



Streamlining Clinical Trial Agreement Negotiations: Avoiding Common Pitfalls for Faster Signatures

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Speaker Introduction



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- Leads team of contract reviewers that apply each of our site-side clients' contracting standards.
- Clients vary significantly in size and complexity and are located across the US.

Streamlining Clinical Trial Agreement Negotiations: Avoiding Common Pitfalls for Faster Signatures



- Contract negotiations involve two or more parties who are trying to get the best outcome for themselves.
- Further complicating the process, there are a lot of moving parts with competing deadlines orbiting them.
- The various involved parties often have significantly different approaches to the process.
- Thus, there are both procedural and substantive considerations to advance negotiations.
- Often a few small adjustments can save a negotiation weeks of spinning wheels, getting you to signatures and the patients quicker.

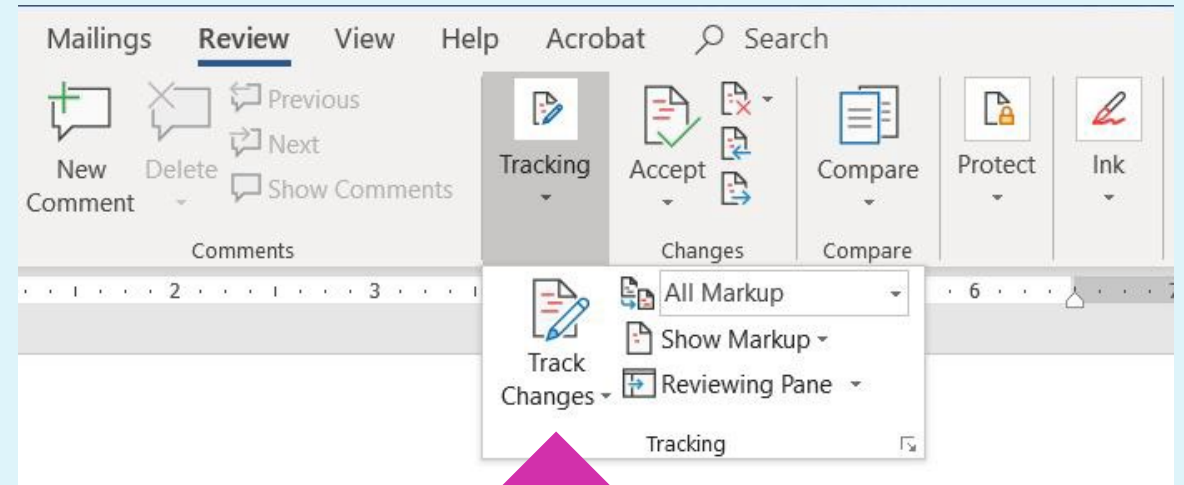
Common Delaying Practices

- Both sponsors and sites can occasionally engage in long-standing cultural practices in their contracting office which may have another purpose but ultimately delay the negotiation process.
- Each practice we'll go over in the next several slides can potentially add weeks or MONTHS of additional time to a contract negotiation.
- If you see something that is commonly done that isn't helping conclude negotiations quickly and successfully, ask yourself: "Is there a good reason we do it that way?"

Delays in Negotiations

Tracking Changes

- As common and easy to use as tracking changes are, they are still frequently misused.
- It is universal industry standard to track all changes made to a document when redlining and negotiating.
- This practice allows both parties to clearly see what edits are made between versions. It also helps document the history of the negotiation (who did what and when did they do it) which can help clarify efforts later in the process.



Delays in Negotiations

Impacts of Failing to Track Changes

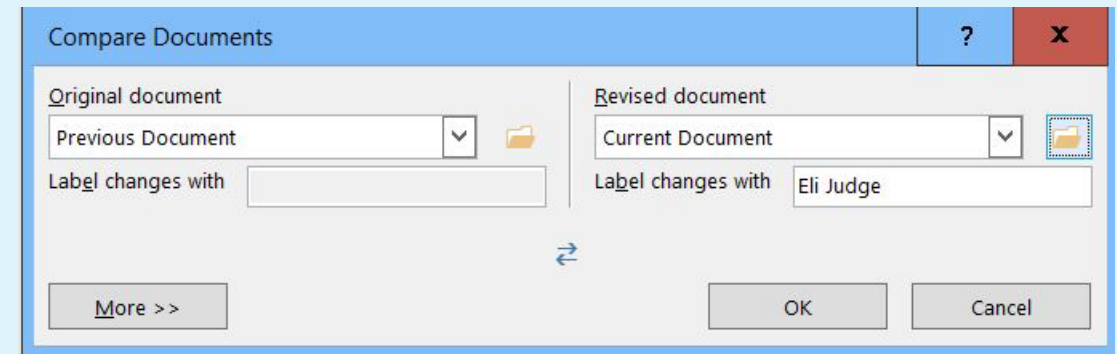
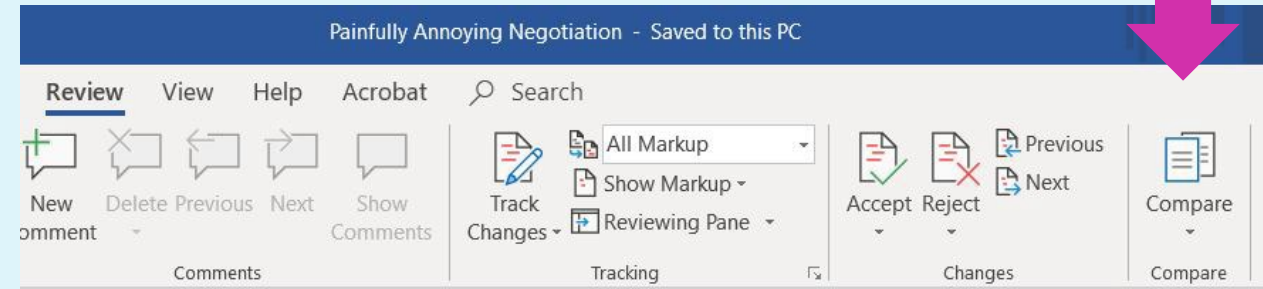
- Poisons the well between the parties
- Dramatically slows down the negotiation process
- Compels the other party to go through all documents with a fine-toothed comb to see if other changes weren't tracked
- Causes your organization to develop a reputation that can be difficult or impossible to dispel

Not tracking changes is a ~~really great~~ bad faith way to conduct your negotiation. Everyone will ~~really love~~ consistently dread working with you and it absolutely ~~won't~~ will have any impact on your reputation. Your organization will also ~~not~~ certainly develop a reputation regarding your totally ~~not~~ annoying negotiation practices. You should absolutely use ~~Machiavellian tricks~~ good faith tracking practices to ~~deceive~~ collaboratively work with the other party!

Delays in Negotiations

Locking the Document

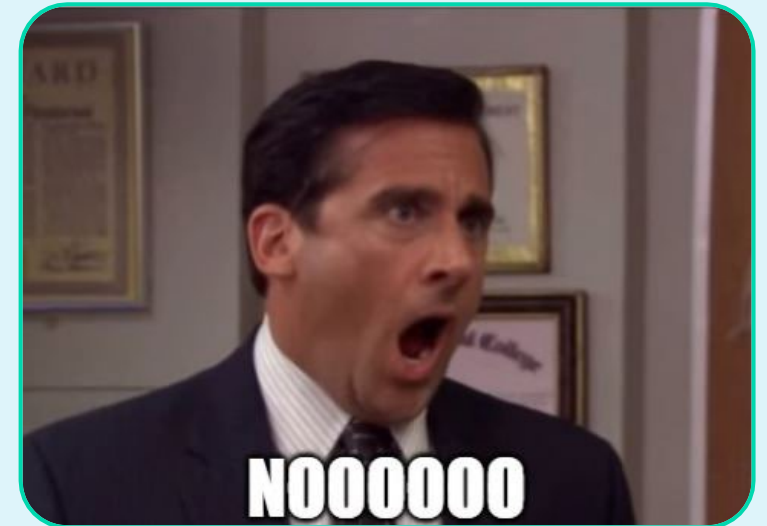
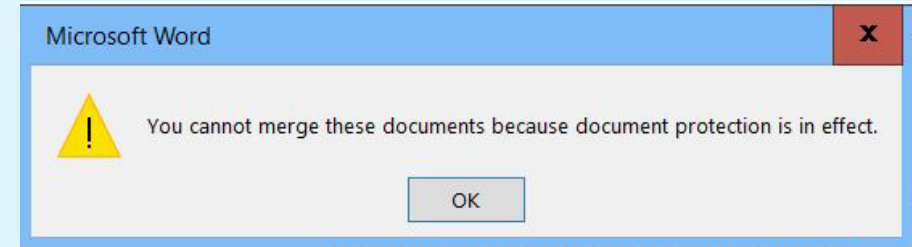
- The document comparison tool in Word allows you to compare past versions of the agreement so you can see what has changed between versions. This can be a massive time-saver.
- It will produce a version of the agreement that highlights what has changed, regardless of whether the changes were tracked using the “Track Changes” feature.
- Both parties should be in favor of each side’s ability to use this feature as it can dramatically speed up the negotiation process.



Delays in Negotiations

Locking the Document

- If a Word document is locked, only the party that has the code to unlock it can compare versions. The compare feature in Word is effectively disabled.
- A locking party will commonly say that they add locks to force the other party to track changes, but with an unlocked document, **both parties** can compare the versions and see what changes were made regardless of whether it was tracked or not. *That is the main point of the comparison feature!*
- Such locks often significantly slow down how quickly the other party reviews the agreement because they are denied a major time-saving tool. Other times, they can cause concern that one party is hiding changes behind locks!



Delays in Negotiations

Requesting Clarification

- Requesting clarification on changes in a redline can be an important way for a party to understand why edits are needed.
- Answers to those questions can speed up negotiation by demonstrating that edits are necessary for unavoidable legal, ethical, or practical reasons, or help the parties come to a consensus.

EJ **Eli Judge**
Sponsor: Why did you add this?

Eli Judge
Institution: Because we're legally obligated to include it by State Law 123.4.

Eli Judge
Sponsor: Great, thanks!

EJ **Eli Judge** 3 minutes ago
Institution: Why do we have to wait 18 months to publish?!

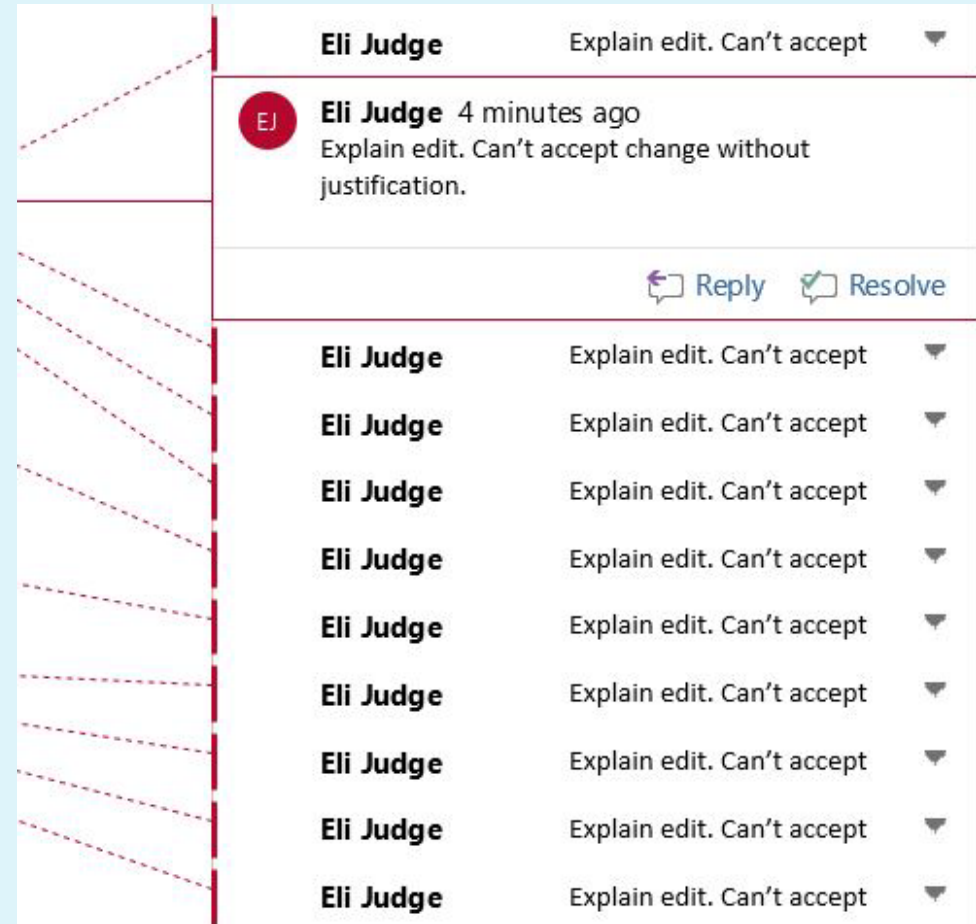
EJ **Eli Judge** 3 minutes ago
Sponsor: Because we need to coordinate multi-site publications across all sites and the delay period of 15 minutes you suggested is too short.

EJ **Eli Judge** 4 minutes ago
Institution: That makes sense! Thanks for helping further a productive and fun negotiation!

Delays in Negotiations

Requesting Clarification

- Unfortunately, you can have too much of a good thing.
- Requesting clarification on virtually every change in the agreement can cause negotiations to enter a dead stop in progress.
- Some negotiators will claim that they are required by their internal policy to ask for clarification for edits before sending the version for internal review. Asking for clarification does not replace a party's need to infer justification when the reasoning for the edits are self-evident.



Edits That Our Negotiators Have Actually Been Asked to Justify

No entity engaged in clinical trials should need justification for why these edits are being requested.

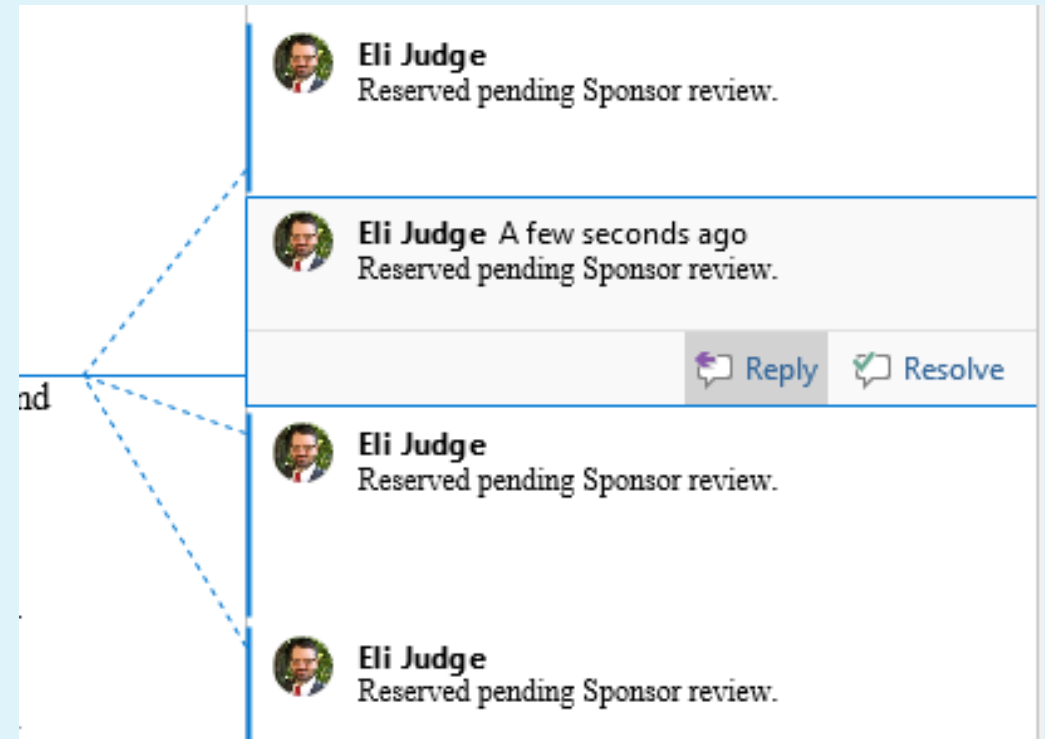
- Explain why site wanted sponsor to comply with applicable laws.
- Explain why site added language saying that the sponsor doesn't own a patient's protected health information.
- Explain why site corrected its own legal address after the sponsor negotiator mistakenly listed the name and address of an entirely different institution in the contract.
- Explain language that prohibited sponsor or CRO from bribing government officials to get more business.

- Explain why site added language allowing the sponsor to inspect the site for protocol compliance.
- Explain why a section number reference was updated; the original number on the page cited to a section that didn't exist.
- Explain and provide justification for an edit that the sponsor had made (in other words, the sponsor made an edit in the document and the CRO asked the site to explain why the sponsor made it.)

Delays in Negotiations

Everything is Reserved

- Reserving things (indicating that items in the agreement are still being internally reviewed) can be a helpful way to make sure progress can still be made in other parts of the document while negotiation is ongoing.
- However, like justification requests, this practice can be abused.
- It's a judgment call between rounds, but if most of the agreement is stalled in a reserved state, it may be time to just elevate. Otherwise, you're asking the other party to effectively do a half-review, send it back through the process of being queued in their workload, and waste time.



Delays in Negotiations

Delete and Replace

- When making changes, there are few things a person can do that are less helpful than deleting the language and replacing it with substantively the same language.
- Also, a justifying comment that only says “(sponsor/site) prefers this language” is almost always unhelpful. This amounts to saying, “We want it this way because we want it this way.” Not productive!
- Making desired changes to existing language will always be better than replacing terms outright (unless there’s a substantive, explained reason otherwise).





“When you have to kill a man, it costs nothing to be polite.”
- Winston Churchill

Why we don't always love surprises...

- Before a trial begins at a given site, the sponsor and the site will coordinate to schedule and attend a Site Initiation Visit (SIV). These meetings exist for the sponsor to train the Principal Investigator and the rest of the study team on the protocol and other procedural necessities with the study at the site.
- This will typically take place once the regulatory requirements are completed (like IRB approval) and when the contract/budget for the study has been completed.

Complications in Negotiations

Why We Don't Always Love Surprises

- Sometimes the study team and the sponsor coordinate to schedule the SIV before the contract negotiation is complete. This may often come as a surprise to the site contract negotiators.
- This kind of surprise might force the site negotiator into making concessions in the contract terms that would require engaging in lengthy elevations to get approval. If those approvals aren't granted, weeks of time might have been wasted.
- If the parties and the study team instead all work collaboratively toward setting completion goals, and adequately communicate those expectations, timelines can be set at a realistic and deliberate pace (perhaps with some elevations done up front) without wandering into pitfalls that could cost days or weeks of delays.



Pictured: the study team informing the site's contract reviewers that an SIV has been scheduled for the beginning of next week even though the contract negotiation is only one round in.

Virtues and Vices: Conference Calls

- Calls often serve an essential role in the last few stages of a successful negotiation.
- They can cut through the back-and-forth of email exchanges and skip a negotiation to its conclusion.
- For these calls to be effective, it's generally important for both parties to come armed with authority and knowledge to make decisions on the outstanding topics, or at least provide possible alternatives that will help further the negotiation. Otherwise, you're not negotiating anything; you're just having a pleasant chat.

Virtues and Vices: Conference Calls

- An appropriately timed call can be a huge boost to the speed and efficiency of a negotiation if done properly.
- Avoiding a call when few issues remain leads to unnecessary delay to completion. Don't be afraid of calls! They may save you time!
- On a related note, leaving adequate comments with justification for your edits becomes very helpful for a productive call if that seems to be where the negotiation is headed. Much of the material that might be discussed may already have justification available to the other party, saving time both on the call and in the grander negotiation.

Complications in Negotiations

Virtues and Vices: Conference Calls

- A quick side note on calls: occasionally, it may seem like a productive idea to get the whole band together (including the PI and study team) for the negotiation conversation if a lot of the outstanding issues are clinical in nature. That can be a good idea! However, the decision to invite people not directly involved in the negotiation of the contract's terms (like the PI) should be made collaboratively by the parties, and not unilaterally by one or the other.
- While there can be an innocent reason for one party inviting non-negotiators to the call, this might frequently lead to confusion, conflict, and delay. The study team/PI may not be aware of the broader legal/regulatory obligations the site might have that serve as the reason for specific contract language, so their attendance might lead to misunderstandings on why language is being fought over. Sometimes a site will find they're negotiating against their own PI/client on a call! This often leads to significant delays in the negotiation because concessions made on the call might need to be walked back once substandard things are later elevated for final legal approval.

Complications in Negotiations

Virtues and Vices: Conference Calls

- The solution to a lot of these problems is properly preparing and briefing study team members that you know will join the call on the remaining contentious issues in the contract before the call takes place.
- That way, the sponsor/CRO will be less able to describe the status of those issues/language in a way entirely favorable to them or force you into agreeing to language you'll have to walk back later, costing time.
- Alternatively, if the dynamics (and sometimes politics) behind their participation allow for it, you might consider asking the PI/study team to sit out the call despite the sponsor's invitation.



Complications in Negotiations

Ending on a Happy Note

- There are some great, proactive things you can do right away to speed up your negotiations immediately!
- Be open, if not eager, to mirror past agreements if the legal realities of your organization allow for it. If you've recently "updated" your contract template or standards, don't reject the idea of mirroring if doing so would only require adjusting a few things from the previously settled contract. Working with a contract that's 80% settled is better than another that's at 0%! You can also use a mirror as a "starting point" to save time.

Complications in Negotiations

Ending on a Happy Note

- Entities with general control over the contract (usually the sponsor) should be active and honest about cleaning up the edits between rounds. A reviewer is far more likely to jump to work on a document that doesn't look like a horror show! Just be sure to be honest and precise about cleaning up edits or you'll torpedo progress for the rest of the negotiation.
- Be friendly! And if you can't do that, be respectful. Reviewers will dread working with a rude or dishonest reviewer, which means they will put off a given project in favor of others, leaving your contract to languish in someone's inbox for days or weeks.



Q&A

Time for Audience Questions!

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