

Break the contracting bottleneck to speed site activation

With the proper training data, Al can automate information gathering, document drafting and workflow.

By:

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The pharmaceutical industry is increasingly integrating artificial intelligence (AI) across its value chain, transforming stages from drug discovery to patient recruitment and clinical operations. Its usefulness extends beyond discovery to streamlining clinical operations. It will be crucial in driving efficiency through intelligent site identification and selection as well as activation.

The subtask within the activation process where Al can have perhaps the greatest impact is contracting. Often the process of contract preparation, budgeting, negotiation and review, contract finalization and execution, and document collection is a bottleneck to enrolling patients and beginning the trial. At each step, Al can significantly save time and money by automatically discovering and summarizing information and accelerating document creation.

Such benefits are available today through natural language processing (NLP) platforms such as one we created for a global pharmaceutical company that accurately extracts and summarizes relevant content and specific biomedical keywords from highly technical, preclinical trial reports without losing any specifics.

By performing keyword-based text extraction and summary generation with fine-tuned language models, this approach generated concise and coherent summary documents. It saved scientists 8 to 10 hours per document created, reducing document creation time by up to 25%. Using such capabilities to speed information gathering and reduce the overall document lifecycle, we estimate Al can cut the <u>time required for site budget and contract negotiation</u> alone by 30% to 35%. This could increase the efficiency of the sponsor and site staff, reduce time and costs, speed the delivery of new treatments to patients, and drive revenue from those treatments to life sciences companies.

This article explains how Al can be used in the steps of the site contracting process and how to apply Al most effectively.

Phase	Key Al use case	Benefit
Preparation	Gather information, summarize via NLP	Establishes an accurate and comprehensive foundation
Budgeting	Develop budgets using current and past data	Leads to accurate costs, activity lists, actual vs. budgeted costs
Contract drafting	Pre-populate contract drafts including financial terms	Saves time, accurate terms, rules, regulations, insurance
Contract negotiation	Streamline communication, automate reminders	Reduces time, effort
Legal review	Compare with applicable policies, laws, regulations	Ensures compliance, faster reviews
Contract finalization	Automate notifications for signing and next steps	Reduces cost, time, effort



Preparation

This phase includes gathering information about the scope of the study, the associated protocols, the number of patients, insurance requirements, applicable local laws and regulations, and projected costs and budgets based on past trials with similar protocols and requirements.

Al can automatically gather much of this information from public records, previous contracts in contract management systems, and current protocol documents. The output includes summaries—provided through NLP channels such as chatbots—of the names and contact information of key stakeholders, key changes accepted in drafts of previous contracts, and key policies and regulations applicable to the current contract.



Budgeting

This involves developing proposed budgets for each site, considering for each of them their size, the associated trial protocols, local regulations, fair compensation to the site and proper indemnification for all parties. It should also provide all stakeholders, via NLP, the lists of activities required of the trial at that site, and the actual vs. budgeted costs.

As with the previous phase, Al can automatically gather current information about local costs from public sources, past costs from prior contracts, and the history of negotiations with each site to inform the sponsor's pricing and negotiation strategies. It can also automatically gather current protocol documentation to ensure the budget accurately reflects costs for activities such as site setup, patient screening, per study visits, lab procedures and patient reimbursement.



Contract drafting

In this phase the sponsor or contract research organization (CRO) creates proposed contracts for each site outlining the rights, responsibilities and obligations of all parties involved in a clinical trial. The terms include the number of subjects to be enrolled, ownership of the study data and the right to publish it, the responsibilities of the sponsor or the CRO and the site, and compliance with the study protocol, government laws and regulations.

The draft will also include financial terms, such as the project deliverables and expected payments for each, based on past budgeted or actual spending for various activities and protocols across geographies. The cost data will be associated with key activities, not just from a budget perspective but also as it relates to project milestones. The contract will also describe the relevant rules and regulations of any given region or country and include provisions for insurance and indemnification for all parties.

While the sponsor or CRO staff will still review the contract, the Al-enabled drafting saves time and increases productivity by eliminating the need to begin the drafting process from scratch.

Our work with clients worldwide has demonstrated the feasibility of this approach. We achieved 95% data extraction accuracy, were able to standardize 80% of the data and provided NLP-based, automatic data extraction from unstructured data sources.



Contract negotiation

Al can streamline communication and workflows during the back-and-forth process of discussing the terms, resolving differences and reaching an agreement between a trial sponsor or CRO and a site. It can track open questions, the location of related documents and send automated reminders for actions through a contract management platform, bypassing email with alerts that include links to related documents that require action. NLP can also provide answers to queries such as "What are the unresolved areas in the contract that need my attention?", thereby eliminating the need to sift through emails or earlier contract drafts for that information.

It can also automatically generate lists of "frequently asked questions" related to each contract, such as why certain boilerplate text was or was not included, or why pricing for an activity falls outside of usual parameters. This eliminates much time-consuming, routine communication.

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Legal review

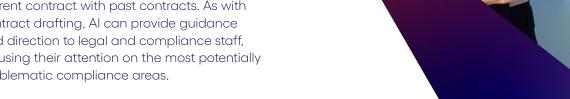
The complex workflows required to assure proper indemnification and compliance with corporate policies, as well as applicable laws and regulations, are ideal for streamlining by Al. Al can automatically gather and analyze information about relevant internal and external policies, laws and regulations, and help ensure these requirements are met by comparing the current contract with past contracts. As with contract drafting, Al can provide guidance and direction to legal and compliance staff, focusing their attention on the most potentially problematic compliance areas.

The Al deliverables include automated comments, via NLP, on draft contracts—highlighting areas for further review or where changes need to be made. As in other phases, Al assistants can find common errors and prompt for correction to minimize multiple iterations of documents.



Contract finalization and execution

This phase includes the signing of the contract by all parties and notification of other stakeholders to begin the next steps of site activation, such as initial payments, training of staff and patient recruitment. Al reduces the cost, time and effort required in this phase with automated notifications to stakeholders to sign the contract, and rapid notification of other stakeholders to move forward with the next steps in site activation.



Implementation tips

As with any use of AI, the quality of the output for site contracting is determined largely by the quality of the data on which the AI model is trained. Among the best practices we recommend assuring the proper data quality to speed site activation are:

- Ensuring all documents (e.g., contracts) used for training have been annotated with the relevant
 metadata for correct classification, such as by geography, type of trial, site size and expected
 enrollment numbers. Such metadata can usually be efficiently gathered from a mature document
 (e.g., contract) management system. If a sponsor is not using such a tool, the cost, effort and time
 required to gather the required metadata depends on the number and types of contracts it has
 managed, and the data management standards of its business units.
- Standardizing the metadata across different categories such as region, therapeutic area, trial phase and site type so the Al model can identify and train itself on the broadest range of data and provide the most accurate possible results.
- Limiting the training data to the past 5 to 7 years, as older documents may not be relevant to the current situation (e.g., contracts may not account for recent inflationary pressures or the shift from centralized to decentralized contracts—both changes have significant impacts on the pricing and terms a contract sponsor should now seek).
- Including not only structured data such as databases, but unstructured data such as emails
 (which are not usually captured by standard systems) and documents to train the model on the
 widest range of data. Since much of the detailed review and negotiation is conducted by email,
 this often requires manually uploading it into an Al model for learning and analysis.
- Using a scalable data model to accommodate the data needed to train the Al, and a
 microservice-based architecture to easily scale the data and compute resources needed to train
 and run the Al model.



Speeding site contracting and activation

With the proper types and quality of training data, Al and NLP can eliminate much of the manual drudgework associated with the negotiation and finalizing of budgets and contracts for clinical treatment trials. By providing instant responses to natural language queries, Al can allow sponsor staff to spend less time sifting through contracts and pricing data, and more time finding innovative solutions to contract and pricing issues and speeding treatments to market.



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