Value-Stream Mapping for Clinical Data Management

Author: Moulik Shah, Founder and CEO, MaxisIT

Reduce Clinical Trial Cycle Times with a Lean Approach

Of all the challenges clinical trials face, exceptionally long timelines top the list. Study start-up alone can take up to six months,[1] while the average Phase 3 trial—from protocol finalization to database lock—can take over three-and-a-half years.[2]

Reducing cycle times within any aspect of clinical trials, particularly in data management-related functions, will help sponsors reach their end goal sooner. While AI is climbing up the hype-cycle, without any clear use cases that prove cycle time reduction, we believe technology alone won't move the needle on cycle times. Significant improvements require a combination of modern technology and refined IT and business processes.

A strategy based on value-stream mapping (VSM) can help improve data management process efficiency. Teams can thus reduce cycle times from data reconciliation and last patient last visit (LPLV) to database lock (DBL), among other metrics. And because of its cycle time-reducing potential, VSM can empower clinical data management teams to derive more valuable insights faster.

1. VALUE-STREAM MAPPING

1. https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-020-4079-8
2. https://link.springer.com/article/10.1007/s43441-022-00438-5

What is Value-Stream Mapping?

VSM, aka value-stream analysis or lean process mapping, is a strategy used in lean management, the efficiency template developed by Toyota Motor Company. VSM uses a flowchart to map every value-driving step in a process as well as how the information in those steps flow.
With every value-stream mapped, teams can identify areas of waste and inefficiency.

In addition to mapping the current state, teams develop maps depicting their future state—where they want to go. Next, they develop a plan to get there. The process is repeated periodically, with refinements made along the way.

Lean management has become more common in healthcare over the past several years, as administrators develop methods to improve efficiency while lowering costs.[3] For example, Jacaranda Health, a health care system in Kenya, used VSM to improve operations for its maternity departments. The organization formed a VSM team comprised of frontline professionals that represented all patient touchpoints. The VSM process consisted of a physical walkthrough of one facility, followed by a two-day workshop.[3]

The VSM process served as a catalyst for improved staff engagement. It also helped solidify staff commitment toward achieving short- and long-term goals.

Cincinnati Children's Hospital Medical Center in Cincinnati, Ohio, used VSM to identify ways to improve its IV pump management and maintenance process. In the first year of implementing changes, the organization reduced its IV pump turnaround time from about 40 days to under five days. Over the next four years, the organization sustained a turnaround time of 74 to 94% below baseline.[4]

3. https://academic.oup.com/intqhc/article/29/7/961/4609258
4. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9345645/

Value-Stream Mapping **for Clinical Data Management**

VSM works well for improving repeatable processes. Repeatable processes in clinical trial data management include data-ingestion-to-curation, as well as data-review-to-data-query generation.

The VSM process in clinical data management would look something like this:

Identify current state

Map the existing process for clinical data management. List steps such as data collection, data entry, query generation and resolution, data cleaning, and database lock. Identify all stakeholders involved in each step, from clinicians to data managers to statisticians. Also, identify the tools used at each state, such as the EDC/eSource system, clinical data management system (CDMS), and/or clinical trial management system (CTMS).

Identify waste

Here's where you look for problem areas. Using lean practices, waste includes unnecessary movement, overproduction, and defects. In clinical data management, look for invalid queries, duplicative data entry, data entry errors, delays or other problems in data cleaning, technical limitations, and inefficient communication. For example, how do all the stakeholders involved in data review communicate? Does it happen in an asynchronous way or in a collaborative fashion? If it's the former, that could be an area for improvement.

Design the future state

How would you like to operate instead? The future state may involve updating the data capture system, exploring an EHR-to-EDC integration solution, integrating and automating repeated operational processes, or restructuring team roles and responsibilities, among other goals. Imagine a future state with more real-time engagement and fewer silos. Set ambitious but achievable benchmarks.

Implement change

What steps do you need to take to arrive at the future state? Define what steps need to be taken to effect changes in technology, operations, and/or communication. Monitor the progress toward these steps and adjust as necessary. And make sure to designate responsibilities to specific individuals for accountability.

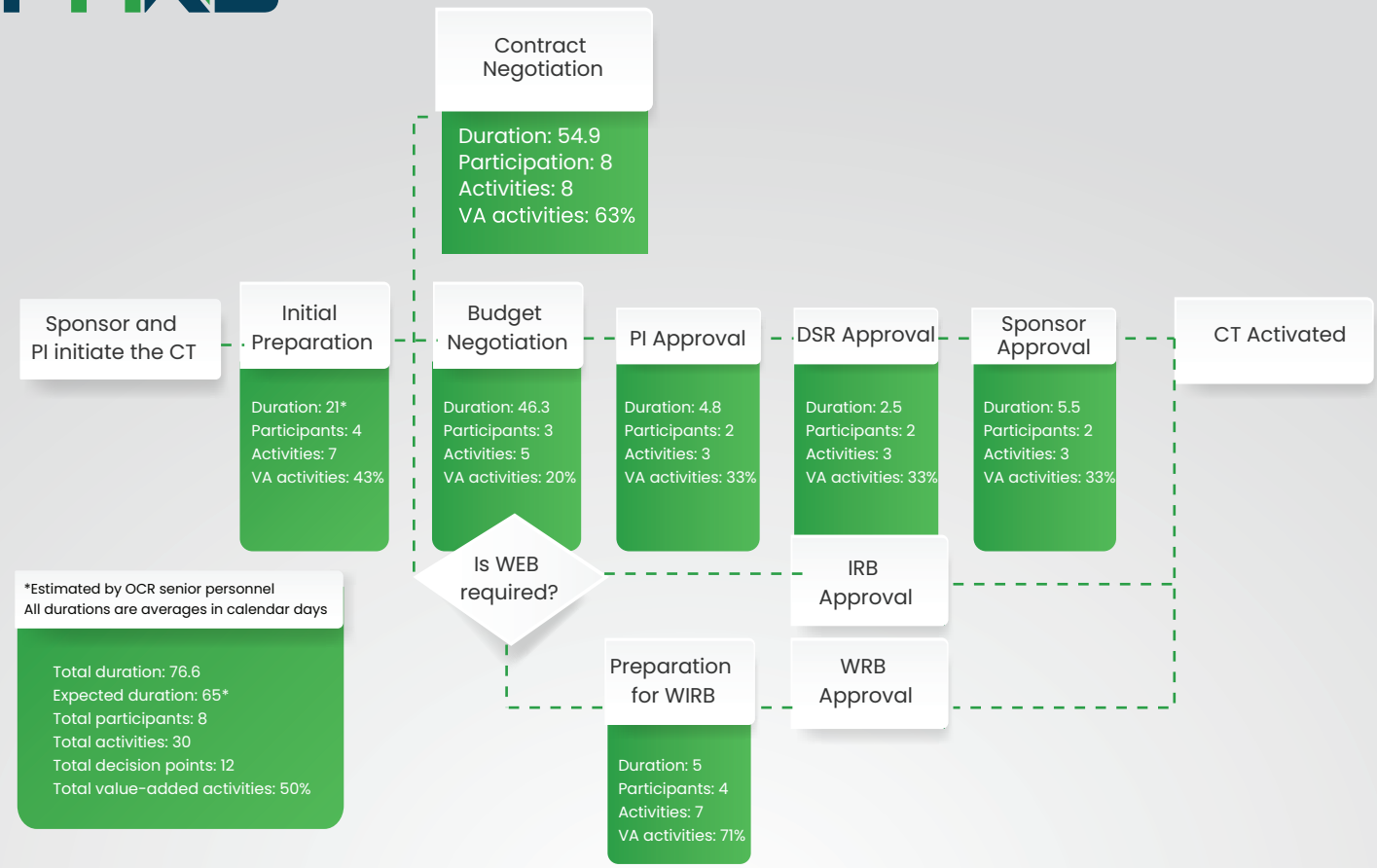


Fig. 1. Administrative process associated with industry—sponsored clinical trial activation at the University of South Florida. CT clinical trial, DSR USF's Division of Sponsored Research, IRB (Institutional Review Board), OCR USF's Office of Clinical Research, PI (principal investigator), VA (value-added), WIRB (Western Institutional Review Board). All durations are averages (median) in calendar days.
*Estimated by OCR senior personnel.

VSM Use Case: Moving to Real-Time Data Access

The image above shows an algorithm for improving administrative processes within an **academic research center. A more applicable scenario could involve data collection and cleaning.**

In a traditional clinical trial, data from multiple sites are manually entered into the EDC. Data cleaning takes place after data collection. Waiting until the end of data collection to start data cleaning delays error correction and interim analysis.

During a VSM process, the team may identify later-stage cleaning as an area of inefficiency. Its future state may involve direct data capture into the EDC and real-time data monitoring. Data cleaning would happen concurrently across the patient data sources. Using this approach, errors and anomalies are caught and investigated sooner. Interim analysis takes place sooner, and the trial moves to database lock weeks faster.

Why Measure Cycle Times?

Cycle time refers to the time spent working on a task, a project, or a service. In clinical research, teams can measure cycle times for elements of a clinical trial or the entire study from a defined start to end point.

Measuring cycle times is essential for performance improvement. It helps organizations or teams determine where they need to improve, and how well they're improving over time. Performance improvement naturally leads to reductions in effort, time, and cost.

The first step to measuring and monitoring cycle times is to establish metrics. What do you want to measure? What's important to your organization or team? Discuss these questions with your subject matter experts and other stakeholders to get a clear idea of which metrics to measure.

Once you start measuring cycle times and monitoring the associated metrics, you'll notice trends and problem areas. Those are what you will improve.
As you define and implement steps to improve cycle times, be sure to designate team members to oversee related tasks. If no one's responsible for measuring and reporting data, how will it get measured?

Thinking of the data cleaning example above, by monitoring and correcting data issues as they occur, and by cleaning data throughout the trial (whether automatically or manually), cycle times for multiple metrics are reduced. Data collection happens faster. Data review happens sooner. And the overall time from LPLV to DBL is reduced, ultimately leading to earlier regulatory submissions, approval, and commercialization.

Putting it Together: The Benefits of Value-Stream Mapping for Clinical Data Management

VSM is a worthwhile exercise for clinical trial sponsors and CROs that want to improve productivity and efficiency. Whithin clinical data management, VSM can help improve the process used to implement AI-based tools, speed up reporting, and clear up communication.

After VSM helped Eli Lilly save its DevOps team about $16 million per year, the company applied VSM to its clinical trials, streamlining the process of loading report data from clinical trial sites into a data warehouse, in two days compared to five weeks before applying VSM. It also helped improve communication with senior management, who received more detailed reports sooner.[5]

Improved efficiency

VSM can help teams identify and potentially eliminate redundant tasks, speeding up processes.

Improved data quality

In applying VSM, a team may uncover steps that raise the risk of inaccurate, missing, or duplicate data. Revising or eliminating these steps leads to higher accuracy, which saves time downstream.

Improved transparency

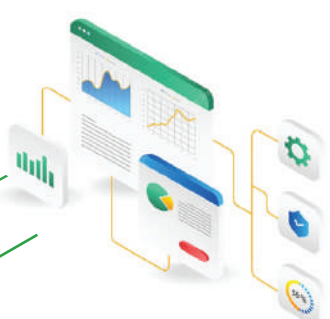
By visually mapping out every step in a process, VSM helps team members understand their role and its impact on the team's goals. This type of clarity helps improve communication and fosters a greater sense of teamwork.

Continuous improvement

VSM isn't a one-and-done process. Repeating it regularly over time enables continuous improvement: new inefficiencies are identified in each cycle, so the team keeps getting better.

Cost savings

Reducing errors and improving efficiency leads to saving time, which resulted in reduced clinical trial costs. A study published in BMJ Open estimated the average cost of a single clinical trial at about $48 million. If the average trial were to take three years, a sponsor could reduce trial costs by $307,600 for every week saved.[6]



5. https://www.techtarget.com/searchitoperations/news/252487359/Value-stream-management-tames-DevOps-chaos-at-Eli-Lilly
6. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7295430/

Value-Stream Mapping Limitations

While VSM is a useful tool for identifying and mitigating waste, it's only one piece of a larger initiative. Clinical trials involve multiple stakeholders, including sponsors, CROs, external vendors, sites, and investigators. Much of their actions are out of the data managers' control; however, improvements in one area can positively impact others.

As you discuss VSM with your team, keep the following limitations in mind:

Marginal gains may not be enough

Marginal, incremental improvements may not be enough to achieve desired clinical cycle time improvements. That's because small wins usually don't address underlying systemic issues present in clinical trial operations. Poor communication across an entire R&D department may be difficult to address from within data management.

Silos may remain

Manual handoffs and redundant processes exist within many aspects of clinical research, including data collection and entry, quality control, data cleaning, and analysis. VSM can help data management teams identify and correct these inefficiencies, but it may take several iterations to address all areas of disconnect.

Leadership buy-in may be delayed

Moving from current to future state could require investment in new technology.
VSM helps data managers build a strong case for the value of integrated data collection, management, and analysis. However, even with data showing strong projected return on investment, leadership may not align with the plan, which could delay progress.

How to Reach Your Future State Faster

New technology plays a pivotal role in data management optimization.
Today's platforms integrate multiple data sources as well as automate routine tasks.
Cloud-based platforms enable real-time data monitoring and analysis and facilitate collaborative reviewing. All these features help improve efficiency and, relatedly, cycle time.

MaxisIT's Data Management Workbench is designed to empower data management teams to reduce cycle times along key metrics. Designed for end-to-end clinical data management, the Workbench integrates across all eClinical systems and other patient data sources to help sponsors move to data review faster. A data management platform powered by artificial intelligence, combined with VSM, can lead to powerful results.

Conclusion

Regulatory agencies, patients, and other stakeholders have long urged drug and device developers to reduce the time it takes to bring a product to market. Clinical data management teams can make an impact on those multi-year timelines by focusing on cycle times in key areas.

Through value-stream mapping, teams focus on individual tasks step by step, identifying inefficiencies along the way and developing plans to improve. Teams that take the time to refine their process will benefit from smoother-running activities, helping to shorten timelines overall.

About MaxisIT

MaxisIT's purpose-fit and intelligent clinical data analytics platform helps improve clinical trial performance, mitigate risk, and optimize clinical outcomes. We provide a centralized and reliable source of truth for diverse data types from various sources, giving life sciences companies real-time insight to shorten cycle time and increase return on investment.

Incorporating an end-to-end clinical data pipeline from intake to visualization, MaxisIT's solutions are powered by AI/ML and metadata-centric approaches. Our impressive portfolio of over 3,300 clinical trials and an unparalleled 100% customer retention rate affirm the quality and reliability of our services.

Moulik Shah
Founder & CEO, MaxisIT

Moulik Shah is a passionate healthcare technology entrepreneur and the visionary CEO of MaxisIT, where he has been at the forefront of leveraging technology to transform pharmaceutical and life sciences clinical trials.

His dedication to improving patient outcomes and his leadership in directing patient-centricity, patient diversity, interoperability, and real-world-data-led collaborations have been at the core of his vision of an integrated healthcare ecosystem based on effective use of data and analytics platforms.

He has been instrumental in driving innovation and progress in the industry. Under Moulik's leadership, MaxisIT has become a leading provider of clinical data and analytics which is driving real-world impact in the pharmaceutical and life sciences clinical trials.

www.maxisit.com | connect@maxisit.com

510 Thornall Street, Suite 180,
Edison, NJ 08837

+1 732-494-2005, ext. 135