ABSTRACT GUIDELINES

SCDM 2022 EMEA Conference

Reconnect

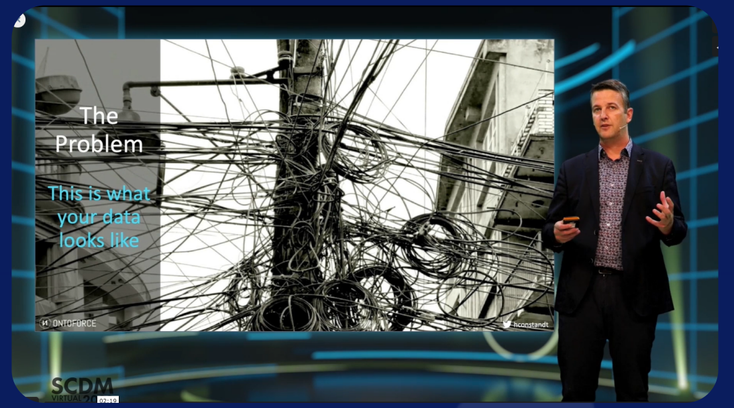
CONTENTS

SPEAKING AT #SCDMEMEA22

We believe world-class education and thought leadership are the driving forces for professional excellence, for innovation, and for advancing clinical data managers around the world. That's why we want our content program to inspire the kind of transformational learning that can change the world of clinical data science.

SCDM's 2022 EMEA Conference is a place for the world's clinical data management industry to reflect on the future. For the first time since the 2019 EMEA Conference in Berlin we are now meeting face to face again. That is why our conference theme is "**Reconnect**". Attendees expect to see cutting edge content that will raise the bar of excellence in the profession.

Our attendees enjoy hearing from their mentors, from industry leaders and from their peers. They like to be inspired, challenged and motivated. Our session chairs and speakers are the heart of the SCDM EMEA Conference, and we look forward to hearing your ideas.



WHAT DO THE MOST SUCCESSFUL PRESENTATIONS HAVE IN COMMON?

HAVE ONE BIG IDEA

Develop an idea worth sharing and express it clearly and simply. Your idea may be an assumption that you wish to challenge, or, a unique perspective on a common topic, or even an innovative concept that has the power to advance the profession. Remember to summarise your idea in one clear message.

DEVELOP A TWIST

If your idea can be stated in a catchy or provocative way, our attendees will pay more attention and remember it easily. Be thought-provoking and not afraid to offer a slightly contrary challenge to what is expected.

OFFER REAL VALUE

Our attendees want to be inspired, but they also want valuable, practical takeaways. Make sure you answer the key questions relating to your topic and prepare a virtual handout for the attendees to use in the office.

WE ARE LOOKING FOR THE BEST SPEAKERS IN THE INDUSTRY

ENGAGING

Our best speakers tell personal stories and carefully use humour to emphasise a key point they wish to make.

HONEST

Typically, they are very open and transparent, particularly when revealing data and other relevant information. They ensure that the truth prevails, even when it may not be particularly attractive.

OPINIONATED

Rarely do they sit on the fence. Instead, they voice a clear opinion - and, always in a respectful and humble way.

RELAXED

Being relaxed, but passionate about your topic goes down very well with the SCDM audience. The best speakers do not use gimmicks or appear stuffy and excessively formal.

5 PRINCIPLES

1. All content must be original and not a rehash of a presentation given at another industry event.

2. If your submission is successful, the cost to cover any fees (such as registration) must be covered by you.

3. There is no additional charge to speak at the SCDM EMEA Conference. On the contrary, you benefit from a 20% reduction on the standard registration fee.

4. Successful proposals are selected on the merit of the idea and the Session Chair.

5. You are responsible for the concept, creation and delivery of your presentation. The SCDM Team is on hand to guide you and is the official contact point for confirmations and changes.

CONDITIONS

Presentations from vendors are welcome, however vendors are asked to respect the scientific nature of this meeting and not to promote their products and services during their presentation.

In order to provide attendees with a broad range of perspectives, SCDM reserves the right to limit the number of presentations chosen from a single company.

Presenters are required to attend several conference calls with the conference co-chairs and session chairs during the preparation process.

CONFERENCE THEMES

RBQM

INNOVATION AND TECHNOLOGY

THE HUMAN BEHIND CLINICAL DATA MANAGEMENT

REGULATORY CORNER

SESSION FORMATS

SCDM accepts submissions in the following formats in the following formats:

Storytelling

Oral Presentations

Panel Discussions

By May 8

Submit your abstract

You should do this through the online content portal. Proposals submitted directly to SCDM Team will not be considered.

May 8 - 19

Review Process

The length of the review process is dependent on the number of submissions we receive. We aim to get back to you ASAP!

20-23 May

Confirmation

If your proposal is successful, a member of the SCDM Team will contact you with an initial offer of a slot, subject to speakers being confirmed and session content agreed. Once everything has been finalised, we will list the conference speakers online and in marketing communications.

End of May to 1 week prior the Conference

Ongoing and Final Preparations

The SCDM Team will work with all session chairs and speakers to ensure you deliver a successful session and that there is no overlap between different presentations.

ABSTRACT SUBMISSION

REQUIREMENTS

For standardization, the acceptable format of the abstract is limited to a maximum of 1500 characters (including punctuation and spaces). This number does not include abstract title (100 characters) and presenter biography (600 characters).

ABSTRACT REVIEW AND NOTIFICATION OF ACCEPTANCE

- The session chairs will review the abstracts according to the relevance to their proposed topic and select the most appropriate ones.
- All abstract submitters should be prepared to present the abstract as an oral communication within the corresponding session format.
- The Programme Committee reserves the right to assign the abstract to one or the other presentation formats without any reservation.

ORAL PRESENTATION

SESSION DURATION

60-75 minutes
Q&A Included

THE BIG IDEA

A connected series providing a coherent deep-dive.

HOW IT WORKS

SCDM Oral Presentation sessions, which consist of 3-4 presenters per session covering practical, skills-based content. Each presentation lasts 20-25 minutes.

It is an ideal session for capable speakers presenting more specialised presentations.

WHAT IT'S NOT

It is not a corporate sales presentation.

Proposed Sessions

- RBQM: Data Preventive Care - Is it Key to Ensure Data Health ?
- System Integration: Opportunities and Challenges
- Where Ewpectations and Reality Collide: EDC Audit Trail Review

RBQM: DATA PREVENTIVE CARE – IS IT KEY TO ENSURE DATA HEALTH?

RBQM:Data preventive care –is it key to ensure data health?

A doctor, who treats a patient with multiple symptoms, needs to find the ones that are most relevant, as well as understand connections and patterns to come up with the right diagnosis and establish an optimal treatment. Keeping clinical data healthy seems to rely on the same principles: uncover the root cause and prescribe appropriate actions.

It's not only treatment that's important though." An apple a day keeps a doctor away". Preventive care plays key role for us to stay healthy. Can it also be key to ensure data health?

The role of data manager is evolving. The time of data managers responsible only for entering data from paper CRFs and ensuring its consistency mostly through manual review is, gone. Ongoing grow in complexity and digitalization of the clinical trials entails a continuous need of systems automatization.
Now, we can have it all- artificial intelligence, machine learning, natural language processing, dashboards- to keep an eye on our data. We need to be able to diagnose our trials and ensure "preventive care" by implementing risk-based approach in our daily activities. Instead of just prescribing broad-spectrum queries for all symptoms, let's focus on detecting signals from clinical and operational data, recognizing trends, understanding the story behind it, and taking fit for purpose actions. All of this will keep our data healthy and ensure sustainability.

How can we be a GP for our data and give the right diagnose on time?

As in the field of medicine, doctors need to stay up to date with constant evolution and improvements, throughout this session you will learn how we can advance our developments in the risk-based quality management.

TOPIC

RBQM

SESSION LEVEL

Expert - Assumes advanced understanding of CDM Industry: 6+ years' experience

LOOKING FOR

Individuals with experience in risk based management, data analytics, data validations, systems & technologies and involved in the evolutions of Data Management.

SYSTEM INTEGRATION: OPPORTUNITIES AND CHALLENGES

System Integration aims to explore, share and answer relevant questions around integrating different sources. The session will also encourage associates to identify and close specific gaps that prevent them from integrating systems. The intention is to have seamless flow of data across different system and fosters data integrity.

TOPIC

Innovation and Technology

SESSION LEVEL

Advanced - Assumes solid knowledge of CDM industry; 4-6 years' experience

LOOKING FOR

- Clinical System Administrators/Specialists
- EDC leads
- CSV Experts who have integrated systems in their companies or helped companies

WHERE EXPECTATIONS AND REALITY COLLIDE: EDC AUDIT TRAIL REVIEW

This session examines the wide gulf between the requirements and reality for audit trail review (ATR) in most organizations. Audit trail data is complex to navigate, with so many items and labels that it can be difficult to tell what you are looking at. As a result, the reviews are manual and time-consuming processes to execute. The session will highlight recommendations drawn from the eClinical Forum and SCDM Position Paper including, risk-based ATR strategies, suggestions on visualizations, and suggested exception report listings. The speakers will describe the complexities many organizations are confronted with when implementing ATR strategies. To conclude the speakers will lead a discussion with the audience on what more is needed from eClinical systems to better support their ATR priorities.

TOPIC

Regulatory Corner

SESSION LEVEL

Intermediate - Assumes comfort within CDM industry; 1-3 years' experience

LOOKING FOR

Responsible for delivering Veeva Clinical Data Management System (CDMS) strategy, with specific responsibility to Veeva Enterprise Sponsors in the European market. He develops, sustains, and supports the overall Vault CDMS strategy by providing thought leadership, business and technology expertise and by having impact on target access, ongoing engagement, customer perception and adoption of Veeva CDMS. Prior to Veeva, François served in senior management roles managing global teams in clinical data management and running cross functional initiatives within clinical technology and data management sectors at Sanofi, Servier , Aixial & Nestlé. He was also Chief Data Officer at Nestlé and at Aixial. He is also a member of the French Clinical Data Management association (DMB), the eClinical Forum and SCDM. François received the M.S. degree in Clinical Research and Drug Development as well as Clinical Data Management from the University of Pharmacy – Montpellier - France.

PANEL DISCUSSION

SESSION DURATION

60-90 minutes
Q&A Included

THE BIG IDEA

Being the primary format, content here should be inspirational, future-facing and highly memorable.

HOW IT WORKS

SCDM Panel Discussion is facilitated by the Session Chair who guides the panel and the audience through the topic.

The panel format allows for a brief introduction and then discussion among the panellists and audience.

The panel, composed of 3-4 experts or practitioners in the field, shares facts, offers opinions and responds to audience questions either through questions curated by the moderator or taken from the audience directly.

The panel aims to offer the audience a thought-provoking discussion thatanalyses a topic from different angles.

WHAT IT'S NOT

We want to avoid having a set of presentations, one after another.

Similarly, it should not be a one-on-one interview conducted with each panellist in turn.

Many untrained moderators simply ask questions of each panellist, one after another, rather than build the dialogue into a conversation.

Proposed Sessions

- Lab to Shelf through Effective Data Analytics
- Generative AI - Exploring a New World of Possibilities in Healthcare
- Future DM Capabilities and Roles / Sustainable DM - Who are the future Data Managers
- Navigating the DCT Regulatory Landscape

LAB TO SHELF THROUGH EFFECTIVE DATA ANALYTICS

Over the last two years content streaming sites such as Netflix and Amazon have grown in popularity across the world. No doubt the platforms have been able to generate ample interest in the subscribers who pay a premium to binge watch on these platforms. It's amazing how Netflix has been able to suggest type of movies or TV series that will catch a subscriber's attention and ensure that they remain hooked. Not just that, Netflix also knows what kind of content to produce to cater to the ever-changing audience interests. The answer is in the data that is captured at the back-end and analysed by Netflix analysts to provide the subscriber with the most enticing list of movies or TV series' options.

Significance of data in Clinical Research:
We all know the importance of clinical research, considering the increased focus over the past couple of years to quickly bring vaccines to market saving millions of lives. Data analytics played a key role in the discovery of new drugs and vaccines that were identified to either limit the side effects of the disease or save the lives of the people. Data produced by the thousands of volunteers taking part in Clinical Trials was documented, analysed, and provided as evidence to regulatory authorities to get approvals in a highly competitive market.

Capturing research data starts at the laboratory, all the way to the pre-clinical trials (animal studies), clinical trials (human research) and even in the real world (Pharmacovigilance). With research becoming more global than ever, data analytics has an important role to play in identifying the risks early on in the research cycle, resulting in course corrections, investing in the right strategy, saving time and resources. Data analytics also guides the researchers in channelling their efforts to the most appropriate methods that can yield the best results.

Contract research organizations (CROs) and pharmaceutical companies are continuously facing many challenges in areas such as data collection, data validation, data harmonization and data insights due to changing landscape towards patient-centric trials, decentralized trials, reducing clinical cycle times leading to faster submissions, political scenarios and pandemics. Today, data analytics is used to not only provide the best directions and methodologies for research, but also to recruit the most eligible patients in a study which can yield the best clinical information, thus generating meaningful insights and delivering the right medicine to the wider more diverse population.

Data insights through predictive analytics, Natural Language Processing and Machine Learning:
The latest that data science can contribute to research is in the area of Natural Language Processing (NLP), Machine Learning and Predictive Analytics in clinical trials. NLP is one of the best breakthroughs in clinical research wherein the data gets captured in respective segments as the patient speaks to the computer. NLP has been able to segment data of various patients based on their medical records and pathology reports or direct patient medical information from the clinical notes of the physicians.
Predictive analytics helps to extract useful information from large clinical trial datasets, trends, and associations where there are many variables, resulting in better data insights and effective decision-making. Data Scientists use predictive models based on machine learning algorithms to check risk indicators thereby ensuring patient safety and also to check progress of the trial with respect to primary and secondary objectives.

Some of the outcomes that predictive analytics and machine learning algorithms have assisted Clinical domains are as follows:
• Predicting clinical trial outcomes: Providing insights into which patients will respond and how to a particular treatment based on their genetic make-up, age, medical history, and other characteristics. Predictive analytics can also be used to detect adverse events during clinical trials by analyzing real-world evidence such as electronic health records and insurance claims data in addition to clinical studies.
• Predict the side effects to medications: Using data analytics to predict which set of patients in the study population will most likely experience certain side effects.
• Interaction prediction between drugs: Predictive/machine learning modelling can be used to extract insights from the adverse events that could occur when two or more drugs are given together to the patient. It can also help to identify the lower-risk interactions through the analysis of available virtual patient models before actually using the drugs in humans.
• Predict clinical trial enrollment: Utilizing clinical data, machine learning modelling techniques can be used to predict the patient groups (responders) that are most likely to enroll for the clinical trials.
• Predict clinical trial dropout rates (non-responders): Predictive/machine learning modelling can be used to predict clinical study completion, or how likely it is for a clinical participant to complete the full course of treatment.

Therefore, with the world of research is moving faster than ever before, there is unprecedented speed in taking a molecule from the lab to the shelf and thereby providing the much-needed benefits to the patients and address their unmet medical needs. With data becoming accessible and interoperable and artificial intelligence becoming more ubiquitous in the area of research, the provision of international collaborations through connected-data is also speeding up research.

Although, data experts are developing predictive models and machine learning algorithms, the need for human intervention to carefully analyse and interpret the data usefulness is key to keep developing data science.

TOPIC

Innovation and Technology

SESSION LEVEL

Expert - Assumes advanced understanding of CDM Industry: 6+ years' experience

LOOKING FOR

Individuals who have implemented or in process of implementation of such mechanisms to further enhance DM skill set and role

FUTURE DM CAPABILITIES AND ROLES / SUSTAINABLE DATA MANAGEMENT - WHO ARE THE FUTURE DATA MANAGERS

Description available soon

TOPIC

The human behind Clinical Data Management

SESSION LEVEL

Expert - Assumes advanced understanding of CDM Industry: 6+ years' experience

LOOKING FOR

Individuals who are already in the journey wherein they have implements strategies to up skill their DM staff

NAVIGATING THE DCT REGULATORY LANDSCAPE

The session will be focused on exploring the current regulatory landscape surrounding decentralized clinical trials. This session will take from industry initiatives and workstreams to allow participants to understand and navigate the regulatory and health authorities when planning for and conducting decentralized clinical trials. The session will hear directly from industry work groups and provide diverse presentations addressing effective playbooks and regulatory assessment initiatives that are aimed at helping to inform and educate the session attendee.

TOPIC

Regulatory Corner

SESSION LEVEL

Advanced Expert- Assumes deep knowledge of the CDM industry; 8+ years' experience

LOOKING FOR

Individuals experience me with and knowledgeable of regulations and standards surrounding decentralized clinical trials

STORYTELLING SESSION

SESSION DURATION

60-75 minutes
Q&A Included

THE BIG IDEA

Bring technical concepts to life through real-life case studies.

HOW IT WORKS

2-3 case studies (15 minutes each; 10 minute Q&A) themed around the same scenario/ issue are told as engaging stories.

The case studies should reflect the authentic experience of an individual, a team, or a community.

WHAT IT'S NOT

It is not a corporate sales presentation

A series of boring or aloof presentations.

Similarly, they should not lack practical guidance on the application of the topic being discussed.

Proposed Sessions

- Disruptive Technologies Simplified: Real World Case Studies
- Enhanced approaches for local laboratory data collection in Clinical Data Management

DISRUPTIVE TECHNOLOGIES SIMPLIFIED: REAL WORLD CASE STUDIES

We have been hearing about several different technologies driving the adoption of virtual and decentralized clinical trials over the past 5 years, but we struggle to find case studies to show how these technologies were actually implemented on the ground. This session will feature technology and industry leaders sharing their stories about the positive and negative things they encountered over the past couple of years implementing technologies like RBQM, ML, AI, RPA, etc. We can learn from them and together we can have a greater chance of successfully implementing these technologies in the future.

TOPIC

Innovation and technology

SESSION LEVEL

Expert - Assumes advanced understanding of CDM Industry: 6+ years' experience

LOOKING FOR

Individuals with experience in the topics explained above. Not all of them nee to be KOL in these areas - I think it's important to share the stories as they unfold on the ground - we can all learn from it.

ENHANCED APPROACHES FOR LOCAL LABORATORY DATA COLLECTION IN CLINICAL DATA MANAGEMENT

The collection, management and maintenance of local lab data is critical within a clinical trial; With the ever increasing need for greater visibility, near real time data access, and so providing the ability to enable quick and informed decision making.

How can technology play its role in supporting these needs in the following areas;
- Reduce site burden at local lab data collection and entry
- Metadata driven automations to data ingestion
- Robotic Process Automation (RPA) or Machine Learning (ML) to minimize manual involvement, and improve quality
- Visualisation for insights on augmented data review, exploration and traceability
- Potential future smart device, ML/AI (Artificial Intelligence) solutions

TOPIC

Innovation and Technology

SESSION LEVEL

Advanced - Assumes solid knowledge of CDM industry; 4-6 years' experience

LOOKING FOR

Experienced in handling end to end local lab activities from a Clinical Data Management perspective (not central labs)

QUESTIONS?

NICOLAS VELASQUEZ

Conference Programme Coordinator

EMAIL ADDRESS

scdmevents@scdm.org

PHONE NUMBER

+32 2 320 24 95

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SCDMDataDriven

TWITTER

@SCDM_DataDriven

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Society for Clinical Data Management (SCDM)