# The Role of the Data Manager in Advancing SAE Reporting from Paper to EDC

*By Lucy Spencer*

## Introduction

The sweeping shift in clinical trial reporting from paper to electronic data capture (EDC) has brought with it some generally accepted conclusions – the primary and least debated of which may be that EDC results in faster access to data. However, to date, one vital component of clinical trial data management has been largely left behind in this shift: that of the collection, processing, and reporting of serious adverse events (SAEs.) Ironically, the very nature of SAE reporting that lends itself to EDC is also what has held many organizations back from its implementation, that is, the time sensitivity surrounding the reporting of this data and the criticality of the data. By understanding the reasons underlying the lack of progress in moving SAE reporting to EDC, and then considering the benefits and challenges associated with this paradigm shift, data management can effectively work towards a solution.

In assessing the reasons SAE reporting has largely trailed the industry trend from paper to EDC, it is helpful to acknowledge the inherent difference between safety and non-safety data. This distinction lies in the regulatory reporting requirements of SAEs based on seriousness, expectedness, investigator reported relationship, and country specific legal requirements. The urgency of this safety data is such that the success of the trial and well-being of its participants is quite literally dependent upon timely, accurate reporting to regulatory authorities. Consequently, safety personnel often possess areas of expertise far different from their data management colleagues and are too frequently excluded from database development activities.

The stringent reporting requirements and separation of many safety teams from data management are possible contributors to the lack of safety process integration with EDC. Another often cited factor is familiarity with current processes. Choosing the lesser of two evils, many organizations will stick with a reliable, yet outdated, fax or paper based system over the looming unknown that comes with shifting existing processes to EDC. When faced with the increased importance of the safety reporting task to the drug development process, this apprehension is understandable.

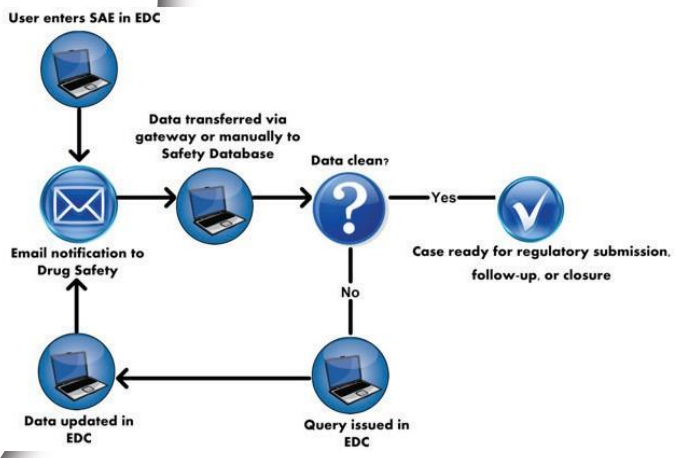
## Benefits of SAE Reporting in EDC

Clinical data management must take an active role in progressing SAE processing within EDC and advocate the collective benefits such a shift would bring. Primary among these benefits is the tangible time savings for the clinical site in elimination, or vast reduction, of redundant clinical data entry. Traditional paper SAE reports require the clinical site to document a large quantity of data that is available elsewhere in the EDC; notably, demographic, medical history, study drug administration, and concomitant study drug data, among other data. This reduction in redundant reporting will not only save considerable energy in data entry efforts on the part of the site, but also significantly reduce the need for costly and lengthy data reconciliation by data management.

Also of wide benefit to multiple functional areas is the standardization of systems. With many study sites participating in large numbers of clinical trials, integration of processes is of real benefit to the end site user. Harmonizing entry and verification processes of safety and non-safety data within a unified EDC database is logical and beneficial from the site and clinical perspective.

If configured well, integration of SAE reporting within EDC can also facilitate data handling workflows (Figure 1.) Notification of initial SAEs can trigger automated safety alerts to both sponsor safety groups, as well as other applicable parties such as contract research organizations, resulting in real-time notification. Additionally, query workflows that have existed peripherally to the clinical database can be managed within the EDC, providing a comprehensive audit trail of query activity. With data cleaning integrated within the EDC, greater visibility can be obtained to this key safety data and with this visibility, heightened emphasis on query turnaround times and the potential for shortened safety case processing times.

*Figure 1*




## Challenges of SAE Reporting in EDC

As with all emerging technologies, considerable work remains to be done to define and refine processes which will meet the specific needs of safety teams and enhance, rather than hinder, the vital daily work they perform.

To date, the largest challenges in implementing SAE reporting in EDC are system limitations. If the EDC system cannot provide the needed documentation and notifications required for the safety case processing cycle, regardless of the preference of the study team, its use is not a feasible option.

If the basic functionalities of the EDC support SAE reporting, considerations must be taken to establish back-up reporting methods if the EDC system becomes unavailable. Guidance must be provided as to how supporting documentation (e.g. hospital/discharge letters) will be received; while many EDC systems allow for uploading of documents, safeguards must be in place to alert the safety team if this uploaded documentation is revised. A method must be available to allow for on-demand SAE reports to be printed in PDF format from the EDC system. Lastly, and most importantly, a means must be implemented to highlight new or revised information to the initial SAE report. As a change to seriousness, event term, expectedness, or relationship has the potential to

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affect regulatory reportability, this component is imperative to the success of any EDC safety reporting system.

Even under ideal circumstances where the EDC system technology can be designed to meet the specific requirements of safety, another real and overlooked obstacle in its success lies in the human component. The timely nature of SAE reporting necessitates updated information at the time of the SAE reporting; however, the reality is that more often than not, the data available in EDC is incomplete. The shift to SAE EDC reporting is one that needs to have the full support of all participants, beginning at the site level, to ensure robust data is available.

## The Future of SAE Reporting

With the advent of gateway systems that allow for automated transmittal of EDC safety data to dedicated safety databases, even more efficiencies may be realized. Gateways eliminate manual entry into safety databases by transmitting electronic case files that adhere to the E2B standards developed by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) directly from the EDC system to an E2B compatible safety system. As data are incrementally transferred from the EDC and capabilities exist to highlight updated information in follow-up reports, follow-up reporting cycles may be significantly streamlined. While this synchronization of data is currently available, considerable work remains to be completed to make it a viable option for many organizations. Especially for those just delving into the SAE reporting shift to EDC, the validation and logistics of a gateway system may put it out of near reach.

In the interim, EDC databases can be developed that offer a multitude of significant benefits through carefully designed AE/SAE EDC forms and advanced programming.

## Conclusion

With the recent guidance released in *Clinical Data Acquisition Standards Harmonization (CDASH) Serious Adverse Event Supplement Version 1*, the shift of SAE reporting to EDC is being recommended by the leading industry authority:

> *"Electronic data capture (EDC) is recognized as an efficient and time saving method for capturing clinical data. EDC also offers a more efficient process for SAE information capture than the traditional paper form; sponsors can use information already available in the Clinical Data Management System (CDMS) to populate the same data elements on an SAE report form. Typically, such data are housed in a clinical study database. All SAE data that are not extracted from the clinical study database are typically housed in a separate safety database. The relationship between drug safety data and clinical trial data that commonly manifests in two distinct data acquisition processes can be enhanced by minimizing duplicative data collection and easing the safety data reconciliation processes."*

While the risks involved with changing methods for a process as critical as SAE reporting are real, the potential benefits arguably outweigh the risks. Progress in this area will not be realized until an open communication between all stakeholders can be broached and integration started. As with many technological advances, data management must spearhead this effort by endeavoring to understand the particular requirements of safety and innovating processes that will make SAE reporting in EDC the new standard. A true collaboration between data management and safety is the key to this success.

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***Author Biography:***

***Lucy Spencer,*** *Manager, Clinical Data Management at SynteractHCR, Inc. has fifteen years of experience in Data Management and has worked closely with the SynteractHCR, Inc. Safety team to institute SAE reporting processes across multiple EDC systems.*

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