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LETTER

# Letter from the Chair

Patrick Nadolny

With a passion for data, SCDM continues its mission and steps forward to progress the evolution of our industry toward Clinical Data Science (CDS). To some, the concept of data may seem abstract, cold, and complex. For our industry, however, data is the lifeblood of everything we do in clinical development and could mean the difference between a patient having an answer or having no answers at all. As the 2024 Chair of the SCDM Board, my personal objective is to move from reflection to action, establishing a new norm for Clinical Data Management (CDM) and drug development in general.

**So first, let's explore SCDM's decisive 2024 actions:**

2024 is the year in which we harvest the investments of 2023 and help our CDM industry to evolve toward CDS, in a Data Centric and Patient Driven world. On January 25th, SCDM hosted its traditional chair address webinar on the State of the CDM Industry. During this webinar, I announced a **new SCDM branding** which visibly anchors our vision "*to lead the clinical data science industry for a healthier world.*" To be meaningful, rebranding needs to be accompanied with tangible actions. So, in the same webinar, **Carole Schaffer**, our Vice Chair of the Board and Chair of the Education Committee released our **new industry competency framework** and the upcoming release of a **new CCDA Exam** planned for later this year. This, and other initiatives in 2024, will help SCDM to deliver on its mission to *"Prepare our industry and professionals for the evolution of the management of health data through education and certification programs."*

Our new industry competency framework combines our traditional CDM competencies (e.g., our CDM roots) with the additional competencies required for evolve towards CDS to meet the demand of drug development today and in the future. It is a living framework that serves as a reference for delivering all SCDM contents (including webinars, JSCDM articles, new Good Clinical Data Management Practice© (GCDMP) chapters, conferences and much more). You can also use it to compare the competencies in your own organization against where our industry is heading!

Our strong desire to partner with global regulators and law makers was demonstrated when **Andrew Thomson** from the **European Medicines Agency** and **Andrzej Rys** from the **European Commission** joined the webinar for a panel that focused on the evolution of the industry and which addressed Real World Data and how to close the gap between drug development and health care.

Since then, we have worked diligently behind the scenes to progress further on our promises. In April and as announced during our largest EMEA SCDM event to date, we:

- launched our **new SCDM website**,
- released a free on-demand webinar on **CDS 101**,
- are consolidating CDM industry **comments on the Draft FDA Guidance** on "Use of Data Monitoring Committees in Clinical Trials" and
- have initiated the development of a **new GCDMP chapter on risk-based CDM**.

Last but not least, in our quest to better serve patients and sites, we are entering into a long-term collaboration with the **Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center)**. MRCT launched a **Clinical Research Glossary**,[1] which offers easy-to-understand clinical research definitions. The first version of the glossary covers over 170 terms, ranging from the simple to the complex. This glossary offers many opportunities that include but are clearly not limited to:

- the creation of patient's instructions that are understandable by patients (e.g., ePRO completion instructions, clear e-Inform Consents),
- the development of training materials that provide those new to the industry an avenue to understand core concepts faster and
- the release of JSCDM articles that are accessible to non CDM experts.

SCDM is supporting the evolution of such a meaningful glossary and will work to maximize its potential. MRCT and SCDM will offer educational opportunities to members of the clinical data science community to grasp those opportunities and ultimately better serve the needs of patients. Over the coming years, we will collaborate on a few initiatives to demystify and simplify complex clinical research concepts.

**Now, let's reflect on the predictions we made in 2019** in our SCDM Reflection Paper on the evolution toward CDS.[2] As shared with Clinical Leaders earlier this

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year, SCDM "predicted that data management would evolve into clinical data science due to the influx of data sources and emerging protocols with new trial designs. This evolution has already begun, and its progress hinges on four main drivers: **risk-based methodologies, AI, complex protocol designs, and DCTs**".[3] So, where are we with those 4 drivers?

In our SCDM January webinar, I addressed the adoption of **AI**, which is accelerating since the emergence of Generative AI. The key is to find the sweet spot for human and computer synergies. While some activities will be automated using AI, AI is not about replacing humans. It is about enabling humans to achieve a different level of reasoning that would not otherwise be possible. "In this context, computers and humans working together could make better predictions than either a group of humans or a group of machines could do on their own."[2]

Additionally, those leveraging AI will likely surpass those who are not. AI-enabled professionals will reach a different level of efficiency and performance, thus reaching an increased level of quality and predictability, which will accelerate drug development.

In our evolving world, it will become impossible to keep up with the increases of data **V**ariety, **V**olume and **V**elocity using existing systems and processes. It is imperative to focus on what matters and to leverage machine computing and "reasoning" power to detect threats to patients' safety and to the reliability of trial results[4] (e.g., **V**alue & **V**eracity). So, managing the 5Vs of Clinical Data is our CDS mission.

Another imperative is giving as much choice and voice as possible to patients. While technologies that support **Decentralized Clinical Trials (DCT)** are still maturing post-Covid, placing patients in the driver's seat must remain a focus. This means allowing patients to participate in DCTs in the way that they want. It means being inclusive and allowing all patients to participate without barriers, adapting to their choices and lives (e.g., location, language, technological and financial abilities, disabilities, professional and personal constraints). As mentioned before, including patients involves also making sure we understand each other. This is why our new SCDM collaboration with MRCT is so important! SCDM has the firm intention to expand its collaboration to patients' and sites' advocacy groups to progress this important matter. As a profession, we must remember that patients and sites are way more than a number in our electronic Case Report Forms (eCRFs).

**Risk-based methodologies** are reshaping how we conduct clinical trials, moving us beyond a one-size-fits-all approach to a more tailored, strategic framework. It's like steering a ship through treacherous waters with the help of advanced navigational tools. These methodologies not only enhance our ability to foresee and mitigate risks but also enrich the quality and improve efficiency of our clinical studies. Regulators are supporting and advocating for such approaches. ICH E8 even states in its section 3.3.1 on Culture, that "**Inflexible, 'one size fits all' approaches should be discouraged.** Standardised operating procedures are necessary and beneficial for conducting good quality clinical studies, but study specific strategies and actions are also needed to effectively and efficiently support quality in a study".[5] So, adopting risk-based CDM (rb-CDM) is no longer an option but a must. This is why SCDM is prioritizing the creation of a new GCDMP chapter on this critical topic.

Like for DCT, the technology to efficiently operationalize **complex protocols** is still evolving. Nonetheless, there is a growing number of Adaptive and Master protocols, especially in early phase studies, to accelerate drug development and this trend is not going to slow down. The US Food and Drug Administration (FDA) released a draft guidance on Master Protocols[6] in December 2023 and a guidance on Adaptive Designs[7] back in Nov 2019. For now, CDM professionals still need to mostly leverage existing processes and technologies to operationalize such protocols. It unfortunately means creating pragmatic but often complex workarounds, specific to your own company's framework.

In addition to the four drivers, **resiliency** to disruptions has emerged as a critical focus considering recent events such as Covid-19 and the war in Ukraine, and natural disasters, such as the earthquakes in Turkey and Japan. These disruptions reached such a point that the FDA released a guidance in September 2023 on "Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions due to Public Health Emergencies."[8] The guidance mentions that disruptions "can include (but are not limited to) hurricanes, earthquakes, military conflicts, infectious disease outbreaks, or bioterrorist attacks." The 2024 Global Risk Report[9] from the World Economic Forum includes "Extreme Weather" and "Cyberattacks" in the top five risks! So, readiness to handle unforeseen disruptions requires our attention!

In summary, while we are observing an acceleration of the AI potential and some adoption delays for DCT as a result of process and technology limitations, our 2019 predictions were and are still valid. Our CDS path remains intact and stronger than ever. If you want to learn more about those five areas, listen to the free on-demand, SCDM webinar on CDS 101 available in our SCDM Learning Hub.

So, the field of clinical data management is at a pivotal moment of transformation. The challenges we face are complex, but they are also catalysts for innovation and progress. As we navigate this evolving landscape, our guiding principles should be adaptability, patient centricity, and a relentless pursuit of operational excellence.

The future we're building is one in which clinical trials are more efficient, are data driven, inclusive, and are closely aligned with the needs and realities of patients worldwide. It's a future well within our reach, and every step we take towards it is a step towards better health outcomes for all.

In closing, let me express my excitement and optimism for what lies ahead. Together, let's embrace our CDS journey with open minds and a firm commitment to accelerate drug development and enabling faster and efficient clinical trials for, and with, patients and sites.

If you are as excited as I am, please visit our SCDM website to explore the opportunities to learn more, share your insights in our SCDM Journal or contribute as a volunnteer[10] to a healthier world!

Patrick Nadolny
SCDM Chair of the Board

## Competing Interests

The author has no competing interests to declare.

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