cognizant®

Shrinking clinical development timelines with Scrum methodology

Life sciences organizations are in constant pursuit of shorter clinical development cycles. In most cases, technology is seen as the primary method for shrinking timelines and optimizing processes. But in focusing on digital innovations, are companies overlooking other valuable opportunities to drive progress? In fact, is technology even the answer for every challenge within the clinical development cycle?

One area that is crucial to overall cycle time reduction but remains challenging to optimize is **last patient last visit (LPLV) to database lock (DBL)**. This interval—the period between the last patient visit and the point where trial data is fully verified, cleaned and locked—is critical as it impacts the timeline for data analysis and regulatory submission, ultimately influencing the speed at which new therapies can be brought to market.

The average LPLV to DBL period lasts more than two months. Shaving even a few hours off that timeline can potentially determine whether a company wins or loses a patent race. Reducing this interval by weeks or days can have a significant impact on time-to-market, revenue generation and market share.

Unfortunately, improvement has been elusive in this area. The elongated LPLV to DBL timeline has multiple root causes, which must be addressed not just through technological solutions, but also process improvements. In this article, we explore how companies can think outside the box to tackle LPLV to DBL challenges with an unlikely solution: Scrum methodology.

Average LPLV to DBL timelines

2010	2024	Target future state
18–20 weeks	8–10 weeks	1 week

A closer look at LPLV to DBL challenges

To reduce the LPLV to DBL timeline, companies must first understand the challenges within the existing process that they must overcome.

To lock the database, all data must be source data verified (SDV), cleaned and signed by the principal investigators at each site. If any data fields remain pending for SDV, the clinical research associate (CRA) responsible for the site will follow up with site personnel, including the clinical research coordinator (CRC), principal investigator (PI) and any local lab vendors.

In large trials, which may involve up to 200 sites, even a few outstanding fields at each location can result in weeks of communication and follow-up. The timeline can be extended even further if these queries are unanswered, and a clinical data manager needs to coordinate with site personnel.

Once all case report forms (CRFs) are clean and without open or unresolved queries, SDV is complete, and the PI must sign off on all casebooks. In all, this process typically takes 8–10 weeks.

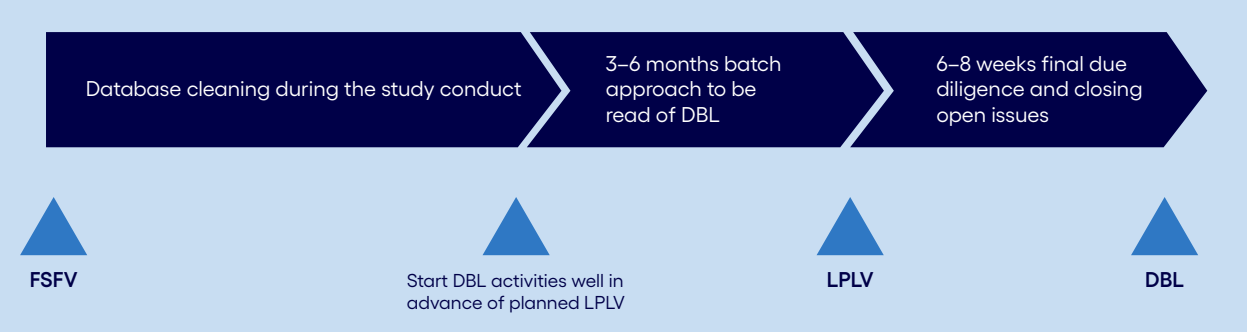
Fortunately, these steps are relatively easy to track within a single electronic data capture (EDC) system. However, the real challenge lies in reconciling and cleaning external data from multiple vendors, often delivered to the sponsor or clinical research organization in varying file formats. A single trial can involve 10 to 12 vendors and sources, including ECGs, biomarkers, central labs, wearables and sensors. This data is typically loaded in batches and reconciled with the EDC data at regular intervals. Any discrepancies are flagged and communicated to the vendor via email, who then addresses them by rectifying the data files as needed.

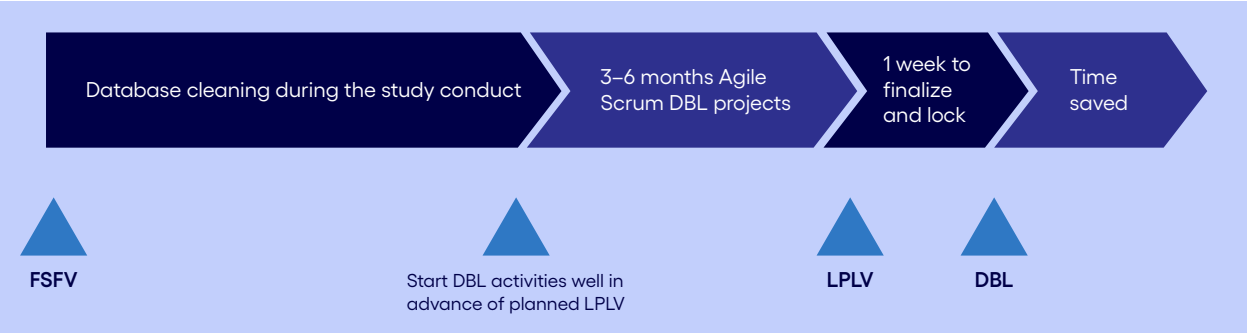
The cleanliness and completeness of external data remains the most challenging factor in reducing the time to database lock. While technological advancements have helped aggregate data and provide visual dashboards to monitor data status, timely human intervention is still essential to manage the overall process and coordinate with different stakeholders.

With data coming from various sources and managed by multiple vendors, creating synergy through technology alone is difficult. This issue has evolved into a people and process challenge more than a technological one. Companies have an opportunity to dramatically shorten the review window by implementing a sophisticated methodology that would increase stakeholder accountability, break departmental silos and create more transparency.

Shrinking the DBL window to one week with Agile methodologies

Current/traditional approach





Agile Scrum approach

Figure 1: Current/traditional approach vs Agile Scrum

One way to achieve significant improvement in LPLV to DBL timelines is by applying Scrum methodologies. Scrum is an Agile project management framework used to deliver complex projects through iterative progress. It emphasizes collaboration, flexibility and incremental delivery.

Though Scrum is primarily used in software development, there are some interesting parallels to clinical trials, and LPLV to DBL in particular. Most notably, Scrum methodology helps data managers engage stakeholders in a consistent and timely way, uniting the entire team around a common goal. By establishing clearer visibility into progress and dependencies throughout the process, the stakeholder group understands their specific role in the workflow and takes on accountability for how their tasks impact the work of others. This can dramatically shrink the amount of time it takes to complete a project while also maintaining performance standards.

Scrum methodology is especially valuable for large clinical trials that involve a high number of subjects and require coordination across diverse internal teams and partner organizations. By fostering collaboration, transparency and iterative planning, Scrum enables teams to effectively adhere to timelines, manage resources and adapt to challenges.

Here we share some of the defining elements of Scrum and how they can be used to reduce cycle times for life sciences companies:

1. Scrum masters

Every Scrum project has a Scrum master. This person plans the overall project and ensures proper engagement with key stakeholders throughout the program.

In the LPLV to DBL stage, the primary challenge is keeping multiple stakeholders updated on progress and ensuring timely follow-ups. Appointing a program leader to serve as a Scrum master to oversee all aspects of the project and coordinating with key stakeholders—such as clinical operations leads (who manage site coordination), external vendor representatives, and members of the safety and medical teams—could streamline the process, enhancing organization and efficiency.

2. Shared accountability

In a Scrum model, teams collectively share responsibility for overall performance and achieving goals. While the Scrum master oversees the project and key players, the organization and leadership within individual teams are equally critical. Providing all team members with Scrum training and ensuring they understand their expanded roles—such as monitoring dependencies and contingencies—helps teams achieve the speed and agility the model is designed to deliver.

For instance, in a traditional approach, the head of data management might lack direct visibility into other organizational areas. By contrast, an Agile model adopts a more collaborative approach, incorporating stakeholders from various functions and vendor organizations. These stakeholders gain direct visibility into goals through Sprint planning meetings; they can also track progress using advanced management tools like Jira sheets and real-time dashboards.

Agile methodology also fosters better alignment on priorities, resource availability and goals. For example, a traditional lead data manager would assess program element criticality and conduct manual checks with key divisions. In an Agile approach, the team collaboratively conducts Sprint planning, bringing together stakeholders across departments and partner organizations to create a unified plan, establish timelines and ensure proper resource allocation.

As roles within clinical trials continue to evolve, incorporating an upskilling program can prepare team leaders—such as lead data managers and clinical data scientists—with Agile methodology training. This equips them to act as Scrum masters during critical program phases, such as DBL, enhancing collaboration and efficiency during this critical period.

3. Sprints

In Scrum, work is organized into small, manageable units called Sprints—typically lasting two to four weeks—during which specific features or improvements are developed, tested and potentially released.

This concept could be particularly useful for DBL because the process consists of multiple distinct, but interdependent, steps. By breaking out tasks such as data cleaning, SDV and external data reconciliation into multiple Sprints, teams can focus on the most urgent tasks while also recognizing dependencies.

In the graphic below, we outline how the LPLV to DBL period can be broken down into a series of Sprints.

Sprint project tracker

Task in progress Task completed

LPLV	90 days before	Scroll to week #	2
02-Oct-24	04-Jul-24		

Sprint	Priority	Start	Finish	Duration	Status	% Complete
Project summary		**04-Jul-24**	**02-Oct-24**	**65 day(s)**		**49%**
Sprint 1		**04-Jul-24**	**18-Jul-24**	**11 day(s)**		
EDC data cleaning SDV (batch 1)	High	04-Jul-24	10-Jul-24	5 day(s)	Red	10%
Biomarkers (batch 1)	High	08-Jul-24	15-Jul-24	6 day(s)	Yellow	20%
Central lab reconciliation (batch 1)	Medium	10-Jul-24	18-Jul-24	7 day(s)	Green	30%
Sprint 2		**19-Jul-24**	**08-Aug-24**	**15 day(s)**		
EDC data cleaning SDV (batch 2)	High	19-Jul-24	01-Aug-24	10 day(s)	Red	40%
Safety reconciliation (batch 1)	High	22-Jul-24	05-Aug-24	11 day(s)	Yellow	50%
ECG data (batch 1)	Medium	28-Jul-24	08-Aug-24	9 day(s)	Green	60%
Sprint 3		**09-Aug-24**	**14-Sep-24**	**26 day(s)**		
EDC data cleaning (batch 3)	Low	09-Aug-24	22-Aug-24	10 day(s)	Yellow	70%
eCOA (batch 1)	High	16-Aug-24	02-Sep-24	12 day(s)	Green	80%
Questionnaires (batch 1)	Medium	10-Sep-24	14-Sep-24	4 day(s)	Red	90%
Sprint 4		**18-Sep-24**	**02-Oct-24**	**13 day(s)**		
All sites PI signature	Low	18-Sep-24	27-Sep-24	8 day(s)	Green	100%
All sites cleaning SDV	Medium	15-Sep-24	23-Sep-24	6 day(s)	Yellow	15%
Screen failure	Low	21-Sep-24	02-Oct-24	8 day(s)	Red	25%

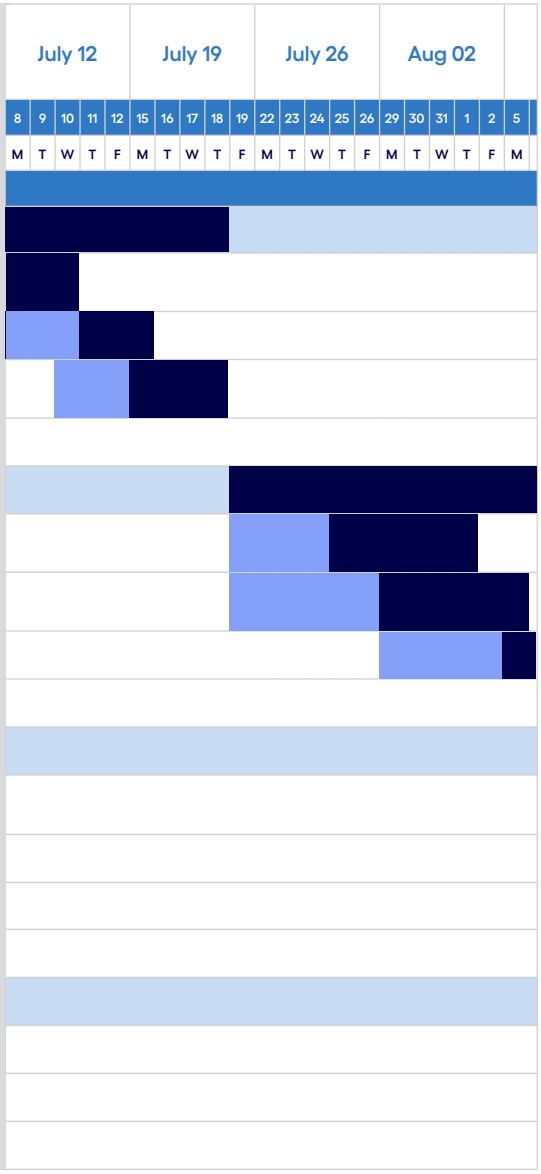


Figure 2: LPLV to DBL timeline

When reviewing this chart, it's important to note that task timelines associated with LPLV to DBL remain the same even when applying Scrum methodology. The projected time savings achieved from this methodology do not stem from efficiency gains within the workflow, but rather from the outcome of close collaboration and high visibility throughout each Sprint. This is what enables the team to "lock" data at the end of each task with minimal follow-up or additional review among team leaders and vendors. In so doing, the team can reduce the total LPLV to DBL timeline by several weeks, potentially shrinking the final lock period to just one week.

While this article focuses on applying Scrum methodology to the LPLV to DBL phase, the approach can be extended to the entire clinical trial. For example, in a trial scheduled to run for three years, six interim lock projects could be implemented. Each of these interim locks would consist of six Sprints over the 90 days leading up to the lock date, enabling teams to remain continuously "lock-ready."

4. Status checks

Another defining element of Scrum methodology is frequent status checks. The Scrum master typically conducts daily review meetings to ensure each Sprint stays on track. This is a useful way to identify delays or disruptions early on that could impact other steps, allowing the team to plan accordingly.

Again, this feature can be of incredible help during the LPLV to DBL period since being able to lock the data requires engagement from multiple stakeholders across various sites and organizations. By having more frequent status checks, members of the team remain accountable for their tasks and help to ensure they do not negatively impact other workflows.

5. Tracking

Scrum teams use advanced tracking tools, such as Jira or Confluence, to monitor progress. These tools provide visibility into each Sprint, helping teams prioritize work, track completion status, and quickly identify any blockers or issues that need resolution to keep the project on track.

To provide leadership with visibility into the data readiness of multiple trials at the program level, DBL teams can develop custom dashboards within one of these tools. This would allow teams to integrate data from multiple sources, enabling clinical teams to track progress in real time and support informed decision-making.

Capturing the value of process improvements in DBL and beyond

By applying the Scrum methodology to the LPLV to DBL process, it is possible for teams to reduce this critical period from 10 weeks to just one—a remarkable time savings in an area where even one day can influence the awarding of a patent and, by extension, which company will dominate the market for years to come.

While LPLV to DBL is a critical period within the clinical development lifecycle, it is but one step within a series of thousands that teams must take. In our work with life sciences companies, we have identified other areas where process improvements can play a role in shortening timelines.

For example, in recent years, teams have been able to leverage process improvements to significantly shorten the time required to progress from final protocol approval (FPA) to database go-live. In 2010, the process of building data collection systems like EDC typically took 20–22 weeks. Today, that timeframe has been reduced to just 4–6 weeks—the result of several process enhancements, such as starting preparations early with a draft protocol, leveraging standardized CRF libraries, conducting online screen review meetings with study teams and adopting no-code/low-code technology for study configuration in EDC. Additionally, the focus has expanded beyond EDC to include parallel builds of other critical systems like eCOA, RTSM and CTMS, ensuring everything is operational before site initiation.

These advancements have streamlined processes and shortened timelines, demonstrating how targeted improvements can optimize key phases within the clinical development lifecycle. When applied to other areas, the time savings can potentially amount to months—enabling teams to make submissions faster and, ideally, get to market sooner.

Taking the next step: Accelerating clinical development through Agile processes

To shrink standard timelines, companies must leverage both technological and process-based solutions to overcome challenges and streamline workflows. By adopting Scrum methodologies, companies can bring a fresh approach to addressing the complexities of LPLV to DBL, unlocking new opportunities to drive meaningful cycle time reductions that can help them fulfil their core mission of making life-saving and life-changing treatments available to the people who need them even sooner.

For more information about how Cognizant's life sciences team can help your organization improve clinical development through digital technology and process improvements, please visit the life sciences section of our website.

Authors

Kavitha Lokesh
VP, Head of Life Sciences R&D
Industry Solutions and Products

Hemant Gawande
Clinical Data Transformation Lead,
Life Sciences R&D Industry Solutions

cognizant

Cognizant helps engineer modern businesses by helping to modernize technology, reimagine processes and transform experiences so they can stay ahead in our fast-changing world. To see how Cognizant is improving everyday life, visit them at www.cognizant.com or across their socials @cognizant.

World Headquarters
300 Frank W. Burr Blvd.
Suite 36, 6th Floor
Teaneck, NJ 07666 USA
Phone: +1 201 801 0233
Fax: +1 201 801 0243
Toll Free: +1 888 937 3277

European Headquarters
280 Bishopsgate
London
EC2M 4RB
England
Tel: +44 (01) 020 7297 7600

India Operations Headquarters
5/535, Okkiam Thoraipakkam,
Old Mahabalipuram Road,
Chennai 600 096
Tel: 1-800-208-6999
Fax: +91 (01) 44 4209 6060

APAC Headquarters
1 Fusionopolis Link,
Level 5 NEXUS@One-North,
North Tower
Singapore 138542
Tel: +65 6812 4000

WF3542400