How a Risk-based Approach to UAT and Real-time Updates are Shaving Weeks off EDC Study Builds

Veeva and Vertex talk about the opportunity for UAT process and technology innovations to reduce database build times.

User Acceptance Testing (UAT) is the second most common cause of database build delays.[1] Running your existing process more efficiently may save a few days on a study, but to shorten your build and release times by a few weeks, the UAT process must change.

Using an Agile Design methodology, Veeva cut the study build and release time for Vertex by over 50%. Much of the time savings resulted from implementing an interactive UAT process with real-time updates. During their first two study builds, Veeva and Vertex discussed how a risk-based approach to UAT could save additional time and effort. This whitepaper reflects the conversations between Vikas Gulati, executive director of data management and metrics at Vertex Pharmaceuticals, and Richard Young, vice president of clinical data strategy at Veeva, discussing four ways to reduce the burden and duration of UAT for EDC systems.

As an outcome of this discussion, Vertex and Veeva established the following key performance indicators for study start-up and protocol amendments:

	2018*	2019	2020
EDC study build (protocol to database release)	13-14 weeks	6 weeks	4 weeks
Protocol amendment (including contract updates)	1-2 months	2 weeks	1 week

* 2018 numbers reflect the typical durations prior to Vertex working with Veeva Vault CDMS.

[1] Tufts Center for the Study of Drug Development, Impact Report vol. 20, No. 3, "*eClinical data volume and diversity pose increasing challenges and delays,*" 2018.

No UAT for Approved/Validated Database Elements

Richard: One place where we can really save time is in reducing the number of forms and edit checks that require UAT. Ideally, if you test a form or an edit check in one study and re-use those elements in the next study, you wouldn't need to UAT them again.

Vault CDMS delivers a fully productized "Study Differences Report" that shows exactly what has changed between one study version and another. Wherever we can prove that nothing has changed from one study version to another, you should not need to test them again (assuming of course, the original source is a tested/validated environment).

Vikas: Your differences report was particularly exciting for us because re-use in our case report forms (CRFs) is such a priority. A key part of our approach to building studies is using standards. We have an extensive, well-governed standards library and encourage as much re-use as possible. That helps on quality and consistency but didn't save us time on UAT because there was no validation that a change hadn't been made.

With Veeva's Study Differences Report, we will no longer need to UAT standards that haven't changed from one study to the next. We are very excited for how it will reduce the number of checks that need UAT and the overall UAT burden. This is a prime example of technology enabling a process change. The differences report in Vault CDMS plays a critical role in changing an acceptance process that has been stagnant for decades.

Object	Object Type	Field	Difference	Study A	Study B
			Same		
			Same		
			Same		
			Same		
			Deleted		
			Deleted		
			Deleted		
			Deleted		
			New		
			New		
			New		
			New		
			Modified		
			Modified		
			Modified		
			Modified		

The Study Differences Report documents what has been added, removed, changed, or remains the same between two studies or following a study amendment.

> 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 Pharmaceuticals

Testing Some Edits Checks Outside of the EDC

Vikas: In general, our teams have anywhere from 300 to 500 edit checks per study that are programmed. And I wonder, do we really need 100% of those edit checks performed in the EDC?

We absolutely need quality, but most edit checks never fire. Some checks will only ever be used once, for example when you receive your external data as a single transfer at the end of the study. So, can you take a risk-based approach and move some subset out of the EDC? Checks performed within an EDC have significant overhead when you consider all the cross functional teams reviewing them. You need to explain what the checks are and how they run, write appropriate dummy data, and wait for reviewer comments. The more people involved, the longer it takes. We need to make sure the effort matches the reward.

I'm investigating whether can we save time and resources if some of those checks are delivered in a different way. Which of the checks can data management and the vendor handle? Which can be run as listings, in other tools, or in JReview just looking at the raw data?

Richard: Could the Differences Report help here by reducing what needs to be re-tested?

Vikas: The Differences Report will save re-testing forms and checks from one prior study, but there will be other checks in our library, that don't typically fire, and weren't in the comparison study used for the Differences Report. In these cases, a risk-based approach may still make sense.

You see, as part of our process we are double and triple testing everything—developers are testing it during validation, QA is looking at it, Vertex data management is looking at it, plus all the other functional areas. So, there are multiple layers of checking happening. I'd like to change our UAT to be more of a risk-based approach, rather than enlisting every team to review every edit check.

Richard: To accurately assess the risk level of an edit check you need insights into what fires and what doesn't. To that end, we've productized a set of reports that show the effectiveness of each query. These are real-time views into your KPIs, such that your team can evaluate decisions from one study to the next, refining their approach each time.

40% faster
than their typical
13-14 week builds

Making Strategic Use of Protocol Amendments

Vikas: There is another risk-based opportunity within UAT and that is going live with the vast majority of your edit checks tested and using an amendment to incorporate any changes resulting from the UAT of the few remaining edit checks. Completing 100% of testing before FPI is certainly ideal, but our data shows there is usually a subset of checks that take more time and add delay. In reality, there is an amendment and change order in virtually every study we do. And the number of changes per study is going to increase with personalized medicine and as adaptive studies become more prevalent.

When a change order is coming and the stat checks are complicated, holding off until the first change order gives you time to develop thorough testing. We used to say we need 100% SDV and now we take a risk-based approach. We can think more pragmatically about UAT checks as well. Instead of blindly assuming "I need 100% of the checks complete before going live," we can evaluate what's in the 90% we want to go live with and what's in the 10% that deserves more time?

Richard: I think the fear of amendments is in many ways a result of technology limitations and the enormous cost of database migrations and taking the EDC offline. If your EDC can make changes with minimal effort and no downtime, then amendments can be treated as an opportunity to load-balance your UAT efforts.

Vikas: Most pharmas and CROs treat change orders like something to be avoided at all costs instead of as an opportunity. I think we can use change orders strategically as part of a risk-based approach to UAT and shorten timelines for the build.

Richard: In my mind, I separate those two things "change orders" and amendments or other changes to the database. There's the process of changing the database, and then there's the contractual piece, where there is a change order and incremental cost from your CRO. I think there's a chance here for our industry to change our expectations for that process.. If you accept the volume of work gets shifted slightly to the right, why is there a financial implication? Certainly, if there is a major redesign because of an amendment, a change order is appropriate. But, if we accept that 10% of the work will occur after first patient first visit, why should there be a change order? Load-balancing your UAT is a process improvement that is held back by traditional contract agreements.

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>
> – Richard Young, Veeva

Vikas: Agreed. It represents a process evolution that would need to be reflected in the contract. This part of risk-based UAT re-defines what an EDC build could look like. We could define the process to include the first 90% before go-live, and the remaining 10% as an amendment but not a change order. And that would be the full build. Anything subsequent would entail payment for a change order. If there is no process, technical, or financial penalty associated with making a change, we can adopt a more agile process with a shorter overall timeline.

Moving from Ping-Pong UAT to Live UAT Roundtables

Vikas: Another major time-saver is moving away from the ping-pong approach for UAT to a live roundtable approach for UAT. Traditionally, there is lots of back and forth. The vendor does a UAT, sends us the database. We do our UAT, send them comments. The vendor makes the updates, sends it back to us and we do another round of UAT. And it takes a while to get comments from all the different stakeholders, so each of these ping-pong exchanges lasts a one week or two.

With Veeva performing our builds, we have an interactive roundtable approach to UAT. As we are reviewing and providing feedback, the software is getting updated right then and there. We can communicate our feedback and test the updates in real-time. Live, interactive UATs are a game changer, saving a good three to four weeks from our timeline.

Richard: This is another process innovation enabled by technology. Veeva provides an Agile Design approach that allows for collaboration and rapid iteration. Changes in Vault CDMS are immediately reflected in the user interface; and the system automatically generates a "spec" documenting the current design, so you don't need to manually document the desired change before it gets made. These real-time updates and automated specification documents minimize the overhead and delays associated with design changes.

It works just as well when a CRO is involved. People can come together in a physical room or in an online meeting. The whole point of the process is to bring all the stakeholders together, make decisions, and fix things immediately, not a week later.

½ prior target
of 12 week build times

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Vikas: My colleague, Michelle Harrison, pointed out that during UAT for the first Veeva build, we had trouble keeping up. At one point, we had completed what was typically three rounds of UAT in about two days. Just as soon as we had provided feedback, it was already incorporated and we were QC'ing and double checking again.

Richard: We should have done a better job of setting expectations for that first study since the approach was so new and different. By the second study, both teams were aligned and committed to the timelines. Once people saw how much faster the process could move, they seemed eager to adopt the new approach.

Vikas: We are lucky that innovation is part of the Vertex culture. While it is a large company, employees are encouraged to innovate. We're constantly looking for ways to do things better and faster, while keeping our quality or improving it. Innovation is key and that's one of the reasons we partnered with Veeva. We consider this a partnership and look forward to the journey.

The above discussion was drawn from conversations between Vertex and Veeva throughout the early part of 2019.

Looking ahead: Of the four UAT strategies discussed in this paper, only the live UAT roundtables contributed to achieving six- and eight-week study builds in their first two studies. The companies anticipate additional time savings once the Study Differences Report and risk-based approaches are adopted.