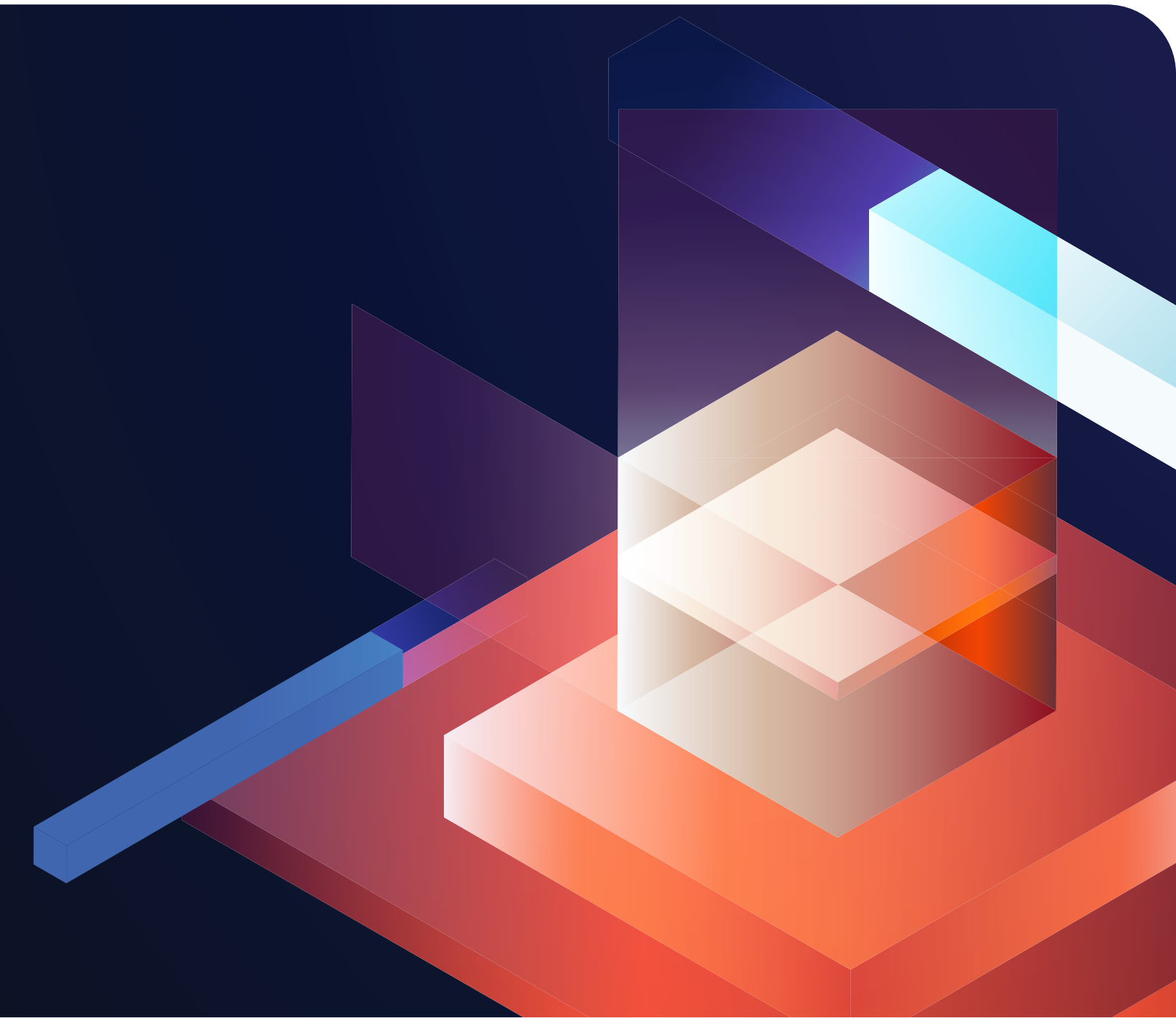
Veeva

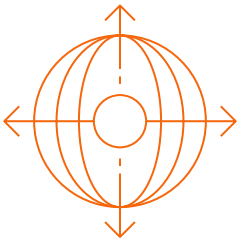
EBOOK

How to Adopt a Clinical Platform

Find the right path for your organization to flexibly implement a clinical platform



The rise of clinical platforms



Clinical trial protocols, processes, and regulatory environments are increasingly complex yet dynamic.

What was once linear and singular is now multi-faceted and varied. We have more data from more sources, paired with more experimental AI projects in search of better efficiency. Industry's reaction to that complexity resulted in a patchwork of systems, which created its own set of downstream challenges.

Sponsors and sites prefer **consolidated systems** with streamlined processes. A clinical platform that unifies cross-functional systems offers the ability to simplify and standardize the trial experience for all stakeholders and generate greater efficiency.

A platform approach also embeds flexibility and makes it easier to adapt to changes in protocols, processes, and regulations.

For example, end-to-end study startup time can be reduced by 50% by simplifying site feasibility and initiation – leveraging libraries and automation to auto-populate fields across multiple systems. Instead of manually setting up the same site in CTMS, eTMF, RTSM, EDC, and eCOA, enter the site information once in CTMS and automatically configure it in those connected systems.

Standardizing the process for data collection from sites and patients also increases data quality and reduces the effort to clean data. Standardizing the build process has driven down the time from protocol approval to FPI, taking clinical development systems off the critical path.

This ebook will offer guidance and best practices to adopt a clinical platform. The advice is based on 10+ recent clinical implementations, ranging from emerging biopharma to top 20 biopharma. In most cases, we assume that the sponsor or CRO already uses Veeva CTMS and/or eTMF (although sometimes the clinical platform approach **begins** with Veeva EDC).

An important factor is realizing value quickly with flexibility for a variety of situations. For most companies, we recommend an agile implementation process that requires less upfront investment in time and resource planning, while scaling according to company size.

Key considerations

There are four questions that shape the situational guidance:

01. What is the **scope of technology** to consolidate or implement?

02. What is your ideal or current **operating model**?

03. Who manages your **standards strategy**, and how effective is the program?

04. How **committed is your team and leadership** to a clinical platform approach?

01

KEY CONSIDERATION 01

Scope of technology

Dozens of systems are used in clinical development, from protocol finalization to submission.

First, define which capabilities will be part of the clinical platform, and which systems will become 'legacy'. For reference, one large biopharma was able to sunset over 100 systems as part of a Veeva Clinical Platform implementation.

EDCs are used in most studies and, together with a clinical data workbench, are foundational for clinical data collection and management. Veeva's modern EDC introduces significant efficiency savings, while Veeva CDB provides a single hub to aggregate, manage, and clean all data. Identify must-have value drivers, such as effort reduction, that the technology will support.

A large biopharma was able to sunset over 100 systems as part of a Veeva Clinical Platform implementation.

Considering other non-EDC data sources, where are there opportunities to consolidate? For example, is there an opportunity to reduce the number of eCOA providers and instead standardize one or two for all studies? Consolidation of preferred vendors simplifies the overall technology landscape and creates operational efficiencies.

We recommend building a library (complete with integrations) over time that can be leveraged by study teams. Note which clinical systems can benefit from out-of-the-box Veeva Connections (e.g. Veeva CTMS, Payments, or RTSM) and which require integration with third party vendors.

KEY CONSIDERATION 02

Operating model

Most sponsors considering a clinical platform already own – or plan to own – their critical clinical technology. To realize the full value and operational efficiencies of technology, it's a good time to think about the right future state of your operating model.

In general, we find that a hybrid operating model – combining in-house resources with FSPs or other service partners for certain tasks – is often the best approach. Understand the 'as is' process with current technology, and identify who completes each task during study build and study conduct. Discern the processes that are working today from those that aren't working. Later, when defining SOPs for the new platform, determine which processes need to change. Changing operating models is a large undertaking and it will take time to build in-house capabilities.

An agile implementation allows an organization to move quickly without requiring all the answers in advance.

A general idea of your future operating model is important to understand, but it does not limit the implementation of the platform. An agile implementation allows an organization to move quickly without requiring all the answers in advance.

For example, some Veeva customers have adopted a platform strategy with only two or three in-house resources that build and deploy studies, flexing with additional support for testing on more complex studies. This "lean team" approach has been used in a wide range of company sizes – from the largest top 20 biopharmas to **emerging biopharmas**.

KEY CONSIDERATION 03

Standards strategy

Creating and maintaining a **standards library** of forms, rules, assessments, and data listings is critical for platform efficiencies. Developing as many reusable assets as possible, directly on the platform, reduces the need for study-by-study development, eliminates repetitive testing, and simplifies the build process. By standardizing, smaller teams can do more without specialized technical skills.

Platform implementation is an opportunity to create or update a standards strategy, and if a dedicated team doesn't exist already, bring this standards capability in-house.

We believe that platform agnostic standards do not truly exist. Any standard that is built to be used by all platforms does not take advantage of all of the capabilities offered by any one platform. An 'agnostic' standard must use the lowest common denominator of capabilities. We recommend using deployment as a chance to step back, evaluate your data flow, and refine standards to leverage the new capabilities offered by a modern platform.

KEY CONSIDERATION 04

Commitment to change

Transforming the clinical development process can be a multi-year effort. Some organizations are eager to transform and have strong executive support to change, while others are more reluctant.

In either case, we recommend finding the right initial studies, communicating clear goals, creating early wins, and setting the governance for continuous improvement.

If there is strong commitment to change, then the number one goal is to reach 'all new study starts' on the new platform. It is important to continually refine processes, of course, but this is an important milestone to begin to sunset legacy systems and increase long-term value.

Iterative agile implementation

A traditional waterfall deployment model (analyze, design, implement, and test) is a proven way to mitigate risk. However, it is rarely the most efficient and cost effective.

For most organizations, we propose an agile and iterative deployment for a clinical platform. Our goal with this methodology is to start fast and show continuous value. Each study deployed adds to standards libraries, refines processes, and builds towards the future state operating model. Each phase of the plan builds on the last and avoids throwing away work.

This methodology could apply to all organizations, but it's especially applicable to organizations that do not have the ability to make large upfront investments or that do have some resistance to change.

Four phases of agile implementation

These four phases are best practices for clinical platform implementation, and can be modified or rearranged to best suit the organization.

PHASE #1

Platform assessment and core library

The first phase is intended to quickly get users in the system for hands-on learning so that the platform capabilities can be efficiently assessed. This is an investment of the sponsor's time and it is important to create value during the assessment phase. After brief formal training for a small set of users on the product, we quickly move to a tailored plan for the sponsor.

Instead of the typical approach of building a mock study, the recommended approach is to begin with a standards library. Building standards gives teams the hands on experience needed to define processes without having the full effort of a mock study. The value of the platform is maximized by having a strong standards library and focusing on adding to the library as part of the assessment process immediately adds value to the platform.

We recommend that the sponsor start with building a library of commonly used or 'Core' library forms, prioritizing forms that are required for integrations with other systems like AE or Con Med forms. Additionally, assess the Veeva eCOA library to determine if any additional assessments are required. Begin to strategize listing and autochecks in Veeva CDB.

In parallel with the library build initiation, or before, the platform will need to be validated in alignment with the sponsor's standard process. This effort is always a prerequisite to a first study in production, but more importantly it will ensure any assets built for the library are done with the correct process and documentation so that they can be leveraged in the future.

PHASE #2

Initial studies

The first studies on the platform should be used to not only prove the technology capabilities, but also the value case for the proposed future state operating model. It is important to clearly define the value metrics so progress can be accurately measured. Often the value metrics are aligned to key study milestones like FPI.

For the first study, strike a balance between what is necessary for successful conduct and the investment required. For example, integrations with external systems make the platform more efficient and are required at scale, but can be the most costly and time consuming to develop. If integrations are deemed necessary, they should be built in a reusable way.

Process design should begin to evolve for the first study. Veeva will build the first study on the platform while mentoring and training the sponsor team. The Veeva build process provides best practices that the sponsor can leverage as a foundation for future improvement. Study conduct should align as close as possible to the existing process for initial studies.

PHASE #3

Scale

After successfully implementing the initial studies, the lessons learned will guide the next phase to scale to all studies.

The most important milestone during this phase is reaching 'all new study starts' on the clinical platform, or prioritizing the clinical platform for new studies. Reaching this milestone will allow us to move into planning for the migration of legacy studies, if desired, and sunsetting legacy systems.

Similar to an agile study build process, we recommend using the same principles to add additional studies. Every study should leverage reusable assets from the library (forms, assessments, listings, and integrations). If the library does not contain assets required, those will be built and then added to the library for reuse. The librarian role is important for evolving the library over time.

In this phase, the sponsor should also start moving towards the future state operating model. Define long term team structure, organize build teams for maximum efficiency, and identify sourcing strategy. For example, the sponsor may decide to bring study build resources in-house but leverage FSP or service partners to augment the team with additional testers or CRAs.

Some sponsors with fully outsourced studies on Veeva technology have brought them into their Veeva Domain, shifting conduct from FSO providers to their internal, or FSP, resources.

PHASE #4

Platform expansion

The platform strategy will continuously improve and evolve to meet the needs of future trials. Veeva releases three times annually and publishes processes for adopting new capabilities and improvements that will maximize the value of the platform.

After the foundation is deployed, the next set of platform capabilities is assessed, tested, and then deployed at scale for future studies. Mature technology categories like eCOA or RTSM should be the priority for expanding the platform.

Example adoption plans

A growing number of organizations are realizing the benefits of implementing a clinical platform by adding applications over time. Here we demonstrate two examples of sponsors that started with one or two Veeva Clinical Platform applications, and expanded gradually after building a core library and developing processes with initial studies.

Adoption plan A

A medical devices company that conducts a wide variety of clinical trials, with different ways of capturing, reviewing, and reporting on data, decided to adopt a platform approach over time.

The team, consisting of data managers, database developers, standards associates, and programmers, began using Veeva EDC in 2019, expanding with eight more applications over the following five years across the Veeva Clinical Platform **[Figure 1]**.

Figure 1: Timeline of Veeva Clinical Platform implementation

Rather than year-on-year implementation of new systems, the team took a strategic pause in year 3 to refine the use of current technology, develop standards, and stabilize processes. The company also internalized their data management function during this time.

The company created a dedicated team to oversee all implementations, which helped them cross-train application builds and implement learnings for each sequential application. They reduced the time to adopt each new system, from three months for Veeva CDB in year 4, to 22 days for Veeva eCOA in year 5.

It took less than 30 days to build the initial study EDC database with Veeva. Then, the team began EDC builds themselves, with three studies built in less than 90 days.

Before the company fully implemented the Veeva Clinical Platform, they chose to build a foundation of processes and operational metrics. The team invested 12-15 months in building a standards library within Veeva EDC. This focus on standards allowed the team to:

- Increase adherence to CRF standards from 50% with just 20 CRFs, to 90% as they expanded to therapeutic area standards
- Maintain template CRFs as a baseline for new studies, reducing time in development, testing, and deployment
- Reduce data cleaning and lock time where clinical data management is on the project critical path
- Prioritize data transfer technical solutions of large instrument datasets, enabling real-time data review
- Develop a clear vision for adopting new data management tools like a clinical workbench (Veeva CDB)

Developers were responsible for builds across all Clinical Platform applications, helping them embed deep knowledge of the study and feel more ownership for overall delivery. This was advantageous for data managers, who had one point of contact for all clinical data needs across a particular study.

Key Insights

Adopt a phased platform approach with strategic expansion

Invest in internal expertise and dedicated oversight to maximize system capabilities

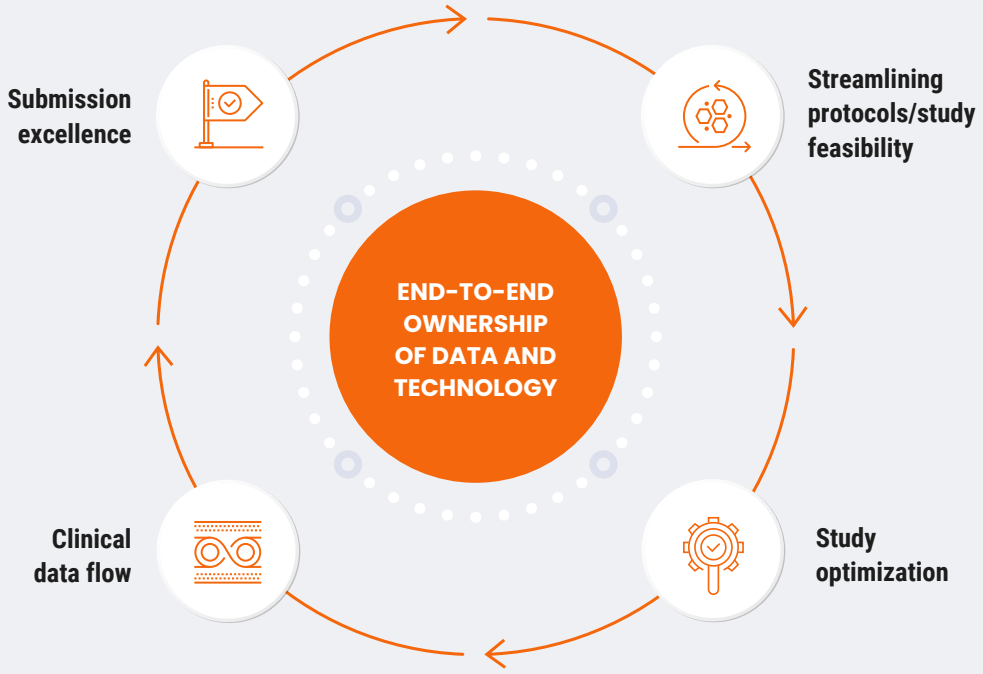
Prioritize standardization and thoughtful tool integration to ensure speed and quality processes

Implement with a balance of focused action and strategic pauses to reflect and refine

Adoption plan B

A top 20 pharma company had the goal of bringing clinical data technologies in-house to gain operational efficiency and end-to-end ownership of data and technology **[Figure 2]**. This approach expands the Veeva Clinical Platform by adding to the Clinical Operations capabilities already in place. The strategy is driven by the company's need for transformative change, while recognizing the value in a partnership that could evolve with their needs.

Figure 2: Strategy for in-housing clinical trial technology



Following the standard Veeva Enablement process, the Veeva team configured the first set of studies while mentoring the sponsor team. Leveraging the lessons learned from the initial configurations, the sponsor in-house teams quickly began to configure studies on the platform and define processes that would be used moving forward for subsequent studies. Due to the agile nature of the build process, the joint Veeva and sponsor teams were able to build in parallel to accelerate the process and meet the needs of the sponsor's pipeline.

While the initial studies were being deployed, a standards committee was created. To start, the committee led the eCRF library build using the forms built for initial studies and focusing on standard forms used across the majority of studies. After the initial library deployment, they expanded the library to include a set of standard rules to accelerate the build process overall, drive quality, and simplify study operations.

In less than 12 months, the sponsor was able to bring study build resources in-house and reach the milestone of all new study starts on the platform. The team is now continuously improving the platform by activating additional capabilities and collaborating with Veeva to pull in new features introduced with each of the three-yearly releases.

As a next step, the sponsor is in the process of changing the operating model to bring more data management operations in-house. Currently, the company has service partners performing data management activities on its Veeva Clinical Platform, with the goal of transitioning those tasks to in-house teams. This will give the sponsor more control over its data management activities and support a centralized data review strategy to reduce the effort and time to clean data.

This transformation is an example of successful change management. Rolling out new clinical systems to all therapeutic areas requires a considerable effort to achieve the desired adoption. The sponsor used change champions as a single leading voice on process development and a point of contact for the rest of the team during implementation. This approach enabled a smooth roll out for study teams using the platform for the first time. Change champions are now being adapted for the in-housing of data management to facilitate the transformation.

Key Insights

Consider deploying new technology and processes in phases

Change champions are critical to developing process and communicating internally

Learn by doing – start with early adopter studies and library builds and use that experience to define SOPs

Transformation requires leadership and careful planning

Conclusion and next steps

Don’t let the fear of change restrict your company’s ability to gain platform efficiency today and lay a foundation for growth. Contact your Veeva Account Partner to discuss what agile implementation of a clinical platform would look like for your organization.

Get in touch to discuss your organization’s adoption plan.

Veeva

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