



Fast and Successful EDC Study Builds with Veeva Vault CDMS

By Janine Del Vecchio, Insmmed Incorporated

You may think that late-stage changes to a study are the exception and not the rule, but if you poll data managers, you'd probably find that last minute requests are the norm. You can almost anticipate you'll face protocol changes and/or CRF design changes and just have to manage.

During our first study build with Veeva's EDC there was a late-breaking shift in strategy. Our Phase II, early stage feasibility study in a new indication turned into the program-leading first trial. As we were finalizing the database build, the MDs recommended that we establish data collection standards for the new indication—starting with this first study.



Janine Del Vecchio
director of data management
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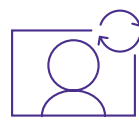
Success Highlights



30 eCRFs,
22 built directly from
the protocol



Rules and edit
checks completed
within one week



Integration with
Suvoda for IVRS



UAT completed
in 7 days

/// *It was a total change in mindset and late in the game.
It would be a crunch to maintain existing timelines.* ///

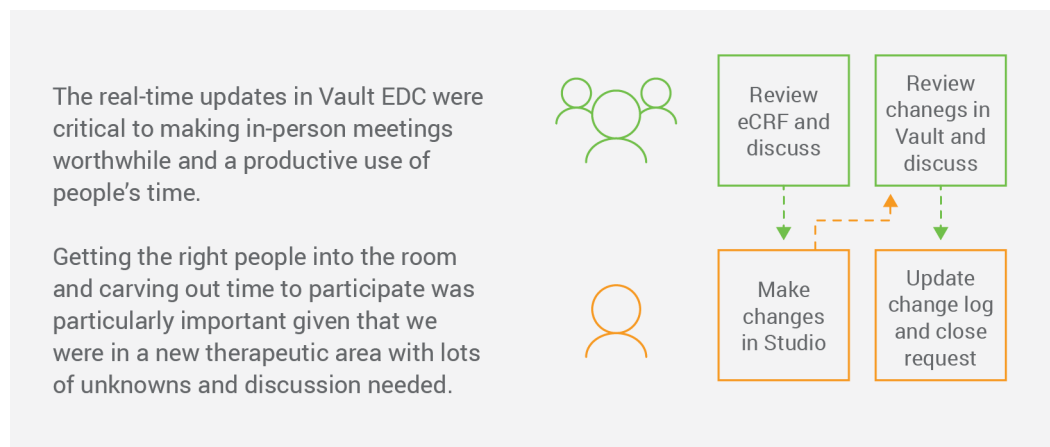
Given the new challenge, we were thankful that our Veeva team was so dedicated and responsive. They never left our side and dug in deep to immediately address each requested change. In a time like this, it would have been easy to panic and make silly mistakes. Instead, everyone was executing beautifully.

INSMED – AT A GLANCE
 Headquarters: Bridgewater Township, NJ
 Year Founded: 1998
 Employees: 400
 Global Presence: 7 Countries
 Ticker Symbol: INSM (Nasdaq)

The People, Processes, and Technology that Made it Possible

The onsite development of case report forms (CRFs) was particularly helpful. We got to see in real time, what the proposed changes looked like. There was lots of back-and-forth between the Insmed functions, “Is this what we want? No, could we make it look like this? Oh, well, on second thought... let’s make it this way.” All of that was implemented right in front of our eyes, which was extremely helpful to making decisions and hitting our deadline. Veeva contributed ideas and made recommendations during these discussions; their first-hand clinical experience and expertise designing CRFs proved invaluable.

An Interactive Design Review Meeting with Real-time Updates to the Study



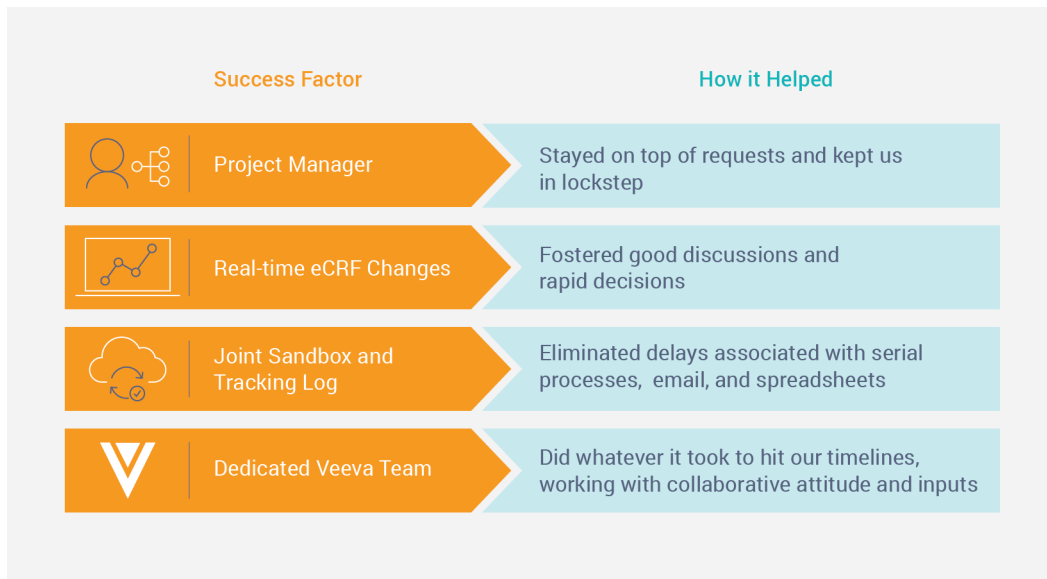
Veeva’s lead configuration specialist was a data manager herself, which was demonstrated by her sound advice. Her input was highly regarded and sometimes a tie-breaker. Our objective was to develop CRF designs that would make data collection user friendly and avoid confusion for our sites. Sub-optimal data collection designs can at times be the outcome when EDC programmers work strictly from specifications, therefore having a team that understands data management was really awesome and helped us achieve our objective.

Throughout the development process, we were in close communication with Veeva. Rather than use email which would have been difficult to keep track of the entire picture, we kept a shared CRF change log. Our team used the log to specify requests and Veeva used it to implement the updates or request clarifications and track completed work. We also had direct access to Veeva’s development sandbox, so we could review and approve the updates as work progressed. The shared view allowed both teams to move quickly and kept us in lockstep regarding what had been implemented and what hadn’t.

Conclusion

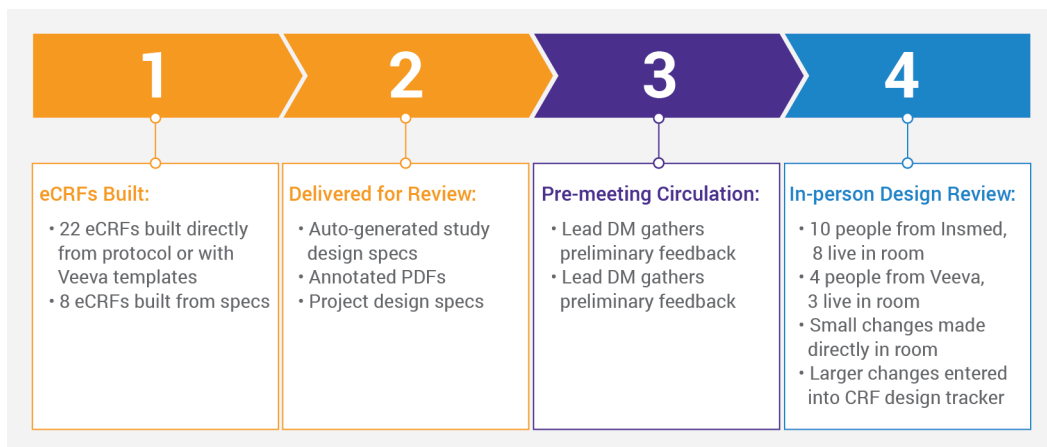
Even with a change in approach affecting CRF designs, we still hit our deadline. Huge kudos go to the Veeva CDMS team. If it weren't for their dedication, we never would have made it. We're so appreciative for Veeva's commitment to our success.

Facing Last-minute Changes – Four Keys to Success

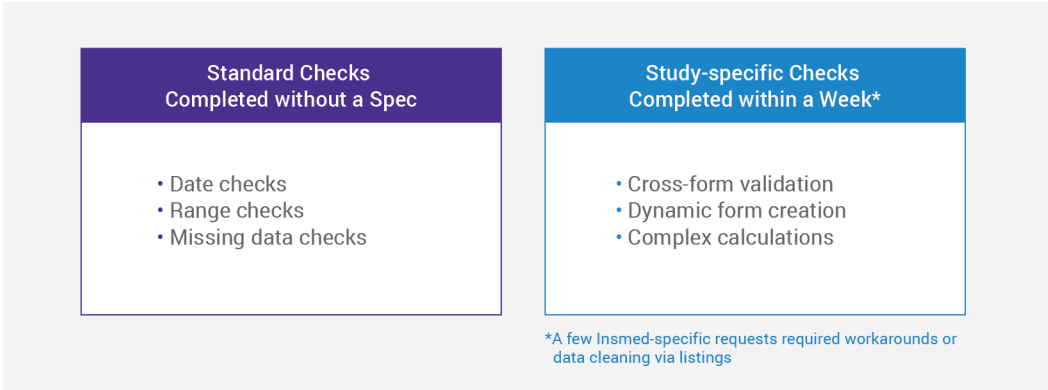


Overview: An Agile Design Process for Insmed's Study with Veeva Vault CDMS

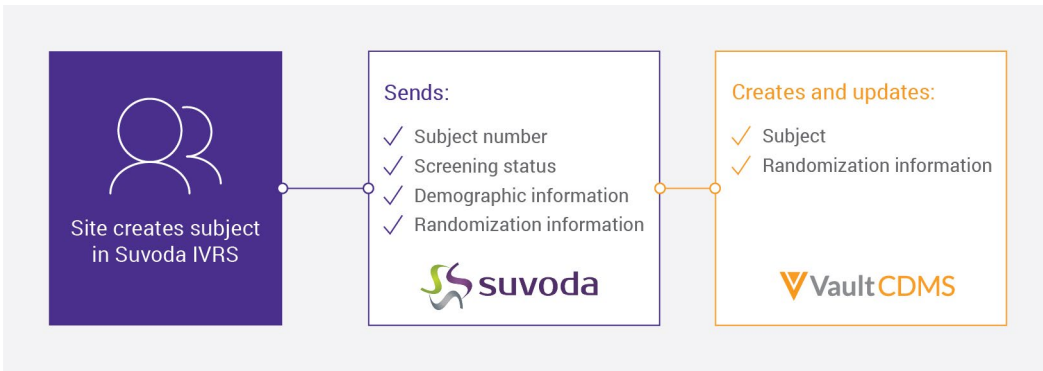
eCRF Development and In-person Design Review



Rules and Edit Checks Completed Within One Week, Most without Needing a Spec



Integration with Suvoda IVRS for Randomization



UAT Completed in Only 7 Days

