Veeva

WHITE PAPER

Right Sizing Change When Changing EDCs

Transformation initiatives in data management can deliver savings surpassing $1 million dollars per study. But transformation isn't necessary to benefit from a modern EDC.

Many of the world's largest biopharmas hit a tipping point with their legacy infrastructures and embarked on **global transformation initiatives** to modernize their clinical data management capabilities. These transformations have gained 50% faster build times and reduced 50% of data cleaning effort.

But the benefits of switching EDC systems aren't limited to companies seeking transformational change. Those eye-catching accomplishments can overshadow the dozens of incremental gains achieved with only small or superficial changes.

Companies that stick with an aged EDC to avoid the real and perceived costs of adopting a new system incur significant incremental operating costs for each trial. Older EDCs require more programming and testing, while decreasing flexibility and constraining innovation in adjacent systems.

While every organization has natural barriers to change, any can adopt a new technology successfully by choosing the right approach for their operating model and appetite for change. This whitepaper outlines four approaches for capitalizing on a modern EDC to improve your agility and efficiency, while maintaining those processes that are important in your organization.

Selecting the right advances for your organization

A modern EDC will offer an array of different technology-enabled process improvements. Some advances require a process change and others accrue to all. Organizations can evaluate options against their strengths and needs to pursue improvements that make sense for them.

The following table organizes the most common changes associated with a modern EDC according to the significance of change management required. We recommend evaluating the different options based on your organization's needs and appetite for change. Some changes are easy to adopt and still deliver significant impact.

Potential changes should also be evaluated based on the scale and scope of their impact. For example, using repeating event groups to replace multiple matrices greatly improves the build experience for programmers—a significant impact on a relatively small group of people. Whereas using automated and dynamic to-do lists for targeted SDV saves time for data managers and CRAs each and every monitoring visit.

FIGURE 1
Levels of change to improve EDC processes

	Low Change Options	Medium Change Options	High Change Options
Build	• Use legacy build process • Use a system-generated differences report to eliminate regression testing • Use a system-generated specifications document for compliance	• Use abbreviated requirements instead of detailed specifications • Make build changes during live review workshops	• Get enabled to build in-house • Adopt full Agile Design process
Casebook Forms and Structure	• Create new eCRFs for individual study • Use rules and dynamics to eliminate custom functions • Use repeating event groups and dynamics to replace matrices	• Add new eCRFs to library on a study by study basis	• Create net new library of all CRF standards • Track standards usage and deviations
Study Execution	• Automate distribution and tracking of end-of-study materials	• Use dynamic to-do lists for targeted SDV	• Centrally manage local lab normals

Four approaches to moderate organizational change when adopting a new EDC

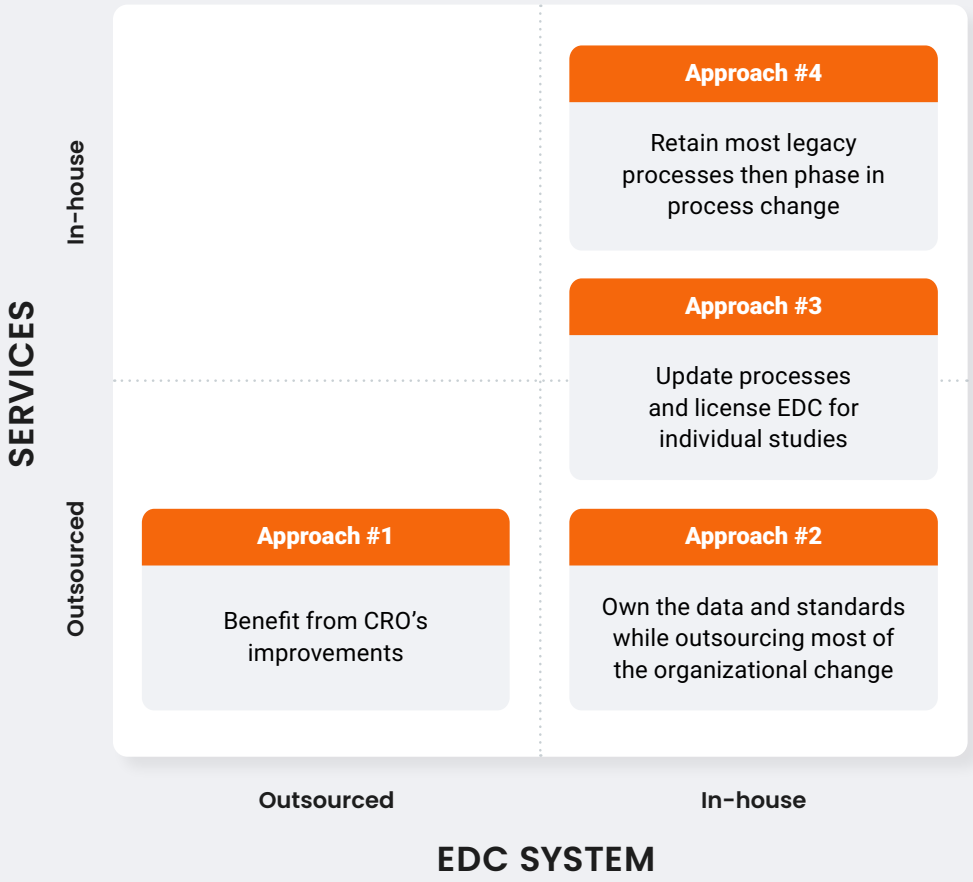


FIGURE 2
Approaches can vary by operating model across data management staffing and system ownership

Approach 1: Outsourcing to CRO with a modern EDC

The fastest and easiest route to benefiting from a modern EDC is to include it in your outsourcing arrangement, whether by working with a contract research organization (CRO) that standardizes on your EDC of choice, or specifying that EDC as the preferred system for the next trial. In either case, the CRO owns the technology and the sponsor's SOPs remain unchanged.

When outsourcing data management, the drivers behind high costs and lengthy timelines are hidden from the sponsor. Outdated technology is a primary contributor to high EDC setup costs due to the heavy dependence on custom programming in older EDCs. A study can require 50-250 custom functions or more depending on its complexity. With the average custom function requiring four hours of work for writing, documentation, and testing during the build and amendments, the cost for this work can add up quickly. When CROs use better technology the benefits accrue to both parties. Fortrea, one of the leading global CROs, is modernizing its technology infrastructure to offer sponsors greater agility at scale.

Bireshwar Saha, global head of clinical programming & analytics at Fortrea describes the implications of working with older EDCs, "When considering the impact of custom functions, it's not just the initial programming but the testing, documentation, and maintenance of them through amendments. That work requires a specialized skill set and those resources can be scarce. Working with Veeva EDC provides an immediate reduction in build time and reduces our dependency on expensive, specialized resources."

Saha describes the benefits: "Eliminating custom functions reduces complexity and the overall cycle time, and improves quality. Many more capabilities are productized and configurable in Veeva EDC." Saha's team ran a comparison and found a 35-40% efficiency gain, requiring fewer edit checks, unique forms, and repeat pages.

A modern EDC also makes it easier to handle complex protocols and frequent change requests. Saha explains, "For a complex oncology study, using repeating event groups, visits, and forms instead of building everything individually is a game changer. We can simply update the number of cycles rather than having to go through an expensive change control each time there is a design change. That saves a lot of effort previously spent carrying changes from the upfront screens through to downstream listings and outputs. Our customers want speed. Replacing programming with simple configurations and dynamics helps us deliver that."

As the number of trials a sponsor runs concurrently grows, the cost benefit calculation for outsourcing system ownership changes. This is especially true when working with a modern EDC. With legacy systems, the dependency on programmers meant it may never make financial sense to bring the EDC in house. **Eliminating custom functions changes the cost-benefit calculation, which has led an increasing number of sponsors to bring the EDC in-house.** Sponsors that may want to bring the EDC in-house in the future can leave their options open by working with an EDC provider that can port the entire EDC and collected data from a CRO's domain to the sponsor's domain without disrupting sites or other users.

> *"As an industry it is important that we get medicines to market faster. And what we are seeing is anywhere from a 30 to 50% efficiency in driving down cycle times through the functionality of Veeva EDC."*

Eboni Russell
VP, Global Head Clinical Data Management, Fortrea

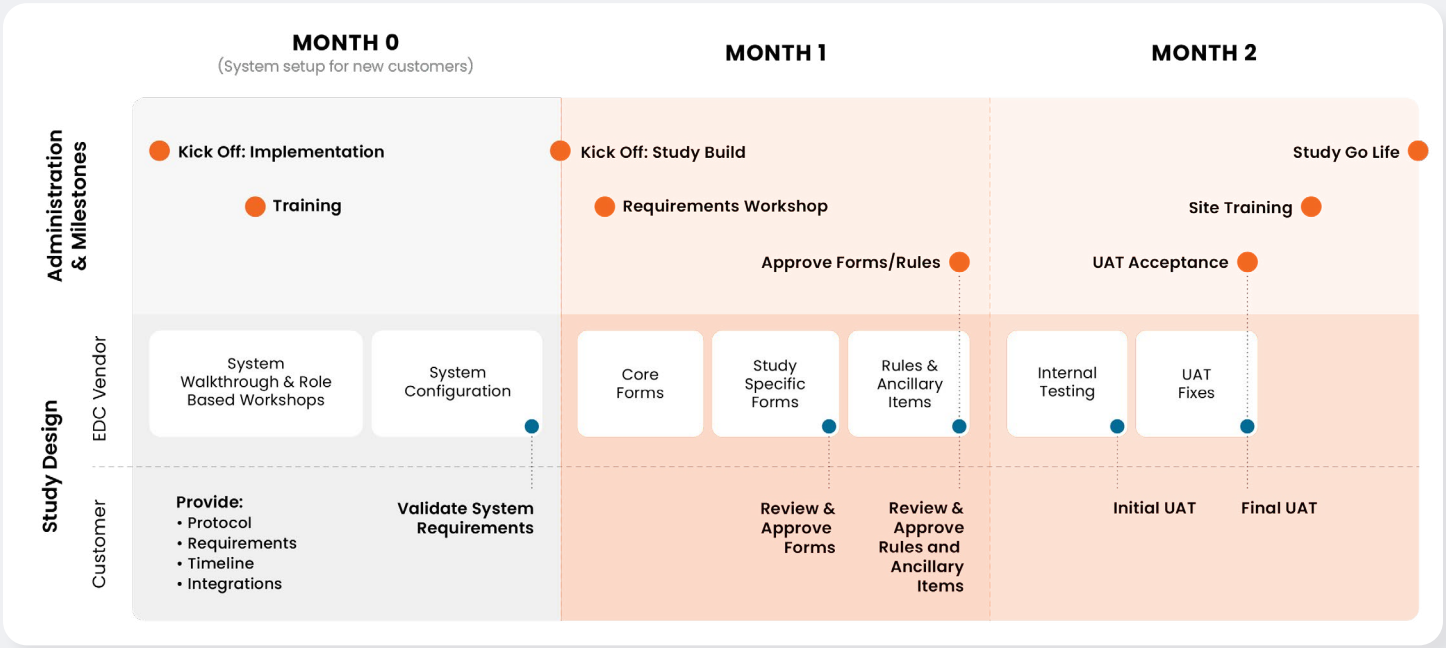
Hear the full story

Approach 2: Own your EDC system while outsourcing builds and data management

A second approach for adopting a modern EDC while minimizing internal change is to license the EDC system directly while outsourcing part or all of the data management function. External experts perform the build and help companies leverage the full system functionality, while working within the parameters of your startup processes. The two primary benefits of this approach are gaining ownership of your data and establishing your own eCRF standards.

When bringing the EDC in-house, sponsors should own the build process even when performing the build is outsourced to the CRO or EDC vendor. When you own the process, you may use your traditional process to further minimize change, or leverage the faster and more collaborative Agile Design methodology typically used with a modern EDC. A sample timeline for a 12-week study build is provided in [Figure 3]. While many builds with a modern are 50% faster than a sponsor's historic median times, a 12-week schedule sets realistic expectations for initial studies.

FIGURE 3
Sample study startup timeline



Approach 3: Study by study adoption and change

Adopting a new EDC for an individual study rather than enterprise-wide is another means to lessen the organizational change required. Licensing a new EDC on a single study basis narrows the number of parties involved, enabling you to train users and manage change with one study team at a time. This approach works well for companies that are interested in a clinical platform but aren't ready to make a full commitment. It's also optimal for studies with complex protocols or other scenarios where using modern technology provides out-sized benefits compared to traditional EDCs.

For companies looking to get started with a new EDC using a study-by-study approach, one path would include a medium-level change to study builds, low-level change for casebook forms and structure, and low-levels of process change during study execution. The rationale for each recommendation is outlined in the table below.

FIGURE 4

Sample selection of changes with a study-based approach to EDC licensing

	Recommendation	Rationale
Build	Medium change options	• The greatest change is for the Study Designer and/or Programmer, a role which can be filled externally. • The second greatest change is for the lead data manager, who can be guided through the process individually without broader change management. • The change for study team members reduces the review and approval burden and is thus readily accepted.
Casebook Forms and Structure	Low change options	• Re-building forms for a study necessitates downstream changes to form completion instructions and programming, but the benefits from reduced edit-checks and form innovations make the incremental work worthwhile, especially considering the likelihood of reusing new forms in subsequent studies.
Study Execution	Low change options	• While keeping all other processes intact, sponsors may want to automate the distribution of end-of-study materials. Here the traditional process is highly manual and borne with little affection by data managers and site personnel. Automating the process is easily adopted and appreciated by both parties.

CASE STUDY

A multi-national biopharma based in New Jersey with over 400 employees licensed a modern EDC for a single Phase II study and found that its agility and flexibility were critical to hitting its timeline. What started as an early stage feasibility study turned into a program-leading first trial in a new indication.

The study team was working in a new therapeutic area with lots of unknowns and discussions needed. Getting the right people in the room enabled the team to evaluate, discuss, and make informed decisions. Performing the updates in real time made the in-person meetings worthwhile and enabled rapid progress. Their director of data management explained, "Most of the changes were implemented right in front of our eyes, which was extremely helpful to making decisions and hitting our deadline."

The remainder of the development was done with the teams in close communication. Rather than use email and spreadsheets, they kept a shared CRF change log to specify requests, request clarifications, and track completed work.

"We had direct access to the development environment, so could review and approve updates as the work progressed," comments the director of data management. "The shared view allowed both teams to move quickly and kept us in lockstep regarding what had been implemented and what hadn't."

The sponsor benefited from the agility that an advanced build environment provides while maintaining its existing processes for SDV and data cleaning during study conduct.

Study build highlights with a modern EDC and Agile Design

22 of 30
eCRFs built directly from the protocol

One week
to write all rules and edit checks

Seven working days
to complete UAT

Most of the changes were implemented right in front of our eyes, which was extremely helpful to making decisions and hitting our deadline."

Director of Data Management
Multi-National Biopharma

Approach 4: Phase in process change with company-wide adoption

Many organizations use the pending termination of an existing contract as the impetus to change software providers. When this occurs, you may need to adopt the new EDC company-wide rather than study-by-study. In this scenario, the best strategy to minimize organizational change is to take a phased approach. You can maintain many existing processes initially and then leverage new functionality over time, choosing when and where it makes sense for your organization.

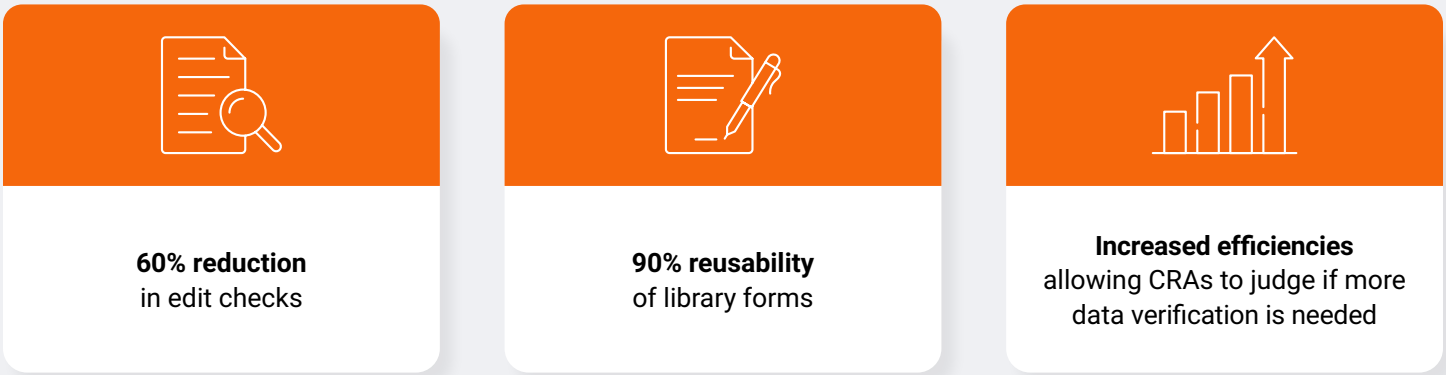
A top 20 biopharma with employees in 70+ countries, was able to adopt and deploy a modern EDC globally in just six months. In order to hit its aggressive timeline, the company took a staggered approach to process change. In the first phase, it largely maintained existing processes, while leveraging new EDC capabilities wherever it could. A number of the EDC advances delivered benefits even within existing processes.

Previously, studies contained over 1,000 edit checks on average. With a modern EDC, the biopharma's study average is now under 400 edit checks — a 60% reduction and significant time savings for every trial going forward. Reuse of library forms now averages 90% in current studies. The company is also seeing efficiencies during SDV with dynamic T-SDV lists and additive review capabilities that allow CRAs to judge whether additional data verification is needed.

Now that the initial phase is complete and multiple teams have experience with the build environment, the company plans to incorporate more of the Agile Design build practices, such as live form reviews. In the third implementation phase, it will make the remaining changes needed to maximize productivity gains available with the new EDC platform.

FIGURE 5

Efficiencies gained while maintaining most legacy processes for study build and execution



A stepwise journey to valuable change

Your current EDC has gotten you this far. Looking ahead, with growing regulatory requirements and study complexity, a reliance on custom programming and related testing will impact your ability to maintain speed and accuracy. Studies are advancing and your EDC capabilities should too.

There are multiple ways to approach change when adopting a new EDC. Greater efficiencies are readily available even when outsourcing the EDC or bringing it in-house for a single study. And while transformational advances do require change, you can start small and incorporate new ways of working over time. Each new study benefits from the prior investments and presents an opportunity to improve a different area.

Vikas Gulati, executive director of clinical data management and metrics at Vertex Pharmaceuticals, connects the necessity of change to achieving their goal of a six-week build: "You cannot compress a 12-14 week timeline to six weeks just by working faster."

Experiencing success can feed a desire for further improvement. Many sponsors evolve their approach over time, often starting with outsourcing a more modern EDC and after seeing its relative simplicity, bringing the EDC in-house.

Ultimately, the journey towards a modern EDC is a progressive one, where initial successes and the realization of tangible benefits pave the way for increasingly ambitious advances in clinical data management.

> *You cannot compress a 12-14 week timeline to six weeks just by working faster."*

Vikas Gulati
Executive Director of Clinical Data Management and Metrics, Vertex Pharmaceuticals

Read their full story

Get tips on how to evaluate, choose, and switch to a new EDC system

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