



## TOPIC BRIEFS AND PERSPECTIVES

# Practice of Clinical Data Management Worldwide: Introduction to the Special Issue

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Clinical data management and its contemporary analog, clinical data science, represent a subspecialty of biomedical research that has undergone tremendous change over the past four decades. Originally conceptualized as a job that specialized in the collection and processing of clinical research data, it has now evolved into a formal and well-recognized biomedical subspecialty devoted to the care and treatment of clinical research data. The evolution of this profession has not been well documented in the scientific literature until now.

Regulatory bodies and public opinion have set forth expectations for professionals striving to acquire and manage large volumes of data with ever increasing speed and quality. Pharmaceutical, medical device, and clinical research organizations have followed suit by developing software and systems that are often helpful, yet discordant from one another and the technical and business-related needs of the profession. Included in this technical revolution is a profession very much in transition, one that must reconcile the foundational and transactional activities of its past (e.g., case report form design, data review/listings, programming) with the more professional and scientific responsibilities of its future. Disciplinary and geographic boundaries notwithstanding, this is the content to which clinical data management and clinical data science scholarship must commit itself to be an accepted partner in the clinical and translational science community of the 21st century.

The *Journal of the Society for Clinical Data Management: Informatics and Data Science in Clinical Research* (JSCDM), in its inaugural year, has prioritized acknowledging and promoting the scientific practice of clinical data management and clinical data science (CDM/S) throughout the world. As such, JSCDM's first special issue is devoted to offering a snapshot of the origins, aspirations, and challenges faced by clinical data management and clinical data science communities in four regions of the world: Australia, Japan, Ukraine, and the United States.

Investigative teams from each country were asked to give readers an authentic look into CDM/S in their respective countries, including a brief history of the profession; how the practice of CDM/S varies with respect to industry, academic, and nonprofit sectors; the field's contribution to the broader landscape of scientific and biomedical research; perspectives on the recruitment and training of clinical data managers and clinical data scientists; and any unique challenges faced by professionals in their locale today. Requests for submission were solicited via a special call for proposals in the fall of 2020 distributed through JSCDM and the Society for Clinical Data Management's webpage, as well as postings on several social media sites. The journal and the International Network of Clinical Data Management Associations continue to advocate for the concerns of clinical data management professionals worldwide—by promoting relevant reflections and research. All articles in this issue went through the Journal's formal peer review process.

Anyone who conducts research in the field of CDM/S will find Banach et al.'s work on the history of the field foundational. They trace the evolution of the field from its roots in the Food and Drug Act of 1906 to its role in translational science today. The authors provide detailed attention to the various roles clinical data managers perform across a range of settings. Finally, they anchor their discussion in important legislation and guidelines that have shaped the profession along the way.

Houston and Probst highlight recent developments in Australia by discussing the field's relationship with regulatory guidelines and newly evolving technology. Because of this relationship, Australia has one of the world's fastest growing research communities, with clinical trials growing at a rate of 5% per year and projected to account for A\$2 billion of the country's economy over the next 10 years. Australia does indeed appear at the forefront of a cohesive, national collection of data-rich resources for the worldwide community.

The evolution of CDM/S in Japan has taken a different, more technical route. As Yamaguchi et al. point out, it was precisely the vision of Professor Yasuo Ohashi and other industry-based biostatisticians who saw the need for clinical data managers in the late 1980s. With their

eye on the science of clinical data management, and an unwavering focus on data quality, Japan is building their national infrastructure for clinical trial data management by investing in an academically rigorous community of professionals.

Within the context of a state-owned healthcare system, clinical data management in Ukraine must evolve using a more creative model. Boichuk and Glushakov give readers a glimpse into a state-owned healthcare system that has not professed a need for clinical data managers or clinical data scientists. Yet, taking advantage of their strong medical education system and its accomplished history in information technology, Ukraine's newest research professionals are now coming from private sector partnerships between established clinicians and

international Contract Research Organizations and life science companies worldwide.

This special issue on the Practice of Clinical Data Management Worldwide offers four insightful perspectives on the evolution and practice of CDM/S in four very different regions of the world. Each article has a story to tell that helps make CDM/S what it is today and what it will be tomorrow. It must be kept in mind, however, that the four perspectives included here represent only a portion of what is actually possible. We encourage investigators and CDM/S professionals from other countries and regions of the world to share their experiences in subsequent issues!

### Competing Interests

The author has no competing interests to declare.

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