PRAXIS

Praxis Eliminates Manual TMF Migrations and Reduces Transfer Prep Time by 84%

Katie Kelly has spent more than a decade working in clinical trials, and she knows the importance of keeping trial master file (TMF) management straightforward. Kelly is the associate director of clinical study operations at Praxis Precision Medicines, a Boston-based clinical-stage biopharma.

Kelly started an initiative called TMF Tuesdays, where her team shares key TMF topics at the company's all-hands meeting. "It started as a joke, but it got people laughing and they thought it was fun," she remembers. "Now, people will come to me and say, 'Happy TMF Tuesday!' It's a lighthearted way to gain people's buy-in." These internal initiatives coupled with Praxis' move to Veeva Vault eTMF in September 2021 have enhanced the company's TMF management processes and inspection readiness.

Praxis Precision Medicines

COMPANY SIZE

80+ employees

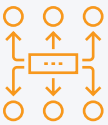
HEADQUARTERS

Boston, Massachusetts, United States

VEEVA SOLUTIONS

Vault eTMF
Vault RIM
Vault QualityDocs

Brought TMF in-house with a lean team of three



Cut TMF migration preparation time from 25 days to four days, an 84% decrease

Shortened timelines for receipt of final TMF by an average of three months

Bringing TMF in-house with a three-person team

Before implementing Vault eTMF, Praxis outsourced TMF management to a large CRO. The company decided to **bring its eTMF in-house** to increase oversight, access to documents, and simplicity.

Now, Praxis' TMF team of three manages their eTMF in-house and invites CROs to work in their system. Everyone on study teams, from data managers to regulatory affairs specialists, is responsible for uploading their documents into Vault eTMF. Then, the TMF team classifies them. Kelly values the reassurance that in-house document classification brings. "I'm able to look at any classification in any study in Vault eTMF and feel confident that we've inputted the correct data," she says.

Kelly's team also uses the Veeva **TMF Bot** to automatically classify uploaded and mobile-scanned documents. "The TMF Bot helps reduce the time my team spends manually classifying documents," she says.

Eliminating manual TMF migrations

Before automating document transfer, Praxis went through several manual end-of-study migrations with its CROs. "Every CRO had different systems, so we ended up having to do a document-by-document review to make sure that our information was right."

Since implementing Vault eTMF, Kelly has used **TMF Transfer** to automatically transfer completed documents and data records between Praxis' and its CROs' eTMF systems to streamline the move in-house. This includes:

- Study country and site records, including select fields
- Approved documents, including approved versions and audit trails
- Other document and data records needed to meet regulatory requirements

"After we set up the initial connection, it was just ready to go," says Kelly. Now, Kelly's team typically does not need to review document listings or audit trails. "Everything is automatically in the system in a matter of minutes," she says. "TMF Transfer takes exponentially less time."

> "Now that we use Veeva Vault TMF Transfer, my team no longer reviews document listings or audit trails. Everything is automatically in the system in a matter of minutes."

Katie Kelly,
Associate director of clinical study operations, Praxis Precision Medicines

Kelly's team cut their TMF migration preparation time from 25 days to four days, an 84% decrease. They also reduced the number of people needed for study closeout from three to one while shortening closeout timelines by an average of three months.

↓ 84%

decrease in TMF migration prep time with TMF Transfer

Providing CRO access to Vault eTMF

For emerging biopharmas, asking **a CRO to work in your eTMF** might feel daunting. But, it may be the best option to meet a company's needs as it matures. For Praxis, bringing TMF in-house allowed consolidation of all TMF documents in a single system.

When managing relationships with CROs, Kelly recommends getting involved from the very beginning and clearly outlining responsibilities. Praxis includes the expectation that CROs work in its system in each RFP process and decides on a study-by-study basis which tasks CROs will own. "If we were to start a new study tomorrow, I'd be involved in everything from the RFP process to the kick-off meeting to make sure our CRO knows exactly what to do," she says.

Lessons learned from eTMF implementation

For companies embarking on an eTMF implementation, Kelly suggests having a robust plan for configuration before going live to avoid having to retrain employees. The plan should include milestones, classifications, and any other key eTMF features.

Kelly also recommends choosing an eTMF system that fits your organization's broader technology landscape. For example, Praxis takes advantage of the Vault Connections between **Vault RIM** and **Vault QualityDocs**. **Vault Connections** are Veeva-delivered integrations that seamlessly transfer data Vault QualityDocs, I can easily crosslink them in Vault eTMF when they're and

documents. “If we’re authoring protocols in Vault RIM or study plans in Vault QualityDocs, I can easily crosslink them in Vault eTMF when they’re approved,” says Kelly.

Next steps for Praxis

Now that the Praxis team has optimized their baseline eTMF processes, they’re looking to expand. This includes expected document lists (EDLs) that empower teams to identify documents and take action. They’ll also identify which reports and dashboards are most meaningful for monitoring TMF health. “One of my priorities is to bring the larger study team together to figure out what metrics are important for us to measure, and how we can represent them in Vault eTMF reports and dashboards,” says Kelly.

The Praxis team is already looking ahead to continually strengthen audit- and inspection-readiness as they move toward their first new drug application. With eTMF in-house, Kelly is confident that Praxis is ready for any upcoming **audits or inspections**. “It gives me confidence to know that we’re in control of our eTMF,” she says. “We can make the changes we want and we control how quickly they happen. It makes managing our TMF so much easier.”

> “If we’re authoring protocols in Veeva Vault RIM or study plans in Veeva Vault QualityDocs, I can easily crosslink them in Veeva Vault eTMF when they’re approved.”
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> **Katie Kelly,**
> Associate director of clinical study operations, Praxis Precision Medicines

Learn more about how Vault eTMF can improve trial efficiency and inspection readiness.