

Value of Hosted Clinical Data Environments

By Michelle Zubatch

April 14, 2006 | Most healthcare organizations running clinical trials purchase clinical data management systems (CDMS) from major vendors such as Oracle or less expensive solutions. These systems track case report form (CRF) data completed by investigators during the various phases of a clinical trial to fulfill FDA approvals and protocols. Many clinical IT vendors who specialize in a particular niche market, such as ClinPhone for its IVR systems or Phase Forward for its remote data capture solutions, have expanded their product offerings by selling CDMS that integrate with their flagship products. These systems tend to be much less expensive than the dominant competitors, although there may be compromises on functionality for some users. Some smaller pharmaceutical and clinical research organizations attempt to create custom solutions internally — with mixed results.

A major problem is that CDMS try to be all things to all departments while wrapping technology around a solution that changes with every trial. Moreover, these systems often need to be integrated with other critical solutions such as safety systems, data dictionaries, and remote data capture solutions. The cost of supporting these disparate systems usually far exceeds purchasing them. Although most companies can afford such expense, many smaller clinical research organizations, medical device companies, educational facilities, and venture capital pharmaceutical firms lack the funding initially to properly maintain them internally.

The cost of CDMS can run into hundreds of thousands of dollars for licensing fees, implementation costs, help desk support, and upgrades. Although most of these fees are unavoidable, hosting helps ease the pain of yearly maintenance. Consulting firms that offer hosted environments handle the staffing as well as hardware maintenance and at a much lower monthly fee than an in-house solution. Furthermore, recruiting trained and reliable resources internally to support such an infrastructure is an industry-wide challenge. Smaller companies usually cannot afford to compensate these individuals appropriately. The most costly and prohibitive particulars are the regulatory requirements that must be met to use the system for clinical trials: testing and validation. For many smaller pharmaceutical and clinical research organizations, it is the only affordable solution.

The Perfect Host

Instead of burning through the venture capital, different levels of hosted environments are available from clinical consulting vendors for efficiency-conscious clinical firms. A hosted environment is a secured and validated environment with a full set of systems and support services from technical and functional experts housed externally from the client. A reputable full-service consulting firm will include help desk support. With this option, all overhead costs translate into low monthly fees, allowing firms to budget their expenses while easing cash flow. This option also alleviates management of additional resources, upgrade worries, training issues, and hardware maintenance.

The two types of client solutions available are called “shared” and “dedicated” as named from the hardware environment in which they reside. Each has advantages and restrictions (see Table).

The main difference between these two is the hardware environments. The shared environment will yield the highest savings. Consultants speed deployment by executing only the test cases pertaining to the cloning action of the database. In this option, the entire environment has previously been through full validation and testing prior to cloning, alleviating the need to perform the IQ, OQ phases again, which are typically the most time-consuming phases of implementation. Upon cloning, the system requires only minimum PQ execution to be considered validated. Along with the monetary savings, installation is completed quickly, in about a week.

Dedicated environment clients have more control over hardware decisions. However, this option requires a larger investment purchasing hardware and consulting time. Clients also may “feel” more secure about their database information. They have full control over which application versions are implemented. The biggest benefit in selection is that clients can move their servers in-house when they are ready and have the infrastructure to support the system. One disadvantage is that full validation must be performed, taking about six weeks to complete.

Both options provide much lower infrastructure expenses and less responsibility than in-house hosting. Additionally, both come with a fully trained and equipped technical team. Over the years, trial organizations stand to accumulate substantial savings utilizing the systems hosted by ASP providers as opposed to hosting them internally.

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