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LETTER FROM THE CHAIR

As I write my final letter as the 2021 Chair of SCDM, I would like to acknowledge the distinct privilege and honor it has been to lead the organization during a year of continued uncertainty and ambiguity. I am immensely proud of how everyone at SCDM - my board, our volunteers, partners and staff - have risen to the challenge of a second COVID year. Both collectively and individually, they have viewed it as an opportunity to further innovate and expand, and to serve our members in new and better ways.

Our annual professional education conference (AC) has always been the primary occasion for our community to meet and interact, where we share and disseminate knowledge within the clinical data management field. It has been the pre-eminent learning and knowledge gaining space for our industry. Under the excellent stewardship of my predecessor, Michael Goedde, one of SCDM’s key approaches for tackling the effects of the pandemic was the rapid digitalization of our AC. Moving it to the virtual space provided a highly-preferable alternative to cancelation and enabled the continuing education of CDMs without any time delay. Ultimately our community agreed and it became the largest conference in the history of SCDM.

Writing this commentary on our 2021 annual meeting, allows me to illustrate just some of the innovative work that our SCDM conference team of volunteers and staff has undertaken and how well SCDM as a whole has further adapted to the limitations posed by the pandemic. From the outset, we wanted to produce a highly-valuable learning moment that leveraged the power of technology and digital platforms to connect virtually with all our members and partners across the world. With inclusivity as a core value and recognizing the rare combination of circumstances presented by the pandemic, my fellow SCDM leaders quickly identified that we had a unique opportunity to transform our 2021 AC into SCDM’s first Global Conference. Thanks to tireless support of our EMEA and India leaders who agreed to integrate their regional activities into one global event*, I am immensely proud that no other SCDM professional education conference has been more international nor more well-attended. In a year where we all suffer digital fatigue and where many conferences have been reporting depressed attendance numbers, SCDM has grown its attendance by 50% this year to over 1,500 attendees and attracted CDMs from close to 40 countries around the world.

Sanjay Bhardwaj | Chair
On offer through the conference was an awesome line up of topics ranging the full spectrum of clinical data management from AI/ML and DCTs to RBQM and Technology, Data and Communication, and more. We also featured an expanded range of academia sessions so that all professionals, no matter their level of experience or background, would find plenty of interesting, informative and valuable content. With the theme of “Future Now,” our conference kicked-off in style with an impressive and extremely inspiring keynote presentation given by Prof Chris Lintott, University of Oxford, UK. As a non-industry expert, this was also a first for us. Chris is one of the world’s leading astrophysicists and using his own experience of handling terabytes of new data each day, he offered us a guide as to the future of AI capabilities and how CDMs will be able to tackle increasing data volumes and complexities. He strongly advocated that the future of big data and AI will be in learning how to collaborate with the machine tools that we’ve built rather than necessarily relying on them to take over from us. His keynote session and all other conference sessions are available as an on-demand resource; don’t miss the opportunity the watch them again!

Another conference first was our ground-breaking session on the pathway to a COVID-19 vaccine entitled a ‘Jab of Hope’. The session featured insights from data management heads from Pfizer, Johnson & Johnson and AstraZeneca who revealed how they raced to develop their vaccines in record times. I am so proud that members of the SCDM community have played a pivotal role in helping, literally, the entire world. It was a great session and a humbling one when listening to their experiences of having to perform at their very best whilst in the most accelerated and pressured period they have ever faced.

The future of DCTs (spoiler alert: our conference concluded it’s hybrid), data integrity, outsourcing models, the shifting regulatory landscape, RBQM analytics and new data sources were just some of the many critical items under discussion. Other initiatives, new this year, included our informal speaker corners and very popular daily conference summaries; they all added to a greater learning experience for participants.

SCDM | Annual Report 2021

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The quality and value of this year’s conference was outstanding and the extensive catalogue of prominent global leaders in our industry sharing the latest news, best practices, and actionable advice was second to none. This has only been made possible thanks to the generous and unwavering support of our conference co-chairs, the session chairs and presenters, regulatory representatives, committee chairs, exhibitors and sponsors, and SCDM’s professional staff at MCI. Thank-you all!

My term of office as the Chair is fast drawing to a close and I shall soon be handing over stewardship of our fantastic organization to Mayank Anand. As I do so, it will be in the full confidence that SCDM has, so far, not just survived the pandemic but that SCDM has strengthened further its leadership role. Our global conference this year has shown ourselves to be innovative, forward-thinking and embracers of change. And, no other organization is more credible in leading our industry’s evolution from CDM to CDS.

Thank-you for your support and friendship throughout this year; I look forward to meeting you in person next year at our 2022 Annual Conference in San Antonio, Texas on September 11-14.

Kind regards,

Sanjay Bhardwaj
SCDM Chair of the Board 2021, Past Chair 2022.

*Our China conference was held before the decision to switch to a global conference; it was also highly successful and outperformed expectations.*
ABOUT SCDM

The Society for Clinical Data Management (SCDM) is a non-profit professional society founded to advance the discipline of Clinical Data Management. The common interest of all members of SCDM is quality clinical data management practices.

Our Mission

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

Our Vision

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

SCDM was founded in 1994 and has grown to be a premier clinical data management organization that comprises upwards of 2,800 members in over 45 countries across the globe who represent the biotechnology, medical device, and pharmaceutical industries as well as members of the academic, regulatory, and scientific research communities. Third-party organizations such as Contract Research Organizations, consulting firms, hard- and software vendors, and placement firms and represent an important portion of

Our values:

Knowledge and Contribution of our Members:

The collective professional knowledge, experience and engagement of our members are our greatest assets. SCDM relies on and embraces the active participation and contributions of our members and volunteers.

Scholarship:

SCDM encourages and promotes rigor and discipline in the research of topics affecting our industry. Our positions, publications, and programs are the result of careful review and/or scholarly investigation.

Quality and Continuous Improvement:

SCDM is committed to the development and enhancement of products, services, and relationships of the highest quality.

Open Communication:

SCDM encourages open communication and information sharing. We provide our members with insight into the organization’s initiatives and activities.

Integrity:

SCDM exemplifies and expects honesty and integrity.
The world’s leading CDM community

SCDM continues to inspire CDM professionals across the globe. Our rapidly growing communities in China, India, Japan, EMEA and the Americas are interacting through conferences, networking events and an interactive community platform to strengthen a true collaboration as a global community.

› A growing community

<table>
<thead>
<tr>
<th>Year</th>
<th>Members</th>
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<tr>
<td>2018</td>
<td>1,500</td>
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<tr>
<td>2019</td>
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<tr>
<td>2020</td>
<td>2,500</td>
</tr>
<tr>
<td>2021</td>
<td>3,000</td>
</tr>
</tbody>
</table>

› Membership by region

- Americas: 26%
- APAC: 66%
- EMEA: 8%
Leadership & volunteers

› 2021 Board of Trustees

Sanjay Bhardwaj
CHAIR

Amy Neubauer
TRUSTEE

Reza Kostami
TRUSTEE

Michael Goedde
PAST CHAIR

Anshad Mohammed
TRUSTEE

Richard F. Ittenbach
TRUSTEE

Mayank Anand
VICE CHAIR

Carol Schaffer
TRUSTEE

Patrick Nadolny
APPOINTED TRUSTEE

Deepak Kallibundi
SECRETARY

Maria Craze
TRUSTEE

Meredith Zozus
ADVISOR

Jonathan R. Andrus
TREASURER

Peter Stokman
TRUSTEE

Kelly Chelnik,
Chair of the Certification Committee

Anita Shen,
Chair of the China Steering Committee

Tim Breen,
Chair of the Webinars Committee

Joe Fitzgerald,
Chair of the Online Courses Committee

Peter Stokman,
Chair of the EMEA Steering Committee

Marysasser Holloway,
Chair of the GCDMP Committee

Deven Babre,
Chair of the India Steering Committee

Tanya Sun,
Chair of the Membership Committee

Meredith Zozus,
Chief Editor of the JSCDM

Patrick Nadolny,
Chairs of the Innovation Committee

Zack Lemka,
Chair of Academic Relations

Susan Howard,
Chair of Content Alignment

Mike Lange,
Chair of Marketing Advisory Committee

Takuhiro Yamaguchi & Tempei Miyaji,
Co-chairs of the Japan Steering Committee

Rakesh Maniar, Michael Buckley and Linda King,
Co-chairs of the eSource Implementation Consortium Taskforce
SCDM strategic map 2020-2022

SCDM’s three-year strategic plan, detailing our goals and activities for 2020-2022, was agreed upon in the fall of 2019 during the Baltimore board meeting.

We determined that by the end of 2022 our distinctive ability to build and integrate world-class education and thought leadership, the clinical data scientist network and regulatory influence will have secured us recognition as the trusted global leader and authority on clinical data science.

The three main priorities for this strategy are thought leadership, education, and advocacy.
Good Clinical Data Management Practices (GCDMP©)

The Good Clinical Data Management Practices (GCDMP©) standard provides a reference to clinical data managers in their implementation of high-quality Clinical Data Management processes and is used as a guidance tool for clinical data managers when preparing for CDM training and education.

> Get Your GCDMP© Copy
Toward Clinical Data Science: Papers

The SCDM Innovation Committee started the journey toward Clinical Data Science (CDS) in the middle of 2018 by assembling a team of industry innovators. The first step was to share our insights on the reasons leading to our CDM evolution into CDS. As such, the committee published a first reflection paper on the drivers of the CDS Evolution in June 2019. The next step was to elaborate on the required technology enablers through a second reflection paper released in March 2020. Then, we evaluated the potential impact of the CDS evolution on the roles through the third reflection paper published in August 2020. These 3 papers combined provided a complete picture of CDS from a people, process, technology and regulatory point of view.

SCDM REFLECTION PAPERS

In parallel, the Innovation Committee launched a CDS Portal within the SCDM Website to promote its work. The committee also leverage the reflection paper content during the annual conference leadership forum in 2018, 2019, 2020 and 2021.

In 2020, the Innovation Committee started to co-lead the development of the Audit Trail Review position paper with the eClinical Forum which was published in April 2021. This position paper was concretely showing how to implement one key concept of our discipline evolution.

In 2021, the strategy has been set to move from reflection to position. The committee is in the process of writing a Position Paper on Clinical Data Science. Paper is targeted for Q1-2022. At the same time, the committee expect to complete the release of the 12 Topic briefs leveraging all prior publications before the SCDM 2022 Annual Conference.

Last, moving from position to action, the committee is initiating work with the Certification program to create a CDS Certification exam in 2022 based on all the published content to date.

Upon completion of the 2022 objectives, the Innovation Committee would have realized the SCDM Vision of “Leading innovative clinical data science to advance global health research and development”.

Leading Innovative Clinical Data Science to Advance Global Health Research and Development.
On March 2021, SCDM transitioned Data Basics to a scholarly, peer-reviewed, online and open access journal: the Journal of the Society for Clinical Data Management (JSCDM). This is the next step in SCDM’s work to promote the translation of new innovations into practice, demonstrating our commitment to advance the CDM profession worldwide.

“The expanded scope of the publication will help fill a gap in the biomedical literature by publishing articles with an applied focus toward data collection, management and use in the design, conduct and reporting of and sharing resources from clinical studies. Together the Journal and the Good Clinical Data Management Practices (GCDMP) serve the profession by connecting the translational cycle between data and informatics science and their application in practice.”

- Meredith Zozus (JSCDM Editor-in-Chief).
Online education

Over 2,100 participants from more than 40 countries came together to access SCDM’s online education series on cutting-edge topics, including DCTs, AI in drug development, vaccines and adaptive trials.

2,100+ learners
20 live webinars
25 on-demand webinars
5 courses

WATCH AGAIN

1. State of the Industry - So much for the game changers, what’s next for CDM?
2. 2020’s Biggest Game Changers Revealed
3. SCDM Education
Due to COVID-19, the SCDM Annual Conference had to be transformed into a virtual format for the past 2 editions. 2020 was a learning year, on what really a virtual conference is and its true value. What was meant to be a challenge, gave SCDM an opportunity to further innovate and to broaden its outreach and to be able to run a truly global conference, by combining regional conferences (India, EMEA and AC) into one Global edition.

The expanded Global Conference solidifies an ongoing commitment to connect and inspire clinical data managers around the world with outstanding education and thought leadership. Recognizing the power of virtual to connect with attendees anywhere, SCDM aimed to bring all CDMs together in the industry’s single largest international gathering in 2021.
This year’s conference has marked a number of milestones: it was our first global conference, we had more speakers and sessions than ever before and we were honored with a record-breaking attendance for an SCDM event of 1650 attendees. Thank you for being a part of it!

“I thoroughly enjoyed the conference and would recommend anybody with a passion in Data Management to attend. There was so much shared during the 3 days about ML and AI, decentralized studies and new tools that can ease the data collection and management. The presentations in the conference showed changes that need to be adapted from the way one works and who keep looking for new ways to better the current process. I can say for certain that I came away with more knowledge at the end of the conference.”

- Selvanathan Kalaiselvi, Boehringer Ingelheim Pharmaceuticals, Inc.

“If you want valuable insights about Clinical Data Management then SCDM is your answer. A great conference to attend where the best minds in the industry come together and share their views on new technology. Thank you SCDM.”

- Raju Nair, LabCorp

“The future of data management is being defined and championed here.”

- Nicole Pollard, Medidata Solutions

“The SCDM Conference is a ‘must do’ for any leader in the clinical data management/data science industry. You can connect and hear from key industry experts, openly share ideas, and leave with more tools in your toolkit. This is a powerful network where we can make an impact on human health.”

- Ami Dudzinski Mehr, Veeva Systems
Become a Session Chair at the biggest CDM conference in the world

CALL FOR SESSION CHAIRS
Submission Deadline: January 9, 2022

scdm2022.org
SCDM 2021 China Conference

SCDM 2021 China Conference was successfully held this June 17-19 in Shanghai. It was the very first SCDM face-to-face conference after COVID-19. The two-day event welcomed 320 attendees ranging from industry experts, regulators, scholars, and clinical data management professionals. Unlike past face-to-face conferences, this year over 60% of the participants came from the pharma industry. More local pharma companies joined this event.
CCDM®, the leading certification for CDMs

The CCDM® designation is the most up-to-date measure of knowledge, education and experience.

In the past year, we have been tirelessly working to bring the SCDM CCDM® exam to date and we are proud to announce that the Beta Exam is completed with over 243 participants from different regions all over the world. The Beta Exam had two forms with 150 questions each, and below is the overall psychometric analysis overview:

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<thead>
<tr>
<th>Statistic</th>
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<tr>
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<tr>
<td>Minimum score</td>
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<td>54</td>
</tr>
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</tr>
<tr>
<td>Reliability</td>
<td>0.89</td>
<td>0.86</td>
</tr>
</tbody>
</table>

In 2021, we also optimized the examination process and we launched the new and improved version of the CCDM® exam. SCDM has decided to go fully digital with the CCDM renewal, which will be available very soon.

> Get Your Certification here
Industry dialogue with powerful network and strategic collaborations with regulators.

SCDM Continues to engage key stakeholders in the industry, by participating in conversations with the regulators, and creating platforms and avenues such as the Regulatory Town Hall and the Leadership Forum at SCDM events to engage and share best practices.

At the SCDM Global Conference, the Regulatory Town Hall welcomed over 645 participants, with panelists from the FDA, EMA, and MHRA on current key topics concerning Clinical Development and the Data Management discipline.

› Leadership forum

The Evolution of Clinical Data Management in the Today’s Changing Landscape of R&D
SCDM Global Conference | September 23-24, 2021

leadership forum article

› Staying on Top of Shifting Sands as Clinical Research Transforms

From COVID-driven shifts in working patterns and the growing use of advanced technologies, to rapidly evolving processes and regulations, the clinical research industry is standing on the precipice of great change.

It means we have a golden opportunity to shape the future of our sector, using all the skills and tools at our disposal to create a more efficient, data driven, patient-centric CDM discipline. With this in mind, the Society of Clinical Data Management (SCDM) held a two-day Leadership Forum event, bringing 70 data experts from across the spectrum of the industry together to discuss the big questions, and how best to proceed from a people, technology, regulation, and process point of view.
SCDM encourages industry dialogue through partnerships in education, delivery of innovative content, and many more initiatives.

Our achievements are the production of unwavering commitment and support of our partners and in 2021 we were successful to have 15 corporate partners. We thank you for your unwavering support.

SCDM Corporate Partners
We build and integrate world-class thought leadership, education, and advocacy to be the trusted global leader and authority on clinical data science.

2022 will be the final year of our current 3-year strategic plan. Our overall objective is that by the end of 2022, our distinctive ability to build and integrate world-class education and thought leadership, the clinical data scientist network and regulatory influence will have secured us a recognition as the trusted leader and authority on Clinical Data Science.
OUR OFFICES

GLOBAL HEADQUARTERS
280 Boulevard du Souverain,
B-1160 Brussels,
Belgium

General enquiries
info@scdm.org

Annual Conference
Scdmevents@Scdm.org

Education
Learning@Scdm.org

Events & Corporate Sponsorship
Sales@Scdm.org

NORTH AMERICA OFFICE
7918 Jones Branch Drive,
Suite 300 McLean,
VA 22102, USA

info@scdm.org

INDIA OFFICE
Silver Astra, 64, 6th Floor,
Cardinal Gracias Rd, Akal Society,
J. B. Nagar, Tarun Bharat,
Andheri (East),
Mumbai-400059,
India

info-in@scdm.org

CHINA LIAISON
info-cn@scdm.org

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