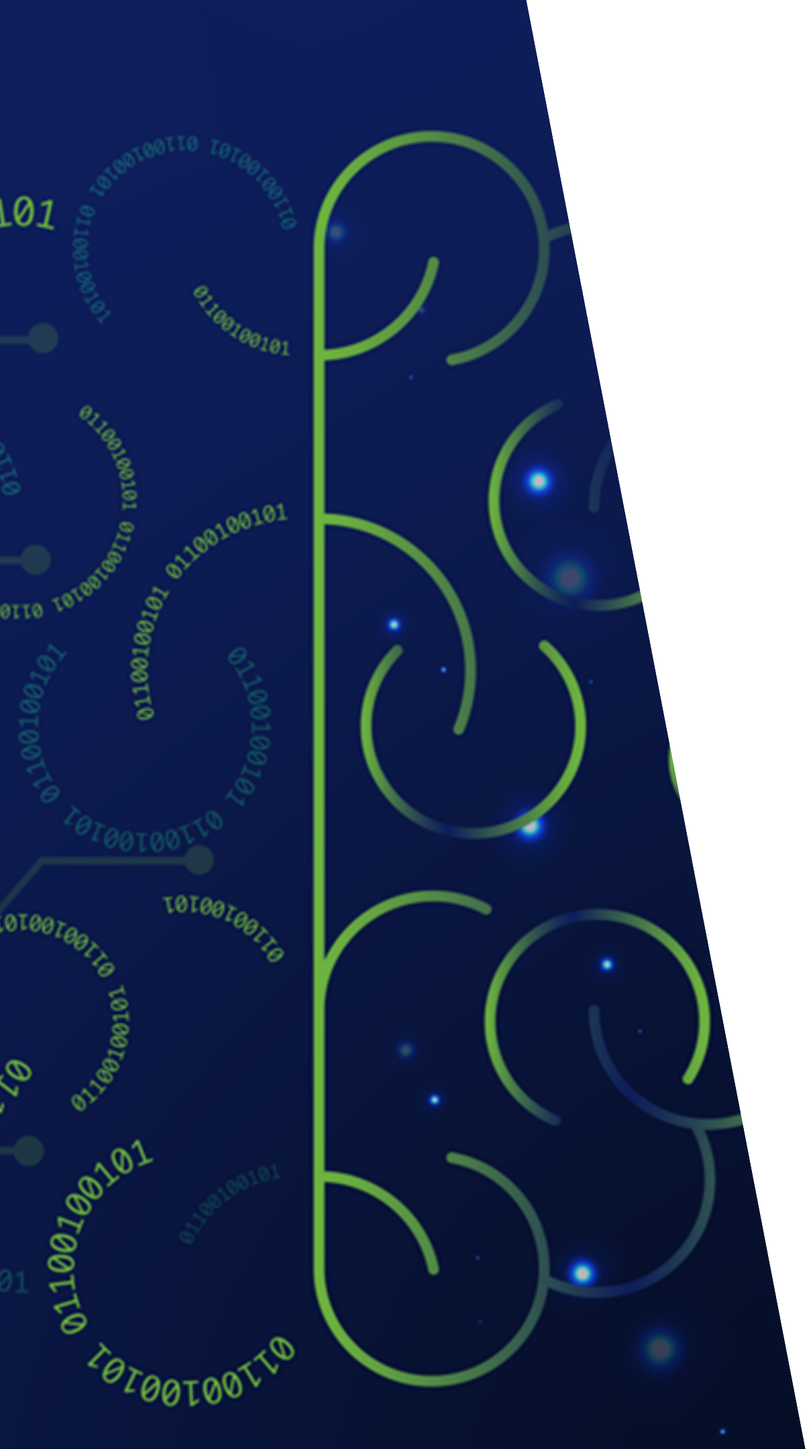
ABSTRACT GUIDELINES

SCDM 2022 Annual Conference

Reconnect



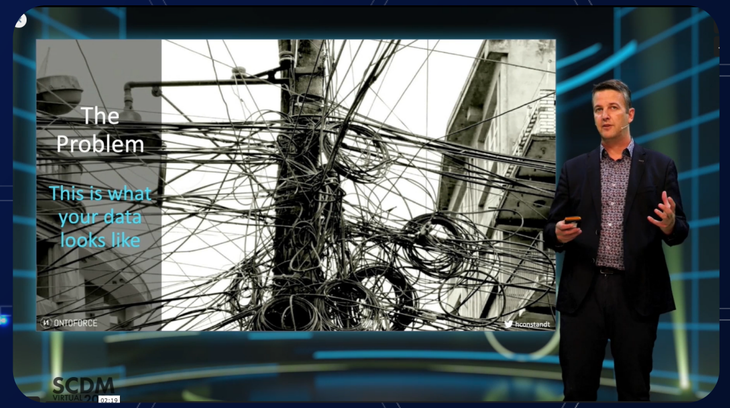
CONTENTS

SPEAKING AT #SCDM2022

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 Annual Conference is a place for the world's clinical data management industry to reflect on the future. 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 make the SCDM Annual Conference and we look forward to seeing 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 be 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 Annual 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 (with the exception of the Pitch Arena and Pressure Cooker session).

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

AI + COGNITIVE TECH

Examining proven solutions, as well as work that is still in prototype, that aim to advance, enrich or improve data sourcing, aggregation and interpretation

DCTs + EFFICIENCIES

Exploring the strategic decentralization of Clinical Trials and how redsigning study protocols, patient engagement and data platforms influence overall outcomes

RB-CDM + DATA INTEGRITY

Focusing on the key tools to ensure data generation and collection systems always have the power to perform and deliver data integrity and reliability.

CDS + TRANSFORMATION

The big CDS idea – evolving from CDM and COVID to focus on what's next after a period of time in which everything changed.

TECH-LED INNOVATION + ANALYTICS

Celebrating innovations in the fundamentals of technology, data and communications that unlock better data insights and improved business performance.

HUMAN + MACHINE

Focusing on the powerful and ever-evolving possibilities present when the human and machine collaborate and work in tandem. Relevant soft skills development will also be considered

REGULATIONS + STANDARDS

Exploring and expanding the thinking around clinical trial regulations and reporting standards, this track aims to support the evolving regulatory agenda and drive it forward.

WILD CARD

Celebrating high-impact content that goes beyond the norm and shifts traditional approaches to (but not limited to) models, tools, platforms, apps and algorithms.

SESSION FORMATS

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

Ignite Presentations

Oral Presentations

Panel Discussions

SESSION FORMATS

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

Poster Presentations

Roundtable Discussions

By April 27

Submit your proposal

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

April 28 - May 30

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!

Beginning of June

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.

June to 2 weeks 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 or poster presentation.
- The Program 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

- How to measure success in a decentralized trial
- Leveraging Metadata to Accelerate Clinical Trials
- RWE/RWD/Registries/Natural History Studies-How do I make sense of it all?
- Data Management-Driven Change in the RBM to RBQM Transformation
- The Journey to Responsible and Ethical AI
- Collect, Curate, Consume: Sculpting the stepping stones to a Clinical Data Science Infrastructure
- Evolving Data Manager - Data science is no longer novelty
- Using HL7 FHIR to Automate Clinical Trial Data Transfers

HOW TO MEASURE SUCCESS IN A DECENTRALIZED TRIAL

How to measure success in a decentralized trial

Over the past year, it is estimated that one quarter of all clinical studies have included a decentralize component or components . We have seen the way we collect clinical research data significantly change due to COVID related travel restrictions. We have seen the increase of data collection from virtual/telehealth visits, home health providers in a patient's home, and wearable medical devices. Our tools for measuring performance and success within these types of studies need to change to stay relevant to this new paradigm.

Traditional data management metrics, as referenced in the GCDMP are broken down into paper-based metrics and EDC based metrics. Currently there isn't any mention of metrics in decentralized trials. Metrics such as 'the number of days from Patient Visit complete to eCRF page entered in EDC system' may not be relevant with direct data capture technologies. Some items such as 'Calendar days from time query generated to query response on EDC system' are no longer measured in days or weeks, but oftentimes can be measured in hours.

This presentation will provide thought leadership on a new analytics methodology to measure the compliance, timeliness and quality in a decentralized trials environment.

TOPIC

DCTs + Efficiencies

SESSION LEVEL

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

LOOKING FOR

- Individuals who are involved with study analytics including the use of ML and AI

LEVERAGING METADATA TO ACCELERATE CLINICAL TRIALS

This session will explore methodologies and tools used to facilitate/automate database build, SDTM creation, and submission based on clinical data standards metadata. The session will showcase examples of how we can connect data and process utilizing digitized protocols and clinical data standard metadata.

TOPIC

Tech-led innovation + Analytics

SESSION LEVEL

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

LOOKING FOR

- Individuals with experience in database build, SDTM mapping, metadata curation

RWE/RWD/REGISTRIES/NATURAL HISTORY STUDIES- HOW DO I MAKE SENSE OF IT ALL?

Industry leaders talk about about Real World Data (RWD), REAL World Evidence (RWE), Registries and Natural History Studies. Do you know the difference?
Did you know you may be able to use a Registry to support an FDA filing?
The FDA recently released a draft guidance, “Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry”

This session will break-down the guidance and provide:

- The definitions of RWD, RWE, Natural History studies per the FDA
- Discuss what makes a registry a good fit for a regulatory submission
- How to design and plan for a registry that is intended to be used in a regulatory submission
- The four things that every registry must have to be considered for submission
- 5 Examples of data to be included in a registry
- Discuss validation of edit checks and queries as they pertain to registries
- Pros and Cons of linking your registry to another data source

If you are curious and want to know the answers to these questions or just want to learn more about registries and the latest FDA guidance, this session has you covered.

TOPIC

Wild Card

SESSION LEVEL

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

LOOKING FOR

- Experienced individuals in Data management specifically registries and Regulatory submissions

DATA MANAGEMENT-DRIVEN CHANGE IN THE RBM TO RBQM TRANSFORMATION

The industry has widely discussed a shift from Risk-Based Monitoring (RBM) to Risk-Based Quality Management (RBQM). Implementing RBQM cannot be about bolting on new technology or new business process; it must be transformation of the existing technological and process frameworks so that risk identification and management is native to study conduct.

This session examines how a platform approach integrating RBM with standards, specifications, data management and data review can provide study collaboration opportunities via holistic access to real-time data, issues and quality management. When risk-based monitoring, quality tolerance limits and centralized statistical monitoring are brought together with data management review and cleaning activities, new analytics-centered approaches can focus teams not just on where risks are, but on how risk is changing over time - providing the user with agency to action the insights of RBQM. Learn strategies and considerations for building an integrated infrastructure approach that ensures RBQM transformation, and hear case studies about how data management is driving RBQM change today.

TOPIC

RB-CDM +
Data Integrity

SESSION LEVEL

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

LOOKING FOR

- Leaders representing, DM, Ops/Monitoring and Technology at Pharma/Biotech who can provide perspective on how DM is at the forefront of the RBQM transformation

THE JOURNEY TO RESPONSIBLE AND ETHICAL AI

AII offers a tremendous opportunity not only to increase efficiencies, reduce clinical trials costs but has the capability to transform the current clinical trial landscape. However, deploying AI without anchoring to robust compliance and core values may expose significant risks including data privacy, health & safety issues, backlash & legal problems. Launching AI without an understanding of its social impact can be risky to a company's reputation & brand. There tends to be an underlying assumption that AI algorithm's predictions are inherently better than human ones but there is often little evidence to support this. Written by humans, algorithms can pass on the same unconscious biases that their creators possess, leading to harmful outcomes. We need to remember that AI lacks general intelligence(empathy, common sense), which can lead to unfavorable outcomes. Responsible & Ethical AI advocates using AI with good intention to empower patients, payers, clinicians and investigators.

TOPIC

AI +
Cognitive Tech

SESSION LEVEL

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

LOOKING FOR

- Individuals and Leaders working in Life Sciences Industry, Data Scientists, AI experts

COLLECT, CURATE, CONSUME: SCULPTING THE STEPPING STONES TO A CLINICAL DATA SCIENCE INFRASTRUCTURE

Data Science has been with us for some time, but it was the advent of COVID that saw data science change from a nice to have to a critical means by which to monitor data remotely. With central monitoring becoming more common, it has naturally seen organizations need to develop an infrastructure with which to collect, curate and consume multiple data sources to allow for analysis, as well as result in a shift towards this work being done by traditional data management roles as opposed to dedicated 'data scientists' or clinical roles.

The intention behind this session is to discuss what is needed to develop a data science infrastructure and what that means, from being able to ingest from different sources of data, to mapping this data into a consumable format and then utilizing this data in a way to produce visualizations and exploratory analytics that provide value to the study. The session will also explain the importance of DM understanding their role in analytic review and how risk identification and governance is a key component in developing a successful infrastructure. Finally, the session will look at the need for a data science infrastructure to be cross-functional, and for all roles to have an understanding of the analytics and outputs, breaking down the barriers between what is considered to be data science and what has traditionally been though of as data review activities.

TOPIC

CDS + Transformation

SESSION LEVEL

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

LOOKING FOR

- Ideally, individuals who have worked with visualizations and analytics, individuals with experience in developing a central monitoring strategy but with a focus on data or individuals who have a data science background

EVOLVING DATA MANAGER - DATA SCIENCE IS NO LONGER NOVELTY

The world has changed to everything being virtual as part of its getting aligned to the world where a pandemic has defined face to face as history. Decentralized trials are gaining momentum and the regulators are keen to review protocols faster, approve them with quick turn around times, provide regulatory support for decentralized trials conduct, monitoring of drugs more easier through regulations and centralized monitoring a reality. With this in mind, I would like to bring a larger clinical data management perspective through industry experts on how the role of a traditional data manager has evolved and how it would look like in a post COVID world.

It is definitely not about data collection through historic sources anymore or reviews through traditional tools. Data is more real-time, unstructured and could be acquired through multiple sources. Can the data manager really decipher and make decisions based on the different sources of data and help clinical scientists to make clinical decisions on clinical trials faster is going to be key. Multiple analytical models are available for a data manager to make decisions today and we will also be talking about decision trees and sensitivity analysis as part of the presentations.

We will also be talking about inter operability of data from different sources and how the role of data manager changes as part of the analysis.

TOPIC

CDS + Transformation

SESSION LEVEL

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

LOOKING FOR

- Individuals with DCT and data analytics exposure, preferably on RBM studies.

USING HL7 FHIR TO AUTOMATE CLINICAL TRIAL DATA TRANSFERS

We'll present real world evidence for the use of HL7-FHIR data transfers (lab data) currently in production between an academic site (MSK) and biopharmaceutical firm (Genentech/Roche) for their clinical research protocols.

We'll include industry and academic thought leaders and subject matter experts who are moving the needle for further use adoption of HL7-FHIR for the transfer of clinical research data across their portfolios. We'll draw these experts from SCDM eSource Implementation Consortium, Project Vulcan, TransCelerate, and the FDA.

TOPIC

Tech-led innovation + Analytics

SESSION LEVEL

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

LOOKING FOR

- Sites, technology firms, and biopharmaceutical companies with experience in leveraging HL7-FHIR in Clinical Research. Individuals who have deployed this technology or are about to.

IGNITE PRESENTATIONS

SESSION DURATION

45-75 minutes
Q&A Included

THE BIG IDEA

Fast-paced presentations built around one stellar idea.

HOW IT WORKS

Ignite sessions are fast-paced sessions designed to generate awareness and stimulate discussion.

An ignite session features up to 6 presentations (5-10 minutes each & max 20 slides) around the same topic or on related topics.

To maintain energy and a high cadence, presentation slides automatically advance every 15 seconds. An ignite session is a truly energetic and dynamic session, designed to keep the speaker and audience on their toes.

WHAT IT'S NOT

It is not a deep-dive presentation but rather the conveyance of one critical idea.

Slides should not be complex and overly wordy. Use brief statements of images instead.

Proposed Sessions

- Create Your Own Personal Brand
- Federated learning: a collaborative effort to achieve Smart Healthcare
- Good Machine Learning Practice
- Selected Shorts: Masters of Innovation

CREATE YOUR OWN PERSONAL BRAND (PECHA KUCHA 20X20)

In this world, our reputation can be our strongest asset or our biggest liability. Therefore, personal branding is no longer just a competitive edge rather a requirement for anyone looking to get their dream job or take their careers to the next level. The personal brand is what a person wishes to do in order escape the anonymity of the profession, to become visible in a certain circle or for a particular cause. Therefore, building up a personal brand thus have tons of benefits, both personally and professionally and it is your promise to the world building trust. For CDM professionals, it can help open many doors in the future. Effective personal branding would allow to build trust with prospective clients and employers and therefore it plays an immense role in carving a niche for people and organization. 75% of HR recruiters are looking for jobs online and 85% of recruiters have mentioned that employee's online reputation influences their hiring decision to a great extent as they conduct extensive research of people online before interviews. In terms of an organization, employees in companies that invest in personal branding initiatives, 27% are more likely to stay in the company and feel optimistic about the future and believe their company is competitive. To delve further in the process, it is important to understand from personal branding experts in the industry, organizations themselves and experts outside industry to explore and address this holistically.

The proposed Ignite session will be in Pecha Kucha format, involving speakers to present using 20 visual slides, 20 seconds per slide. So almost in 7 mins, one presenter will complete and moderator will introduce the next speaker to carry forward the session. It's a quick format and extremely dynamic, and this helps creating vividness and capsules of information bites. For a speaker, it helps enhancing their style and improves their storytelling.

We should be able to cover all presentations in 30 mins with total duration of discussions by moderator for 10 mins and finally it will be followed by 15-20 mins of Q&A with speakers which will give our audience chance to ask questions and clarify their doubts

TOPIC

Human + Machine

SESSION LEVEL

Novice - Assumes some knowledge of the CDM industry; 1 year experience

LOOKING FOR

- 1 speaker from CDM domain who has created own personal brand;1 speaker from an organization that lays emphasis on creating personal brand and has seen merit over a period; 1 speaker from social influencer domain to understand from their perspective what is personal brand and 1 personal branding expert

FEDERATED LEARNING: A COLLABORATIVE EFFORT TO ACHIEVE SMART HEALTHCARE

With disparate data sources, in healthcare, approaches of centralizing the ML training data on one machine or in a datacenter will be impractical soon. Federated Learning (FL) is a method used for training ML models with data from multiple sources while maintaining data anonymity and removing numerous barriers to data sharing. Federated Learning decentralizes machine learning by eliminating pooling data into a single location.

This approach enables organizations to collaborate on developing models without directly sharing sensitive yet difficult to obtain data with each other. Eventually, over time, with several training iterations, the shared models get exposed to a much wider range of data than any single organization could utilize in-house, which ensures superior efficiency of the models.
This session intends to discuss various use cases of Federated Learning in healthcare and enumerate how FL helps in future-proofing the much-hyped Smart Healthcare.

TOPIC

AI +
Cognitive Tech

SESSION LEVEL

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

LOOKING FOR

- Clinical Data Scientists, Data science leaders

GOOD MACHINE LEARNING PRACTICE

AI/ML applied to data management will need some guidelines from Regulators. This session's goal is to ignite discussions around an emerging concept called Good Machine Learning Practice (GMLP) with Sponsors/CROs/Technology & Regulators discussing various aspects that need to be considered while implementing AI/ML.

This would include topics like Accuracy, Feature Engineering, Model training, Risk and Mitigation controls.

TOPIC

AI +
Cognitive Tech

SESSION LEVEL

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

LOOKING FOR

- Experienced AI/ML implementors

SELECTED SHORTS
MASTERS OF INNOVATION

This innovative session it is similar to an ignite session which would allow you to pitch. The session is looking for innovative case studies or niche topics, which will be presented to the overall audience in a short presentation of 3 minutes. When all presenters have finished their pitch, you will be assigned a virtual room where you will be able to have a more in-depth discussion with the delegates interested about your topic.

The session moderator will ensure that attendees have the chance to swap between the different virtual rooms 2-3 times during the session hence the discussion/ presentation will be ran several times throughout the one hour session.

TOPIC

Wild Card

SESSION LEVEL

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

LOOKING FOR

- Innovative case study
- Niche topics

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

- Automating Data Classification & Practical Data Use Cases for AI/ML
- DCT-More than Buzz-Real-world Examples of Large Scale DCT
- Covid-19 Data - Clinical Trials Meet Public Health
- Rocket fuel for future clinical research
- Raising Our Standards: Collaboration and Technology for External Vendor Data
- Reality Leaves A Lot to the Imagination, Doesn't It?
- Decentralized Clinical Trials - An Introduction and Overview
- Talent Shortages in CDM. What You Can Do About It.
- Is EDC era coming to an end?
- Reimagine Patient Centricity with Tx

AUTOMATING DATA CLASSIFICATION & PRACTICAL DATA USE CASES FOR AI/ML

Processing of clinical trial data often gets held up by an early bottleneck of being able to understand the data structures for incoming data in order to map it into a common structure.

This presentation outlines an approach, using a combination of a rules-based approach coupled with machine learning techniques to automate the classification of data. This includes identifying attributes such as the data domains, variables, attributes or the variables, the natural keys to uniquely identify each record, and relationships between the variables.

All this information provides a wealth of details that can then be leveraged by other utilities within a clinical data repository to automate data transformations, generation of data listings, visualizations, and to provide study specific guided user experience. This and other real-world use cases for AI/ML within data management will be explored and discussed.

TOPIC

AI +
Cognitive Tech

SESSION LEVEL

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

LOOKING FOR

- Individuals with practical experience implementing AI/ML with results for data management

DCT-MORE THAN BUZZ-REAL-WORLD EXAMPLES OF LARGE SCALE DCT

DCT, DHT, Telehealth, Telemedicine, Virtual, Remote, Hybrid, Flexible - terms that have exploded over the past two years - but what are the real examples of these in action?

This session is focused on sharing with attendees real examples of large scale decentralized trials.

The session will share the good, the bad and timely information that will allow attendees to understand how to effectively navigate implementing a flexible approach to running clinical trials where the execution is reimagined and is aimed at improving the overall sponsor, site and patient experience.

TOPIC

DCTs + Efficiencies

SESSION LEVEL

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

LOOKING FOR

- Speakers with experience in implementing and managing decentralized trials

COVID-19 DATA - CLINICAL TRIALS MEET PUBLIC HEALTH

The Covid-19 vaccines have been a game-changer for many who felt they could finally emerge from being homebound. Clinical research on these vaccines continues to better understand how they work in younger age groups, how boosters should be administered and, of course, any long-term effects or adverse events. Concurrently, the world struggles to access and manage data related to the occurrence of Covid-19, test results and vaccine administration information. Such data may be found in electronic health records, but more typically these data are either gathered by public health officials or they are not reported.

Early experiences with Covid-19 vaccine administration foreshadow the exacerbation of a problem that has plagued us since implementation of the first technologies devoted to health data ---lack of interoperability and inadequate access to our own personal health data when we need it. This is particularly disconcerting to those who would like to have electronic verification of vaccination and to ensure that this verification will be accepted broadly around the globe. Vaccine passports, travel passes, vaccine certificates or related credentialing apps are in development by a multitude of technology vendors, many partnering with major electronic health record vendors and other organizations interested in providing travelers with electronic proof that they have been vaccinated. These apps and approaches will fail or be much less effective without international exchange of the appropriate data in a manner that is readily understood and accepted by the necessary parties, including the traveler.

In an effort to address the gap between clinical research and public health, the Learning Health Community's Global Initiative for Public Health Transformation (GIPHT) Initiative and the global standards development organization, Clinical Data Interchange Standards Consortium (CDISC) have partnered to develop the V1.0 Vaccine Administration Standard. This standard leverages the WHO core data set, in addition to the eHealth Network's recommended dataset and international standards for clinical research (CDISC) and healthcare (HL7) to make available one global standard that includes adequate metadata such that app developers who use this standard can create apps that will be interoperable with others that also use this standard. International agreement around a core set of data elements and metadata to document vaccine administration could take us one step closer to being able to make informed decisions based on trustworthy data.

To put this accomplishment into context, a publication by Ros et al. (January 2021, Learning Health Systems Journal) proposes the opportunity of resolving the larger problem with a true systems approach: "Addressing the Covid-19 Pandemic and Future Public Health Challenges Through Global Collaboration and a Data-driven Systems Approach". While it may take years to develop a full systems approach, we can proceed in the right direction by agreeing on how to best to share research, healthcare and public health data for specific use cases such as vaccination records.

This esteemed panel will discuss the progress, challenges and opportunities that could avail the global public to better data upon which to base decisions. These real world data (RWD) have different characteristics from clinical trial data and include vaccination data, adverse event data, clinical trial data and other relevant information related to the Covid-19 pandemic. The challenges include not only agreeing on data exchange parameters and understanding safety profiles, but also privacy and the rights and wishes of each individual.

TOPIC

CDS + Transformation

SESSION LEVEL

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

LOOKING FOR

- Individuals with experience in the above topics and perhaps case studies

ROCKET FUEL FOR FUTURE CLINICAL RESEARCH

In the past decade, real-world data (RWD) has been gaining momentum to produce real-world evidence (RWE) to benefit future patients. The growth and global expansion of the COVID-19 pandemic in the past year accelerated the use of RWD to explore the association of COVID-19 with comorbidity, predict the prognosis of COVID-19 patients, shape health care policy for the pandemic, and bring clinical products to market faster. The FDA, regulatory bodies around the world, and the industry have increased their reliance on RWD to come up with innovative approaches to fight the pandemic that could well serve them post-pandemic.

COVID-19 clinical trials were designed while the world was still learning about the virus. RWD has been the only data available for learning about the natural history of the virus, relevant outcome measures, and meaningful time-point assessments for studies. Fortunately, the technology for data collection and data sharing had been in place for several years, which facilitated the use of RWD.

The pandemic has created an immediate need for innovation and rapid solutions that can only be fueled by RWD. Soon, all of these efforts will result in development and democratization of a high-quality RWD and RWE ecosystem that is utilized to rapidly improve patient care around the world.

TOPIC

Wild Card

SESSION LEVEL

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

LOOKING FOR

- Individuals with experience in use of real-world data in clinical studies

RAISING OUR STANDARDS: COLLABORATION AND TECHNOLOGY FOR EXTERNAL VENDOR DATA

Problem:

- For years, focus has been on EDC/CRF data collection requirements
- Most sponsors have high standardization and reusability forms that enable quick transformation to SDTM standards
- Majority of clinical trial data are now collected outside of the EDC (~70%)
- Sponsors, CROs, and Vendors are all using different data collection requirements that all need to be transformed to the submission standards
- As the volume and complexity of external vendor data continues to grow, it becomes more challenging to maintain internal standards and tools to handle this data
- If Sponsors, CROs, and Vendors collectively address this issue, it will save an enormous amount of time and money for all parties

Pain Points:

- Biospecimen Data
  - Biomarkers, Immunogenicity, Pharmacogenomics, Sequencing
  - Niche vendors and academic sites
- Digital Data
  - Imaging, eCOA, and Digital Biomarkers
  - Decentralized trials
  - Real world evidence
  - Electronic health record data

Solutions:

- Organized effort between Sponsors, CROs, and Vendors to determine structure and format of External Vendor Data Collection Standards
  - Not just CDISC standards – will increasingly also need to think about HL7 & FHIR (and potentially other standards in the future)
  - Controlled Terminology and Value Level Metadata usage in Data Transfer Agreements
  - Increased adoption of LOINC codes
- Harness advances in technology to effectively manage this paradigm shift
  - Moving away from spreadsheets to cloud-based solutions
  - AI/ML could play a huge role in bringing uniformity to data from disparate sources/standards

TOPIC

Tech-led innovation + Analytics

SESSION LEVEL

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

LOOKING FOR

- People with strong backgrounds in DM, particularly around management of vendor data. They should also be very future-facing in terms of technology utilization and emerging trends within our industry.

REALITY LEAVES A LOT TO THE IMAGINATION, DOESN'T IT?

"Why regulators and reality collide"; an interesting idea, but do you think it is a fair assessment ? After all, it was John Lennon that said "Reality leaves a lot to the imagination"

Join this interactive panel discussion of regulatory experts from industry and governing authorities who will share their insights on this (mis?)perception and discuss whether these 'collisions' are foregone conclusions in our industry, or if they can be mitigated with improved communication across channels. Panelists will explore how to navigate potential collision points as the world of clinical data management more broadly evolves. Real world examples and future hypothetical scenarios will be used to explore instances where these collisions could have been realistically bypassed.

Thoughtful interaction and perspectives from the audience is highly encouraged. Attendees will come away with regulators' perspectives to common data management issues, how the clinical trial industry interprets regulatory guidance, and steps to take to promote cohesion between regulators and the industry.

TOPIC

Regulations + Standards

SESSION LEVEL

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

LOOKING FOR

- This session would be most beneficial with an FDA regulator presence that has a comprehensive understanding of the shifting dynamic of clinical data management as it relates to clinical trials. Conversely, a speaker from a large drug manufacturer that can speak to macro and micro regulatory pain points. A data manager from a CRO would be helpful to explain the downstream effects from a regulatory perspective that affect smaller organizations without a dedicated regulatory department that may not be recognized when implementing the guidance.

DECENTRALIZED CLINICAL TRIALS - AN INTRODUCTION AND OVERVIEW

As remote access technology takes foothold and continues to expand its presence into our everyday lives, it is critical that the clinical trial industry should also further embrace decentralization and remote access to effectively reach more patients and expedite faster and more accurate results. Decentralized clinical trial pioneer, Scott Weidley, leads an expert panel discussion that presents a comprehensive introduction to decentralized trials, a recounting of their real-world success stories and challenges, and a glimpse into what's ahead for this emerging technology and the industry.

The session breaks down numerous case studies of successful decentralized and hybrid trials which have demonstrated that not only do decentralized trials achieve optimal results, but also that they are here to stay due to the vast benefits over traditional clinical trial models.

The panel explains in detail why decentralized trials are uniquely primed to leverage established decentralization technology, as well as recent innovations in the field, that introduce a more efficient, cost-effective, and inclusive clinical trial processes to a wider audience that is not only ready to embrace decentralization - but already is experiencing and benefiting from remote data-centric solutions.

TOPIC

DCTs + Efficiencies

SESSION LEVEL

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

LOOKING FOR

- Individuals who have used and/or deployed traditional clinical trials and also individuals who have benefitted from decentralized clinical trials

TALENT SHORTAGES IN CDM. WHAT YOU CAN DO ABOUT IT.

Clinical Data Management is growing in demand and organizations are scrambling to find professionals with the necessary skills to fill these positions. The primary reason for this shortage of talent is the lack of information or training on clinical data management in the educational system.

Few universities offer undergraduate, graduate, or continuing education programs in this area. As a result, graduates are not able to get jobs in this field through their education alone. Currently, there are more job postings for Clinical Data Managers than qualified candidates.

This means that many organizations are unable to find people who have the skills they need and end up having to post their jobs for an extended period of time before they can hire someone. These hiring delays cause high turnover rates and high costs associated with training new staff. Offshoring of most data review roles have led to lack of pipeline of CDM Leads.

We will discuss these reasons and more. Further we will discuss what can we do to fix this shortage and where is this going in the future with all the developments in AI/ML solutions and such developments in the industry. We will make it a very interactive session with the attendees.

TOPIC

Human + Machine

SESSION LEVEL

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

LOOKING FOR

- Individuals from CRO CDM Operations, Pharma CDM, Operations, Recruitment Agency, HR from CRO / Pharma

IS EDC ERA COMING TO AN END?

The change in that rate of adoption of newer technologies that we are witnessing in clinical trial space is unprecedented. The war speed research to find a drug or vaccine for COVID19 has made us to re-think traditional data collection, cleaning and analysis process as a whole.

With decentralization of clinical trials as much as 70 % of the clinical data is already seen coming through sources other than EDC. Many of the currently authorized for emergency use drugs against COVID19 are based of EHR data. Multiple combination already approved drug therapies were tried on COVID patients and then the data was used to seek Emergency Use Authorization (EUA). Data coming from wearables, EHR and other external vendor eliminates need of SDV. The modern data lake cum data analytics platforms have entirely changed the way we have been cleaning the data traditionally. Use of APIs/Web services have expedited information exchange between sponsor and multiple vendors.

With implementation of AI/ML in data conversion, anomaly detection we have been able to achieve database lock timelines never before. Hence data cleaning has now already been taken outside EDC. Data archiving is definitely efficient from data lakes as we can archive a consolidated trial data coming from multiple sources. Taking all this into account, in the coming days, just for features like signing off CRFs we may not want to have a separate system like EDC.

The futuristic clinical trials can be imagined without having an EDC platform at use.

TOPIC

Tech-led innovation + Analytics

SESSION LEVEL

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

LOOKING FOR

- People who have been working in consulting space to build newer data collection, cleaning, data lake, data analytics, data conversion platforms.

REIMAGINE PATIENT CENTRICITY WITH TX

Total Experience (Tx) is the new tech buzzword gaining ground since the pandemic has taught the industry to explore and achieve differentiation via capitalizing on new experiential disruptors. This strategy connects the concept of “multiexperience,” i.e., how users perceive and interact with the digital world, with customer, employee, and user experience disciplines. Social structures, businesses, and trials are becoming more remote, virtual, and distributed. Standalone approaches and applications may threaten to fuel fragmentation and erode patient experience efficiency.

When the industry is exploring new and innovative technology-laden concepts of putting patient at the center of the trial, Tx could be the next revolution transforming the concepts of technology-literate patients to patient-literate technology. There is a need to learn patient behaviors automatically via suitable technology to proactively respond to a patient’s next action and create realistic training simulations for associated healthcare and allied staff. For example, unified services may help patients move easily through self-service enrollment with integrated advisor’s view across multiple touchpoints.

Such approaches enable communication with patients and stakeholders across many human senses while providing a richer environment for delivering nuanced information. New approaches such as data democratization, use of IoB for patient centricity, etc., were discussed and debated in the previous SCDM sessions. This session will attempt to bring all the concepts under one umbrella and discuss the possibilities of going beyond the traditional patient-centric approaches to find an answer to the question – “Should the healthcare industry embrace a Tx strategy?”

TOPIC

Wild Card

SESSION LEVEL

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

LOOKING FOR

- Senior decision makers, strategist and technology experts having vast experience in CDM industry.

ROUNDTABLE DISCUSSION

SESSION DURATION

45-75 minutes
Q&A Included

THE BIG IDEA

A space for speakers to deliver CDM best practice and actionable ideas.

HOW IT WORKS

The Forum Stage is the SCDM Roundtable Discussion and features a flexible format to presentations. Sessions may look quite different from each other but they have one thing in common: it allows for extended discussion among a small group.

Roundtables are an ideal forum for having the speakers very accessible to the SCDM audience, for giving and receiving targeted feedback, and for engaging in in-depth discussions.

WHAT IT'S NOT

Roundtables are not Panel Discussions conducted in long-play format.

Equally, the discussion should not be lacking in focus or in learner outcomes.

Proposed Sessions

- How Imaging Quality Control Automation Improves Your Endpoint Data
- Measuring and maintaining high quality on Clinical Trial Data. Is CDM doing enough?
- The FHIR Standard as the eSource strategy going forward
- RBQM: Kicking the can down the road OR smart/efficient focused reviews ?
- Data Analytics - Protecting Data Integrity, Endpoints and Patient Safety

HOW IMAGING QUALITY CONTROL AUTOMATION IMPROVES YOUR ENDPOINT DATA

Medical images on clinical trials are often an afterthought when it comes to setting up a clinical trial. However, image assessments can be an important component of endpoint and safety data.

Managing medical images in clinical trials can be complex and, if not managed properly, can lead to many quality challenges and delays, which can have a significant impact on endpoint data.

However, enabling automation can help alleviate these challenges and ensure quality along every step of the process including image upload and submission, de-identification, and data reconciliation. All of these steps are critical to ensuring the most robust and highest quality data. When configured properly, technology can assist by automating critical tasks and also assist in flagging gross errors in every step of the process.

In this roundtable, we will discuss each step of the imaging workflow, and how advances in technology can assist with automating critical tasks and also assist in flagging gross errors.

TOPIC

Tech-led innovation + Analytics

SESSION LEVEL

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

LOOKING FOR

- This will be a roundtable that will include speakers with CRO experience setting up Data Management activities for imaging clinical trials.

MEASURING AND MAINTAINING HIGH QUALITY ON CLINICAL TRIAL DATA. IS CDM DOING ENOUGH?

With the proposed modernization of ICH E8 and the “fit-for-purpose data quality” as one of the essential considerations for clinical trials, the industry is reassessing the investment of efforts for Clinical Trial Data quality assurance and control. Who should participate in the process? How much effort should be invested?

This session aims to share and discuss evolving approaches to measure, control and improve the quality of Clinical Trial Data from a Clinical Data Management perspective.

TOPIC

RB-CDM +
Data Integrity

SESSION LEVEL

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

LOOKING FOR

- Individuals with experience in Quality and compliance, individuals who support quality assurance and control activities in their organizations

THE FHIR STANDARD AS THE ESOURCE STRATEGY GOING FORWARD

The eSource on FHIR session will present and discuss the current experiences, initiatives and thinking around the use of the FHIR standards to support prospective clinical research studies and real world data projects.

The session will consist of short presentations exploring the FHIR standards for study specification, data collection and data management in support of prospective and retrospective clinical studies.
Topics such as 'expectations of FHIR for clinical research', 'current experiences working with FHIR', 'standards, standards, standards or mapping and semantics' and 'future HL7 FHIR directions' will be explored.

TOPIC

Tech-led innovation + Analytics

SESSION LEVEL

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

LOOKING FOR

- Individuals with experience/working with/supporting FHIR with a clinical research focus

RBQM: KICKING THE CAN DOWN THE ROAD OR SMART/EFFICIENT FOCUSED REVIEWS ?

RBQM is a dynamic full study approach which if applied correctly should reduce the burden on a study team by redirecting attention and effort only to issues that matter. This has been approached in many ways by different companies however some underlying aspects are common.

The use of technology for data surveillance/monitoring and breaking down silo approaches across departments to ensure a collaborative approach is followed when managing risks. As a result, many companies have focused on operational teams such a Data Management and Clinical operations collaboration, and most have brough the statistician in to be part of the risk management process.

However, many have not thought about bring the statistician in to monitor data for potential submission readiness. This may seem straight forward, however, it is standard practice for companies use platforms such a Pinnacle21 to validate data in order to quickly highlight data with potential quality issues for submission. The question has to be asked, is the so to speak “can” being “kicked down the road” for the delayed identification by the statistical programming team? Or are efforts being applied on the RQMB side sufficient to prevent this scenario?

Lets get some statisticians, data managers and vendors around a table to discuss where the line is with regards to focused review; what the role of statistician should be; what are some do’s and don’t; and hear about some case studies.

TOPIC

RB-CDM +
Data Integrity

SESSION LEVEL

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

LOOKING FOR

- Individuals who have experience in the RBQM process and planned execution.

DATA ANALYTICS - PROTECTING DATA INTEGRITY, ENDPOINTS AND PATIENT SAFETY

In this session we will focus on harnessing and leveraging the power of the data to create proactive, actionable insights to ensure three main areas of focus; protecting data integrity, patient safety and study endpoints. We will dive deep in to analytics, how do you embed Data Science within your processes, best way to view the data, innovative data review approaches when working in a reduced SDV model and what analytics to apply to various data sources.

Who are your players, how to capitalize on the skill-sets of your resources, where should these players be positioned within your company to ensure successful execution of data analytics across various functions, considering data access, data ingestion, and technology.

TOPIC

RB-CDM + Data Integrity

SESSION LEVEL

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

LOOKING FOR

- Individuals with experience with data science, analytics and data visualizations

QUESTIONS?

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