

シンポジウム3 ●世界と未来のデータサイエンス

2 Introduction to the Society for Clinical Data Management

Society for Clinical Data Management (SCDM)/Duke Clinical Research Institute
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The Society for Clinical Data Management (SCDM) was founded in 1994 with the goal of becoming the world's leading advocate for the discipline of clinical data management. SCDM is a non-profit organization serving clinical data management and research professionals by providing education and certification.

SCDM was created to advance the discipline of clinical data management through present and future challenges. In the past 26 years, society members have promoted quality and excellence in data management and helped develop and support clinical data management professionals all over the world.

Through collaborations and partnerships in the last 26 years, SCDM developed a range of tools and networks designed to advance the industry and increase the value of certification.

The mission and vision of SCDM is focused on three essential concepts: connect, inspire, educate.

SCDM Vision

Leading innovative clinical data science to advance global health research and development.

SCDM Mission

Connect and inspire professionals managing global health data with global education, certification, and advocacy.

Good Clinical Data Management Practices (GCDMP)

One of the most important SCDM achievements is the GCDMP standard developed by SCDM volunteer subject matter experts (SMEs) across the clinical research indus-

try. The first version of GCDMP was published in 2000, and has since been recognized by regulatory authorities around the world as the definitive guide for best data management practices. GCDMP describes minimum standards and best practices for, and methodology used in, the management of data from clinical studies.

In recent years, SCDM decided to revise the GCDMP by making the document evidence-based. To accomplish this task, SCDM created several chapter-writing groups, each consisting of three or more SMEs who are Certified Clinical Data Managers (CCDMs), with the exception of one non-certified member per writing group. The non-certified member may be a junior data manager not yet eligible to sit for the exam or a senior data manager who has decided not to sit for the exam. To date, several of the evidence-based chapters have been released.

When a chapter is published, writing-group members meeting International Committee of Medical Journal Editors (ICMJE) guidelines for authorship are recognized as authors; all others are recognized in an acknowledgment statement.

Until two years ago, only SCDM members had access to the GCDMP. The society then decided to make this valuable document available to the public. Today, everyone can access the current version of the document through SCDM's website.

Organizational Structure

SCDM is managed by a board of trustees whose members are elected by over 2400 SCDM members around the world. Each elected member serves for three years as a

member of the board of trustees. The executive committee is made up of elected board members. SCDM also benefits from an advisory board consisting of top industry experts.

All SCDM programs and events are managed by committees and task forces that are made up of volunteer SCDM members and led by a chair and co-chairs. The committees are:

- Membership
- Education
- Content alignment
- Certification
- GCDMP
- Academic
- Annual conference
- Innovation
- eSource Implementation Consortium

In addition, four steering committees within Europe, China, India, and Japan cover SCDM activities around the globe.

Certification

SCDM established the Certified Clinical Data Manager (CCDM®) program to help clinical data managers institute a standard of knowledge, education, and experience by which they would be officially recognized by the profession.

The CCDM® program has been designed to identify credible, trained, qualified, and committed professionals in clinical data management and provides real-time feedback for organizations seeking to hire the best and the brightest in their field.

Education

SCDM offers a full range of educational opportunities to complement professional development as a clinical data manager and to assist in preparing for the CCDM® Certification Exam. As an International Association for Continuing Education and Training (IACET) certified provider, SCDM offers continuing education units (CEUs) for its education programs.

The SCDM online learning courses are specifically designed for those seeking to balance their professional and personal lives.

Instructor-led online courses consist of three to five weeks of intensive learning, each week corresponding

to one lesson. The estimated time commitment consists of eight to ten hours for the best possible learning experience. Throughout the course, participants engage in interactive assignments and discussions with their peers and receive guidance and feedback from the instructor. Participants set their own schedules, and all materials are accessible any time. On-demand online courses are designed so learners enjoy the experience at their convenience by accessing the courses at any time and as often as they like, pause, rewind and fast-forward to learn at their own pace.

SCDM webinars are a leading source of professional development and continuing education for clinical data managers and related professionals. During SCDM webinars, expert presenters address industry trends and share best practices.

Live webinars are scheduled events that consist of a one-hour presentation from a hand-picked industry expert followed by a question and answer session, ensuring that participants leave with new insights that they will be able to use immediately in their professional environment.

Events

Every year, the SCDM Annual Conference provides an opportunity for the largest gathering of clinical data managers in the world. In addition, regional annual conferences in Europe, China, and India provide opportunities for data managers in each region to attend an SCDM conference, and benefit from the latest information and advancement in the industry.

eSource

eSource Implementation Consortium was established under the auspices of the SCDM in 2017, bringing science, industry, technology, and regulators together to work on the rollout of eSource applications that leverage electronic health records (EHR), electronic data capture (EDC), and clinical data management systems (CDMS). Members have a seat at the table of discussions and decisions surrounding transformations in the clinical trial sector. The consortium aspires to develop data exchange specifications for core safety and various therapeutic area efficacy domains. The steering committee includes members of academia, pharma, Health Level Seven (HL7), and technology companies.

White Paper

In recent years, SCDM has published several white papers to explore the new and complex environment that data managers are facing. These white papers include:

- eSource Implementation in Clinical Research: A Data Management Perspective, June 12, 2014
- eSource in Clinical Research: A Data Management Perspective on the Use of Mobile Health Technology, September 30, 2016
- The Evolution of Clinical Data Management to Clinical Data Science: Part 1: Drivers, A Reflection Paper

on the impact of the Clinical Research industry trends on Clinical Data Management, June 4, 2019

- The Evolution of Clinical Data Management to Clinical Data Science: Part 2: The technology enablers, A Reflection Paper on how technology will enable the evolution of Clinical Data Management to Clinical Data Science, March 5, 2020

REFERENCE

SCDM.org.