Reconnect at SCDM 2022 Annual Conference
The world's leading CDM Conference
San Antonio, Texas
September 11-14, 2022

Destination
San Antonio

www.scdm2022.org
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SCDM, through its remarkable international Annual Conference, has been championing Clinical Data Management (CDM) excellence since 1994 with the goal of providing the benchmark for CDM knowledge and education that drives progress in the industry.

We run the SCDM Annual Conference for anyone in the Clinical Data Management industry who believes in applying thought leadership and practical content to advance the role of CDMs. The SCDM Annual Conference exists to drive progress across the world and to support the evolution from Clinical Data Management toward Clinical Data Science.
EMBARK ON A DIGITAL TRANSFORMATION JOURNEY

Want to improve your cycle times by 50% or more?

It’s time for change. Our industry has relied on pushing more and more resources into outdated work practices. Innovative companies are now using digital transformation to improve cycle times, minimize risk, increase quality, and achieve better clinical results across hybrid/virtual trials using patient-centric technologies.

Gain benefits across your Clinical Development organization

**CLINICAL DATA MANAGEMENT**
- Access an authoritative single-source-of-truth data repository
- Easily convert data into industry standard formats (CDASH, SDTM, Adam, Define, ODM, CT, LAB, SEND and others)
- Works with 15+ eClinical systems, 8+ CROs & 50+ wearable APIs

**CLINICAL OPERATIONS**
- Gain actionable insights to shorten your time to market
- Review all clinical trial data across remote/virtual trials
- Risk Based Quality Management (RBQM)

**BIOMETRICS**
- Powerful programmer-friendly statistical programming
- Choice of analytics tools and editors
- Secure validated regulatory compliant environment

**TALK TO US**
MaxisIT is at SCDM 2022 - Booth # 307 & 406

**DMW**
Data Management Workbench

**CTOS**
Clinical Trial Oversight System

**SCE**
Statistical Computing Environment

+1-877-MAXISIT (629-4748), +1-732-494-2005, ext. 135
sales@maxisit.com
WELCOME TO SAN ANTONIO, TEXAS!

At the SCDM 2022 Annual Conference, you can expect practical insights, workshops, big idea presentations and, of course, exciting debates - all in the spirit of sharing the latest insights and learnings between industry experts from all over the world.

Hyatt Regency Hill Country Resort and Spa
9800 Hyatt Resort Dr, San Antonio,
TX 78251,
United States

LET’S RECONNECT

Reconnect with the global Clinical Data Management community, celebrate imaginative ideas and pioneering mindsets and get inspired at SCDM 2022 - the International Annual Conference of Clinical Data Management.

We are building a modern, not-to-be-missed experience that allows our community to come together in an engaging and relevant way. After two years of virtual connection, our 2022 conference will bring peers, colleagues and friends together to discuss today’s biggest industry challenges and collectively take the next steps towards the Clinical Data Science future.

Through curated, innovative and thought-provoking content and exciting networking opportunities, the SCDM Annual Conference promotes Clinical Data Management excellence and extensive peer-to-peer knowledge sharing. We promise you an amazing in person experience with content and networking that will ‘WOW’ you!
CONFERENCE HIGHLIGHTS

• **Discover** more about the Educational Sessions in the SCDM 2022 Annual Conference program, led by our Conference Co-Chairs.

• **Start** the day with a **Sunrise Awakening** activity by attending the SCDM Morning Yoga or Sunrise Run/Walk.

• **Seize** the opportunity to win exciting prizes with the **“Where’s SCDM?” contest**.

• **Join** SCDM’s Leadership Forum on Sunday, September 11 from 9:00AM to 5:15 PM.

• **Get involved** in one of the many networking opportunities available during the conference, such as the **Networking Reception**.

• **Visit** the Exhibit Hall and meet our Sponsors and Exhibitors to experience new products and innovative industry technology.

• **Explore** key CDM topics in greater depth at our **Pre-Conference Workshops**:
  - AI and Machine Learning: What it is and its Impact on Data Management
  - Clinical Site Immersion
  - Data Requirements for an FDA Submission

**REGISTER NOW**
Medidata has gone beyond EDC and delivered the next-generation of clinical data capture and management capability. Come learn how.

Visit us at
Booth 401–403
NETWORKING OPPORTUNITIES

Sunrise Awakening
Tuesday, September 13 at 7:00 AM
Aunt Mary’s Lounge at Hyatt Resort

Feed your body, mind and soul during our Sunrise Awakening activities.
Join in for a yoga session or a 5km morning walk or run to get energized for the second day at #SCDM2022.
These activities are free to join. Please make sure you confirm your attendance during the registration process.

MORNING YOGA
Flow with us on Tuesday, September 13 from 7:00 AM until 8:00 AM. The yoga session will be outside in a relaxing environment. We will provide yoga mats, water and T-shirts, so all you have to do is show up and enjoy the flow.

SUNRISE WALK / RUN
Looking for a higher intensity activity? For those wanting to speed up their heartbeat, join the team for a 5km morning walk or run where you will be able to enjoy the beautiful surroundings of the Hyatt Resort. Water and T-shirts will be waiting for you at the start and end point of the route.

Networking Reception
Tuesday, September 13, at 6:30 PM

Be with us on **Tuesday, September 13** for a real Texan-style evening at Henry’s Hollow, located on the premises of the conference venue.

Join in for a toast, a bite and, of course, a lot of dancing. Break free from the virtual meetings and get togethers, and reconnect live with your peers. Start practicing your country line dance and **don't forget to bring your cowboy boots for the evening!**

- Dress code: Cowboy chique
- Ticket price: $ 250.00

Thank you to the Networking Reception sponsor:

[3M MEDI DATA]
BROKER DATA INTO BREAKTHROUGHS

Ingest vendor data on time, on your terms

BOOTH 211
PRE-CONFERENCE WORKSHOPS

Sunday, September 11, 2022

One day before the SCDM 2022 Annual Conference kicks off, we are excited to offer you the possibility to join Pre-Conference Workshops that will allow you to explore key CDM topics in greater depth.

The Pre-Conference Workshops are interactive 4-hour long sessions run by practitioners and leading global education organizations. These sessions will provide a hands-on learning experience that will enable you to gain new insights and explore new strategies and tools in your day-to-day work.

Participants in the Pre-Conference Workshops will earn 4.0 CEU’s/session after the successful completion of each session and post-session assessment.

Pre-registration is mandatory and an additional fee of $525 will apply.

AI AND MACHINE LEARNING: WHAT IT IS AND ITS IMPACT ON DATA MANAGEMENT

Leader: Prasanna Rao, Senior Director & Global Head of AI/ML, Pfizer

Sunday, September 11
8:00 AM to 12:00 PM

SDQ-Smart Data Quality hands-on workshop will provide participants an immersive experience to work with state-of-the-art AI system in order to explain how Artificial Intelligence, Machine Learning and Rule engine work together along with human experts to reconcile Clinical Trial data.

Part 1: Workshop User Guide & Registration on SDQ Platform
Monday, September 5 to Friday, September 9

During Part 1 of the workshop, participants are provided access to enter their test Clinical data into a (mock) EDC system. Participants are encouraged to create realistic examples of CRF data including sample discrepancies which the SDQ AI system will then utilize to correctly predict discrepancies.

Part 2 & 3: Live Workshop & Prediction Analysis
Sunday, September 11, 8:00 AM – 12:00 PM

During Part 2, Pfizer Subject Matter Experts (SMEs) and our partner, Saama technologies, will conduct an overview of the AI methodology for data reconciliation along with SDQ implementation best practices. Part 3 is also a live session where the participant-entered-data in Part 1 is used for machine predictions which are analyzed live by SMEs.

- Introduction to Smart Data Quality (SDQ): The three components of SDQ and how they all work together
- Methodology to analyze and onboard studies
- Machine Learning teach cycles
- Prediction Analysis
**CLINICAL SITE IMMERSION**

**Leader:** Meredith Nahm Zozus, Professor, Div. Chief, Director Clinical Research Informatics, Univ. of Texas Health Science Center San Antonio

**Sunday, September 11**

8:00 AM to 1:00 PM

Most Data Managers have never seen a clinical investigational site. Don’t be that Data Manager!

Enrich your knowledge of clinical operations and data collection by experiencing operations at a live Clinical Research Site at the University of Texas Health Science Center at San Antonio. In this half-day workshop, attendees will tour the site and gain a greater understanding of site processes from study feasibility analysis, institutional site start-up, recruitment, study conduct and data collection.

As a participant, you will see demonstrations of site-based data systems including feasibility analysis tools, the clinical data warehouse, the site Clinical Trial Management System (CTMS), and electronic data collection from the EHR. You will work and talk with site personnel including Study Coordinators, Research Administrators, Investigators and Informaticists and to see common site information systems such as the clinical data warehouse, the site CTMS, the EHR, and EHR-to-eCRF data extraction tools.

**DATA REQUIREMENTS FOR AN FDA SUBMISSION**

**Leader:** Dan Crawford, Senior Director, Veeva Systems

**Sunday, September 11**

1:00 PM to 5:00 PM

This session will provide an overview of the requirements for submitting standardized electronic data and documents to Regulatory authorities (FDA, PMDA). We will also highlight some of the tools the FDA uses to facilitate their review and their approach to reviewing the safety and efficacy portions of a submission.

Topics will include the following:

- Regulatory History of Submitting Standardized Electronic Data
- CDISC Overview
- Metadata Submission Model
- aCRF
- Define.XML
- Study data Reviewers Guide
- Technical Conformance Guide
- Study Data Standardization Plan
- Traceability
- Pooling of Data
- Coding
- Terminology
- PMDA Submissions
- FDA Review Tools
- An FDA Reviewers Approach to Clinical Review of a Submission
- Breakout sessions with exercises
LEADERSHIP FORUM

SUNDAY, SEPTEMBER 11 FROM 9:00 AM TO 5:15 PM

This is an exclusive event for industry leaders and an additional attendance fee of $500 applies. If you would like to participate and have not received a personal invitation, please click on one of the buttons below and follow the registration process to submit your application.

REGISTER FOR THE LEADERSHIP FORUM

Over the last decade, the evolution of clinical research practices and supporting regulations, as well as massive advances in technology, have fundamentally changed the nature of clinical research data. Therefore, data management strategies must evolve in a manner consistent with these changes and in particular, reflect the risks, complexity, and value of the data collected. The Clinical Data Management discipline is morphing into Clinical Data Science.

The 2022 SCDM Leadership Forum will provide industry and regulatory leaders with opportunities for in-depth discussions of the issues associated with this evolution, in particular as they relate to process, technology, people and regulatory considerations.

Over the course of the forum, we will go on a highly interactive journey covering four topics:

I. Technology

Technology is changing our clinical data industry and the data industry is changing the technology requirements.

Rapid digital transformation, including robotic process automation, machine learning (ML) outlier detection, smart query tools and central ingestion of high volume/high complexity data streams (e.g. real world data (RWD), decentralized clinical trial (DCT) data) is not just a theory anymore but roadmaps are built to drive short and long term business value.

Moderator: Ward Lemaire, Head of Data Management, Janssen
II. People
Developing and attracting talent in an employee driven market to facilitate the evolution to Clinical Data Science.

Over the past year, we have seen a dramatic increase in hiring at Pharmaceutical and CROs, as well as other technology companies across the globe. This has created an increased demand for talent and an employee driven market, resulting in large increases in salaries and a lowering of expectations from higher levels. In this session we will discuss the impact of working from home, increased demand, counter offers, and the erosion of internal equity on the labor market and employee retention. We will discuss what we can do as an industry to improve and how we can continue to expect more from our associates as we evolve Clinical Data Science in this environment.

III. Processes
Adapting processes at the same pace as technology changes.

Recent progresses in the technologies available to support clinical research offer important opportunities to transform our processes to focus on the quality of critical data, process more data faster, make clinical trials more accessible to patients and sites, and improve our cycle times.

IV. Regulatory
Current regulatory thinking about technology and process changes impacting Clinical Data Science.

In an ever-changing clinical and data landscape, it is equally important to understand how the regulatory landscape is changing in tandem. This session will be an opportunity for us to enter in a dialogue with regulators on topics such as draft guidances, DCTs and discuss how the regulatory landscape is changing.
Veranex delivers best-in-class clinical data management, statistical programming, and biostatistics through teams that are flexible, scalable, and responsive to your need.
MEET OUR KEYNOTE SPEAKER

Amy Abernethy is the President of Verily’s Clinical Studies Platforms, where she oversees the company’s clinical evidence generation platform product vision and related clinical research portfolio. Dr. Abernethy was most recently Principal Deputy Commissioner of Food and Drugs of the US Food and Drug Administration (FDA) and the agency’s acting Chief Information Officer.

Dr. Abernethy is a hematologist/oncologist and palliative medicine physician who has authored more than 500 publications.

Landscape shifts in clinical research and clinical evidence generation

The pandemic played a key role in the evaluation across the drug lifecycle, especially when we talk about data. But a central challenge has been data and how to handle data quality mismatch, and we saw a big need for measuring and documenting data quality across data sets.

Clinical studies are shifting to adapt to demands and are covering longitudinal data and evidence. At the same time, regulators and industries are addressing data quality issues.

It is now clear that clinical studies in the future will look different, but how? And how will the role of CDM change after incorporating data sources into clinical studies? What skills will be needed?
We are proud to present our 2022 Mobile Application!

Access the most updated conference information at the tip of your fingers. Now it is easier than ever to:

- LEARN about the program.
- BUILD your personalized agenda.
- ENGAGE during live sessions.
- FIND your way around the venue.
- DISCOVER this year’s exhibitors.
- RECONNECT with your peers.

Download the APP

Stay connected with the SCDM Mobile App!

Where's SCDM?
Can you find these SCDM members and leaders?

Deepak Kallubundi
Labcorp

Meredith Zozus
UT Health San Antonio

Patrick Nadolny
Sanofi

Richard Young
Veeva Systems

Look around the conference venue and when you spot one of them, take a picture together. Share the four pictures on social media with the hashtag #SCDM2022.

Participate in the game and win one of the following prizes:

- A free SCDM webinar for the first delegate who captures the four members (Pictures with more than one of the four leaders are allowed).
- A 2023 conference pass for the lucky one chosen in the raffle which will take place during the closing ceremony – make sure you stick around.

Posts across Facebook, LinkedIn and Twitter will be considered.

The winners will be announced during the Closing Ceremony on Wednesday, September 14.
The Foundation of Digital Trials

Celebrating 10 Years!

Sept. 12 | 6:30 PM | Luckenbach Pavillion

Visit us at

Booth #506

eclinicalsol.com  info@eclinicalsol.com
MEET OUR SPONSORS

Technology

Platinum

Gold

Silver

Corporate Partners

Supporters Club

Medtronic  UCB
I’m looking behind the numbers to find key insights. And I do it

Join Our Team of Data Managers

From oncology to vaccine development, we’ve helped develop almost 99% of the 200 top-selling biopharmaceuticals on the market. This wouldn’t be possible without our diverse, global team and their commitment to the patients who rely on them.

Now, it’s time to add your perspective. Join us in reinventing medicine and advancing healthcare – with the flexibility you need to balance work and life – as a member of our Global Data Operations team.

Visit us at Booth #600 to learn more!

It’s Time to Make a Difference With Heart™.

insde.co/oydv
VISIT OUR DEDICATED VENDORS

We are looking forward to you exploring the exhibit hall this year. With our largest number of companies, academic institutions and associations to date, it could be the place where you find critical solutions to your research and business challenges. In 2022, you will be voting for your favorite giveaway. Make your voice heard and show your appreciation for the favorite exhibitors!

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EXHIBITION FLOORPLAN

![Exhibition Floorplan Image]
Syneos Health is the only fully integrated biopharmaceutical solutions organization purpose-built to accelerate customer success. We lead with a product development mindset, strategically blending clinical development, medical affairs, and commercial capabilities to address modern market realities.

A career with Syneos Health offers endless opportunities:

• Collaborate with customers to deliver **all their data acquisition, data cleansing and associated data analytics need** to support clients across all therapeutic areas throughout all phases of product development.

• Work alongside passionate data management experts to speed innovative therapies to patients

Collaborate with colleagues across the product lifecycle, all focused on one goal: Shortening the Distance from Lab to Life®
PRODUCT SHOWCASES

Monday, September 12 - 1:00 PM - 1:30 PM

Product showcase
Bandera AB

NextGen Data Management - Bridging the Gap between Clinical Care and Clinical Research with EMR to eSource Integration
Fredericks F

Deliver High-Quality Data, Faster with the Medidata Clinical Cloud®
Brady A

Integrated eConsent, EDC, and ePRO -- supporting clinical research in decentralized, traditional, and hybrid models
Fredericks G

Pinnacle 21 Data Exchange: Transforming External Vendor Data Management
Fredericks E

Monday, September 12 - 3:15 PM – 3:45 PM

Unburdening stakeholder’s (participants, site, sponsor) lives by IQVIA’s fast, flexible and proven eCOA technology
Brady A

An Innovative statistically driven approach for RBQM, integrated with 5D strategy under D2P Analytics framework
Fredericks F

A New Paradigm in CDMS
Fredericks E

Accelerating New Science and Doing Development Differently
Fredericks G

SCDM 2022 Annual Conference
San Antonio, Texas | September 11-14, 2022

22
**PRODUCT SHOWCASES**

**Tuesday, September 13 - 10:30 AM - 11:00 AM**

- **Innovation in Clinical Data Analytics – Delivering automation and driving informed actions to improve outcomes**
  - Bandera AB

- **Centralized Data Strategy: The Foundation for Digital Clinical Trials**
  - Fredericks F

- **Enabling patients to use their health records for your clinical trial**
  - Brady A

- **eClinical Technology Strategy: Best-of-Breed Solutions vs eClinical Platforms**
  - Fredericks E

**Tuesday, September 13 - 1:15 PM - 1:45 PM**

- **Study Build to Launch: DCT in 30 minutes**
  - Brady A

- **Meet Huma the Next Generation Digital solution delivering innovation in research...**
  - Fredericks F

- **From Source to Submission: Making the Data Work for You**
  - Fredericks E

- **Accelerating Digital Trials with Best-in-Class Technology**
  - Bandera AB

- **Persistent Omni Data Platform**
  - Fredericks G
Clinical ink’s eSource ecosystem ingests all incoming electronic data into a unified data platform to support analytics within and across studies, regardless of how it was captured. Our distinct eSource methods include Direct Data Capture (DDC) and eClinical Outcome Assessments (eCOA) for a wide range of phases and therapeutic areas.
WELCOME TO SAN ANTONIO

Founded during a Spanish mission in 1718, San Antonio is a historical and colorful city blended with Mexican and Texan culture. It offers architectural and cultural elements which date back to early Spanish colonial life and it is named after the Portuguese priest Saint Anthony of Padua, who organized a Spanish expedition in 1691.

San Antonio is the second-most crowded city in Texas with a fast-growing economy and a vibrant bilingual population. Moreover, it is proud to be the second largest majority-Hispanic city in the United States and an important military base. It is possible to hike or bike along tracked trails to discover the five Spanish frontier missions, which were designated UNESCO World Heritage sites.

If you’d rather enjoy something more eccentric, the city offers you the chance to attend quirky parades, culinary events and to experience singular local entertainment. San Antonio’s culinary heritage is what should attract you the most. Did you know that San Antonio is also called “The City of Gastronomy”? The city will offer you the perfect blend between authentic tradition and innovation. Do not forget to start your journey with the iconic puffy tacos or with the most delicious George’s bank sea scallops!

Despite its historical atmosphere, you can enjoy many modern, dynamic and diverse events.

LOCAL ATTRACTIONS & FUN FACTS ABOUT SAN ANTONIO
LOCAL ATTRACTIONS

Alamo
Tejas Rodeo Company
Go RIO San Antonio Cruises

Historic Market Square
Majestic Theatre
Tobin Center For The Performing Arts

Natural Bridge Caverns
The Culinary Institute of America

MORE INFO HERE
San Antonio loves to celebrate. That is why each April, since 1891, the city hosts a 10-day festival which is the biggest and most attended. Fiesta San Antonio counts more than 100 events and three million visitors. Crazy, right?

San Fernando Cathedral – built in 1738 – is the oldest church in Texas and hosts almost 5000 people every weekend.

San Antonio shopping district «El Mercado» is the largest Mexican market outside of Mexico. Want to buy Mexican products without being in Mexico? This is the right place for you then.

Shaquille O’Neil played high school basketball in San Antonio and his team won the 1989 state championship. Another thing that the city is really proud of.
OPTIMIZE YOUR CLINICAL TRIALS WITH iMEDNET

Intuitive platform
Flexible development suite
Simple data checks
Quick site adoption
Transparent pricing
Rapid study builds

A comprehensive EDC-centric eClinical solution for life sciences sponsors and CROs

EDC
✓ Randomization
✓ Trial Supply Management
✓ Payments
✓ ePRO
✓ Adjudication
✓ API Integration

A trusted and experienced partner

With over two decades of experience and thousands of studies with biotechnology, pharmaceutical, medical device sponsors and CROs around the world, we have the knowledge, technology and experience to help you achieve success. Our flexible and comprehensive EDC-centric eClinical platform improves the efficiency of clinical studies of all types and phases.

Request a Demo
hello@mednetsolutions.com
mednetsolutions.com
TRAVEL AND VENUE

TRAVEL

9800 Airport Blvd, San Antonio, Texas, 78216

San Antonio airport is located 8 miles north of downtown San Antonio. It is the main international airport and serves Greater San Antonio Area in Texas. The Airport hosts exhibits and installations, both rotating and temporary. SAT is also proud to offer many services to members of the armed forces and their families.

HYATT REGENCY HILL COUNTRY AND SPA

9800 Hyatt Resort Drive, San Antonio, Texas, United States, 78251

Hyatt Regency Hill Country Resort and Spa is a marvelous location situated 20 minutes far from the centre of San Antonio. You will be surrounded by 300 acres of historic ranch land and pleased with comfortable charm and authentic hospitality. The hotel offers you several activities and amenities to make your experience even more memorable. You will have access to many on-site activities, such as guided nature walks, and to places to relax. What is more, all rooms are marked by an inimitable and picturesque rustic décor.

Shuttle Service

For those staying at the Hilton Hill Country Hotel or the TownePlace Suites, free shuttle buses will be facilitated to transfer you to and from the conference venue. A dedicated email will be sent to all participants staying at the Hilton or TownePlace.
THANK YOU

Our mission is fueled by our global network of enthusiastic expert volunteers. Behind every successful event there is an extraordinary volunteer team. We are truly grateful for the valuable work you have done for the Society and the CDM community!

YOUR DEDICATION IS ESSENTIAL TO THE WORK THAT WE DO.

Conference Co-Chairs
Stephen Cameron, ICON
Carol Schaffer, Pfizer
Shobhit Shrotriya, Accenture
Richard Young, Veeva Systems

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