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CELEBRATE THE WORLD’S LARGEST
CLINICAL DATA MANAGEMENT CONFERENCE

SCDM 2020
ANNUAL CONFERENCE

SEPTEMBER 13-16
SAN ANTONIO

EXPLORE. COMMUNICATE. PIONEER.
Dear Members,

Our 25<sup>th</sup> anniversary year is coming to a close and it is a great time to celebrate our accomplishments and look forward to next year!

- We started the year off with defining a new vision and mission to boldly lead and provide direction for the Society as the discipline continues to evolve.
- We have invested in and launched two brand new interactive, state of the art platforms this year: one for delivery of education and the other for collaborating as a global community.
- Giving you more flexibility in education, we have our first on demand, on-line course in mobile health while also maintaining our established webinar and instructor led on-line courses.
- Keeping up with changing best practices and a focus on an evidenced based approach, we have a large initiative to update the GCDMP chapters with multiple chapters out for public comment this year and several scheduled releases by end of year.
- Also in alignment with the GCDMP updates, the new beta certification exam is ready and taking applications!
- The Innovation Committee released a reflection paper on the Evolution of Clinical Data Management to Clinical Data Science- a must read and guide for SCDM for the years to come!
- The launch of the Innovation Committee’s SCDM eSource Implementation Consortium in June is key in expanding our thought leadership in this future key data source space.
- Our global community engagement is strong with a very successful inaugural 3 day conference in Europe, 4 India events (3 single day events, 1 Annual Conference) which are growing year on year, an exciting China annual conference with great participation and last but not least a highly successful Leadership Forum and Annual conference in Baltimore where 876 people attended!

We also hope you enjoy this issue of Data Basics where our members and experts share their knowledge on topics important to you. If you have a topic of interest or have research on a topic to share, we would love to hear from you! Please see our website to share your ideas and content.
We have accomplished a great deal in 2019 but have more to do in 2020! We need our volunteers and their expertise now more than ever in this evolution from clinical data management to clinical data science. Working together, we can achieve our vision and mission...

**SCDM Vision (our aspirational view of the Society):** Leading innovative clinical data science to advance global health research and development

**SCDM Mission (what we do):** Connect and inspire professionals managing global health data with global education, certification and advocacy

Finally, many thanks to everyone for all of your support and enthusiasm in making this **25th anniversary** year a great one. I am so appreciative and honored to be your Chair this year and look forward to supporting the **Board and the Society in 2020 as Past Chair**. I’m very proud to be a part of such a great Society!

Kindest regards,
Linda King,
2019 Board Chair,
SCDM

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**Become SCDM Volunteer in 5 Steps!**

1. **Go to the SCDM Community platform**
2. **Complete your profile**
3. **Search for opportunities**
4. **Join a Committee, Taskforce or a Project of your choice**
5. **Congratulations! You are SCDM Volunteer**

**Go to:** [community.scdm.org/volunteer](community.scdm.org/volunteer) and join!
Dear readers,

Our SCDM Mission and Vision are focused on three essential concepts -- Connect, inspire, educate. Additionally, committees within SCDM seek to "raise awareness on the upcoming industry trends affecting Clinical Data Management (CDM) and prepare for its evolution toward Clinical Data Science."

Every issue of Data Basics is published in service of these important ideas and this issue is no exception.

We hope that our readers enjoyed the 2019 Fall Issue, which celebrated SCDM’s 25th anniversary by publishing 25 previously published articles that are still timely and valuable today. Continuing in this vein, we have decided to publish 2 additional selections from our archives as a little “lagniappe” (for good measure), along with 3 brand new articles.

To highlight emerging industry trends -- our first article, "Improving Patient Engagement and Regulatory Compliance with the Electronic Informed Consent Platform for Clinical Research Studies", highlights the results of innovative efforts at Memorial Sloan Kettering (MSK) to meet the challenges of clinical trial informed consent head-on. Then, Derek Petersen’s article published in 2017, "Electronic Health Records as a Mode of Source in Clinical Investigations: Considerations for Clinical Data Management", explores the timely topic of direct source data from EHRs.

Next, to educate -- we've included Meredith Nahm Zozus’ article published in 2007, “Data Gone Awry”, a foundational article laying out the timeless good data management principles, with useful recommendations for new and experienced data managers alike.

In our other practical educational offering, Tanya Sun proposes a simple experience-based strategy for success in “How to Handle a Difficult Site”.

Finally, to connect and inspire -- Chris Matheus’ well-written piece, “Networking for Career Management”, brings front and center the importance of remembering that Clinical Data professionals are in an emerging landscape. It is critical to maintain an industry perspective which is broader than one’s current position and company for long term success.

We’re proud to round out the SCDM 25th Anniversary year with a mix of current articles and past gems that are worth carrying forward.

We hope you all enjoy the upcoming holidays and look forward to the New Year!

Debu, Janet & Claudine
2020 Online Course & Webinar Schedule

Our online learning courses are specifically designed for those seeking to balance their professional and personal lives. For more information and to register, please see [here online courses and webinar].

### 2020 Online Course Schedule

<table>
<thead>
<tr>
<th>START DATE</th>
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<tr>
<td>February 10 – March 8, 2020</td>
<td>Project Management for the Data Manager</td>
</tr>
<tr>
<td>March 16 – April 12, 2020</td>
<td>Metrics and Identifying Data Trends</td>
</tr>
<tr>
<td>April 13 – May 10, 2020</td>
<td>Selecting and Implementing Electronic Data Capture (EDC1)</td>
</tr>
<tr>
<td>May 11 – June 7, 2020</td>
<td>Managing Clinical Trials Utilizing Electronic Data Capture (EDC2)</td>
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<tr>
<td>June 8 – July 5, 2020</td>
<td>Data Quality in Clinical Research</td>
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<tr>
<td>July 6 – August 2, 2020</td>
<td>Developing Data Management Plans</td>
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<td>August 3 – August 30, 2020</td>
<td>Locking the Electronic Data Capture System (EDC3)</td>
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<td>August 31 – September 27, 2020</td>
<td>CRF Design</td>
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<td>September 28 – October 25, 2020</td>
<td>Processing Lab Data</td>
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<tr>
<td>October 26 – November 22, 2020</td>
<td>Influence of the Statistical Analysis Plan (SAP) and Randomization on Data Collection</td>
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### 2020 Webinar Schedule

<table>
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<tr>
<td>February 12, 2020</td>
<td>An Innovative Approach in collecting Protocol Deviations for Clinical Trials using EDC</td>
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INTRODUCTION

The informed consent (IC) process is the foundation of human research participant protection, and studies have shown that enhancing the consent experience with introductory videos and visual aids can improve participant engagement and comprehension.\(^1,2\) There is widespread consensus that the current paper-based IC process can be improved to create a more participant-centered process that empowers research participants to make a truly autonomous choice to enroll in a clinical research study. The Memorial Sloan Kettering (MSK) electronic IC (eIC) platform was developed to augment the educational opportunities for research participants, to reduce administrative time and effort associated with paper-based consenting, to improve the IC audit trail and regulatory compliance, and to streamline the development of consent documents for clinical research studies.

The eIC platform includes 4 distinct tools: 1) the eIC module, where the consent form is reviewed/signed; 2) an eIC management tool that sets user access levels; 3) a processing utility that ensures the most recent Institutional Review Board (IRB)-approved consent form is discussed, displays metrics for completed consents, transmits signed forms to the electronic health record (EHR) and online Patient Portal (PP), and verifies that each form sent was received; and 4) an informed consent document authoring platform. This web-based platform is device-agnostic and browser-independent; it is now used by 35 clinical services for 36 institutional and externally-sponsored therapeutic and non-therapeutic clinical trials. The consents for 3 clinical trials in the platform have an educational video embedded in the eIC, and 5 have an embedded image flow that provides an overview of the trial timeline for tests, procedures, and clinic visits.

The operational implementation of the eIC platform at MSK aligns with the four basic principles of bioethics: beneficence, non-maleficence, autonomy, and justice. The eIC module was developed to comply with the electronic consenting regulatory framework of the US Food and Drug Administration (FDA),\(^3\) the Medicines and Healthcare Products Regulatory Agency (MHRA) GXP data integrity guide,\(^4\) HIPAA, and other applicable local and state laws.

METHODS

Efficacy assessment

To evaluate the pros and cons of the eIC platform versus paper consenting, we assessed: 1) the availability of the completed, signed document in the EHR, 2) processing time, 3) the completion and accuracy of entries in required data fields, and 4) targeted audit results of the eIC process. To assess participant engagement with the eIC module, a five-question survey with free-text response options was developed to solicit feedback on the eIC process. Routine internal audits are regularly performed on the eIC platform to ensure compliance with institutional and regulatory guidelines.

In accordance with the bioethical principle of autonomy, the potential research participant chooses whether to use the eIC platform or paper-based consenting, either singly or in combination, throughout the informed consent process and during the clinical trial. The informed consent discussion takes place in real time, either in person or remotely via two-way video. In both settings, the informed consent discussion fully addresses the questions and concerns of potential research participants.

The MSK eIC includes all the required elements in the IRB-approved written consent form, and only IRB-approved consent documents are available in the eIC platform.
**User-friendly**

The eIC is easy to navigate, allowing users to move through the document without bypassing any required elements of the consent form. The module incorporates electronic utilities that encourage participants to access supplemental information before documenting their consent, and it allows IRB-approved MSK staff to consent participants and to sign the consent form electronically on an MSK workstation and/or laptop with a trackpad and/or mouse, iPad, etc. The eIC module displays the consent form in a series of tiers, presenting the document to the participant in an easy-to-understand style and order. Access to the platform is restricted to hospital WiFi (with off-site access via Virtual Private Network).

**Reduces administrative time and effort; sends signed consents to EHR and PP in seconds rather than days**

To certify that the eIC module was built and operationalized according to regulatory best practices for electronic consenting, we: 1) developed a standard operating procedures (SOP) for the use of the eIC platform; 2) wrote infrastructure SOPs for use of the eIC application in the areas of information security, disaster recovery/tiering, software development lifecycle, software change control, training, and software validation; 3) established an external and independent audit process to assess the module for 21 CFR Part 11 compliance; 4) included documentation from the MSK IRB/Privacy Board that supports the utilization of electronic consenting as part of the institution’s consenting process for participants in all clinical trials; and 5) submitted an MSK electronic signature certificate statement to the FDA, attesting to MSK’s intention that electronic signatures are legally binding and equivalent to traditional handwritten signatures.

**RESULTS**

The eIC platform was launched as a pilot program in January 2016, and it went into use in our clinics in November 2016. As of July 2019, 201 active consenting professionals are using the module, and 5,320 research participants have been consented. Average eIC monthly accrual from January to June 2019 was 485 (+/- 45) (Figure 1). Compared with paper consent forms, which take about 72 hours to post to the EHR, the signed eIC is sent and stored in both the EHR and the online PP in less than 2 minutes. The eIC platform decreases the administrative effort (labeling, collating, certifying that the scanned document is identical to the original sent for scanning) associated with paper-based consenting by 15 minutes/form.

We compared results of 170 participants consenting to 1 trial during the same timeframe; 85 used eIC and 85 used paper. eIC use increased the accurate completion of required data fields in the consent forms by 4%, versus paper.

**Figure 1: System Validation Lifecycle**
Participant survey showed that 95% of users would recommend eConsent

Surveys were sent to 2,283 users of the eIC, and 588 (26%) responded (Figure 2). Most respondents (480, 82%) indicated that electronic consenting was very easy (223), or easy (257) to use. Only 21 respondents (4%) indicated that electronic consenting was somewhat difficult or difficult to use, and 87 expressed neutral feelings about the experience. The majority of respondents (551, 94%) indicated that they would recommend electronic consenting to another research participant at MSK. Free-text responses were submitted by 295 respondents (50%); the consistent theme of these comments was that the electronic consenting process is simple, convenient, and user-friendly.

Figure 2: Placement: sidebar at mention in text

**How comfortable are you with technology**

<table>
<thead>
<tr>
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<tr>
<td>Comfortable</td>
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<tr>
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<td>14%</td>
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**How difficult or easy was the eConsent to use?**

<table>
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<tr>
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**eIC module certified 21 CFR Part 11-compliant**

The eIC module software documentation, processes, and validation efforts were successfully certified as 21 CFR Part 11-compliant by a third-party auditor. The auditor confirmed that the eIC module software development lifecycle was mature, and that a committed quality software development practice plan was in place. The platform is also compliant with the regulatory requirements under Common Rule 45 CFR Part 46.

**Rigorous quality control of consenting process**

Our internal Clinical Research Quality Assurance Unit performed a targeted audit on the eIC process to evaluate whether: 1) the completed and signed consent document meets all regulatory requirements, and 2) consenting professionals are appropriately utilizing the eIC module in compliance with IRB SOPs for informed consent. 389 eICs were reviewed, involving 89 consenting professionals and 14 trials across 8 Departments/Services. eICs completed between June 2018 and June 2019 were randomly selected for review. The audit reviewed the quality of the eIC document in the EHR to ensure that all signatures, dates, and time stamps were clearly visible and correct, all pages were present, no degradation in image quality had occurred, and all questions were completed.
The audit also evaluated whether the consenting professionals were following IRB SOPs to ensure that the correct version of the consent was discussed and signed, that assent was obtained (when applicable), and that the eIC was signed by MSK staff listed as a consenting professional on the trial face sheet. No issues were reported regarding the quality of the eIC documents, and only minor issues with consent practice processes were noted. By contrast, audit results for paper-based consenting during the same time period reported issues with IC document quality and processes. These issues are common among most sites that maintain ICs in an EHR.

DISCUSSION

The increasingly complex design of clinical trials and the participation of increasingly diverse patient populations require that the IC process include innovative multimedia approaches that can enhance the consenting process and more fully inform potential research participants. However, it is unreasonable to expect all research participants to engage with electronic consenting in the same way (or at all). Some populations or individuals may prefer one method, or they may be more comfortable using a combination of the two methods. For example, the participant may use the paper form while the consenting professional utilizes the eIC. Preserving participants’ autonomy to choose the consenting method that works best for them was an underlying goal in our implementation of the eIC, and this goal is consistent with those of the FDA Guidance on the use of electronic informed consent and the Clinical Trials Transformation Initiative recommendations for informed consenting.

The decision to build the eIC module in-house, rather than purchasing an off-the-shelf application, was driven by an assessment of our research participants’ needs and the lack of anything in the marketplace that met our requirements. After weighing the risks, benefits, and costs, our decision to develop a custom solution was based on the following principles: 1) to include potential research participants and MSK consenting professionals in our iterative design process to develop the most intuitive user interface, 2) to integrate the eIC platform with MSK systems to allow for a seamless experience by the research staff, 3) to implement a standard platform for all informed consent documents, and 4) to provide a consistent MSK brand experience for study participants. Building the eIC platform has enabled us to incorporate vital user interface enhancements and to resolve any internal system issues quickly and reliably. This nimble response time could not have been achieved with any off-the-shelf system due to concerns about security, privacy, and HIPAA regulations.

Acceptance of new processes and innovative applications in clinical research can be slow because of the unproven track records and performance standards of these methods. Concerns about security, development costs, and the acceptance of digital signatures are among the main barriers to adoption. Building a new application requires a site to have an in-house system development and maintenance team. Other barriers to implementation include: 1) resistance to changes in clinical workflow, 2) variable access to the necessary hardware, 3) adding existing consent documents to the eIC platform, and 4) the need for continuing software validation efforts being conducted in-house if they are not outsourced to a third-party auditor. The success of the MSK eIC module results from the efforts of a multidisciplinary team comprising: 1) clinical research informatics and technology, 2) the IRB/PB, 3) consent writers and editors, 4) application developers and analysts, 5) a quality assurance team, and 6) members of the operations staff.

Regulatory and privacy concerns are routinely raised as major barriers to implementation of an eIC platform. To address these concerns, our eIC implementation framework uses a two-pronged approach: 1) robust application documentation and software validation procedures, and 2) audit and “smart tool” functionality built into the application on the back end. These smart tools increase compliance with the IC process by using multiple system validations for developers and end users.
CONCLUSION

We plan to expand our preliminary analysis of eIC usage by creating an assessment tool to gauge participant understanding/engagement in the consent process. We will enhance the eIC module with translations of the English-language consent forms and develop an option to “hover” over terms in the consent form to access additional information. The eIC module works synergistically with our existing informed consent processes to ensure that all potential clinical trial participants are fully informed and that they can choose the consenting method that best suits them. The MSK eIC platform provides an innovative operational model for electronic consenting in the academic medical setting, enhances the engagement and understanding of study participants, and improves quality and compliance in the consent process.

REFERENCES

The current assembly of source-data types and data-collection modalities is incredibly diverse within the existing landscape of clinical investigations. The form and function of electronic data capture (EDC), for example, has seen tremendous advancements from the years of paper case report forms (CRFs) to the current age of electronic case report forms (eCRFs). Additionally, handheld devices that electronically capture patient reported outcomes (ePRO) outside of the routine clinical setting have also seen increased adoption during this time. While these advancements have occurred more centrally within the realm of clinical investigations, the digitization of health records within the traditional clinical-practice environment has also gained momentum during this time. This subsequently increases the potential to further bridge the gap between the practice and investigational spaces.

In May of 2016, the United States Food and Drug Administration (FDA) released a draft Guidance entitled “Use of Electronic Health Record Data in Clinical Investigations”. The intent of the document is to: 1) solicit comments from various stakeholders within the clinical landscape, 2) identify concepts and processes that need further discussion, and perhaps 3) subsequently expedite a more interoperable future between clinical investigations and clinical practice.

Herein, this report will focus on certain preliminary considerations related to the Clinical Data Manager’s stake in a future where electronic health records (EHR) are utilized as a mode of source data in clinical investigations.

TECHNICAL CONSIDERATIONS

There are many technical considerations that relate to the utilization of EHR data for clinical investigations. Perhaps the most important point to understand is the FDA’s declaration that current EHR systems do fall under the application of Part 11 of Title 21 of the Code of Federal Regulations (21 CFR, Part 11).1 The FDA’s assessment of 21 CFR, Part 11 compliance will begin with the systems specifically employed by the sponsor to support the investigation (e.g., traditional EDC).

The HER environment, however, will not go unattended in terms of oversight. The FDA makes it clear that the ability to verify the quality and integrity of data submitted to the agency must be preserved, regardless of the data’s origin(s).2, 3 This means that data stored in an EHR system may be subject to inspection, just as any other data source would be. At a minimum, controls implemented within an EHR environment should include: 1) the limitation of access to authorized users, 2) the enduring identification of author(s) for all records, 3) the implementation of audit trails to track the origin(s) and subsequent changes to the data, including the identification of data originators and date/time stamps, and 4) the maintenance of records for the requisite duration for inspection. Further, the attributes of ALCOA (attributable, legible, contemporaneous, original and accurate) for electronic source data must also persist, regardless of the system(s) or process(es) used to handle the data.4 Beyond these basic controls for EHR systems utilized as a mode of source in clinical investigations, EHR administrators may strive to obtain certification for their system(s) through the Office of the National Coordinator (ONC) for Health Information Technology (IT). ONC Health IT certification demonstrates an elevated level of rigor to which an EHR system is held as it pertains to data sharing, confidentiality, reliability and security - thus giving the FDA additional reassurances during an investigation.4 Perhaps the greatest technical hurdle that lies ahead for the utilization of EHR as a mode of source will be the challenge to design a database paradigm that permits EHR and more traditional investigational systems to interoperate. The degree to which these systems interact will vary. For example, in a less integrated relationship between the systems, a direct transfer of data may occur between the still separate databases. This would not be unlike the existing functionality available between various DC platforms and ePRO vendors where data collected via handheld devices is automatically synced and populated within the eCRF database. Conversely, full interoperability between clinical-practice and research databases could eventually translate into a blended EHR/ investigational platform where all data is managed as a single, cohesive dataset. On the largest technical scales,
this would require the functional compatibility between the primary data standards for the healthcare and research industries, Health Level 7 (HL7) and the Clinical Data Interchange Standards Consortium (CDISC), respectively. The CDISC Biomedical Research Integrated Domain Group (BRIDG) model has already begun the process to assimilate these two archetypes. To build on that momentum, where and when possible, sponsors and clinical investigators may engage and encourage healthcare organizations and EDC vendors to explore the development of electronic systems that are enabled to interoperate more extensively. Regarding the implications for fully-blended EHR/ investigational platforms, what still remains to be seen is the stance the FDA will take with respect to 21 CFR, Part 11 compliance. The design and use of such a system may not contain an innately obvious distinction between the clinical practice and investigational domains. Thus, questions remain in terms of the scope of regulatory oversight that will be enforced, as compared to contemporary investigational systems, such as EDC. Regardless of the degree to which various data sources interact within a given clinical investigation, an overview of the utilized sources and processes should be outlined within the data management plan whenever an EHR system is employed as a form of source. A detailed diagram, including an explanation of the checks and balances utilized to protect the integrity of the data, may sometimes be the most elegant format to express the characteristics of that data-flow process.

**ADMINISTRATIVE CONSIDERATIONS**

The distinct separation of EHR and investigational data in terms of purpose and ownership has historically been addressed through the informed-consent process where trial subjects are educated on and agree to the scope and intent of the data collected regarding their participation in a trial. New opportunities within the blended EHR/ investigational landscape will also mean new consequences for that consent process. For example, an interoperable system where medical providers other than the principal investigator could have access to investigational data would require full disclosure and agreement by the subject through informed consent.

Both sponsors and health care institutions should proactively seek to understand and prepare for the complex set of new implications related to data sharing and governance. In particular, sponsors should tailor the informed-consent process as necessary to ensure the protection of subjects’ privacy.

**BENEFITS**

While certain benefits may seem self-evident within a future where data collected directly from clinical practice is squarely juxtaposed to, if not commingled with, the clinical investigation setting, change of any degree within this highly regulated environment must be approached with caution and due diligence. That said, the advantages are tangible. The latency of data entry from the EHR to the clinical investigation environment (e.g., EDC) could be drastically reduced, if not eliminated entirely, depending on the extent to which interoperability is achieved between the systems. Further, in a fully interoperable setting, transcription errors would cease to occur when transcription is no longer necessary.

In addition, the combination of data from different clinical sources (e.g., physician notes, laboratory results, pharmacy records, etc.) could more quickly coalesce into meaningful and actionable reports resulting in a more agile monitoring process. A more agile monitoring process could then translate into a more efficient evaluation of safety signals, thereby increasing the protections for subject safety. This near real-time information could then also expedite the decisions of go/no-go.

Finally, if we take an extended view of this interoperable future and overlay the principles of big-data, the convergence and pooling of information from clinical practice and clinical investigations could accelerate the surfacing of hard-to-spot medical trends, especially those within under-served and/or specialty populations where data may be sparse. The implications of this prospective future from a public-health perspective are immense. The possibilities in this regard are perhaps the most significant and exciting of all.
CONCLUSION
The eventual merging of clinical-practice and investigational data collecting and archiving systems offers the potential to bring about the next vanguard movement in healthcare. The way forward into that future is, however, paved with many challenges, both technical and administrative. All stakeholders, including healthcare organizations, individual investigators, CROs and sponsors, should actively contribute to and surveil the process to ensure that future is formed in a way where the desired outcomes are achieved while simultaneously protecting the rights and safety of trial subjects.

REFERENCES
1. FDA Guidance for Industry - Electronic Source Data in Clinical Investigations
2. 21 CFR Part 312
3. 21 CFR Part 812
4. FDA Draft Guidance for Industry - Use of Electronic Health Record Data in Clinical Investigations
5. SCDM White Paper for eSource Implementation in Clinical Research: A Data Management Perspective

ABOUT THE AUTHOR:

Derek is the Clinical Data Management Portfolio Lead for the Multiple Sclerosis franchise at Biogen. He has worked within clinical research for more than twelve years and received his certification in Clinical Data Management (CCDM®) in 2012. Derek also serves on the Data Basics Editorial Board for the Society for Clinical Data Management. Prior to data management, he worked in program management for a large healthcare system in the United States. His areas of interest include risk-based quality assurance, data quality metrics and data harmonization.
INTRODUCTION
Merriam-Webster’s Dictionary defines data as “factual information, such as measurements or statistics, used as a basis for reasoning, discussion, or calculation” (1). Data are to be found everywhere, in any number of forms: numerical measurements, photographs, geospatial codes, videos, textual observations, questionnaire responses, DNA sequences, biological samples, test artifacts, and field notes are all considered data. Data form the basic building blocks for all scientific inquiry, including the clinical research enterprise. Research, both subjectivist and positivist, draws information from recorded observations. The accuracy, validity, and reliability of data all have a direct effect on the quality of the conclusions drawn from them. The quality and integrity of data collected during a study are essential to the ultimate quality of scientific research (2).

RESEARCH DATA MANAGEMENT
Data management is inextricably intertwined with the scientific method, and is an essential part of almost every research endeavor. In fact, the Institute of Medicine (IOM) defined quality data as “Data strong enough to support conclusions and interpretations equivalent to those derived from error-free data” (3). Although difficult to operationalize, meeting this definition of quality data requires knowledge and even control of data accuracy. In addition, a fundamental precept of scientific inquiry is that studies are reproducible, e.g. raw data can be reconstructed from the analysis files and study documentation and vice versa, or, alternatively, that if an identical repeat study were run it would arrive at the same results. Activities and practices necessary to provide adequate data quality and maintain reproducibility should be the paramount task of a data manager. A fundamental precept of data integrity is that raw data can be reconstructed from the analysis files and study documentation and vice versa.

WHY IS DATA MANAGEMENT SOMETIMES OVERLOOKED?
Despite its foundational importance to scientific inquiry, good data management practices and even principles are sometimes overlooked by investigators and research teams in both commercial and academic settings. Data management and regulatory training are usually not included in graduate or medical school curricula. In addition, institutional training for investigators and research teams often focuses on human subject protection, and good clinical practices (GCP). Training in the regulations and principles applicable to data management are often not available for, or required of, research administrators, investigators and research teams. For example, they may not be aware of the steps necessary to ensure that data are sound enough to support research conclusions and are compliant with the regulatory requirements stated by federal and international agencies. When research leadership lacks knowledge of good data management principles, organizations run the risk of creating and implementing policies that do not support and enforce good practices. Data management is often performed by people other than the investigators. Where the investigators are unaware of principles and good practices, individuals with little or no training are sometimes asked to perform data management tasks. In addition, ill-prepared investigators and administrators cannot provide without appropriate supervision. Hence, the scenario of office assistants or technicians being asked to create a spreadsheet or a “quick” Microsoft Access database and “just enter the data.” Investigators cannot require or provide for things of which they are unaware. Significant amounts of research are performed in settings, academic or otherwise, where researchers are sustained by funding designated for individual projects. In this context, funding supports the scientific aims of the project, and often cannot be spent on training personnel. Indirect support from grants and contracts, meant to provide funding for “overhead” such as training and infrastructure, is often not available to or allocated by individual investigators with staff to train and manage. Small research groups sustained in this manner can lack the fiscal resources to support research infrastructure such as formalized job descriptions, written procedures, oversight, equipment, software, and specialized technical
Data Gone Awry
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expertise. Lack of sustaining infrastructure leads to significant turnover of support personnel and hence loss of the research facilities’ knowledge and expertise. Experienced personnel may need to find other work when a project ends and leave the organization or group. This perpetuates a state wherein the research group must depend on the variable skills of individuals, rather than a predictable infrastructure that yields consistent performance.

The lead investigator for a clinical trial must balance many priorities with limited project funds. The opportunity to collect more data may be far more enticing than system security, back-ups, database design, or resources for documentation and testing. Answering additional scientific questions competes with sustaining infrastructure and operational tasks for allocation of precious funds. In addition, investigators without a firm grasp of data management principles are not likely to be aware of tasks that need to be done, the resources required, or the impact of not doing them, upsetting a delicate balance. Acquiring useful data depends on planning, design, testing, consistency and documentation. In a busy research setting and in the absence of appropriate training and organizational support, data management tasks may not be done well, or may not be done at all.

WHEN DATA GO AWRY

Given the importance of good data to science, it’s hard to imagine that lapses occur in research. However, there are significant forces that may lead even dedicated investigators and research teams astray with respect to proper data management. Moreover, there is a continuum of departure from good clinical data management that ranges over misunderstanding, error, lack of training, lack of capability, lack of oversight, sloppiness, negligence, and outright fraud. Due to the relative paucity of published accounts of data mishaps, it is hard to estimate the rate at which they occur in clinical research. However, FDA inspection statistics from the Clinical Investigator Inspection List [CLIIL for 2004–2006 show an average 4.7 % Official Action Indicated [OAI] rate (4). The top five types of findings noted failure to adhere to the protocol [15 instances], inadequate and incorrect records [9 instances], failure to obtain patient consent [7 instances], inadequate drug accountability [7 instances], and other [7 instances]—accounted for 69% of OAI findings.

These figures come from the significantly regulated drug development industry, in which most clinical site investigators receive at least study-specific direction on data management tasks. Some problems are caused by inappropriate handling of data; others occur upstream in the research process but may be detected through electronic data surveillance methods. Still other problems occur after the data management process during analysis and dissemination. Because data management spans and affects a large part of the research process, data managers should be concerned with identifying, preventing, and correcting problems where possible. “Ironically, there is a major difference between a process that is presumed through inaction to be error-free and one that monitors mistakes. The so-called error-free process will often fail to note mistakes when they occur.”(2)

CASE STUDIES: DATA PROBLEMS

The following case studies are real examples of data problems from multicenter clinical trials. Each scenario discusses the causes of the problems, how they were detected, what (if anything) was done to correct them, and the effect they had on the research. Learning through other’s experience through open dialog about situations such as these will help everyone be more vigilant. Although there are limited published accounts of problems such as these in the clinical research industry, we are fortunate to have the work of Muraya and Coe, which documents some common data related problems in basic scientific research (5). To contribute scenarios to our body of knowledge, and to discuss those presented here, please post on the SCDM Discussion Forum.

Scenario 1: Parakeets in a multicenter clinical trial.

A large, multisite, clinical trial was sponsored by a large pharmaceutical company to obtain marketing authorization for a drug. After the last patient visit and subsequent locking of the database, an oddity in the ECG data was noticed during the final review of tables and listings. The mean heart rate, QT-interval, and other ECG parameters for one site were significantly less than the values from any other site; in fact, the values were similar to those that might be expected from parakeets, rather than human subjects. The data listed on the data collection forms was checked and
was found to match the data in the database, ruling out data entry error, and there were no single outliers within that site to skew the data. Upon investigation, it was discovered that an improperly calibrated ECG machine at the site was the source of the discrepant values. The trial data had to be analyzed both with and without the ECG data from the aberrant site. Data-related problems include lack of instrument calibration, lack of investigational site training, failure to adequately oversee site activities, and failure to check the data earlier in the process.

**Scenario 2: Albuterol challenge.**

In a clinical trial of subjects with asthma conducted at 12 sites, the main eligibility criterion was that subjects must show a certain percent increase in peak expiratory flow rate (PEFR) following inhalation of albuterol. Several sites had a significantly higher eligibility rate than the others. Fortunately, this was noticed early in the course of the trial by an astute monitor, who asked the site staff to walk her through their procedures during a routine monitoring visit. The sites were using nebulized albuterol, as opposed to the albuterol inhaler provided for the eligibility challenge. The protocol was amended to specify that inhaled albuterol from the study kit provided to each site should be used to establish eligibility, and additional clarification and training was provided to the clinical investigational sites. No further action was taken; the trial was a randomized, active-controlled trial, and the study team relied on randomization to lessen the impact of the error. Data-related problems included inadequate specification for study measurements and lack of site training.

**Scenario 3: I’ll just fix it.**

A small organization performed an adjudication process in which two reviewers examined source document records of clinical events to ascertain whether or not a particular clinical event, meeting the protocol definition actually occurred. Disagreements between reviewers were resolved by committee. Each reviewer completed a paper form with the results of their review. A staff member then compared both review forms to identify discrepancies to forward to the committee. An inspection of data at the end of the trial revealed that reviewers and staff made corrections without dating and initialing, and sometimes obscured original responses with their corrections. Data-related problems included a lack of reviewer training and oversight, use of manual processes, lack of process oversight, and control.

**Scenario 4: I’ll answer for the patient.**

The data collected in a government funded multicenter clinical trial included questionnaires answered by subjects. There were weekly group teleconferences during which each site reported their data collection status and rate of data completeness at each visit. During the trial, the site investigator became aware that the data collector had been completing assessments for subjects who missed their scheduled appointment. The data gathered at that site during the tenure of the data collector could not be used. Data-related problems included failure to oversee data collection by the site investigator, failure to adequately monitor sites, fraud, and possible overemphasis on data status metrics.

**Scenario 5: Those aren’t real patients.**

A now-infamous clinical investigator participated in over 200 pharmaceutical clinical trials for over 47 companies (6). During these trials, the investigator and his staff submitted data for nonexistent subjects, substituted illegitimate lab samples from persons who would meet eligibility criteria, and manipulated lab instrumentation and prescribed medications not allowed by the study protocol to obtain certain data values. This misconduct was reported to several clinical trial monitors by site staff, by several monitors to their management, and by individuals to the government; follow-up on these reports was not swift. When monitors approached the site investigator, he sent letters to the CROs and study sponsors demanding that those monitors be replaced. In 1999, he and several accomplices pleaded guilty to fraud. Data-related problems included fraud,* reluctance to challenge authority, failure to act swiftly on complaints, and lack of appropriate response to reports of problems by monitors.
PREVENTING PROBLEMS: GOOD DATA MANAGEMENT PRINCIPLES

Whether in basic sciences or clinical research, good data management can prevent many of these scenarios, and has the potential to help detect many of those problems it can not prevent. Some important data management principles that apply to any research are:

1. The analysis must be reconstructable from the raw data and vice versa. This means that the raw data must be collected and maintained, that changes must be clearly documented, and that data processing methods must be documented.

2. The data collected should answer the scientific question under investigation.

3. Each data element should be non-ambiguously defined such that individuals not involved with the research can understand and use the data.
   a. Ensure that knowledge about the data resides in the organization, not within individuals.
   b. Use standards.

4. Data should be measured, recorded and processed consistently.

5. Data should be measured, recorded and processed such that it meets the desired accuracy level.

6. Measurement, recording and processing methodologies should not alter the meaning of the data.

7. Data should be measured, recorded and processed in a timely manner.
   a. Data should be recorded as close as possible to the time of measurement or observation.
   b. Data checking should occur as close to measurement or observation as possible.

8. Data should be attributable to the measurer/observer, recorder, test subject, measuring device, location and time point.
   a. Ensure that knowledge about the data resides in the organization, not within individuals.
   b. Use standards.

9. Data and metadata should be stored so that it persists unadulterated for the required time period.
   a. Maintain data back-ups. Think negative; keep “an heir and a spare”(7).

10. Expect things to go awry.
    a. Oversee data collection
    b. Monitor the research and data collection process, not just the data.

Basic principles serve as a foundation for practice. They guide us to good practices in new and undefined situations. This is particularly important when the industry is undertaking new types of research, managing new types of data and employing new technology. Adhering to these basic principles of good data management can help to ensure a successful research project that contributes to the body of knowledge.

As clinical and basic science research become increasingly sophisticated and expensive, few investigators can afford to risk the costs that accompany ignorance of good data management principles.

“What you get out depends on what you put in; and as the grandest mill in the world will not extract wheat-flour from peascods, so pages of formulae will not get a definite result out of loose data.” —Thomas Henry Huxley, Collected Essays (1894).

*Note: Fraud can be difficult to detect. Automated screening and detection requires statistical techniques that are unfortunately not routinely used in clinical research.

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Medicine Institute. Her research career has focused on data quality in health care and health-related research including collection and management of data for clinical studies and assessment and use of EHR data in clinical studies. In addition to over 100 published articles, she has led the development of six national/international data standards, and recently published The Data Book, covering fundamental principles behind the collection and management of research data. Dr. Zozus serves SCDM as the Chief Editor of the Good Clinical Data Management Practices (GCDMP).

REFERENCES

**NOTE: As mentioned, this edition includes articles re-published from past Data Basics issues. Given that some of the articles are several years old, not all the cited web site URLs still work.

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ABSTRACT
It seems that we have all come across a time during our career as a Data Manager that we have to deal with a ‘difficult’ site: a site that keeps making the same errors repeatedly in spite of corrections, a site that seems to pay no attention to carefully prepared instructions, a site that does not respond to emails and calls no matter how many contact attempts are made. It can pose risks to the study if you have a ‘difficult’ site as it slows down the project, lowers the team morale and impacts data quality. It would help a lot if Data Managers knew how to work with a ‘difficult’ site. In order to handle this situation, based on my 16-year experience as a Lead Data Manager, I propose a three-step approach: 1) Find the root cause, 2) Identify short-term and long-term resolutions, and 3) Involve people who can help you.

INTRODUCTION
As a Data Manager, we work very closely with sites on a daily basis to ensure timely data collection and accurate data quality. Site users are one of our most important stakeholders. We work together to have data entered, discrepancies resolved, and queries responded to in an accurate and timely manner. It would make your life much easier if you have a ‘dream’ site: a site that enters data on time and correctly, a site that always resolves any discrepancy successfully at the first attempt, a site that responds to any of your questions within the same day. However, in reality, most of us have experienced the opposite: a site that keeps making the same errors repeatedly in spite of corrections, a site that seems to pay no attention to carefully prepared instructions, a site that does not respond to emails and calls no matter how many contact attempts are made. It can pose risks to the study if you have a ‘difficult’ site as it slows down the project, lowers the team morale and impacts data quality. During my 16 years in the industry, I have worked with a large number of different sites. Some of them were considered ‘difficult’ sites. In this article, I will share some tips based on my experience on how we, as Data Managers, can work with these ‘difficult’ sites effectively. It involves three steps: 1) Find the root cause, 2) Identify short-term and long-term resolutions, and 3) Involve people who can help you.

FIND THE ROOT CAUSE
When a site signs up to participate in a study, they have every intention of becoming a ‘good’ site - a site that works effectively and efficiently with the study team, produces data of good quality and contributes to scientific findings that benefit human beings. Otherwise, they would not bother to join the study team in the first place. That is why it is important to find the root cause for some of them becoming hard to work with during the study. Based on my observations, the root cause can reside on both the site’s side and the Sponsor’s side.

From the site’s side, it may be because the site does not have enough staff supporting the study, or the experienced staff have left the study and the new staff are still at the training stage. For some international sites, they may encounter language barriers that result in site staff not fully understanding instructions and/or emails from the data management group.

From the data management side, it may be because our database design is not user-friendly, our instructions on data entry and discrepancy management are confusing and hard to follow, or the timeline for data entry and data management is not realistic. It is critical to identify and understand the root cause first in order to plan for resolutions.
IDENTIFY SHORT-TERM AND LONG-TERM RESOLUTIONS

Depending on the root cause, there are short-term and long-term resolutions. Short-term resolutions focus on resolving the immediate problems that arise. Long-term resolutions focus on preventing the immediate problems from happening again. The tables A1-A3 display examples of problems and the short- and long-term resolution tactics that data managers can apply.

Table A1:

<table>
<thead>
<tr>
<th>Examples of Immediate problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>• a site keeps making data entry errors</td>
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<tr>
<td>• a site continues providing incorrect answers to queries</td>
</tr>
<tr>
<td>• a site is always late in data entry and discrepancy management</td>
</tr>
<tr>
<td>• a site is always late in data entry and discrepancy management</td>
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</tbody>
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Table A2:

<table>
<thead>
<tr>
<th>Short-term resolution tactics</th>
</tr>
</thead>
<tbody>
<tr>
<td>• provide clear instructions on data entry and query resolution</td>
</tr>
<tr>
<td>• clarify on wordings in CRF instructions and queries</td>
</tr>
<tr>
<td>• work with the study team to extend the timeline for data entry and discrepancy management as needed</td>
</tr>
<tr>
<td>• if the Data Manager experiences a trend of a site not responding to emails or queries — share the observation with the CRAs and elicit their help to work with the site to create a communication plan</td>
</tr>
</tbody>
</table>

Table A3:

<table>
<thead>
<tr>
<th>Long-term resolution tactics</th>
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<tbody>
<tr>
<td>• review the database design to ensure that it is user-friendly</td>
</tr>
<tr>
<td>• review data entry guidelines and discrepancy management guidance to ensure they are easy to follow</td>
</tr>
<tr>
<td>• review the query wording to ensure that it is clear to recipients</td>
</tr>
<tr>
<td>• review the timeline to ensure that sites are given sufficient time</td>
</tr>
<tr>
<td>• recommend additional trainings as needed when the Data Manager observes that the site continues to have a high number of data entry errors</td>
</tr>
<tr>
<td>• bring it up to the study team if the Data Manager is concerned that a site does not have enough staff support (which leads to late data entry and discrepancy management and irresponsiveness to contacts from Data Management)</td>
</tr>
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</table>
INVOLVE PEOPLE WHO CAN HELP YOU

Running a study is teamwork, so Data Managers are definitely not alone. I advise Data Managers to identify people who can help and involve them when dealing with sites. In most cases, CRAs would be our first contact. It is recommended to keep the CRAs in the loop when a Data Manager identifies an issue at the site. If CRAs are not able to help, the Data Manager should escalate following the company’s structure (for example, to Study Manager, to Clinical Director, etc.). Data Managers should build a strong working relationship with CRAs. This can help the Data Manager work with sites more effectively, because:

- CRAs have more knowledge about the site than Data Managers do (I have found that most CRAs know their site staff personally as they see each other at site monitoring visits);
- CRAs can help Data Managers understand the sites better and can help Data Managers identify the correct root cause and build up an effective plan for the sites;
- CRAs can help Data Managers train sites on data entry and discrepancy management, channel back feedback and questions from sites to Data Managers and facilitate the communications between Data Managers and sites;
- CRAs are especially helpful when Data Managers have to work with sites that do not use English as their first language. CRAs usually speak their language and can help Data Managers communicate with sites in an efficient way.

ADDITIONAL THOUGHTS TO SHARE

It is important to notice the issues at a site as early as possible. If you inherited a study from another Data Manager, talk to him/her to find out what sites s/he has experienced issues working with and ask why. If you have a new study, find out if your sites have worked on other studies sponsored by your company and get some feedback from the Data Managers from other studies. Observe your sites’ performance from the beginning of the study and monitor closely during the study, especially when changes are made to the database. If you see an increase in data entry errors and/or lateness in data entry and discrepancy management, bring it up with the sites, find out why and work with them as early as possible.

It is important to find the most effective way to work with a site. Different site staff have different styles. Some may find email communications with instructions clearly spelled out helpful, while others may prefer receiving a call or having a Video Conference with screen share so that you can walk them through corrections step by step. It is always helpful to build a good rapport with your sites. Remember that Data Managers and sites are on the same team. Make sure that your sites understand that you are always there to help them, not to criticize them. When Data Managers work with international sites, it is always good to understand the culture difference and try to adjust your work style to fit in their culture. Although most studies are required to be conducted in English, we should appreciate that English is not the first language for some international sites, so it is recommended to communicate in a succinct and clear way. When an international site has questions, I personally find it helpful to schedule a Video Conference and demonstrate changes on the screen first. Then I follow up with a simple and straightforward email with all the steps that they would take to resolve the issue.
CONCLUSION

During your career as a Data Manager, you may have already encountered or will come across someday one or multiple ‘difficult’ sites. That is no doubt. Do not panic. Do not complain. We have all experienced it. Always keep in mind that no sites want to be ‘difficult’. As Data Managers, it is important for us to conquer the difficulties by finding the best way to work with them. It should start with identifying the root cause of problems and then, based on the root cause, creating a plan for short-term and long-term resolutions. It is always helpful to involve anyone who can help in the situation. A good Data Manager is required to have strong technical intelligence and emotional intelligence. Working with a ‘difficult’ site requires both. Every site is different. The Data Manager is expected to notice issues at sites, work with them to resolve the issues, and last but not least, build up a good rapport with sites. In the long run, a happy site will provide data of good quality, help to improve the team morale and help the study move in a successful direction.

ABOUT THE AUTHOR:

Dr. Sun is a clinical project manager (PMP certified) and clinical data manager with strong research background and extensive industry experience. She has over 18 years of progressive experience in clinical data management and 12 years of clinical project management experience on domestic and international projects across different therapeutic areas. She is currently a Principal Lead Data Manager at PRA Health Sciences. She holds a Ph.D. in Public Policy. She is the Chair of the Membership Committee at SCDM.
INTRODUCTION

“Networking” to some people sounds more complicated than it is and may even generate feelings of discomfort. “Networking” isn’t meeting strangers with a common interest in a noisy bar and shouting at each other, “What do you do?”, although I’m sure many of you have experienced such an event.

To understand the role that networking plays in career management, let’s start with the evolving definition of NETWORKING.

- Investopedia describes NETWORKING as: the exchange of information and ideas among people with a common profession or special interest, usually in an informal social setting.
- Dictionary.com describes NETWORKING as: a supportive system of sharing information and services among individuals and groups having a common interest.
- Cambridge Dictionary describes NETWORKING as: the process of meeting and talking to a lot of people, esp. in order to get information that can help you.

Historically, definitions of networking stressed the point was to meet people and determine how they could help you. That self-centered approach has given way to the understanding that the purpose of networking is to create a mutually beneficial relationship. In her book Helpful: A Guide to Life, Careers and the Art of Networking, Heather Hollick presents the purpose of networking is to be helpful – leveraging who you know and what you know to help other people be successful, and surround yourself with other people who do the same.

MY NETWORKING PHILOSOPHY

My networking philosophy is: connecting people and companies to companies and people for their mutual benefit. It is nice to see that Business Dictionary has added: Networking is based on the question – “How can I help?” and not “What can I get?”

Why Network? In the past, even as recent as 15 to 20 years ago, networking outside one’s company (think of a large pharmaceutical company) didn’t seem necessary. There were still plenty of people who had been at the same company for 15 – 30 years and were doing well with no thought to changing jobs. Then mergers, acquisitions and restructuring shook the industry. People who had been at a company for many years and who were well networked within that company suddenly were out of work and realized they had no business network outside of that company. That is exactly what happened to me and I made sure to learn from that experience.
Lessons Learned

#1: Look at your situation with a wider perspective

While in shock, worrying if I’d have to move my family and going on interviews, I learned a lesson from a chance encounter with a former colleague who was in the same boat that as I was in. We were both flying to New Jersey for interviews and I told him I didn’t have a good feeling about the company I was interviewing with, it had no culture, and the employees didn’t seem friendly. He suggested I look at it differently – “could you do the job for a year?” is what he asked me. My reply was, “of course.” He helped me realize that there was nothing wrong with taking the job, making the most of my severance, and continuing to look for a role that reflected the highest and best use of my skills. And who knows? Maybe the job would be better than I first thought. This bit of advice completely changed my attitude and I interviewed as if this was the perfect job for me. I got the job. It turned out to be an okay fit but I kept one job opportunity open and when they offered me the position 5 months later, I took it.

#2: Use this job to get to your next one

Your new may not be THE job that carries you through the rest of your career. Some have called such an experience, a “mulligan” or a “do-over” job. Through the experience you learn that you are employable and you’re more in the driver’s seat than you think. Your goal is to find the company and culture that fits you, and where you want to invest your energy and talent.

#3: Be prepared

I do not consciously recall saying to myself “I’ll never be in that situation again.” However, a look at my behavior since then indicates that I took that to heart. At every conference I attended, I introduced myself to the people in the booth on either side and across from me at the conference. When I wasn’t in the booth, I walked the exhibit hall asking questions, meeting people and learning about their companies and services. In the past 15 years, when corporate restructuring or a personal decision to be in the market for a new job, I had job offers and was working within a short period of time.

#4: Networking must be an integral part of managing your career

Making and maintaining mutually beneficial relationships will help you get promoted, take on challenging assignments, solve and help others solve work problems and successfully address issues.

Having polled many audiences at DIA networking workshops over the past 10 years, the percentage of people who are in their current job due to networking is around 85%. Very few people are in their current job in our industry by replying to online job postings.

Networking also helps your career by:

- Being seen as proactive, active, resourceful, smart, and engaged
- Bringing new experiences to your life
- Building loyalty, trust, and dependability
- Increasing your communication skills, influence, and patience
NOW, HOW DO YOU DO THIS?

In almost every state there is an organization to foster and support biotech and pharma companies. NJ Bio, PA Bio, NC Biotech are examples. Join them and find out when they have events. LaunchBio (https://launchbio.org/) is an organization that hosts monthly events with speakers on relevant topics to the industry and are located in: Cambridge, MA; Durham, NC; Los Angeles, CA; New York, NY; San Diego, CA and San Francisco, CA.

Now, how do you really do this?

- When attending events, if there’s an opportunity to pre-register, do so.
- This usually means you get a printed name tag. Wear it.
- Put the name tag on the right side of your chest. This makes it visible to who you meet as you shake hands.
- Dress sharp and professional.
- Make eye contact.
- Smile, be positive and maintain a pleasant demeanor.
- Be Personable – remember and use people’s names.
- Be helpful – look for ways to offer information, to a favor, or make an introduction.
- Be someone others WANT to connect to.
- Ask “what are you working on?” instead of “what do you do?”
- Be interested – ask others for their business cards (and have yours ready for them).
- Follow up – thoughtfully and invite to connect on LinkedIn.
- Put down your phone.

Conclusion

Finally, a section from Heather Hollick’s book carries this noteworthy message: “Your network…stays with you from job to job and career to career. It is entirely your creation and no one can take it away from you… build a network that becomes your tribe – the people to whom you are loyal and who, you trust, are loyal to you.”

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President of Matheus BD Connections, LLC

Chris is a successful business development professional with over 20 years’ experience in the clinical research industry. Much of his focus has been on eclinical technologies used to improve the efficiency and manageability of clinical trials. Chris started Matheus BD Connections (https://www.matheusbd.com/) in 2018, having previously worked for Quintiles, CB Technologies, ICON Clinical Research, Endpoint, YPrime and Lexitas. Matheus BD Connections provides business development services (sales, partner identification, introductions, connections and marketing) to niche service providers which provide high quality clinical research services. Mr. Matheus continued attention to networking has helped progress his career and achievements. In 2013, he founded FOCM Networking (https://focmnetworking.com/), an organization putting networking into practice.

Mr. Matheus has an undergraduate degree in Business Administration from the University of Arizona and an MBA from California State University, Los Angeles. He is a member of the DIA Annual Planning Committee and co-chair of the Professional Development track for the annual meeting. He has been a member of SCDM or attended the SCDM annual meeting for all but a few of his 23 years in the industry.

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