

MONEYBALL FOR CTAs



Data-Driven Insights to Accelerate Clinical Trial Agreement Negotiations



The negotiation of Clinical Trial Agreements (CTAs) between research institutions and sponsors (typically pharmaceutical companies) is a notoriously complex and time-consuming process, often delaying the launch of crucial clinical trials. This study leverages a unique dataset of over 4,000 clauses from actual CTA negotiations to identify common sticking points, preferred positions, and, most importantly, prevailing market outcomes.

Inspired by the “Moneyball” approach in sports, our analysis reveals that despite varied starting positions, CTA negotiations frequently converge towards established norms on numerous key issues. These findings suggest that a significant portion of current CTA negotiations may be unnecessary, with our analysis suggesting that up to 85% of the specific issues we analyzed could potentially be streamlined. By adopting a data-driven, market-based approach to drafting and negotiating CTAs, institutions and sponsors may be able to dramatically reduce negotiation time, accelerate trial initiation, and ultimately bring life-saving treatments to patients faster, without compromising their substantive interests in the final agreement.

This research highlights the potential of legal analytics and AI to transform the clinical trial landscape, fostering greater efficiency and collaboration in medical research. It also serves to reduce friction between sponsors and institutions by reducing the amount of negotiation, making it easier for them to work together, and creating an environment where institutions and sponsors are less hesitant to work together for fear of a protracted negotiation.

This study was prepared in collaboration with numerous leading academic medical centers who proactively contributed anonymized agreements for the purpose of making this study possible.



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Introduction

Clinical trials are the cornerstone of medical advancement, providing the crucial evidence needed to bring new therapies and treatments to market. However, the initiation of these trials is often hampered by a significant bottleneck: the negotiation of Clinical Trial Agreements (CTAs). These complex legal documents, governing the relationship between research institutions (e.g., hospitals, universities) and sponsors (e.g., pharmaceutical companies), are essential for outlining the rights and responsibilities of each party, ensuring patient safety, and protecting intellectual property.

The traditional CTA negotiation process is often characterized by protracted back-and-forth exchanges, with each party advocating for its preferred positions on a wide range of issues, from indemnification and publication rights to data ownership and subject injury compensation. This process can take several months, and in some cases over a year, to complete, delaying the start of critical research and ultimately hindering the delivery of new treatments to patients in need.

The prevailing assumption, similar to that in M&A NDA negotiations, is that the initial drafting party holds a significant advantage. However, based on the insights gained from our previous study on M&A NDAs (“NDA Moneyball”), we hypothesized that CTA negotiations, despite their complexity, might also exhibit predictable patterns and converge towards established market norms, regardless of initial drafting positions.

This study, which we are calling “CTA Moneyball” seeks to test this hypothesis by applying a data-driven, “Moneyball” approach to CTA negotiations. By analyzing a large dataset of actual CTA clauses and negotiation outcomes, we aim to identify these market norms, quantify the potential for negotiation reduction, and provide actionable insights for both institutions and sponsors to streamline the CTA process and ultimately accelerate the pace of medical innovation.

Methodology

To conduct this study, we leveraged a unique dataset provided to us of clause-level data from real-world CTA negotiations, encompassing over 4,000 negotiated clauses. Each negotiation was analyzed using the Sponsor's form agreement, the Institution's initial revision, and the final executed agreement. This data was then carefully categorized using an Issue ID system that identified key points of negotiation ("issues") across the dataset and sorted them into the following categories: CONFIDENTIAL 3

1. Topic (e.g., Audits and Inspections, Confidential Information, Data and Safety Monitoring, etc.)
2. Issue (e.g., Sponsor Monitoring and Inspections, Retention of Confidential Information following Termination of Study, Institution's Notification Requirement for Information Affecting Subject Safety, etc.)

This data represents a diverse range of institutions and sponsors, offering insights into a significant segment of the CTA landscape, though we recognize it may not capture all variations across the industry.

Similar to our NDA study, we employed a multi-step approach:

1. Data Categorization and Normalization: We organized the raw agreement data into a structured format, using AI to extract comparable plain-language issue outcomes for each issue across many agreements. This normalization process allowed us to compare clauses with varying language but similar intent.
2. Frequency Analysis: We determined the frequency with which each issue outcome appeared in each round of negotiation, providing insights into the most commonly negotiated issues and the typical negotiation patterns for each issue.
3. Outcome Analysis: Most importantly, we analyzed the final negotiated outcomes for each issue across all of the agreements in our dataset, identifying the commonly accepted positions that emerged from the negotiations, regardless of the starting positions of each negotiation. This allowed us to determine the prevailing "market tendencies" for each issue within our sample.

Results

A Deep Dive into the Data

Our analysis of over 4,000 negotiated clauses from real-world Clinical Trial Agreements (CTAs) revealed compelling patterns and, importantly, predictable outcomes. This section provides a deeper dive into the data, showcasing the “market tendencies” that emerged and illustrating how this knowledge can transform the CTA negotiation process. We will walk through some of the most frequently negotiated CONFIDENTIAL 4

issues and demonstrate how often negotiations end up at a common, predictable outcome.

3.1 Understanding the Landscape: CTA Topics under Analysis

Before we dive into specific negotiation points, it’s helpful to understand the select components of a typical CTA that we analyzed. While language can vary, certain clauses appear almost universally, reflecting their fundamental importance in governing the conduct of clinical trials. These include provisions related to:

- **Confidential Information:** Defining what constitutes confidential information, outlining obligations to protect it, and specifying procedures for its return or destruction.
- **Data and Safety Monitoring:** Establishing requirements for reporting adverse events, serious adverse events, protocol deviations, and any information that might affect the safety of study participants or the approval status of the study with the Institutional Review Board (IRB).
- **Indemnification:** Allocating responsibility between the institution and the sponsor for potential liabilities arising from the study, including who is responsible for covering legal claims and damages.
- **Insurance:** Specifying insurance coverage requirements for both the institution and the sponsor to protect against potential risks.
- **Intellectual Property:** Determining ownership rights to inventions, data, and reports generated during the study.
- **Publication Rights:** Establishing procedures for the review,

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deferment, and publication of study results, balancing the sponsor's interest in protecting its intellectual property with the institution's academic freedom.

- **Study Data:** Clarifying ownership, access, and usage rights for the data collected during the trial, including provisions for research, teaching, and patient care.
- **Subject Injury:** Outlining the sponsor's responsibility to reimburse for the costs of diagnosing and treating injuries sustained by participants as a result of the study.
- **Termination:** Defining the rights and obligations of both parties in the event that the study is terminated before its completion.

3.2 Negotiation Hotspots: Where the Battles are Fought

While many clauses are relatively standard, our data reveals certain “hotspots” where negotiations are most frequent and intense. These often center around:

- **Indemnification:** This is a major area of contention. Institutions and sponsors often clash over the scope of indemnification. For example, based on our analysis, items for which the sponsor must indemnify the institution typically include sponsor's negligence (70% of final agreements in our sample), use and disclosure of Study Data or results (60%), breach of agreement (55%), and willful misconduct (55%). On the other hand, we found that institutions are typically only required to indemnify the sponsor in the cases of institution's negligence (90%) or willful misconduct (80%), with the next most common cause for indemnification of the sponsor being failure to adhere to the Protocol (40%).
- **Publication Rights:** Publication rights are another frequent battleground. Key issues include the length of time a sponsor can delay publication to review the data or file for patent protection, the process for the sponsor to review proposed publications, and the institution's right to publish independently if the sponsor does not pursue a multi-site publication. Our data

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suggests a tendency for a 30-day sponsor review period (65% of the agreements we analyzed) and an 18-month waiting period for independent publication if no multi-center publication is planned (90%). All of the agreements in our dataset (100%) allow for study data to be present in a proposed publication.

- **Study Data:** While sponsors are generally designated as the owners of study data (95% of agreements in our sample), institutions fiercely protect their right to use this data for essential academic purposes. Our data shows that institutions retained these rights in the vast majority of agreements we analyzed: 100% for research, 95% for teaching, 95% for publication, and 85% for patient care. Patient medical records (85%) and source documents (75%) are typically carved out from the definition of Study Data, while routine internal documents (50%) and research notebooks (50%) are also commonly excluded.
- **Confidential Information:** The duration of confidentiality obligations is frequently debated. Our data shows a tendency for obligations that survive for 5 years after the end of the agreement (65% of agreements we analyzed). Institutions also seek to ensure that they can retain a copy of confidential information for specific purposes, such as regulatory compliance, after the return or destruction of other materials. Our analysis shows they are almost always successful in this regard (80% of cases in our dataset).
- **Subject Injury Reimbursement:** Negotiations often focus on the specific conditions that are excluded from the sponsor's reimbursement obligation for subject injury. Our data reveals that negligence by the institution is a common exclusion (70% of the agreements we analyzed). Other common exclusions include pre-existing conditions not exacerbated by study participation (55%) and willful misconduct or malfeasance by the institution (55%).
- **Data and Safety Monitoring:** The timeframe within which the Sponsor must notify the Institution of information affecting subject safety is often up for debate. While both parties are often expected to notify the other of information affecting study

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safety (80% of agreements in our sample), Sponsors are nearly always required to do so (95%). The timeframe is where there is some variability. Based on our analysis, the most common position is that such information will be reported “promptly, or in a timely manner appropriate to the risk involved,” which occurs in 50% of agreements.

- **Intellectual Property:** Our data shows that in most final agreements (85% of those we analyzed), there is a clause explicitly stating that neither party transfers any existing IP to the other. Furthermore, for inventions not derived directly from sponsor IP, ownership is deemed to remain with the inventor in 50% of the agreements.

3.3 The “Market Norms”: Predictable Outcomes Emerge

Despite the often-intense negotiations, our analysis reveals a striking pattern: final agreements most often converge towards predictable outcomes on many key issues, regardless of the starting positions in the initial drafts. These prevailing outcomes represent the “market tendencies” in the CTA landscape based on our dataset.

Here are some examples of these market tendencies, drawn directly from our dataset:

- **Indemnification:**
 - Sponsors are only sometimes required to indemnify institutions for the use of study data or results (30% of final agreements for data, 40% for results).
 - Sponsors are required to indemnify institutions in all agreements we reviewed (100%). Common exclusions from this indemnification include the institution’s negligence (95%) or failure to follow protocol (85%).
- **Publication Rights:**
 - A 30-day sponsor review period for proposed publications is the most common outcome (65% of agreements in our dataset).

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- An 18-month waiting period for publishing independent study results (if no multi-center publication is planned) is common (90%).
- Institutions are always allowed to publish study results following a joint, multi-center publication (100% of agreements we analyzed)
- **Data Ownership and Use:**
 - While sponsors typically own the study data (95% of agreements), institutions generally retain the right to use the data for research (100% of agreements we reviewed), teaching (95%), publication (95%), and patient care (85%).
 - Institutions typically do not have to destroy study data following termination (70% of agreements we analyzed).
- **Confidential Information:**
 - Institutions are generally allowed to retain a copy of confidential information after the return or destruction of other materials for specific purposes like regulatory compliance (80% of agreements we reviewed).
 - Confidentiality obligations typically survive for 5 years after the agreement ends (65% of cases in our dataset).
- **Subject Injury:**
 - Sponsors typically reimburse for reasonable costs of diagnosing and treating injuries directly caused by the study drug/device (85% of agreements we analyzed).
 - Negligence by the institution is a common exclusion from sponsor reimbursement (70%).
- **Data and Safety Monitoring:**
 - Both parties are generally expected to notify each other of information affecting study safety (80% of agreements in our sample).
 - Sponsors are almost universally expected to notify the

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- institution of information affecting subject health or safety (95% of agreements we reviewed).
- Based on our analysis, the Sponsor is typically expected to continue to report any information affecting Subject safety for 2 years following study termination or completion in 90% of agreements.
- **Intellectual Property:**
 - Neither party transfers any right in or license to any patents, copyrights, data, or other intellectual property arising outside of this agreement to the other party (85% of agreements in our dataset).
 - The inventor of any Non-Sponsor Invention (Inventions not based directly on sponsor IP) is deemed the owner of the invention (50% of agreements we analyzed).

3.4 The Power of Prediction: Reducing Negotiation Time

By understanding these market tendencies, institutions and sponsors can dramatically reduce negotiation time and friction. If an institution's template agreement already reflects the most common outcomes, many negotiation points become moot. Similarly, sponsors can anticipate the likely results and focus their efforts on truly contentious issues.

Our analysis suggests that by adopting a market-based approach to drafting, starting with these common outcomes as the default positions, negotiations could potentially be reduced by up to 85% for the specific issues we analyzed. While our study focused on a defined set of common negotiation points, based on our experience, we believe that applying this market-based approach to other negotiated issues would likely yield similar efficiency gains, though additional research would be needed to confirm this. This is because a significant portion of current negotiations appears to revolve around issues that ultimately converge towards these standard positions, regardless of the initial proposals.

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In essence, by starting where negotiations are likely to end, both parties may be able to save valuable time and resources, accelerating the initiation of clinical trials and ultimately benefiting patients waiting for new treatments. While achieving 100% efficiency may not be realistic, even approaching a 50% reduction in unnecessary negotiation would have a profound impact on the speed and cost of bringing new therapies to market.

Discussion

The findings of this study have significant implications for the CTA negotiation process. They demonstrate that a data-driven, “Moneyball” approach could potentially be applied to complex legal agreements in the life sciences domain, revealing hidden patterns and streamlining negotiations without sacrificing substantive outcomes.

By understanding the prevailing market tendencies observed in our dataset, both institutions and sponsors can make more informed decisions about their drafting and negotiation strategies. Sponsors can proactively incorporate these commonly accepted positions into their template agreements, potentially reducing the need for extensive back-and-forth exchanges. Institutions, in turn, may be able to anticipate the likely outcomes of negotiations and focus their efforts on truly contentious issues, rather than engaging in protracted discussions over clauses that are likely to converge towards a standard position.

This market-based approach not only could save time and resources but also potentially foster a more collaborative and transparent negotiation environment. By aligning expectations and reducing friction, institutions and sponsors may build stronger relationships, facilitating future collaborations and ultimately accelerating the pace of medical innovation.

Limitations

It is important to acknowledge the limitations of this study. While our dataset is substantial, it may not be fully representative of all CTA negotiations, particularly those involving smaller institutions or niche research areas. The percentages reported throughout this study

reflect our specific sample and should not be interpreted as definitive industry-wide standards. Additionally, the “market tendency” may not always be the optimal outcome for every institution or sponsor, especially in unique or complex research projects.

We must also emphasize that the projected efficiency gains represent theoretical outcomes based on our analysis of specific negotiation points, not all possible points of negotiation in a CTA. Additionally, real-world implementation may yield more modest improvements initially until parties adjust their expectations and norms. While our experience suggests that similar efficiencies might be achieved across other negotiation points not covered in our study, this remains to be validated through further research. Finally, human factors, such as negotiating styles and institutional policies, will continue to play a role in shaping the negotiation process. It should also be noted that there may be bias introduced based on the data provider’s own negotiating tendencies and the composition of our sample.

Conclusion

“CTA Moneyball” demonstrates the transformative potential of legal analytics and AI in the clinical trial landscape. By leveraging data to identify prevailing market outcomes, we can move beyond anecdotal evidence and subjective judgments to create a more efficient and data-driven CTA negotiation process. This approach has the potential to significantly improve negotiation time, accelerate trial initiation, and ultimately bring life-saving treatments to patients faster. It may also serve to reduce friction between sponsors and institutions.

As the field of legal analytics continues to evolve, we anticipate further refinements in our ability to predict negotiation outcomes and tailor agreements to specific needs. The future of CTA negotiations may lie in a collaborative, data-informed approach that prioritizes efficiency and transparency, ultimately fostering a more robust and productive research ecosystem. We invite institutions, sponsors, and other stakeholders to join us in this journey towards a more streamlined and effective clinical trial landscape, and to contact us to learn more about how to make this a reality.