

# Analysis of Professional Competencies for the Clinical Research Data Management Profession

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**Abstract. Objective:** This job analysis was conducted to compare, assess and refine the competencies of the clinical research data management profession.

**Materials and Methods:** Two questionnaires were administered in 2015 and 2018 to collect information from data managers on professional competencies, types of data managed, types of studies supported, and necessary foundational knowledge.

**Results:** In 2018 survey, 67 professional competencies were identified. Job tasks differed between early- to mid-career and mid- to late-career practitioners. A large variation in the types of studies conducted and variation in the data managed by the participants was observed.

**Discussion:** Clinical research data managers managed different types of data with variety of research settings, which indicated a need for training in methods and concepts that could be applied across therapeutic areas and types of data.

**Conclusion:** The competency survey reported here serves as the foundation for the upcoming revision of the Certified Clinical Data Manager (CCDM<sup>TM</sup>) exam.

**Keywords.** Professional competencies, clinical data management, SCDM

## 1. Introduction

The Society for Clinical Data Management (SCDM) is a non-profit organization for Clinical Data Management professionals. It published the first version of the Good Clinical Data Management Practices (GCDMP) in 2000 [1], and established the Certified Clinical Data Manager (CCDM<sup>TM</sup>) program in 2004. The job tasks of professional clinical data managers have periodically been surveyed to maintain the exam [2].

## 2. Methods

This survey was administered at the SCDM meeting, 23-26 September 2018, in Seattle WA. The tasks were obtained from previous surveys and job analysis work through the SCDM [2, 3].

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### 3. Results

The response rate for our survey was 58.8%. The majority of the respondents 77.6% worked in private or publicly traded company. Respondents indicated a variety of organization types, the most frequently reported being pharmaceutical companies 38.7%. Eighty-two percent of the respondents indicated that they were practicing clinical data managers and 55% of the respondents indicated that they supervised clinical data managers. Respondents reported an average of 12.6 years working in clinical data management, and 16% of them reported being certified.

Most respondents (90.8%) managed data for randomized controlled trials (RCTs), but respondents also managed data for other types of studies. Respondents reported clinical data management tasks performed in their organization across the spectrum of design, programming, data processing, testing, project management, and training and review task domains. Future tasks they expected to perform included, risk-based monitoring, centralized monitoring, data visualization, maintaining awareness of new technology, new technology adoption, process improvement, metadata management, and data warehousing. At 77% and 74%, the respondents indicated data from personal wearable devices and data from home monitoring devices as types of data they expected to manage in the future.

### 4. Discussion

Our survey updated the previous professional job analysis and helps to monitor changes in work done by professional Clinical Research Data Managers. Changes between the 2015 and 2018 data confirmed a trend toward growth of the profession in terms to managing data for varied types of studies and data. This stands in contrast to the historical norms of data managers serving mainly one type of research and a limited variety of data. New tasks are consistent with application of basic informatics methods in clinical research contexts. This diversification calls for curricula and formal degree programs to educate Data Managers in general principles and methods that can be applied to new research settings, studies across the continuum of clinical research and varied types and sources of data.

### 5. Conclusion

The results of this study serve as the foundation for the Certified Clinical Data Manager™ exam and inform the scope of the practice standards for the profession, the GCDMP.

### References

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