Clinical research data management tasks and definitions

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Abstract

The initial SCDM task list consisted of 67 tasks grouped into 9 categories but contained no definitions. Later, in 2004, SCDM released their National Certified Clinical Data Manager (CCDM) certification exam and associated core competencies. The current core competency set for the exam consists of 112 tasks grouped into 26 categories called core competencies.1

A different approach to identification of clinical research related tasks was taken by Deitzer et al, who abstracted tasks from 20 cancer clinical trial protocols.2 This list, however, is significantly broader than operations performed on clinical trial data.

Introduction

The first formal list of clinical trial data management tasks was published in Data Basics in 1999. This task list helped scope the Good Clinical Data Management Practices (GCDMP) document, and provided a foundation for the certification exam. Periodically revisiting foundations like the growing evidence base and the task list is important to our field. We started work in the fall of 2007 to re-survey those tasks associated later released to the membership. This work was approved by the Duke University institutional review board at the corresponding author’s institution.

Results

A total of 75 tasks were identified. Authoritative definitions were found for 55 of the tasks. The remainder were defined by the authors.

Conclusion

Task commonalities exist across industry and academically oriented studies. Thus, it is likely that a common vocabulary can be achieved. Maintaining such a task list is important to a discipline because it scopes and defines competencies required for practice in the discipline, and provides a link to the evidence base on which practice recommendations should be made.

References


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