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 Veeva 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 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 adopting Veeva EDC while maintaining those processes that are important in your organization.

Selecting the right advances for your organization

Veeva EDC offers numerous 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 common changes associated with Veeva EDC according to the level 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 lessen organizational change when adopting Veeva EDC

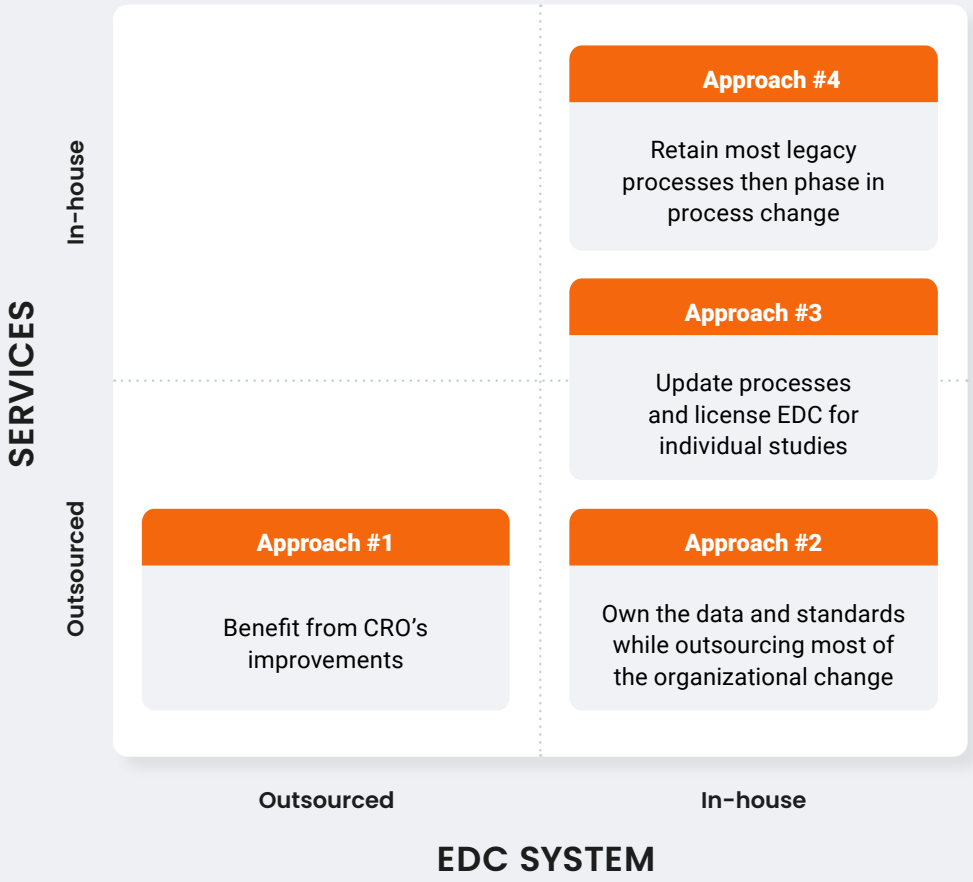


FIGURE 2

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

Approach 1: Outsourcing the EDC

The fastest and easiest route to benefiting from Veeva EDC is to include it in your outsourcing arrangement, whether by working with a contract research organization (CRO) that standardizes on Veeva, or by specifying Veeva 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.

Ideal for:

- No internal DM team
- Run relatively few trials
- Have complex protocols

Benefits:

- Reduces EDC setup time and costs
- Easier for CROs to respond to change requests

CASE STUDY

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 Veeva 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.**

> *"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

Future proof your decision

If a sponsor using Veeva EDC through their CRO decides they want to own their own data, Veeva can port the entire EDC and collected data from the CRO's domain to the sponsor's domain without disrupting sites or other users.

Approach 2: Own the EDC + Outsource the Services

A second approach for adopting Veeva EDC while minimizing internal change is to license the EDC system directly while outsourcing part or all of the data management function. With this approach, external experts perform the build and leverage the full system functionality, while working within your SOPs. 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 Veeva EDC. A sample timeline for an 8-week study build is provided in Figure 3. While many builds with Veeva EDC are 50% faster than a sponsor's historic median times, a 12-week schedule sets realistic expectations for one's initial study.

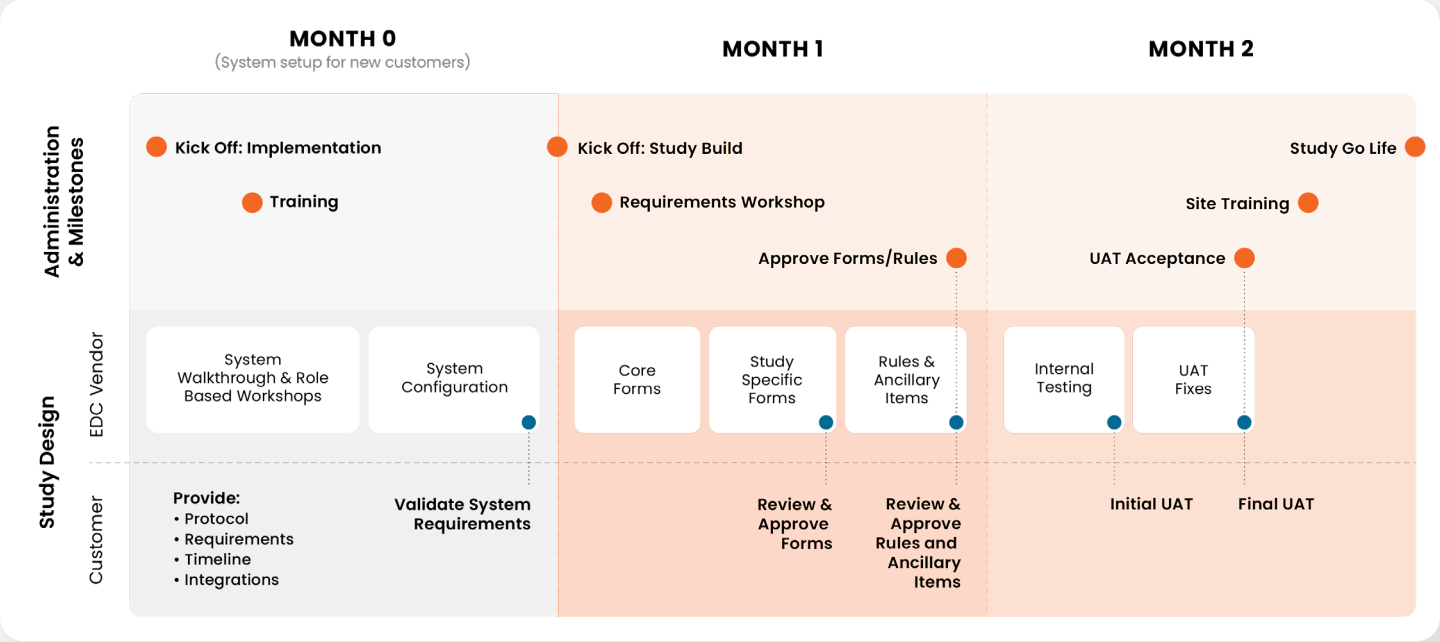
Ideal for:

- Sponsors wanting to own their own data and maintain existing processes
- Have growing pipeline of trials

Benefits:

- Gain ownership over data and establish eCRF standards
- Automation opportunities with Veeva CTMS, RTSM, and Safety
- Less impact on other business units

FIGURE 3
Sample study startup timeline



CASE STUDY

Pacira BioSciences Inc., (Pacira) a company committed to delivering innovative non-opioid pain therapies, recently embarked on an initiative to bring its core clinical systems in-house while maintaining its outsourcing relationships for the EDC build and data management. Pacira has worked with a range of CROs and had mixed experiences when it came to accessing its data and working around technology limitations. The company decided it was important to own the systems that manage its clinical documents and data.

Pacira's Senior Director of Clinical Data Operations, Armand Matejunas, was brought on board to develop scalable capabilities to enable Pacira's future growth. Veeva was selected for EDC, eTMF, CTMS, and RTSM systems to bring in-house. In addition to greater control over their data, they can now automate data flows and tasks between systems--a key contributor to scaling their capabilities.

The EDC implementation went first and has gone smoothly, without requiring significant change management. "We've been able to bring Veeva EDC in-house without requiring a lot of change management because we are still outsourcing the data management function," he says. "Other than system validation, not a lot has changed."

One of the drivers for their decision was the desire for greater flexibility with a hybrid resourcing model. As they prepare to run a greater number of trials in the coming years, they've determined that with a few key hires they will have the staffing and systems needed to run smaller studies in-house while still outsourcing larger trials.

Pacira's top reasons for bringing the EDC in-house:

Greater access and control over data

Greater efficiency by automating tasks and data flows

Flexibility to run trials internally or externally

pacira BIOSCIENCES

Pacira BioSciences, Inc. delivers innovative, non-opioid pain therapies to transform the lives of patients. Pacira is building on their decade plus legacy with next-generation innovations for chronic, postsurgical and musculoskeletal pain.

Approach 3: Study-level 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 Veeva EDC using a study-by-study approach, one path could 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.

Ideal for:

- Sponsors seeking to sample Veeva EDC
- Sponsors seeking gradual change management
- Studies with urgency and need for speed
- Studies with complex protocols

Benefits:

- Allows for training users and managing change one study at a time

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/Medium 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. 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 Veeva 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: Company Adoption + Phased Change

Many organizations use the 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 Veeva 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 Veeva EDC capabilities wherever it could. A number of the Veeva advances delivered benefits even within existing processes.

Previously, their studies contained over 1,000 edit checks on average. With Veeva's 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.

Ideal for:

- Enterprise license for legacy EDC is expiring
- Prefers enterprise-wide licensing agreements over study-specific licensing
- Facing tight deadlines or budgets

Benefits:

- Doesn't require significant upfront investment in change management
- Faster roll-out across wide geographies
- Flexibility to prioritize changes as needed

FIGURE 5

Sample Time Savings Estimate

Form logic and other innovations in Veeva EDC have made many simple edit checks obsolete. For estimation purposes we will assume a 60% reduction in checks delivers roughly 40% time savings across specification, programming, and testing.

Process Step	Time Required for 1000 Edit Checks	Savings with a 40% Reduction in Effort
Create data validation specification	75+ hours	30+ hours saved
Program, configure, and QC edit checks	375-500 hours	150-200 hours saved
Perform user acceptance testing	175-250 hours	70-100 hours saved

For each study going forward, the sponsor could save between 250 – 330 hours during study builds. At $100/hour for data management and/or programming time, the savings would be $25,000 – $33,000 per study, just from reducing the number of edit checks.

There are additional savings stemming from the time historically spent reviewing data and issuing queries when edits checks fire. Veeva's smarter forms improve data quality and save data managers time during study execution.

A stepwise journey to valuable change

Your current EDC has gotten you this far, but with study complexity on the rise, it is also limiting your speed, agility, and ability to modernize. A heavy reliance on custom programming introduces risk and increases build and operating costs for every trial. Given the costs associated with the status quo and the efficiencies gained with Veeva EDC, the relevant question is--how to make the switch.

The four approaches to change management in this piece were designed to help any organization map their path to a new EDC. 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. Experiencing success feeds a desire for further improvement. Many sponsors have evolved their approach over time, initially outsourcing Veeva EDC and after seeing its relative simplicity bringing EDC ownership in-house.

The approaches outlined in this piece also hold true for other clinical data systems. Using a modern EDC creates a foundation for successfully adopting newer technologies such as a data workbench or eCOA. A phased approach to change management can enable a broader range of companies to implement a full clinical data platform--a strategy that produces a multiplier effect on the efficiency gains from each individual system.

Studies are advancing and your EDC capabilities should too.

Align the scope of change management to the scale of your goals

> *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 Veeva EDC

Veeva

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