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Negotiating Clinical Trial Agreements with For-Profit Companies

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Objectives

- Identify essential steps to prepare for contract negotiations.
- Describe strategies for negotiating key contract provisions.
- Discuss practical tips for on-line, phone and in person negotiations.



The Problem

- According to research compiled by the *Association of Clinical Research Professionals*, **each day trial delays of a drug's time to market costs sponsors between \$600K and \$8M.**
- Contract and budget negotiations, and approval are responsible for 49% of study delays, followed by patient recruitment, which causes 41% of delays (CenterWatch Survey, 2009).



Factors Contributing to Contract Delays

- Multiple parties.
- Various laws and regulations.
- Global considerations.
- Internal policies and procedures.
- Experience and knowledge of negotiator.

The Consequences of Contract Delays



- Loss of opportunity.
- Budget compromises.
- Increased risk.

Solution

Effective Contract Negotiations

- Negotiation: Discussions between two or more parties in an attempt to reach a mutually acceptable agreement or resolution.
- Skill that can be enhanced with training and experience.



Preparing for Negotiations



Why prepare for a negotiation?

Negotiate strategically

Minimize having to think on your feet

Maximize leverage

You might only get one chance



Preparing for Negotiations: Understand Your Subject Matter

Gather relevant materials:

- Protocol.
- Site/country list - knowledge of local country laws and regulations, translations.
- Equipment List.
- Timelines - site initiation visit, recruitment and enrollment.
- Insurance policies - coverage.

Preparing for Negotiations: Understand Your Team-Your Process

Identify Deal Breakers:

- Know when to walk away. This decision can only be made if you understand your subject matter and your internal team.
- Distinguish “Want” versus “Need”



Preparing for Negotiations: Understand Your Team-Your Process cont'd

Escalation Process:

- Know internal escalation process.
- Understand what needs to be escalated and to who. For example, Insurance to risk management.
- Intellectual Property: all changes, only certain change.
- Know your own scope of authority and when to get the decision maker involved.

Preparing for Negotiations: Understand Your Team-Your Process cont'd

Review of Final Terms:

- Identify who within your organization needs to review final terms.
- Account for the time it will take for the final review.
- Communicate with your internal team - early and often.

Preparing for Negotiations: Understand Your Team-Your Process cont'd

Signature process:

- Account for process and time it takes to obtain final signatures.
- Discuss this upfront to avoid delays.
- Plan for out of office and identify alternative signatory; Signature matrix.
- Wet ink versus electronic signatures.

Preparing for Negotiations: Understand Your Team-Your Process cont'd

Routine Assessment of Templates:

- Review drafting and formatting - poorly drafted contracts create ambiguities and waste time.
- Update laws, regulations and internal policies.
- Review for audit and compliance concerns.
- Confirm roles and responsibilities are clearly delineated e.g. notice, signatures, entity.

Preparing for Negotiations: Understand The Other Party

Understand The Other Party:

- Listen to the other party to gain information.
- Identify their goals and pressures.
- Know who you will be speaking with from other party: do some research prior to the call: LinkedIn, company/firm website.



Negotiation Strategies



Negotiating Strategies: Relationship Development



Goal = create a win-win for both parties

- Remember, you have to work with the other side after the contract is negotiated.
- Establish rapport-talk about the weather, kids.
- Listen and ask questions.



Negotiating Strategies: Establish Your Priorities

- What you must have vs. what you want.
- Initial review of the agreement:
 - Review the sections that typically cause delays.
 - Discuss these early on.
 - Determine if problematic terms are negotiable
 - Decide whether or not to move ahead (Budget, indemnification).
- Keep a list of requirements and parameters.

MS3

Slide 18

MS3

are you wanting to list all problem/high problem areas? May not be necessary here as listed on slide 24.

MSLEG, Tuesday, September 26, 2017

Negotiating Strategies: Policies

- Whose policy will prevail.
- Is there a way to compromise.
- Identify risks does the level of risk warrant a policy exception.



Negotiating Strategies: Contracts

- Previous Contracts Negotiated Between the Parties:
 - Avoids delays required to re-negotiate terms - No Legal Review.
 - Makes internal control easier due to consistency of terms.
- How to manage “You accepted this in past contracts” & “Everyone in the industry is doing this”.
 - Identify policy changes that might impact use of prior language.
 - Ask specifically, “who is everyone”? It might be other sponsors/sites. Focus on what makes your company different: Academic/Non-profit status, size of company, or product.



Negotiating Strategies: Templates

- Using your template automatically puts you in a stronger position: familiarity, control of edits, timing of each draft.
- Template changes: Offer exact language, do not simply state “Unacceptable”.
- Budgets: Use past budgets only to identify costs not adequately reimbursed.

Negotiating Strategies: Delays and Impasse

Look at possible alternatives in order to avoid risking study timelines:

- Letter of intent.
- Start up Agreements.
 - Pros:
 - Study timelines stay on track.
 - Study start up activities can continue under defined terms. For example, scope, payment.
 - Cons:
 - Shifts focus from CTA to temporary agreement. Without stated deadlines, parties often continue to work under the temporary agreement.
 - Change negotiation process- make a call to the other party.



Process

Delays and Impasse: study specific considerations.

- Phase.
- Subject Injury.
- Intellectual Property.
- Indemnification.



Concessions versus Leverage

Concession.

- Definition according to Merriam-Webster:
 - Something granted - “give up”.
 - Something done or agreed to usually grudgingly in order to reach an agreement or improve a situation.

Leverage.

- Definition according to Merriam-Webster:
 - Influence or power used to achieve a desired result.

Concessions versus Leverage Cont'd

Concessions and Leverage.

- What is important:
 - You have already determined what you are willing to give up (concessions) – Use this as leverage.
 - You have already invested time to understand the needs of the other party- use this as leverage to get what you want.
- Avoid being the only party making concessions:
 - Keep track of concessions- use them as leverage.

Concessions versus Leverage Cont'd

Concessions and Leverage.

- Expect something in return for a concession
 - Mutual obligations “indemnity”
 - Useful in stalemates- “if we agree then we expect... more business, publication rights,

Concessions versus Leverage Cont'd

Common Leverage Points.

- Study timelines, close of enrollment period, prior agreements:
 - Site Leverage Points – Identify particular qualities- what makes a site a valuable site quality research, compliance with timelines, successful enrollment.
 - Sponsor Leverage Points - novel product, established site relationship.

Negotiation Indemnification

Example:

“To the extent not prohibited by local law, Institution hereby agrees to indemnify and defend Sponsor, and its directors, officers, employees, representatives, successors, and assigns (“Sponsor Indemnified Party”) and to hold Sponsor Indemnified Party wholly harmless from and against any and all Losses incurred by Sponsor Indemnified Party...”.

Issue - site is prohibited by state law from indemnifying.

Identify possible concessions and leverage each party can use based on their specific needs to negotiate favorable terms.

Negotiation Indemnification

- What site needs: Site needs this clause to be removed - compliance with law.
- What sponsor needs: Sponsor needs protection from site's negligence.

Negotiation Indemnification

Compromise

“Sponsor will not be responsible for, and the Institution shall be solely responsible for any and all Losses incurred by Sponsor arising out of or related to or as a result of or alleged to be the result of (a) negligence or willful misconduct on the part of the Institution and/or the Principal Investigator; or (b) research activities contrary to the Protocol or the terms of this Agreement.

Negotiation Indemnification

Concession by sponsor:

Site responsibility clause agreeing to be responsible for its own negligence.

Concession by site:

Liable for its negligence, potentially broad scope of liability.

Negotiation Audit

Example:

“...to the extent legally permissible, permit sponsor and its designee to attend any such audit or inspection, and to assist Institution in responding to all responses and requests related to such audit.”

Negotiation Audit

What does site need:

Autonomy, compliance with site policy, security of privileged information.

What does sponsor need:

Accuracy in information about study, knowledge of any audit concerning study in order for proper management.

Negotiation Audit

Identify possible concessions and leverage each party can use based on their specific needs to negotiate favorable terms.



Negotiation Audit

Concession by sponsor:

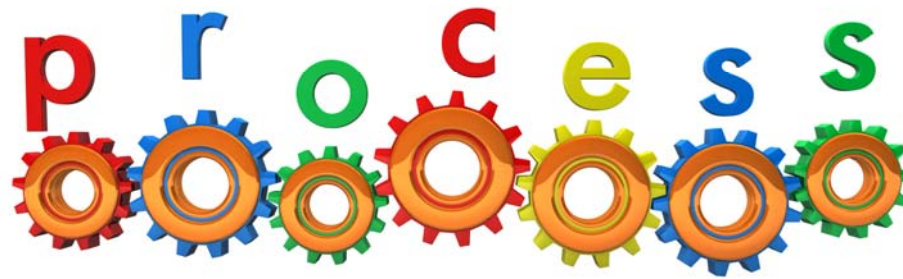
Agree to abide by site policy.

Concession by site:

Agree to allow sponsor's input and to use good faith in reviewing sponsor's comments and to provide copies of response to inquiries.

Negotiation Process

Without an established process to track versions, manage edits and communications, negotiations can quickly get out of hand.



Negotiation Process

Document Control Procedures:

- Identify who will make the changes and provide revised version.
- Establish process for version control.
- Establish negotiation timelines.

Negotiation Process

Track Change Management Process.

Lack of track change management leads to confusion. It is difficult to determine which terms have been agreed upon and who made edits.

- Agreed upon revisions - accept and delete track changes in next version.
- Locked documents - good or bad?
- Redline your own agreements.

Negotiation Process

- Cut and paste with discretion:
 - Do not simply cut and paste sections from another contract. Review inserted text for consistency of terms. Example: “XX Pharma” versus “Sponsor”; “Principal Investigator” versus “Investigator”.
- If you are adding text, do not track the formatting changes. This is not necessary.

Negotiation Process

Example:

Institution represents to sponsor that Investigator is an employee of Institution and that accordingly Institution is responsible for Investigator's performance under this Agreement. In the event that Principal Investigator is no longer employed by Site, Site agrees to notify sponsor immediately.

Negotiating Platforms

One negotiation can involve one or all of the following platforms:

- Email.
- Phone.
- In-Person.
- Web Based.



Negotiating Platforms: Email

Pros:

- Creates a record of negotiations.
- Flexible - 24/7 ability to review and forward comments.
- Ability to track changes allows the other party to quickly identify edits. But, consider running a redline in addition to the track change version.

Cons:

- Overuse - lack of defined process.
- How many rounds before a call is required.
- Need to explain: edits can be time consuming. Edits provided without context or explanation require further communications to clarify.
- Potential security risks.

Negotiating Platforms: Telephone

Pros:

- Verbal ques, potential for misunderstanding.
- Can be used as an adjunct to email negotiations.

Cons:

- Easy to delay by avoiding or not returning calls.
- Potential for unidentified participants.

Negotiating Platforms: In Person

Pros:

- Parties focused on negotiations.
- Dedicated time to resolve issues and reach final agreement.
- Home advantage.

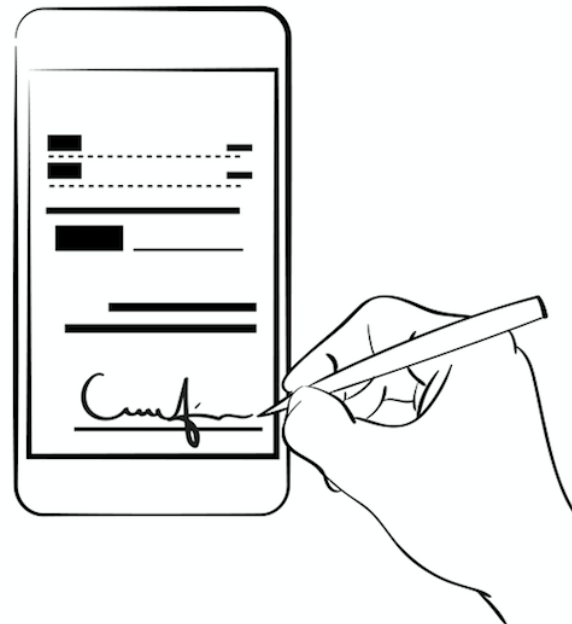
Cons:

- Electronic negotiations have become the rule.
- Face to face negotiations require travel and additional costs.
- Home advantage.



Web Based Negotiations: THE WAY OF THE FUTURE

- Existing methods require document exchange, and inefficient document turnaround times.
- EDC, CTMS, CDMS, eSignature.



Web Based Negotiations: THE WAY OF THE FUTURE

- Web based portal.
- Single point of entry for all designated users. Serves as a repository for all documents helping to streamline document management.
- Users have access to all study documents 24/7.
- Secure 3 levels of security – 1. System security, 2. User security (individual sign in credentials) and 3. Document security (encryption, blocked to copying, printing and forwarding, SOPs, cost, training).





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Thank You!

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