WEBINAR SUMMARY

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Scrip
Informa Pharma Intelligence

Modernizing Clinical Trial Processes to Bring Novel Cancer Therapies to Patients Faster

Rik Van Mol, Vice President, Development Cloud Strategy, Europe, Veeva
Stephen Nabarro, Head of Clinical Operations and Data Management, Cancer Research UK, Centre for Drug Development

KEY TAKEAWAYS

- eTMF applications are modernizing clinical trial processes.
- Cancer Research UK's Centre for Drug Development decided to implement an eTMF system to reduce costs, improve quality, and enhance process efficiencies.
- After approving the business case, Cancer Research UK was able to move quickly, implementing the validated system "out of the box" within six weeks.
- The Veeva eTMF system has delivered on Cancer Research UK's goals of providing a return on investment in less than five years, improving quality by maintaining study eTMFs in a permanent inspection ready state, and achieving greater productivity with active TMF management.

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OVERVIEW

In quickly evolving fields like oncology, experts are constantly striving to deliver innovative cancer treatments to patients faster. Active trial master file (TMF) management is a growing trend that improves inspection readiness, provides better visibility into TMF status, and improves central and remote auditing capabilities.

Cancer Research UK's Centre for Drug Development recently implemented a Veeva Vault eTMF system. The results have been positive. Moving to an electronic system has eliminated paper archiving expenses, provided staff with a single source of truth, and dramatically improved process efficiencies. By leveraging technology, the organization will be able to develop drugs faster and at lower cost to maximize patient benefit.

CONTEXT

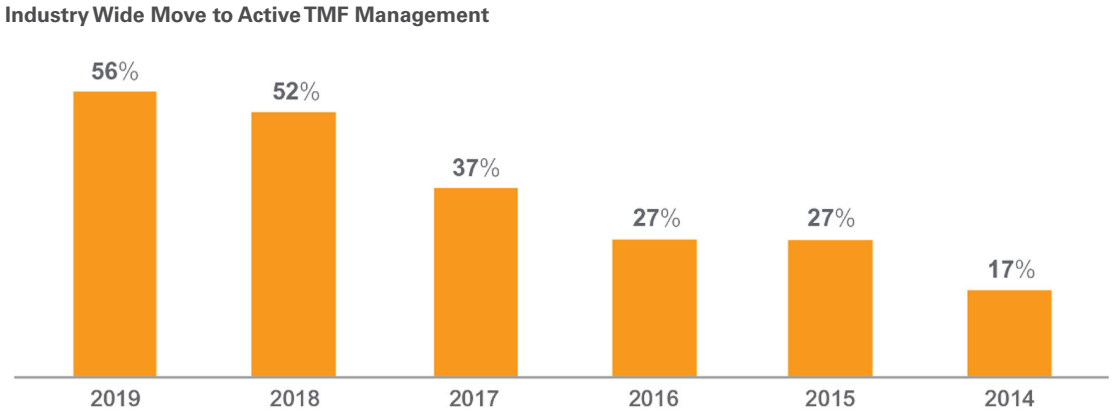
Rik Van Mol discussed how eTMF systems are revolutionizing clinical trials. Stephen Nabarro shared how Cancer Research UK's Centre for Drug Development created a business case for an eTMF solution and then implemented a Veeva system.

KEY TAKEAWAYS

eTMF applications are modernizing clinical trial processes.

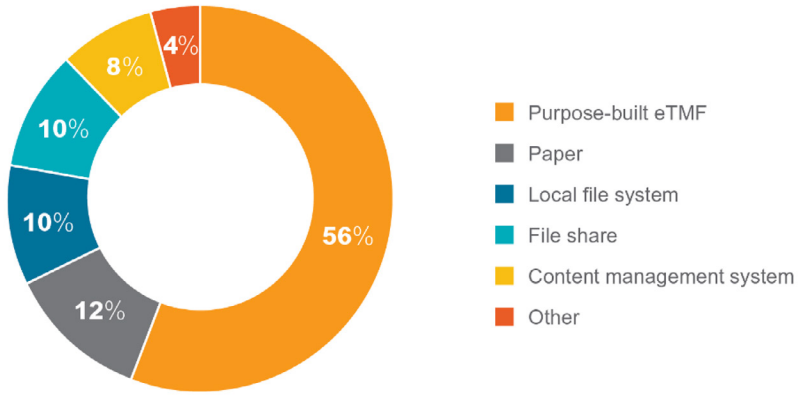
Based on data from the Veeva 2019 Unified Clinical Operations Survey, Rik Van Mol discussed how adoption of eTMF applications is affecting clinical trials.

- **The number of companies using active TMF management has tripled since 2014.** Today, more than half of sponsors and CROs are using a purpose-built eTMF application compared to only 17% in 2014.



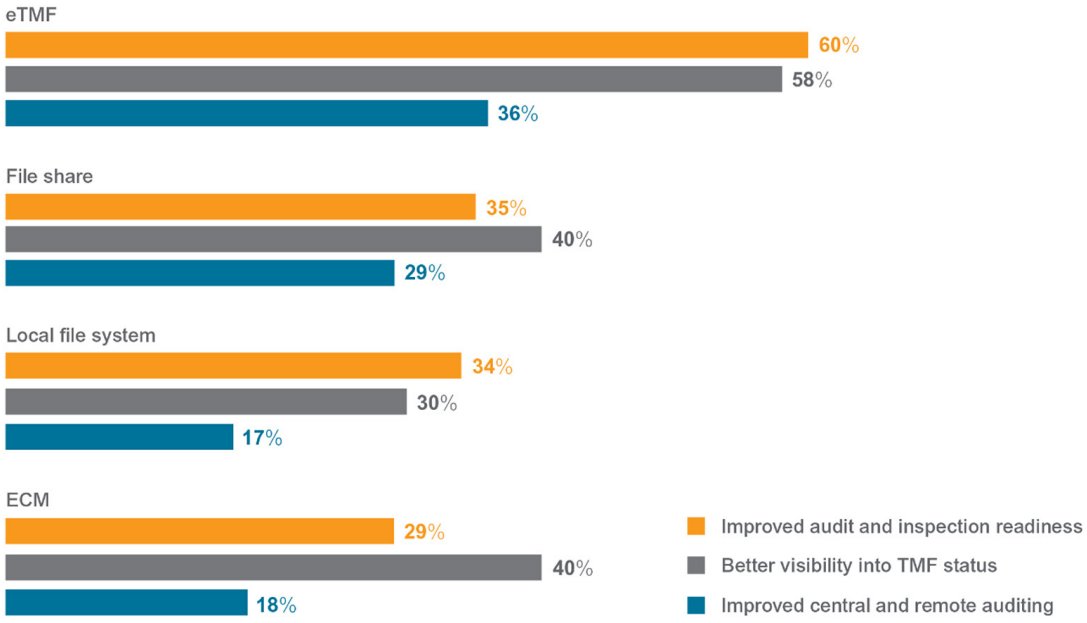
- **Organizations are shifting from passive TMF models to active TMF management.** The use of content management systems has declined sharply. Today, only 8% of the industry is managing TMFs with a content management system, compared to 31% in 2017. Over half of survey respondents are using purpose-built eTMF systems.

Active TMF Management is Supported by Purpose-Built eTMF Applications



- **Active TMF improves inspection readiness.** Companies with purpose-built eTMF systems have improved audit and inspection readiness, better visibility into TMF status, and improved central and remote auditing capabilities.

Benefits Delivered by eTMF Systems



Active TMF operating models provide numerous advantages over passive models. These include electronic documents rather than paper; eTMF access by sites, CROs, and sponsors; integration with other eClinical systems; and real-time KPIs and metrics that can be used for active management.

> Veeva Vault eTMF supports seamless collaboration between sponsors, CROs, and investigators. It allows a continuous state of inspection readiness. All operational data is available and reporting dashboards enable organizations to analyze bottlenecks and promote more efficient operations.
>
> *Rik Van Mol, Veeva*

Cancer Research UK's Centre for Drug Development decided to implement an eTMF system to reduce costs, improve quality, and enhance process efficiencies.

Cancer Research UK is a nonprofit organization that is the largest funder of cancer research in Europe and the second largest funder worldwide. Cancer Research UK's vision is to reach the day when all cancers are cured. In the UK, if a person is diagnosed with cancer, he or she has a 1 in 2 (50%) chance of surviving for 10 years. Cancer Research UK's goal is that by 2034, 3 in 4 (75%) cancer patients will survive for 10 years.

Cancer Research UK's involvement in drug development ranges from funding basic lab research to supporting translational research and clinical trials. Cancer Research UK works with over 150 NHS hospital trusts in the UK and supports about 250 clinical trials.

Cancer Research UK's Centre for Drug Development (CDD) sponsors, funds, and manages a portfolio of early phase clinical trials. Over 25 years, CDD has brought 160 new agents to the clinic, and six have led to new medicines. CDD's portfolio is similar in size to a medium-sized pharmaceutical company. The organization manufactures drugs through two units for small molecules and biologics. All expertise exists in-house for biomarker work and coordinating preclinical translational work.

In 2017, CDD created a business case to secure funding for an eTMF system. This business case was based on three pillars:

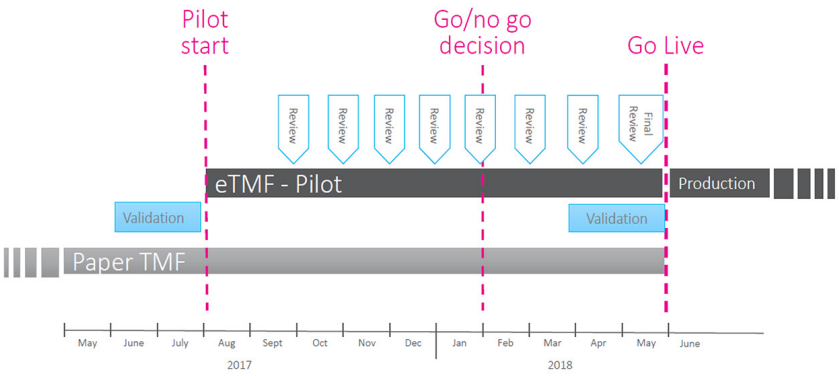
1. **Cost effectiveness.** The cost of storing paper trial master files is high. An eTMF system would reduce the need for storage space and off-site archiving, while improving process efficiencies. The Cancer Research UK team estimated that an eTMF system would pay for itself in less than six years.
2. **Improved quality from a regulatory perspective.** An eTMF system was expected to reduce the number of audit and inspection findings. Cancer Research UK established KPIs of a 90% QC pass rate and a 30-day timeline to file documents.
3. **Process efficiencies.** Paper TMF systems rely on numerous manual processes and Microsoft Excel spreadsheets. Using timesheet data, Cancer Research UK baselined how long these manual processes took. They used this data to calculate the benefits of automation. With the paper system, for example, CTA resources spent 15 hours per week maintaining paper TMF archive lists.

After approving the business case, Cancer Research UK was able to move quickly, implementing the validated system "out of the box" within six weeks.

Three weeks after the business case was approved, Cancer Research UK signed a contract with Veeva for an eTMF system. Cancer Research UK decided to implement the system "out of the box," with minimal configuration. During the pilot period, the organization used the eTMF system and maintained paper trial master files in parallel. During the pilot, an agile approach was taken and four test and learn cycles revealed what worked and what modifications were needed.

By the end of the pilot, Cancer Research UK had the confidence to go live with the eTMF system. Prior to going live, the organization revalidated the system with everything that had changed during the pilot. After the go-live date, Cancer Research UK began archiving its paper documents.

Cancer Research UK's eTMF Implementation Timeline



TIMELINES	
Business case approved	1st month
Implementation kick off	5th month
Application testing and configuration changes	6th month
Validation of the core system configuration	7th month
Start pilot	8th month

Three key learnings, based on Cancer Research UK's eTMF implementation experience, are:

- **Focus on the people and provide intensive, continuous support.** Every end user matters. Don't underestimate the time needed to support people during the change process.
- **Use strong communication to identify and address issues early.** Cancer Research UK relied on different communication methods. Each team had super users. In addition, project sponsors attended the pilot teams' study team meetings. These sessions highlighted opportunities for better guidance, training, and step-by-step guides.
- **Plan how to embed the system back into the business, once the eTMF becomes "business as usual."** Cancer Research UK empowered the functional groups so they felt ownership for the trial master file.

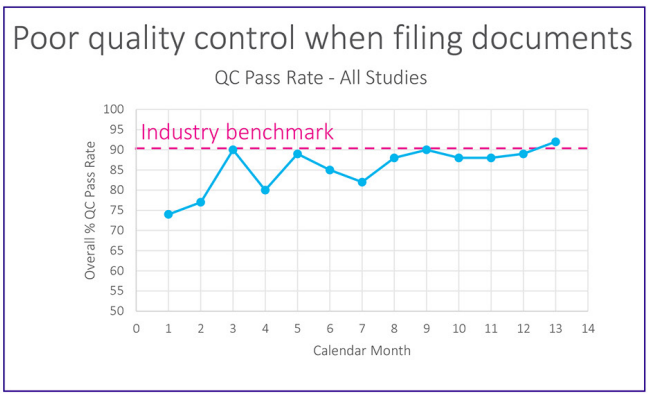
The Veeva eTMF system has delivered on Cancer Research UK's goals of providing a return on investment in less than five years, improving quality by maintaining study eTMFs in a permanent inspection ready state, and achieving greater productivity with active TMF management.

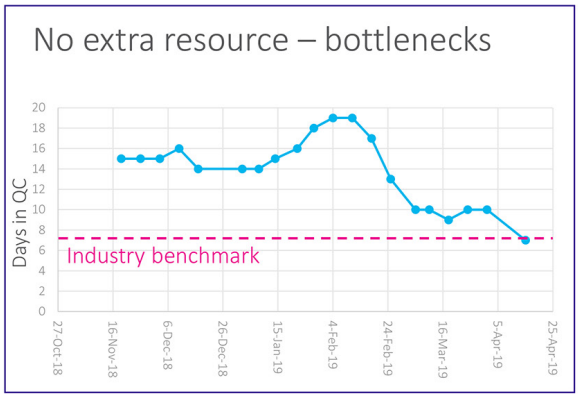
Cancer Research UK has seen several benefits from adopting an eTMF system:

- **An expected ROI in less than five years.** All new trials use an electronic trial master file. This has eliminated the need for offsite archiving of paper files. Employees have embraced electronic files and don't view paper files as a safety blanket.
- **The eTMF system provides a single source of truth.** Staff can access essential documents anywhere, anytime. Cancer Research UK defined 60 active end users as a measure of success for system uptake. That goal has been achieved. Login and search data suggest that employees are using the system regularly.
- **The new technology revealed flaws in Cancer Research UK's quality processes.** During the pilot, the organization found poor quality control when classifying and filing documents. Cancer Research UK also discovered that creating and uploading documents to the eTMF required additional quality control review time. In response, the organization changed and refined its processes to reduce review times in order to achieve industry benchmarks.
- **Veeva's QC dashboards have been a useful oversight tool for managers.** Cancer Research UK has now hit the industry standard for quality of documents at the time of upload. More than 90% of documents take less than 30 days to file.

- **The eTMF system has strengthened collaboration.** Collaboration with internal partners and teams is helping Cancer Research UK realize the benefits of the eTMF technology.
- **Process efficiencies are evident in study set-up, recruitment, and preparation for archive.** With the paper TMF system, it took 1.5 hours of CTA time to set up lever arch files. With the eTMF solution this process takes less than 10 minutes. During the recruitment phase, the paper TMF approach took 15 hours of CTA time per week to maintain archive lists, 15 hours to manually file documents, and 80 hours of study team time for periodic TMF reviews. The eTMF system has automated archive lists and documents are filed electronically. As a result, CTAs can focus on QC review instead. Cancer Research UK predicts over 50% time savings with periodic eTMF-based reviews. The preparation for archive took study teams over 300 hours with the paper TMF system. This is expected to be reduced by 80% with the eTMF solution.

eTMF Technology Revealed Quality Issues





> We are now entering our third evolutionary stage of eTMF use. We have a lot of confidence in the system from an operational perspective and we want to scale it up. We're now looking at migrating our older studies into the eTMF to maximize the benefits of having the system.
>
> *Stephen Nabarro, Cancer Research UK*

BIOGRAPHIES

Stephen Nabarro

Head of Clinical Operations and Data Management, Cancer Research UK Centre for Drug Development

Stephen is a clinical research professional with more than 15 years' experience in oncology research and drug development. Scientific background includes a PhD in pediatric oncology at University College London and a Postdoctoral Fellowship at the Medical Research Council Laboratory of Molecular Biology in Cambridge. He is a specialist in clinical trial operations within the Cancer Research UK Centre for Drug Development.

Rik Van Mol

Vice President, Development Cloud Strategy, Europe, Veeva

Rik is a senior executive with 20+ years of experience in both management consulting and cloud software in the life sciences/pharmaceutical sector. His experience has been built in assisting clients through complex transformation programs across the life sciences value chain for most of the world's largest companies. Rik is a recognized industry thought leader with deep expertise in architecting, launching, and implementing innovative and industry-leading strategies and solutions.

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