Is **EDC** the next **CDMS**?

THE LINES BETWEEN EDC AND CDMS CONTINUE TO BLUR as technology catches up with practicality and the need for cleaner data faster.

GLEN DE VRIES, COFOUNDER AND CHIEF TECHNOLOGY OFFICER OF MEDIDATA SOLUTIONS WORLDWIDE, DISCUSSES WHY EDC IS NOT A REPLACEMENT FOR CDMS BUT IS THE NEXT LOGICAL EVOLUTION.

The semantic distinction **between EDC and CDMS will become difficult to discern. CDMS has always contained a component of capture,** albeit one based on transcription rather than direct entry.

For sponsors, clinical data management systems (CDMS) have traditionally formed the hub of a data management department's IT infrastructure. Data managers typically worked within their CDMS to ensure the completeness and accuracy of trial data through automated edit checks, manual reviews, and utilities to load and reconcile any trial data provided by labs, devices, or other sources. According to Glen de Vries, cofounder and chief technology officer at Medidata Solutions Worldwide, the reason CDMS was their primary system was because transcription of paper CRFs into CDMS marked the beginning of the period when a data manager could interact with clinical information.

"Logging into the CDMS in the morning would be as automatic and natural to the data manager as opening a word processor would be to a novelist," he says. "And it still is."

But Mr. de Vries says because fundamental shifts are occurring in clinical trials, the first system a data manager logs into in the morning may not be a CDMS for much longer.

"The increasing adoption of EDC parallels, and is a reflection of, the increasing desire to review clean data earlier in the trial process," he says. "And the expanding adoption of EDC means that more data managers mark the first time data are available to them by when information is entered into EDC by the site — long before it reaches a CDMS database."

The compelling reasons why a data manager would even need a separate CDMS are similarly diminishing. EDC tools have typically included edit checks, query management, and manual data review tools, but in many cases Mr. de Vries says they had limitations that required aspects of those activities to be executed in another downstream system.

"Today's more sophisticated EDC platforms in many cases include industrial-strength data management tools, meaning that data managers can perform all of their work in a single system," he says. "In some cases, today's EDC platforms also include faculties to batch load lab and other data and double-data entry capabilities so that hybrid studies with paper CRFs and online eCRFs can be handled without the separate overhead of deploying and managing a CDMS database."

MAKING A CASE FOR LEGACY SYSTEMS

A case can sometimes still be made for maintaining legacy CDMS systems because they are deeply integrated with other hubs within a pharma, biotech, or device company.

"Even if a company's EDC system is providing the trial manager with a complete study database, there may still be needs around safety, documentation, site reimbursement, signal detection, data warehousing, or resource allocation and management that stem from an existing CDMS installation," Mr. de Vries says. "However, even in those cases, integration toolkits and off-the-shelf components to connect to those systems directly is slowly becoming the rule, rather than the exception, within the EDC industry."

SEPARATING EDC FROM CDMS

Mr. de Vries says, in the end, the semantic distinction between EDC and CDMS will become difficult to discern.

"CDMS has always contained a component of capture, albeit one based on transcription rather than direct entry," he says. "And since capturing data is one of the first things done within an EDC system, not the last, the word capture at the end of EDC's acronym obscures the true potential and utility of many systems."

In the case of both CDMS and EDC, Mr. de Vries concludes, data are gathered, managed, and — increasingly with EDC — passed on for downstream analysis. Perhaps EDC is therefore not a replacement for CDMS, but can be considered as its next logical evolution.✦

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