The 5 Hallmarks of an Agile EDC

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What is Agile Design?

Agile Design is a modern approach to building data collection casebooks that addresses many challenges with the traditional EDC build process. Using modern technologies and new capabilities that support best practices, we can solve common issues and delays inherent in legacy EDC systems, such as the inefficient back and forth when reviewing a specification or performing UAT, and the reliance on custom functions.

> **Agile Design is predicated on a vision to empower data managers and cross-functional teams to work together more collaboratively and efficiently toward continuous improvement.**

While no one can predict all the requirements of a given study nor the exact changes that may be needed later on, technology can prepare for the types of requirements and changes by providing flexibility at the foundation so that these idiosyncrasies don't derail the study build or execution. With the right capabilities, an Agile EDC system makes the study build process faster and study amendments easier to manage.

Veeva EDC is the only EDC system built with Agile Design principles from the start and can handle all types of clinical studies – from the quick and simple to the most advanced.

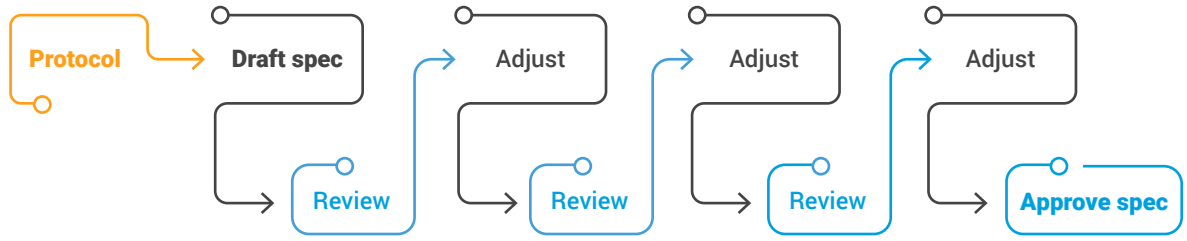
How can you tell whether an EDC system is built on Agile Design principles? It allows you to build the study you want to run with optimal efficiency and *makes your organization more agile too.*

The five hallmarks of an Agile EDC

There are certain capabilities you should look for when evaluating an EDC to determine if it will increase your organization's speed and agility. Here are the top five indicators of an Agile EDC system.

1. Ability to "spec in the system"

One of the major drawbacks to existing EDC systems is that the process of creating a specification happens entirely outside of the system. Traditionally, a data manager takes a protocol and translates its requirements into a specification. That specification must be reviewed and approved by the study team and is then given to clinical programmers who build the study.



Example of a typical back-and-forth process a study team goes through to create an EDC specification from a protocol. Each review cycle can extend up to several weeks and often lasts as long as the slowest reviewer.

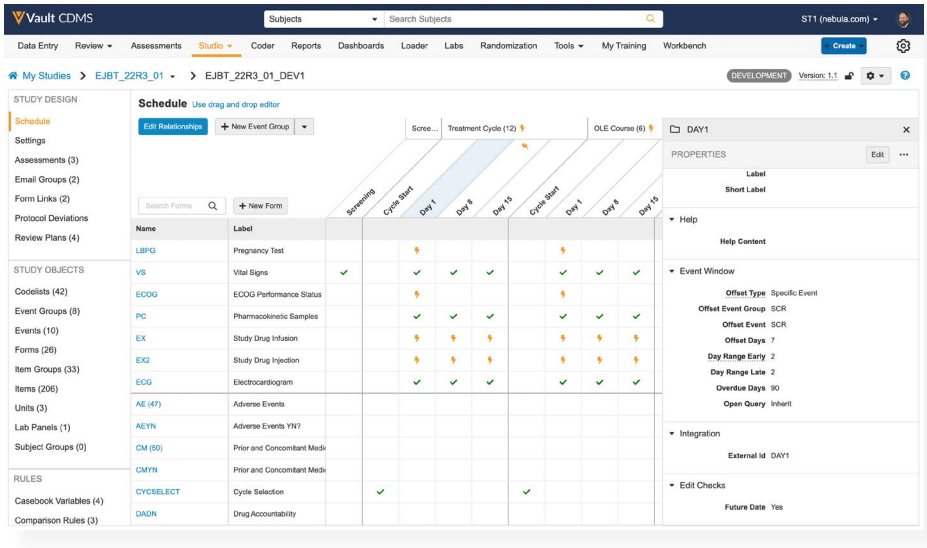
The inherent problem with traditional EDC systems is that they don't empower data managers to build studies themselves, hence the need to translate protocols into programming specifications. Veeva EDC solves this problem by providing a Specification Studio that makes it easy for someone to configure most of a study, even if they cannot write code.

The Veeva EDC Specification Studio ("Studio," for short) provides a dynamic, drag-and-drop interface that has abstracted the parts of a study into components that can be manipulated as needed. Abstracting and modeling the study as components – not as code – allows study designers and cross-functional study teams to shortcut the process of creating, reviewing, updating, and finally approving a spec. They can use the components in Studio to *build* the spec.

Vault stores these specifications as study metadata. That study metadata is also used to produce the live study in Veeva EDC. In doing so, the specification and execution metadata are one-and-the-same. People reviewing the specifications can do so with Vault's auto-generated study design spreadsheets and annotated PDFs, or within the EDC system itself.

This allows those most familiar with the study requirements and the data to become study builders directly, without having to translate the protocol into an external specification for clinical programmers.

The Specification Studio makes it easy for someone to configure most of a study, even if they cannot write code.



Screenshot of Veeva EDC's Specification Studio, where data managers can use a drag and drop interface to create, review, and update a study.

CASE STUDY: ALCON

When Alcon, a global company specializing in eye care products, adopted Veeva EDC they were able to take advantage of the Specification Studio to empower their data managers and speed up their study build.

"We [enabled] our data managers to develop the clinical databases. That allowed us to eliminate a spec process which took time and iterations between two different skill sets."

Leianne Ebert, head of data management, Alcon

The two skill sets she mentions are the data managers' expertise about the study itself, such as how it should be run and what data was required, and the expertise of clinical programmers, who were necessary to successfully build studies in their legacy system. By using the Veeva EDC Specification Studio, they were able to redirect their clinical programmers to other priorities, such as their Standards Library.

"The more experienced data managers build rules themselves. We [programmers] help the less experienced data managers and mentor them on the best way to complete a task. We're also working on our standards to minimize errors and complete a good library of forms and rules to pull from."

Clinical programmer, Alcon

The data managers at Alcon also appreciate their new ownership of the study builds.

"In the time it takes to write and review a spec, we can build the database by ourselves. Data managers work with data concepts and the clinical team on a daily basis, which makes it easier for us to design the CRFs and build the database."

Program data manager, Alcon

This new agile approach helped Alcon empower its employees to contribute according to their highest value. After adopting Veeva EDC, 100% of their data managers indicated they preferred the new system.

2. A true standards library

A key aspect of making it possible for data managers to "spec in the system" is the availability of a true standards library. Leveraging standards is valuable within an Agile Design process because it enables the study designer to focus on the protocol and study-specific data requirements, rather than re-writing specs for forms that are "standard" across studies. Many organizations fail to take full advantage of data collection standards because they can be hard to enforce and maintain.

Many EDC vendors claim to offer a "library" when they only really provide form reuse. These fake libraries lack the classification and organizational structures that help users find the appropriate forms. Veeva EDC provides a true library for the creation, curation, and sharing of EDC standards, including capabilities such as:

- A dedicated environment for standards managers/librarians to design, review, and approve the standards that function as templates for EDC study designers.
- Case report form (CRF) classification structures such as therapeutic area, study phase, country, and more, that make it easy to locate study-appropriate standards.
- Usage tracking and reporting for the study objects themselves. If a standardized form is modified for a study, the usage and deviation are tracked. Usage and deviation data are aggregated across all studies to give librarians the information needed to establish the standard's value to the business, identify which need enhancements, and how they should be modified.

Another limitation of many EDC standards libraries is that standardized form templates are limited to form definitions and cannot include dynamic rules or advanced edits such as cross-form edit checks. This typically means additional work is needed to use the standard in each study. This duplication of work is inefficient and increases the risk of standards being altered or ignored from study to study. Ideally, you should be able to develop standards into your EDC one time and then incorporate those standards to every relevant study in that system.

However, standards cannot be overly rigid either, as there may be variations or exceptions that exist for a specific study. The question then is how can we save effort by having global standards, but still allow adjustments as necessary to stay agile?

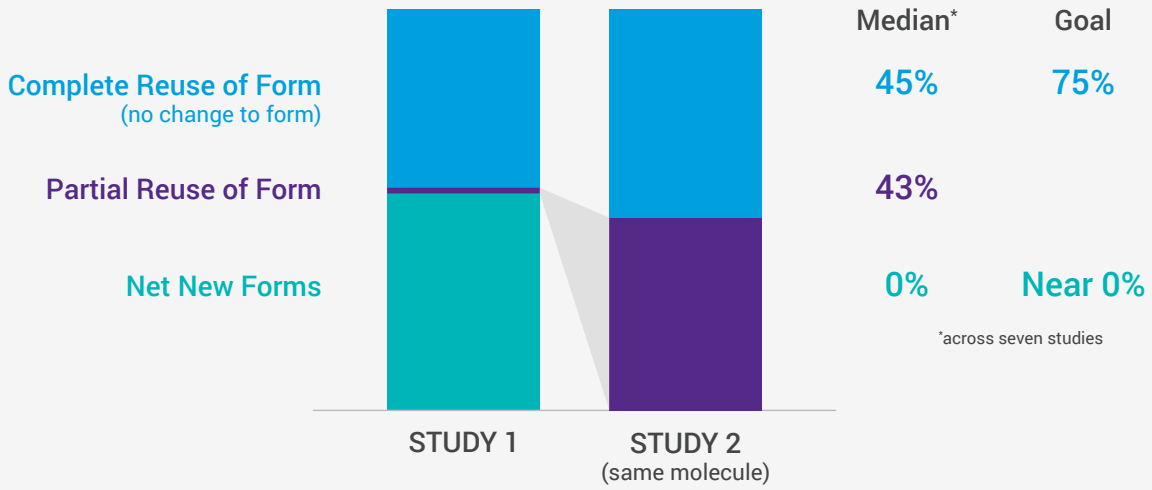
With Veeva EDC, each new study can inherit its baseline forms from a global standards library. When a new CRF is created from a template, it will inherit the rules and controls from the template, and standard values can be modified at the form level to handle any study-specific requirements.

When study designers make changes and potentially deviate from standards, it is important that the system identify these deviations to ensure appropriate review and approvals are obtained. Veeva EDC's library and differential reports provide clear and efficient ways to identify deviations from the standards, including exactly which properties are different. Veeva EDC uses change control mechanisms and best practices to prevent unintended deviations that can result in additional downstream programming costs or, worse yet, errors in analysis.

Maintaining a library of established, reusable, and adjustable standards saves time and helps study designers build the casebook directly within the EDC using the library and the protocol as the primary inputs.

CASE STUDY: VERTEX

Vertex used a pre-existing standards library to create a new standards library and casebook template in Veeva. Using the templated case report forms (CRFs) greatly improved build efficiency – helping the team cut expected build timelines in half. All but one of the forms for the first two studies were completely or partially reused from their templates.



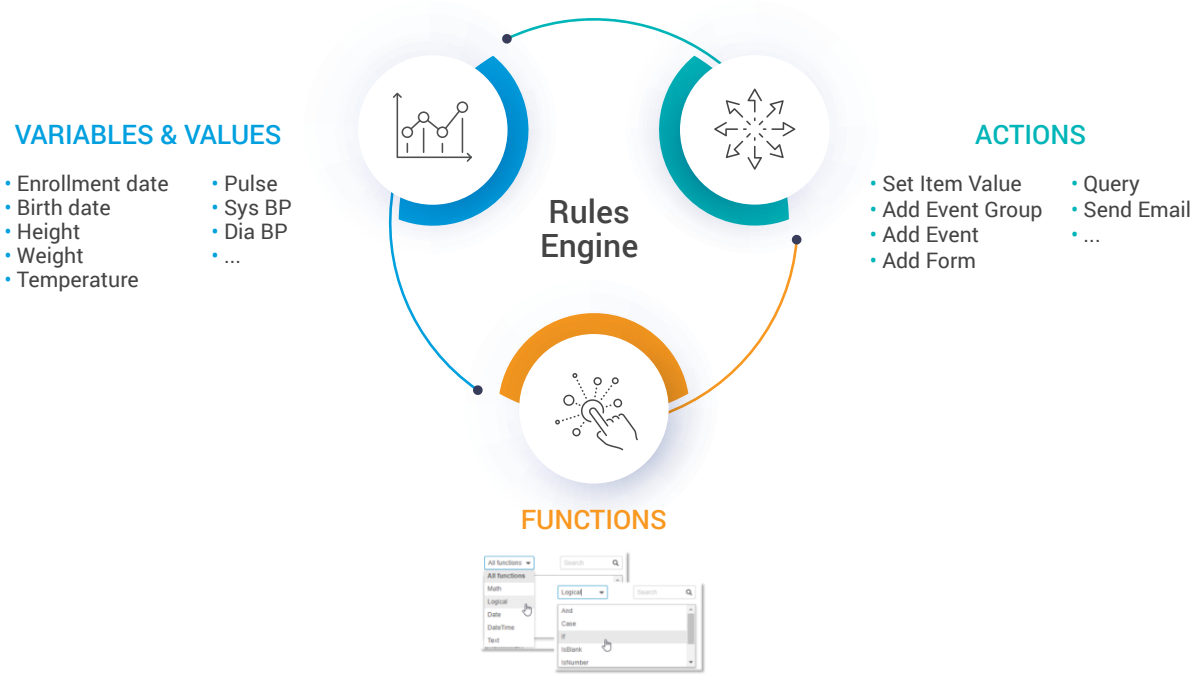
"Partial reuse" or modifying the template study forms increased from <1% to >48% between the first and second study of one molecule.

3. Rules and edit checks without custom functions

Custom functions are one aspect of legacy EDC systems that cause more problems than they solve. Custom functions are programs that must be created to compensate for the limitations of the EDC system. The workaround code is the responsibility of the Sponsor or CRO to create and maintain and not the EDC vendor. Because they are written outside of traditional EDC systems, custom functions are difficult to create, test, and maintain, especially if changes are made to the EDC system or the study at any point after the custom function is applied. Any modifications to the system or study may require a full review of every custom function applied to ensure that the new changes don't break them. Although they are necessary to "fill in the gaps" of functionality in legacy systems, they increase the risk of disruption to the study as it changes and evolves over time.

> **The real difficulty in building a study lies in the edit checks – that's where you require a programming background. But that's not needed with Veeva EDC. If you know how to use Boolean logic and if/then statements, you can write edit checks in Studio. It is very intuitive and easy to use.**
>
> **Harbal Sidhu, senior manager of clinical data systems, ICON**

The answer is to get rid of custom functions altogether. How? By incorporating the capabilities served by custom functions as standard features within the system. Veeva EDC achieves this through its advanced rules engine and more robust native features within the system.



The rules engine uses pre-defined variables, functions, and actions to help users script their own rules and dynamics.

Veeva EDC's rules engine can perform a large variety of tasks based on conditions and entered values, represented as variables/values, functions, and actions. Any unique combination of these three components constitutes a new rule. These rules can then be applied where necessary as business logic or edit checks throughout the system. This is a core underlying mechanism that enables Veeva EDC to provide myriad capabilities that previously could only be addressed with custom functions.

Needing a custom function for every aspect that doesn't quite fit in the system causes a lot of delays, not just for the build but for validation and when making changes. Using the rules in Veeva EDC as opposed to custom functions is a big game changer for us. It makes complex designs easy to program.

Tanya du Plessis, vice president of data strategies and solutions, Bioforum

With the rules engine, data managers and programmers can create the unique rules and processes specific to each study without writing any external code. This eliminates the risk of running custom programming outside the system, which may break during regular software upgrades or amendments to the study. The rules engine is a huge advantage to study teams, because they can confidently uptake new features, fixes, and changes to their study without worrying that their custom functions, and consequently their studies, will be put at risk.

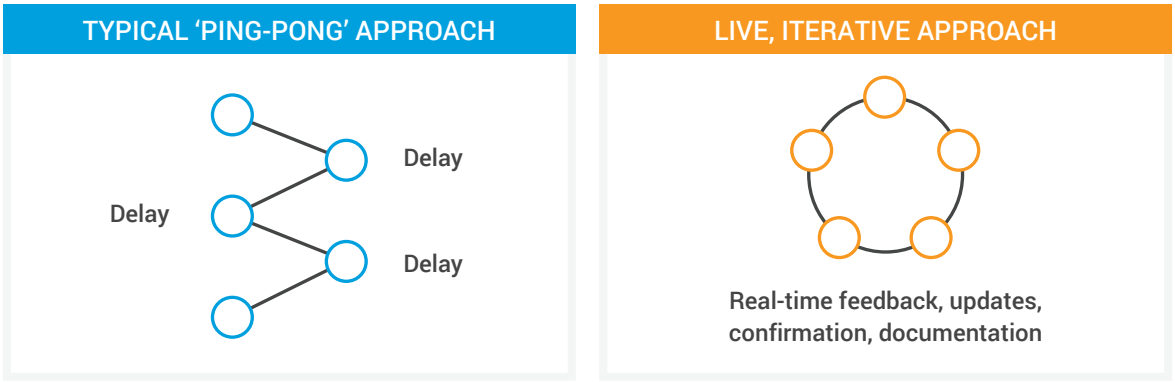
Study designers can also define the logic that drives dynamics and automation within the rules engine. Built-in dynamics are critical to creating more agile, flexible casebook designs within your EDC system. For a study with multiple arms and treatment cycles, traditional methods would require data managers to pre-build every single event for each arm and treatment cycle. In Veeva, the treatment cycles, visits, forms, and edit checks can

all be dynamically generated for each different study arm. Rather than building 20 unique events across five unique arms, you can build fewer master definitions and Veeva EDC will use dynamic rules to automatically execute the others as required.

This reduces manual work involved in study startup, but also empowers the study team to make multiple changes throughout the course of the study with minimal effort and no delay on the build side.

4. Interactive design reviews and UAT

Traditional user acceptance testing (UAT) suffers from many of the same problems as the traditional specification writing process: constant back and forth between the study team and the clinical programmers who build the database. Often the process would take a similar format to the specification writing process:



On the left, an example of a typical back-and-forth process a Study Team goes through to complete user acceptance testing for a study build. Each delay could be several days or up to several weeks between each step. On the right, an example of a live, iterative UAT process with real-time feedback and updates to accelerate the review process.

However, the process in Veeva EDC is dramatically improved, thanks to the ability to make and review changes in real time. This streamlined process leads to accelerated user acceptance of forms because reviewers can interact directly with the system and see the actual forms and behaviors, rather than deciphering descriptions in the spec document. Instead of a long back-and-forth process, study teams can test and make changes or corrections immediately during the review.

> **Live UAT updates are a game-changer. By providing feedback, fixing problems, and testing updates immediately, we can eliminate three to four weeks from our timeline. A recent UAT was completed in just two days.**
>
> **Vikas Gulati, executive director of clinical data management and metrics, Vertex**

The live testing process can also support higher-quality study designs. Not only does the study team get to interact with the actual system – they also get to review it together, leading to critical discussions and debates between team members. When reviews are done asynchronously, people don't benefit from hearing each other's observations and perspectives. Working together in real-time allows teams to discuss proposed changes and ultimately arrive at decisions that are better and longer lasting.

Just as with the design process, the ability to create and test the casebook within the system can eliminate the back-and-forth that used to be required between testers and clinical programmers. Now testing, just like spec'ing, can be done live, collaboratively, and expediently.

Working together in real-time allows teams to discuss proposed changes and ultimately arrive at decisions that are better and longer lasting.

Traditional UAT processes also lump together the form acceptance and functional testing processes. Forms will inevitably change, requiring costly re-work to update existing edit checks and custom functions. Veeva splits this process, allowing teams to get acceptance of real forms first, before configuring edit checks and dynamics – keeping re-work to a minimum when changes occur.

5. Amendments made easy

Agile Design is not just limited to the process of creating specs and testing the casebook. It also applies after a study is live.

Veeva EDC makes it easy to change your casebooks, whether it's during the design process or after your study has launched. You can deploy fixes and improvements as you go. Each change is seamless, sites are not impeded from data entry, and your organization were able to adjust, pivot, and improve as necessary.

Since there are no custom functions, they don't need to be retested when casebook changes are made. Additionally, Veeva EDC provides an auto-generated Study Differences Report that shows everything that has been added, removed, or modified between versions. This report eliminates the need for regression testing. Only the items that are new or modified need to be tested and verified.

We did 11 post-production changes with no downtime or migrations.

Evelyn Dorsey, director of data management, Cara Therapeutics

This agility gives control back to the sponsors, CROs, and sites, rather than forcing all stakeholders to wait on the limitations of their legacy EDC system. Eliminating these headaches will improve data integrity, site relationships, and facilitate study completion.

Implementing amendments is faster with Veeva EDC due to the significant reduction in testing required.

The impact of Agile Design on EDC

Better user experience

Overall, the Agile Design process provides a more efficient and enjoyable experience for everyone involved in the build.

Data managers are empowered to build forms directly and have greater control over how casebooks are designed and run, rather than relying on clinical programmers to interpret their needs correctly. Programmers focus their valuable time on tasks where specialized skills are required. Study team members review and test the builds instantly – gaining a better understanding of what will and won't work to achieve their intended goals. Each member contributes their expertise where it matters most and gains more time for activities that relate to the quality of the study and its data.

Faster build cycles

Customers who have adopted the Agile Design process report dramatically faster build times. After a couple of studies, many achieve an improvement of 50% time savings over their average build times in other systems.

Faster builds are achievable because:

- Reuse of standards and templates remove duplication of effort from study to study.
- Data managers build, model, test, and update their specifications directly in the system, eliminating the back-and-forth process that used to cause significant delays.
- Most rules and edit checks are created with the rules engine, not custom functions, which removes complexity and simplifies testing.

Each item can produce noticeable time savings on its own, but collectively, the time savings grow significantly. As users get accustomed to the system, these gains continue to increase.

> **Agile Design really does make a difference. The whole build process is much faster and much easier for everyone involved.**
>
> **Jennifer Neumann, director of clinical data management and programming, Kronos Bio**

Promote collaboration, consistency, and visibility

Because specifications can now be recorded within the system and not outside of it, study teams are able to collaborate, build and test a study together much more efficiently and with higher quality. UAT with Veeva EDC has gone from weeks to just days, finding solutions to problems collectively, rather than relying on an inefficient back-and-forth process.

Leveraging global standards also ensures there is consistency across studies, while still supporting exceptions as needed. Visibility into change requests on standards allows data managers to consider the validity of their standards over time and improve them as time goes on. The global standards library provides a reliable backbone for protecting data quality, reducing the data validation volume later on, and generally providing better outcomes for the study.

Conclusion

Today's studies are more complex and demand an EDC system that can adapt quickly and easily to changes and new requirements that arise regularly in clinical studies. Veeva EDC was designed to address the historic challenges with legacy EDCs and enables a collaborative build process that is faster and produces higher quality, more flexible casebooks. Agile Design principles address the dynamic nature of today's studies and handle every study's unique requirements.

Learn more about Veeva EDC.