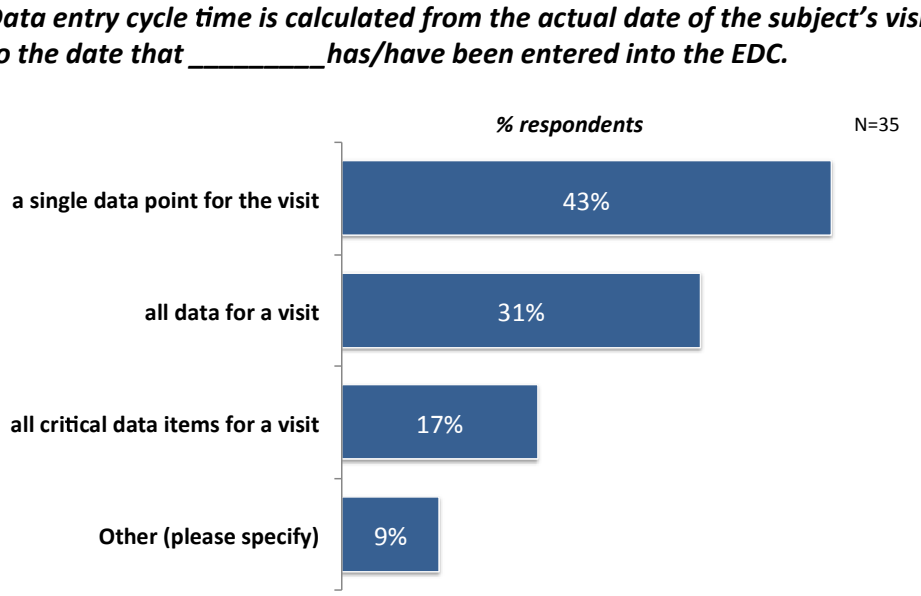

Figure 1: Data entry cycle time calculation methodologies

Key findings from the remaining survey questions are summarized in the Summary of Survey Questions and Key Findings exhibit [Table1].

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List of Figures in Full Report

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To learn more about how you can shape and participate in future surveys or contribute to MCC's performance metrics work groups, please contact Linda Sullivan at lsullivan@metricschampion.org.

To purchase the full report, please visit http://metricschampion.org/publications-2/

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About the Metrics Champion Consortium

MCC—a trusted partner in the clinical trials industry—identifies what to measure, how to assess the critical components of what is changing and how the industry is responding to address the changes to make improvements. MCC continually brings you new insights into the leading trends within the industry.

For more information about MCC metric sets & tools, metric education programs and how you can participate in MCC work groups, please visit http://www.metricschampion.org

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