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How to Get Data and Safety Managers **on the Same Team**

INTRODUCTION

Every successful clinical trial must protect patients while collecting complete, accurate data that supports evaluation of the safety and effectiveness of the drug or device.

These two responsibilities to protect patients and the data are so critical that they typically have dedicated teams or managers assigned to each function. Yet data and safety managers depend on each other, like two detectives trying to solve the same mystery. One gathers evidence, while the other provides additional context to interpret it.

Without strong communication between them, you could miss a critical piece in the puzzle. At the very least, you could be duplicating efforts, leading to inefficiencies in the process. Here's a closer look at why data and safety managers are so important to a clinical trial, what can go wrong when they aren't aligned and how to improve collaboration between them.

What A Data Manager Does

A data manager is responsible for developing data plans for a clinical trial.

A Data Management Plan is a comprehensive document that includes:

- Description of the database and user access controls
- Data collection methods and case report form specifications
- Processes for ensuring data integrity through programmed data checks, automatic queries, and the role of data managers in reviewing data
- Details from the protocol, including the study objectives, endpoints and experimental design
- What data will be collected on case report forms
- The type of controls that will be used (ex., placebo, no treatment, different administration of treatment)
- How the treatment will be assigned and how subjects are randomized
- How data will be documented and stored
- How data will be analyzed, and any interim analyses that are planned (this information may be included in a separate Statistical Analysis Plan)
- How data will be presented in the final report

The data manager often plays an important role in selecting, preparing and maintaining the electronic data capture (EDC) system. They may build the database, develop case report forms to collect data, and test the database. They serve as the main point of contact for providing data related to the trial and should work closely with all team members to ensure they have the information they need.

What's included in a data management plan?

CHECK OUT THESE RESOURCES

What A Safety Manager Does

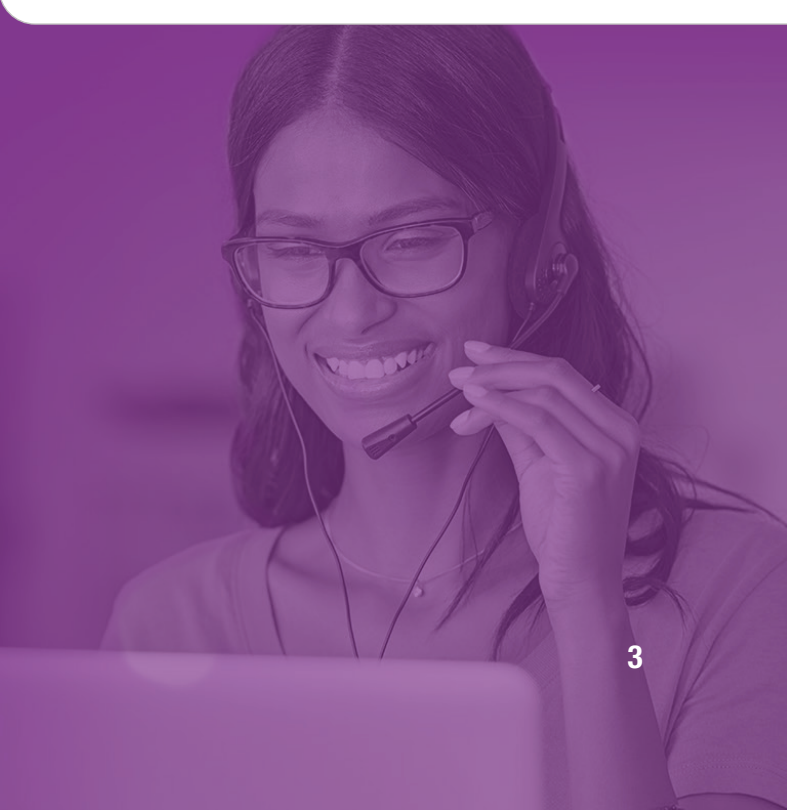
All clinical trials require safety monitoring, according to the FDA, but not all require a formal committee.[1] The safety manager or coordinator is responsible for administration of independent safety boards or committees as needed, including the Data Safety Monitoring Board (DSMB) and Clinical Events Committee (CEC).

That includes recruiting, onboarding and training safety board or committee members. Safety managers also develop the charter that outlines the operations of these groups, including:

- How often they will meet and how they will maintain meeting records
- What data they will review to monitor for effectiveness, safety and study conduct
- How they will consider external data
- How they will interact with others, including the sponsor, statisticians or data managers and the FDA
- When it is appropriate for the board to make recommendations to study protocol or terminate the study

While the DSMB reviews cumulative study data and overall safety effectiveness, the CEC reviews specific endpoints and adverse events, such as a heart attack, and determines whether they were connected to the trial.

A DSMB or CEC runs most efficiently when the clinical specialists can focus on assessing study safety issues, and the safety manager keep the processes and communication running smoothly.



Does Your Trial Need A DSMB or CEC?

Your trial may need a DSMB if:

- You have multiple sites or a complex trial
- You are evaluating mortality or morbidity
- It carries the potential for unacceptable toxicity based on prior data
- It involves emergency research or vulnerable populations (ex., children or elderly)
- It carries ethical concerns that may require termination before completion
- It raises concerns from a regulatory body that advises independent oversight

Your trial may also need a CEC if:

- You have endpoints open to interpretation (ex., determining the severity of a reaction)
- You have endpoints that could be misreported or underreported
- It requires intervention that is not blinded, bringing potential bias

The Problem with Silos

Large projects often have both data and safety teams working separately. When the safety board or committee meets, they rely on the data manager to compile reports.

If the CEC, for example, needs to review specific endpoints but the data management plan and the CEC charter are not aligned, they may not be able to effectively do their job. The data manager and CEC must develop their processes to work together seamlessly.

At the same time, if the DSMB desires a specific format of safety information to be presented for their reviews, and the data management processes cannot easily generate the desired reports, there can be frustration from both sides.

When it comes to collecting and reviewing data, both teams need to be aligned.

How to Improve Collaboration Between Data and Safety Managers

IMARC Research Safety Manager Melanie Miller and Data Manager Deborah Rovniak have each worked with many different clinical trials. They don't always have the opportunity to work together, but they do work closely with the safety and data teams assigned to their respective projects.

Here are five best practices they shared for improving collaboration between these two critical groups.

1 Discuss data needs before the trial begins

Both sides have specific data needs that often overlap. However, don't assume the information you need is being collected or will be readily available in the format you need it. One helpful practice is to create a "shell" report for the safety monitoring board or committee that includes every data point they will be expected to review, based on the study protocol.

Gather input from all parties involved to determine what types of reports they will need and how often so the data manager can plan to compile them on a regular basis.

How will they need to review information, and how can the electronic data capture system be set up to best support their needs?

This will save everyone time and frustration later. If the data manager knows ahead of time to provide the safety board with a monthly report prior to each meeting, they will be less likely to be bombarded with last-minute requests.

> The easiest way to build your electronic data capture system is to meet with the sponsors and determine what their priorities are from the beginning. Then you can set up the types of reports, queries, and case report forms they want - and avoid needing updates later
>
> - **Deborah Rovniak,** IMARC Research Data Manager

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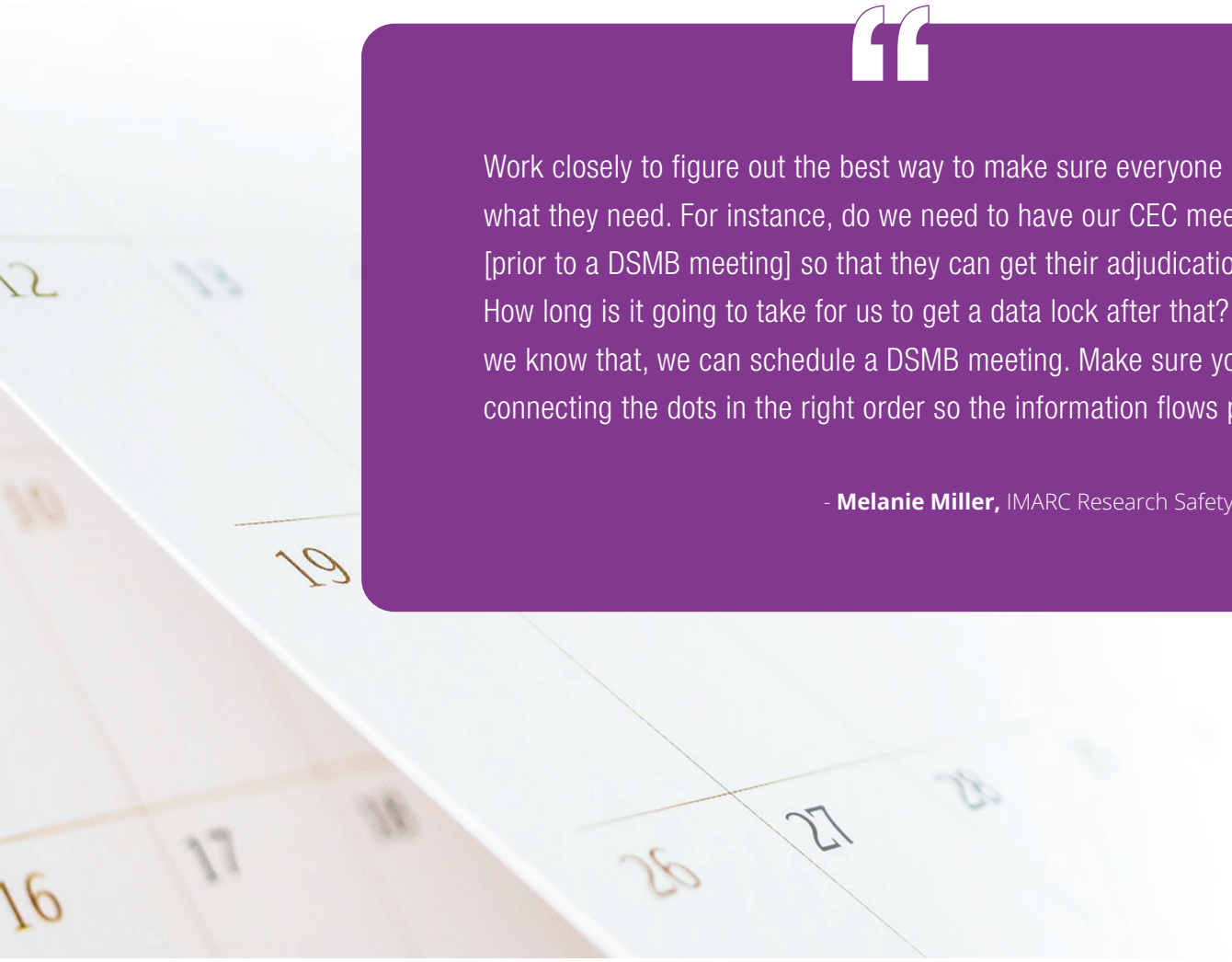
Establish project timelines and processes

Both the data and safety managers should be familiar with the project schedule and key deadlines. Consider creating a spreadsheet that includes each task, who is responsible, when it will begin and when it must be complete. Consider what information needs to be collected and in what format for DSMB meetings and CEC adjudications, then incorporate those processes into study documents such as data and safety management plans, case report forms and EDC reports, and DSMB and CEC charters.



> Work closely to figure out the best way to make sure everyone has what they need. For instance, do we need to have our CEC meet first [prior to a DSMB meeting] so that they can get their adjudications in? How long is it going to take for us to get a data lock after that? Once we know that, we can schedule a DSMB meeting. Make sure you're connecting the dots in the right order so the information flows properly.
>
> - **Melanie Miller,** IMARC Research Safety Manager

3 Train sites to use the electronic data capture system properly

While the data manager can compile regular reports and provide other information as needed, it's also a good idea to empower site personnel to use the electronic data capture system as effectively as possible to avoid simple errors. They should know how to view data and access information quickly. They also need to know when data locks will occur. Safety groups can only review data if it is available and free from errors.

4 Meet regularly throughout the trial

Establish regular meetings with the project manager, monitors, data manager and safety coordinator to discuss the status of important tasks, determine who needs information and when they need it. You can also use this time to review processes that may need to be revisited and make them more efficient for everyone. Upcoming safety group meetings, a database lock, or other study milestones can inform ways for safety and data managers to work efficiently together to share information.

5 Maintain consistent communication

Both the safety and data teams want mutual respect and support. Ensuring each knows the best way to communicate with the other is an important part of forging a good working relationship.

While some team members may be accustomed to email exchanges, it can be difficult to maintain a record of these communications. Consider using shared files that are transparent to everyone. When longer discussions between individuals are necessary, consider whether they need to be recorded and transcribed for others.

How IMARC Research Can Help

While these best practices can go a long way toward improving collaboration between your data and safety teams, there are clear advantages to outsourcing both operations to a contract research organization like IMARC. Our team follows established processes for consistent data and safety management.

We can help you select the right electronic data capture system, build it according to your specifications and work with site monitors to ensure data is entered accurately and in a timely manner. If you have decided to use electronic tools like patient-reported outcomes, electronic consent, or uploading DICOM images for CEC review, we can help you manage that process and ensure compliance. We can also sort, clean, lock and analyze your clinical trial data and assist with database locking as your trial comes to a close.

IMARC also offers full-service safety management. That includes recruiting qualified physicians for a data safety monitoring board or clinical events committee, communicating with members and documenting meetings.

When your data and safety manager are part of the same team already, you don't have to worry about playing the mediator between them.

Instead, you can focus on meeting key milestones, securing approval and bringing your device to market faster.

Need support with data or safety management?
Contact us today to discuss how we can help.

CONTACT US

Rachel Silver-Kessler, Director of Clinical Support Services and Data Management

Rachel has been at IMARC for nearly a decade, holding various roles including monitor, auditor, trainer, manager for DSMBs, CECs and medical monitors. With assistance from Melanie Miller (quoted in this whitepaper) Rachel oversees the administration of independent safety oversight of studies. More recently, Rachel also took responsibility for IMARC's Data Management service offering. Her oversight for both safety management and data management has illustrated the need for the two services to work together seamlessly.

Rachel has been a member of the Association for Clinical Research Professionals since 2011 and became certified in 2013. She holds a Bachelor of Science degree in Biomedical Engineering from Case Western Reserve University and a Master of Science in Health Sciences, Clinical Research Administration from George Washington University.

Writing Credit: Deborah L. Rovniak and Melanie A. Miller

Sources

1. Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees

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As a global, ISO 9001:2015-certified, full-service medical device CRO, IMARC has over 20 years of experience helping manufacturers conduct compliant clinical research and ultimately earn approval.