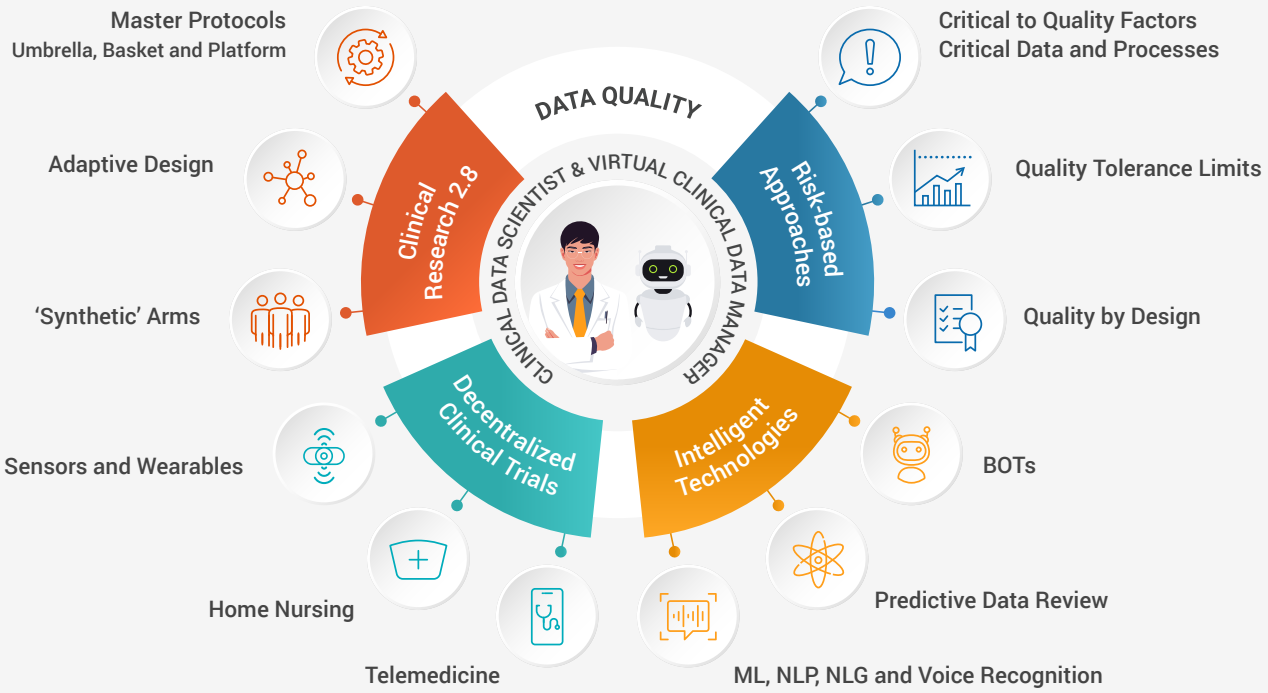
5 Hidden Data Management Issues that Decrease Clinical Capacity

Clinical data: your technology stack and the drug development cycle

The life sciences industry is evolving. Organizations are grappling with more data than ever before due to scientific and technological advances — wearables, ePRO, genetic biomarkers, and more — as well as innovative strategies like adaptive trials that require faster, ongoing data analysis to reach key clinical insights more efficiently.

Data managers are actively preparing for this shift. The Society for Clinical Data Management (SCDM) calls it "a second evolution" in the data management profession, the first being the adoption of EDC systems nearly 20 years ago. SCDM recommends that data managers evolve into data scientists to support the future of patient-driven clinical research.

DRIVING FORCES BEHIND THE EVOLUTION TOWARD CDS



SOURCE: SCDM: The Evolution of Clinical Data Management into Clinical Data Science (2022)

Teams that fail to adjust during this critical tipping point in data management will fall behind their peers at other biopharmas, experiencing:

- Delayed clinical insights
- Increased costs to execute clinical trials
- Overall decrease in clinical capacity

These consequences are even more critical for emerging biopharmas that have less resources than established organizations. The ability to efficiently identify and analyze clinical insights during clinical trials empowers teams to make the most out of their limited budgets.

Empowering your data managers to make the shift toward data scientists starts with your technology stack. The data management team already has a full workload, often made worse by manual workarounds and custom programming required to fulfill requirements in legacy EDC systems. You can free up time by removing what they were doing to compensate for shortcomings in older tools.

Below, you'll see examples of hidden bottlenecks in data management — and how organizations like yours have eliminated them to reach milestones and clinical insights more efficiently.

Common bottlenecks in data management and how to fix

01 Relying on custom programming

Data managers and clinical programmers can prop up the functionality of traditional EDC tools through programming custom functions. Many teams rely on custom programming to achieve their desired study design. For one recent study, a CRO spent more than 1,100 hours to build and test 200+ custom functions. Depending on the billing rate, that's upwards of $100,000 in build costs for the sponsor.

But the more custom programming required, the more time and cost you will spend on building, testing, and maintaining the programming — especially if you are working with a CRO to execute your study.

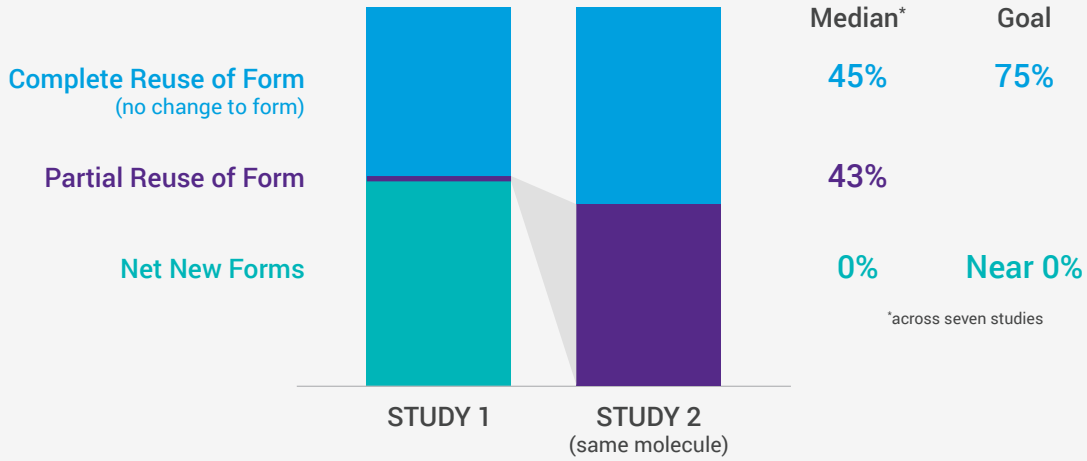
> ***"Custom programming is always a challenge. We don't have the in-house resources to support that."***
>
> **– Deepak Mahadevaiah, Agenus**

Understand the realities of your toolset, and seek to do as little custom programming as possible to support your study. Work with your CRO to identify alternatives that will reduce or eliminate custom programming headaches.

Lotus Clinical Research decreased study startup by 67% with Veeva CDMS. Learn more.

02 No long-term planning for standards and libraries

Without standards and libraries across clinical data, your team will essentially start every study from scratch — building everything from the ground up. If you (or your CRO) are working across multiple different platforms, this will lead to even more manual work and delay study start up time.



Vertex created a new standards library and casebook template in Veeva to make study builds more efficient. The team cut build timelines in half and was able to completely or partially reuse all but one form by their second study. Learn more.

Document study standards and libraries, and ensure your team uses them. If you're working with a CRO, make sure you communicate these standards so they can build studies on your terms.

Standards and libraries are not just for established organizations. Even if you are starting from scratch, your team will still see efficiency benefits after one or two studies. Veeva simplifies the journey from studies to standards, and makes it scalable.

Eli Lilly uses Veeva CDMS to build and maintain their standards library. Learn more about their standards library best practices.

03 Lack of rules and dynamics

Platform Life Sciences conducted a large outpatient COVID trial with 14,000 patients and 12 interventions. At this scale, the manual workarounds required by a traditional EDC system were holding back the study team from getting to critical insights in a timely manner.

> ***"We encountered multiple inefficiencies and inability to move fast."***
>
> **– Michael Zimmerman, Platform Life Sciences**

PLS adopted an agile clinical data model that could support studies with multiple arms, multiple amendments, and drugs across multiple geographies — all without custom functions.

Veeva Vault EDC's **powerful rules engine** uses pre-defined variables, functions, and actions to replace custom functions. Users can create rules to automate tasks, create business logic or edit checks, and dynamically generate treatment cycles, visits, forms, and edit checks.

With the rules and dynamics built-in to Veeva, your team doesn't have to worry about custom functions breaking whenever you have updates during the study. You'll save time on study build, but also prevent unexpected delays when studies change.

Learn more about why PLS chose Veeva Vault EDC.

04 No interactive design reviews or risk-based testing (UAT)

Testing is a key part of the study build process, but it can cause delays — especially in complex, branching trials where hundreds of possibilities need to be validated before study launch. Your team can streamline the testing process by focusing on new elements of your study only.

> ***"With Veeva's Study Differences Report, we will no longer need to UAT standards that haven't changed from one study to the next."***
>
> **– Vikas Gulati, Vertex**

Taking a risk-based approach that identifies pre-approved study elements and removes them from testing efforts can help you get studies up faster.

Plus, Veeva offers an interactive UAT process that allows your team to test and make changes together. Collaborating via email or spreadsheets is like a game of telephone: the true meaning of feedback can get misunderstood, leading to unnecessary edits and a lengthy review process.

Doing design reviews together in the system allows for your team to see the study in the proper environment, have better conversations about feedback, and make decisions — and improvements — faster. You'll not only reduce specification errors and testing with Veeva, but also see better quality study builds.

Veeva's agile, interactive UAT process helped Vertex reduce study build and release times by over 50%. Learn more.

05 Downtime during amendments and migrations

Protocol changes are inevitable. The early changes cause delays in database builds and can even delay the EDC go-live until after FPI. Post-product changes create high-stress work for your data managers and potential down-time for your sites

> ***"In adaptive trial design, amendments are going to happen… it causes a lot of anxiety, not just for data managers, but our end users at the sites due to downtime and other real annoying factors."***
>
> **– Tanya du Plessis, Bioforum**

Rather than striving to eliminate amendments and migrations, you need to make them work better for everyone. Get input from users and work with data management to build a process that causes the least disruption for all parties, ideally with no downtime.

Veeva Vault EDC has simplified amendments to help organizations become more agile. With push-button, no downtime amendments, you can make more changes to the study design, while eliminating costs and manual work — both during the initial study build and subsequent amendments.

Cara Therapeutics made 11 post-production changes with zero downtime on migrations. Learn more.

Increasing efficiency with technology

Every organization is different, and your team may not need support in all of these areas. Ask your team where things could be improved — they'll have ideas, and then you can work with them to implement.

Technology is a key element of data management, and creating a better foundation can help your team work more efficiently. The world's top sponsors and CROs trust Veeva Vault EDC to support complex studies, while eliminating custom programming and downtime during amendments.

Learn why emerging biopharmas choose Veeva for clinical data management. ➔