

Lindus Health Powers Data-driven Trial Decisions with the Aggregate Analysis of ClinicalTrials.gov (AACT) Database

Lindus Health Leverages CTTI's AACT Database

SUMMARY

Lindus Health offers an all-in-one Clinical Research Organization (CRO) solution to support clinical trials from protocol development through data delivery. This case study explores how Lindus Health utilized the Clinical Trials Transformation Initiative's (CTTI) AACT Database to accelerate and enhance clinical trial designs for their customers, detailing their journey from initial implementation to achieving significant, transformative results.

GOAL(S)

In the fast-paced world of clinical trials, leveraging data from prior studies is not just advantageous—it is essential for success. Studies have shown that over 50% of clinical trials face delays, with nearly a third terminated prematurely due to unforeseen issues that could have been mitigated with better data.¹ By accessing comprehensive historical trial data, researchers can make informed decisions, anticipate potential challenges, and design more effective trials.

Lindus Health wanted to harness these advantages by applying data-driven decision-making across its organization. Specifically, it aimed to use relevant data to improve trial design, speed up protocol development, and enhance the predictability of outcomes, ultimately driving innovation and efficiency in their customers' clinical trials.

CHALLENGES

Like many organizations conducting clinical trials, Lindus Health encountered several significant challenges in accessing and utilizing historical clinical trial data. While ClinicalTrials.gov hosts a veritable gold mine of information on nearly all clinical studies conducted in the United States (including a set of interfaces to support answers to common questions), the process of applying those insights to clinical trial designs is often cumbersome and limited. To start, the lack of direct connectivity and intuitive filtering options in ClinicalTrials.gov made it difficult for Lindus Health to obtain the necessary data, significantly hindering its ability to design evidence-based trials efficiently. Also, while the interfaces for common questions are helpful, what if you want to answer a different type of question? What if you want to aggregate and search across this data? What if you want to dive deeper rather than processing individual data records? These limitations were resulting in extended timelines and increased costs, presenting substantial barriers to Lindus Health's research and development goals.

SOLUTION(S)

Enter, CTTI's Aggregate Analysis of ClinicalTrials.gov (AACT) database, a free, publicly available relational repository that contains all information (protocol and result data elements) about every study registered in ClinicalTrials.gov. Content is downloaded from ClinicalTrials.gov daily and loaded into AACT, where it is directly accessible in the cloud. Static copies of the database are also available for download, and the source code is freely available via [Github](#). The AACT Database's user-friendly interface and extensive dataset proved to be invaluable resources for Lindus Health's journey toward data-driven research and development decisions.

TAKING ACTION

Lindus Health implemented the AACT Database in three major projects that exemplify its impact:

- 1. Trial Feasibility Prediction:** In their first major project, Lindus Health focused on predicting the likelihood of trial termination and identifying risk factors in trial designs. Utilizing the AACT Database, they extracted past clinical trial data and applied machine learning models to analyze this information. The resulting model provided risk scores and highlighted factors that could contribute to potential early termination, enabling the team to design more robust and resilient trials.
- 2. Protocol Generation Using AI:** For their second project, Lindus Health aimed to accelerate the creation of trial protocols by generating initial drafts quickly. By leveraging large language models (LLMs), data, and study documents from the AACT Database, they developed a tool that generated protocol templates based on historical trials. This innovative tool allowed researchers to produce protocols that were 80% complete in a fraction of the time it previously took, significantly reducing the initial drafting time and expediting the trial setup phase.
- 3. Outcome Mapping to Standards:** The third project focused on standardizing trial outcomes to improve searchability and comparison. Lindus Health used the AACT Database to map trial outcomes to standardized biomedical concepts. This process enhanced the ability to search and compare outcomes across different trials, making free-text outcome data more structured and usable. This project not only streamlined Lindus Health's internal processes but also contributed to broader efforts within the clinical research community to enhance data usability and standardization.

IMPACT

The use of the AACT Database yielded substantial benefits for Lindus Health, transforming their approach to clinical trials. Through the Trial Feasibility Prediction project, Lindus Health was able to identify and mitigate potential risks early in the trial design process, leading to more robust and reliable trials. The AI-driven protocol generation tool drastically reduced the time required to develop initial protocol drafts by 80%, enabling the company to expedite the trial start-up phase. This efficiency gain was particularly valuable for smaller companies and medical device trials, where speed is crucial. Additionally, the project focused on outcome standardization improved the searchability and usability of outcome data, making it easier to compare and analyze trial results.

One particularly satisfied sponsor working with Lindus Health noted, "I'm used to study start-up taking months but on this trial with Lindus Health, we went from protocol synopsis to first patient in in 6 weeks. Our board has never been happier!"

ADVICE

In reflecting on their journey, Lindus Health offered valuable advice for other companies seeking to leverage the benefits of data-driven decision making in the design and conduct of clinical trials. First, they stressed the value of investing upfront in advanced data analytics capabilities. While the AACT Database provided a wealth of information, having a dedicated team skilled in data analysis and interpretation proved crucial in extracting actionable insights. Lindus Health also advised other companies to prioritize flexibility in trial design, allowing for adaptive modifications based on interim data analyses. This approach not only enhances the likelihood of trial success but also ensures that the study remains aligned with evolving scientific and regulatory standards. With these tips in mind, Lindus Health encourages other organizations to embrace the AACT Database as a valuable tool to transform data-driven decision making across the clinical research ecosystem.

For additional information, please contact Lindus Health: hello@lindushealth.com

CITATIONS

1. <https://www.appliedclinicaltrials.com/view/towards-data-driven-clinical-trial-planning-and-strategy>

ORGANIZATION

Lindus Health

CONTACT

ORGANIZATION TYPE

Industry

IMPLEMENTATION DATE

2021

TOPIC

Quality

RELATED CTTI PROJECT

[Aggregate Analysis of ClinicalTrials.gov \(AACT\)](#)

CTTI RESOURCES

[Database for the Aggregate Analysis of CLINCALTRIALS.GOV \(AACT\)](#)