KCR: Three Lessons from Our Journey to Modernize and Unify Clinical Trial Operations

KCR is a medium-sized CRO with a global reach. They use **Vault Clinical** to drive their digital transformation. The team has managed dozens of studies and hundreds of thousands of documents, all while dramatically improving TMF quality measures.

To support a unified approach, KCR implemented Vault eTMF in 2014, followed by Vault CTMS in 2019 and Vault EDC in 2021. Magdalena Matusiak, KCR's head of data science and documentation services, shares three lessons for success.

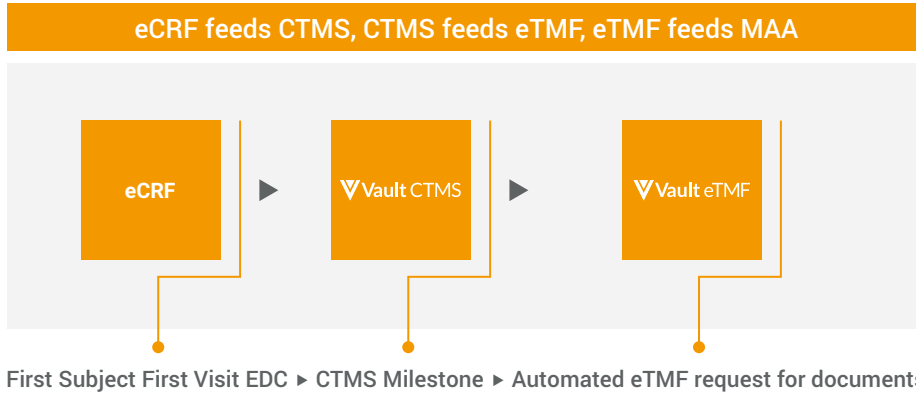| Vault Clinical Products			
IMPLEMENTED	IMPLEMENTED	IMPLEMENTED	FUTURE
V Vault eTMF	**V** Vault CTMS	**V** Vault CDMS	**V** SiteVault **V** Site Connect

💡 **TAKEAWAY #1**
Before implementing new technology, understand the capabilities and use those learnings to develop new processes to maximize value.

Before implementing Vault CTMS, the KCR team learned the full range of capabilities within the application. After that, Matusiak said, "We thought about how to change our processes, approaches, and SOPs so we could really benefit from the technology."

Vault CTMS became the team's communication and process management tool through which subject data and trial documentation flow. They also established automated workflows so that actions trigger downstream activities throughout Vault Clinical, rather than relying on email and other external channels for study communication.

For example, a case report form that marks a study's first subject first visit in Vault EDC is automatically visible in Vault CTMS. Once the milestone is complete, the system generates an automated request in Vault eTMF for milestone-associated documentation.

eCRF feeds CTMS, CTMS feeds eTMF, eTMF feeds MAA

eCRF	▶	**V Vault CTMS**	▶	**V Vault eTMF**

First Subject First Visit EDC ▶ CTMS Milestone ▶ Automated eTMF request for documents

TAKEAWAY #2
Define clear responsibilities for each role, and empower subject matter experts to take ownership of their documentation.
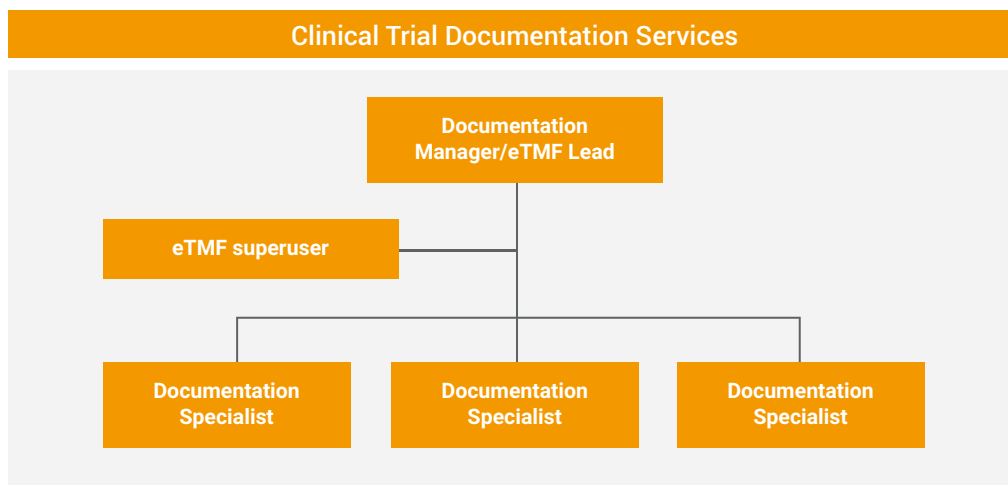
BY THE NUMBERS

25
Countries

40
Clinical studies

1,400
Clinical sites

200,000
eTMF documents

KCR established new teams with clear roles, as well as guidelines for processes such as data entry and quality control (QC). For example, clinical trial assistants were previously responsible for all documentation, but KCR created a new clinical trial documentation team with responsibilities divided among subject matter experts.

"Defining clear roles and responsibilities is the key to success when we think about implementation of new technology," Matusiak said.

Clinical Trial Documentation Services

Documentation Manager/eTMF Lead
eTMF superuser
Documentation Specialist
Documentation Specialist
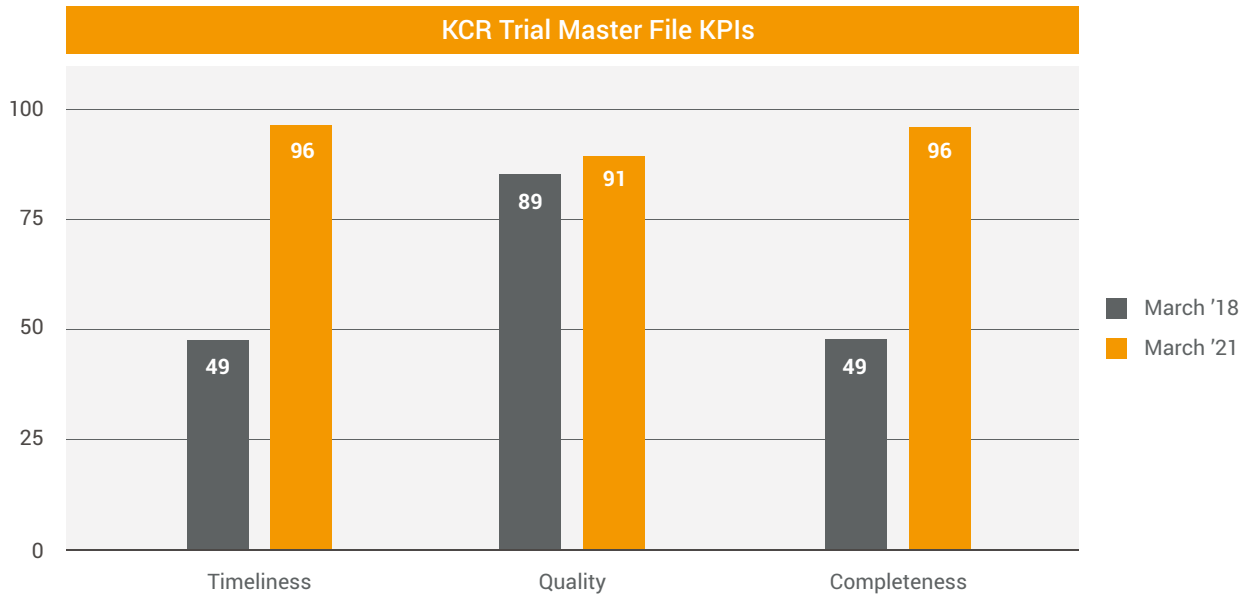Documentation Specialist

TAKEAWAY #3
Use technology to increase transparency and aggregate data to measure success.

The clinical trial documentation team helped define and apply KPIs to support the technology implementation. They also aggregated data from their Vault applications to drive improvements such as increased TMF health. In three years, the team nearly doubled timeliness and completeness of eTMF documents and maintained high quality.

"Even the best technology is useless if we don't have data in sight," Matusiak said. "Data helps to ensure success during technology implementation and beyond."

KCR Trial Master File KPIs

Category	March '18	March '21
Timeliness	49	96
Quality	89	91
Completeness	49	96

Learn more about KCR's digital transformation with Vault Clinical Operations and hear directly from their team in this **on-demand session at Veeva Europe R&D and Quality Summit Connect**.