SCDM 2019 Annual Conference Abstract Submission Guidelines

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The 2019 Annual Conference will be held from September 29 – October 2 at the Baltimore Marriott Waterfront. In preparation for the conference, over 30 session topics have been identified that:

1. address best practices for core components of Clinical Data Management; or
2. serve as "hot topic" sessions that will provide the latest perspectives on key issues confronting our profession.

With this call for abstracts, we are now looking for your input as participants in these sessions. Our goal is to provide our conference attendees with the best content possible for each and every one of these topics.

SESSION FORMATS

The 2019 Annual Conference Task Force invites the submission of abstracts under the following presentation formats:

- **Oral presentations** – the familiar presentation session consisting of three-four 20 to 25 minutes speeches, followed by questions and discussion.
  Submissions will take the usual form of a description of the content of an eventual PowerPoint presentation.
- **Panel discussions** – experts in the field, who share facts, offer opinions and respond to audience questions either through questions curated by the moderator or taken from the audience directly.
  Submissions should consist of a description of how you could participate in and contribute to the topic under discussion.
- **Roundtable presentations** – extended discussion among a small group, the presenter will be giving and receiving targeted feedback, engaging in in-depth discussions, and meeting colleagues with similar interests.
  Submissions should consist of a description of how you could participate in and contribute to the topic under discussion.
- **Ignite presentations** – the session includes several 10-minute presentations on key challenges and solutions within the industry. Each presentation will have a maximum of 6 slides. The result is a fast-paced session that changes topics/ perspectives several times and will keep the audience on their toes.
  Submissions will take the usual form of a description of the content of an eventual PowerPoint presentation.
- **Poster presentations** – structured as an academic presentation but with creative visuals of your research and/or organizational processes presented on a 4' x 8' poster board.
  Submissions should include a summary of background/ problem information, primary objectives of the work, methods used to obtain and analyze the data, results or findings from your work, with a discussion and conclusion that will help others in their work.
- **Storytelling session** - 2-3 case studies (15 minutes each) around the same scenario/ issue.Stories should be about 15 minutes long and 10 minutes should be provided for Q&A. The case studies should reflect the authentic experience of an individual, a team, or a community. Only real-life case studies will be accepted.
  Submissions will take the usual form of a description of the content of an eventual PowerPoint presentation.

Abstracts should be submitted electronically through our website:
https://www.surveymonkey.com/r/SCDM2019AbstractSubmission

QUESTIONS? Contact Alessandra Percuoco, Conference Program Coordinator, annualconference@scdm.org

Please follow the instructions on the abstract form carefully and completely, making sure to use one of the available formats, depending on your intended session.

As terms and conditions of your participation to the conference, kindly note the following:

- No travel/ accommodation allowances are provided to presenters.
- **Presenters are expected to register to the conference; registration fee is not waived.** Presenters will receive a 20% discount off the lowest offered registration fee.
- In some cases, in order to provide our attendees with a broad range of perspectives, SCDM reserves the right to limit the number of presentations chosen from a single company.
- 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 Technology Ignite session).
- Presenters are required to attend several conference calls with the conference co-chairs and session chairs during the preparation process.

ABSTRACT TOPICS

Submitters are invited to propose abstracts for the below mentioned session topics.

Presentation Sessions

Session 1 - Clinical Data Management 2022: A Glimpse into the Future

This is an exciting time to be a part of clinical data management. Technology continues to advance at a rapid pace and the way that we perform our jobs is changing right before our eyes. This presentation will explore 3 areas where technology will have the greatest impact and take us to the data management of the future. Data Workbenches - What are they and why didn't they exist before? What purpose do they serve and how can they help me as a data manager do my job more effectively? Integration of EDC and Risk Base Monitoring (RBM) - How does the integration of RBM and EDC vault RBM into the forefront? How are the issues of programming updates in EDC and system documentation being addressed? What benefits will clinical and data management groups realize with the integration? How does this impact the role of the data manager? eSource - What are the benefits? What is the FDA's stance on eSource? What is the latest on FHIR and how close is eSource to being commonplace in clinical trials. The presenters will answer all these questions and answer any additional questions that arise.

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

Session 3 - Intelligent Machines Take on Clinical Data Management

In this session we will discuss, how Artificial Intelligence will transform Clinical Data Management. Human versus machine battle has already started in other industries. How can we leverage machines to do not just repetitive data cleaning tasks but take on higher complexity tasks in tandem with humans. AI is not magic; data managers & monitors need to train machines so that they can focus on data science. Many colleagues have said, I wish I could ask a machine to reconcile data. Why can't we get a machine to spot missing data and raise queries? In this session, we will address these questions and more. How Risk based monitoring will lead to AI based monitoring. Why should Data Managers embrace disruptive technology? The changing role of a data manager to a data scientist. Data Manager is the

pilot, AI will become the auto-pilot Presentations will be thought provoking as well as reality of current state AI technologies and their limitations. This session will include Pharma and technology vendor point of view on this critical industry transformation opportunity.

Session Level: Expert - Assumes advanced understanding of CDM industry; 6+ years' experience

Session 5 - Developing Industry Best Practices and Metrics for Data from Wearables, Apps and Sensors

Developing Industry Best Practices and Metrics for data from wearables, apps and sensors. The almost daily emergence of another data generating device such as an App, sensor or wearable and its potential use in clinical trials is raising some interesting questions about the role of traditional Data Management and therefore the Data Manager. When faced with new sources of potentially very large and variable data sets, with highly variable delivery methods, what actions should the Data Manager take to insure accuracy, reliability and integrity of this data? Is a new data flow needed? What questions arise about where the data is stored? Where is the data worked on/cleaned/reviewed? Should the Data Manager be concerned about data security? How does this 'new' data compare to any existing gold standards? In seeking answers to these questions, is a 'new norm' developing and is it time to start defining new Best Practices and Metrics with these new processes?

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

Session 7 - Hurdles and Promises of Zero-Site Trials – Embracing the Future through the Data Management Lenses

Zero-Site clinical trials - trials conducted limiting or eliminating the need to make patients recruited at Sites also known as "Virtual Trial". These are a relatively new method of conducting a clinical trial to collect data on the safety and efficacy of a molecule or medical device leveraging technology (apps, monitoring devices, etc.) and inclusion platforms (recruitment, informed consent, counselling, measurement of endpoints and any adverse reactions) to allow the patient to be homebased at every stage of clinical trial.

Promises:

- Number of recruited patients increases considerably if the barriers linked to travel distances are broken down to reach the research centers. Reduces the discomfort associated with travel and simplify the collection of information, can reduce the current high drop-out rate of patients involved in phase III studies
- Electronic medical records can help to identify subjects with specific targeted characteristics and to increase awareness of experimentations and recruit subjects directly.
- Time is reduced from the traditional set-up of multiple study sites. Also offers the possibility of reducing risks in the drug development process
- Livecollection from monitoring devices allows the investigators to calibrate, modify, and possibly even interrupt the study more easily. This is to the benefit of patient safety, allowing a more specific study design and limiting costs in case of study failure.

- Finally, the Zero-Site experimental design could allow groups with an interest (investors, doctors, government agencies, patient advocacy groups and even patients themselves) to have more opportunities to play an active role in the study. Hurdles:
- Sponsors must be sure to completely adhere to regulations.
- Guarantee the privacy of the recruited patients, on the other we must be sure of the truthfulness of the collected data, otherwise the results of the study would be compromised.
- Less number of clinicians interfacing with patients: Zero-Site studies must guarantee the same quality standards as standard ones.
- To increase enrolment and limit the abandonment of Zero-Site trials, as had happened in the remote study, leverage rewarding participants FDA view: FDA has stated that they see benefits in the appropriate use of technology in clinical trials, they are still in the process of learning about Zero-Site clinical trials, the bring-your-own-device (BYOD) model of provisioning and other aspects of today's tech-enabled research environment. In particular, the agency is looking for input on four specific issues: how the FDA could encourage the adoption of technological tools in clinical trials; what are the barriers; how the new research models will influence patients and the eventual limiting action of regulatory requirements.

The guidance document issued by the FDA "Use of electronic informed consent in clinical investigations" explains how federal regulators allow companies to use electronic media (such as interactive websites) to facilitate the informed consent process. This will certainly help companies to conduct Zero-Site clinical trials. Future.Zero-Site clinical trials will be used in areas where traditional models have failed (e.g. for geographically dispersed groups or rare disease populations) and will increase instead of replacing traditional study practices and workflows.

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

Session 8 - Data Integrity in the Age of eSource

In the last decade, digital technologies have transformed every aspect of clinical research. The use of eSource in data collection highlights the importance of data integrity more than ever. While the traditional approaches of GDP (Good Documentation Practices) and ALCOA (attributable, legible, contemporaneous, original and accurate) are applicable to eSource, more process related activities are needed to ensure data integrity. Examples of these activities include improvement in quality culture with transparency and openness in reporting of noncompliance and errors, establishing management governance and quality audits, implementing quality risk management, effectively managing suppliers and service providers, providing training in good data and record management, designing and validating systems to assure data quality and reliability, managing data and records throughout the data life cycle, and addressing data reliability issues. This session provides a framework for dealing with the challenges of maintaining the integrity of scientific research data in the age of distributed and diversified eSource data collection and integration.

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

Session 11 - The Merging of Data Management and Clinical Operations - Welcome to the Future

This session will be moderated by a Data Management expert but will offer a unique opportunity to gain perspective from a variety of thought leaders within Clinical Operations. Senior leaders will discuss how process, methodology, and technology are breaking down the traditional silos of Data Management and Clinical Operations. Attendees will hear how roles across organizations are changing and how technology is enabling this transformation and blurring the boundaries of Data Management and Clinical Operations. If these two distinct groups are not the wave of the future, then what is? The session will include real-life examples from Clinical Operations experts whose role has been to execute activities rooted in Data Management, including: data review techniques, central monitoring, trend and outlier review and other data analytics, supporting the increased focus on holistic quality risk management. A differentiator of this session is that it will focus on the Clinical Operations experience. We plan to use online polling to help understand current practices and viewpoints of our audience members and to challenge the status quo.

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

Session 15 - Better Together: Three Ways Sites and Sponsors are Collaborating using eSource and Data Exchange

When sites are able to seamlessly share data with sponsors using their existing enterprise systems, clinical research gains true efficiencies. There are many efforts underway to promote use of eSource and information exchange between sites and sponsors, and there is a lot to learn from these exciting projects. This session will provide a closer look at three collaborations between sponsors and study sites that include: background of the collaboration, project or pilot. Benefits of the project for sites, sponsors and beyond. Challenges faced and lessons learned. Recommendations for others seeking to undertake similar projects.

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

Session 16 - Centralized Statistical Monitoring: New Tools and Implementations for DM Operations

In the context of multicenter clinical research, Centralized Statistical Monitoring (CSM) is the most efficient way to ensure subject's safety, trial integrity and data quality. As it permits the study team to proactively detect anomalous data trends, CM improves the quality of the regulatory submissions with a direct impact on the time to marketing approval. Since publication of the regulatory guidance on Risk-Based Monitoring (RBM), five years ago, the concept of CSM has developed amid the emergence of technological enablers that make clinical research more data-driven than ever. Today, regulators encourage the use of CM in conjunction with on-site monitoring to oversee clinical trials. Despite its unique potential for improving the quality of clinical trials, CM can appear so technical that sponsors often elect to renounce its use in favor of costly and less efficient traditional monitoring methods. In reality, only a few concepts that are relatively easy to master and which most life science people are already familiar with are required to properly implement CSM. In fact, to plan a CSM strategy, one should be familiar with the concept of risk management which involves identifying risks, estimating their potential impact and devising efficacious mitigation strategies. Then, to perform CSM, one needs to understand how simple statistics related to the means and the standard deviations, can be used to detect outliers. Additional CSM skills include the ability to

detect scientific misconduct using the chi-squared distribution which is closely related to the normal distribution. The objective of this session is to show that performing CSM is relatively easy and accessible to Data Managers inspired by the goal of overseeing trials with optimal efficiency while simultaneously saving on site monitoring resources. This session will demonstrate implementation of the central monitoring techniques using widely available tools such as MS Excel, EDC (edit checks), Pinnacle21 (formerly OpenCDISC) validator and SAS.

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

Session 17 - An Agile Approach to Data Management: Improving the End-to-End Clinical Data Strategy
The new reality of clinical trials is they are always in "startup mode." Teams are challenged to provide high quality data in real time, while flexing to protocol changes and other modifications along the way. Despite this changing landscape, the ultimate goal of a highest quality dataset remains critical. Successful trial execution requires a mindset change and new strategies for a more agile approach to data management. In this presentation, a group of leaders in data management will share lessons learned and best practices in the implementation of agile data management, including: design considerations for data acquisition and integration, intelligent analytics, workflows and process changes.

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

Session 21 - In a Patient-Centered Trial, Where do you Store all that Data?
The patient-centered trial introduces many more sources of data, including eConsent, patient diaries and mHealth devices. This has to be pooled with the classic sources of data, including site-entered information, lab results and imaging data. Where should all that data be collected for analysis? If it goes straight into a back-end data warehouse, how do you implement a feedback loop, such as receiving data for an unknown patient or querying out-of-range values? If it goes into an EDC system, how do you manage all those new integrations, what are the extra obligations on site staff to review the data, and does it need to be SDV'd? This session will provide insights into how organizations are tackling these new challenges and decision points.

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

Session 23 - Getting out of the Weeds - Using AI and Strategic Data Analysis Approaches to Monitor Studies
An overwhelming amount of data in a highly dynamic regulatory environment might leave one with the feeling of being stuck in the weeds. This group of experts will share their knowledge to help you work smarter and more strategically with the use of Artificial Intelligence, Strategic Data Analysis and Data visualization techniques as well as risk based monitoring strategies in order to prioritize the work**.**

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

Session 27 - RBM Advancement in the Changing Clinical Research Paradigm – Where are we Headed to?

Risk-based monitoring (RBM) has steadily evolved over the last seven years. Large organizations are beginning to achieve process maturity in implementing RBM on studies. It is also recognized that the quality of key risk indicators (KRI) and contextual application of the same will expand and improve in the industry in the near future. In recent years, the clinical research paradigm is witnessing transformational shifts in the way clinical research is being executed at the sites. Two key areas where such changes are being observed are:

- Virtual clinical trials and patient centricity
- Digitization of certain clinical research processes

Both of these areas are creating new data sources and large amounts of data which is unprecedented in conventional clinical research execution. Monitoring such studies using current RBM approaches is not scalable when more devices, systems, and data are used. As RBM becomes the new normal to monitor and manage risks and improve the quality of study conduct, it is important to re-pivot RBM to accommodate such changes. The following objectives are being envisaged from the session:

a) Understanding the current state of RBM and the gaps to be addressed in areas such as virtual clinical trials.
b) Provide insights into types of data being generated as a result of digitization of certain clinical research processes, integration and how it can benefit when utilized in RBM.
c) Share frameworks to adapt RBM models for virtual clinical trials.

This session will have speakers who are:

1. Experts who can share their experiences, case studies or journey on specific studies that utilized risk-based approaches to monitoring in virtual clinical trials.
2. Operational managers and or data managers who are working on data from various non-conventional systems such as wearables, ECOA etc. Understanding how they are harnessed and utilized to monitor the execution of studies at sites.

The session aims to share real experiences and practical views so that data managers, operational managers, and central monitors will think beyond traditional data management and RBM approaches. It will also signal how functions need to adaptation to changing clinical research models and times.

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

Session 37 - Bring Your Own Device - Paving the Way for True Patient Centricity

There is a paradigm shift in how data is being captured for clinical research. Patients are demanding a move away from a time heavy model involving site visits, interviews and manual data collection. This is the shift to digital assessments and is often viewed through the prism of eCOA and ePRO as part of a clinical trial. The way eCOA and ePRO are currently implemented has inherent barriers to adoption. Cumbersome provisioned devices, combined with outdated technology and user interfaces have merely automated the paper based approach rather than innovate with the new technology to improve patient experience. The rise of the ubiquitous smart phone and tablet device and unlocked a new approach. BYOD. By allowing the patient to use their own device, many benefits are seen across the entire ecosystem. And regulation is shifting to take advantage of this.

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

Panel Discussion Sessions

Session 2 - Beyond EDC: New Opportunities and Challenges with Diversification of Data Sources in Clinical Trials

The data sources in the Clinical Trials is growing, in numbers, volume of data, as well as diversified technologies being used. More and more trials are using real-world data and data collected from devices, mHealth, smart phones etc. Some studies indicate that average number of data sources per trial is almost doubling, from 4 sources per trial, within 3 to 4 years. Gradually EDC is becoming 'one among many' sources of data with 'other' sources contributing similar or more data-volume as EDC. While the core principles of data management remain intact, such proliferation of data sources necessitate new and different approach. From acquiring the data, to integrating, transforming, and using the same for extracting meaningful insights, need different technological and process implementations. This session will discuss some of these challenges, with speakers presenting their thoughts, case-studies and real-life examples of approach and solutions.

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

Session 6 - Artificial Intelligence to Solve Clinical's "Big Data" Challenges: Practical Today, Predicting Tomorrow

As clinical trials grow in complexity, data management and data science are tasked to manage and make insight from continuous data collection and an exploding variety of data sources. The case for Artificial Intelligence and Machine Learning applications in clinical data is clear – but where are the practical applications today, and what is on the horizon? Which applications of these advances carry the greatest ROI? This panel will collect leaders in clinical data technology and innovation for an interactive discussion examining opportunities and examples for data management transformation via AI and machine learning. Current real-world examples will be shared, as well as predictions for where AI and ML have the potential to take clinical data management and the industry in the future.

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

Session 10 - Getting the Start-up Right for a Virtual Trial – Data Management Insights

Have you been curious about what virtual trials are all about? Are you wondering what may need to be considered to implement virtual trial components effectively for your virtual trials? Would you like to hear from data management experts on their personal challenges and successes as they worked through study start-up on their virtual trials? If so, then this panel is for you! We will start with the foundation of what a virtual trial is and discuss the types of virtual trial sources, pros and cons. The panel will walk through real examples of study start-up for virtual data platforms and sources, discussing their lessons learned. They will also delve into regulatory/privacy considerations and how new technologies will be impacting the ever-changing landscape of clinical trials to better prepare you for your next study build of a virtual trial.

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

Session 13 - Data Processes - Has Yours Jumped the Shark?
Data Management has changed in many ways over the years, but have the related process kept up? This panel will pose this question to data managers in a variety of organization to hear how processes differ among organizations. The panel will discuss the handling of protocol deviations, system implementation responsibilities, data review, standards implementation and data metrics within their organizations. Attendees can use this information to continue to shape their data management role within their organizations.

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

Session 14 - Gimmick or Game-Changer? What eSource Really Does to Clinical Trial Costs and Timelines
The eSource revolution is no longer on its way. It's here. Experts are promising big things with eSource, and organizations that have adopted are using it to reduce costs, race their trials forward, and sharpen their competitive edge. This panel discussion will acknowledge the very real concerns of industry players who remain skeptical of eSource, and leverage data and real-life examples to help organizations get to the heart of a fundamental issue in eClinical technology today: Whether eSource is really all it's cracked up to be.
We'll approach this question with a panel composed of a broad array of clinical researchers that include both users and non-users of eSource. Attendees will gain insight into essential questions like:

- How will eSource affect the revenue I make from monitoring services?
- What does a tablet app have to do with my ability to be first-to-market with a new product?
- Who's using eSource today, and what effect has it had on their trials?
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Session Level: Intermediate - Assumes comfort within CDM industry; 1-3 years' experience

Session 18 - Advice from the Experts for the CDM Career for the Future
It is clear the work in Data Management is changing rapidly due to evolving science, technology and innovation. In this panel discussion, attendees will receive advice from Leaders in Data Management from diverse backgrounds and companies. These leaders will discuss ways in which attendees can expand their knowledge and skills to prepare for increased responsibilities or different roles in their organization or in SCDM. They will also share their journey to becoming a leader.

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

Session 19 - Measuring What Matters: KPIs for Data Quality, Speed, and Cost
Well before any efficacy or safety results become available, data managers are awash in operational data. The statuses of site activation, screening and enrollment rates, turnaround times for data entry and query closure, missed visits, adverse events, SDV tracking, payments -- these are just a few of the dimensions along which today's eClinical systems provide a wealth of real-time data. What practical insights for more efficient operations and better clinical data can we draw from this information? How do data managers distill those insights from reports? With whom and how should they share the results? This panel session sets out to answer these questions. Attendees will leave the session with specific KPIs for a variety of trial types, from fast-enrolling Phase IIs, where data speed is critical, to large, endpoint-driven Phase IIIs, where patient recruitment largely determines timelines. The panel will recommend best practices for communicating KPIs to study stakeholders and holding sites, monitors, and ourselves accountable to key responsibilities. The panelists will also explore the benefits and limitations of data visualizations and study portals for disseminating these KPIs. Optimizing data quality, speed, and cost will form the common thread for all of these related topics.

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

Session 26 - Scaling Patient Centricity with Digitalization
A patient-centric approach is a way healthcare systems can establish a partnership among the clinical trial stakeholders including patients and their families by identifying and addressing patients' needs, and preferences. With the evolving landscape, new concepts of patient connectivity are emerging, and digital health is rapidly gaining popularity and importance in clinical trials. While eConsent, crowdsourcing, direct-to-patient, education systems, virtual trials, wearables, IOT etc. are enhancing patient centricity; the demand for an ideal digital patient also is increasing. It is important to measure the outcomes of patient engagement activities. Do we know for sure that the approaches circling digitalization are not putting digital burden on the patients? Can the healthcare industry move forward without having strategies to measure the effectiveness of patient engagement activities? Is it possible to scale up patient centricity without defining a measurement system and suitable metrics? Establishing a system to measure patient centricity may not be a challenge to be faced by a single company. It demands a collaborative effort. This panel discussion will explore the difficult challenges the healthcare industry is facing pertaining to patient centricity and try to pave the way towards possible solutions.
The key focus areas of this panel discussion include:

1. The recent trends and new opportunities in patient centricity
2. Digitalization and its impact on patient centricity
3. Strategies to scale up patient centricity with digitalization
4. Strategies to define a measurement system and suitable metrics for patient centricity.
5. Barriers to a patient centric culture and solutions

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

Session 28 - Navigating the Dynamics and Challenges of "Clean" Interim Analyses – How to Hit a "Moving Target"

Interim Analyses typically require a sub-set of data to be "clean", and are often executed multiple times through the duration of a Clinical Trial. In fact, Interim Analyses or Submissions are often times the most critical provision of a Clinical Trial, for "Go/No-Go" decisions, or key efficacy endpoint analyses. Cleaning a subset of data is more challenging than cleaning all data at Final Database Lock because data cleaning targets and metrics must parse out only data relevant to the Interim Analysis. And, some of the data targeted can change for various reasons, since the trial is ongoing. This Session will address the below considerations for executing an interim analysis, and encourage information sharing around requirements from regulators. After this session, attendees will:

- Understand different ways data can be "cut" for Interim Analyses
- Have a detailed list of considerations for Data Clean to be applied to and planned for in interim analyses
- Recognize the importance of clearly documenting Interim Analysis scope across all functions
- Hear perspectives from Regulators regarding expectations for "clean"
- Discuss recommendations for how to handle data changes from Interim Analysis to Final Submission
- The scope and definition of clean can vary greatly from study-to-study. It's critical the scope is documented and understood by all functions. We'll start the session by reviewing various ways we generally "cut" data for an Interim Analysis.
- By Subject Complete – this includes Early Termination, Screen Fail, and subjects who complete all assessments in the trial
- By Visit Complete – important to define handling of log pages and non-visit related data
- By Cut-Off Date
- By Data Type (e.g. only AEs, Dosing, Demography)

While there is typically a general classification of the scope of an Interim Analysis (e.g. all data clean prior to a cut-off date), the "devil's in the details". In the next portion of the Session, we'll talk about specific components of data clean to ensure alignment among the CRO, Sponsor, and Regulators. Topics include the following:

- Vendor Data – Transfers & Reconciliation
- Source Document Verification
- Site Engagement and Awareness for Monitoring Visits
- Additional Rounds of Data Review – all appropriate functions
- Coding requirements
- Local Lab Range Collection
- SAE Reconciliation status
- Protocol Deviations
- Investigator Signature requirements
- Resourcing planning
- Locking/Freezing of Data

Interim Analysis data could be added or change from the Interim Analysis to final submission. Expected reasons include Coding Dictionary Upgrades, Protocol Amendments, Database and Edit Check revisions. Unexpected reasons may include Monitoring Visits identifying new AEs for a subject. In this section, we'll look to understand expectations of how we document these

changes, the extent of the reasons needed to explain the change, and how to handle the impacts to our down-stream Tables, Listings and Figures and Clinical Study Report. In this section, we'll also want an overview of requirements from Data Monitoring Committees, Regulatory agencies, Safety Groups and other types of Monitoring Boards review data during a study. We want to understand what they are looking for in terms of clean data, and what pieces of clean are understood to be in flux, since the study is not yet complete.

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

Session 30 - Real World Data to Real World Evidence - A Holistic View from Data Management perspective

In recent years much has been discussed and written about Real World Data (RWD) and Real World Evidence (RWE). What is RWD and RWE? Why we need it? and How to utilize it for everyone's benefit? RWD is the foundation of RWE while RWE is a new way of bridging the gap between Clinical Research and Clinical Practice.

Pharmaceutical companies are investing huge amount of money and time in conducting clinical trials. Results of these trials provide strong evidence of safety and efficacy of the drug. But these trials are conducted in a controlled environment and within a limited population. So, these results cannot be generalized to the large population. This has turned industry towards the using data that is captured at other sources. These sources are Electronic Health Records (EHR), Registry studies, pragmatic trials, devices (wearables, sensors), administrative and healthcare claims database, health surveys etc. This is termed as RWD. This Real World Data can give significant insight and foresight to understand disease, medical product and patient population. RWD is more complex to analyze and process as it is distributed among different systems and sometimes in different regions. It has presented different challenges and opportunities in front of industry.

Many pharmaceutical, CRO and academic institutions are working in collaboration to address the challenges and exploring the opportunities from this vast amount of diversified data. New innovative way of conducting the trial and analyzing data is being implemented. Recently FDA has released its Framework for Real World Evidence Program to give more clarity.

This session will focus on future role of Data Management in Clinical Research.

The goal of the session is to explore and understand journey of Real World Data to become Real World Evidence through different aspects but not limited to:

- Data Governance (Data Integrity, Data Standardization, Data Quality, Data Protection, Data Storage etc.)
- Understanding and Implementing Regulatory Framework
- Use of Technology (Analytics, Data Science, Machine Learning and Artificial Intelligence)
- Stake Holder engagement
- SWOT Analysis

Session Level: Expert - Assumes advanced understanding of CDM industry; 6+ years' experience

Session 31 - Data Driven Innovation in Clinical Trials - Creating Value Chain through Digital Transformation

While this era of digital disruption could increase volatility, it also creates new opportunities for those who are ready to embrace the change. The confluence of digital technologies - social, mobile, analytics & cloud with emerging technologies such as AI, IoT, AR, VR and now block chain has opened myriad opportunities for biopharma companies to innovate and execute clinical trials that lead to enhanced efficiencies, cycle time reductions and cost savings. Digital platforms such as cloud servers and SaaS applications help the stakeholders to access, store, and share data and information more easily, and more coordinated way and help them respond quickly to the changing regulatory and market needs.

However, digital transformation is not just about technology and disruption. The competitive advantage lies in creating the ecosystem with right culture, people and processes running in a framework comprising of agile business models, tools, technologies and data led initiatives, along with a patient-centric focus.

During this session, our expert panellists will discuss:

- Changing landscape of technological, regulatory & ethical challenges in clinical trials – before & after digitalization
- Opportunities to innovate and execute clinical trials efficiently & effectively in this era of digitalization
- Case studies in driving digital transformation initiatives
- What is ahead for clinical trials in 2019 and beyond?

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

Session 36 - Digital Revolution in Healthcare and its Impact on Clinical Data Management

A variety of health and medical data is the standard resource for most clinical research. This data is either collected during the course of ongoing patient care or as part of a formal clinical trial program. These variety of sources could be:

- Electronic health records
- Central Labs
- Diagnostic and Imaging
- Claims data
- Patient / Disease registries
- Health surveys - Electronic Data Capture systems
- Clinical Outcomes Assessments (ePRO, ObsRO, ClinRO)

For decades, a large portion of such data is obtained at the point of care at a medical facility, hospital, clinic or practice. However, it is changing now and it is changing rapidly. With advancements in handheld devices, wearable technologies and devices, widespread data connectivity, increasing amounts of data is being generated outside the point of care. Patient reported outcomes, wearable devices and sensors enabled apparel, mobile healthcare apps and smart watches are increasingly being considered and used in a variety of clinical trials. The amount of data from sources other than EDC is continuing to increase and it is likely to grow to be as much as the EDC in future. Along with that evolution in clinical trial models and definite use of virtual trial models is adding a new dimension for clinical data managers. In this panel discussion, we will discuss:

- Evolving clinical trial models
- Utilizing Real world data in clinical trials
- Rapid expansion of data sources & related technology for clinical trials
- Explosion in amount of external data and challenges to manage
- Data Privacy and confidentiality considerations across regions and systems
- Impact on data manager's role and on CDM planning, design, development, conduct, closeout and archival
- Regulatory viewpoints on such variety of external sources of data
- A view to the future and is data management team ready for more

Session Level: Expert - Assumes advanced understanding of CDM industry; 6+ years' experience

Roundtable Presentation Sessions

Session 12 - Career inspiration and guidance from the C-suite

I propose a round table session creating a rare opportunity for attendees to get face time with senior industry leaders. Each leader will be from a different sector of the industry (CRO, Pharma/Biotech, Technology, Manufacturing or Supply, Software, Technology, etc.) and will come prepared to offer their thoughts on how they built their career, what they look for in their best employees, how to navigate a career whether the attendee's interest is small/large company, management track, technical track, or hybrid. I am seeking abstracts from dynamic leaders with a passion for their work who through their advice and stories of experience are willing to help shape the talent pool within our industry. I will choose a diverse set of experts that can speak to a wide range of challenges and opportunities for our attendees. More and more a talented professional with solid Data Management skills has opportunities to make an impact in a wider range of roles and responsibilities within a broader set of organizations and the round table of senior leaders speaking to this should inspire our attendees while creating a great platform for our senior leaders to bring more awareness to their organization’s efforts and accomplishments.

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

Session 34 - eSource Lessons Learned and Remaining Challenges Roundtable Discussion

eSource is scaling the Garner hype cycle with great strides. Many organizations/companies are currently conducting pilots, scaling to production, and creating partnerships/collaborators. The solution for eSource will require the active cooperation and participation of all stakeholders. The regulatory agencies are demonstrating interest with the recent ONC/CMS proposed rule, EMA guidance, FDA CDER eSource webinar and RWD/RWE guidelines. Standards organizations are fast at work to solve for some of the challenges that are constant across projects and countries. Many presentations have been conducted on eSource and some interactive connect-a-thons, but an opportunity for open dialogue is necessary. SCDM’s conference attendance allows for the maximum representation of eSource stakeholders to gather in a roundtable discussion. This roundtable discussion will focus on the lessons learned from the multiple eSource projects and brainstorm for solutions to the remaining challenges.

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

Ignite Sessions

Session 4 - Technology Ignite - Spark the Future

Presentations should share a personal experience and focus on a solution your company developed (or is developing) to solve a specific challenge CDMs are facing. The main objective is to take the audience on a journey and inspire them while showcasing your company's contribution to the advancement of the industry. It is of course essential that a thorough description of the solution/ business is provided but the presentation should not focus on pitching the company's products or services. It's a fine line between self-promotion and wholesome self-reporting so, as a rule of thumb, if it feels like an advertisement, it probably is, and such presentation will not be accepted. The session consists of 7-8 minutes TED talk style presentations which will be followed by an audience vote for the best presentation. The company that receives the most votes will be awarded with the People's Choice Award during the Closing Ceremony.

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

Session 20 - Selected Shorts

This innovative session will consist of 6-8 presentations on a diversity of sujects and will be kicked off by 2-3 minutes (2 slides) elevator pitches highliting the key elements of each topic/ presentation to the entire audience. Following the pitches,each presenter will be assigned a table for a more in-depth, interactive discussion with the delegates interested in the topic. The session moderator will ensure that attendees have the chance to swap between tables/ topics 2-3 times during the session hence the discussion/ presentation will be ran several times throughout the one hour session.

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

Session 22 - Tell Me Something I Don't Know – What Will Change Data Management the Most?

Following on from 2018, this session will explore the topics most likely impact data management in the next five years. Using a format similar to the FREAKONOMICS "Tell me something I do not know," speakers will have just 12 minutes to present their topic and convince the audience that their topic will change data management most, in the coming 5 years. The presenters must convey their message in a manner that calls the audience to action and seeks their vote. A panel of "experts" will provide feedback and ask 2-3 questions of each presenter. After all presentations, the audience will vote for the topic they think will have the most significant impact on the data management function. The winning presentation will be assessed by the panel and the audience, according to:

- Did you teach me something I did not know?
- Was the information shared interesting and relevant?
- Did the information shared alter my to do list, when I leave the conference?

The four presenters will know who they are up against and their competitors' topics, but nothing else. This leads to the rules - of which there are only two: 1) each presenter must stick to their selected topic, 2) there are no other rules.

Four imaginative and compelling speakers will inspire you with their predictions as to "What will change the roles and lives of our data management audience more than any other in the next five years?".

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

Storytelling Sessions

Session 9 - Roadmap to D-Clinical - Designing Your Digital Data Strategy
Clinical development is going through a second wave of transformation. Now that paper processes have been large converted to electronic ones there is an opportunity to further transform R&D organizations to digital enterprises that use data assets in new ways to maximize efficiencies and scientific value. This session will highlight how digital data strategies are being designed and implemented across R&D organizations and the way digital data strategy impacts different functional areas and stakeholders including data management, clinical operations, IT business partners, quality and compliance, biostatistics and technology providers.

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

Session 35 - RBx - Going Beyond Risk Based Monitoring!
Risk Based Study Execution - How we are taking our project teams and clients past Risk Based Monitoring. The industry is slowly realizing it's not just about the "monitoring" and that all functions need to be involved in assessing and managing risks on our clinical studies. We have implemented a technology tool and new processes and guidelines to help both our internal teams and external clients become comfortable with identifying and managing risks around "the things that matter".

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

IMPORTANT DATES

Deadline	Action	STATUS
Tue, April 30	**Abstract Submission Deadline**	☐
End of May	**Notification of Acceptance**	☐
Fri, June 7	**Early Bird Registration Deadline**	☐
Beginning of June	**Confirmation of Acceptance Deadline**	☐
Fri, August 16	**Draft Presentation/ Poster Due**	☐
Fri, September 20	**Final Presentation/ Poster Due**	☐

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 & 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.
Authors of abstracts selected for poster presentation will be required to print (based on official dimensions) and set up their poster in a dedicated area at the conference venue.

QUESTIONS? Contact Alessandra Percuoco, Conference Program Coordinator, annualconference@scdm.org

ANNEX 1 – SESSION FORMAT GUIDELINES

As SCDM is continuously looking for ways to improve its educational offering and provide an excellent experience to its conference attendees, we are welcoming the submission of proposals for innovative session formats meant to create an outstanding learning environment. We hereby provide a selection of potential session format as a reference only.

Presentation Session (90 minutes)

Presentation sessions consist of 3-4 presenters per session. Each presenter is given around 20-25 minutes to make the oral presentation. The speakers will have a maximum time of holding their presentation and the remaining time will be used for open forum to provide some time to discuss some points of the presentations together with the audience.
The speakers are encouraged to utilize a PPT presentation for supporting their speech. All the presentations and other related materials (such as videos and pictures) should be reviewed and approved by the Session Chairs to avoid

Panel Discussion Session (60-90 minutes)

What is a Panel Discussion?

Important Facts:

- The panel is facilitated by the Moderator/ Session Chair who guides the panel and the audience through the topic.
- 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 that analyses a topic from different angles.

A Panel is not:

- A set of presentations, one after another. The panel format allows for a brief introduction and then discussion among the panelists and audience.
- A one-on-one interview with each panelist. Many untrained moderators simply ask questions of each panelist, one after another, rather than build the dialogue into a conversation. Unless there is interplay among the panelists, have an “up close and personal” interview with each speaker.
- Just Q&A from the audience.

Your to do List Before and During your Panel

Before the session:

Research the topic

Find different angles to cover the topic from and don’t be afraid to bring up controversial points in the discussion.

Develop a bullet- point agenda

Choose between 3 and 5 main points that your panel discussion will cover. This should be sent to your panelists well in advance so that they can prepare. However, the discussion shouldn’t be overly-rehearsed beforehand.

Don't Use Slides

The whole purpose of the panel discussion is to gain insight from the panel discussion and slides will only draw attention away from that.

Synchronize before the event

Make sure to meet with all your panelists a few times before the event. A conference call is always a good solution to brief your speakers and make sure that you are all on the same page. Present the points that you plan to touch on so that they can prepare their input. It could be also interesting to ask the panelists to think of one question they would like to ask their fellow panelists. Those type of questions are normally sharper or more provocative than the questions that you set to answer to your panelist. Additionally, panelists are often more candid hen one of their peers asks them a question, as opposed to the "official moderator."

Spread the word

To fill up the room, you should let people know that you're hosing a panel discussion in the first place. A great thing about panels is that they are ALWAYS composed of several panelists. The more people onboard, the wider the social media reach when they share the news. As a host, start your session campaign by using Twitter, FB, LinkedIn or the SCDM App (if applicable) well before the event to get the word out there. Make sure you tag panelists to encourage them to re-post your update or start posting on their own.

During the session:

Moderate don't perform

"It is essential to maintain a non-judgmental approach to your presenters."

If it is your job to moderate or manage the panel discussion, you need to take a backseat and let your panelists perform. Much like a conductor manages an orchestra, where it is his job to make sure that all the musicians work together in harmony; it is your job to manage the panel. Conductor would never start playing an instrument. He also makes sure that no one instrument dominates the music. Make sure and do the same in your panel discussion.

Introduce the panelists and break the ice

Make the introduction snappy and to-the point so the audience knows who will be talking with them. Introduce your panelist, provide their background to the topic and of course do not forget to also introduce yourself as a moderator of the session.

Try to break the ice at the start in order to create a bonding with your audience. Live polling is a great way how to do it. Live polls don't only allow you to entertain people but also help you to understand who sits in the audience so you can adjust your lingo accordingly.

State your objective at the outset

When introducing the session, a long introduction is not needed. It is important that you highlight why is this topic important and what do you hope to accomplish within the next hour.

Set the ideal length

"You are an airline pilot. It's your job to land this plane on time"

According to panel discussion pioneer, Scott Kirsner, the ideal length of the panel discussion is between 45-60 minutes. It is important to have a certain structure of the discussion so you cover what you intend to within the dedicated time allotment. Check regularly how much time you have left to adjust the pace of the conversation.

Incorporate audience's questions

"Make sure attendees are learning and interacting during panel discussions"

It is highly recommended to not wait until the end of the session to start addressing questions. Once the discussion starts rolling, bring your audience into the discussion. Scott Kirsner advises to involve the participants within first 5 minutes! However, with 74% of the audience fearing public speaking, it is not the easiest task to accomplish. Use the audience engagement tool that allows everyone in the room to ask questions, it is up to you to select the questions that you find most relevant and can create even more discussion.

2-3 panelist should answer the question

When you ask a question, two answers are enough, unless a third panelist with to make intervene. Instead, ask a related question, ask for a concrete example, or simply shift gears and ask your other panelists about something else.

A sharp conclusion

Use the last minutes of your interesting session to poll one last question to the audience or for something forward-looking.

Interesting Reading:

- The Panel Report (pages 8, 15, and 17–21)
- The Moderator Role in Panel Discussion
- Make your next Panel Discussion More Compelling
- The Advantages and Disadvantages of a Panel Discussion
- Three Popular Panel Formats
- Guidelines for Great Panels

Roundtable Session (60-90 minutes)

What is a Roundtable Discussion?

"Roundtable discussions are usually really valuable to attendees—there is a certain energy that comes alive and everyone starts talking and sharing. And they usually do!"

Roundtable presentations are among the most flexible format offered at the conference, and may look quite different from session to session. The one thing that they have in common is that each allows for extended discussion among a small group. Roundtables are an ideal forum for giving and receiving targeted feedback, engaging in in-depth discussions, and meeting colleagues with similar interests.

Purpose of Roundtable Discussion

- To share your knowledge about an area of expertise, program, or research
- To network with colleagues who are interested in your work or research

"Roundtables are a great addition to most conference agendas, but to be successful they need planning, preparation and strong leadership when taking place"

Description

Delegates will be seated at tables of eight to ten – randomly at first. The presenters will each have five minutes at the beginning of the session to present their topic. Time for Q&A will be brief – just to clarify points of fact etc. The real discussion comes later!

Once all five presenters have pitched their idea, each table in the room will be designated to a particular presenter/project. The presenter (+/- co-presenters) goes to their table and the delegates migrate to whichever table was of interest to them in the initial presentations. The delegates will likely have questions for discussion, but the presenter should also bring with them some points for discussion, to get the ball rolling.

The front-of-room presentations, with turn-overs and minimal questions will occupy less than half of the session (max. 5 minutes per presenter), with the remainder available for rich discussions at the tables.

Distribution of Delegates

The Session Chair/ Moderator may use their discretion to request that delegates chose another table if it seems that an uneven distribution of delegates is developing.

Visual Aids

Roundtables do not have traditional audio-visual aids available, but most roundtable presenters bring handouts illustrating their work. If a couple of PowerPoint slides would help the presenters introduce their topic, then this can be accommodated, but the Session Chair will be running strictly to time.

Preparation

The presenters in this type of session should be ready to present their ideas in a succinct fashion, with whatever visual aid adjuncts they see fit. They should also identify some topics of conversation that could be discussed at the tables. Delegates often have plenty to contribute

but sometimes conversation takes a while to warm up, so the Speaker and Session Chair/ Moderator should have some conversation-starters ready to go!

Handouts

Speakers are encouraged to bring 10-15 copies of all materials that they wish to share with session attendees. They should make sure to include their contact information on the first page to encourage follow-up. Past evaluations have clearly indicated that one frustration, in particular for new and international attendees, is the use of 'insider' language, acronyms, and abbreviations that make it difficult to comprehend readily a presentation so this should be avoided as much as possible.

NOTE: Outstanding presenters include as part of their handouts:

- Key lessons to be learned.
- A list of resources (web links, books, people) to learn more.

A Successful Roundtable Has…

A clear focus

The best roundtables are always those with the clearest focus. There are aspects of every profession that are complex. Most issues faced in each profession/industry are, indeed, very challenging. The more precise the topic is the more successful it will be.

Hence it is crucial to theme around specific specialisms/ topic related to the industry. These are nicely self-contained. The participants take a huge amount from meeting people 'like them'. Knowledge shared within a session is important but sign up to meet likeminded professionals.

Comprehensive agenda

Although it is good to have a tight and clear focus for a roundtable you do need a broad and wide potential agenda for discussion. You don't know what the specific attendees are going to want to talk about until they are all gathered in the same room. Having a wide and well researched roundtable is especially important if you have a group of individuals who take a bit of time to warm up.

A strong / knowledgeable moderator

Key role in any roundtable is the moderator. This is the person chairing and often leading the discussion. As for the panel discussion, the session chair/moderator job is to manage the roundtable discussion, you need to take a backseat and avoiding dominating the discussion. On the contrary, it is your job to:

- Tease out themes and patterns in the discussion.
- Involve less confident participants.
- Deter overzealous members of the roundtable and keep the discussion moving in a relaxed but purposeful way.

Interesting Reading:

- How to Run a Successful Roundtable Discussion

Ignite Session (60-90 minutes)

"Ignite. Enlighten us, but make it quick"

Ignite sessions are fast-paced sessions designed to generate awareness and stimulate discussion. An ignite session include 6 presentations (5-10 minutes) around the same topic or on different topics (max. 10 slides) slot to present while the speaker's PowerPoint presentation automatically advances every 15 seconds, creating a truly energetic and dynamic session, which will keep the audience on their toes.

Optional: allow time for Q&A in small groups or with full audience

Please take a moment to watch the video below featuring Scott Berkun giving a great introduction to Ignite presenting (in five minutes): Why and how to give an Ignite talk

Ignite Slideshow Tips

Keep It Simple.

Use relevant images/photos and a few key words to capture the idea you are trying to convey.

Bullets and Text.

Avoid using lots of text. If necessary, use brief 1-3 word statements.

Timing

Slides advance every 15 seconds, so avoid cramming too many topics or ideas intone slide. Instead, give yourself breathing room by spacing ideas and topics across multiple slides. You have 20 slides, so don't be afraid to use them.

Final Suggestion Slide

We highly recommend that your last slide be a "Next Steps" slide. It can be anything that pertains to your presentation.

Storytelling Session (60-90 minutes)

What is a Storytelling Session?

2-3 case studies (15 minutes each) around the same scenario/ issue.

Stories should be about 15 minutes long and 10 minutes should be provided for Q&A. The case studies should reflect the authentic experience of an individual, a team, or a community. Only real-life case studies will be accepted.

Performance Techniques

"Telling a story can captivate an audience; that is, with the right techniques and a little practice."

- Map the plot as a memory technique
- Use story skeletons to help you remember the key events
- Think of the plot as a film or a series of connected images
- Tell yourself the story in your own words
- Create your own version of the story (adapt and improvise)
- Retell it numerous times until it feels like a story

Remember to…

Immerse your audience in the story

Every word and image that you present have to create a clear mental picture of the problem Also, it has to clearly follows a golden rule of presentation-giving which is to use visuals that supplement your story rather than repeat what has already been said.

Show. Don't tell

Whenever you deliver a story, try scene-by-scene construction of events and use dialogue instead of narration.

Build up to S.T.A.R moment

Similar to a climax, a S.T.A.R. moment is a "Something They'll Always Remember" event that is so dramatic that your audience will be talking about it weeks later. this can come in the form of a dramatization, provocative images, or shocking statistics.

End with a positive takeaway

The stories told in the session should conclude with an advice, an explanation on how the challenge was overcome and change for the better.

Interesting reading:

- How to Tell a great Story
- The Power of Storytelling - Seven Tips for Storytelling