

Managing Queues in the Clinical Trial Agreement Negotiation Process

By Norman M. Goldfarb

Any business process consists of a series of steps through which inputs are converted to outputs. A clinical trial agreement (CTA) negotiation process, for example, converts a sponsor's CTA template into a signed CTA. Clinical trial negotiations average 40 days for research sites that use central IRBs and 133 days for sites that use local IRBs.¹ A typical process across both sponsor and site may involve 30 or more steps.² Many of these steps can be streamlined or skipped entirely. Large chunks of the process can be eliminated with the use of a master CTA.³

Each step in the CTA negotiation process consists of four phases:

- Receiving
- Queue (waiting to be processed)
- Processing
- Sending

During a typical CTA negotiation process, reviewing a document and crafting and communicating a response consume very little time. Documents spend most of their time waiting in queues for attention. Active processing may consume only a few hours during a process that takes months to complete.

Work-in-process inventories, i.e., queues, arise in three ways. For example, imagine what happens when a sponsor's CTA template arrives on a site negotiator's desk:

- Some work-in-process is desirable for efficiency. For example, the step of communicating a response to the other party relies on the other party being available. From the perspective of the site negotiator, this work-in-process is in the other party's receiving phase or queue. The site negotiator has limited ability to streamline the sponsor's process, but he can, for example, schedule the time of a teleconference in advance. This article will not discuss this type of queue further.
- The negotiator's review process may consist of multiple sub-steps. For example, he/she may want to review the last CTA signed with the other party; the new CTA template waits while the old CTA is obtained and reviewed. This particular sub-step can be streamlined, for example, by making previous CTAs available online with a marked-up version for easy identification of previous changes. This article will not discuss this type of queue further.
- The negotiator may have a backlog of work. For example, some contract negotiators have over 100 CTAs on their desk. Some of these documents receive no attention until they work their way to the top of the stack. This article discusses this type of queue.

Queues can be stable in size, growing or shrinking:

- If a process is stable, the queues are stable, and inputs equal outputs. The queue can be very large, for example, if there was a period in the past when input was above normal or output was below normal. Even though the process has adequate capacity as measured by input vs. output, response time may be very

slow because of the backlog. Adding temporary resources reduces the size of the queue without increasing the underlying capacity of the process.

- If the queue is growing, input exceeds output. To stabilize the queue, input must be reduced or process capacity increased.
- If the queue is shrinking, output exceeds input. When the queue reaches the desired size, resources can be reallocated to a different process or used to improve quality. If the reallocation is flexible, the resources remain available to handle above-normal loads.

“Just-in-time” inventory is a widely accepted good management practice that minimizes the number of documents in “inventory.” If there is any inventory, it should be held at the beginning of the process. Unpredictability in how long it takes other parties to respond requires mid-process queues, but the size of these queues can be reduced by improving the predictability of the partners, even if their response time cannot be reduced. Organizations can reduce the beginning-of-process queue by limiting inputs, i.e., not feeding new negotiations into the negotiation process, or by increasing the capacity of the negotiation process with efficiency improvements or additional resources.

Mid-process inventory causes numerous problems, including the following:

- Mid-process queues make it difficult to measure how long each step in the process takes. Without this information, it is difficult to identify bottlenecks and improve efficiency.
- It is time-consuming to manage mid-process inventories because the information is harder to obtain. For example, it may be difficult to locate a document and ascertain its status. Status queries reduce process capacity by disrupting productive work.
- Mid-process queues reduce quality. For example, it is difficult for a negotiator to remember the details of negotiations that drag out. If a policy or standard piece of text changes, each affected document must be tracked down. Wasteful renegotiation may be required.
- High-priority negotiations may sit in a queue behind lower-priority negotiations. Pushing a high-priority negotiation past lower-priority negotiations consumes management and negotiator time and disrupts the lower-priority negotiations.
- Mid-process queues make negotiation timelines less predictable. Processing time depends on the preferences of, and pressures on, the responsible person, rather than reflecting the organization’s priorities. Relationships with other parties in the process and with third-parties such as investigators and study managers suffer when there are unexpected delays.
- Mid-process queues reduce job satisfaction and increase stress on negotiators. Negotiators receive complaints that are not under their control to remedy. The carrot of emptying the inbox is just too far away.
- Mid-process queues make it more difficult to evaluate the performance of negotiators. Negotiators that complete negotiations quickly should be compensated accordingly and queried for the secrets of their success. However, if they complete negotiations too quickly, there may be a quality problem.

To minimize these problems, organizations should move CTA negotiation inventory from mid-process queues to one large queue at the beginning of the process. Of course, some work-in-process is necessary for efficiency at some steps, e.g., when response time from other parties is unpredictable. Small mid-process queues help documents flow with maximum speed through the process, minimizing the problems described above.

It is relatively easy to manage a large queue. To start with, the size and characteristics of the queue are easily determined. Management can prioritize each CTA negotiation based on parameters such as:

- Length of time in the queue
- Importance of the site or study to the organization
- Importance of the relationship with the other party
- Likelihood that the other party will cooperate in an efficient negotiation

When a negotiation enters the initial queue, the manager of the process uses these parameters to assign it a priority and a place in the queue. He/she then communicates to all concerned parties an expected date for negotiations to begin. This date includes some slack for likely delays caused by the subsequent addition of higher-priority negotiations to the queue. If someone objects to a date, he/she can make his/her case to the manager of the negotiation department or appeal to that person's supervisor, and so on up the chain.

He/she can also improve the negotiation's priority score. For example, a sponsor can increase its score on the fourth parameter above by agreeing to accept the terms of the last CTA negotiated with the site. A site can increase its score on the second parameter by demonstrating to the sponsor that it can enroll numerous subjects and generate high-quality data. If the initial priority assignment or any subsequent reprioritization is likely to affect the expected completion date of other negotiations, notifications go out to the interested parties.

By making the prioritization process transparent, disappointments and surprises are minimized. For example, if a site has a two-month backlog of CTA negotiations, it is pointless to enter into a new, low-priority negotiation that must be completed within one month. The job of the negotiation department becomes easier. Responsibilities and authorities become more closely aligned. Involved parties become partners in streamlining the process and refining the prioritization parameters. The negotiation process itself becomes a tool to increase negotiation power.

References

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